

# **Study Fact Sheet and Verbal Consent Form**

**A PROOF-OF-CONCEPT RCT OF VERSION 3.0 OF THE SMOKING CESSATION SMARTPHONE APP  
“SMILING INSTEAD OF SMOKING” (SIS)**

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<b>Ethical approval:</b>	<b>Mass General Brigham Institutional Review Boards (protocol # 2020P003466, approved on 12/08/2020)</b>
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## Why is this research being done?

The purpose of this research study is to compare different ways of supporting nondaily smokers in quitting smoking. This study will involve 225 participants. The American Cancer Society (ACS) is paying for the study to be done.

We are asking you to participate in this study, because you are a nondaily smoker who wants to quit smoking, and who is interested in using support materials to help you quit smoking.

Please note that this study is a randomized trial. That means that you will be randomly assigned to one of three groups. You have an equal chance of being assigned to each group. Each group will receive a different type of support for quitting smoking. This support could be a smartphone app or a digital resource packet. We will be comparing the experiences of participants assigned to the three groups to determine if one type of support works better than the other.

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 randomly placed check-questions. These check-items test if you are comfortable using the buttons and sliders to indicate your responses, and that you are reading the survey carefully. For these check-items, you will need 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. You must answer these items correctly in order to qualify for the study. This survey takes about 30 minutes to complete.
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. One of 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.

When you complete this survey, we will call you back to collect this information. If you missed any check items, you will receive payment as described below, but will not be eligible to proceed with the study.

## What will happen in this research study?

- During the course of the study, you would (1) make a quit attempt, (2) use the materials we give you to guide you through quitting smoking for 7 weeks, and (3) complete 5 surveys over the next 6 months.

Specifically, the sequence of events will be this :

- Pass the screening test (as explained above)

- Choose your smoking quit day

- Complete a 30 - 45 minute phone call with us 1 week prior to your chosen quit day. During this call, we will walk you through the materials you will be receiving as part of this study to guide you through quitting smoking. You must be able to electronically receive and open these materials in order to participate in this study.

- Use the materials (i.e., an app or a digital resource packet) we provide you with for 7 weeks, 1 week prior to your quit day, and 6 weeks after your quit day with optional continued use thereafter. If you are assigned an app, we would ask you to complete brief daily tasks in the app. Please note that the actions you take within the app are recorded. For the app you may be prompted to click "okay" to accept terms of use. Please read this carefully, and only click okay if this works for you. If you are assigned the digital resource packet, we would ask you to work through it on your own time, including completing short tasks with paper and pencil. These tasks 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 surveys take about 25 minutes to complete. You can complete them in one sitting or pick up where you left off at a later time. The 6-week survey will be about 10 minutes longer than the other surveys, as we will ask you specific questions about your experience with the quitting smoking materials. You will be compensated extra for this survey.

Please know that it is extremely important for the integrity of this study to obtain your honest and complete feedback. Before you decide to participate in this study, please consider your ability to complete the study. If you do decide to participate in this study, please make every effort to complete each survey. Please answer honestly.

You may, of course, withdraw from this study at any point. Withdrawal from this study will in no way impact your clinical care at the Mass General Brigham, now or in the future.

Please also note that participants may be removed from the study by the study Principal Investigator if they cannot comply with study procedures (e.g., cannot install the app on their smartphone) or cause undue distress to study staff (e.g., becomes belligerent towards study staff).

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

There are two risks in participating in this study:

1. You may feel uncomfortable answering questions: please know that you may skip questions you are uncomfortable answering. The only exception are the check-items we are including in each survey (as explained above).
2. 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 in the importance of confidentiality and in the protection of human research subjects.

There are two benefits to participating in this study:

1. You will receive support in quitting smoking as part of your participation in this study. Thus, you may quit smoking as a result of your participation in this study. Quitting smoking would have a substantial positive impact on your health.
2. Your study participation will provide knowledge about the process of quitting smoking in nondaily smokers. This knowledge will guide the development of materials to help nondaily smokers quit smoking.

## Will I be paid for my study participation?

Yes. You will be remunerated to a total of up to \$150. 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 for that survey. The 6-week survey is longer, as it contains questions about your experience with the quitting smoking materials we gave you. You will receive an additional \$25 for answering these questions.

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). Please note that it may take 4-6 weeks or longer 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.

Time Point	Survey*
Baseline & Screening	\$25
2-week	\$25
6-week	\$50
3-month	\$25
6-month	\$25
<b>\$150 per participant</b>	
<b>* \$10 for a survey with missed check items</b>	

## 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.

### Receiving unencrypted text messages for this study

Text messages by mobile/cell phones are a common form of communication. The Quitting Nondaily Smoking research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Texting in this study is only used by study staff to deliver messages. Study staff are NOT able to receive text messages. If you have a question about the study, you should call 617-724-3129 or email qns@mgh.harvard.edu
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop"

appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

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I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

- ☐ Yes, you have my permission to communicate with me via text-messaging for this study
- ☐ No, you CANNOT use text-messaging to communicate with me for this study

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#### Permission to obtain your app usage data

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As explained above, you may be asked to use a smartphone app to guide you through quitting smoking. Please know that any app we ask you to use was developed and is maintained by reputable researchers and organizations that offer these apps for public health purposes. As is true for any app, these apps record actions you take within the app. That is, they record the time and date of when you click a button in the app or answer a question. This is done for all users of these apps, only a small subset of whom are participating in this study. Your specific data are identifiable through an ID code these apps use for you. As part of this study, we will ask you to provide us with that ID code, so we can request those data from the people responsible for these apps. Do we have your permission to do so?

- ☐ yes, you have my permission to request my app usage data from the people responsible for the app I will be using, using the ID code I will give you after installing the app
- ☐ no, you may not request my app usage data from the people responsible for the app I will be using as part of this study

The reason we want to look at your app usage data is that these data will give us insight into when you used the tools within the app, which is an important consideration for the further development of these tools to better support smokers like you in quitting smoking.

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We fully understand if you are not comfortable with giving us this permission. As this is an important part of the study, however, we cannot enroll you in this study if we cannot access your app usage data.

If you are sure about this, feel free to exit the survey at this time. You can also complete the survey at this time, and before enrolling in the study have a conversation with us about this point, so we can answer any questions you may have.

**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 [qns@mgh.harvard.edu](mailto:qns@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 Hoeppe, Ph.D., at (617) 643-1988 or [bhoeppe@mgh.harvard.edu](mailto:bhoeppe@mgh.harvard.edu).

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

## How do I proceed if I want to be part of this study?

If you would like to proceed to the online survey, which is part of the screening process, please:

- timestamp this Study Fact Sheet by clicking the "NOW" button here, and
- click "yes" to the statement below.

\_\_\_\_\_

I AGREE TO PARTICIPATE IN THIS SCREENING SURVEY

- ☐ Yes  
☐ No

Once we have reviewed your survey responses, we will contact you to proceed with the remaining parts of the screening test. If you are eligible to enroll in this study, and you decide you would like to participate in this study, we will ask you for your verbal consent to participate in the study during a phone call with study staff.

# Verbal Consent

Study ID

([REDCap auto-assigned])

As you know, this is your study enrollment phone call. Before I ask you to confirm that you would like to proceed with enrolling in this study, I would like to review the Study Fact Sheet with you.

- ☐ study staff answered any questions that come up  
☐ verbal consent conversation stopped here

We emailed you a copy of this Study Fact Sheet on [phone screening arm 1][date emailed sfs] to the email address you gave us during the phone screen interview, that is, [phone screening arm 1][email confirm].

When you completed the online survey on (just read date)[phone screening arm 1][start time], you also saw this Study Fact Sheet as the first page of that survey.

We also discussed some of the details of the study during our initial phone screen call. Now that you have had a chance to review the Study Fact Sheet at your leisure, I want to ask you if you have any questions about this study?

Let's recap some of the important key points. Here are some "true or false" items for you. Don't worry if you get any of these items wrong. We will simply review that part of the Study Fact Sheet again to clarify anything that wasn't clear.

- ☐ For any item participant gets wrong, staff will direct participant to that section of the Study Fact Sheet, and review together.  
☐ verbal consent conversation stopped here

I can withdraw from the study at any time. Withdrawing from the study - that is, choosing to no longer participate in this study - will in no way impact my clinical care at the Mass General Brigham, now or in the future

- ☐ True  
☐ False  
(correct answer: TRUE)

If I enroll in this study today, I will be asked to make an attempt to quit smoking. My chosen quit day is 8 days from today.

- ☐ True  
☐ False  
(correct answer: TRUE)

As part of the study, I will be asked to use the smoking cessation materials the study staff provides me with. I will be asked to use these materials for 7 years.

- ☐ True  
☐ False  
(correct answer: FALSE; 7 weeks not 7 years)

There are three randomized groups in this study. I have an equal chance to be assigned to any of these three groups. Depending on what group I will be assigned to, I may either be asked to use a smoking cessation app, or to use written materials provided to me as a pdf file.

- ☐ True  
☐ False  
(correct answer: TRUE)

As part of the study, I will be asked to complete surveys. I need to come to the study's office to complete these surveys.

- ☐ True  
☐ False  
(correct answer: FALSE; surveys are completed online)



I will be paid for completing surveys, up to a total of \$150. I may receive less than \$150, if I do not complete a survey, and/or if I answer check-items incorrectly.

- ☐ True  
☐ False  
(correct answer: TRUE)

Thank you for reviewing these details with me.

I also wanted to check in about the two specific things we highlighted in the Study Fact Sheet.

1. We asked you if we can communicate with you about this study via text-messaging. You indicated [phone screening arm 1][consent 9a] . I just wanted to confirm that this is correct?

- ☐ yes, correct  
☐ no, not correct - manually change answer on the Study Fact Sheet form in REDCap

2. We asked for your permission to request your app usage data from the people responsible for the smoking cessation app, if you were assigned to a group that uses an app. You indicated [phone screening arm 1][grant permission] . I just wanted to confirm that this is correct?

- ☐ yes, we have permission to get app usage data  
☐ no, we do not have permission to get app usage data

#### DO NOT ENROLL

We fully understand if you are not comfortable with giving us this permission. As this is an important part of the study, however, we cannot enroll you in this study if we cannot access your app usage data.

Thank you for confirming/clarifying these answers. Do you have any further questions for me?

- ☐ Yes - discuss all additional questions  
☐ No - proceed with formal verbal consent

Okay, one more thing, at this point I need to confirm your current smoking status. (staff complete smoking status with ptsp)


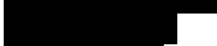
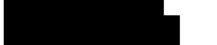
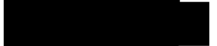
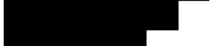

- ☐ smoking status form confirms that this is a nondaily smoker  
☐ smoking status form shows that this is no longer a nondaily smoker

At this point, I would like to formally invite you to enroll in this study. Would you like to enroll in this study?

- ☐ Yes  
☐ No

(MM-DD-YYYY)

Name of staff person obtaining verbal consent

- ☐   
☐   
☐   
☐   
☐   
☐   
☐ other

Please write down the name of the staff person obtaining verbal consent:

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I'm sorry, unfortunately your answers to those questions indicate that you are no longer a nondaily smoker meaning you are not eligible to participate in this study.

If you do still want some support while quitting smoking, check out the website created by the National Cancer Institute (NCI) called Smokefree.gov. The website address is simply: <https://smokefree.gov/> This page provides information about quitting smoking, and lets you sign up for text-messaging programs, smartphone app, social networking programs and other ways to help you quit smoking.