Motivating a Spectrum of Cancer Patients to Quit Smoking: Intervention Development and Feasibility

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TITLE: Motivating a Spectrum of Cancer Patients to Quit Smoking: Intervention Development and Feasibility

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A. SPECIFIC AIMS

Tobacco smoking is causally related to at least 12 cancers types. Although the strongest causal links have been found for lung and head and neck (H&N) cancers, other cancers have a moderate causal link [1]. A cancer diagnosis often motivates individuals to quit smoking, but more than one third continue to smoke. Relatively little smoking cessation research has been conducted in the oncology patient population. Moreover, the majority of studies have focused on patients with the cancers most directly associated with smoking: lung and/or H&N. This is logical, given that smoking prevalence is highest among these cancer patients, and research (including our preliminary study) indicates that they are the most motivated to quit smoking. However, across cancer types, continued smoking after diagnosis carries multiple potential negative consequences: poorer cancer treatment efficacy, greater risk of treatment complications, development of second primary tumors, and cancer recurrence [2]. Continued smoking also places patients at greater risk of other, non-cancer health consequences [1]. Thus, regardless of cancer type, smoking cessation is critically important for cancer patients [3, 4]. In sum, there is an urgent need to extend smoking cessation motivation and behavior change interventions to include patients with cancers across the cancer spectrum, particularly those with cancers not widely associated with smoking that have been largely ignored by previous trials.

According to multiple conceptual models, behavior change is influenced by an individual's interpretation and judgements of an event (e.g., its significance, cause, and meaning). Based on this foundation, McBride et al. [5] built a heuristic model in which an event offers a significant "teachable moment" if it (a) increases perception of personal risk and outcome expectancies, (b) prompts strong affective or emotional responses, and (c) redefines self-concept or social role. These reactions produce a cognitive response that influences individuals' motivation, skills acquisition, and self-efficacy, which ultimately influence the likelihood of behavior change, including smoking cessation.

The goal of this project is to develop and pilot a brief, easily-disseminated intervention for recently diagnosed patients with a cancer not widely known to be associated with smoking (i.e., those with moderate or unknown smoking-related etiology). Based on the teachable moment model (TMM), the primary aim of the intervention is to increase motivation to quit smoking by communicating about the role of smoking in the etiology (where applicable), treatment, and prognosis for the patient's specific cancer type.

Specific Aim 1. To develop, using a systematic, iterative process, a minimal intervention, specific for each cancer type, to increase motivation to quit smoking in patients recently diagnosed with a cancer not widely known to be associated with smoking. We will follow a three-phase process: (1) Qualitative assessment of representative cancer patients regarding knowledge about their cancer and smoking, and their perceived needs and preferences regarding motivation to quit smoking; (2) Development of messages and other intervention content to boost motivation to quit smoking based upon the TMM and Phase 1 results; and (3) After a full draft of the intervention has been developed, presentation of the initial draft of the materials to the target population, with modifications based on their feedback. As per the TMM, we expect to leverage personal risk perceptions, emotional response, and challenge to self-concept by targeting the brief intervention for each patient's cancer type, focusing initially on five cancer types (breast, colorectal, gynecological, skin melanoma, and bladder). Building on our team's prior research and proposed formative work in Phases 1 to 3, we expect to create targeted self-help interventions in the form of booklets/pamphlets for each type of cancer.

Specific Aim 2. To assess feasibility and acceptability of the intervention among the target populations. Once the minimal intervention is developed in Aim 1, it will be distributed to cancer patients who are current smokers and have been diagnosed with one of the five cancer types above (N=50). We will evaluate if the intervention is feasible (e.g., screening, recruitment, completion of assessment measures, and follow-up) and acceptable (e.g., self-reported patient satisfaction). These data will provide valuable information in preparation for a subsequent, fully-powered randomized trial in which our motivational intervention will precede an evidence-based smoking cessation intervention.

In summary, the goal of the intervention is to harness the motivational power of this potential teachable moment beyond lung and H&N cancers. Given the clinical importance of smoking cessation to all cancer patients, this research has potential for wide impact upon cancer treatment outcomes and quality of life.

B. SIGNIFICANCE

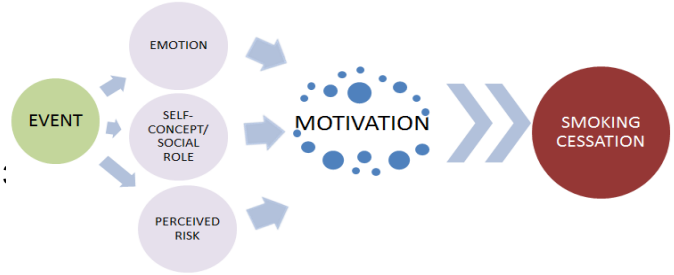
B1. Effects of smoking for cancer patients. Smoking is the leading preventable cause of death worldwide. One of its major health consequences is cancer. Whereas many people associate smoking with lung and head and neck (H&N) cancers, the 2014 Surgeon General's report indicates that smoking is actually associated with 12 different types of cancer including lung, H&N, acute myeloid leukemia, bladder, cervix, colorectal, esophagus, kidneys, larynx, liver, pancreas, and stomach [1]. Studies indicate that, although a high percentage of lung cancer patients attribute their cancer to smoking, people with other cancers that are also smoking-related (e.g., colorectal) are less likely to identify smoking as a primary cause of their cancer [6]. Consequently, they appear less likely to quit smoking [7] or seek smoking cessation treatments [8]. Although smoking is involved in the etiology of some types of cancer, **continued smoking after a diagnosis of cancer has adverse effects regardless of cancer type**. Smoking after a diagnosis of any cancer type has been associated with an increased mortality, development of second primary tumors, reduced cancer treatment efficacy, reduced quality of life, and higher cancer recurrence [1, 2, 9]. Patients who continue smoking are also at greater risk of other, non-cancer health consequences (e.g., cardiovascular disease) [1]. **Thus, it is important for all cancer patients to quit smoking, regardless of cancer type.**

B.2. Smoking cessation among cancer patients. Despite the importance of smoking cessation in the oncology patient population, few studies have tested the efficacy of smoking cessation interventions for cancer patients. Moreover, studies have failed to find significant intervention effects in this population [10]. Several barriers may hinder smoking cessation in cancer patients, including high nicotine dependence, high stress, and unawareness of the numerous cancer-related benefits of quitting smoking [11]. In addition, the majority of the studies have focused on lung and H&N cancer patients [e.g., 12, 13], likely because these are cancers widely known to be caused by smoking and they have high smoking prevalence rates. A key finding from previous studies is that patients with lung or H&N cancers were more likely to quit smoking than patients with other types of cancer. Schnoll et al. [7] found that patients with lung and H&N cancers were more likely to be abstinent at the 6 and 12 months follow-up compared to patients with other cancers. Similarly, Wakefield et al. [14] found that patients with smoking-related cancers (lung, H&N, and bladder) were more likely to quit smoking. In both studies, the authors suggest that this difference is likely a consequence of differential smoking cessation motivation across cancer types, highlighting the need for interventions aimed at motivating patients with cancers other than lung and H&N to quit smoking. Indeed, we found in our preliminary findings from a smoking relapse-prevention trial for cancer patients, that those with cancers other than lung and H&N demonstrate less motivation to quit smoking [15]. Moreover, it has been found that patients with tumor sites not typically associated with smoking are less likely to enroll in smoking cessation treatment [8]. **Thus, a first step toward increasing smoking cessation across cancer types is to target cessation motivation, particularly among patients diagnosed with cancers not widely known to the public as associated with smoking.**

B.3. Link between motivation and behavior change. Smoking cessation typically involves two different processes: motivation to quit and the actual cessation attempt. Consequently, interventions typically focus on one or the other: motivating smokers to try or helping them to quit [16, 17]. This distinction has been recognized by leading models of tobacco cessation [18], it is incorporated into the USPHS Clinical Practice Guidelines, which includes the "5 Rs" to enhance cessation motivation [19], and it forms the foundation of interventions such as Motivational Interviewing [20], which was developed specifically to enhance motivation for change. A motivational model that is particularly relevant for smokers recently diagnosed with cancer is the Teachable Moment Model (TMM) [11], which forms the basis for the present proposal.

B.4. Teachable Moment Model (TMM). A diagnosis of cancer is usually an event that increases motivation to quit smoking. This is also known as a Teachable Moment (TM) [5]. Hochbaum´s Health Belief Model and subsequent models considered the TM as a cognitive experience in which the

Figure 1: Teachable Moment Model



interpretation of the event (e.g., significance, cause, meaning) determines subsequent behavior change. Based on this, McBride and Ostroff [11] indicated that a TM (Figure 1): (1) increases perception of personal risk and outcome expectancies, (2) prompts a strong affective or emotional response, and (3) redefines self-concept or social role [5]. Consistent with this conceptualization, Gritz et al. [21] followed 840 lung cancer patients and found that 83.2% quit smoking at the time of diagnosis. According to the TMM, a smoker diagnosed with cancer likely has reactions such as, "if I continue smoking I will probably reduce my chances of surviving" (risk perception), "I feel very guilty and afraid when I light up a cigarette" (emotional response), and "what is everybody going to think if I continue smoking after getting cancer?" (self-concept/ social role). These or similar reactions influence an individuals' motivation that will directly impact their smoking cessation. However, patients with cancers not widely known to be associated with smoking may have lower perceptions of risk, less smoking-related emotion response, and less redefinition of their self-concept and social role regarding smoking. So, as a consequence of the differences in the link to smoking by cancer type, the TM may not be operating equivocally across cancer types. **Therefore, in the present project we will address each of the three constructs of the TMM to increase smoking cessation motivation in patients with a cancer not widely known to be associated with smoking.** We will focus on breast, colorectal, gynecological, skin melanoma, and bladder cancers. Two of these are not currently considered smoking related (e.g., breast and skin melanoma) and three have sufficient evidence to support a causal role of smoking (e.g., colorectal, gynecological, and bladder) [1]. These cancers have high prevalence in the population, they usually have high rates of smoking, and most have a better long-term prognosis compared to other types of cancer (e.g., pancreas, liver). Thus, a wide range of the cancer population could benefit from this intervention. If successful, it could be extended to all types of cancer in the future, including lung or H&N cancer patients with low cessation motivation. Although the ultimate goal is smoking *cessation*, this project addresses an important first step toward that goal—motivation to quit smoking.

B.5. Self-help Smoking Cessation Interventions. Self-help refers to interventions using written (hard copy and/or electronic) or video materials requiring minimal, if any, direct personal assistance. They are usually low cost and easy to disseminate [22]. Our research group has over 20 years of experience in the development of self-help interventions that have demonstrated efficacy for smoking cessation [23] and relapse prevention [24, 25]. For example, in our most recent smoking cessation trial, participants who received our series of self-help booklets were significantly more likely to be abstinent compared with a traditional self-help intervention (30.0% vs. 18.8%, respectively at the 24 month follow-up) [23]. These interventions, developed in the format of a series of booklets called "Forever Free," are based on cognitive-behavioral theory and empirical research. They have been adapted for special populations, such as pregnant women [26], e-cigarette users [27], and ethnic minorities [28]. Particularly relevant to this project, our group developed a self-help video intervention to help cancer patients who recently quit smoking to maintain abstinence [29]. **In the present study, based on lessons learned from our previous work, we will develop self-help materials, in the form of a booklet/pamphlet, targeted by cancer type** (e.g., "If You Have Colorectal Cancer…Why You Should Quit Smoking Now"). Paper interventions have shown similar effectiveness in smoking cessation with cancer survivors when compared to web formats [30]. Moreover, they have the advantage that they are easy to disseminate, users do not need Internet access, and they are usually more user-friendly for certain population groups (e.g., the elderly, people with low education). Our team obtained positive feedback when asking cancer patients about their satisfaction using booklets for smoking cessation [31]. **Notably, the planned self-help materials will be targeted to each cancer type.** Targeting should increase the likelihood of patients (a) reading the materials; (b) considering the content relevant to themselves and not rationalizing that the risks do not apply to them; and (c) responding to the TM with increased motivation to quit smoking.

B.6. Summary. It is critical that cancer patients quit smoking, regardless of cancer type; however many continue to smoke and appear unmotivated to quit. In synchrony with the TMM, motivation to quit smoking by cancer patients is presumably influenced by (a) the perceived connection between smoking and cancer type; and (b) awareness of the benefits of quitting smoking after a cancer diagnosis. In this project, **we will develop a minimal self-help intervention to increase motivation to quit smoking in patients with cancers not widely known as smoking-related**. Patients with enhanced cessation motivation should be more likely to quit smoking or to receive cessation assistance. In addition, this application addresses several of the NCI funding

priorities [32, 33] including: developing novel behavioral interventions for tobacco dependence, increasing the reach of interventions, and addressing cessation motivation.

The scientific premise of this study is based on previous research demonstrating that cancer patients experience barriers (e.g., emotional distress, low perceived risk) that reduce cessation motivation and willingness to enroll in formal cessation programs. This may be especially evident in patients with a cancer not typically related to smoking. Using the theoretical foundation of the TMM and our experience with self-help interventions for smoking cessation/relapse prevention, we aim to develop a low-cost intervention to boost cessation motivation for patients who exhibit lower levels of motivation to quit—patients with cancers not widely known to be associated with smoking.

C. INNOVATION

The proposed project is innovative along several dimensions. First, it will be the **first study focused primarily on increasing motivation to quit smoking** in the cancer patient population. Since motivation is a strong predictor of behavioral change [34, 35], this intervention has the potential of improving cessation rates in the future. Second, cancer patients are a difficult population to recruit, and a motivational intervention thus could be used to increase participation rates in smoking cessation trials [8]. Third, **the intervention will focus on cancers not widely known by the public to be associated with smoking.** To date, tobacco research in the oncology patient population has been mainly focused on cancers most closely associated with smoking (e.g., lung and H&N) [10]. Although it is important to address smoking behavior in those patients, cessation benefits patients across the cancer spectrum, and people with other cancer types have not received focused attention with respect to smoking. Fourth, the intervention is expected to be **targeted by cancer type** to increase knowledge and motivation to quit smoking, as predicted by the TMM. More generally, interventions personalized to the specific characteristics of the population have been found to be more effective than standard materials [36], but this level of personalization has not previously included cancer type for smoking behavior. Fifth, although the use of self-help interventions is not in itself novel, they have been rarely used with cancer patients. Interventions for cancer patients have primarily been provider delivered, and they have not separated the motivation and cessation stages. Thus, the proposed intervention would be innovative as a **theory-based, systematically-developed, low-cost, easily disseminated motivational intervention.**

D. APPROACH

D.1. Preliminary Studies

D.1.1. The research team. The PI, **Úrsula Martínez, PhD,** has a background in smoking cessation treatments for the general [37] and oncology patient populations [38]. Since arriving at Moffitt Cancer Center in 2016, she expanded her expertise in smoking cessation treatments for cancer patients by contributing to ongoing studies. She will lead this project, supervising and overseeing study activities. She will have the support of a research team with expertise in all aspects of the proposed research: development and evaluation of self-help interventions (**Thomas H. Brandon, PhD,** and **Vani N. Simmons, PhD**), smoking cessation among cancer patients (Brandon, Simmons, and **Graham Warren, MD, PhD**), medical knowledge to evaluate clinical data (Warren), formative research (Simmons), and the TMM theoretical model (**Colleen McBride, PhD**).

D.1.2. Cancer and smoking cessation. Dr. Martínez co-led a systematic review of the effectiveness of smoking cessation interventions for H&N cancer patients [38]. During the review process, it was evident that there was a dearth of research aimed at smoking cessation in cancer patients, particularly by cancer type. Cancer-specific studies tended to be limited to either lung or H&N cancers [12, 13, 39-42]. **Thus, there is a need for research on interventions for patients with cancers less-strongly associated with smoking.**

In addition, our team recently completed a randomized controlled trial (RCT) testing the efficacy of a smoking relapse-prevention intervention for cancer patients [29]. Secondary data analyses [15] classified 357 cancer patients by the degree of smoking-relatedness of their cancer type: “very related” for lung and H&N (*n*=134), “somewhat related” for gastrointestinal, genitourinary, gynecological, and hematological (n=86), and “unlikely related” for all other cancer types (n=137). Logistic regression indicated that smoking-relatedness was positively associated with (1) plan to stay smoke free (AOR=1.46[1.07, 1.99], *p*=.018) and (2) maximum

confidence in being smoke free in 6 months (AOR=1.78 [1.31, 2.41], *p*<.001). Multiple regression revealed that smoking-relatedness was inversely associated with (3) expected difficulty in maintaining abstinence (b=–0.67, *p*=.002) and positively associated with (4) self-efficacy to not smoke (b=1.36, *p*=.010). Moreover, each of the four motivational variables predicted abstinence two months later (*p*s<*.001*), as did smoking-relatedness (*p*=0.035). In a multivariable model with smoking-relatedness and the four motivational variables, the former lost statistical significance (*p*=.289). Using backward stepwise procedures, the final multivariable model included plan to stay smoke free, maximum confidence in being smoke free, and higher self-efficacy (*p*s<.05). **These results are consistent with our conceptualization of smoking-relatedness influencing cessation motivation (presumably via TMM variables), which in turn influences cessation outcomes. This suggests the potential value of targeted education relating cancers other than lung and H&N to smoking, with respect to cancer etiology (where applicable), treatment, and prognosis.**

D.2. Overview of study design and methods

To achieve the proposed project aims, we will conduct two rigorous studies. For Study I (Aim 1), we will utilize qualitative methods to collect data on smoking and cessation motivation among patients with cancers not widely known to be related to smoking. This will assist in the development of a motivational intervention. In Study II (Aim 2), we will assess feasibility and acceptability of the intervention.

D.2.1. Study I (Specific Aim 1): Intervention development (months 1-11). The goal is to create a clear, usable, understandable, and acceptable intervention. We will follow a 3-phase process:

Phase 1 (months 1-5): In-depth interviews will be used to identify key information for the content of the intervention. In-depth interviews were selected (vs focus groups) because smoking is a sensitive topic for cancer patients due to perceived stigma [43], and ease for scheduling. Based on lessons learned during our previous research [44], we anticipate conducting 15-20 hour-long in-depth interviews. Following the principle of theoretical saturation [45], interviews will stop once we find we are not receiving new information, so the final number will vary depending on the information obtained. Using a semi-structured interview guide, we will assess topics such as: knowledge about the association between smoking and their cancer type, benefits/ barriers of quitting smoking, perceived risks of continued smoking, cessation motivation, preferred intervention delivery (mail vs. directly from a provider), level of specificity needed (e.g., a gynecological cancer pamphlet vs ovarian cancer specific pamphlet), and perspectives on how to maximize the impact of the intervention by cancer type. Interviews will be transcribed and the content analyzed. The data will be coded and key themes will be identified by two trained, team members. Texts will be analyzed for frequency (times the comment was mentioned), extensivity (how many participants made the comment), intensity (how strongly the comments were expressed), and specificity (how clearly focused was the comment). NVivo (Scientific Software Development) will assist in organization and analysis of the data. Agreement between coders will be evaluated using a Kappa statistic and codes will be refined until at least 85% agreement is achieved.

Phase 2 (months 6-7): Development of the intervention content. Information from Phase 1 will guide intervention content development, as with previous *interventions developed by our team* [31, 44, 46]. This will be synthesized with existing literature to create messages designed to boost motivation to quit smoking. Following the TMM, messages will be framed to increase perception of personal risk and outcome expectancies (e.g., relating smoking to the etiology of the patient's cancer type, if applicable: "*When a person takes a puff from a cigarette, the smoke goes straight to the lungs.* Then, the toxins in the smoke travel in the body and affect other organs. When tobacco smoke reaches the colon and rectum, it harms the DNA. This causes a change in healthy cells that can become cancer. However, it is not too late to quit smoking. If you have colorectal cancer and you smoke, quitting will help you in many ways.*"* Additionally, smoking cessation will be tied to successful cancer treatment and outcomes with statistics specific for each cancer type (e.g., "High oxygen levels are vital to make radiation treatment work well. Smoking drops the oxygen in your blood. This makes it harder for radiation to work. Thus, quitting smoking will help your cancer treatment to be more effective"). Messages will be designed to prompt strong affective or emotional responses (e.g., with disease-specific vignettes collected during Phase 1), and to redefine self-concept or social role (e.g., discussing life/social changes associated with each cancer type, and with smoking cessation). Because we will create separate brief intervention materials for *each* cancer type, during this phase we will also learn how to best personalize the intervention by cancer type. Thus, we will emphasize in each booklet/pamphlet specific statistics and risks of continued smoking for each cancer (e.g., treatment related complications), and personal

vignettes depicting patient scenarios with that cancer diagnosis. For example, the booklet/pamphlet for colorectal cancer patients will describe the link between smoking and colorectal cancer, the importance of quitting smoking prior to surgery (including colectomy or colostomy), chemotherapy, or radiation therapy, with as much colorectal-cancer specificity as possible. Per National Comprehensive Cancer Network (NCCN) guidelines, it is important to educate cancer patients about the benefits of quitting smoking to increase their motivation to quit smoking [9, 31]. Our aim is to focus each booklet/pamphlet on the past and future smoking-related risks associated with the specific cancer, with a mix of risks/benefits framed messages designed to maximize the TM and motivate cessation. Thus, we will create a different booklet/pamphlet for each of the five cancer types, written at a 5-6th grade reading level on the Flesch-Kincaid scale, and including graphics to ensure comprehension among a population with diverse age, education, and literacy levels. During this phase, we will work with our experienced graphic designer to ensure that the materials will be visually attractive and appealing.

Phase 3 (months 8-11): Learner Verification of intervention materials. The initial draft of the intervention will undergo learner verification to assess for suitability. Similar to our previous studies [28, 31], in this process, materials will be presented to 20-25 cancer patients, (a purposeful sampling approach will be used to capture viewpoints from patients diagnosed with the various cancer types; 4-5 patients will be recruited for each cancer type) to analyze reactions to the intervention regarding tone, messaging style, etc. We will assess acceptability, attraction, understanding, self-efficacy, and persuasion [47]. During a one hour interview, we will ask questions such as, “What is the general message?”, “Is there anything that bothers you?”, “What do you think about the length?” We will use an iterative process, and modifications will be made along the way.

D.2.1.1. Inclusion Criteria for all phases of Study I. We will recruit individuals who are smokers and recently (i.e., within prior 6 months) received a diagnosis of breast, colorectal, gynecological, skin melanoma, or bladder cancer. We will consider smokers to be individuals who report having smoked at least one cigarette in the past 30 days, in accordance with NCCN Guidelines [48] and as utilized by previous studies [8, 49]. Other inclusion criteria are: a) able to read/write English; b) able to give informed consent; c) not currently enrolled in a smoking cessation program. Patients with distant metastases will be excluded, as participation may be burdensome. Male patients diagnosed with breast cancer will be excluded as lifetime risk for breast cancer in men is very low (less than 1% of breast cancer worldwide).

D.2.1.2. Recruitment procedures and compensation. Similar to our prior studies, we will use an existing electronic system to generate a report of recent diagnosed patients reporting current smoking. In coordination with clinical staff, potential participants will be called over the phone or approached during medical visits and informed about the aims of the study. If interested, they will be screened, and those meeting inclusion criteria will be invited to participate. After obtaining informed consent, the research assistant will then escort the participant to a room where the interview will take place. If necessary, the interview will be scheduled for another day or conducted over the phone. Our team has been successful recruiting cancer patients using these methods, obtaining high participation rates (80-86%) with cancer patients [29, 50]. Participants will be compensated $20 in cash if the study is conducted in person, or with a gift card or electronic gift card for the same value if it is completed over the phone.

D.2.1.3. Assessment and measures. For descriptive purposes, participants in Study I will complete a baseline assessment that will include the measures reported below in section D.2.3.

D.2.2. Study II (Specific Aim 2). Assessment of feasibility and acceptability (*months 12-21*). We will evaluate patients’ satisfaction (acceptability), and if the intervention is feasible and adequate for a future efficacy trial (e.g., screening, recruitment, completion of assessment measures, and follow-up). After completing a baseline questionnaire, 10 participants from each cancer type (*n*=50) will receive a booklet/pamphlet corresponding to their specific cancer type. They will also be given an insert describing the smoking cessation services offered at MCC, with contact information for the tobacco treatment specialist (TTS) (*a professional trained to help tobacco users*). The insert will also include a link (both as a text-based address and as a QR code, to facilitate use) to a website where participants will find information for the Quitline and existing smoking cessation websites (e.g., smokefree.gov, tobaccofreeflorida.com, cancer.org/healthy/stay-

away-from-tobacco/guide-quitting-smoking). Each insert will have a personal code that will allow us to track who visited the study site. One week and one month later, participants will be contacted and assessed on whether they read the booklet/pamphlet (demand), change in the TMM elements (risk perception, emotional response, and self-image), and their motivation to quit smoking (preliminary efficacy). We will also assess their satisfaction with the intervention (acceptability). Finally, we will ask them if they contacted the TTS or if they would like us to make a referral for them, and we will count the number of participants who visited the study website. Although this study is not designed or powered to examine smoking cessation outcomes, we will assess smoking behavior and quit attempts to pilot the methods that would be used in a subsequent RCT. When institutional COVID policy allows, we will collect breath carbon monoxide (CO), using 5ppm as the cutoff [51, 52], to confirm self-reported abstinence from smoking. In cases for which follow-up is not conducted in-person, a session will be scheduled to conduct CO testing.

D.2.2.1. Inclusion criteria. Study II inclusion criteria will mirror those in section D.2.1.1.

D.2.2.2. Recruitment procedures and compensation. Potential participants will be identified as described in section D.2.1.2, and will be compensated $15 for completing pre- and post-assessment and $20 for the one month follow-up in cash if the study is conducted in person, or with a gift card or electronic gift card for the same value if it is completed online or over the phone.

D.2.3. Assessment and measures. Participants will complete assessments at baseline, one week after the motivational intervention, and at 1-month follow-up (see Table 2). Post-intervention assessments will be conducted in person coordinated with a scheduled medical visit when possible, but we will offer phone, electronic, and mail options to accommodate patients' individual situations and preferences.

Demographic and cancer-related variables. Age, sex, education, marital status, and race/ethnicity will be included. Time since diagnosis, cancer stage and cancer treatment will be recorded from medical chart review.

Tobacco measures. Participants will complete the Cancer Patient Tobacco Use Questionnaire (C-TUQ) [49, 53], a 22-item questionnaire that assesses tobacco use among cancer patients in a rigorous and standardized way (e.g., number of years smoking, number of cigarettes per day, smoking behavior since cancer diagnosis). They will also complete the Fagerström Test for Nicotine Dependence (FTND) [54], a standard and validated measure of nicotine dependence [54, 55].

Perception of smoking relatedness. In absence of a validated measure, we will assess patients' perception of the role of smoking in the etiology and successful treatment of their cancer type using Likert scales and the Revised Illness Perception Questionnaire (IPQ-R) [65].

TM measures. For **perceived risk**, we will use the Perception of Risk (POR) [56] questionnaire that assesses how continued smoking affects cancer (e.g., "smoking after a diagnosis of cancer impairs physical healing"). For the assessment of **affective and emotional response**, we will use the International Positive and Negative Affect Schedule Short Form (I-PANAS-SF) [57] and the Fears of Cancer Relapse/Recurrence (FAC) scale [58] and one item created ad hoc for assessing the role of smoking in cancer relapse. The PANAS assess positive and negative affect and the FAC assesses beliefs and anxieties about possible cancer recurrence [58]. In the absence of a validated measure of **self-image**, we will create a questionnaire to assess how patients perceive themselves as a patient now and in the future following the conceptualization proposed by Hoyle and Sherrill [59] of the role played by possible selves in motivation and behavior change.

Motivation. The Contemplation Ladder [60] will be the primary measure of motivation. It is a valid measure for the assessment of readiness to quit smoking [60] and has been used previously with cancer patients [61]. The Stages of Change Algorithm (SOC) [62], is also widely used and has been used with cancer patients [14, 56]. Finally, we will use the short form of the smoking abstinence-related motivational engagement (ARME), which is a valid and reliable measure of cessation motivation that includes items related to the smokers' daily experience (e.g., "I spend a great deal of time thinking about becoming or staying smoke-free."), and four global items to assess abstinence motivation: "I am committed to being smoke-free;" "It is important for me to be a non-smoker;" "I want to become or stay smoke-free;" and "I am devoted to being smoke-free" [66].

Table 2. Timing of Assessments for Aim 2

	Baseline	Post-motivation intervention	1 month follow-up
Demographic and cancer information	✓		
Tobacco measures	✓	✓	✓
Perception of smoking relatedness	✓	✓	✓
Teachable Moment measures	✓	✓	✓
Motivation	✓	✓	✓
Treatment Satisfaction		✓	

Treatment satisfaction. Treatment satisfaction and acceptability of the intervention will be assessed using items based on the Client Satisfaction Questionnaire (CSQ) [63]. This is a standard measure used across health care delivery, including smoking cessation self-help interventions [23, 26].

D.2.4. Data Analysis Overview. Descriptive analyses will be conducted to describe the demographic and clinical characteristics of the participants. Qualitative analysis for Study I was described under D.2.1. For Study II, acceptability and feasibility will be evaluated using descriptive statistics. More detailed information has been included in the Form E Statistical Design and Power section, attached.

C.2.5. Recruitment feasibility for both studies. MCC is a large NCI-designated comprehensive cancer center with the 3rd highest patient volumes of all U.S. Cancer Centers. In 2016, over 56,000 patients were seen at MCC, and 15,540 new cancer patients received treatment. Based on patient volumes and smoking prevalence at MCC, and national 5-year survival rates [64], we selected five types of cancer as the focus of the study: breast, colorectal, gynecological, skin melanoma, and bladder. To estimate the availability during the course of the study of cancer patients who are current smokers, by disease site, we accessed 2016 data from MCC's Electronic Patient Questionnaire (EPQ). Because the EPQ was not yet fully implemented, these estimates are likely to be very conservative: breast (*n*=174), colorectal (*n*=64), gynecological (*n*=110), skin melanoma (*n*=126), and bladder (*n*=82). As our previous studies with cancer patients have shown outstanding participation rates (≥80%) [29, 50], these numbers far exceed the total of 85 patients needed for this project.

D.2.6. Study design considerations.

D.2.6.1. Selection of cancer types. We will recruit patients with breast, colorectal, gynecological, skin melanoma, or bladder cancer. In preliminary analyses with our patients at MCC, we found that these were the types of cancer with higher rates of smoking and with generally high 5-year survival rates [64]. Moreover, colorectal, gynecological, and bladder are moderately smoking-related, whereas breast and skin melanoma are not. Thus, we will be able to examine if cessation motivation depends on cancer smoking relatedness. In Study I, we will determine if it is acceptable for our materials related to gynecological cancers to be broad and inclusive of all gynecological cancer types, or if we will need to develop materials by specific disease sites (e.g., cervical, ovarian). If this intervention is successful, it can be extended to other cancer types.

D.2.6.2. Smoking Motivation vs Cessation Intervention. We decided to focus on a motivational intervention instead of including an evidence-based smoking cessation intervention because: (1) our preliminary data suggest that cessation motivation is inversely associated with the cancer's smoking-relatedness [15]; thus, by increasing the perceived relevance of patients' smoking to their specific cancer and its treatment, we expect to increase cessation motivation; (2) clinical pragmatism—to proactively reach patients without disrupting their cancer treatment experience or the functioning of the cancer clinics requires an initially brief intervention; and (3) systematic research—because the novelty of this line of research involves its motivational focus on specific cancer types, it is reasonable to focus this initial research effort on that aspect. Motivation for quitting smoking is an essential first step towards smoking cessation.

D.2.6.3 Study Timeline. A detailed description of the study timeline has been included in the Form E attachments.

D.2.7. Future directions. This study will inform a future RCT. If the intervention meets our a priori criteria with respect to demand, feasibility, and acceptability, we anticipate submitting an R01 to NCI in which the intervention will be combined with an evidence-based smoking cessation intervention and compared against no-treatment and contact-matched comparison conditions in the oncology clinic setting.

E. PROTECTION OF HUMAN SUBJECTS STUDY I

E.1. Risks to Human Subjects

E.1.1. Human Subjects Involvement, Characteristics, and Design

In this study, we will conduct a qualitative assessment of representative cancer patients regarding knowledge about their cancer and smoking, and their perceived needs and preferences regarding motivation to quit smoking. This will guide the development of messages and the content of the intervention. Once a full draft of the intervention has been developed, it will be presented to the target population and we will make modifications according to their feedback.

Participants in this study will be 35-45 individuals who recently (i.e., within 3 months) received a diagnosis of breast, colorectal, gynecological, skin melanoma, or bladder cancer at Moffitt Cancer Center. To be eligible for the study, participants must: a) have smoked at least 1 cigarette in the previous month; b) be able to read and write English; c) not currently enrolled in a smoking cessation program; d) be able to give informed consent; and d) have no additional cancer diagnoses. Patients receiving palliative treatment or with distant metastases will be excluded, as participation may be burdensome. Male patients diagnosed with breast cancer will be excluded as lifetime risk for breast cancer in men is very low (less than 1% of breast cancer worldwide).

E.1.2. Study Procedures, Materials, and Potential Risks

This study does not involve any deception. Potential participants will be called over the phone or approached by a trained research assistant and will be screened for eligibility criteria using a brief eligibility screening form. Eligible patients will be asked if they would like to participate in a study of tobacco use by cancer patients. They will be asked to review a consent form and will be provided the opportunity to ask any questions. All subjects will sign consent forms prior to their participation. Informed consent and consenting procedures will adhere to the Advarra Institutional Review Board guidelines. For the participants who complete the study remotely, we will consent them verbally and we will provide them a copy of the informed consent via email or mail and we will request a waiver of documentation of consent from the IRB.

Following the informed consent, participants will complete a baseline questionnaire and will be interviewed for about an hour. The following materials will be used:

a. Questionnaires measuring sociodemographic characteristics, smoking history and nicotine dependence, perception of smoking relatedness of their cancer, risk perception, affective and emotional response, self-image, and motivation to quit smoking.
b. Audio-tapes and transcripts of interviews.

Participants may be sharing personal information about themselves during the in-depth interviews. In addition, tobacco smoking for cancer patients may be a sensitive topic due to perceived stigma. Thus, in the event that a patient appears distressed, a social worker will be available to assist with making the appropriate referrals.

E.2. Adequacy of Protection Against Risks

E.2.1. Informed Consent and Assent

Potential participants will be called over the phone or approached by a trained research assistant during a visit to the Moffitt Cancer Center. They will be screened for eligibility criteria using a brief eligibility screening form. Eligible patients will be asked if they would like to participate in a study of tobacco use by cancer patients. If willing to participate they will be escorted to a private room where the research assistant will explain privately the informed consent. Then, they will be asked to review the consent form and will be provided the opportunity to ask any questions. All subjects will sign consent forms prior to their participation. Informed consent and consenting procedures will adhere to the Advarra Institutional Review Board guidelines. Participants not able to provide informed consent will be excluded from the Study. If necessary, this would be completed remotely by mail, email, or the phone.

E.2.2. Protections Against Risk

The potential risks are judged to be minor. We recognize that some patients may experience some discomfort in completing the measures. In the event that a patient appears distressed, a social worker will be available to assist with making the appropriate referrals.

Patients may provide personal information about themselves during the in-depth interviews, as well as on screening or demographic questionnaires. All research staff will receive training in research ethics. Confidentiality will be maintained by using subject numbers on data, rather than subjects' names or their patient IDs to avoid data breach. Subject data will be available only to research staff. Paper data will be kept in locked filing cabinets in locked laboratory rooms; electronic data will be stored on password-protected, secured servers at Moffitt Cancer Center. Identifying information will not be reported.

E.3. Potential Benefits of the Proposed Research to Research Participants and Others

The main benefit to participants is involvement in research that may lead to the development of interventions to help cancer patients to increase their motivation to quit smoking. However, participation may motivate some patients to quit smoking, which has multiple health benefits, particularly for this population.

E.4. Importance of the Knowledge to be Gained

Improved knowledge regarding how to increase smoking cessation motivation in patients with a cancer not widely known to be related to smoking could have dramatic public health implications. The ultimate aim of this study is to motivate patients to eventually quit smoking, which will improve health, quality of life, and survival for these individuals.

E.5. Inclusion of Women, Minorities, and Children

E.5.1. Inclusion of Women and Minorities

Given that two of the cancer types included in the study are exclusive of women, we expect that the percentage of women (60%) in the sample will be higher than men. The inclusion of minorities in the proposed study is driven by the characteristics of the patient population undergoing cancer treatment at the Moffitt Cancer Center. The "Targeted/Planned Enrollment Table" displays the expected level of participation by minorities. The Moffitt Cancer Center makes ongoing, active efforts to increase patient diversity. Dr. B. Lee Green, as the Executive Director of Institutional Diversity, has increased advertisements and announcements for the Moffitt Cancer Center distributed at community events and churches that are preferentially frequented by minorities. Hispanic and African American advisory boards were created, patient navigation programs were developed, and outreach efforts to local minority physicians and religious leaders were increased. All these efforts resulted in the classification of Moffitt Cancer Center at the number 4 ranked health care facility on Diversity Inc's 2017 "Top Hospitals & Health Systems" list. Based on these initiatives and on our planned efforts to compose a diverse sample, we expect that approximately 10% of the sample will include Hispanic/Latino patients, and approximately 15% will be African American.

E.5.2. Inclusion of Children

The diseases under investigation occur most frequently in adults, with median age at diagnosis of 73 for bladder cancer, 62 for breast cancer, 67 for colorectal cancer, between 49 and 63 for gynecological cancers, and 64 for skin melanoma. Moreover, Moffitt Cancer Center does not treat pediatric patients. Therefore, we do not anticipate any children will be enrolled in these studies.

E.6. Recruitment and Retention Plan

Similar to our prior studies, we will use an existing electronic system that will allow sorting for patients reporting current smoking. In coordination with clinical staff, potential participants will be called over the phone or approached during medical visits and informed about the aims of the study. If interested, they will be screened and those meeting inclusion criteria will be invited to participate. To maximize our recruitment rates, the interview will take place on the same day of a medical visit, if possible. Thus, after obtaining informed

consent, the research assistant will escort the participant to a room where the interview will be conducted. However, if necessary, the interview will be scheduled for another day or conducted over the phone. Participants will be compensated $20 in cash if the study is conducted in person or in the form of a gift card or electronic gift card for the same value if conducted remotely.

Since there are no follow-ups in Study I, a Retention Plan is not provided.

E.7. Study Timeline

Preparation of baseline measures and interview materials	Month 1
Study I recruitment and in-depth interviews	Months 2-5
Development of intervention materials and elaboration of first draft of intervention	Months 6-7
Learner Verification, modification and final draft of intervention	Months 8-11
Manuscript preparation: development of intervention materials	*Months 12-13*

F. PROTECTION OF HUMAN SUBJECTS STUDY II

F.1. Risks to Human Subjects

F.1.1. Human subjects Involvement, Characteristics, and Design

In this study, we will evaluate if the intervention is feasible (e.g., screening, recruitment, completion of assessment measures, and follow-up) and acceptable (e.g., self-reported patient satisfaction and number of participants reading the study materials).

Participants in this study will be 50 individuals who recently (i.e., within 6 months) received a diagnosis of breast, colorectal, gynecological, skin melanoma, and bladder cancer at Moffitt Cancer Center. To be eligible for the study, participants must: a) have smoked at least 1 cigarette in the previous month; b) be able to read and write English; c) not currently enrolled in a smoking cessation program; and d) be able to give informed consent. Patients with distant metastases will be excluded, as participation may be burdensome. Male patients diagnosed with breast cancer will be excluded as lifetime risk for breast cancer in men is very low (less than 1% of breast cancer worldwide).

F.1.2. Study Procedures, Materials, and Potential Risks

This study does not involve any deception. Potential participants will be approached or called over the phone by a trained research assistant and will be screened for eligibility criteria using a brief eligibility screening form. Eligible patients will be asked if they would like to participate in a study of tobacco use by cancer patients. They will be asked to review a consent form and will be provided the opportunity to ask any questions. Informed consent and consenting procedures will adhere to the Advarra Institutional Review Board guidelines. Patients will be consented verbally and will be provided a copy of the informed consent for their records (via email or mail for those patients who consent over the phone). We will request a waiver of documentation of consent from the IRB.

Following the informed consent, participants will complete a baseline questionnaire and will be given the intervention materials. They will be contacted a week and a month later for a follow-up assessment. The following materials will be used:

c. Questionnaires measuring sociodemographic characteristics, smoking history and nicotine dependence, perception of smoking relatedness of their cancer, risk perception, affective and emotional response, self-image, motivation, and treatment satisfaction.
d. Breath to be analyzed for carbon monoxide from subjects who self-report smoking abstinence at follow-ups.

Participants may be sharing personal information about themselves in the questionnaires. In addition, tobacco smoking for cancer patients may be a sensitive topic due to perceived stigma. Thus, in the event that a patient appears distressed, a social worker will be available to assist with making the appropriate referrals.

F.2. Adequacy of Protection Against Risks

F.2.1. Informed Consent and Assent

Potential participants will be approached by a trained research assistant during a visit to the Moffitt Cancer Center or called over the phone. They will be screened for eligibility criteria using a brief eligibility screening form. Eligible patients will be asked if they would like to participate in a study of tobacco use by cancer patients. For in-person visits, patients willing to participate will be escorted to a private room where the research assistant will explain the informed consent. Then, they will be asked to review the consent form and will be provided the opportunity to ask any questions. Patients who are contacted over the phone will receive a verbal explanation of the informed consent, they will have the opportunity to ask questions, and will be sent a copy via mail or email for their records. Informed consent and consenting procedures will adhere to the Advarra Institutional Review Board guidelines. We will request a waiver of documentation of consent from the IRB. Patients not able to provide informed consent will be excluded from the Study.

F.2.2. Protections Against Risk

The potential risks are judged to be minor. We recognize that some patients may experience some discomfort in completing the measures. In the event that a patient appears distressed, a social worker will be available to assist with making the appropriate referrals.

Patients may provide personal information about themselves during the screening or questionnaires. All research staff will receive training in research ethics. Confidentiality will be maintained by using subject numbers on data, rather than subjects' names. Subject data will be available only to research staff. Paper data will be kept in locked filing cabinets in locked laboratory rooms; electronic data will be stored on password-protected, secured servers at Moffitt Cancer Center. Identifying information will not be reported.

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The potential risks are judged to be minor. We recognize that some patients may experience some discomfort in completing the measures. In the event that a patient appears distressed, a social worker will be available to assist with making the appropriate referrals. The main benefit to participants is involvement in research that may lead to the development of interventions to help cancer patients to increase their motivation to quit smoking. However, participation may motivate some patients to quit smoking, which has multiple health benefits, particularly for this population.

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for the Moffitt Cancer Center distributed at community events and churches that are preferentially frequented by minorities. Hispanic and African American advisory boards were created, patient navigation programs were developed, and outreach efforts to local minority physicians and religious leaders were increased. All these efforts resulted in the classification of Moffitt Cancer Center as the number 4 ranked health care facility on Diversity Inc's 2017 "Top Hospitals & Health Systems" list. Based on these initiatives, and on our planned efforts to compose a diverse sample, we expect that approximately 10% of the sample will include Hispanic/Latino patients, and approximately 15% will be African American.

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F.5.3. Recruitment and Retention Plan

We will use an existing electronic capture that will allow sorting for patients reporting current smoking. Potential participants will be called over the phone or approached during medical visits and informed about the aims of the study. If interested, they will be screened and those meeting inclusion criteria will be invited to participate. The research assistant will escort the participant to a room where they will go through the informed consent. After consenting, patients will receive the intervention materials. However, if necessary, this session will be scheduled for another day or conducted remotely to accommodate to patients' preferences. Patients recruited over the phone will receive the study materials over the mail and/or email. All participants will be contacted again one week and one month after receiving the intervention materials. To increase retention rates, follow-up assessments will be conducted during a scheduled medical visit, but we will offer phone, electronic, and mail options to accommodate patients' individual situations and preferences. To increase retention of participants in the study, they will be compensated $15 for completing the pre- and post-intervention and $20 for completing the 1-month follow-up in cash if the study is conducted in person, or with a gift card or electronic gift card for the same value if it is completed online or over the phone.

F.5.4. Study Timeline

Intervention delivery, assessment of acceptability and feasibility	Months 12-21
Follow-up assessments	Months 13-22
Manuscript preparation: feasibility and acceptability outcomes	Months 22-24

F.6. Data and Safety Monitoring Plan

F.6.1. Overview

Although this is an extremely minimal risk study, the Principal Investigator, Dr. Martínez, will implement a DSMP to ensure that the expected risk/benefit ratio is maintained throughout the study and that the confidentiality and accuracy of the data are preserved. The research assistant will receive formal training in the Division of Population Sciences about ethical conduct of research, consenting participants, implementation of study protocols, etc. In addition, he/she will be trained by the PI on recruitment, interviewing, and data collection. All members of the study team will receive training in research ethics and HIPAA procedures, as well as study-specific training provided during research team meetings. The study team will meet weekly to discuss study progress, including participant recruitment and retention, data management, any participant complaints, and confidentiality issues. Given the nature of the study, the probability of an adverse event occurring is extremely low. However, as per IRB policy, any serious or unexpected adverse events will be reported promptly (within 2-5 business days, depending on the nature of the event) to the IRB and the PRMC.

F.6.2. Quality Assurance for Data Collection

The PI and research assistant will meet weekly to discuss recruitment and data collection issues and the study team will meet biweekly to discuss any possible additional issues.

F.6.3. Quality Assurance for Data Management

Data will be collected via paper and pencil measures. Data entered by staff will be double-entered and compared for inconsistencies. Validity checks of data values and ranges will be conducted upon data entry and again prior to analysis. To ensure participant confidentiality, baseline and follow-up assessment data will not include any unique identifiers.

F.6.4. Data Integrity and Security

To protect confidentiality all participants in the study will be provided a study number not linked to their own patient or tumor IDs to avoid data breach. Once all data have been linked to individuals, all identifiers will be deleted. IRB approvals and participant documents will be kept in a locked location. All computers will be password-protected. Only trained grant personnel will have access to data.

F.6.5. Identification of Adverse Effects

Potential risks of the study are judged to be minor. In the case of a patient experiencing discomfort completing the measures or appearing distressed, a social worker will assist with making the appropriate referrals. The PI will monitor the study for adverse events and report adverse events to the institution's protocol monitoring committee, IRB, and funding sponsor as required.

F.7. Overall Structure of the Study Team

The primary site of the study will be the Tobacco Research and Intervention Program (TRIP) at the Moffitt Cancer Center. All study investigators have offices at TRIP. We will use an electronic system that will allow sorting for patients reporting current smoking. Potential participants will be called over the phone or approached during medical visits at the respective clinics.

The PI of the study, Dr. Martínez, has background in smoking cessation treatments for the general and oncology patient population. She will be supported by senior co-investigators, Drs. Brandon and Simmons, who have expertise in all aspects of the proposed research and a history of successful NIH funding. The team is enhanced by the inclusion of Dr. Warren as a consultant who will provide medical expertise. Finally, a research assistant will be trained to help with recruitment and follow-up of study participants.

F.8. Statistical Design and Power

We expect to include a total of 50 cancer patients (10 per cancer site) in this study. Assuming follow-up of 80% of enrolled participants across the 5 cancer sites, 2-tailed α of .05, and power (1-β) of .80, this study will be powered to detect a small-medium effect size (f) of .20.

Acceptability and feasibility will be evaluated using descriptive statistics. For acceptability we will assess patients' treatment satisfaction through the mean scores of a questionnaire based on the CSQ and open-ended feedback from participants. This questionnaire will also inform about how many participants read the intervention materials, which will be used as an indicator of demand (criterion: ≥80% of participants enrolled in Study II). Feasibility will be measured by the number of patients meeting inclusion criteria to participate in the study, agreement to participate in the study (≥75% of those meeting inclusion criteria and approached to participate), percentage of participants completing baseline assessment measures (≥85% of those who agree to participate in the study), and percentage of participants completing the one week and one-month follow-up assessment (≥80% of those who completed baseline). Changes in cessation motivation and Teachable Moment Model variables will be assessed using repeated-measures Analysis of Variance (ANOVA). Finally, we will receive data from MCC's TTSs on whether participants followed through with referrals to them and we will capture basic website analytics. These will serve as behavioral indicators of cessation motivation.

Other collected variables will also be examined on an exploratory basis. For example, sex differences will be analyzed, as will differences between cancers typically affecting women (gynecological, breast) versus men (bladder).

The pilot study will not include a control group, nor be powered to test moderator or mediator variables. However, results will inform on the feasibility and scope of a potential, subsequent RCT.

F.9. Dissemination Plan

This Study will be registered as an NIH funded trial at ClinicalTrials.gov within 21 calendar days after the first human subject is enrolled. Rationale for the study, description of patient eligibility, recruitment procedures, location of study procedures and contact information will be provided. Moffitt Cancer Center's institutional policy, "Clinical Trials Registration and Reporting Requirement" mandates that the Clinical Research Operations team within the Office of Clinical Research Administration registers institutional clinical trials following IRB approval and documents registrations by other entities for external trials according to prescribed timelines. Reporting responsibilities may not be transferred without approval by the Vice President of Clinical Research Administration.

Informed consent documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

Final results from this trial will be submitted to ClinicalTrials.gov within 12 months after final data collection for primary outcome measure. Manuscripts submitted for publication will include all required data including participation and dropout rates, demographic and baseline characteristics, primary and secondary outcomes, report of any adverse events, full description of the methods, original analytic plan and final statistical analysis results.

It is our intention to disseminate the results of this study within the research community in national and international conferences and through publications in journals with wide diffusion.

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