Interactive Parent-Targeted Text Messaging in Pediatric Clinics to Improve Child Health and Wellness

IRB Number: H-36857

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Sponsor: National Institute of Dental and Craniofacial Research (NIDCR)

Principal Investigator: Belinda Borrelli, PhD
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3-29-2019 IRB Approved Informed Consent Form

BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH AND DENTAL MEDICINE

RESEARCH CONSENT FORM

Basic Information

Title of Project: Interactive Parent-Targeted Text Messaging in Pediatric Clinics to Improve Child Health and Wellness

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Sponsor: National Institute of Dental and Craniofacial Research (NIDCR)

Principal Investigator: Belinda Borrelli, PhD
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Co-Principal Investigator: Michelle Henshaw, DDS, MPH
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Study Phone Number: 617-358-6243

Text messaging (TM) is an important form of communication today. Text messaging has become a common way of having a conversation and in some cases obtaining health information. The study involves testing two text message programs: one about child oral health and one about child wellness, to see whether these programs can result in improved child wellness and improved child oral health. You and your child are being asked to participate because your child has received medical care at one of the pediatric clinics that we are partnering with, your child is younger than 7 years old, and your child has their first tooth showing. Your and your child's participation in the study is voluntary. The study is sponsored by the National Institute of Dental and Craniofacial Research (NIDCR) and is being conducted through Boston University.

Purpose

The purpose of the study is to find out if text messaging programs, provided to parents and caregivers, will improve their child's oral health and wellness.

What Will Happen in This Research Study

If you agree to participate, you will be one of approximately 850 parents and caregivers and their children who will participate in this study. The total amount of time we ask you to participate in this research study is 24 months.

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General Study Activities:

1. Text Messages: You will receive either a text message program about children's oral health or a text message program about child wellness. The type of text message program you receive will be determined completely by chance. You will receive approximately 2 sets of texts per day for the first month, and then daily texts for the next three months, plus survey questions. One year after enrolling in the study you will receive another 4 weeks of texts.
2. Questionnaire: Prior to starting the text messaging program, you will be asked to complete a questionnaire about your knowledge, attitudes, and practices related to child health and wellness, including dental health, as well as demographic information. This questionnaire will be repeated at 12 and 24 months and will take approximately 35 minutes to complete. Half way through the text message program (2 months) and at the end of the text messaging program (4 months) we will ask you to complete a shorter questionnaire.
3. Child Dental Screening: A licensed dental hygienist, who is part of the study team, will provide a dental health screening for your child prior to starting the text message program. The dental screening will take approximately 7 minutes and be repeated 12 and 24 months later. During the visit, for quality control purposes, we will audio tape how the dental hygienist provides the screening results so that we can make sure that the dental hygienist gives everyone the same information. You will be given a written copy of the results of your child's dental screening. Because this is a simple screening that does not include x-rays, some cavities may not be identified. The dental hygienist or other study team members can help you make a dental appointment for your child if you would like. If you decide to take your child to a dental appointment, the dentist will bill your child's insurance or bill you for the cost of services provided.

Risks and Discomforts

The primary risk of this study is a loss of confidentiality. However, there are procedures in place to protect you against this – see the Confidentiality section below for details. There is a possibility that during the questionnaire or text messages, some of the questions about health habits or your opinions, may be uncomfortable or embarrassing. However, you do not have to answer any questions that you do not want to answer. During the dental screening, the dental hygienist may find that your child has cavities and we will share that information with you. This information may be upsetting. However, as described above, the dental hygienist or other team members can help you make a dental appointment for your child if you would like. There are two potential risks of text messaging: accidents and thumb and joint pain. Texting while driving or walking could increase the risk of accidents. Frequent texting may increase the risk of thumb and joint pain. The number of texts involved in this study is not likely to result in thumb and joint pain. To prevent TM related injury, you should not view, send, or receive texts while driving or walking. There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Potential Benefits

Everyone in the study receives text messages about child health, so you may learn more about child health and wellness.

Your child will receive dental screenings at no cost and you will be offered help with making a dental appointment for your child.

However, it is possible that you or your child receive no direct benefit from participating.

Alternatives

If you choose not to participate in this study, you can speak with your child's doctor about your child's oral health and wellness during your child's medical appointments and make a dental appointment for you child on your own.

Costs

There are no costs to you or your child for being in this research study.

Payment

You will receive $60.00 after completing the questionnaire, the dental screening for your child conducted by the study clinical examiner, and successfully 'opting' into the text message program by replying to an initial text. You will also receive $60.00 after completing questionnaires at dental screenings for your child at 12 and 24 months. You will receive $40.00 for completing the shorter questionnaires at 2 and 4 months after you enroll in the study. After you complete the first questionnaire, you will also receive an additional $40.00 if 3 of the 4 subsequent questionnaires are completed, or $70.00 if all 4 of these are completed. Thus, the total possible compensation for each adult participant is $330.00. All payments will be made in form of gift cards.

During the text message program, we will ask you questions that have a "$" sign. Each time you provide an answer to these questions, your name will be entered into a monthly raffle for a $100.00 gift card. Every time that you answer one of these "$" questions, you will have another entry into the raffle, increasing your chances of winning each month. After the winning name is drawn for that month, a new month will begin and all previous entries will be cleared.

Confidentiality

We will do our best to keep your information and your child's information safe. However, we cannot guarantee confidentiality.

The information that you gave us, as part of the screening process, will be securely stored by the researchers as part of your study information. However, your and your child's name and contact information will be linked to your answers via a unique study ID number.

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

Federal and state agencies, if they are required by law or are involved in research oversight, may access information about you from this study including your and your child's health information. 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.

We will protect your and your child's information by identifying all of the data we collect with a

unique study ID number, which will only be linked to your name through a document kept securely locked at the study team office. Only study team members will have access to the master document, except in rare circumstances, in which the data may be requested for review by law or by the study sponsor. All paper forms will be kept in a locked filing cabinet at the study team location. We are partnering with a text message company named "Agile Health." They will not have access to your study ID number, so they will not be able to link all of the questionnaire data or clinical exam data with your name or your child's name. However, in order to make the text message program personalized to you and your child, Agile Health will need to know your first name, your child's first name and age, your mobile phone number, your email, your preferred language to receive and send text messages (English or Spanish), and health habits such as reading to your child and tooth brushing. Text messages may also ask about your motivation and confidence to engage in health habits, dental visits, child safety, and other child health and wellness behaviors. Your answers to the text messages will be able to be seen by Agile Health but used only for the purposes of this study. You do not have to answer any questions that you do not want to answer.

Electronic forms are kept in a secure HIPAA protected database located at the University of California, San Francisco. All eligible participants who are consented will be asked if they want us to keep their contact information for future studies.

The link between identifiers and the data will be destroyed 7 years after the study has concluded and data are analyzed. We will keep participant names separately to confirm that no one who had previously participated in our usability or pilot study is enrolled in the larger clinical trial.

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 or biological samples are covered by a CoC. The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples 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 or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

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.

Future Use of Data

We might use your research data in future studies. These future studies might be done by us or by other investigators. Before we use your data, we will remove any information that shows your identity. There still may be a chance that someone could figure out that the information is about you.

Subject's Rights

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

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If you do not agree to be in this study or if at any time you withdraw from this study, you or your child will not suffer any penalty or lose any benefits to which you or your child are entitled. You and your child's participation is completely up to you. Your decision will not affect your or your child's 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.

We may decide to have you or your child 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 your child, 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 our project director at 617-358-6243.

You may also call 617-638-7207 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: _____

Printed name of parent/legal guardian

_____

Printed name of child

By signing this consent form, you are indicating that you have read this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate and have your child participate in this research study.

_____ _____

Signature of subject Date

Researcher: _____

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that she/he understands what is involved in the study and freely agrees to participate.

_____ _____

Signature of person conducting consent discussion Date