Development of a Mindfulness-Based Treatment for the Reduction of Alcohol Use and Smoking Cessation

NCT03734666

ICF V10

Dated 01/20/2021

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**"Project RISE"**
Sponsor:	**National Center for Complementary and Integrative Health**
Principal Investigator:	**Christine Vinci, Ph.D.**
Telephone: **(24 hour number)**	**(813) 745-5421** **(800) 456-3434**
Address:	**Moffitt Cancer Center** **4115 E Fowler Ave** **Tampa, FL 33617**

You are being asked to take part in a research study. Before you agree to take part in this study, please ask as many questions as you need to be sure you understand the possible risks and benefits.

This consent form has important facts to help you decide if it is in your best interest for you to take part in this study. If you have questions that are not answered in this consent form, one of the research staff will be able to give you more information.

WHAT IS THIS STUDY ABOUT?

The purpose of this study is to develop a treatment that can effectively help people change their alcohol use and quit smoking. We are asking you to take part in this research study because you: (1) are over 18 years of age; (2) are a current cigarette smoker; (3) currently drink alcohol; (4) are motivated to quit smoking and decrease alcohol use within the next 60 days; (5) have a valid address, (6) have a functioning telephone number; and (6) can speak, read, and write in English.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 80 participants will take part in this phase of the study at Moffitt Cancer Center.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to participate in this study, you will be asked to complete a video-conferencing orientation session, 8 weekly group visits, two assessment phone calls, and two follow-up phone calls after today. You will also be asked to complete several questionnaires including questions about your mood. At the end of this visit, we will schedule you for your video-

conferencing orientation visit. For the 8 study treatment visits, you will attend a weekly video group treatment for changing your drinking and quitting smoking.

Each meeting lasts 2 hours and will take place via Zoom, a video-conferencing app. You will be randomized to one of two group study treatments, both of which will provide strategies to help you quit smoking and change drinking. You will be asked to complete some questionnaires before each visit. Before visits 4 and 8, you will be asked to complete a phone call to answer questions about your smoking and drinking.

Before visit 5, you will receive a supply of nicotine patches in the mail. All participants will receive nicotine patches. You will be encouraged to start wearing these the same day as visit 5, since that is the scheduled quit date. You will be mailed with a week's supply of patches prior to each following treatment session. All participants are expected to attend the entirety of group sessions barring unforeseen circumstances (e.g., emergencies).

Each group session will be video and audio recorded for staff training and staff supervision purposes. The content of the sessions will be used to develop best practices for group facilitators. Additionally, should a group participant be unable to attend a session they may make up the session by watching the video recording. You will not be audio or video recorded during the Orientation session. During the group sessions, 1-2 additional individuals will be on the call to support the facilitator, should any technological issue arise for participants.

After study treatment ends, you will be asked to complete two phone calls as a follow-up to your treatment. The first call will be scheduled about 5 weeks after the last study treatment meeting. During this session, you may be invited to participate in an in-depth interview to discuss your experience with the program. This discussion will be video recorded in order to accurately capture what is said. You may choose how much you share and you are welcome to decline to answer any questions.

You will receive a final phone call about 8 weeks after the first follow-up call. This phone call will consist of questions about your smoking and alcohol use since your last in-person visit.

Throughout the study you will receive study-related emails for appointment reminders, surveys, etc. By verbally agreeing to participate in this study, you are agreeing to opt-out of encrypted emails to receive study related materials. This may increase risk for a breach of confidentiality if another individual has access to your email account. Please ask the study staff if you have any questions about how to best protect study-related information in your email account.

WHAT ARE MY ALTERNATIVES TO BEING IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits.

You do not have to be in this study to receive treatment to change alcohol and tobacco use. Talk to the study staff or your primary healthcare provider about your alternatives and the risks and benefits.

WHO IS PAYING FOR THIS STUDY?

The National Center for Complementary and Integrative Health through the National Institutes of Health is paying for this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It will not cost you anything to be part of this study. The nicotine patches will be provided at no cost to you.

Additionally, if you indicate you do not have the proper devices to attend Zoom study treatment groups, tablets, webcams, and/or microphones will be provided. If you are provided the devices, you will be mailed the materials before your Zoom Orientation session. Before receiving equipment, you will be asked to verbally agree to return equipment once the last study treatment session is completed. After the last study treatment session, pre-paid, pre-addressed shipping materials will be provided to mail the equipment back to the lab.

WILL BEING IN THIS STUDY HELP ME?

Participating in this study may help you decrease your alcohol use and quit smoking, which has clear benefits for your health. It is possible that being in this study will not help you. However, the data obtained from this study may help to create better tools to help other people change their alcohol use and quit smoking in the future.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

Participating in the study could cause you to feel uncomfortable or upset. Please tell the study staff or principal investigator if you feel uncomfortable or upset while participating in the study at any time.

You may also potentially experience nicotine withdrawal symptoms. These symptoms may include:

- feeling grumpy/irritable,
- feeling frustration or anger,
- feeling anxious,
- having difficulty concentrating,
- increased appetite,
- restlessness,
- depressed mood,
- or difficulty sleeping.

Generally, these symptoms are uncomfortable but do not pose significant risk to your health or well-being.

You will be provided with nicotine patches to aid in your quit attempt. Prior to using the patches, you will be provided with a detailed description of the indications for the patch, possible side effects, and known health conditions that may prevent you from using the patch. The most common side effects seen with nicotine patches include:

- Skin irritation
- Itching
- Dizziness
- Headache
- Fast heartbeat
- Nausea
- Vivid dreams

The patches are available over-the-counter, and do not pose a significant health risk to most people. That said, if you do have a reaction to the patch, you should stop using them.

There is a risk of a loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study staff or principal investigator if you would like to know more about how your information will be protected while you are in this study.

There may be risks to your participation that are not known at this time.

Women Who Can Get Pregnant or Are Breastfeeding

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time. All women will be tested for pregnancy during the study.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience a side effect or a change in the way that you feel, call the principal investigator at the telephone number listed on the first page of this form.

By providing verbal consent, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-4219. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. Moffitt Cancer Center cannot pay for lost wages, disability, or discomfort. A copy of this statute is available upon request at 813-745-1869. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law. The Moffitt Cancer Center and investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study

WILL I GET PAID?

You will get paid for being in this study.

Orientation: You will receive a $10 gift card for participating in the Orientation session. After Orientation you will be emailed questionnaires to complete; if you complete the questionnaires within 24 hours, you will receive an additional $5 bonus gift card.

Zoom Orientation: You will receive a $10 gift card for participating in the Zoom Orientation session.

Visit Measures: You will be sent an email link with questionnaires to complete prior to each group session. These will be sent to you 48 hours before your group session.

Visits 1-4: For group sessions 1-4, you will receive a $5 gift card for completing each set of measures prior to the group sessions, and an additional $5 bonus gift card for completing them within 24 hours.

Phone Call Visit 4: For completing the phone call before session 4, you will receive a $15 gift card.

Visit 5: For completing the measures before session 5, you will be paid a $20 gift card, with an additional $10 bonus gift card if you complete the measures within 24 hours.

Visit 6 and 7: For completing measures before sessions 6 and 7 will you be paid a $5 gift card for each set, with an additional $5 bonus gift card if you complete the measures within 24 hours.

Phone Call Visit 8: For completing the phone call before session 8, you will receive a $15 gift card.

Visit 8 and Follow-Up Call #1: For completing measures before session 8 and the first follow-up phone call you will be paid a $20 gift card, along with a $10 bonus gift card if you complete them within 24 hours.

Follow-Up Call #2: You will be compensated with a $25 gift card for completing the second follow-up call. You will receive a $10 bonus gift card for collecting and mailing back your saliva sample.

We are compensating you for completing the questionnaires, the saliva sample, and for any other expenses you may incur for attending the visit (for example, childcare). You can receive a up to $240 for completing all aspects of the study. You will be paid after we receive each completed set of measures or after the call has been completed.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

You can decide after providing verbal consent that you no longer want to take part in this study. If you decide you want to stop taking part in the study, tell the principal investigator or study staff as soon as you can.

ARE THERE REASONS THE PRINCIPAL INVESTIGATOR MIGHT TAKE ME OUT OF THE STUDY?

Even if you want to stay in the study, there may be reasons the study staff or principal investigator will need to take you out of it. The principal investigator has the right to take you out of the study at any time with or without your agreement.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

We will take the following steps to protect your confidentiality throughout this session and the entire study: 1) you will be assigned an ID number; 2) we will record information about you by number and not by name; 3) all data collected during this study will be kept in a locked filing cabinet or password-protected computer file; and 4) your name, address, and other contact information will be kept confidential by the study staff and not shared with those outside of the orientation session.

Information that you share during the orientation session will be kept confidential, and may only be shared with the study staff. However, there are situations in which confidentiality may be broken for your safety and the safety of others. These situations include but are not limited to: disclosing that you may have thoughts or plans to harm yourself or others, reports of possible abuse to a child, elderly person, or vulnerable adult. Under these circumstances, the study staff may contact the appropriate authorities and disclose information that has been shared during the interaction in order to protect the safety of you and those individuals potentially at risk of harm.

By providing verbal consent, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

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, documents, or biospecimens 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, documents, or biospecimens 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 (see below); 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 the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law. To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: National Center for Complementary and Integrative Health
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

Additionally, the following people and/or organization(s): University of New Mexico

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the principal investigator and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy

regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By providing verbal consent, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.
Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the principal investigator listed on the first page of this form. Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a copy of this form

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00027389.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

DO YOU WANT TO BE IN THIS STUDY?

If you decide not to take part in this study you will not lose any rights you normally have.

It is up to you to decide whether you want to take part in this study. A representative of the Moffitt Cancer Center has answered your questions to your satisfaction.

You freely give your consent to take part in this study. You understand that by verbally consenting you are agreeing to take part in research.