

Informed Consent

Protocol Title: Technological Innovations in a Behavioral Treatment for Cigarette Smoking

Please read this consent document carefully before you decide to participate in this study.

Purpose of the research study:

The purpose of this study is to see if an internet-based intervention can help you quit smoking.

What you will be asked to do in this study:

You may be asked to be in this study if you are a regular smoker, healthy, age 18 or older, and would like to quit smoking. The first thing we will ask you to do is to complete a questionnaire about your social and medical history, and about your smoking patterns. As with all questionnaires, you do not have to answer any question you do not wish to answer.

There is a lot of information to explain to you about this study. Please make sure to ask me questions at any time, if you do not understand something.

Trained research assistants will oversee your progress through the study. You will be asked to use a computerized, Internet-based system to measure how much you have been smoking.

We will monitor your smoking by taking breath carbon monoxide (CO) measurements. The CO device is about the size of a calculator, and you just blow into a small tube, similar to a breathalyzer. The device provides a read out of your CO level. Most of the time, CO samples will be considered “positive” (which means that you smoked recently) if they are greater than 4 parts per million (ppm), and negative if they are equal to or less than 4 ppm. The more you smoke the more CO is in your blood and the higher your CO reading. CO can also be elevated by second-hand smoke, so it will be important to avoid places where you might be exposed to second hand smoke while you are trying to quit.

We will mail you some equipment to borrow while you’re in the study so that you can measure your CO. You will be asked to make video recordings of yourself blowing into the CO meter. The video will be recorded with a web camera that will sit on or near the computer monitor. You will be asked to send your video recording to us, the research staff, via the Internet so that we can verify your CO sample. We will loan you the web cam and CO monitor. You are expected to return all equipment when you are done with the study. You will be able to record and send your video clip with little effort; it should take about one to three minutes.

You will usually be asked to provide breath samples twice per day. You will always receive feedback about your smoking status (whether you are positive or negative for recent smoking). We will allow you to miss several CO samples during the study without penalty. We will remind you that you missed a sample, and we will tell you the consequences of continuing to miss CO samples. We will make every attempt to work with you if your schedule presents problems, but please keep in mind that providing regular samples is an important part of the study. Video recordings can be submitted between 12:00am and 11:59pm, so the schedule is very flexible.

At different points during the study, you may be able to earn money, that will be deposited into a Paypal account, when you submit video recordings. As soon as you begin to earn money, you can start spending it. Clinic staff will periodically transfer your earnings into your Paypal account. If you know that there is something you specifically want to purchase, but the clinic staff have not yet transferred the money into your account, then you can request a transfer at any time by sending the clinic staff an email at XXXX. Transferring money into your Paypal account can take a couple of days, but once you receive the money you can spend it however you like. If you like, you will be able to transfer the money from Paypal directly into your own bank account when the funds become available.

How do you earn money for submitting videos? There are two possible ways. The way in which way you earn money for submitting videos will be determined randomly, like the flip of a coin, before you start the study. One way to earn money is by simply sending in your CO samples. The other way to earn money is by reducing or quitting smoking, as shown by the video recordings you submit. We will also help you set goals and help you quit smoking. We will give you detailed instructions about how you will receive money if you agree to participate in the study – there are a lot of details about how it will work. Please feel free to ask me if you have any questions about this. Do you have any questions so far?

In order to enroll in the study, you will be asked to pay a \$XX deposit incentive. Although the deposit is non-refundable, you will have the opportunity to earn \$XX during the study (your original \$XX deposit plus an additional \$XX or submitting videos, completing surveys, and returning the equipment), so you will always have the ability to earn back more than your deposit.

You can view your account earnings, and progress in the study, by viewing a web page that we will set up for you. Your web page will not contain any identifying information about you; only you and the research staff will know that the web page is yours.

Time required:

You will be asked to participate for a minimum of seven weeks. Upon enrolling, you will earn \$XX for completing a group of online questionnaires, asking questions about your mood, recent activities, and smoking patterns, and you will have the option of completing an additional questionnaire for \$XX compensation (described more below). During the first four weeks of the study you will be asked to submit two video recordings per day, separated by a minimum of 8 hours. At the end of the first four weeks, you will earn \$XX for completing another group of questionnaires online. During the last three weeks of the study you will only be asked to submit two videos per week. At the end of the seventh week you will again have access to an optional questionnaire for \$XX compensation, and we will provide you with packaging to return the equipment we loaned you. You will earn \$XX for returning the equipment to us. Finally, we will follow-up with you three and six months later to see how you're doing. At these three and six month contacts we will ask you to complete the questionnaires again, and you will be compensated \$XX each time for doing so. Your answers on the questionnaires will not influence how much you earn for completing them. After the six month follow-up, we will provide you with packaging to return the equipment we loaned you, and you will again earn \$XX for returning the equipment to us.

Optional Additional Questionnaire:

You will also be asked to complete a set of optional questionnaires twice during the study. The purpose of these questionnaires is to compare participant's experiences across different technology-based interventions. We will ask about your health, mental and social well-being, views about the use of various mood-enhancing substances, and perspectives on technology-based interventions.

Risks and Benefits:

Long-term smoking is associated with increased health risks such as cancer and heart disease. Symptoms of nicotine withdrawal you might experience during abstinence might include craving cigarettes, restlessness, irritability, increased appetite, increased eating, dizziness, difficulty concentrating, and depressed mood. We will provide you with some resources for dealing with craving and withdrawal symptoms, including a document from the National Cancer Institute. There is a risk that your electronic information could be accessed, and you may be concerned about this, and how the potential of such access could affect confidentiality. There is a risk that you could become distraught during the study due to life events (e.g., death of a loved one). It is possible that other emergencies could arise during the study that clinic staff may need to address. Finally, there is a risk you could lose the \$XX deposit incentive that you pay at the beginning of the study. Additionally, there is minimal risk that security of any online data collected in this study may be breached, but since, (1) the online host uses several layers of encryption and firewalls, and (2) your data will be removed from the server soon after you complete the study, it is highly unlikely that a security breach of the online data will result in any adverse consequence for you. Your answers to surveys will be identified with a code. The code will only be linked to your identity on a hard copy list that will be stored in a locked filing cabinet and will only be accessible to the research staff working on this study.

Compensation:

During the intervention periods, you can earn money that will be deposited into your Paypal account. Once the money has been deposited into Paypal you can use it however you wish. The amount of money that you will earn for each video submission will change from video to video and will be described in greater detail after you enroll. We cannot tell you the exact amount you will earn because it will partly depend on what you do while you're in the study, however; you can potentially earn up to \$XX. As we described above, you can earn the money depending on your smoking or depending on whether you submit your CO samples. It will depend on the group you get assigned to. Also, you will be compensated \$XX for each of the initial, four-week, three-month, and six-month assessments, \$XX for each of the optional assessments (initial and seven-week), and \$XX each time you return the equipment (\$XX additional dollars, for a total of \$XX possible earnings).

Confidentiality:

Your identity will be kept confidential to the extent provided by law. Your information will be identified by a code number. The list connecting your name to this code number will be kept in a locked file cabinet in the laboratory. When the study is complete and the data have been analyzed, the list will be destroyed. Your name will never be used to identify any of the information obtained from you. We will ask you to select a user name so that it does not suggest your true name. We will download this information to a computer that will be accessible only by research staff. Also, the video files you send with your web cam are located on a secure, encrypted server and will be destroyed when the study ends. Only research staff will view your video files.

Voluntary Participation:

Your participation in this study is completely voluntary. There is no penalty for not participating.

Right to withdraw from the study:

You have the right to withdraw from the study at any time. If you withdraw, we will pay you any monetary earnings you have accumulated up to that point.

Whom to contact if you have questions about the study:

XXXX

Whom to contact about your rights as a research participant in the study:

XXXX

If you are still interested, please complete the Consent form and press submit when you are finished. **Before proceeding, we want to make sure that you understand the procedure by having you answer the questions (select each correct answer):**

- 1) The study will last a minimum of:
 - a. 2 weeks
 - b. 7 weeks
 - c. 9 weeks
 - d. 12 weeks

- 2) We will monitor your smoking during the study by using small breath monitor to measure breath carbon monoxide (CO).
 - a. True
 - b. False

- 3) The money that I earn in this study will be deposited into my Paypal account.
 - a. True
 - b. False

- 4) Although how you earn money will depend on your randomly determined group assignment, you will definitely have the opportunity to earn _____ amount of money during the study:
 - a. \$XX
 - b. \$XX
 - c. \$XX
 - d. \$XX

- 5) You have the right to withdraw from the study at any time.
 - a. True
 - b. False

Consent

If you are interested in participating in the study, please check the items below:

- The conditions and procedures of this research project, as described in this Informed Consent, have been explained to me. I have been given the opportunity to ask questions about the project and I know whom to contact if I should have additional questions about the research or my rights as a participant.

- Any information about me as a result of my participation in this research will be kept confidential to the extent provided by the law.
- I can print out and/or save this document for my records.
- I wish to participate in the study. I agree to follow the conditions and procedures described in this Informed Consent.