TITLE: Mindfulness-based ecological momentary intervention for smoking cessation among cancer survivors

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1. SPECIFIC AIMS

Continued tobacco use among cancer survivors (hereafter called survivors) is a cause of second primary cancers and high mortality.[1,2] Despite greater acute health risks from resuming smoking for individuals with cancer, smoking prevalence among survivors is higher than, or comparable to, those without a cancer history.[3] Importantly, regardless of the high quit rate at cancer diagnosis,[4] more than half of survivors who attempt to quit resume smoking within a few months.[5] Notably, existing smoking cessation trials for survivors have not demonstrated consistent results.[6] Such results might be due to a lack of understanding in the dynamic relation between cancer-specific (e.g., fatigue, pain, fear of cancer recurrence) and general smoking processes (e.g., negative affect) contributing to smoking relapse in real-time.[4] Given the prominent role of distress as a predictor of smoking relapse[7,8] and chronic distress among survivors,[9] it may be more challenging to reduce the effect of distress on smoking in this population vs the general population. Importantly, the synergistic effect of cancer-specific and general smoking vulnerabilities are linked to a higher likelihood of relapse.[5,10-12] Given the projected 31.4% increase in the number of survivors by 2030,[9] there is an urgent need to develop targeted, accessible, and scalable smoking cessation interventions for survivors to improve quality of life and decrease mortality.

Mindfulness-based interventions (MBIs) have great potential to enhance tobacco abstinence. MBIs have demonstrated efficacy among general smokers for craving and relapse.[13] The primary mechanism of MBIs is the weakening of the association of distress and smoking through enhanced self-regulatory processes.[14] Although promising, there has been only 1 single-arm, feasibility study examining an MBI for smoking cessation among survivors, which consisted of 8 weekly 2-hour in-person group sessions.[15] This time-intensive and in-person format of traditional MBIs has been identified as a barrier to access.[15,16] It also fails to leverage treatment delivery in the real world where efforts to quit smoking take place. Using a mobile health (mHealth) approach may address both issues. However, little effort has been made to integrate the core therapeutic elements of MBIs with mHealth, which could constrain the processes of acceptance and awareness.[17] Thus, an mHealth MBI for smoking cessation tailored for survivors, with an emphasis on the strategic delivery of practices and implementation of core therapeutic ingredients would enhance accessibility, target key mechanisms, lessen patient burden, and reduce cancer-specific cessation barriers for patients (e.g., shame, guilt). Further, including psychometrically sound measures to assess momentary changes of relapse vulnerabilities in real-time would aid in testing the efficacy of an mHealth MBI. The overall objective of this application is to develop a mindfulness-based ecological momentary intervention (mindEMI) for smoking cessation for survivors.

Aim 1. To develop a mindfulness-based EMI (mindEMI) targeting cancer-specific smoking vulnerabilities through an iterative multi-step process. Three phases are planned: (1) In-depth qualitative interviews with 15 survivors on their perception of existing mHealth MBI approaches and feedback on the utility and acceptability of key MBI practices (e.g., breathing meditation, brief mindfulness strategies); (2) Create an initial draft of the intervention

Aim 2. To pilot test the mindEMI among cancer survivors. We will obtain feedback from another 10 survivors who will pilot the prototype of mindEMI that will deliver the MBI in real-time at both random moments and when high levels of smoking vulnerability are self-reported via EMA. The primary outcomes will be participants' open-ended feedback along with perceived utility and likability of the mindEMI and retention through the end of treatment.

This novel cessation intervention and demonstration of key feasibility and acceptability benchmarks, combined with the focused training plan, will lead to a future R01 trial of mindEMI for smoking cessation tailored for survivors. Ultimately, the intervention will dismantle cancer-specific and general risk factors of smoking relapse, with high accessibility, scalability, and the ability to intervene in real-time, thus increasing effect.

2. BACKGROUND AND SIGNIFICANCE

2.1. Cancer and Smoking

Continued smoking after a diagnosis of cancer is linked to an increased risk of lowered effectiveness of cancer treatment, cancer-related mortality, developing a secondary primary cancer, worse quality of life,[18,19] and increased cancer treatment costs ($3.4 billion/year).[20] Despite greater acute health risks of resuming smoking, higher smoking prevalence is observed among cancer survivors ("survivors") than those without a cancer history.[3,21] Among those who make a quit attempt after cancer diagnosis (e.g., 31.4%),[5] the relapse rate of over 50% is alarming.[4,5] As such, promoting smoking cessation is recognized as an essential part of cancer care.[22,23] However, the efficacy of smoking cessation interventions and strategies that are effective for general smokers has been minimal for survivors.[6,24] This is likely due to a critical gap in the literature: Lack of understanding in real-time dynamic relations between cancer-specific (e.g., pain) and general smoking vulnerabilities (e.g., negative affect), which might synergistically increase the likelihood of smoking relapse.[5,10-12] Given the impact of chronic distress in relapse,[7,8] survivors may face a particular challenge with cessation. With the projected 31.4% increase in the number of survivors (i.e., 22.1 million) by 2030,[9] there is an urgent need to develop targeted and scalable smoking cessation interventions for survivors with an emphasis on the interrelations between cancer-specific and general smoking vulnerabilities to improve mortality and quality of life.

2.2. Mindfulness and Smoking

Mindfulness-based interventions (MBIs) that cultivate awareness and acceptance of momentary experience[25,26] are a promising approach to tobacco abstinence among survivors. From a theoretical perspective (e.g., Monitor and Acceptance Theory),[27-30] MBIs are particularly efficacious for those in high stress situations, as MBIs can weaken the association between triggers (e.g., distress) and learned behaviors such as substance use, thereby reducing reactivity to triggers. This process occurs through purposefully paying attention, in a non-judgmental way, to the automatic cycle of triggers and present-moment experience. Among general smokers (i.e., non-cancer survivors), empirical evidence supports this theoretical framework by demonstrating a weakened association of craving and smoking[31] through enhanced self-regulatory processes[14] and decreased neural response to cigarettes[32] and emotional cues,[33] leading to successful quitting.[34,35] Notably, MBIs have demonstrated efficacy in enhancing smoking outcomes among general smokers for craving, relapse,[13,34-36] and abstinence.[34,35,37,38] Nonetheless, MBIs for smoking cessation among survivors have been limited to 1 small-scale feasibility study conducted via in-person group treatment.[15]

There are at least 3 reasons why MBIs hold promise for survivors who continue to smoke. First, MBIs improve cancer-related psychological difficulties, implicating their potential in smoking cessation for survivors. Meta-analyses have shown that MBIs improve pain, fatigue, quality of life, fear of cancer recurrence, and sleep disturbance.[39-41] Further, in general population, mindfulness is positively associated with motivation to engage in behaviors because of genuine interest.[42] Thus, MBIs may aid in managing cancer-related psychological difficulties that may interact with general smoking vulnerabilities, thereby facilitating quitting through enhanced motivation to sustain cessation efforts.[34] Second, MBIs may facilitate extinction of learned smoking behaviors (e.g., craving = grabbing a cigarette) by purposefully paying attention to the "autopilot" process of smoking (i.e., awareness), cultivating the ability to stay with craving and stress (i.e., acceptance), and enhancing self-regulatory processes, thereby attenuating the likelihood of smoking relapse.[14,43] Survivors are more likely to face challenges in cessation because of the synergistic effects of cancer-specific and general smoking vulnerabilities, as indicated by a higher rate of continued smoking among those with a tobacco-related cancer (vs other cancers)[21] and higher smoking prevalence compared to those without a cancer history.[21,44] Third, MBIs may alleviate cancer-specific cessation barriers such as guilt, shame[4,5,10] among survivors. Contrary to other tobacco cessation approaches (e.g., cognitive

behavior therapy), MBIs put less emphasis on psychoeducation and skill-building and more on an individual's experiential learning. Although MBIs provide psychoeducational content, the focus is to cultivate resiliency to distress[45] through an inquiry-based learning process (i.e., explicit exploration of one's experience during mindfulness practices). Such process can aid in the reduction of guilt and shame by shifting in perspective (i.e., decentering) and taking a more objective perspective toward a given situation.[46]

2.3. mHealth and Smoking

Smoking cessation interventions delivered via smartphone applications (apps) have flourished over the last 5 years[47-53] and their feasibility and acceptability have been supported with high retention and abstinence rates among general smokers.[48,50,52] A noted advantage of mHealth is the ability to deliver intervention content when it is most needed, such as the moment of vulnerability that precipitates lapse/relapse of smoking.[54] As revealed by ecological momentary assessment (EMA) studies among daily smokers, momentary risk factors of relapse include negative affect (NA),[55] urge,[55] positive affect (PA),[56] stress,[57] and the varying real-time dynamic relations of risk factors in the course of cessation efforts,[58] consistent with the Dynamic Model of Relapse in substance use.[59] Though data are limited, such momentary risk factors are highly likely to be amplified by cancer-specific smoking vulnerabilities among survivors. Thus, if the intervention is delivered in the presence of momentary vulnerability (i.e., ecological momentary intervention [EMI]), the smoking abstinence would be facilitated. Figure 1 summarizes our conceptual framework that is informed by several theoretical models described above.[27-29,59] Indeed, preliminary results from EMIs[49,50] support this approach.

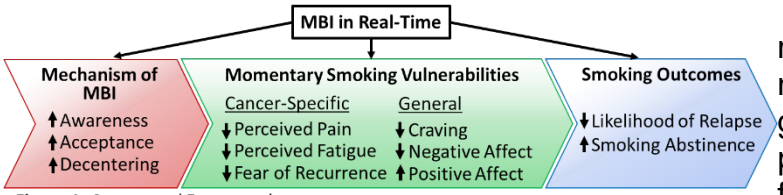

Figure 1. Conceptual Framework

To date, there has been 1 full-scale randomized controlled trial (RCT) of an mHealth MBI for smoking cessation among general smokers,[47] in which a smartphone app provided 22 modules of an MBI in various forms (e.g., audio, video) for 22 consecutive days.[60] Notably, the association between craving and smoking was significantly weakened in the MBI arm (vs inactive control) and cue reactivity decreased at the neuronal level, which was associated with reduced daily cigarette use.[32] These promising results suggest that an MBI delivered via app is not only feasible but may also alter the strength of the association between craving and smoking at both behavioral and neuronal levels. However, biochemically verified abstinence at follow-up was not different between conditions, potentially because of a non-intended treatment component in the control condition (e.g., self-monitoring).[47] This app is currently being tested among young adult survivors,[61] although it has not been tailored for survivors and does not incorporate EMI design or inquiry exercises,[47,60] a key therapeutic component of MBIs that facilitates the learning process of acceptance and awareness.[17] Given the more frequent mindfulness practice, the better cessation outcomes,[37] MBIs could be maximized by promoting the practice of mindfulness both briefly and regularly in the context of cessation in real-life, and when the vulnerable moment is captured by psychometrically sound items via EMA.

To the best of our knowledge, there are no mindfulness-based EMIs (mindEMIs) for smoking cessation specifically developed for survivors. Only 1 study has examined the feasibility of an MBI delivered in-person for smoking cessation among survivors.[15] However, its time-intensiveness (weekly 2-hour in-person group sessions for 8 weeks) is not only a potential barrier to accessibility,[15,16] but it also does not leverage treatment delivery in the real-world context where quitting takes place. Given the promising efficacy of MBIs using technology in improving quality of life in the general cancer population,[39] a mindEMI for smoking cessation tailored for survivors, with an

emphasis on both practice and inquiry-based learning processes, would not only enhance accessibility and target key smoking mechanisms, but also reduce patient burden.[22]

2.4. Innovation

This study is highly innovative in several ways. First, this work will be among the first to integrate mHealth and MBIs for smoking cessation for survivors by retaining crucial theoretical and empirical components of MBIs (i.e., inquiry,[17] acceptance and awareness,[25,26] and formal meditation[26]). In particular, this work will address a significant gap in the literature: (1) Developing MBIs targeting cancer-specific smoking vulnerabilities integrating extant theories[27-29,59] and evidence from general smokers;[55-58] and (2) leveraging unique windows of opportunity for intervention delivery (i.e., EMI)[54] in real time among survivors. Second, this work will be a novel mHealth MBI that integrates survivors' direct input in its development through qualitative interviews and an iterative process. Given the limited evidence on the efficacy of extant cessation strategies among survivors,[6] the intervention design will be informed by survivors who will assess the utility of brief mindfulness strategies and formal mindfulness meditations. Thus, the proposed intervention is not only theoretically driven but also user-centered. Third, mindEMI would potentially maximize MBI efficacy for smoking cessation through the regular and momentary practice of mindfulness at key vulnerable moments in the real-world context, as evidenced by positive cessation outcomes through frequent mindfulness practice[47] and timely delivery of the intervention.[49,50] Fourth, as compared to the intensiveness of traditional in-person MBIs, our proposed mHealth approach has high potential for scalability and cost-effectiveness, thereby reducing cessation barriers for survivors.[4,5,10] Fifth, EMA will be used to assess real-time data that capture both cancer-specific and general risk factors of smoking relapse to intervene, using psychometrically sound measures. To the best of our knowledge, EMA has not been widely used to examine smoking behaviors among survivors,[62] although EMA has been used to assess other health behaviors, such as sleep among individuals with a cancer diagnosis.[63] Further, few EMA studies have tested the reliability of EMA scales used.[55,64] Our study will provide a more accurate reflection of the dynamic relation between cancer-specific and general smoking vulnerabilities, informing future interventions for survivors.

3. PARTICIPANT SELECTION

3.1. Aim 1: Development

3.1.1. Participants

Interested participants will be screened over the phone and eligible participants will be scheduled for their interview. Inclusion criteria will include: (1) ≥18 years old; (2) having smoked at least one cigarette (even one or two puffs) within the past 30 days; (3) having been diagnosed with cancer; (4) valid home address and functioning phone number; (5) being able to read, write, and speak English; and (6) having a smartphone. Smartphone ownership is not expected to be a barrier to recruitment given that 85% of Americans and 76% of low-income individuals own a smartphone.[65] Exclusion criteria will include (1) being enrolled in a smoking cessation program.

3.1.2. Recruitment

Aim 1 will involve original data collection, conducted either in-person or remotely. Qualitative and quantitative data will be collected from cancer survivors to inform the development of mindEMI. Survivors who are current smokers will be recruited in 2 ways. First, using electronic medical records at Moffitt, a trigger that is configured in the electronic system will notify our study team weekly of patients who are classified as current smokers, and study staff will contact potential participants. This recruitment strategy has been successfully implemented by co-primary mentor, Dr. Simmons's research team[66,67] (recruiting 4.6 cancer patients per month, who were interested in quitting but have

not completely quit, similar to the current proposal's sample characteristic).[12] She successfully recruited 7 and 12 cancer patients per month in her R03[12] and R01,[68] respectively and recruited one of the largest samples of this population in the literature to date (N = 412). Second, Dr. Pabbathi's team at the Cancer Survivorship Clinic at Moffitt will connect potentially eligible participants with the study team, and the study team will contact them.

3.2. Aim 2: Usability Testing

3.2.1. Participants and Recruitment

Aim 2 will recruit 10 survivors, independent from Aim 1, to pilot the prototype mindEMI. Recommended sample size in usability studies is at least N=10 to capture 94.7% of potential usability problems, which guided the current sample size,[69] accounting for 30% drop out with a desired final sample size of 10 (will recruit N=13). Recruitment and eligibility will mimic Aim 1, with the addition of a few eligibility criteria. Additional inclusion criteria: (1) Willing to give quitting a try as part of the study; (2) Having a smartphone that allows installation of the app; and (3) Willingness to download and use the app daily. Additional exclusion criteria: (1) current use of smoking cessation medications (e.g., patch, gum, lozenge, nasal spray, inhaler, or any other nicotine replacement products or medications such as Chantix, Zyban, or Wellbutrin with the intent to quit smoking); (2) evidence of current psychosis; and (3) current/planning pregnancy or lactation. During the phone screen, we will ask participants to consult their physicians before nicotine patch use, if they endorse medical conditions (e.g., recent heart attack, heart disease, angina, high blood pressure not controlled by medications, stomach ulcer, diabetes type 1).[70]

3.3. Inclusion of Women and Minorities

Both men and women and members of all races and ethnic groups are eligible for this trial.

4. STUDY DESIGN AND METHODS

4.1. Aim 1

4.1.1. Aim 1: Design

Qualitative data will be collected to inform the development of the mindEMI among survivors, followed by configuring the smartphone app with key MBI practices.

4.1.2. Aim 1: Procedure and Data Collection

Survivors (N=15) will complete a single individual in-depth qualitative interview with a brief survey which will last about 1 hour. The thematic analysis literature recommends the sample size of 6 to 16.[71,72] Thus, we will recruit 15-20 participants for analyses. The proposed procedures are based on recommendations in the literature and Dr. Simmons's prior qualitative work.[72,73] Following the phone screen, eligible participants will provide verbal informed consent and will be scheduled for the phone, zoom, or in-person interview per participant's preference. During the interview, the following topics will be addressed: (1) Several key formal mindfulness meditations (e.g., breathing) of various lengths (5-15 minutes) adopted from Mindfulness-Based Cancer Recovery,[74] Mindfulness-Based Relapse Prevention,[75] and Dr. Vinci's studies[76-78] will be briefly introduced. Participants will be guided through 1 to 2 meditations, before giving feedback. Participants' perceived utility and acceptability of the meditations will be assessed via a brief scale developed for Time2Quit[77] (benchmark: ≥75% reporting useful).[79] (2) Brief mindfulness strategies (content areas: fear of cancer recurrence, pain, fatigue, and self-compassion; each takes 1 to 3 minutes to complete) will be presented. Participants will practice several strategies, after which overall feedback and comprehensibility of the strategy will be obtained. (3) The mHealth component will be introduced. Preferred frequency and timing of the practice and delivery of MBIs, means of delivery (prompted vs user-initiated), and inclusion of MBIs addressing

cancer-relevant distress will be assessed. (4) Given the perceived need and importance of human support in the mHealth smoking cessation literature,[80-82] feedback on preferences for counseling, including modality (in-person vs phone), and timing will be obtained. Participants will be compensated $20 for completing the interview. Participants can also receive a bonus of $5 for each online survey completed within 24 hours of being sent the link. Interviews will be audio-recorded and transcribed for content analysis. Using an inductive thematic saturation approach,[71] interviews will continue until saturation is met, when no more new information (i.e., the number of new themes) is obtained. Following the interviews, the prototype of mindEMI will be fully developed and pilot tested in an independent sample of survivors who currently smoke.

4.1.3. Aim 1: Measures

Participants' demographics and perceived utility and acceptability of the meditations and mindfulness strategies will be assessed via a brief scale developed for Dr. Vinci's prior study on a 6-point Likert scale.[77] (benchmark: ≥75% reporting useful).[79] Semi-structured interview will ask for the participants' feedback and suggestions on the planned intervention (See the interview guide for specific questions).

In a brief survey, we will use both an established questionnaire as well as questions adapted from previous studies. Participants will complete a survey of demographics (e.g., ethnicity, race, sex, sexual orientation, gender identity, marital status, education, employment status, income), smoking history as assessed by Cancer Patient Tobacco Use Questionnaire (C-TUQ),[83] nicotine dependence using Heaviness of Smoking Index,[84] The Contemplation Ladder,[85] previous experience with contemplative practice and perceived usability of mindfulness as assessed by the items developed for Dr. Vinci's Time2Quit study,[86] and perceived usability scale of the Technology Acceptance Model measure.[87]

Additionally, clinical characteristics (e.g., cancer type, date diagnosed with recent cancer) will be assessed by chart abstraction.

4.1.4. Aim 1: Intervention

NA

4.1.5. Aim 1: Adverse Reactions

Minimal risks are anticipated for this study. Research staff will report any potential AEs immediately to the PI. The PI will report AEs to the IRB within five business days using the required reporting format. Any SAEs (using the FDA definition of SAEs) will be reported within two days to the IRB and NIH using the required reporting format. Given the relatively minimal risk nature of the proposed research, this is considered a highly remote possibility. Any IRB actions in relation to this protocol will also be reported to NIH.

4.2. Aim 2.

4.2.1. Aim 2: Design

Pilot the prototype of the mindEMI in an independent sample of survivors and obtain feedback to inform the final version of the mindEMI.

4.2.2. Aim 2: Procedure and Data Collection

Aim 2 will be conducted remotely. Importantly, the mindEMI content will comprise brief mindfulness strategies and meditations selected and/or modified *per survivors' feedback* from Aim 1 and EMA items will assess *both cancer-specific and general smoking relapse vulnerabilities* by including psychometrically sound items including cancer-specific items.[88-91] Thus, the prototype will be adapted specifically to survivors.

Study participation will last 4 weeks, with 2 assessments and 3 brief counseling sessions (Figure 2). Participants will be enrolled in the study once they have completed the baseline survey. Treatment will entail brief cessation counseling over the telephone or Zoom conferencing tool per participants' preferences, provision of written cessation materials (i.e., NCI's Clearing The Air booklet),[92] and nicotine replacement therapy (NRT) in the form of nicotine patch and its instructions (e.g., suggested areas of body to put on) sent via mail; and brief mindfulness strategies/meditations delivered one-week pre-quit and 2 weeks post-quit. The mailout will also include instructions on how to use the app, and details about the study timeline. Meditations will continue 3 weeks post-quit.

Following the phone screen, eligible individuals will provide verbal informed consent and will be scheduled for the 1st counseling session. Baseline measures will be sent via REDCap to be completed online prior to the 1st session, during which participants will be oriented to the app for mindEMI and EMAs. The quit date (QD) will be scheduled for within about one week after the 1st session.

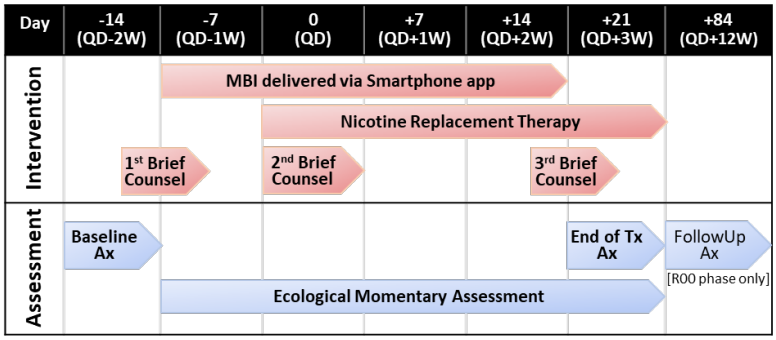

Figure 2. Study 2b Participant Flow of mindEMI
(Note. QD = Quit Date, W = Week, Ax = Assessment, Tx = Treatment)

The 2nd session will occur around the QD and the 3rd session will take place approximately at the end of treatment (i.e., mindEMI; QD+2W).

During the week following the 3rd session (QD+3W), the end of treatment measures will be sent via REDCap and a brief phone interview will be conducted to collect feedback on mindEMI. Interviews will be audio-recorded and transcribed for content analysis. Smoking status will be measured using 7-day point prevalence of abstinence ([PPA]; no self-reported smoking in prior 7 days). The counseling sessions will be scheduled at/around the appointment that coincides with our timeline, remaining flexible if there may be medically related changes in schedules (e.g., unanticipated complications) or unanticipated conflicts. EMAs will be completed over 4 weeks. Participants will be compensated $30 and $60 for completion of baseline and end of treatment assessments (including a brief phone interview), respectively. Those who complete a brief phone interview at the end of treatment will be compensated an additional $30. Participants can also receive bonus compensation for each online survey completed within 24 hours of being sent the link ($5 at both baseline and the end of treatment).

Concerted efforts to keep retention high will include phone calls if incomplete EMAs are observed for more than 2 consecutive days, obtaining a functioning phone number, home address, and the name and phone number of 2 collaterals who can provide contact information if the participant is unreachable, and providing compensation for completing assessments, including increased compensation during later study periods.

4.2.3. Aim 2: Measures

Baseline and end of treatment. At baseline and end of treatment, the self-reported following will be measured: Demographics (baseline only), smartphone-related information (e.g., operating system), smoking history/status,[83,93] nicotine dependence using 2-item Heaviness of Smoking Index,[84,94] smoking-related cognitive and affective processes (e.g., withdrawal symptoms),[85,95-97] team developed measure of previous experience with contemplative practice developed for Dr. Vinci's Time2Quit study (used in Aim 1),[86] mindfulness using Avoidance and Inflexibility Scale,[98] Five Facet Mindfulness Questionnaires,[99] Self-Compassion Scale,[101] affect using Positive and Negative Affect Schedule,[102] depression using Patient Health Questionnaire, anxiety using Generalized Anxiety Disorder-7,[105] and cancer-relevant variables including pain, fatigue, and fear of cancer recurrence.[106-108] Chart abstracted cancer variables (e.g., cancer type) will allow us to describe the heterogeneity in our sample. At the end of treatment, additional items will be assessed: smoking status, nicotine patch

use, changes in smartphone and/or carrier, perceived utility and acceptability of the mindEMI using team-developed items that were used in our team's previous studies (e.g., "How helpful were the mindful skills?")[86,109-111] as well as validated measures.[87,112-114] During the end of treatment interview, open-ended questions on the mindEMI and feedback on the app and format of counseling (e.g., number of treatment sessions) will be assessed using the team developed items (e.g., "What did you like about using the app?").

App data. EMA measures will consist of self-reported items on state mindfulness using 3 items selected from extant validated measures,[115-117] 6 affect items,[102,118] 1 craving item ("I have an urge to smoke"), using a multiple-point Likert scale, and the number of cigarettes smoked and nicotine patch use (yes/no) as well as psychometrically sound cancer-specific items that include: 1 fatigue item (on a 11-point Likert scale),[107] 1 pain item (on a 11-point Likert scale),[106] and 1 item on fear of cancer recurrence (on a 4-point Likert scale).[91,108,119,120] The EMAs can be completed in <2 minutes.

4.2.4. Aim 2: Intervention

App used for mindEMI. MetricWire app, by MetricWire (metricwire.com) will be used to deliver the mindEMI. This research-oriented app has been widely used for EMI and EMA studies. Notable strengths of the app include high flexibility in customization of EMA and EMI design and its potential for future scalability (i.e., operates on both Android and iOS).

mindEMI Intervention Content and Logistics. Here we describe the components of the mindEMI. Formal mindfulness meditations (5-20 minutes) will be in the form of audio recordings in the app; a prompt to complete the meditations will be pushed 1 time/day at a time pre-determined by the participant (i.e., fixed). Meditations will be primarily adopted from feedback from survivors in Study 2a and existing literature.[74,75] The 'inquiry' exercise to reflect on meditations will be completed 1 time/day, following meditations.

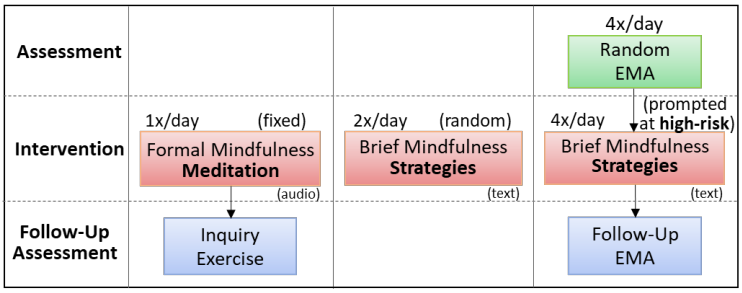

Figure 3. Overview of mindEMI and EMA

Brief mindfulness strategies (1-3 minutes) modified in Aim 1 will be delivered in the form of text in 2 ways: (a) when either high cancer-related stress, craving, or NA is indicated via EMA (i.e., prompted at high-risk), and (b) at random. This delivery approach aims to promote the cultivation of mindfulness specifically during high-risk situations, and also more generally when craving/distress may be low. We expect that the meditations will provide a foundation of mindfulness, whereas the strategies will promote the momentary application of mindfulness.

Random EMAs will be pushed 4 times a day. A day will be blocked such that participants can receive up to 6 mindfulness strategies per day, up to 4 of which will be delivered when high risk is detected via EMA (Figure 3). Following prompted strategies at high-risk moments, a follow-up EMA comprised of 4 items (i.e., craving, NA, timing, helpfulness) will be pushed. Both mindfulness strategies and meditations will be available on-demand in the app. The 'inquiry' exercise will also be completed when participants complete on-demand meditations.

4.2.5. Aim 2: Adverse Reactions

Minimal risks are anticipated for this study. Data including self-report and interview (psychological and medical) involve risk of breaches in confidentiality. Participants will always be given the option to refuse to answer any questions on the measures that may be distressing. For Aim 2, data will also be collected via smartphone. As such, there are always risks associated with privacy when collecting data in this format.

Successful abstinence may cause irritability, anxiety, general distress, and difficulty concentrating. The nicotine patch that participants will wear beginning on the quit date in Aim 2 will be the

appropriate dose for their level of smoking, and the patch should aid in the management of withdrawal symptoms. The nicotine patch and smoking cessation counseling have been shown to be safe and effective for smokers attempting to quit (e.g., the patch is available over-the-counter). However, side effects to the patch may occur and include skin irritation/ rash, nausea, dizziness, dry mouth, diarrhea, nervousness, headache, vivid dreams or sleep disturbances, irritability, and irregular heartbeat.

Risks will be protected against as described below. This study involves no investigational drugs or devices.

Emergency procedures will be in place should any psychiatric emergency arise during the screening and/or treatment processes. Although this is likely to be very rare, all study personnel will be trained in these procedures.

Potential side effects from the nicotine patch (Aim 2) will be monitored by study staff and the PI. Participants will be told of potential allergic reactions and side effects in response to the patch and nicotine side effects, and also told that they are free to remove the patch at any point in time. Should participants experience side effects, they will be advised to discontinue the patch, and also told to contact the PI and study staff. Given three phone counseling calls will be scheduled with participants, and that discussion of the patch will be conducted at these times, we do not anticipate any issues with monitoring patch side effects. Additionally, initial eligibility screening will exclude those with medical conditions that are contraindicated for the patch. Research staff will report any potential AEs immediately to the PI. The PI will report AEs to the IRB within five business days using the required reporting format. Any SAEs (using the FDA definition of SAEs) will be reported within two days to the IRB and NIH using the required reporting format. Given the relatively minimal risk nature of the proposed research, this is considered a highly remote possibility. Any IRB actions in relation to this protocol will also be reported to NIH.

5. STUDY CALENDAR

	Year 1 (Month)												Year 2 (Month)											
Activity	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Prepare interview materials, measures, and protocol for Aim 1	x	x	x																					
Aim 1: Recruit participants (N=10)				x	x	x	x	x	x	x														
Aim 1: Data collection				x	x	x	x	x	x	x														
Develop prototype smartphone app for mindEMI										x	x	x												
Staff testing the mindEMI											x	x												
Aim 2: Recruit participants (N=10)													x	x	x	x	x	x						
Aim 2: Data collection													x	x	x	x	x	x						
Finalize the full version of mindEMI																			x	x	x	x	x	x

6. REGULATORY AND REPORTING REQUIREMENTS

6.1. Institutional Review Board

No subject is to be enrolled on this protocol until the Center's Institution Review Board has approved it.

6.2. Monitoring

The Protocol Review & Monitoring Committee will monitor this study.

6.3. Informed Consent

The investigators and the research associated with the study are responsible for obtaining consent by the participants in a manner approved by the Institutional Review Board.

6.4. Investigator Study Files

Research records are the responsibility of the investigator. They will be available for review by the sponsors of the trial, health care personnel involved in this study, the IRB, and the SRC.

6.5. Data Sharing

As required by NIH rules, Dr. Yang and her mentoring team will make the data collected in the current project available to outside investigators. Specifically, de-identified data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. A data-sharing plan has been developed by Dr. Yang and her mentoring team to disseminate the research outcomes in a timely manner. Overall, shared data will be made available via mechanisms including NIH-designated Data Repositories (e.g., http://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html) or direct data transfer by Moffitt Research Information Technology (IT) following necessary approvals. The timing of data and resource sharing or public release will follow the corresponding guidelines as outlined in the corresponding NIH policy.

7. STATISTICAL CONSIDERATIONS

7.1. Sample Size/Accrual Rate

Aim 1. Aim 1 will recruit 15-20 cancer survivors who smoke for analyses. We will use an inductive thematic saturation approach, whereby interviews will continue until saturation is met, when no more new information (i.e., the number of new themes) is obtained. The thematic analysis literature recommends the sample size of 6 to 16. Thus, our sample will be 15-20 participants for analyses. Accounting for a drop out rate of ~30%, we will consent 26 participants. Dr. Yang will lead the qualitative analysis while consulting with Dr. Simmons who has expertise in this area; resources available at Moffitt for qualitative analysis will also be used.

Aim 2. Aim 2 will consist of 10 cancer survivors who smoke, independent from Aim 1, to pilot the prototype mindfulness-based ecological momentary intervention (mindEMI). Recommended sample size in usability studies is at least N=10 to capture 94.7% of potential usability problems, which guided the current sample size, accounting for 30% drop out with a desired final sample size of 10 (will recruit N=13).

7.2. Data Analysis

Aim 1. Two approaches of qualitative analysis will be used. First, the transcripts will be coded and key themes will be identified by 2 trained study staff. Texts will be analyzed for frequency (number of times the comment was mentioned), extensivity (number of participants making the comment), intensity (expressive strength of the comments), and specificity (degree of clear focus of the comment). A software, NVivo will be used to analyze the data. Coder agreement will be assessed using a Kappa statistic (≥.80). Second, based on the principles of saturation in qualitative research, details of narratives will also be a focus of analyses. Qualitative analytic strategies such as immersion-crystallization will be implemented, in which the researcher reviews the data both intuitively and reflectively until the most relevant theme to the research questions arises. Descriptive analyses will be conducted on the data collected through survey and chart abstraction (M, SD, %).

Aim 2. The primary outcomes will be participants' open-ended feedback, and perceived utility and likability of the mindEMI based on the Aim 1 benchmarks and retention (≥75% through end of treatment). Dr. Yang will lead the qualitative thematic content analyses of the feedback and conduct descriptive analyses on usability measures (M, SD, %).

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