Texting in Community Health Center Dental Clinics to Reduce HIV Risk: RCT

Informed Consent Form

NCT Number: NCT06088277

NIDCR Grant Number: UG3DE031249

BU GDSM Protocol Number: H-43228

Principal Investigators: Michelle Henshaw DDS, MPH
Curt Beckwith MD, FACP, FIDSA

NIDCR Program Official: Hongen Yin MD, PhD, MHSc

NIDCR Project Scientist: William Elwood, PhD

Version 1.2
22 Feb 2023

RESEARCH CONSENT FORM

Basic Information

Title of Project: Texting to Reduce Risk of HIV Infection

IRB Number: H43228

Sponsor: National Institutes of Health

Principal Investigator: Michelle Henshaw, DDS, MPH
mhenshaw@bu.edu
560 Harrison Ave, suite 301
Boston, MA 02118

Study Phone Number: 857-225-7841

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 asking you to be in this study because you are receiving dental care at one of the dental clinics that we are partnering with. We are doing the research to learn if text messaging can be used to help people live healthier lives and reduce their risk of being infected with HIV. If you agree, you will receive text messages about reducing HIV risk or living a healthy life and complete 4 surveys. You will be in the study for 12 months, 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 risks of being in the study are feeling uncomfortable or embarrassed about questions on the survey. You will find more information about risks later in this form.

You might benefit from being in the study because you will learn information about how to reduce your risk of HIV infection or how to live a healthier life. You will find more information about benefits later in this form.

Purpose

The purpose of the study is to find out if these text messaging program will reduce risk for HIV infection and improve overall wellness.

BMC and BU Medical Campus IRB
IRB NUMBER: H-43228
IRB APPROVAL DATE: 02/22/2023

What Will Happen in This Research Study

If you agree to participate, you will be one of approximately 266 people who will participate in this study. The total amount of time we ask you to participate in this research study is 12 months.

General Study Activities:

1. Text Messages: You will receive either text messages about ways to reduce HIV risks or text messages with information about healthy living. The type of text message program you receive will be determined completely by chance. The chance of being assigned to each text message program is 50%, like flipping a coin. You will also receive text messages that will ask you questions about your expectations, motivations, or confidence in reducing risk of HIV or maintaining a healthy lifestyle. You will receive approximately 5 sets of texts per week for the first 3 months, and then 3 texts per week for the next three months.

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 HIV risks and wellness, as well as demographic information. This questionnaire will be repeated 3, 6 and 12 months after enrolling and will take approximately 30 minutes to complete.

Risks and Discomforts

There is a possibility that during the questionnaire or text messages, some of the questions about health habits or risk for HIV, may be uncomfortable or embarrassing. However, you do not have to answer any questions that you do not want to answer.

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 text message related injury, you should not view, send, or receive texts while driving or walking.

There is a risk to the confidentiality of your health information. We take special efforts to protect your health information, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Potential Benefits

The benefits of being in this study may be that you may learn more about health and wellness. 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 about how to use text messaging programs to help prevent people from getting infected with HIV or live healthier lives.

Alternatives

The following alternative activities are available if you choose not to be in this study: speaking with your doctor about your wellness and HIV risk during your medical appointments

BMC and BU Medical Campus IRB
IRB NUMBER: H-43228
IRB APPROVAL DATE: 02/22/2023

Costs

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

Payment

You will receive:

- a $60.00 gift card after 'opting' into the text message program by replying to an initial text and completing the first questionnaire
- a $60.00 gift cards after completing questionnaires at 3, 6 and 12 months.
- If all surveys are completed, you will receive a bonus $60 gift card.
- The total possible compensation that you may receive is $300.00 in 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 $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. The number of $ questions will range from 1-4 questions each month. After the name is drawn for that month, a new month will begin, and all previous entries will be cleared. Because you will receive text messages over the course of six months, you will have the chance to earn entries into 6 raffles.

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 proposes to share your data with Agile Health. Data that is not stored at Boston Medical Center or Boston University is outside of our control. Your information could get out or be used by Agile Health for other purposes that are not related to the study. Please carefully read and think about the Agile Health's Terms of Service and Privacy Policies before agreeing to give them any of your information. If you do not want to share your data with Agile Health, that is completely acceptable, but you cannot be in the study.

This study gives you the option of communicating using text messages and emails. This is because some people like the option of communicating by email and/or text message. It is important for you to understand that regular email and text are convenient but are generally not secure. As a result, information about you could be intercepted by someone not involved with the study. We will give you the option of using add secure and unsecure options such as secure email Data Motion, non-secure email, and/or non-secure text.

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

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 your participation in 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

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.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible. You should also tell us if you ever have concerns about being in the study.

It is unlikely, but 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 Michelle Henshaw at 617-358-3384.

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.

BMC and BU Medical Campus IRB
IRB NUMBER: H-43228
IRB APPROVAL DATE: 02/22/2023

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form
- 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 (who has read this consent form) 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

BMC and BU Medical Campus IRB
IRB NUMBER: H-43228
IRB APPROVAL DATE: 02/22/2023