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Test of daily app-based mindfulness meditation preceding a planned smoking quit attempt date on abstinence: Protocol for a randomized controlled trial recruiting across the 58 counties of California

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Abstract

A majority of the 34 million people who currently smoke cigarettes report wanting to quit smoking yet most attempts to quit end in relapse. Mindfulness Training (MT) is an intervention package used to reinforce an individual's practice of mindfulness meditation in daily life. MT delivered by phone app offers daily prompts to guide bouts of mindfulness meditation, that is, sustained attention to moment-by-moment experience without behavior reactivity. Daily bouts of meditation offer individuals a replacement behavior for smoking during a quit attempt, and MT app instruction aims to increase an individual's skill in non-reactivity when they experience cravings. Our study objective is to test the effect of MT on abstinence during a quit attempt among people who currently smoke and who are willing to make a voluntary quit attempt on a selected near-term date. Our delivery of smartphone app-based MT occurs daily for the two weeks preceding a planned quit date. Study participants are randomized to MT or the psychoeducation control group and asked to self-administer their app-based intervention two times a day in 10-minute segments for 14 sequential days for a total of 280 minutes. This preparatory period capitalizes on time to help participants orient toward a near-term goal to quit smoking, practice mindfulness meditation, and increase the skill of non-reactivity during states of craving to smoke. We recruit people who smoke cigarettes from all 58 counties in California. We test the hypothesis that an app-based MT will outperform a time-matched psychoeducation control on increasing smoking abstinence. Findings contribute knowledge to the addictions treatment field about whether MT delivered by app can increase smoking cessation in a geographically diverse sample.

Keywords: mindfulness, meditation, smoking, quit attempt, cessation, addiction, NCT05440903

1. Introduction

Cigarette smoking is linked to a variety of diseases that are responsible for nearly 500,000 deaths annually and which incur a yearly cost of $300 billion in health care dollars.[1, 2] A majority of the 34 million people who currently smoke report wanting to quit smoking, yet most quit attempts end in relapse.[3] Many quit attempts likely do not lead to prolonged abstinence because those who are willing to quit commonly self-initiate *unassisted* quit attempts, meaning attempts made without support of a program, medication aid, and/or counselor.[4] Considering this reality – that most quit attempts are unassisted and most of these will fail – it is possibly useful to develop behavior interventions that are low-cost and easily accessible to support individuals desiring to quit on a near-term date. Our standpoint is that some people who smoke and want to quit might be best supported by these remote types of behavior intervention that focus on reinforcing competing, health-oriented, behavior such as mindfulness meditation.

Mindfulness based interventions (MBIs) refer to intervention packages that reinforce mindfulness meditation in daily life. MBI content functions to guide individuals to pay attention to perceptual and sensory experiences of their mind and body while in various relaxed postures such as lying down, sitting, standing, slow walking, and light stretching.[5] While meditating, the individual holds an intention to attend to the fluctuating experiences of the mind with as little analytic and behavior reaction to those experiences as possible (i.e., the learned skill of non-reactivity). This process, involving relaxed posture, focused attention, and non-reactivity, purportedly sensitizes an individual to feel more aware in the present moment and so have greater access to a wider range of lived experience (i.e., pleasant, unpleasant, and neutral) as opposed to a focus on changing fluctuating states of experienced deprivation (e.g., cigarette craving and the associated desire to smoke to satiate that deprivation).[6, 7] When applying this approach to smoking cessation, we propose that introducing a MBI to an individual prior to their voluntary smoking quit attempt date reinforces a replacement behavior (i.e., meditation at least

twice per day) as well as provides a new learned skill in non-reactivity to deprivation as a means to manage cigarette cravings. In concept, the greater the number of times an individual is non-reactive to cravings, the lower their probability of smoking when cravings occur in the future.

The literature supports a net benefit to health associated with participation in various MBI programs (e.g., Mindfulness Based Stress Reduction; Mindfulness Based Cognitive Therapy) in both normative and clinical samples.[8, 9] Empirical tests of MBIs are growing in field of addiction recovery,[10] particularly for alcohol and other illicit drug use disorders.[11, 12] Relatively less is known about the effect of MBIs on smoking cessation among people who smoke and who are willing to make a voluntary quit attempt while assisted by an app. A meta-analysis of randomized controlled trials suggests that MBI intervention assignment is associated with an increased likelihood of remaining abstinent after a quit attempt.[13] Further, experimental studies show that individuals in a state of smoking deprivation, after a single 7-minute mindfulness meditation practice bout, show less psycho-physiological dysregulation in response to an anxiety provoking task [14] that is shown to induce smoking behavior during abstinence.[15] Further, following a smoking cue exposure task used to induce craving, people who smoke display brain activity associated with less effortful response inhibition following a single 15-minute mindfulness meditation bout [16].

In a comparative efficacy trial, adults with nicotine dependence were randomized to four weeks of an in-person, group-based MT (adapted for smoking cessation) or the American Lung Association's cognitive behavioral program.[17] The MT group showed significantly greater point prevalence abstinence at 4 month follow up (31% vs. 6%). In a separate RCT comparing remote MBI mobile delivery adapted for smoking cessation to mobile app monitoring only (i.e., experiential sampling of smoking behavior and related symptoms), both study groups showed a significant reduction in cigarettes smoked per day; however, there was no difference between groups in 7-day point-prevalence abstinence from smoking at 6 month follow up (MBI group =

10% vs. monitoring control = 12%).[18] When we pool the evidence in the field on MBIs for smoking cessation to date, we find the available literature indicates a signal for MBIs to support smoking cessation, yet intervention delivery methods differ (i.e., group-based, individual-based mobile app), study comparison conditions vary (e.g., behavior monitoring, standard of care, psychoeducation) and treatment effects of MBIs on abstinence are mixed (e.g., large effect reported for in-person MBI as well as null effect reported for an app-based MBI adapted specifically for smoking cessation).

1.1 Study objective

Our study objective is to test the effect of a mobile app-delivered MBI intervention package (i.e., Headspace) relative to a time-matched mobile app-delivered psychoeducation intervention package control group on smoking outcomes among people who currently smoke and who are willing to make a quit attempt on a near-term date. Our delivery of the interventions daily for the two weeks leading up to a planned quit date affords people who smoke the opportunity to orient their quit attempt, practice mindfulness mediation and increase their skill in non-reactivity to cravings. We design a parallel between-group randomized controlled trial to test the hypothesis that an app-based MBI will outperform a time-matched psychoeducation control on smoking abstinence across a one-month follow up period. We also administer an experimental stressor task (the Trier Social Stress Test [TSST], which has been shown to increase smoking urges in the laboratory and predict relapse in the natural ecology)[19, 20] on the quit date to determine the effect of MBI on non-reactivity during the initial hours of acute nicotine withdrawal (i.e., deprivation). We recruit people who currently smoke from all 58 counties in the state of California. We anticipate findings will contribute knowledge to the addictions treatment field about whether MT delivered by app can increase smoking cessation in a geographically diverse sample.

2. Methods

2.1 Study design

This is an assessor-blind, parallel-group, human subjects randomized controlled trial (RCT) recruiting across all urban and rural geographic regions in state of California (n=58/58 counties). The trial is designed to test a daily behavioral app-based intervention prior to a self-directed cigarette smoking quit attempt among people who currently smoke daily. Study groups include an app-based mindfulness based intervention (app-MBI) program or app-based psychoeducation (App-Ed) program, both being available to the public. App-Ed functions as an attention control to account for time, attention, expectancy, and other extraneous factors elicited from research trial participation. All participants are asked to voluntarily self-administer their app-based intervention two times a day in 10-minute segments for 14 sequential days for a total of 280 minutes (i.e., the adherence denominator). The study opened for trial enrollment in July 2021 and carries an anticipated enrollment completion date of May 2023. Study assessment of smoking behavior is conducted prior, during, and immediately after intervention, and at 30-day follow up using smartphone-based daily diary surveys, timeline follow back (TLFB) calendar, interview, and online survey methods. The trial is registered with clinicaltrials.gov (NCT05440903) and is IRB-approved (UP-20-00900). This trial started during the COVID-19 global pandemic.

2.2. Participants and procedures

Individual adults are currently recruited via online Craigslist advertisements, and participants complete all study protocols and interviews remotely either at home or at their preferred location using a secure online videoconferencing platform. This method extends our reach of recruitment as well as addresses the in-person limitations caused by the ongoing

pandemic and associated state and local oscillating social isolation policies. Interested individuals who view the advertisements follow a link to complete an online survey demonstrating interest in the study, then make a voluntary request to be contacted by the study team. Study staff then contact positive screens by phone to interview each individual and confirm their study eligibility. A 15-minute phone screen is used to determine initial study eligibility and to schedule a baseline interview for those passing the screener. During the screening call, study staff confirm current smoking status (i.e., smoking 5 or more cigarettes per day for the past 2 years). Those screened receive electronic informed consent documents to e-sign and return after completing a phone-based verbal informed consent process led by a trained study staff.

Individuals consented are assessed for additional eligibility criteria (see section 2.3) during a study baseline videoconferencing interview led by trained study staff. Those who are eligible then transition to study participant status and receive the baseline survey to complete prior to their remote baseline interview with the study staff. The baseline interview lasts 120 minutes wherein participants complete surveys and are counseled on study participation. This interview session includes a 20-minute planning segment to discuss their smoking behavior and to set a quit date on the subsequent 14th day following the interview date. At the end of baseline interview, participants transition to being enrolled in the trial after they are randomly assigned to a study group. Study staff help the enrolled participant install and register the assigned app on their personal device. Staff unblinded to a participant's study group do not complete outcomes assessments.

Participants go on to voluntarily complete their daily app-based intervention for 14 days then attend the post-intervention interview coincident with their scheduled quit date. The immediate post-intervention interview includes verbal initiation of the voluntary quit attempt, survey completion, and completion of an online version of the Trier Social Stress Test (TSST,

detailed below in the Measures section). All app content remains available for use for all participants during the post-intervention follow period. Participants complete prompted phone-based daily diary of smoking behavior for the 14 days following the quit attempt, as well as the timeline follow back (TLFB) calendar of smoking events that covers the 30-day period following the quit attempt (see Figure 1 for a timeline of study procedures for enrolled participants).

Participant compensation can reach a possible maximum of $300 U.S. dollars for completing screening baseline intake survey ($30), baseline interview ($40), daily diary report ($15 possible per week across 4 weeks for maximum possible $60), daily audio app trainings ($2.50 for each of 28 possible sessions over 2 weeks for maximum possible $70), post-intervention videoconferencing interview ($40), and 30-day follow-up surveys ($20), and a bonus for completing over 80% of surveys across 4 weeks of daily diary assessments ($40).

2.3 Eligibility requirements

Individuals who are eligible to participate in the study are 18 years of age or older, smoke daily (at least 5 cigarettes per day) for the past 2 years, willing to make a self-directed cigarette smoking quit attempt, and current residents in the state of California (verified by a state-issued ID with a California mailing address). People who are ineligible are not fluent in English, lack access to remote video capability (computer, camera and internet, smartphone), have an ongoing mindfulness or meditation practice of more than 5 minutes per day within the past 30 days, and any use within the past 30 days of any nicotine replacement products (i.e., nicotine patch, gum, lozenge) or smoking cessation medications (i.e., Chantix [varenicline], or Wellbutrin, Zyban [bupropion]). Ongoing mindfulness practice of more than 5 minutes per day is excluded in order to test effect of taking on a new study treatment (meditation) as the independent variable. Cessation aids are excluded in this study for the purpose of detecting singular behavior intervention effects rather than interactions with pharmacological effects.

2.4. Randomization and blinding

Author M.K. randomly assigns one study intervention to each participant in 1:1 allocation ratio using computer-generated randomly selected block permutations with a range of 4-20 assignments per block. The block method reduces potential selection bias as with simple randomization but also offers the advantage of increasing the likelihood of balanced allocation to groups.[21] Study staff responsible for supplying the app allocation to participants during baseline interview are given the randomization list with the assigned app information only. These staff members who train participants on app use are not involved in outcomes assessments, thus all study outcome assessors are blinded to study group allocation to eliminate extraneous influences caused by staff behavior.[22] Participants are unaware of their app assignment until the end of the baseline interview when instructed to use the assigned app. PIs are blind to trial datasets that include the group assignment variable during the active trial and up to the analysis of the primary trial outcomes. A third-party statistician, guided by a priori decision rules, will independently test the trial effects on outcomes and deliver results to the PIs to eliminate extraneous influences of investigator expectation and bias.

2.5. Interventions

2.5.1. App-based mindfulness training (app-MT)

App-MT refers to the Headspace software application recordings (https://www.headspace.com; the *Foundation Pack*). Headspace offers pre-recorded introductory mindfulness meditation audio instructions guided by experienced meditation teachers (see Table 1). Study participants are instructed to voluntarily complete 10 minutes of Headspace twice per day for 14 days, a total recommended dose of 280 minutes. App-MT practice begins the day after the baseline interview (i.e., intervention day 1). Participants are

encouraged to listen at two separate times each day to support habit formation and to maximize daily exposure with low time burden. Adherence to this training regimen is tracked by study staff and is operationalized as the number of times an individual used an intervention session out of a total of 28 possible sessions (2 sessions per day for 14 days). As participants have minimal prior experience with mindfulness attributed to the study eligibility criteria, all recommended trainings are at the beginner level. Participants have access to all sessions offered and are not restricted to a particular sequence. All participants in this group also receive a conventional smoking cessation standard of care (i.e., a pdf copy of NCIs “Clearing the Air” publication that contains cessation information and worksheets to support a quit attempt, https://www.cancer.gov/publications/patient-education/clearing-the-air-pdf).

2.5.2. App-based psychoeducation (app-Ed)

App-Ed refers to TED Talks audio recordings offering psychoeducation by experts on field-specific topics (https://www.ted.com; see Table 2). Study participants are instructed to voluntarily complete 10 minutes of TED Talks twice per day for 14 days, a total recommended dose of 280 minutes. Sessions were originally selected by the study team to be of interest to the public yet not include content on meditation, smoking, or content appearing to cue behavior change associated with smoking. Similar to app-MT, app-Ed practice begins the day following the baseline interview (i.e., intervention day 1). Participants are encouraged to listen at two separate times each day to maximize daily exposure with low time burden. Additionally, participants are instructed to listen with “full mindful attention and return attention to the audio when attention drifts”, which matches the app-MT instruction and emphasizes the importance of sustaining attention for each 10-minutes period. Similar to the app-MT conditions, adherence to this regimen is tracked by study staff. Participants have access to all sessions offered and are not restricted to a particular sequence. As with the app-MT group, all participants in this group receive a conventional smoking cessation standard of care (i.e., a pdf copy of the National

Cancer Institute *Clearing the Air* publication that contains cessation information and worksheets to support a quit attempt).

2.6. Measures

2.6.1. Cigarette smoking

The trial primary outcome is cigarette smoking cessation. We use data captured from the 14-day daily diary (collected via the smartphone app RealLife Exp, lifedatacorp.com) initiated on the quit date, as well as the timeline follow back (TLFB) calendar measure (collected via REDCap) completed 30 days after the quit date. [23] We operationalize smoking cessation at the individual level as 7-day point prevalence abstinence as defined previously (i.e., not smoking a single cigarette in the previous 7 days), [24] calculated at two points: 14 days after the quit date, and 30 days after the quit date. During the 14-day daily diary assessment period, a single question (How many cigarettes did you smoke today?) is queried by smartphone prompt nightly at 7pm. Reminders to complete the question are sent once an hour until 11pm or until the participant responds. The TLFB is completed by participants at the study endpoint survey which is 30 days after the quit attempt date. The respondent recall period starts at the quit date and ends at the survey assessment at day 30. The TLFB allows for capture of additional smoking outcomes including, numerical count of cigarettes smoked per day, numerical count of smoke-free days, lapse recovery, and duration of smoke-free intervals (in days) between smoking days.[25] Additionally, given previous studies indicating that daily diary can produce different estimates of the number of cigarettes smoked compared to TLFB,[26] we will be able cross-validate the 14-day phone-based diary data with daily smoking behavior captured on TLFB.

2.6.2. *Behavior change process*

The trial secondary outcomes are smoking cessation-related indicators of the behavior change process. We will operationalize cessation motivation with the Contemplation Ladder, a visual graphic allowing respondents to select their current level of motivation to quit smoking.[27] A low score of 0 represents “no thought of quitting” and a high score of 10 represents “taking action to quit (e.g., cutting down, enrolling in a program)”. The Contemplation Ladder is completed at baseline (intervention day 1) and then again at day 30. We operationalize adherence to the interventions by the number of times an individual used an intervention session out of a total of 28 possible sessions (2 sessions per day for 14 days). We operationalize cessation-related symptoms by participant self-report on the Minnesota Nicotine Withdrawal Scale[28] and the Questionnaire of Smoking Urges.[29]

2.6.3. Non-reactivity on the experimental stressor task

The task-based experimental outcome is non-reactivity to an adverse stressor task during the first day of a smoking quit attempt when the individual in deprived of smoking. Participants provide self-report of reactive arousal on visual analogue scales (VAS) at one minute before and at 5-, 30- and 60- minutes after the Trier Social Stressor Test (TSST), previously adapted for videoconferencing delivery via internet.[30] VAS items include “I have an urge to smoke”, “I feel anxious”, “I feel relaxed”, “I feel stressed”, “I have difficulty concentrating”, and “I feel terrible.” Each VAS has the left anchor “not at all” to right scale anchor “extremely.” The TSST is shown to elicit changes in salivary stress-related biomarkers as well as subjectively reported reactive stress responses in smokers.[31] Participants see real-time visual feedback of the staff evaluator’s video image as well as their own video image to increase self-consciousness of judgement during the task. Participants are asked to deliver a 5-minute speech to convince the staff evaluator (and indicated future expert panel of judges) that they are a good candidate for their dream job. Participants have 5-minutes to prepare their speech then deliver the speech in real time. The staff evaluator maintains a neutral facial

expression and withholds encouragement. If the participant stops talking during the speech, the evaluator prompts them to continue speaking until the allotted time ends. Following this speech task, a 5-minute math task is assigned to the participant whereby they are asked to sequentially subtract 13 from 1,022 and provide verbal responses to be evaluated by an expert panel. If the participant states an incorrect answer, the evaluator asks the participant to stop and start over from the beginning. Participants are debriefed at the end of the study about the true nature of the task and the lack of true panel evaluators.

2.6.4. Sample characteristics

We collect descriptive information about each participant on the study baseline survey to understand the aggregate characteristics of the sample obtained and to verify that randomization assigns characteristics to study groups in similar manner. Measures used will include: a PI-developed personal information questionnaire to assess demographic information and smoking history; the Fagerström Test for Cigarette Dependence;[32] Big Five Personality Inventory;[33] Difficulties in Emotion Regulation Scale (DERS);[34] Brief Fear of Negative Evaluation Scale;[35] Five-Facet Mindfulness Questionnaire;[36] Profile of Mood States;[37] and Cook-Medley Hostility Scale.[38]

2.7 Statistical analysis

2.7.1. Sample size calculation

Between-group proportional difference in 7-day point prevalence abstinence is the primary trial outcome in the intent-to-treat sample analysis. Using G*Power software,[39] we conducted an a priori power analysis to guide our decision on the size of the sample for this trial. Based on a previous trial findings using this same outcome and comparing a MBI to smoking cessation education in adult smokers,[40] we estimated the need for a total sample

size of N=200 participants (100 per study group) to detect a proportional difference of medium size (Cohen's d=0.55) with a calibration of 80% power and two-tailed test with alpha cutoff at 5% (see Figure 1). We will oversample individuals at baseline to compensate for an anticipated overall 10% attrition rate.

2.7.2. Data capture and preparation

Participant and interviewer reported data are currently input and stored in the secured Research Electronic Data Capture (REDCap, https://www.project-redcap.org) system. Participant and interviewer reported data are stored from study assessments made at screening, baseline, intervention, daily diary, immediate post-intervention, and one-month study endpoint. On a bi-annual basis, we will conduct statistical diagnosis tests to verify that data are within measurement range, to examine distributional properties of outcomes variables for normality, and to assess internal consistency and test-retest reliability of obtained measure scores. On an annual basis, we will verify randomization equivalence by group on age, sex, FTND scores, and Contemplation Ladder scores using two-tailed tests and alpha cutoff at 5% with Bonferroni correction for multiple testing.

2.7.3 Trial analysis

Baseline variable aggregate values showing a significant difference (after Bonferroni correction) by study group will be evaluated as model covariates in the prediction of treatment outcomes and included in the final model if deemed influential on the effect of group difference. We will evaluate attrition by comparing the trial enrolled sample to the actual retained sample at study endpoint on baseline values for age, sex, FTND scores, and Contemplation Ladder scores. After standard data preparation is complete, all trial outcomes analyses will then be handed off and completed by a trial statistician not involved in conducting the trial. Group effects

on trial primary and secondary outcomes will be carried out using the ITT analytic approach,[41] meaning all available data from participants enrolled in the trial will be included in analyses if the enrolled participant was exposed to a single dose or more of an intervention. The generalized linear mixed models (GLMM) used to test intervention effects on individual trial outcomes will include a variable for study group (to test the between group effect) and necessary covariates as noted above.[42] Models will include specification for the distribution of the binary outcome variable. We will account for missing data by using all available cases with the full information maximum likelihood (FIML) estimation procedure.[43] We will interpret trial findings with emphasis on the effect size parameter and their surrounding 95% confidence intervals and compare effects to cessation trials that report on established behavior interventions to decipher relative importance to the field of cessation.

3. Discussion

In this protocol report, we detail the research design and methodology of an ongoing human subjects, parallel group, between-subject, randomized controlled trial to test the effect of a app-based MBI intervention package on smoking cessation among people who smoke and are willing to make a quit attempt on a near-term date. We presume mindfulness meditation is the independent variable to function on smoking as the dependent variable given that our selected control group mirrors the intervention package on daily time exposure to app-based digital educational content, study protocols, staff contacts, assessments, monitoring, and compensation schedules. All participants also receive the self-administered smoking cessation workbook developed by the National Cancer Institute (NCI) to control for the existing standard of care offered to the public. Our intervention package is assigned daily, twice per day, for the two weeks prior to a quit attempt date under the rationale that preparation to replace smoking with meditation behavior and to build a skill in non-reactivity to cravings takes practice and trial and error which speaks to the utility of a daily intervention that leads up at a planned quit date.

Smoking cessation trial

We select the Headspace app for the MBI group for its focus on mindfulness meditation rather than for smoking in particular because it is fully designed and available for public purchase and is offered at institutions spanning healthcare, research, education sectors.[44] The Headspace app is not focused on smoking as with the case of MBIs that integrate mindfulness meditation and quit smoking content.[18] Headspace allows us to pinpoint the specific effects of mindfulness meditation as the independent variable rather than the packaged combined effects of mindfulness meditation, monitoring of smoking, feedback and other elements that have been integrated in previous studies.[18] To increase diverse demographic representation in our sample, we recruit and enroll participants from rural and urban regions spanning 58 counties across the state of California and use internet-based videoconferencing technologies as the medium of assessment and task delivery. These research protocols for recruitment, task-delivery, and assessment can be replicated at relatively low cost in future studies.

The trial primary outcome is smoking cessation after a voluntary smoking quit date positioned at the end of a two-week long intervention phase. We operationalize smoking cessation at the individual level as 7-day point prevalence abstinence (at the 14-day and 30-day post quit day time points) using data captured from the 14-day daily diary initiated on the quit date and the TLFB calendar reporting method completed 30 days from the quit date. We will aggregate individual data in a group-level analysis using the intent-to-treat principle. During the 14-day assessment period following the intervention phase of the study, smoking behavior is queried daily by smartphone prompt. The TLFB will additionally allow for capture of secondary smoking outcomes including numerical count of cigarettes smoked per day, numerical count of smoke-free days, lapse recovery, and duration of smoke-free intervals (in days) between smoking days. Our assessment of 7-day point prevalence abstinence at the 14-day time point has merit in that it is not highly vulnerable to recall bias (recall of smoking behavior references a

single day), reduces the proportion of missing data (use of daily prompts with compensation for reporting), and is representative of biochemically carbon monoxide (CO) confirmed abstinence as evidenced in previous studies (90% agreement).[45]

The design characteristics of this ongoing randomized controlled trial contribute to a general overall strength of our study; however, there are ways in which our interpretations yielded from the results produced by the trial will be limited. First, any findings from the current study will be limited to those individuals who own smartphones and who are willing and able to use those devices to engage with intervention content. Second, our outcome measure of smoking is not CO biologically verified due to budget constraints. Our previous work indicates that self-reported smoking is reliable,[46] and so we do not expect any group differences in veracity of self-report. That is, if there is indeed a tendency to underreport smoking, then that tendency should function in both groups equally and thus there would be no threat to trial internal validity. Third, any detected effect by group in this trial may be due to extraneous factors not uncovered by our assessment strategy. For example, instructions in the app-MT group may lead participants to initiate other behaviors as part of lifestyle modification such as change in diet, yogic physical activity, and/or alter social relationships (e.g., seeking out people who do not smoke to spend time with), which are not directly attributable to our desired independent variable (Headspace).

Fourth, given the nature of the behavior intervention, participants become aware of their study group content immediately following trial enrollment which is a ubiquitous artifact of behavior interventions. Recognizing study group in this way can function to differentially reinforce participant adherence to select study interventions and protocols. We will address this concern statistically by examining differential attrition and intervention engagement by group. Fifth, our reliance on a between-groups analysis, although benefitting from randomization to offer equivalence of groups on key characteristics, will lack the additional benefit of within-

between analytics that would offer additional precision for the effect estimate by including individual-level intercepts in the model. However, this concern is most likely moot given the nature of the dependent variable which is operationalized as abstinence which is a time-bound event that did not occur at baseline. It will be possible however to examine a post-hoc interaction effect of nicotine dependence with study group to obtain pilot data suggestive of how dependence relates to smoking abstinence that is in response to app-MT. Finally, the one-month follow period to assess smoking does not allow us to determine sustained abstinence, which is due to funding limitations. This masks the potential to detect lagged effects, effects that increase or decrease over time, and null effects that persist over time.

In summary, we describe in detail the study design and rationale for intervention and procedures for a trial powered to test the effect of a mindfulness meditation app against a psychoeducation control group on a smoking quit attempt in a state-wide sample. We expect that this trial will contribute new scientific insight to support or refute the utility of MBI apps when used pre-emptively to support smoking abstinence following a voluntary quit attempt.

Tables and Figures.

Table 1. Description of the app-MT intervention known as Headspace

Content Domain	**Theme of instruction**
Focused attention	Instructions used to direct the meditators attention to the sensations of the breath.
Resting awareness	Instructions used to help the meditator maintain a mind at rest without focusing or directing attention in any specific way.
Body scan	Instructions used to help the meditator attend to sensations of the body sequential order from the top of the head to the toes.
Noting experience	Instructions used to help the meditator simply “note” the thoughts and emotions that come to mind without judgement.
Friendly-kindness	Instructions used to help the meditator send positive energy and compassion to oneself and others, and to intone gratitude.

Note. All participants are instruction to follow app-based audio twice per day for 10 minutes per sitting for 14 successive days. Participants select their preferred app-MT audio from the menu of sessions indicated in the table.

Table 2. Description of app-Ed group TED Talks content.

Session	Title
1	10 ways to have a better conversation by Celeste Headlee
2	How bumble bees inspired a network of tiny museums by Amanda Schochet
3	How we can teach computers to make sense of our emotions by Raphael Arar
4	Are indoor vertical farms the future of agriculture? by Stuart Oda
5	Why tech needs the humanities by Eric Berridge
6	Why you should treat the tech you use at work like a colleague by Nadjia Yousif
7	A playful solution to the housing crisis by Sarah Murray
8	How I turn negative online comments into positive offline conversations by Dylan Marron
9	How to speak so that people want to listen by Julian Treasure
10	Comics belong in the classroom by Gene Luen Yang
11	The Standing Rock resistance and our fight for indigenous rights by Tara Houska
12	The role of human emotions in science and research by Ilona Stengel
13	Let's teach for mastery – not test scores by Sal Khan
14	To eliminate waste, we need to rediscover thrift by Andrew Dent
15	Why it's worth listening to people you disagree with by Zachary R. Wood
16	How I use Minecraft to help with autism by Stuart Duncan
17	What I've learned about parenting as a stay-at-home dad by Glen Henry
18	How protest is redefining democracy around the world by Zachariah Mampilly
19	Two reasons companies fail — and how to avoid them by Knut Haanaes
20	Why you should love gross science by Anna Rothschild

21	How climate change could make our food less nutritious by Kristie Ebi
22	Don’t fear super intelligent AI by Grady Booch
23	How mobile phones power disaster relief by Paul Conneally
24	3 creative ways to fix fashion’s waste problems by Amit Kalra
25	What reading slowly taught me about writing by Jacqueline Woodson
27	Excuse me, may I rent your car? by Robin Chase
28	The surprising solution to ocean plastic by David Katz

Note. All participants are instruction to follow app-based audio twice per day for 10 minutes per sitting for 14 successive days. Participants select their preferred app-based audio from the menu of sessions indicated in the table.

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