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Informed Consent Form

Delivery of a Smoking Cessation Induction
Intervention Via Virtual Reality (VR) Headset
During a Dental Cleaning: Usability Study

Belinda Borrelli, PhD
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RESEARCH CONSENT FORM

Basic Information

Title of Project:	Delivery of a Smoking Cessation Induction Intervention Via Virtual Reality (VR) Headset During a Dental Cleaning: Usability Study
IRB Number:	H-39053
Sponsor:	National Institutes of Health, National Institute of Dental and Craniofacial Research
Principal Investigator:	Belinda Borrelli, PhD
Email:	belindab@bu.edu
Address:	Boston University School of Dental Medicine, 560 Harrison Ave., Boston 02118
Study Phone Number:	(617) 358-6367

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 the research to learn more about how virtual reality (VR) headsets can be used during dental visits to educate smokers about quitting smoking resources and motivate them to contact the resources. You do not have to want to quit smoking to be in the study. If you agree, you will watch an educational video about smoking using a VR headset while your teeth are getting cleaned, and will receive text messages for 4-weeks afterward. You will be in the study for approximately 6 weeks 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 is loss of confidentiality. Although we will do our best to keep your information safe, we cannot guarantee complete confidentiality. You will find more information about risks later in this form.

You might benefit from being in the study because we will provide you with a list of smoking cessation resources if you are interested. You will find more information about benefits later in this form.

You could get these benefits without being in the study by contacting your health insurance plan and asking for smoking cessation resources or by asking your primary care doctor. You will find more information about alternatives later in this form.

Purpose

VR headsets have the potential to be useful in a dental clinic to educate patients about how smoking affects their health. The purpose of this study is to gather data to understand how VR headsets and videos can be used during dental visits to encourage and facilitate smokers to make contact with effective smoking cessation resources and perhaps quit smoking. Results from this study may be used to inform other health professionals about the ways VR headsets can be used during patient appointments.

What Will Happen in This Research Study

This study will be conducted in three phases. The first phase will take place before, during, and immediately after your dental appointment. The second phase will begin within one day of your dental appointment and will last approximately 4-weeks. Immediately after there will be a third phase which will last approximately 2 weeks.

First phase.

We will ask you to "opt-into" the Boston University text message program by replying to an initial text message sent to your mobile phone. We designed this 4-week program to motivate smokers to contact smoking cessation resources. You will then be asked to complete an initial survey (either on your phone or computer/tablet or in person at the treatment center before your scheduled appointment) about your demographics, mood and oral health habits, your smoking habits, attitudes towards and beliefs about, smoking and smoking cessation. This survey should take approximately 20 minutes to complete. Opting into the text message program and filling out the survey must be completed before the start of your dental appointment otherwise you will not be eligible to continue with the study.

During the teeth cleaning part of your appointment, you will be asked to watch one of two educational videos on smoking cessation (approximately 10 minutes long) using a VR headset and earbuds (the video will not provide you with a VR experience). The educational content in the two videos are similar; however, one video is geared towards smokers who may already be considering quitting smoking whereas the other is geared towards smokers who may be undecided about, or

are not considering, quitting. The researchers will determine which video you will see, based on project needs.

At the end of your dental appointment, there will be a second survey (15-20 minutes long) about your attitudes and beliefs regarding smoking and smoking cessation, and your experience wearing the VR headset and watching the educational video. We will then provide you with printed materials about three different smoking cessation treatment resources (a mobile health program from the National Cancer Institute, the Massachusetts State quitline, and your local clinic-based program) including instructions to help you connect with each treatment resource.

Second phase.

In the second phase of this study, you will receive approximately two text messages per day from Boston University for 4-weeks, starting within one day of your dental appointment. The text messages provide advice, information and problem-solving tips to motivate, encourage and help you connect with the smoking cessation resources that were introduced to you at the dental clinic. Our 4-week text message program is interactive, and some of the text messages we send you will require you to respond. For example, we may ask whether you like a text, and your attitudes towards smoking and smoking cessation. Each week during the program, you will be able to pick the smoking cessation resource you want to connect with. Our interactive text messages are designed to help and make it easier for you to contact the resources. At the end of the 4 week text message program, you will be asked to complete a survey (approximately 20 minutes) similar to the one you did at the beginning of the study (the survey can be completed on your phone or on your computer or tablet).

Third phase.

During this phase, you will have two additional weeks to connect with the smoking cessation resources if you have not already done so earlier. Once you have connected with all three resources, there will be a final five-minute survey to complete. This brief survey will be about your experience connecting with the smoking cessation resources. You will not be required to take part in any smoking cessation treatment offered by the resources you have connected with but rather, we ask you to connect with these resources. "Connecting" with the resources means taking the first steps towards accessing the smoking cessation services they provide. The BU 4-week text message program will guide you through the process of contacting these resources. Below we discuss what is required to 'connect' with each resource in order to receive compensation:

1. The Massachusetts State Quitline: You need only to contact the state quitline and complete their brief intake process (either on the website or via phone) to fulfill one of the three steps needed for compensation. Your answers on the intake questions will not be known to our study. The only data that we will receive from the state quitline is whether contact with the state quitline occurred, whether a decision to start counseling was made, the type of counseling requested, the number of

sessions received, whether a quit smoking date was set, whether you requested nicotine replacement products, and whether nicotine replacement products were sent to you. It is important that we can verify whether you have connected with the state quitline. To do that, we will share your name, date of birth, telephone number, home address and date of study enrollment with the state quitline, so that they can confirm that you have interacted with them. Secure email will be used to transfer the identifiable data to the Massachusetts Quitline. You are not required to receive counseling through the state quitline as part of your participation in the study.

2. Contacting clinic-based smoking cessation resource: You need only to contact one of the local smoking cessation clinics to fulfill one of the three steps needed for compensation. Please note that if you decide to take part in clinic-based counseling, there may be some cost to you or your health insurance. We will verify your contact with a clinic by asking you on a questionnaire. We will not contact the clinic.

3. NCI text message program: You need only to 'opt-in' to the NCI text message program. You do not need to take part in the program. The NCI text message program opt-in information will be given to you during the 4-week BU text message program.

We will not have access to any form of communication or treatment plan that may be in place between you and the above treatment resources. For the Massachusetts State Quitline, we will not have access to any other counseling information than what is outlined in this consent form (see point 1 on page 3 above).

Your participation in the study will be finished after you complete the final five-minute survey at the six-week point.

The information you provide in responding to the survey and the text messages will be protected by identifying the data 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. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

You will be one of approximately 15 subjects who will be asked to take part in the study.

Risks and Discomforts

There is a possibility that during the questionnaire, 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. In addition, if at any time you are no longer comfortable wearing the VR headset, you may remove the device and stop watching the video.

Potential Benefits

The benefits of being in this study may be: A list of smoking cessation resources will be available to you. The educational video you will be watching during your dental cleaning and the text messages you will receive for 4-weeks afterward may help you quit smoking if you decided to quit. However, you may not receive any benefit. Your being in the study may help the investigators learn how to successfully incorporate VR headsets in a clinical setting.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: You might receive smoking cessation resources, or help quitting smoking, by visiting your primary care doctor or contacting your health benefit plan.

Costs

There are no costs to you for being in this research study. Items and services done only for study purposes will be provided at no cost to you. They won't be billed to your health insurance either. You or your health insurance will be billed for all costs that are part of your normal medical and dental care.

Payment

You will receive \$35 after completing all study activities in the first phase (opting into the BU 4 week text message program, completing the initial survey, watching the video with the VR headset and earbuds, and completing the post-video survey). You will receive an additional \$35 after completing the study activities occurring in the second phase (reading the text messages, interacting/responding to text messages that ask for a response, and completing the survey at the end of the 4-week text message program). You will then receive \$40 after completing the study activities in the third phase (connecting, or finish connecting with, all three smoking cessation treatment resources: the state quitline, your local clinic-based smoking cessation service, and the mobile health program of the National Cancer Institute, and complete the final five-minute survey). All payments will be made in the form of gift cards. During the BU 4-week text message program (second phase of the study), 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 \$75 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. If, for some reason, you cannot wear the VR headset, you will not receive full compensation and instead be withdrawn from the study and receive a \$5 gift card as a thank you for your time.

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, and electronic files in computer systems with password protection and encryption. We will protect your 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 this document. We will do our best to keep your information safe, however, we cannot guarantee complete confidentiality.

The link between identifiers and the data will be destroyed as soon as the study has concluded and data are analyzed. We will keep participant names separately to confirm that no one participating in the usability study is enrolled in a larger future clinical trial. The data with the Study ID will be kept for 7 years after enrollment, but it will be de-identified.

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. We will record in your electronic dental record that you participated in this study and wore the virtual reality headset we provided. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

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

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.

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 Hailey Hernandez at (617) 358-6367. 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.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction and that you voluntarily agree to participate in this research study.