PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Bettina B. Hoeppner

PROTOCOL TITLE
An online pilot study of Version 2 of the smoking cessation smartphone app "Smiling instead of Smoking" (SiS)

FUNDING
American Cancer Society

VERSION DATE
October 25, 2018

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

The overall goal of this pilot study is to solicit feedback from nondaily smokers looking for smoking cessation support online (n=270) about Version 2 of a smartphone app we designed to support smoking cessation. Feedback will be collected via passively collected smartphone app usage data, surveys and, in a sub-sample (n=20), online video-conference user feedback sessions. Results will be used to guide the design of Version 3.0 of the "Smiling Instead of Smoking" (SiS) smartphone app. Specifically, our aims are to:

(1) Assess ease-of-use and helpfulness of the app, as rated by app users 6 weeks after their chosen smoking cessation date
(2) Test if within-person changes occur in theorized mechanisms of behavior change as nondaily smokers undergo a SiS app assisted quit attempt
(3) Identify app features in need of improvement, as identified by passively recorded app usage patterns, REDCap open-ended survey items, and, in a sub-sample, user feedback sessions (n=20)

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

The prevalence of smoking has remained stable in recent years, yet nondaily smoking (22% of all adult smokers) is an increasingly prevalent smoking pattern (30% increase in less than two decades). It is disproportionally represented in ethnic minority groups. The cancer risk of nondaily smoking is substantial (40-50% of that seen in daily smokers). Existing treatments are ill-suited for nondaily smoking, because they are based on nicotine dependence, and traditional treatments and treatment modalities (e.g., in-person counseling, medication) do not appeal to non-dependent nondaily smokers. Moreover, cross-sectional, naturalistic and laboratory studies have shown that nondaily smoking differs from daily smoking on numerous important dimensions related to smoking cessation, suggesting the need for specialized smoking cessation support for this population of smokers. Fortuitously, nondaily smokers are motivated to quit smoking, even more so than daily smokers. Like daily smokers, however, they overwhelmingly fail in their quit attempts, demonstrating their need for smoking cessation support. Treatments that target the unique characteristics of nondaily smoking are sorely needed.

To address this need, we are in the process of developing a smartphone app that acts as a behavioral, in-the-pocket coach and uses positive psychology exercises to enhance quitting success. Treatment via smartphone app is promising given the demonstrated effectiveness of texting interventions. It is particularly appealing because it is anonymous, portable, and provides just-in-time support, an important feature for smokers who smoke under specific conditions and circumstances. To support treatment, we use a positive psychology approach. Positive affect enhancement is an empirically sound treatment target: positive affect is psychometrically and neurologically distinct from negative affect, and plays an important role in the days leading up to and following a quit attempt. Enhancing positive affect with brief, self-administered exercises is entirely feasible: in recent years, a large number of positive psychology exercises have been developed that have consistently led to improvements in happiness, reductions in depression, and improvements in overall well-being. The smartphone app administers such positive psychology exercises to enhance and/or maintain positive affect, which is hypothesized to stimulate nondaily smokers to enact healthier alternatives to smoking by broadening their thought-action repertoire, increasing confidence, and decreasing craving and defensiveness about smoking-related health information (Figure 1). The focus on happiness will help overcome treatment resistance, as the pursuit of happiness is generally appealing and non-stigmatizing. To this end, we have worked closely with nondaily smokers in Study 1 (#2017P001106) to develop Version 2 of our "Smiling Instead of Smoking" app. In the current study (i.e., Study 2 in a series of 3 studies funded by the American Cancer Society (130323-RSG-17-021-01-CPPB)), we will conduct a larger pilot study to gain feedback from nondaily smokers on Version 2. Study 3 will be a proof-of-concept RCT of Version 3 of this app.

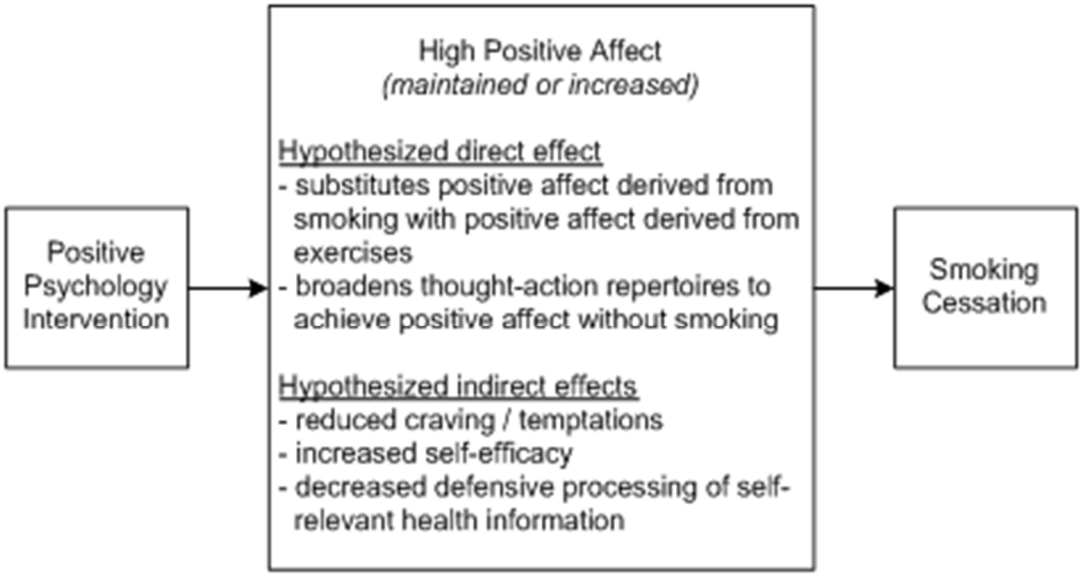

Figure 1. Treatment mechanism.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

An estimated 270 participants will participate (i.e., sign consent) in this study based on the following eligibility criteria: (a) 18+ years of age, (b) smartphone ownership (c) current nondaily smoker, who smokes at least weekly, and no more than 25 out of the past 30 days (i.e., 71% of nondaily smokers), (d) has current quit intention (i.e., 65-74% of nondaily smokers), and (e) interested in helping us develop a smartphone app for smoking cessation. We will stop enrollment when n=90 participants have completed the primary endpoint of the study, which is the 6-week follow-up. Our study will be conducted entirely remotely and will require a screening process prior to enrolling participants on the app. Based on our experience in Study 1 (#2017P001106), we expect that 1/3 of participants who initially provide consent will pass the screening process and be retained for the 6-week follow-up. Thus, we are estimating that n=270 will be necessary to sign the initial consent for this study in order for n=90 to complete the primary endpoint of this study.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Participation will last 6 months, where surveys will be administered prior to the quit day (online, as part of a screening test), and at 2-week, 6-week, 3-month, and 6-month follow-ups of the participant's chosen quit day (Figure 2). Participants will use the app for a strongly encouraged period of 7 weeks (1 week before, 6 weeks following the quit attempt), and optional continued use thereafter.

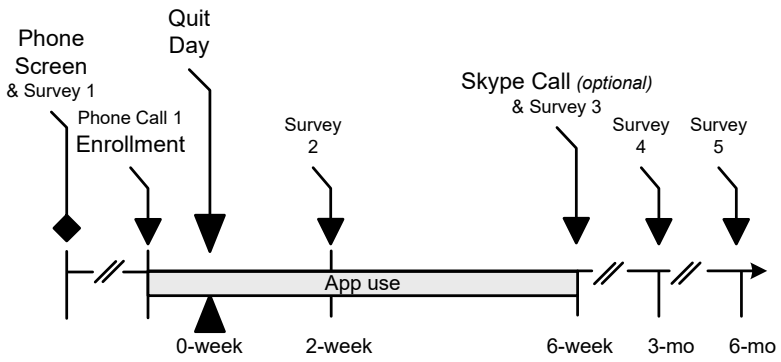

Figure 2. Timeline of Your Study Participation

Participants will complete two types of assessment: (1) surveys, and (2) (in a sub-sample) user feedback sessions conducted via Skype. Potential participants will click-through to the study website. This website will explain that participants must call study staff in order to be phone-screened and to participate in the study. During the phone-screen, participants will be directed to complete an online survey via REDCap. Within the survey, participants will be asked if they would be willing to participate in an online video-conference user feedback session after they have used the app for seven weeks (1 week pre, 6 weeks post their chosen smoking quit day). Participation in the user feedback session is optional. Participants will receive survey links for 2-week, 6-week, 3-month and 6-month follow-ups via an emailed link. If selected for the online user feedback sessions (selected at random from interested participants), participants will receive an email and/or phone call upon completing their 6-week survey to set up the user feedback session.

The online user feedback sessions (n=20) will consist of the participants, and 1-2 members of the study staff. Relatively little guidance will be provided in this setting. Instead, 4 open-ended questions will be posed (i.e., did the app help you in your quit attempt? What did you like? What did you dislike? How could the app be improved?). All conference calls will be video-recorded for later analysis.

Sample size and Power Considerations: The primary goal of this study is to gather qualitative input rather than data to detect a pre-specified effect. The goal of this pilot study is to get input from app users who are interacting with the app and study staff completely remotely, without the benefit of in-person interaction, which is closer to the real-world experience potential users would have than the participants in Study 1. Thus, to identify issues not identified within the smaller sample in Study 1, we tripled the sample size of the current study, Study 2.

Planned Analyses:

Aim 1 (Ease-of-use and usefulness). To assess the degree to which SiS Version 2 is easy to use and perceived as useful by nondaily smokers attempting to quit smoking, we will use the Week 6 survey data, and will calculate means and standard deviations for the survey items querying ease of use and usefulness for each feature of the app.

Aim 2 (Within-person changes). To test if nondaily smokers utilizing SiS Version 2 experienced changes over time on constructs theorized to underlie smoking cessation, we will use the online survey data and fit one repeated measures mixed effects model per construct of interest (i.e., desire to smoke, mood, self-efficacy to quit/stay quit, motivation), where the construct will be the dependent variable, and time (0=baseline, 1=2-week, 2=6-week, 3=3-month, 4=6-month) will be the predictor. Correlations over time will be modeled with an unstructured covariance matrix. A contrast statement will be used to compare baseline versus follow-up. Given the explorative nature of this study, we will not correct for multiple testing.

Aim 3 (Identify app features in need of improvement). To identify features of the app that are in need of improvement, we will examine the passively generated app usage data as nondaily smokers enrolled in our study undergo their quit attempts, and will generate descriptive summary statistics on these usage data. To gain deeper insight, we will also conduct user feedback sessions with a randomly selected subsample of participants.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Not applicable.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Risks are expected to be minimal, and include breach of confidentiality, subject discomfort form answering questions about smoking, and discomfort from quitting smoking (see below). We will minimize these risks by safeguarding electronic data capture by using HIPAA-compliant electronic data capture processes, assuring participants that they do not need to answer any questions they do not want to answer, and by providing information on how to manage smoking cessation.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of

improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

A subject will be removed from the study if he or she no longer wishes to participate for any reason. A subject may also be removed from the study by the PI, if he or she cannot comply with study procedures (e.g., responds incorrectly to survey check items, cannot install the app on his/her smartphone) or causes undue distress to study staff (e.g., becomes belligerent towards study staff).

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Potential Risks: Participation will last 6 months, where surveys will be administered at enrollment, 2-week, 6-week, 3-month, and 6-month follow-up. Participants will use the app for a strongly encouraged period of 7 weeks (1 week before, 6 weeks following the quit attempt), and optional continued use thereafter. Additional tasks are potential participation in online video-conference user feedback sessions, as summarized in Figure 2. As such, the potential risks in the study are considered minimal and include (1) potential discomfort related to completing questionnaires about potentially sensitive information such as smoking, (2) potential breach of confidentiality and/or privacy, and (3) potential discomfort in quitting smoking (i.e., withdrawal symptoms, craving, etc.).

Protection Against Risks: For the possibility of subjective discomfort from answering questions, any distress will be minimized by assuring participants that they can refuse to answer any question that they do not feel comfortable addressing and that they may withdraw from the study at any time without penalty. To protect against breach of confidentiality, we will assign a numeric study ID to each participant, which will be the primary identifier by which this person's progress through the trial will be reviewed. The database linking names and study identification numbers will be kept in a separate password protected file. Only study staff will have access to this database. All staff are or will be fully trained in relevant ethical principles and procedures, including confidentiality. All assessment and treatment procedures will be closely supervised by the PI. Most of the data will be captured electronically. For surveys and data entry by study staff, we will be using Partners implementation of REDCap (Research Electronic Data Capture) https://redcap.partners.org, which is a secure, web-based application designed to support data capture for research studies, and which is fully compliant with HIPAA-Security guidelines. The data generated by using our custom-built app (i.e., app usage data) will be kept on secure

servers behind a firewall within the Partners network. The app will be hosted by secure ERIS/Partners servers. All data collected through the app will be transmitted using Transport Layer Security (TLS) encryption to prevent eavesdropping and tampering information while it is in the transmission pipeline. Finally, the Skype user feedback sessions will be video-recorded in Skype, and summary information will be entered by study staff into the study's REDCap database. All Skype correspondences are transmitted using the Advanced Encryption Standard (AES) if both users are using Skype accounts (i.e., the participant is not Skyping from a landline or mobile telephone number). Thus, we will require that all participants taking place in the user feedback sessions will use a Skype account to ensure security. Screen recordings of the user feedback sessions will be stored in a shared folder on secure MGH servers that only study personnel will have access to. All data for all participants will be kept strictly confidential, except as mandated by law. Regarding the potential discomfort in quitting smoking, participants will receive information about how to alleviate cravings as part of their study participation. Given that study participants are nondaily smokers, who regularly abstain from smoking for several days, these discomforts are expected to be minimal.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Potential Benefits: All participants will receive behavioral counseling and smoking cessation resource information as part of their study participation. They will also engage in positive psychology exercises designed to increase positive affect to support smoking cessation. Consequently, participants in this study may quit smoking as a result of their participation, which would have a positive impact on their health. Furthermore, study participation will provide generalizable knowledge about the process of smoking cessation in nondaily smokers, which can be used to guide the development of further treatments to support smoking cessation in this growing population of smokers.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or

ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

We are limiting study participation to persons who own a smartphone, because only such persons could benefit from the intervention. The criterion for having a current quit intention is necessary, because we will ask participants to quit as part of this study, and because the intended target audience of this treatment will be nondaily smokers who want to quit smoking.

No studies that we are aware of describe sex differences in the prevalence of intermittent smoking. Thus, we expect to enroll and retain female and male participants at equal rates. We do, however, expect to recruit and enroll slightly more participants of ethnic or racial minority status than reflective of general population rates, because studies indicate that intermittent smoking is more prevalent among African Americans, Asians, American Indians, and Latinos than Whites. There are no foreseeable risks associated with the inclusion for women and minorities in the study.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

We will exclude people who do not speak English, because the app we are developing is currently only available in English. Moreover, several of the scales we will be administering in the online surveys are only available in English.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

We will use both commercial advertising (e.g., Facebook) and grass-root efforts (e.g., Craigslist, quit smoking forums). We will use stratified enrollment to ensure that our final sample will (a) be equally balanced between men and women, and (b) reflect national prevalence rates of

nondaily smoking in terms of ethnicity and race, where we will enroll no more than 54% non-Hispanic White participants, as per the 2014 National Health Interview Survey (http://www.cdc.gov/nchs/nhis/nhis_2014_data_release.htm), which shows that 54% of nondaily smokers are non-Hispanic White.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Participants will be remunerated according to the following remuneration schedule:

Table 1. Remuneration Schedule

Visit	Phone Conversations	Surveys
Enrollment	$20	$25*
2-week		$25*
6-week	$25	$50*
3-month		$25*
6-month		$25*
$195	With Skype session	
$170	Without Skype session	
	* $10, if check items are answered incorrectly	

Payment will be by check, where participants will receive a total of five checks, corresponding to the five study interactions at enrollment, 2-week, 6-week, 3-month and 6-month follow-up. Participants are remunerated $25 for each survey they complete (with the exception of the 6-week survey, for which they will be remunerated $50), unless they fail to answer 100% of the five randomly placed reading alertness check items correctly (e.g.: "Please answer "not at all confident"."), in which case they receive $10. (Correctly answering all check items is a screening criterion, which is explained to participants during the screening phone call).

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects

https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

During the phone screen, research staff will provide an overview of the study, and will answer any questions participants may have about the study. If deemed eligible after the phone screen, study staff will send participants a link to the online baseline survey, which contains an electronic consent form. Additionally, study staff will also email a pdf copy of the online consent form to participants, and direct them to the HarvardScholar website that provides this information in written format, so that prospective participants have an opportunity to review the consent form at leisure, prior to encountering it as the first page on the REDCap survey. This is the same process we have used to obtain informed consent for a remote-only longitudinal study on the use of the texting intervention SmokefreeTXT to support smoking cessation in nondaily smokers (protocol #2016P002555). The online consent form will outline the nature of the study, risks and benefits to participation, details on remuneration for participation, and how to contact with PI or IRB staff in case they have any concerns (see attached). Participants must click "I agree to participate in this study" to proceed to the baseline survey.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the

study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Oversight of internal monitoring of the participants' safety will be conducted by the PI, Dr. B. Hoeppner. Drs. Kelly and S. Hoeppner will also participate in the development and administration of the plan.

The PI and co-investigators will meet weekly on the project, at which time they will evaluate the progress of the trial, review data quality, recruitment, and study retention, and examine other factors that may affect outcome. They will review the rates of adverse events to determine any changes in participant risk. A brief report will be generated annually for the study record and forwarded to Massachusetts General Hospital's Institutional Review Board. The Investigators will be available to meet outside of the weekly meetings, if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol. Dr. B. Hoeppner will conduct daily oversight of participant safety. She will meet weekly with staff to review participant progress.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

Any adverse events that are observed and/or reported will be immediately reported to Dr. B. Hoeppner. Serious adverse events (SAEs) will be reported to the Massachusetts General Hospital IRB immediately by telephone and by written report within 24 hours of our receipt of information regarding the event; SAEs will also be reported in writing to the American Cancer Society. Adverse events will be reported to the Massachusetts General Hospital IRB and the American Cancer Society annually.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The PI will oversee the collection, maintenance, and analysis of all data. During weekly meetings with study staff and co-investigators, the PI will review the accuracy and completeness of the study questionnaires, consent forms, and app data. The study procedures and plans will also be reviewed during these meetings to ensure that they remain in line with the approved protocol.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

To protect the privacy of each participant, we will assign a numeric study ID to each participant, which will be the primary identifier by which this person's progress through the trial will be reviewed. The database linking names and study identification numbers will be kept in a password protected file. Only study staff will have access to this database. All staff are or will be fully trained in relevant ethical principles and procedures, including

confidentiality. All assessment and treatment procedures will be closely supervised by the PI. Most of the data will be captured electronically. For surveys and data entry by study staff, REDCap (Research Electronic Data Capture) will be used, which is a secure, web-based application designed to support data capture for research studies, and which is fully compliant with HIPAA-Security guidelines. The data generated by using our custom-built app (i.e., app usage data) will be kept on secure servers behind a firewall within the Partners network. The app will be hosted by secure ERIS/Partners servers. All data collected through the app will be transmitted using Transport Layer Security (TLS) encryption to prevent eavesdropping and tampering information while it is in the transmission pipeline.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Not applicable.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Not applicable.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Not applicable.

Consent Form

Why is this research being done?

The purpose of this research study is to test the ease of use and usefulness of a smartphone app we developed to support nondaily smokers in quitting smoking. This is the second study in a series of three studies, and will involve 90 participants. The American Cancer Society (ACS) is paying for the study to be done.

We are asking you to participate in this study, because we would like you try out Version 2.0 of our app and tell us about your experience while using it. Your feedback will help shape the third version of this app, which we plan to make publicly available free of charge.

In order to participate in this study, you must first complete a screening test. To pass the screening test, you must:
1. Complete an online baseline survey (this one), which will contain five randomly placed check-questions. For these items, we will ask you to respond in a specific fashion. For example, a question may read "Please answer 'not at all confident.'" You will need to click the bubble or move the slider to indicate "not at all confident" to answer this question correctly. We are inserting these check-items in the survey to make sure you are reading the survey carefully, and are comfortable with using the buttons and sliders to indicate your responses. You must answer these items correctly in order to qualify for the study.
2. Provide contact information for two individuals (e.g., family members, friends) who can assist research staff in locating you for follow-up assessments. We will contact them based on the information you provide to ask them if they would be willing to help us locate you in case your contact information changes before the end of the study. We will tell them that you are participating in a study tracking health behaviors. Your two contacts must confirm they are willing to serve in this role.
3. Provide your social security number and mailing address to enable us to pay you by check. Our home institution, Massachusetts General Hospital, requires payment by check for research study participation due to tax purposes.

What will happen in this research study?

- Pass the screening test (as explained above)
- Choose your smoking cessation quit day
- Complete a 20 minutes phone call with us 1 week prior to your chosen quit day. In preparation of this call, we will email you a how-to guide for using the SiS app, which you can consult at your leisure. During the phone call, we will walk you through downloading, installing, and using the app, including scheduling your quit day in the app.
- Use the app for 7 weeks, 1 week prior to your quit day, and 6 weeks after your quit day. App use involves the completion of daily happiness exercises, logging the cigarettes you smoke as you smoke them, and completing 1-2 "challenges" each week that are designed to keep you on track with quitting smoking for good.
- Complete 4 more online surveys (2 weeks, 6 weeks, 3 months, and 6 months after your quit day). The 6-week survey will be longer than the other surveys, as we will provide you with summary information on your app use, and will ask you specific questions about your app use.
- (Optional) Participate in a user feedback session with study staff via Skype to talk further about your experience using our app. This Skype session will occur 6 weeks after your chosen quit day.

What are the risks and/or benefits of this research study?

There are two risks in participating in this study:
- Subjective discomfort from answering our questions: please rest assured that you may skip any question you are uncomfortable answering, with the exception of check-items.
- Breach of confidentiality: we believe this risk to be minimal, because we are collecting data via technologies that are fully HIPAA compliant, and because our study staff is properly trained about the critical importance of confidentiality and in human research subjects' protection.

There are two benefits to participating in this study:
- You will receive smoking cessation support as part of your participation in this study, and thus, you may be able to quit smoking. Quitting smoking would have a substantial positive impact on your health!
- Your study participation will provide generalizable knowledge about the process of smoking cessation in nondaily smokers, which can be used to guide the development of further treatments to support smoking cessation in nondaily smokers.

Will I be remunerated for my study participation?

Yes. You will be remunerated to a total of up to $195. For each online survey you complete, you will receive $25, unless you miss one of our check items. In that case, you will receive $10. The 6-week survey is longer, as it contains information about your app usage. You will receive an additional $25 for answering these questions about your app usage. You will also receive compensation for taking the time for the 20min (or so) phone call occurring 1 week prior to your quit attempt, during which we will walk you through downloading, installing and using the app. Finally, if you complete the Skype user feedback session after finishing app usage, you will receive an additional compensation of $25. The Skype user feedback session is optional, and will only be completed with some of the participants. We will select participants for these feedback sessions at random, selected from those participants who would like to participate.

To pay you, we will mail you checks to your US mailing address. For that, we will need to know your social security number, as we are required to keep a record of research remuneration amounts for tax purposes, if the remuneration exceeds $50, as it does in this study.

We will mail you checks after you complete each online survey (i.e., screening, 2, 6, 12, and 24 weeks after your quit date) and right after you complete the Skype user feedback session. Please note that it takes approximately 10 business days after you complete your survey for the check to be mailed out to you. We will send you an email when we have received your survey, checked the check items, and requested our accounting department to mail out the check to you.

Overview of study remuneration

Visit	Phone Conversations	Surveys
Enrollment	$20	$25*
2-week		$25*
6-week	$25	$50*
3-month		$25*
6-month		$25*

$195 If you complete the Skype session
$170 If you don't complete the Skype session
* $10, if check items are answered incorrectly

What else do I need to know?

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

Who can I contact if I have questions or concerns about this study?

If you have questions about the study, our study staff can be reached at (617) 724-3129 or sis@mgh.harvard.edu.

If you have concerns or complaints about this research and its procedures, risks and benefits, you may contact the Principal Investigator of this study, Bettina Hoeppner, Ph.D., at (617) 643-1988 or bhoeppner@mgh.harvard.edu.

If you would like to speak to someone not involved in this research, please contact the Partners Human Research Committee at (857) 282-1900.

Thank you for considering participating!

If you would like to enroll in this study, please:
- timestamp your consent by clicking the "NOW" button here, and
- click "yes" to the statement below.

_____

I AGREE TO PARTICIPATE IN THIS STUDY

◯ Yes
◯ No