Informed Consent Form: Non-Scan Protocol

Construal Level as a Novel Pathway for Affect Regulation and Cancer Control

NCT04620915

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Consent to Participate in the Smoking Study

You are invited to participate in a research study conducted by Dr. Elliot Berkman's Social and Affective Neuroscience Laboratory in the Department of Psychology at the University of Oregon. The goal of this research is to investigate different ways to help people quit smoking. We are also interested in the changes that might happen as part of these smoking cessation programs, and how different people respond to them. This study is funded by the National Institutes of Health.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to investigate different ways to help people quit smoking, and to learn more about the changes that may occur as part of the smoking cessation process. • **Duration.** It is expected that your participation will last 3 months plus a 3-month follow-up phone call. • **Procedures and Activities.** You will be asked to attend an initial 90 minute remote session, a 60 minute remote pre-training session, a 45 minute remote post-training session, and a 30-minute follow up call 3 months after the end of the training program. In between the pre- and post-training sessions, you will take part in an 8 week experimental training program where you will receive text messages that are intended to help you quit smoking and complete several online modules at home. • **Risks.** Some of the foreseeable risks or discomforts of your participation include discomfort from the questions asked or emotional distress from the failure to quit smoking. We have strict safety protocols in place to account for these risks. • **Benefits**. There are no direct benefits, but the trainings may help you reduce or quit your smoking habits; however we cannot guarantee you will benefit. You will also be contributing to the initial steps of creating an effective, individualized intervention for persistent smokers trying to quit. • **Alternatives.** Participation is voluntary, and the only alternative is to not participate.

You have been invited to participate in this project because you meet the age, smoking habit, and other eligibility criteria, and you have reported wanting to quit smoking. *Your participation in this study is entirely voluntary.* Please read the information below and ask questions about anything you do not understand before deciding whether or not to participate. You will be given a copy of this consent document.

What is the purpose of this study?

We are hoping to learn more about how people can quit smoking. We believe that new knowledge gathered from participants in this study will provide us with information that

can be used to create effective interventions to help people quit smoking. By being in this study, you will help us learn about the different processes involved in the quitting process and how they are related to your smoking habits.

What does participating in the study involve?
All procedures will take place remotely via Zoom and phone call. This study will take place over the course of approximately six months. If you participate in our study, we'll ask you to complete the following activities, which are described in more detail later:

- Initial preparatory session: 90 minute remote Zoom appointment
- Pre-training baseline session: 60 minute remote Zoom appointment
- Training program: 8 weeks of daily text messages, weekly phone calls, and online modules to be completed at home
- Post-training endpoint session: 45 minute remote Zoom appointment
- Follow-up call: 30 minutes via phone, 3-months after the end of the training program

Initial preparatory session – Zoom (90 minutes)
During this first session, you will go over the consent form with a researcher. Should you agree to participate, you will be asked to complete several questionnaires about yourself and your habits. If, at any time, you do not want to continue answering questions, you are free to stop without penalty. We will also ask you to provide the name and contact information for someone who will always know where you are in case we lose touch with you. We will contact these people if we are unable to reach you for one week or more or in case of an emergency, as described in the potential discomfort and risk portion below. We will discard their contact information at the end of the study or sooner at your request.

You will be asked to answer some questions via online modules, called Daily Diaries, between your initial preparatory session and your pre-training baseline appointment.

Pre-training baseline session – Zoom (60 minutes)
Following the completion of the first round of Daily Diaries, you will be asked to complete a 60 minute Zoom session with a researcher. We will go over the training program instructions in-depth, you'll choose your preferred type of nicotine replacement therapy (NRT) that will be mailed to you following this appointment, and you will work with a researcher to choose your quit date (i.e., day 1 of the training program). You will also be asked to complete another round of surveys.

Training program (8 weeks)
The training program will take place over the course of 8 weeks and is comprised of four main components. You will be randomly assigned to one of three conditions. There is an equal chance of you being assigned to each condition. The training in all three conditions follows the same format but might influence your smoking in different ways. Starting the day before your quit date, you will begin to receive automated text messages from us, encouraging you to think about smoking and quitting in certain

ways. The second component of the training is a series of at-home, online modules that you can complete on a computer, smart phone, or tablet, at your convenience. The third component of the trainings includes the regular use of nicotine replacement therapy (NRT), such as nicotine gum or patches. We will provide you with an NRT of your choice, such as Nicorette gum or NicoDerm patches. The fourth component of the training program consists of weekly check-ins conducted via a short phone call.

During the course of the training series, we will be in regular contact to check in and to track the trajectory of your smoking habits. You will receive daily text messages to track the number of cigarettes you smoke per day and a weekly phone call to check in and monitor your use of the NRT. You will also be asked to complete another round of Daily Diaries.

Post-training endpoint session/Weekly Call 8 (45 minutes)
Your last weekly check-in call will be conducted over Zoom and is expected to take about 45-minutes. The researcher will ask you the standard check-in questions asked during the weekly phone calls throughout the study, and you will be asked to complete another round of surveys.

You will be asked to complete another series of Daily Diaries between your endpoint session and your follow-up call.

Follow-up call (30 minutes)
We will schedule a call for three months after the completion of the training program. During this call, you will be asked various questions regarding your smoking habits. At the end of this call, you will be debriefed on the study.

What is the payment for participation?
You will receive $20 for completion of the initial preparatory session and $15 for the pre-training baseline session. You can earn up to $115 during the training program; the amount you earn is dependent on your level of engagement with the different components of the training program. If you choose to participate in the study, you will receive a thorough breakdown of how this payment is calculated. You will receive an additional $10 for the combination 8th weekly call/post-training endpoint session. You will receive $5 for attending your 3-month follow-up call and can receive an additional $5 bonus for completing the appointment within the preferred time frame. You can also earn up to $13 for both rounds of Daily Diaries that fall outside of the training program. In total, you can receive up to $196 for completing this study.

In the event that you choose to withdraw from the study (or that we, the researchers, must end the study before intended), you will receive payment for each session you participated in.

Please be aware that compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored

confidentially and separate from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

What are potential discomforts and risks of participating?
Some of the questionnaires and tasks deal with health, smoking habits, and smoking risks, which may cause anxiety and discomfort for some people. You may also feel stimulated, anxious, nervous, or bored during the training. If this occurs, you are encouraged to take a break and/or ask questions. Under no circumstances will you be pressured to respond to any question.

We recognize that certain mental health issues are commonly associated with persistent smoking, and that some of these may become worse if you fail to quit. The strategies you will engage with over the course of the study are experimental. The primary goal of this research is to investigate the effect of the trainings on underlying brain patterns; though there is a possibility that they may help you quit, we cannot guarantee results.

In this study, researchers will not be providing psychological services like therapy or mental health treatment and are not entering into a therapeutic relationship with you. Please keep in mind that our study team is not available for crisis intervention or emergency response support. We do not monitor for risk of suicide in real time and our team is not available for crisis response. Suicide hotline numbers and other mental health resources will be shared periodically throughout the study in case you need them.

If you have a plan to kill or harm yourself that you intend to act on, or we believe that you may act in a way that could seriously risk your life, we will contact your emergency contact and/or reach out to mental health or emergency services to arrange for emergency support. These steps will involve disclosing your personally identifiable information to these providers. We cannot control what will happen when emergency services become involved.

It is possible that engaging in our training program may involve risks which are currently unforeseeable. Should any arise throughout the duration of the study, you will be notified as soon as possible.

What steps are taken to lessen potential discomforts and risks?
Throughout your involvement in the study, we will monitor certain aspects of your overall well-being. This is done in an attempt to track potential mental health risks that commonly occur alongside persistent smoking. Our staff are all trained in these measures and accompanying safety protocols, in case of emergent psychological distress. To minimize risk, we will provide various online mental health resources and hotlines throughout the study. This psychological information collected will only be used for risk management and will not affect your participation in the study.

At all times, these researchers will strive to treat you with courtesy, respect, kindness, sensitivity, and flexibility. Any questions or concerns that you express will be answered to the best of the researcher's ability in a timely and courteous manner.

What are the anticipated benefits of participating in this study?
There are no guaranteed direct benefits to participating in the study. You may find that the trainings help you quit or reduce your smoking patterns. In a broader sense, by becoming involved in this project, you will be contributing to the advancement of scientific research about behavior change and smoking cessation.

What are the anticipated benefits of this study to society?
The information from this study will help us to learn more about the typical patterns related to self-control and addiction. Such information may ultimately be used for designing more effective programs for those trying to quit smoking. It may also lead to the design of helpful, individually tailored interventions for persistent smokers trying to quit.

What are the alternatives to participating?
Since we are currently testing the interventions, they are not availability outside this study. The only alternative to participating in the study is to choose not to participate. Please be aware that your relationship with the University of Oregon will not be affected if you choose not to participate.

What is my financial obligation for care? Will I be compensated for injury?
Neither you nor your insurance company will be billed for any costs associated with your participation in this research. We take your safety very seriously and rigorously follow high safety standards. It is highly unlikely that you would be injured in the course of this research study, but if you were to be physically injured because of this project, you and/or your insurance company would be responsible for your doctor bills.

How will the researchers protect my privacy and confidentiality?
Only the researchers in the Social and Affective Neuroscience Laboratory will know that you are participating in this study. On rare occasions, individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: the study sponsor (NIH) and the Institutional Review Board (IRB) that reviewed this research. No information about your identity will be disclosed to others without your written permission, except if necessary, to protect your rights or welfare (for example, if you were to be injured and needed emergency care) or if required by law.

When the results of this research are published or discussed in conferences, absolutely no information will be included that would reveal your identity. All data collected from you as a part of this project will be labeled with an anonymous code number.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information and documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

How might my data be shared?
Scientific advances can often be achieved more quickly when scientists share information with one another. By agreeing to share your data, you will be making a free and generous gift for research that might help others. It is possible that some of the research conducted using your data could eventually lead to the development of new methods for studying behavior change, new diagnostic tests, and so forth.

Your data from this study might be used for other, future research projects in addition to the study you are currently participating in. Data from this study may also be submitted to other online repositories (websites). However, your data will always be deidentified so that any personally identifying information (e.g., name, birthdate, physical appearance, contact information, etc.) will be removed. To the best of our ability, your data will not contain information that can directly identify you.

_____ Please initial here if you would like to agree to provide your deidentified data for future research. By initialing, you agree that these data may be shared with other investigators at other institutions from around the world. The details, results, and implications of these studies are unknown.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I want to withdraw from the study?

Your participation in this research is ***entirely voluntary***. If you choose not to participate, that will not affect your relationship with the University of Oregon. Even if you decide to participate, you are free to discontinue participation at any time without penalty. You may not, however, withdraw data that was collected prior to your withdrawal. There are no known risks associated with early withdrawal from the training program.

Can the researcher withdraw me from the study?
Circumstances may arise which might cause the researcher to end your participation in sessions before the completion of the study. This decision may be made to protect your health and safety, or because we determine based on past sessions that you are not eligible to continue in future sessions. For example, if you become distressed during the baseline session (e.g. while responding to survey questionnaires), we may choose not to continue with further testing sessions for your own benefit. If such a decision is made, it will be explained clearly to you.

Will I be informed of new findings?
During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in this research that might cause you to change your mind about continuing to participate in the study. If significant new information is provided to you, we will ask for a renewal of your consent, reflecting the new information.

Who is conducting this research?
This research is being conducted by Elliot Berkman, a professor in the Department of Psychology at the University of Oregon. The research is funded by the National Institutes of Health. If you have any questions about the research, or if you experience an injury or negative reaction related to this research, please contact him at:

Elliot Berkman, Ph.D.
Office: (541) 346-4909
berkman@uoregon.edu

What are the rights of participants in this research?
You may withdraw your consent at any time and end participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. An Institutional Review Board (IRB) is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions regarding your rights as research participants, you may contact Research Compliance Services at:

Research Compliance Services
5237 University of Oregon
Eugene, OR, 97403
(541) 346-2510
ResearchCompliance@uoregon.edu.

STATEMENT OF CONSENT
I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)
I have explained the research to the participant and answered all of their questions. I believe that they understand the information described in this consent form and freely consent to participate.

Name of Research Team Member	Signature of Research Team Member	Date