RESEARCH CONSENT FORM

Basic Information

Title of Project:	Delivery of a Smoking Cessation Induction Intervention Via Virtual Reality (VR) Headset During a Dental Cleaning: Randomized Controlled Trial
	NCT04524533
IRB Number:	H-40368
Sponsor:	National Institutes of Health, National Institute of Dental and Craniofacial Research
Principal Investigator:	Belinda Borrelli, PhD
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Study Phone Number:	(617) 358-6294

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 motivate quitting smoking. **You do not have to want to quit smoking to be in the study**. If you agree, you will randomly assigned to one of two groups. Both groups will watch a video (10-12 minutes long) through a VR headset during their dental cleaning at either the Boston University Goldman School of Dental Medicine (BUGSDM) patient treatment center (dental clinic) or Tufts University School of Dental Medicine (TUSDM). The content of the video will differ between groups. The video that you will watch will be determined entirely by chance. You will then receive text messages regularly for 4-weeks then bimonthly during the rest of the study period, as well as complete questionnaires before and after your dental treatment, 1 month after treatment, and 3, and 6 months later. You will be in the study for 7 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 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 information about the resources for smoking cessation that may help you stop smoking if you decide to quit. 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 on a variety of topics, including quitting smoking. The purpose of this study is to test whether videos shown through a VR headset combined with text messages after your appointment motivate smokers to seek treatment for cessation and/or quit smoking. Results from this study may be used to inform dental practitioners as well as other health professionals about the ways health technologies can be used during patient appointments.

What Will Happen in This Research Study

Before your Clinic Visit at Boston University Goldman School of Dental Medicine or Tufts University School of Dental Medicine

We will ask you to "opt-into" the Boston University 4-week text message program (BU-VR 4-week text message program) by replying to an initial text message sent to your mobile phone. The text messages will not begin until after you have your dental appointment. Before your appointment, you will be asked to complete a baseline survey (either on your phone, computer or tablet, or in person at the dental clinic if you arrive early for your scheduled appointment) about your demographics, oral health habits, smoking habits, and attitudes towards smoking and smoking cessation. This questionnaire should take approximately 20 minutes to complete. These steps must be completed before the start of your dental appointment; otherwise, you will not be eligible to continue with the study. Not completing these steps will not affect your dental care or your appointment.

When you arrive at the dental clinic for your appointment, we will briefly review the study eligibility criteria to confirm you are still eligible for the study. You will then be given a study brochure describing what you will have to do to complete the study and receive compensation. You will also be given information about resources for quitting smoking.

Before the start of your teeth cleaning, you will be randomly assigned to one of two different groups. Both groups will watch a video using a VR headset and earbuds during dental cleaning and both groups will receive regular text messages for 30 days after the dental appointment. Each group will watch different videos and have different text messages (the videos will not provide a VR experience). Which one of the two groups you will be assigned to is determined by chance, that is, a computerized system will allocate you to either one or the other group. This procedure of allocating participants is called randomization and is typical in these types of studies. Videos are approximately 10-12 minutes in length and provide tips on managing stress and quitting smoking.

After your clinic visit: Post-video Survey and BU text message program

Immediately after you leave the clinic, you will be asked to complete a 10-minute survey (either on your phone, computer or tablet), about your attitudes towards smoking and smoking cessation, and your experience watching the video with the VR headset. This survey must be completed within 10 days of your dental appointment to receive compensation.

You will start receiving text messages from the study soon after your dental appointment. The number of text messages you receive will vary depending upon the group you are randomized to, but will be no more than approximately 2 messages per day for 4 weeks. Some of the text messages will require a response. After you complete the 4-week text message program, you will receive additional text messages periodically throughout the follow-up periods (1, 3, and 6 months later).

Follow-up Surveys

You will be asked to complete three surveys (approximately 20-30 minutes long) after the 4-week text message program: one immediately after the 30-day text message program, and two others (3 and 6 months later). These surveys will ask about smoking habits and attitudes towards smoking (the survey can be completed on your phone or, on your computer or tablet). Depending on whether your smoking has changed during the study (e.g., you have quit smoking), we will ask you to provide a saliva sample. The sample will only be used to analyze cotinine, a by-product of nicotine found in the body that is used by many researchers to differentiate between smokers and non-smokers. No other drugs or medications can be detected. If we ask you for a saliva sample, a study research assistant will arrange to travel to your house or meet at another convenient location to collect the saliva sample. If the study research assistant is unable to arrange a location or if restrictions due to Covid-19 prevent traveling, then a saliva sample will be collected remotely as resources and time allow. Testing kits will be mailed to your home with instructions on how to collect and return the sample to the research study team. No other tests or analysis will be performed on your saliva sample, and samples will be destroyed after analysis.

Contacting external resources to help you quit smoking is optional. These resources include the Massachusetts State Quitline and local clinics. However, as part of the study, we need to ascertain whether study participants have made contact with the Massachusetts State Quitline, and the type

of services requested. We will receive only the following data from the Massachusetts State Quitline: whether contact occurred, whether a decision to start counseling was made, the type of counseling requested, the number of sessions received, whether a quit date was set, whether nicotine replacement products were requested, and whether nicotine replacement products were sent. To procure this information, we will share the name, date of birth, telephone number, home address and date of study enrollment of BU-VR study participants using secure email with the Massachusetts State Quitline. Participants' data would not be used for anything else other than establishing whether or not contact with, and utilization of, the Massachusetts State Quitline services occurred.

During the study, participants may contact different resources for smoking cessation. However, we will only obtain direct information about use from the Massachusetts State Quitline and not from any other phone or clinical service (e.g., smoking cessation clinic, family physicians etc.).
We will not have access to any form of communication or treatment plan that may be in place between you and any of the 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.

You will be enrolled in this study for a total of 7 months. Your participation will be finished after you complete the final survey at the 6 month follow up period.

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 700 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. Texting while driving or walking could increase the risk of accidents, and you should not read or respond to text messages while driving or walking.

We will use a service called "Agile Health" to send the text messages to you. Agile Health is contractually obligated to protect your privacy as an authorized Business Associate of Boston University. Agile Health will have access to your phone number, your name, your motivation to quit smoking, the texts we send you, and your responses. 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 HIPAA

compliant, with all data encrypted in transit and at rest, and messages are delivered with encryption. As such, your data is highly secure while it is in the control of Agile Health and its messaging gateway partner. However, there are certain inherent risks in using SMS 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. Additionally, while a data breach is unlikely, it is possible. We will do our best to protect your data using the strategies outlined in this document.

Potential Benefits

The benefits of being in this study may be that the resources that we provide may help you quit smoking. 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 to motivate smoking cessation.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: You might receive quit smoking 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.

Payment

You will receive up to $170 in the form of gift cards for taking part in the study. Payments will be made according to the following schedule. You will receive a total of $50 for completing an initial questionnaire before your visit ($30) and a satisfaction questionnaire after your visit ($20), which must be completed within 10 days of your appointment. During the text message program, if you answer text messages with a "$" sign, you will be entered into a monthly raffle for $50. You will receive one raffle entry for each question you answer increasing your chances of winning each month. Your odds of winning the raffle will depend on the number of text messages with a "$" sign you answer, and on how many other participants respond to "$" texts. At the end of the 4-week text message program, you will be asked to fill out a questionnaire for which you will receive $40 if you complete it within two weeks of our sending it to you ($30 if you complete it after two weeks). There will be two more questionnaires 3 and 6 months later. You will receive $40 for completing each questionnaire within two weeks of our sending it to you or $30 if you complete it after two weeks.

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. At all of the follow-up assessments, we may ask you for a saliva sample to verify your smoking status. If we do that, you will receive a $25 gift card each time you provide the sample as compensation for your time and effort.

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 saliva in a medical-grade freezer securely located at the Boston University medical campus. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. 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 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. We will record information from this study in your medical record, such as information related to your medical care. 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 and biological samples 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 medical book or journal.
- Adding results to a Federal Government database.
- Using research data in future studies, done by us or by other scientists.
- Using biological samples 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.

Retention

If at any point in the study we are unable to reach you by the contact information you provided, we will use a paid online directory or people search engine (ex. Spokeo, White Pages) as a means to verify or update your contact information. We will only do this if we discover we have incorrect contact information and study staff attempts to use alternate means have been exhausted. For example, study staff may reach out to your cell phone number and discover the phone number has been disconnected or now belongs to a different person. Staff will then reach out via home phone number, email, letter or alternate contact. If these methods prove to be unsuccessful, study staff will then utilize an online directory or people search engine in an attempt to find updated contact information.

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.

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 the BU-VR study at (617) 358-6294. Also, call this number 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.

BMC and BU Medical Campus IRB
IRB NUMBER: H-40368
IRB APPROVAL DATE: 06/12/2024