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Wake Forest University
School of Medicine

A NOVEL DIALECTICAL BEHAVIOR THERAPY BRIEF INTERVENTION FOR CIGARETTE SMOKING BY PATIENTS WITH CANCER: AN OPEN CLINICAL TRIAL

Informed Consent Form to Participate in Research

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1. SUMMARY

You are invited to participate in a research study. The purpose of this research study is to learn more about how **Dialectical Behavior Therapy – Skills Training (DBT-ST)** can help patients with cancer who smoke cigarettes cut down on or stop their smoking. DBT-ST gives people ways to deal with the emotions and stress that can get in the way of changing smoking habits. You are invited to be in this study because you were diagnosed with cancer (at any time) and currently smoke. Your participation in this research study will involve attending 8 virtual group DBT-ST sessions that will last about 60 minutes each. These virtual group sessions will occur weekly over the course of 8 weeks (or up to 10-12 weeks if sessions are missed and make up sessions are needed or holidays occur). Participating in the study will also involve completing several electronic surveys before the first session, after the fourth and eighth group session, and 1 month after completing all sessions.

Participation in this study will involve attending virtual group DBT-ST sessions and taking electronic surveys. All research studies involve some risks. A minimal risk of this study that you should be aware of is unintended sharing of your health care information. Another minimal risk of this study is that you may feel anxious or sad as you talk about cancer and smoking during the virtual sessions. You may or may not benefit from participation in this study. A possible benefit is that you may learn skills for better managing emotions and stress that may help you quit or cut down on smoking. You may learn more about yourself. You may also feel that you are helping other patients with cancer.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices include referral to psychosocial oncology counseling or treatment in the cancer center tobacco cessation clinic. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Marcia McCall, PhD at [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

2. INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you were diagnosed with cancer (at any time) and smoke now. Taking part in this study is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with

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your friends and family.

This study will take place at Atrium Health Wake Forest Baptist Comprehensive Cancer Center. Study visits (sessions) will be completed in a virtual format.

3. Why Is This Study Being Done?

The purpose of this research study is to learn more about how a Dialectical Behavior Therapy Skills Training (DBT-ST) brief intervention can help patients with cancer who smoke cigarettes cut down on or stop their smoking. The study team would like to learn how the DBT-ST intervention impacts patient's emotions, distress, and coping skills. They also want to learn if this intervention is something that patients with cancer who smoke would consider completing if it was offered as part of their routine care.

4. Who is Sponsoring this Study?

This study is being sponsored by the Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC). The sponsor is providing money or other support to the researchers to help conduct this study.

5. How Many People Will Take Part in the Study?

A total of 20 people will take part in this study. Some people may be screened for the study but will not be eligible to participate.

6. How Long Will I Be in the Study?

Your participation in the study is planned to last about 4 months or up to 6 months. You will complete surveys and participate in virtual group sessions over the course of 8 weeks (or up to 10-12 weeks if sessions are missed and make up sessions are needed or holidays occur). Approximately one month after you complete the last virtual session, you will complete surveys and a phone interview, and a study team member may follow-up with you later.

7. What Is Involved in the Study?

If you take part in this study, you will have the following tests and procedures:

Visit	During this visit, you will	How long is this visit?	Reminders
Pre-Study (completed by phone call)	• Review and sign this consent form first • Complete demographics, cancer history, and medication use forms • Collect health status information	*15 minutes*	
Before Session 1 (completed electronically)	• Complete electronic study surveys • Receive compensation ($35 after completing all surveys)	*35 minutes*	Study team member will send reminders to complete electronic surveys before session

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Visit	During this visit, you will	How long is this visit?	Reminders
			1.
Session 1 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Session 2 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Session 3 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Session 4 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Before Session 5 (completed electronically)	• Complete electronic study surveys • Receive compensation ($35 after completing all surveys)	*35 minutes*	Study team member will send reminders to complete electronic surveys before session 5.
Session 5 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Session 6 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.
Session 7 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card (completed between sessions)	*60 minutes*	Reminder will be sent via Redcap to complete session evaluation. Study team will email diary card.

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Visit	During this visit, you will	How long is this visit?	Reminders
Session 8 (virtual)	• Participate in DBT-ST virtual group session • Complete session evaluation survey • Complete DBT-ST diary card • Complete electronic study surveys • Receive compensation ($35 after completing all surveys)	*60 minutes*	Study team member will send reminders to complete electronic surveys after session.
Follow-up by phone (about 1 month after session 8)	• Complete phone interview for an overall evaluation of the DBT-ST intervention Interviews will be audio-recorded. • Complete electronic study surveys • Receive compensation ($35 after completing all surveys, $40 for completing the interview, and a $50 bonus if all study activities were completed)	*60 minutes*	

If you miss a group session, you will review a narrated slide show and be asked to complete an electronic attestation stating that you have made up the session. All group sessions and interviews will be audio-recorded.

The virtual sessions will include a group of approximately 5 to 8 individuals and a session facilitator (that is, the person who will be leading the session and providing DBT-ST). The first session will involve an orientation where the facilitator will introduce DBT-ST and provide a general overview of key concepts. The subsequent sessions will involve mindfulness skills (for example, mindfully managing cravings to smoke and awareness exercises), emotion regulation (for example, awareness of emotions and impulses and taking opposite actions to feelings), and distress tolerance (for example, planning for distress and healthy distractions). The final session will include a review of key skills shared over the course of the sessions.

The electronic surveys involve completing 8 questionnaires, which include Serious Quit Attempts to measure the number of quit attempts you have made; Distress Tolerance Scale to measure your ability to manage stress; Difficulties in Emotion Regulation Scale to measure your ability to manage emotions; Cancer Patient Tobacco Use Questionnaire to measure tobacco use; Depression Anxiety and Stress Scale to measure any depression, anxiety, and stress you may be experiencing; Mental Adjustment to Cancer Scale to measure any hopelessness and fatalistic beliefs you may be experiencing; Mindful Attention Awareness Scale to measure mindfulness; and DBT Ways of Coping Checklist to assess coping via DBT skills. If you are unable to complete the surveys electronically, and you agree to participate by signing this consent, a study team member will help you complete the surveys over the phone.

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8. Will I receive the results of the study?

Research results that are not clinically relevant will not be disclosed to you.

9. What are the risks of the study?

Being in this study involves some risk/inconvenience to you. You should discuss the risk of being in this study with the study staff. These can be physical, emotional, financial, or social. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we do not know about yet, so be sure to tell the study team about any unusual symptoms.

The risk of harm or discomfort that may occur as a result of taking part in this study is not expected to be more than occurs in a subject's daily life or from routine physical or psychological examinations or tests. If distress occurs, patients will be assessed by the principal investigator (mental health counselor) and referred to behavioral health treatment if indicated. Any concerns that participant is in danger of harming self or others will be reported to proper authorities.

We do not anticipate any breach of confidentiality as no records will be shared with any personnel outside the research team. All medical information including assessments and other medical records will be recorded and stored in a database. The database will exist on a password protected secured server. Medical records data will be abstracted by the Research Designee. All records will be kept confidential.

As part of this study, you will be asked questions about your mood and emotions, including questions about psychological distress, stress, depression, anxiety, and thoughts of harming yourself. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

10. Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the results of this study will benefit other people in the future. The benefits of participating in this study may be of benefit to subjects who smoke by impacting a reduction in smoking. Other potential benefits include improved ability to deal with emotions and stress and improved ability to cope with a cancer diagnosis. Because everyone is different, no one can know in advance if the study will help you.

11. What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

12. What Are the Costs?

Study costs, including any study products or procedures that would only be done as part of the study will be paid for by the study sponsor. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

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13. Will You Be Paid for Participating?

You will be paid $35 for completing the electronic surveys at each timepoint. You will also be paid $40 for completing the phone interview at follow-up as well as a $50 completion bonus for completing all the study activities. If you withdraw for any reason from the study, you will receive compensation at each timepoint for which all electronic surveys were completed, and compensation for the phone interview if completed, but you will not receive the $50 bonus.

14. Will Your Research Records be Confidential?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless you give your permission or is required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity.

A description of this clinical trial 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 Web site at any time.

TEXT MESSAGE COMMUNICATION. I give permission to Atrium Health - Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication, and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

15. Who will see my Protected Health Information?

Who may have access to my information:	***Purpose:***
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.

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Consultants and employees of Atrium Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Atrium Health and the Wake Forest University School of Medicine to remain accredited.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information. This includes direct access to your medical records.

Please note that the principal investigator or study staff may also share personal information about you if required by law (for example, if the principal investigator or study staff suspects that you are going to harm someone or yourself). If you have questions about this, please ask the study team.

How will my information be used for this study?
You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

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How will my information be kept confidential?

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization, we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

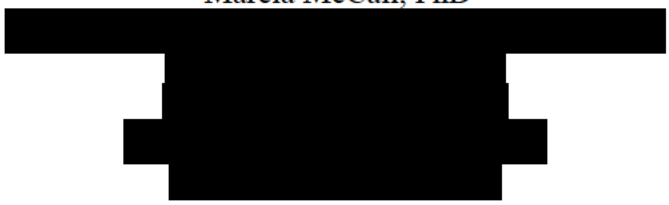
To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the principal investigator. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

Marcia McCall, PhD



If you cancel your authorization, no new information will be collected without your permission. The principal investigator and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

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16. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in the best interest of your physical, mental or emotional health, your condition worsened, new information becomes available, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

17. Whom do I call if I have questions or problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Marcia McCall during office hours or after hours at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

18. Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.

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- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the healthcare team.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records, and used and processed (manually and by computer) for the purposes of the study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, principal investigator, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

Participant signature Date Time am/pm

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

Name of person obtaining informed consent (print)

Signature of person obtaining informed consent Date Time am/pm

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