

PROTOCOL TITLE:

Video Interventions for Dependence On Smoking (VIDeOS) for Cancer Patients: A Randomized Controlled Pilot Study

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

To date, interventions for smoking cessation among cancer patients have largely either been unsuccessful at improving cessation rates. Further, individuals may have difficulty accessing available cessation resources, such as individuals from rural areas and low socioeconomic backgrounds. Thus, it may be important to not only adapt cessation interventions to meet the unique needs of cancer patients, but also to adapt intervention delivery modalities to extend their accessibility among diverse cancer patients. Previous studies have shown that videos are effective at facilitating smoking cessation,¹ but this intervention has not yet been tested among cancer patients. The proposed study seeks to conduct a pilot trial to test a novel intervention modality to deliver an evidence-based intervention tailored to the unique needs of cancer patients to determine if this is an acceptable and feasible intervention can potentially increase knowledge about smoking cessation, and subsequently lead to making more quit attempts.

The current study will be the first to test the acceptability and feasibility of a video-based smoking intervention tailored to cancer patients to improve accessibility to cessation interventions. This may have a significant impact on future treatment of smoking among cancer patients, which then can have substantial impact on treatment outcomes, quality of life, and cost effectiveness of cancer treatment. Other smoking cessation protocols are in progress within the Alliance portfolio, including a protocol for smoking cessation using text messaging to reach rural cancer survivors. The current study is unique in employing videos as text messages are limited in the amount of information they can convey. Texting protocols involve sending a limited number of messages each day that are restricted in the number of words that can be included. Using videos allows for more detailed information to be delivered, including functional information about how to employ cessation strategies (e.g., how to correctly use a nicotine patch). Videos also cater to a variety of unique abilities that may be particularly relevant for patients with cancer. Texting requires literacy skills and visual acuity that may not be accessible for all patients. Videos allow for individuals with difficulty reading text to access the information, and closed captioning can cater to individuals with hearing difficulties. Thus, videos may be a better option for delivering more detailed smoking cessation interventions to those with unique abilities that preclude them from accessing other resources.

Specific Aims of the proposed research are:**Focus Group**

Aim 1: Obtain feedback from individuals with cancer who smoke related to 2-3 of the videos created for the pilot intervention to make appropriate changes.

Primary Aims

Aim 1: Create videos that deliver an evidence-based smoking cessation intervention tailored to the unique needs of cancer patients that have been identified in former work.

Aim 2: Assess feasibility and acceptability of the intervention and novel modality (i.e., videos) using standardized measures and assessing metrics of intervention engagement (e.g., percentage of patients who accessed a video, percentage of videos watched, facilitators and barriers to watching videos).

Hypothesis: Based on previous literature supporting the use of video to facilitate health behavior change, cancer patients will report high levels of acceptability and feasibility of a video-based smoking cessation intervention.

Aim 3: Assess retention rates between groups, operationalized as response rates at follow-up.

Exploratory Secondary Aims

Aim 4: Assess changes in quality of life and knowledge about quitting smoking at 1 week, 1 month, and 3 months.

Aim 5: Assess number of quit attempts and changes in smoking status at 1 week, 1 month, and 3 months.

2.0 Background

Smoking cigarettes after cancer diagnosis poses significant health risks

Cigarette smoking is the leading cause of preventable death in the United States (US)² and results in an estimated \$170 billion in healthcare spending annually.^{3,4} Cigarette smoking also poses unique risks to individuals with a cancer diagnosis, regardless of whether the cancer is attributable to smoking. These risks include an increased likelihood of having metastatic disease at time of diagnosis,⁵ a second primary cancer,^{3,6} worsened side effects of cancer treatment,^{5,7} and worsened wound healing.⁸ Given the many possible negative health consequences, it is critical for cancer patients to successfully achieve smoking cessation.

Many cancer patients continue to smoke after diagnosis

Smoking among individuals with cancer remains alarmingly high. It is estimated that between 9-33% of cancer patients continue smoking after diagnosis. However, this may be an underestimate due to stigma and shame associated with smoking with cancer.⁹ One study using National Health and Nutrition Examination Survey (NHANES) data found that *63.9% of cancer patients in the sample who smoked prior to diagnosis continued smoking*. At the Hollings Cancer Center at MUSC, the site of the proposed study, 9.3% of patients seen over a 19 month period were identified as currently smoking, although this may also be an underestimate. Thus, it is clear that there is significant room to improve cessation outcomes among cancer patients.

Existing tobacco treatment options

Current clinical practice guidelines for smoking cessation among cancer patients recommend a combination of behavioral (e.g., counseling) and pharmacological interventions (e.g., nicotine replacement therapies, varenicline).¹⁰ However, smoking cessation is often not addressed as part of routine cancer-related care. A recent review of smoking cessation interventions for cancer patients indicated that, of 36 interventions tested since 2012, only 4 yielded statistically significant abstinence rates compared to their control groups. These interventions included intensive telephone counseling, contingency management, and supplying or making recommendations for NRT.¹¹ One trial also included sending supplemental text messages in addition to counseling. Thus, there is a critical need to develop effective interventions for cancer patients. Less than 1% of physicians providing care in cancer centers express a desire to provide tobacco treatment services themselves,¹² and also have limited time and training to provide such services.¹³ Initiatives such as the Cancer Center Cessation Initiative (C3I) have established tobacco treatment programs in cancer centers where patients can be directly referred by their cancer care providers, but there is still significant room to improve the reach of such programs as median reach across cancer centers is 15.4%.¹⁴ Many underserved populations, such as those in rural areas,¹⁵ individuals from minoritized backgrounds, or those with low socioeconomic status^{16,17} have limited access to these resources.

One potentially accessible intervention modality that has shown promising results in facilitating health behavior change is using videos to deliver the treatment information.¹⁸ Previous studies have shown that online videos are effective at facilitating smoking cessation.¹⁹ For example, the Centers for Disease Control and Prevention has

implemented the “Tips from Former Smokers” campaign since 2012. These include commercials airing on television and online that present antismoking messages (e.g., anti-smoking message delivered by someone with throat cancer who has received an appearance-altering surgery). Ongoing assessment of this campaign has shown that viewers are more likely to make a quit attempt and have higher intent to quit.¹⁸ However, videos often encourage quit attempts and provide an overview of risks of smoking and potential benefits after cessation, but lack practical advice about how to achieve cessation using empirically supported methods. The PI of the proposed study is currently collecting data about smoking videos online by reviewing the most watched video and the videos deemed “most relevant” on YouTube using particular search terms (“quit smoking,” “stop smoking,” “smoking cessation”) and preliminary results indicate that very few videos provide in-depth information related to strategies to quit, including making behavioral changes or proper use of smoking cessation medications and nicotine replacement therapies (e.g., patches, gum, lozenges). Thus, while these videos may increase quit attempts and intent to quit, they do not necessarily give people the tools they need to be successful.

Additionally, using videos to deliver smoking cessation interventions has not yet been tested specifically among cancer patients. A review of video-based interventions for a variety of health behaviors found that video interventions can significantly increase desired health behaviors, and suggested that interventions for smoking cessation be tailored to the target population and gain-framed.²⁰ Thus, it is important to ensure that video adaptations of cessation interventions for cancer patients are adequately tailored to their unique needs (e.g., cancer-specific stressors²¹) and the current study aims to test if these videos may be helpful for smoking cessation among this vulnerable population.

3.0 Intervention to be studied

In this parallel group pilot randomized-controlled trial, cancer patients will be randomized to Video Interventions (VI; $n = 20$) or treatment as usual (TAU; $n = 20$). The VI group will be sent the created videos via text message or email, depending on preference. The NCI “Clearing the Air” booklet will be sent to all TAU participants via text or email as well so that all participants receive some sort of external communication. Participants will be instructed to review the materials over the next week.

The videos will be informed by an ongoing qualitative study being conducted by the PI. The PI is currently conducting interviews with cancer patients receiving care through Hollings who report current cigarette smoking to ask about their thoughts about potential video interventions. This includes their thoughts about content they would be interested in receiving, who they would like to see presenting the information, how long the videos should be, how many there should be, etc. The current study has budgeted for creating 12 videos that are 1-5 minutes in length. However, based on preliminary data, we expect to create 5-6 videos as participants have indicated they do not want videos to have redundant content and they would be willing to watch about 5 videos at a time. Each video will address in-depth information about a specific topic to ensure the videos are not long in duration and could be accessed at a later time should the patient be looking for specific information. Videos will address how to properly use NRT, specific strategies for managing cravings, managing triggers for smoking, and managing general and cancer-related stressors. Video topics will be finalized upon completion of the qualitative study. The theories behind designing the interventions are the Theory of Planned Behavior and the Health Belief Model. The Theory of Planned Behavior suggests that attitudes, subjective norms, and perceived control influence intention to make health behavior changes, which leads to actual behavior change. The Health Belief Model posits that perceived barriers, perceived severity of the health threat, perceived susceptibility to the health threat, and perceived benefits of health behavior change influence actual changes in health behaviors. Through these videos, we aim to encourage health behavior change (i.e., smoking cessation) by increasing knowledge about smoking cessation and providing corrective information for concepts that often are misunderstood (e.g., role of nicotine in smoking harms) so that patients understand the benefits of quitting,

the continued harms of smoking after a cancer diagnosis, and promote attitudes that quitting after a cancer diagnosis is still beneficial.

To enable patients from a wide range of backgrounds and experience to feel connected to these videos, we hope to employ speakers from a wide range of identities in the videos. We are also recruiting participants from a wide range of identities and backgrounds in our qualitative study to learn more about what individuals would like to see in the videos. To connect with individuals from a wide range of cancer types, we will highlight the shared harms of smoking. Smoking can be harmful to health and cancer treatment no matter what type of cancer a person is diagnosed with. It can also contribute to the onset of other cancers no matter the initial diagnosis. Individuals with cancer who smoke also report high levels of cancer-related stress, as uncovered in the PI's previous work. Thus, we will be providing information that relates to smoking and cancer generally.

4.0 Study Endpoints

Initial focus groups will be conducted to provide thoughts and feedback about the first 3 videos made.

This study will have the following major endpoints: 1) assess feasibility and acceptability of the intervention and the novel intervention delivery modality, 2) assess retention rates in the different groups, 3) explore changes in knowledge about quitting smoking, quality of life, and smoking status over time (exploratory secondary aims). Acceptability and feasibility will be assessed using the Acceptability of Intervention and Feasibility of Intervention measures, which are standardized measures for assessing how acceptable and feasible a new intervention may be. Higher scores on these measures indicate higher levels of acceptability and feasibility. The answer responses are rated from 1-5 (1 being the lowest, 5 being the highest), and a rating of 4 for each of the 4 questions per measure will indicate that the intervention is acceptable or feasible. We will also be measuring feasibility of the intervention by assessing the percentage of participants able to access the videos and the percentage of videos watched. If most participants endorse that the videos are adequate related to these issues, then we will consider the videos a feasible intervention.

5.0 Inclusion and Exclusion Criteria/ Study Population

Research staff will determine if participants meet inclusion criteria when they call to tell the participant about the study.

Inclusion Criteria:

- 1) Ages 18+
- 2) Receiving care at MUSC
- 3) Must be able to read and understand English
- 4) Currently smoking cigarettes (any amount)
- 5) Diagnosed with cancer (any type; in active treatment/not in remission or post-treatment)
- 6) Has not opted out of research contact

Exclusion Criteria:

- 1) Unable to understand study procedures. Should the potential participant behave in such a way that demonstrates they are not comprehending the study procedures, we will discontinue enrollment.

6.0 Number of Subjects

Focus groups to provide initial feedback about the videos will include 10 participants total.

The total number of participants needed for the pilot study is 40 (20 per study arm). As there may be participants who pass away or withdraw prior to exposure to the intervention, we will consent up to 50 participants. We will not consent more people than can be randomized so as to not exceed our recruitment goals of 20 per group. We have consulted with a statistician, Dr. Naomi Brownstein, to determine if this sample size is appropriate. The primary quantitative component of the study is designed as a pilot feasibility trial with primarily descriptive statistical analyses. Assuming the minimum hypothesized benchmarks of 0.8 for feasibility, acceptability, and proportions who watched videos, 20 participants in a group will provide 95% confidence intervals around the estimates with an expected width of 0.379. The maximum possible width of the intervals, which would correspond to the estimates of 50% feasibility/acceptability, would be 0.456. Accounting for 20% dropout (N=16 per group yields an expected interval width of 0.424 and a maximum interval width of 0.507. Even in the unlikely scenario that we experience 40% dropout, yielding the sample size per group of N=12 recommended elsewhere (CITE) yields a maximum interval width of 0.578 and an expected interval width of 0.487.

Exploratory comparisons in this cohort between groups are designed for planning purposes only.

7.0 Setting

This study will be conducted remotely. No study procedures will be conducted in person. Research staff will conduct all remote study procedures in private spaces.

8.0 Recruitment Methods

Participants will be recruited via the opt-out Tobacco Treatment Program at the Hollings Cancer Center for focus groups and the full pilot trial. The Tobacco Treatment Program uses a data management service called Telask. Telask downloads EHR data from Epic every morning and produces a report of all individuals seen at HCC the previous day who were identified as currently smoking cigarettes. That list is provided to MUSC Tobacco Treatment Program counselors who then proactively reach out to the patients to offer smoking cessation pharmacotherapy and behavioral counseling. This is a routine, standard clinical service at MUSC. The Tobacco Treatment Specialists will ask about the patient's interest in participating in a study where they will receive information about quitting smoking and then take surveys asking about their experiences with smoking and what they thought about the intervention (either videos or booklet). Contact information for individuals who indicate their interest in participating will be transferred to research staff for contact via an Excel sheet located on Box. Study staff will then call the participant to describe the study, read a study information statement, and ask if they would like to participate. Eligibility will be confirmed by study staff prior enrolling the participant. The research team will only contact individuals who have not opted out of research contact.

Participants will also be recruited through cold-contact measures. The research staff will work with an honest broker to develop a list of Hollings Cancer Center patients who have received any type of cancer diagnosis and will call the phone numbers provided by the honest broker. A cold-calling script will be used when contacting participants by phone. The study team will not cold-contact any patients who have opt-ed out of receiving contact about research or has reached their cold contact limit.

Recruitment of underrepresented minorities and rural patients is critical to the success of the current study. Biweekly data checks will be conducted by the PI to ensure there is adequate recruitment of individuals from diverse backgrounds and geographic locations, and recruitment strategies will be adjusted if needed.

9.0 Consent Process

For the focus group, a waiver of written consent is requested given that this is a minimal risk study. All study procedures will occur virtually and providing written consent electronically may preclude some individuals from participating. They will be read an introduction to the study at that time that describes the nature of the study, study procedures, and explains what they will be asked to do.

For the pilot trial, participants will be called by study staff to be enrolled in the study. They will be read an introduction to the study at that time that describes the nature of the study, study procedures, and explains what they will be asked to do. They will be able to ask any questions and will be asked if they agree to participate. We will provide a reminder to participants about the study participation terms, compensation, and their right to withdraw at any time at the top of each follow-up survey. Participants will be informed that all data are confidential, will be kept private, and will only be used for research purposes.

Participants can stop study participation at any time if they feel uncomfortable or do not wish to continue. Contact information for study staff will be included should the participant have questions. We are asking to waive having the written consent because we are hoping to recruit patients with a wide range of digital literacy and mobility levels. This study will be entirely remote, and one of the main points of these videos is to increase accessibility of empirically supported smoking cessation treatments. Past work by the PI assessing South Carolina Medicaid data indicates that people in rural areas often do not receive tobacco counseling despite having a smoking diagnostic code. Hollings serves cancer patients from all over the state who often drive hours to attend medical appointments, and will schedule several appointments in a day to save themselves extra trips. This does not always allow for tobacco treatment appointments through established programs. We hope to expand the reach of tobacco cessation treatment using these videos and make them as easy to use as possible so that even those with lower digital literacy are able to have access. However, if someone does not have enough digital literacy to sign an e-consent form or does not have the mobility or full use of their hands needed to sign the form, then they would be excluded. This is not consistent with the goal of the studies, which is why we are requesting a waiver of written consent. This will not alter the rights of participants and will not impact their welfare.

10.0 Study Design / Methods

Focus groups will be conducted (N = 10) to provide feedback on the initial 3 videos to ensure video style, content, etc. is acceptable. Changes to videos will be made based on feedback. The focus group will include a virtual meeting via Microsoft Teams hosted by MUSC. Participants will watch one video at a time together and then engage in discussion about the video. Study staff leading the focus groups will use a semi-structured interview guide to lead the discussion. A survey to obtain demographic information and smoking history will be administered via REDCap using a link sent to participants ahead of the meeting. Participants will be emailed gift card codes after the focus group ends.

Participants in the pilot intervention study will complete a baseline assessment prior to randomization (over the phone with research staff or through REDCap link, depending on preference). At baseline, study staff will also conduct a chart review to extract information about cancer diagnosis and treatment information for the purpose of characterizing the study population. Specifically, we will extract information about the type(s) of cancer diagnosed, stage of disease, and if they are or are not currently being treated. This is the only time a patient's chart will be accessed during this study. Information will be entered into REDCap under a record that lists the participant ID number rather than their name. Once the assessment is complete, they will be randomized to one of two groups: VI or TAU. Both groups can still receive counseling from the TTS that initially contacted them should they wish to engage in these services. We will collect data about treatment engagement at all follow-ups via self-report on the follow-up surveys. The VI group will be sent the created videos. These videos are being developed and a list of content areas and basic information to be included in the videos has been created. We will seek IRB approval for the finalized scripts once they have been developed. A link to the NCI "Clearing the Air"

booklet will be texted or emailed to all TAU participants so that all participants receive some sort of external communication. Participants will be instructed to review the materials over the next week. Participants will be asked to complete short follow-up assessments by phone or independently using REDCap links one week, one month, and three months post-randomization. All assessments completed by study staff over the phone will have participant responses entered into REDCap.

The surveys should take approximately 20 minutes to complete. Questions related to demographics and smoking history will be pulled from large-scale epidemiological surveys from the CDC such as BRFSS and NHANES. Cancer history questions are also from BRFSS. We will also use the Fagerstrom Test of Nicotine Dependence²² to measure nicotine dependence levels and contemplation ladders²³ to assess readiness and confidence to quit smoking. The Patient Reported Outcomes Measurement Information System (PROMIS)-29 will be used to assess quality of life, and other investigator-derived questions will be used to ask specifically about the created intervention informed by previous research by the PI's mentor, Dr. Alana Rojewski. Additionally, questions from previous work by the PI will be used to inquire about smoking cessation medication use. Lastly, we will include the Acceptability of Intervention and Feasibility of Intervention measures described previously.

We will also conduct chemical verification of smoking status using an iCOquit device that measures carbon monoxide levels by a person blowing into the device. This is a non-invasive measure. These devices will be mailed to participants at time of randomization. Participants will use this device at each follow-up time point and will enter the value in the follow-up survey.

All information will be collected via self-report on the surveys.

Compensation

For the initial focus groups, participants will be given a \$30 Amazon gift code for participating.

After each assessment, participants will be compensated with a \$25 gift card, and will receive an extra \$25 gift card if they complete all assessments. Participants will be compensated using Amazon voucher codes.

Statistical Analyses

Prior to data analysis, we will assess patterns of missing data to ensure missingness does not differ based on participant characteristics. Multiple imputation will be used should missing data within a given variable exceed 5%.²⁴ Intent-to-treat analyses will be used. Demographics, acceptability and feasibility scores (primary outcome), and cessation knowledge will be described using means and standard deviations or frequencies as appropriate. Statistical analyses will be conducted using IBM SPSS version 25 and Mplus. Significance levels will be 0.05.

We will be collecting data about when the patient was initially diagnosed to account for this information in the statistical analyses. We will also be collecting data about cancer type to account for this in statistical analyses and see if there are potential differences between cancer types that may require further attention in future trials. Information about cancer diagnoses will be collected within the self-reported survey measures.

11.0 Specimen Collection and Banking (if applicable)

N/A

12.0 Data Management

The research team (PI, mentor, and designated staff) have established procedures in place to minimize the risk of any confidentiality breach. To minimize this risk, data and all other digital research records will be stored on the password-protected MUSC network and REDCap (a secure, password-protected data management system maintained by MUSC). All precautionary measures will be taken to ensure that data remains confidential. Some identifying information is needed to ensure unique participation (no duplicate participation) and for participant remuneration. We will only collect the minimum amount of identifying information needed and will delete this information from the research record when the study is complete. We will be asking participants for their email address for the purpose of remuneration and their name to help track participation over time. Additionally, we will collect mailing addresses during study enrollment so that study staff can send iCOquit devices to participants after randomization. This information will be stored completely separately from all survey responses. A master list of names linking participants to their participant ID will be saved on Box and will only be accessible to study staff. De-identified data sets will be created and used for analyses after the data collection period has ended. Identifying data will be present in the data on REDCap, but we will not include these variables when data is downloaded, and all identifying data will be destroyed after study completion.

Related to cold contact procedures, the list of patients for contact will be housed in a REDCap database separate from the study's database. Only individuals who consent to participate in the study will be added to the study database, and will be protected using the same procedures described above. Only IRB-approved study staff will have access to the REDCap database listing the individuals for cold contact.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

N/A

14.0 Withdrawal of Subjects (if applicable)

Participants may withdraw during the study without penalty but will not be compensated.

15.0 Risks to Subjects

There are minimal risks to subjects who participate in this study.

Loss of Confidentiality. There is the risk of breach of confidentiality. The research team has procedures in place to minimize the risk of any confidentiality breach. Electronic records are stored in password-protected databases. Much of the data collected uses a participant ID (participant coding system). Participant names and email addresses will be saved in a separate survey and will not be included with survey responses. No specific or general participant information will be left in public access areas, and no oral communication regarding participants with identifiers will be made in any public areas. Participants will be informed of these potential risks within the information statements (see section 9.0) and will have the option to leave the study at any point.

16.0 Potential Benefits to Subjects or Others

The participants may benefit from the intervention that is being tested, as they will be videos or a booklet that provide detailed education related to smoking cessation and ways to achieve cessation. This benefit is not guaranteed. This study will inform investigators if the intervention is feasible to implement, acceptable to participants, and effective for increasing knowledge, which may lead to larger trials and future implementation of this resource.

17.0 Sharing of Results with Subjects

A summary of study results we will be shared with respondents who request such a summary.

18.0 Drugs or Devices (if applicable)

N/A

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