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1) Protocol Title

Smartphone Application versus Group Mindfulness-based Smoking Cessation Intervention for Cancer Patients and Survivors: Reach versus Effectiveness

2) Objectives*

Smoking is a major public health problem among cancer patients and survivors in the US. Their access to clinical-based cessation treatment is limited, and current evidence-based interventions fail to meet their needs. Our proposed study aims to tackle two major barriers to smoking cessation in cancer patients and survivors, by:

1) Increasing their access to treatment through the use of smartphone technologies to deliver the intervention, and
2) Addressing their high level of depression by using MT for smoking cessation.

Findings will inform a larger study of the effectiveness of cessation approaches with great potential for translation and dissemination to cancer patients and survivors who smoke throughout the US.

3) Background*

A. Cigarette Smoking among Cancer Survivors.

Cancer patients and survivors are a rapidly growing population and an important target for tobacco treatment interventions. Smoking cessation is essential after cancer diagnosis to improve clinical outcomes and lower the risk of treatment complications[1]. In 2016, it was estimated that there were 15.5 million cancer survivors, with 98% of these individuals receiving a cancer diagnosis as an adult.[1,2] Approximately, 18.7% of cancer survivors continue to smoke after cancer diagnosis.[3] Continued smoking after cancer diagnosis can lead to the development of potential treatment interactions, secondary cancers, and comorbid conditions. In contrast, there are numerous benefits to smoking cessation, even after a cancer diagnosis, including a greater response to treatment protocols and reduced risk of mortality.[6-8] Therefore, given the large population of smoking cancer patients and survivors and the importance of smoking cessation in this population, improving smoking cessation among this population is a high priority.

B. Challenges for Cessation Efforts in Cancer Survivors.

There have been only few randomized controlled trials of smoking cessation interventions for adult cancer survivors. Most of these interventions were tested in small studies, focused within the health care setting,[9,10] and did not demonstrate a desirable effect.[10-12] In addition, several reviews concluded that current standard tobacco cessation interventions are not specific for cancer

survivors and have not demonstrated the same efficacy compared to the general adult population.[10,13] In particular, one of the major logistical problems with smoking cessation efforts in cancer survivors is that of geographic diversity. While cancer survivorship is common and growing, the number of cancer survivors, for example, in any given medical practice, is likely to be very low. Moreover, a meta-analysis review concludes that depression in cancer survivors is roughly twice as common as in healthy controls during the first 2 years after cancer diagnosis, while risk of anxiety disorders persist for up to 10 years or more.[14] Younger and middle-aged long-term survivors of hematologic cancers were at highest relative and absolute risk to be psychologically impaired.[15] Continued smoking among survivors were significantly associated with having feeling of hopelessness, sadness, and anxiety most of the time, moderate to severe stress, symptoms of depression, and lower reported physical and emotional well-being in multiple studies.[16-18] Therefore, it is crucial to identified innovative smoking cessation interventions that are easily accessible and responsive to the special needs of cancer survivors.

C. How to Address the Unique Psychosocial Profile of Cancer Survivors?

Depression and craving are two major predictors of smoking relapse. Depression and anxiety among cancer patients and survivors are higher than that in the general population. Smoking cessation on the other hand is a major life stressor and is strongly linked with psychological stress, depression, and negative and positive affect that can lead to relapse.[19,20] One promising strategy for smoking cessation in cancer patients and survivors is *Mindfulness Training* (MT). MT proved to be effective in reducing both self-report and objective indices of negative affect and psychological stress.[21,22] MT also can help smokers control craving by being less emotionally reactive and less prone to relapse related to avoidance of distressing symptoms.[23] MT has been operationalized into two components: 1) maintaining attention on immediate experience, and 2) maintaining an attitude of acceptance toward that experience, which can improve individuals' ability to avoid absorption in maladaptive mental patterns, behaviors, and emotional reactions that lead to depression.[24,25] MT was feasible and effective in cancer survivors at improving psychological symptoms of anxiety and stress, quality of life, emotional well-being, and immunological status. Yet, MT for smoking cessation in this population and current cancer patients has not been implemented or tested.

D. How to Increase Access to Treatment?

An increasing body of evidence indicates that technology-based interventions may be well received by cancer patients and survivors and hold promise for health promotion initiatives.[26-29] Smartphone-based applications (Apps) has emerged as an important tool for health-related behavioral interventions. Two systematic reviews conclude that *smartphone-based smoking cessation apps* are effective and significantly increase access to treatment.[30,31] Smartphone apps provide a promising medium to deliver an intervention due to the propensity for widespread dissemination, their availability, relatively low cost, and ease of use. Compared to in-person treatment, this approach can be standardized, reduce stigma associated with seeking treatment, allow the use of multiple methods to deliver the intervention (e.g., video, audio), facilitate the integration of the treatment into user's daily life, help tracking user's progress 24/7, and simultaneously boosting user's engagement, a strong predictor of smoking cessation.[32-35] In the US, smartphones' ownership is projected to reach at least 90% by 2020.[36]

Recently, our Consultant Dr. Brewer developed an evidence-based mindfulness smoking cessation app "*Craving-to-Quit"* adapted from an in-person (group) MT relapse prevention smoking cessation intervention that proved to be effective in the general population.[37-40] In Brewer et al., although the control group was an active treatment (has the same intensity -- 8 counselling sessions but used different strategies of behavioral counseling for smoking cessation), smoking abstinence rate at the end of treatment was very promising in the in-person (group) mindfulness intervention (36% vs. 15% in the control group).[37] Building on his work, and using a sequential explanatory design mixed-method approach of quantitative and qualitative research, we propose to: 1) test in a pilot 3-arm randomized clinical trial (RCT) among cancer patients and survivors' smokers the feasibility, acceptability, and potential efficacy of the "*Craving-to-Quit"* app versus group MT smoking cessation intervention (the original intervention of the craving-to-quit), and usual care; and 2) fine-tune the intervention based on feedback from participants for further testing in Phase II large-scale RCT. The pilot clinical trial will provide quantitative data about the feasibility, acceptability, and potential efficacy of mindfulness-based smoking cessation among cancer patients and survivors, while interviews with members of that group later will offer insights to further improve the intervention. This study will establish preliminary evidence on the feasibility and potential efficacy of mindfulness-based smoking cessation among cancer survivors using two delivery modalities, the smartphone app and group MT compared to usual care. Using the app to deliver the MT smoking cessation intervention holds an immense promise to maximize the reach of the intervention to entire cancer population, while delivering the intervention in-person (in groups) promises to maximize the effectiveness of the intervention.

E. Innovation

In addition to targeting a vulnerable population at high risk of tobacco-related health disparities, the originality of this project stems from utilizing smartphone app, a novel, low-cost and highly scalable delivery method, to deliver mindfulness training merges a new treatment for smoking cessation in cancer patients and survivors. Mobile MT can potentially improve efficacy by bringing MT into real-world contexts, allow an intervention to be delivered in multiple methods (e.g., video, audio), and help tracking progress consistently.[23] MT helps smokers in reducing depression and gaining greater sense of control over craving by being less emotionally reactive and less prone to relapse-related distress,[23] two major predictors of smoking relapse.[37,39,41] In addition, the RCT design will allow a direct comparison between the feasibility, acceptability, and potential efficacy for two delivery modalities for MT (group vs. smartphone app), compare to usual care.

4) Inclusion and Exclusion Criteria*

A. Inclusion Criteria

To be eligible participants should:

- Be 18 years and older
- Cancer survivors (based on the NCI definition — "a person is considered to be a survivor from the time of diagnosis until the end of life" National Cancer Institute Dictionary of Cancer Terms, 2014)[52]
- Cancer patients currently in active treatment
- Have smoked ≥ 5 cigarettes/day in the past year
- Be interested in making a quit attempt in the next 30 days
- Own a smartphone (apple/android)
- Read/speak English
- Able to consent
- Have no plans to move in the next 3 months
- Are not pregnant or planning to be pregnant in the following 3 months

Any histologic subtype of cancer is qualified for entry into this study.

B. Exclusion Criteria

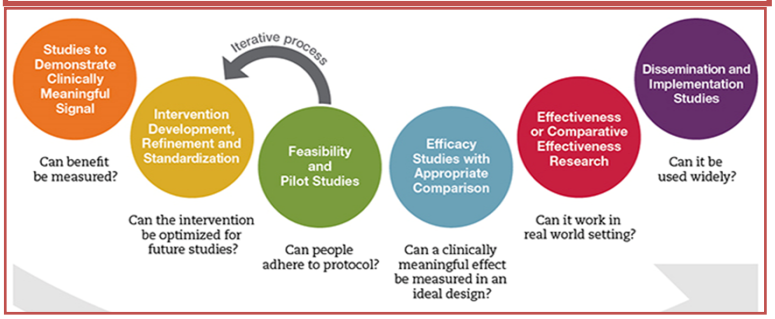
Participants would be excluded if they:

- Have contraindication to NRT (past month myocardial infarction, history of serious arrhythmias/or unstable angina pectoris, dermatological disorder)
- Are currently being treated for a psychiatric condition.
- Are currently being treated for smoking cessation**,** alcoholism, or illicit drug use
- Are adults unable to consent
- Are individuals who are not yet adults
- Are pregnant women
- Are prisoners

5) Procedures Involved*

The National Center for Complementary and Integrative Health (NCCIH) conceptual framework for clinical research in the mind and body will guide the pilot testing of the intervention.[50] This project will address the first 3 questions in the framework: 1) is the intervention feasible and acceptable? 2) is the intervention beneficial? and 3) can the intervention be optimized for future studies? To answer these questions, we will: (1) conduct 3-arm pilot RCT among cancer patients and survivors smokers to test the feasibility, acceptability, and potential efficacy of (1) the *Craving-to-Quit* app vs. (2) group MT, and (3) Usual Care (UC) intervention (control group), and (2) conduct post-intervention interviews with participants to refine the two interventions.

The National Center for Complementary and Integrative Health (NCCIH) conceptual framework for clinical research in the mind and body.



Study Timeline

During the first 2 months, we will focus on training staff, preparing study protocol and instruments, preparing the data entry program, and ensuring IRB approval and creating list of potential participants from the cancer registry. Aim 1 (RCT) will take place during the following 9 months. We will recruit 10-12 participants per month during the first 5 months. Follow-ups and the process evaluation

interviews (Aim 2) will be completed in the following 3 months. Final analysis and reporting of study results will be conducted in the final 2 months.

Mon 1	Mon 2	Mon 3	Mon 4	Mon 5	Mon 6	Mon 7	Mon 8	Mon 9	Mon 10	Mon 11	Mon12
• Training staff • Preparing study protocol • Ensuring IRB approval		• Recruiting for the pilot RCT (10-12 participants per month)					• Completing the 3-month follow-ups • Conducting the process evaluation interviews			• Analyzing data • Reporting of study results	

A. Aim (1). Conduct a 3-arm Pilot Randomized Controlled Trial (RCT)

Design

We propose a three-arm pilot RCT among cancer patients and survivors smokers (n=30 total; 10/arm) designed to evaluate the feasibility, acceptability, and potential efficacy of: (1) the *Craving-to-Quit* vs. (2) group MT for smoking cessation, and (3) Usual Care (UC) intervention (control group). Participants in the three study arms will receive 6 weeks supplies of Nicotine Replacement Treatment (NRT). In addition to matching NRT between groups, this design allows us to compare the effectiveness of MT smoking cessation intervention delivered by *Craving-to-Quit* app vs. group MT; and whether each of the MT interventions improve cessation over the UC. Participants are randomly assigned to blocks of 6, based on gender stratification to one of the treatment arms in a 1:1:1 ratio using a computer-based random number generating. Given the pilot nature of the study, participants will be randomized in sequence for the app, the in-person, and then the UC group with the goal to reach 10 participants in each group. All participants will receive a follow-up assessment at the end of treatment and 3-months after quit date. Dr. Asfar, who has years of experience in training and supervising cessation trials,[45,47,48,51] will direct and oversea the trial and will be responsible for the training of two Research Assistants (RAs) in recruitment and conduct of the cessation trial (e.g., human subjects protection, cessation pharmacotherapy, the study's protocol). The team will meet weekly with Dr. Asfar for supervision, and case review. Participants will receive a $50 incentive ($15 at the baseline assessment, $15 after their quit date, and $20 at the 3-month follow up). All study procedures will be conducted remotely via Zoom . We will use REDCap to collect our data. No data are collected from the medical record.

All participants will attend an orientation session, which will be conducted via Zoom. Informational materials will be sent to participants via email or mail, and NRT will mailed.

Interventions

1. Usual Care (UC)/control: Participants in this group will receive a brief advice to quit smoking, 6-week supplies of NRT, and self-help materials to quit smoking.

2. *Craving-to-Quit* app for smoking cessation intervention: This intervention is based on the theory of mindfulness-based cognitive therapy (MBCT) for relapse prevention. The MBCT uses cognitive behavioral therapy methods in collaboration with MT techniques. Cognitive methods focuses on the development of personal coping strategies that target solving problems and changing unhelpful patterns in cognitions (e.g. thoughts, beliefs), behaviors, and emotional regulation. MT focus on becoming aware of all incoming thoughts and feelings and accepting them, but not attaching or reacting to them. This process is known as "Decentering" and aids in disengaging from self-criticism and rumination that can arise when reacting to negative thinking patterns. Participants in this group will receive one orientation session, 6-week supplies of NRT, the "*Craving-to-Quit"* app, and two brief follow-up phone calls.

a. *Orientation session:* This session will occur 21 days before quit date. It will be moderated by a certified instructor in MT, and will last approximately 90 min. During the session, a research associate will explain the purpose, format, and procedures of the study, and will go through the written informed consent and have the participant complete the baseline assessment. Participants will then watch a video that explains the specifics of their respective arm's study activities.

Then, participants will be instructed to download on their phone the "*Craving-to-Quit"* app and will receive a 60-minute tutorial explaining the app content and features to troubleshoot any issues, followed by training on how to use the app and to practice MT techniques introduced in the app. Participants will be instructed to start using the app in the next day, and set a quit date within the next 2 weeks. Participants will receive 6 weeks of NRT, and will be instructed to start using the NRT at the quit date.

b. *The Craving-to-Quit app:* The app is comprised of 22 modules for 22 days, 5–15 minutes each, designed to teach MT using audio, video, and animation. Participants have access to only one new module per day, and subsequent days are locked to prevent skipping ahead (pls. see LOS from Ms. Roman from MindSciences). The app teaches three basic formal MT techniques including *Body Scan* (bringing awareness to different parts of the body to foster awareness of body sensations that constitute cravings and affective states), *Loving-Kindness* (repeating phrases such as "may X be happy" to foster acceptance of oneself and others), *Breath Awareness* (paying attention to the breath wherever one feels it most strongly in the body to help retrain the mind away from habitually engaging in self-related thinking toward a more present-centered awareness), and one informal MT RAIN (Recognize, Accept, Investigate, and Note what cravings feel like as they arise/pass away). In RAIN, participants are asked to identify their smoking trigger, rate their craving, and choose between using RAIN to ride out their craving, or completing an audio-guided exercise to 'smoke mindfully' by paying attention to the moment-to-moment experience and bodily sensations of smoking. The app also includes other features such as social support (quit friend sign-ups, the tip of the week), activity feed (to track interaction with the app), and my morning stats (to track smoking).

c. *Two brief follow-up phone calls.* The first phone call will occur one day before the quit date to remind participants about their quit date and provide support. The second will occur at the end of treatment (around day 60 after quit date) to review progress, provide support, and schedule the 3-month follow-up visit. Each phone call will last approximately 15 minutes.

3. The group MT smoking cessation intervention:

Participants in this group will receive twice weekly group sessions (eight total during 4 weeks) that were manualized and delivered by instructors experienced in MT (a single therapist with >4 years of training in MT). The intervention includes components that are well-matched with Craving-to-Quit. The overarching theme of momentary awareness and acceptance of cravings and affect (e.g., stress, anxiety etc.) will be introduced and reinforced in complementary ways throughout the training. Each session will last 45-60 minutes.

a. *Session (1):* Will introduce participants to the concept of how smoking can become a habituated behavior triggered by an environmental, physical, or mental stimulus through associative learning. It also will explore how cravings feel in the body and how MT can help individuals become more aware of these processes.

b. *Session (2):* Will examine how thoughts, emotions and body sensations become triggers for craving and smoking, and introduce a technique to 'mindfully' work with cravings (Recognize, Accept, Investigate and Note what cravings feel like as they arise; acronym: RAIN).

c. *Session (3):* Will introduce how difficult emotions perpetuate smoking as well as a standard meditation technique called loving-kindness as a way to work with them. Loving-kindness is practiced through directed well wishing, typically by repetition of phrases such as 'may X be happy.'

d. *Session (4) (quit date):* Will teach participants how cravings thwart long-term goals, and reinforce mindfulness techniques as a way to help individuals disengage from habitual responding and realign with their goals.

e. *Session (5):* Will introduce participants to mindfulness practice in everyday life, including "awareness of breath" meditation and mindful walking ("four modes of walking", during which individuals practice systematically noting objects that they see, and then objects that they hear, then objects that they smell, and then tactile objects such as the pressure of their feet on the ground).

f. *Session (6):* Will explore the automaticity of thought, and how thoughts can lead to habitual behaviors.

g. *Session (7):* Will reinforce the concept of acceptance and its role in changing habits. It will also explore how both mental and physical actions can "plant seeds" for future actions and habits.

h. *Session (8):* Will summarize the course tools and explore ways of maintaining these in the future. Home practice will be suggested after each session as a combination of formal MT meditations (the "body scan" which teaches

individuals to systematically pay attention to different parts of their bodies as a way to reduce habitual mind-wandering and strengthen their attentional capacities, loving-kindness, and awareness of breath, which through focused attention on the breath also is intended to help individuals retrain their minds from habitually engaging in self-related pre-occupations -such as thinking about the past or future, or reacting to stressful stimuli- to more present moment awareness), and informal practices (four modes of walking, mindfulness of daily activities, mindfulness of smoking, RAIN). Each participant receives a meditation practice CD.

Retention, Follow-up, and Quality Assurance

Extensive retention measures will be taken (e.g., collect contact information for close friends and family members, distribute newsletters). All participants will receive a follow-up assessment at 3 months after quit date to assess their smoking status and adherence to ART as well as get information about concomitant smoking and NRT use, use of additional NRT or cessation drugs (e.g., bupropion), and use of other tobacco methods. Breath CO will be collected at the 3-month follow-up points for participants who report abstinence. The breath sample will be collected with a portable CO monitor (coVita **iCO™ Smokerlyzers®)**). Cut-off of 6 ppm for CO will be used to determine abstinence (Benowitz et al 2002).

Outcome measures

1. Baseline Assessment:

- *Demographics and cancer history:* Age, race/ethnicity, relationship status, education, employment, income, time since cancer diagnosis, and cancer type and treatment (from medical chart), time since ending cancer treatment (if out of active treatment).

- *Smoking*: Smoking history, past quit attempt, motivation to quit, confidence in quitting, Fagerström test for nicotine dependence,[63] 12-item smoking self-efficacy to resist urge to smoke,[64] and 15-item Minnesota nicotine withdrawal scale (i.e., craving, irritability, anxiety, depression).[65]

- *Mindfulness skills*: The five facet MT questionnaire that measures MT skills related to observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.[66]

- *Others: Use of technology, The 20-item Centers for the Epidemiologic Study of Depression (CES-D) scale,*[67] social support,[68] quality of life,[69] and alcohol and substance use (ASSIST).[70]

2. Three-month Follow-up Assessment:

- The follow up assessment will occur at 3 months (+30 days) after quit date. The visit will last approximately 45 minutes.

- All baseline assessment will be re-administered except demographics.

- *Usability:* In the app group, measures of usability will be measured by: 1) The absolute number of times logged into the apps will be calculated for each user to obtain the mean number of using each app, 2) self-reported number of completed days for the app. And 3) level of comfort with the app "I am comfortable using the app." In the group MT arm, we will collect information on number of sessions that was attended.

- *Acceptability:* The acceptability will be assessed by 3 items "How satisfied were you with the intervention?", "How likely are you to recommend this intervention to a friend?" and "How useful was the intervention?" Participants in Arms 2 will also complete The System Usability Scale (SUS) at call 1 & 2 and the 3-month follow-up to evaluate the overall usability of and satisfaction with the app (John Brooke, 1986).

Feasibility: We will monitor rates of recruitment and effort required (e.g. number of staff hours) as well as the number of screenings conducted, proportion eligible, and proportion who agree to enroll. Feasibility of recruitment will be operationalized as an enrollment rate of 70% or higher (an established standard in the RCT literature). We will also record number of rescheduled, cancelled, and missed assessment visits as well as received visits/calls in each treatment arm to inform estimation of staffing needs and retention protocols for a planned efficacy RCT. Other outcomes are rate of attrition (not having a final visit at the end of treatment), rates of several categories of attrition (mortality, withdrawal from the study, transfer to non-study clinics, loss to follow-up without identifiable cause), and response rates to questionnaires (operationalized as 70% or higher), adherence/compliance rates (operationalized as completing at least 70% of the app's module in arm 2 & 3), and time needed to collect and analyze data. As an evaluation of the feasibility of the app-based intervention, we will call participants in Arms 2 & 3 weekly during the 3-month trial to ask a brief set of questions about their mindfulness practice and use and opinions of the app.

- *Smoking Cessation:* Main smoking cessation outcome is 7-day point-prevalence abstinence (defined as self-report of not smoking in the past 7-days; not even a puff) confirmed by expired carbon monoxide (CO) level of < 10 ng/ml at the 3-month follow up. Secondary outcome is the reduction in number of cigarettes smoked per day.[71,72] Relapse is defined as smoking at least once/week on two consecutive weeks.[73]

- At the end of the intervention and 3-months after the intervention, all 3 groups will be asked to complete a survey with similar items to the baseline survey.

- Breath CO will be will be collected at the 3-month follow-up points for participants who report abstinence. The breath sample will be collected with a

portable CO monitor (Micro CO™ by Micro Direct, Inc.). Cut-off of <6 ppm for CO will be used to determine abstinence (Benowitz et al 2002). These portable CO monitors will be mailed to participants for data collection.

B. Aim (2). Conduct a Post-intervention Evaluation

A semi-structured post-intervention evaluation interviews will be conducted with randomly selected participants from the *Craving-to-Quit* app and group MT groups (n=30; 10/group) to further inform our assessment of acceptability and perceived helpfulness of interventions, and identifying key areas for refining the intervention protocols (e.g., improving access, content, usability).

This interview will be scheduled during or after the 3-month follow-up over the phone. It will take approximately 30-45 minutes to complete. Participants will receive $25 for participating.

6) Data and Specimen Banking*

There will be no banking or storage of data or specimens.

7) Data Management*

The primary focus of the proposed formative clinical research will be to examine the feasibility and acceptability of *Craving-to-Quit* app and group MT for smoking cessation to inform a larger planned Phase II efficacy RCT to be considered as a R01 grant application. Although we will conduct intent-to-treat analyses of our combined intervention on primary and secondary outcomes using data from the proposed pilot RCT, this is only to explore the potential for a treatment effect. There is increasing recognition that the effect size estimates from pilot RCTs should be interpreted with caution because they lack sufficient precision for establishing efficacy or informing subsequent power analyses.[74] Therefore, we plan to recruit 30 participants (10/arm with equal gender distribution) to estimate the study parameters.[75] Expecting an overall 20% attrition rate, this will leave us with a sample of 48 participants.[48,76] However, we are planning to recruit more participant to substitute those who withdraw from the trial until we reach our target sample (n=30).

The analysis of the feasibility and acceptability outcomes will be mainly descriptive. We will use Chi-square tests and one-way ANOVA to compare between-group differences in baseline characteristics, indices of treatment implementation, adherence, retention, and treatment perceptions. Attrition analyses will compare respondents who complete all measurements to those who do not based on baseline characteristics.

Direct maximum likelihood estimation and multiple imputation will be used to address incomplete data. For potential effect of treatment, we hypothesis that both active treatment arms (*Craving-to-Quit*; group MT) will achieve better smoking abstinence rates than the UC. Chi-square tests will be used to compare main outcomes (cessation) between the three arms at 3-month follow up. Univariate and multivariable logistic regression models will be used to explore baseline predictors of 3-month smoking cessation and adherence to ART outcomes, and the usability, acceptability, and feasibility of the intervention. Cross-tabulations for ordinal variables and mean and corresponding 95% confidence intervals for continuous variables will be used to explore secondary outcomes including improvement in depression, smoking self-efficacy, craving, quality of life, and mindfulness skills. Although we are unpowered to detect differences by gender, we will consider exploring the gender effect on our main outcomes in our analysis. Data management for preparing data for statistical analysis and statistical analysis will be performed with SAS or R statistical software.

A semi-structured post-intervention evaluation interviews will be conducted with randomly selected participants from the *Craving-to-Quit* app and group MT groups (n=30; 10/group) to further inform our assessment of acceptability and perceived helpfulness of interventions, and identifying key areas for refining the intervention protocols (e.g., improving access, content, usability).

Qualitative analyses will identify emergent themes related to acceptability and specific targets for refinement of content and delivery. Interviews will be audio-recorded, transcribed verbatim, and transferred to dedoose, a secured platform, (https://www.dedoose.com/). This program is designed for the storage, coding, retrieval, and analysis of qualitative data. Two complementary coding schemes will be used: 1) descriptive, which uses words or short phrases to summarize passages of data and 2) in dedoose, in which actual language from participants is used to name concepts and themes. Extensive analytic memos will be written after each interview is conducted, coded, and throughout the analysis process to reflect on code choices, emergent themes and patterns, and conceptual models. Finally, the data will be themed, in which the final sets of codes and their meanings will be transformed into longer and more descriptive themes to organize recurrent meanings and patterns. Themes and definitions will be compared across interviews to ensure consistency and reliability.

Statistical analyses will be done using SPSS, V21, (https://www.ibm.com/analytics/spss-statistics-software).

All study data will be entered and captured by REDCap (http://project-redcap.org/) and Velos (velos.med.miami.edu) which provides secure data capture

for clinical and non–clinical research studies. All data will be stored in the office of the PI located at 1120NW 14ths St, Room 915, Miami, FL 33136.

The University desktops require secure login credentials accessible only to the research team and the hard drive on the desktops have secure encryption technology to prevent identification. The computer is located in the research office accessible only to the research team by entering the office with University ID.

8) **Risks to Subjects***

The risks to subjects, immediate and long range, are considered minimal. Study participants will be asked to complete questionnaires before and after receiving advice to quit smoking, either self-help materials to quit or a behavioral intervention, as well as nicotine replacement for smoking cessation. It is possible that subjects might become psychologically distressed while completing the questionnaires or be dissatisfied with the self-help information or intervention. They will be provided with transdermal nicotine patches that are available over-the-counter. Participants will be required to indicate whether they have any health conditions that may negatively interact with the patches.

To minimize the risk of psychological distress due to questionnaire completion, the measures do not contain private or potentially embarrassing items, and will take about 30-45 minutes for completion time per assessment. To minimize the risk of dissatisfaction with the intervention, we will use an established intervention that has high efficacy. To minimize risks associated with the nicotine patches, subjects will be provided with thorough education of the indications for the nicotine patch, possible side effects, and known health conditions that preclude patch use. The patches are available over the counter; thus, they do not pose a significant health risk to most people. They contain minimal amounts of nicotine (which are much less than they get from smoking), and are absent the remaining 7,000 toxins contained in cigarettes. In addition, we will refer patients with a questionable medical history to their physician or to Jackson Memorial Hospital for consultation.

Though we regard the risks of participating in this study as low, we will take every measure to ensure that every recruiter, interviewer or project personnel, is trained to handle situations sensitively and with empathy. All research staff are

required to complete site mandated training on the Protection of Human Research Participants.

9) Potential Benefits to Subjects*

Individual subjects can potentially benefit from participating in the study because they may be exposed to one of three established evidence-based smoking cessation treatments plus transdermal nicotine patch therapy. Thus, all participants will have the opportunity to make a quit attempt and the possibility of long-term smoking cessation. This is associated with a number of additional benefits including improved health, economic savings, the confidence and happiness associated with becoming an ex-smoker, and reducing their stress as a result to practicing mindfulness.

10) Vulnerable Populations*

This research study does not include vulnerable populations.

11) Setting

The primary study site is the University of Miami Miller School of Medicine Campus. Recruitment will mostly take place at Sylvester Comprehensive Cancer Center clinics. The consent process, participant assessments, and group meetings will take place via Zoom.

12) Resources Available

This project is a collaborative effort between investigators at University of Miami (Asfar, Lee, Koru-Sengul, Antoni) and a consultant from Brown University (Brewer) (Pls. see attached biosketches). Our team of multi-disciplinary experts in smoking cessation, MT, and clinical trial management and analysis is a pioneer in developing and testing novel smoking cessation interventions among vulnerable populations (e.g., minorities, childhood cancer survivors, and construction workers). Drs. Asfar, Lee, and Koru-Sengul have long-term collaboration on several epidemiological studies and community-based cessation trials.[42-44] Dr. Asfar (PI) is a Research Assistant Professor in the Department of Public Health Sciences at the University of Miami (UM). She has more than 10 years of experience in tobacco research. She had led several clinical- and community-based smoking cessation trials using RCT design.[45-48] Dr. Lee (Co-I) has been involved in tobacco research for over 20 years. Recently, he has been evaluating mindfulness-based interventions targeting high-stress occupational groups. Dr. Antoni is a Professor of psychology and psychiatry and behavioral sciences. He is also a behavioral intervention theme leader, and cancer control member at the SCCC. Drs Lee and Antoni will assist Dr. Asfar in the development and testing of the proposed intervention. Dr. Koru-Sengul (Co-I), has been involved for more than 10 years in the design and analysis of clinical trials. She will oversee the data management and analysis of the RCT. Finally, Dr. Brewer (Consultant) has extensive experience in

mindfulness-based smoking cessation interventions,[23,49] and has developed the "*Craving-to-Quit"* app.[37,38] He will serve as a Mindfulness domain expert on this project. All data will be kept at the University of Miami and there will be no data sharing with Brown University.

13) Prior Approvals

N/A

14) Recruitment Methods

Our target sample size is 30 cancer patients and survivors who smoke. The main source of recruitment will be UHealth's Consent to Contact database. The Consent to Contact Initiative will provide a list of identified potential eligible participants who have consented to being contacted for research studies. Flyers will also be distributed at UM/SCCC clinics and various community-based clinics/organizations not directly affiliated with UM/SCCC, such as Jackson Health System (JHS). We will also recruit via advertisements on social media platforms.

We will be provided with a list of potential participants by the Consent to Contact Initiative. We will reach out to cancer patients and survivors who seem to meet criteria and have consented to be contacted for studies. We will be provided with a list of potential participants including their names, contact information, smoking status, and cancer history. Participants from the Consent to Contact list will be contacted by phone and invited to participate in the study. However, interested participants from JHS will contact our research staff first and then receive additional study information. Additionally, they may also scan the QR code included on the study flyer to complete the screening questions independently via REDCap. The staff will describe the study and screen potential participants to determine eligibility. Those who are not eligible, or decline to participate will still be encouraged to quit smoking and given a list of available resources.

Those who are eligible and want to participate will be sent them an email with a link to complete connect to Zoom with the Research Associate and complete a REDCap eConsent informed consent and then the baseline survey. During the initial phone call they will be scheduled for an orientation session and Arm 3 group sessions, if applicable.

ResearchMatch.org will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository **(Vanderbilt University IRB #090207)**.

We will also collaborate with St. Jude who will assist in identifying eligible patients from their hospital. They will provide eligible patients with information about the study, our team's contact info, and study flyer so patients can contact our research staff directly or scan the QR code included on the study flyer to complete the screening questions independently via REDCap. We will in turn provide St. Jude with a list of their patients who have been screened and enrolled so they can update their records. After UM IRB approval is granted, they will pursue IRB approval from their institution and will request a reliance agreement be set up with UM as the IRB of record.

Participants will receive up to a $50 incentive for their time and participation in the program: $15 after completing the baseline assessment, $15 after their quit date, and $20 at the 3-month follow up. Participants who complete the post-intervention evaluation interview will receive an additional $25 for participating. These payments will be made via an electronic gift card or cash transfer app.

Participants can expect to be in the study for 3 months.

15) Local Number of Subjects

Our target sample size is 30 cancer patients and survivors who smoke.

16) Confidentiality

Multiple steps will be taken to guarantee confidentiality. All electronic surveys and forms will be entered and uploaded using Research Electronic Data Capture (REDCap). All REDCap data is securely hosted by the University of Miami's IT Department. Research IT administers project creation, user account management, and movement of projects from development to production. Authentication is performed via CaneID Authentication Service (CAS), the same institution-wide system used for a variety of applications such as mum. Other electronic data will be stored in password-protected files that only the PI and study staff will be able to access. Participants will be assigned an ID# in REDCap and a master key linking names and ID# will be kept in a separate location accessible only approved study personnel.

There are multiple levels of security once placed on the local network. All study personnel will be certified to conduct human subjects' research by the University of Miami Institutional Review Board. All data will be inspected for quality

assurance prior to analysis. Prior to performing statistical analyses on quantitative data, the data will be checked, screened and verified.

In order to enhance privacy when conducting the sessions via Zoom, participants will be instructed not to share the meeting link with anyone; for the privacy of all participants to attend the session in a private setting without others in the background; to change their location if it other people come into the area; to not discuss anything shared in the session with others; and to not share any sensitive personal data during the session. Participants will be also placed in the Zoom waiting room and admitted only by the research staff.

Jackson Health System additional requirement

☒ This section is not applicable because the research is not collecting health information from JHS under a waiver of authorization (without obtaining a HIPAA authorization from the participant)

If health information, including Protected Health Information and/or Personally Identifiable Information are collected from JHS without a signed authorization from the subject (with a waiver of authorization from an IRB or Privacy Board), you must agree to the following:

☐ JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research with a waiver of the requirement for an authorization under HIPAA shall only be stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions for Section 15 of this protocol.

If the data obtained for this research will be acquired from a retrospective "chart review" involving health information from JHS with a waiver of authorization (without obtaining an signed HIPAA authorization from the subject) then the data and the link and/or key to

each subject's identity shall only be maintained in the secure JHS SharePoint environment made available by JHS.

17) Provisions to Protect the Privacy Interests of Subjects

The Sylvester Comprehensive Cancer Center Data and Safety Monitoring Committee (DSMC) will monitor the study according the Cancer Center's data and safety monitoring plan.

18) Consent Process

Participants will be consented using the REDCap eConsent function during a Zoom meeting with the Research Associate. Permission to audio record the consent process will be attained from all participants. All participants will also be offered a copy of the informed consent for their records.

19) Process to Document Consent in Writing

Participants will sign an electronic consent form using REDCap eConsent for participation in this study. In the event that participants have difficulty completing the electronic consent in REDCap via Zoom, we will mail them a copy, have them sign while on Zoom, and ask them to mail it back to us. A copy of consent will be provided to participants. The consent will also include information regarding who they can call if they have any questions regarding their participation in the study. The consent process will be thorough to ensure that any questions participants may have will be fully considered and answered. The consent process will be documented via REDCap and an internal tracking database.

20) Withdrawal of Subjects

Participation in study is voluntary. Participants can elect not to answer any specific question on the survey or interview and can elect not to participate in any procedures or all procedures of the study.

Stopping rules for the individual subject: For any reported adverse event, the PI must decide whether the event should be classified as serious or not. We use the standard UM Clinic IRB definition for Serious Adverse Events per FDA guidelines. The PI or co-investigator (Drs. Lee, and Antoni) will cooperate and provide assistance to any personal physician treating the participant for this adverse event in order to facilitate the clinical management of the patient. If the adverse event is thought to be related to study participation, the investigator may

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request the participant to undergo a physical examination, psychiatric evaluation, and/or laboratory testing whenever appropriate.

21) Waiver of Authorization for Use and Disclosure of Protected Health Information (HIPAA)

☒ Yes. Consent to contact process

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

Notwithstanding the preceding "I confirm" statements above, I agree that neither I nor any member of the study team listed on the IRB submission for this Protocol shall ever re-use or re-disclose any of the information acquired from Jackson Health System in any format, whether **identifiable or de-identified,** to any individual or entity without first obtaining written permission from Jackson Health System, even if such re-use or re-disclosure is permissible by law (e.g., HIPAA).

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PI Signature Date

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