Study Title: Alcohol Cessation Among Head and Neck Cancer Survivors: A Pilot RCT of a Tailored Text Message-Based Intervention

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Informed Consent Form

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Northwell Health

Consent for Participation in a Research Study

Study Title: Alcohol Cessation Among Head and Neck Cancer Survivors: A Pilot RCT of a Tailored Text Message-Based Intervention

Principal Investigator: Michael Diefenbach, Ph.D.

Sponsor: Department of Defense

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to test the successfulness and practicality (feasibility) of an adapted text message program to fit the needs of civilian and veteran survivors of head and neck cancer. The text messages will educate patients and may help them stop drinking alcohol.
What will happen to me during the study?	This research study includes participating in either a control group (standard of care) or an intervention group (text message-based intervention) that will provide you with education about alcohol and its effect on cancer survivors. It also includes answering surveys/questionnaires.
How long will I participate?	The study procedures will last up to 6 months.

Will taking part expose me to risks?	There is no physical harm to you, but some of these questions we will ask you could make you feel anxious or uncomfortable. Loss of
	confidentiality is the main risk of this research (someone finding out you participated in this research).
Are there any benefits to participation?	This research is designed to test the acceptability of this type of intervention program. We also want to test how well it works so we can try this approach with more people in a larger research study. Because we are looking at how well this works, participants may indirectly benefit from learning more about alcohol and its effect on cancer survivors. Information we gather from participants' responses may help future cancer and HNC patients to cut down (reduce) their alcohol drinking.
What are my alternatives to participation?	If you do not want to take part in this study, a generic alcohol cessation text messaging intervention is available through Bottle Cap developed at CASPIR, the Center for Addiction Services and Personalized Interventions Research. You should speak with your provider about any other alternative. Another alternative is not to participate.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions. You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study. This study is being conducted at Northwell Health and the Brooklyn VA.

Why is this research study being done?
We are developing and evaluating a program to help patients like you learn about alcohol use and cancer. The purpose of our study is to inform patients about alcohol and cancer to help cancer survivors stop drinking all together. The study is designed to help both Civilian and Veterans. We hope that this program will educate participants on the negative effects of alcohol on cancer survivors and help them feel better by providing tools to live a healthier lifestyle.

You are being asked to participate in this study because you are a head-and-neck cancer (HNC) survivor.

How many people will take part in this study?
We hope to enroll 69 patients from Northwell Health for this phase of the research.

How long will you be in this study?
If you choose to take part in this study, you will participate up to 6 months.

What will happen in this research study?

After signing this consent form, you will answer some questions about your health. You will then be "randomized" into one of two research study groups described below. Randomization means that you are put into a group by chance; it's like flipping a coin. A computer program will place you in one of the research study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

Both groups, will be provided general information about alcohol. Both groups will also be asked to complete several questionnaires to obtain an accurate assessment of drinking and receive feedback about the reported alcohol consumption. Participants will be asked to complete these questionnaires at baseline and at 3-month and 6-month follow-up assessments.

If you are in group 2, you will also receive a HNC tailored alcohol cessation text message program. A research coordinator will register you at the Bottle Cap website to receive up to three messages, up to three times a week. These messages will be delivered for 3 months.

For all participants, study participation will be complete after the 6-month follow-up assessment.

What are the risks of the research study? What could go wrong?
Some of these questions we may ask you are personal. You may ask to see the questions before decided whether or not to take part in this study. You may feel embarrassed or stressed. If this happens you do not need to answer these questions. You have the right to withdraw at any time during the study. In the unlikely event that you feel very distressed, we will refer you to a licensed social worker from our institution. In addition, another potential risk of taking part in this study is the possibility of a loss of confidentiality or privacy. This means someone may find out that you participated in this research. The study team has plans to protect your information as discussed below.

What are the benefits of this research study?
This research is designed to test the acceptability of this type of intervention program. We also want to test how well it works so we can try this approach with more people in a larger research study. Because we are looking at how well this works, you may indirectly benefit from learning more about alcohol and its effect on cancer survivors. Information we gather from your responses may help future cancer and HNC patients to cut down (reduce) their alcohol drinking.

Will I receive my results?
We may learn things about you from the study activities which could be important to your health or to your treatment; however, we will not share this information with you because these results are considered research results and are not considered clinical information.

If you do not want to take part in this research study, what are your other choices?

- If you do not join this study, you have other choices to help decrease alcohol consumption. For instance, a generic alcohol cessation text message-based intervention is available through Bottle Cap (Center for Addition Services and Personalized Interventions Research). Talk to your doctor about your choices. Another alternative is not to participate.

Are there any costs for being in this research study?
This research study is funded by the Department of Defense (DoD). Participant insurance will not be billed. However, this study uses text messaging to deliver notifications, reminders, and study questionnaires. Completing the surveys will require cellular data if you are not connected to Wi-Fi. Standard message and data rates from your wireless carrier may apply. **Study participants will not be compensated for any costs related to data usage or sending or receiving text messages by the study or by members of the study team.**

Will you receive any payments for participating in this research study?
To thank you for your time, you will be provided with a ClinCard and have the opportunity to earn the following for each completed assessment: $25 for baseline, $25 for 3-month, and $50 for 6-month assessment. The total payment possible over the course of this study is $100. Payment will be made at the end of each study assessment or when you end your participation.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in research, if the total compensation you receive from participation in Northwell research totals $600 or more. Taxes are not withheld from your compensation.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:
- failure to follow instructions,
- failure to show up for in person or virtual interviews
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information that identifies you. We may collect the results of surveys, questionnaires and interviews. We may also collect information from your medical record.

To facilitate payment for your participation in the study, we may collect your name, date of birth, email, and/or address in order to issue a Clincard via the Clincard Greenphire system. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)
- Representatives from the Department of Defense and/or its agents

The Department of Defense is funding this study and is authorized to review research records.

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?

There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part, or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, send an email to **mdiefenbach@northwell.edu**

Your email needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
The researcher may share information about the study, including de-identified data, on the following data sharing website: https://cos.io/. The Open Science Framework is a free, open-source web application built to provide researchers with a free platform for data and materials sharing. There will be no identifiable data posted to this website or used in future studies. In addition, a description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). The Certificate of Confidentiality means that researchers cannot be forced to identify you, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. You should know, however, that researchers may provide information to appropriate individuals or agencies if harm to you, harm to others or child abuse becomes a concern. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer, employer or other person learns about your participation and gets your consent to receive research information, then the researchers will have to provide your information.

Will my information be used for research in the future?
Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent.

Some information collected during this study that can identify you will be kept on file. This information may be used in the future to contact you for future participation in research studies.

This information will be stored on a secure database. It will only be accessible by trained members of the study team. If you change your mind about being contacted in the future, you may follow the procedures outlined above to notify the researcher.

Does the investigator of this study receive money if you take part?

The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by the Department of Defense. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call the study team at (516) 253-7870. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

Witness's Printed Name | Witness's Signature | Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are or may be associated with this study and to answer any further questions relating to it.

Investigator's Printed Name

Investigator's Signature | Date