Official Title

Proof-of-concept RCT to test the integrated mHealth App Intervention (SiS-H) for smoking cessation for people with HIV

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Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: The Quitting Smoking with App Support (QSAS) Research Study

Principal Investigator: Dr. Bettina B. Hoeppner

Site Principal Investigator: N/A

Description of Subject Population: Persons with HIV who smoke

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a person with HIV who wants to quit smoking, and who is interested in using support materials to help you quit smoking. We are doing the research to compare different ways of supporting people with HIV who smoke in quitting smoking. If you agree, you will be randomly assigned to one of two groups. Each group will receive a different type of support for quitting smoking. Both types of support will include the use of a smartphone app; both groups will also be offered nicotine replacement therapy (NRT) patches (if desired). You will be asked to use the smoking cessation support materials for 8 weeks and complete online surveys 2, 6, and 12 weeks after your chosen quit day, if you decide to stay for the whole study.

The main risks of being in the study are a breach in confidentiality and feeling uncomfortable while answering questions about your demographics and smoking behaviors.
You might benefit from being in the study because you will receive support in quitting smoking as part of participating in the study, which may help you quit smoking. Additionally, your participation will help broaden the knowledge about the process of quitting smoking, particularly for people with HIV.

If you decide not to be in the study and want support for quitting smoking, check out the Smokefree website by the National Cancer Institute. The website address is https://smokefree.gov/quit-smoking. This website has useful information about quitting, and lets you sign up for numerous technologies that can help you with quitting smoking, including textmessaging, smartphone apps, and social networking programs.

You will be paid up to a total of $175 by check or reloadable gift card for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Bettina Hoeppner and **Dr. Conall O'Cleirigh** are the persons in charge of this research study. You can call Dr. Hoeppner at (617) 643-1988 M-F 9-5. You can call Dr. O'Cleirigh at (617) 643-0385 M-F 9-5.

You can also call our study staff at (617) 724-3129 or email qns@mgh.harvard.edu with questions about this research study or about the scheduling of appointments or study visits.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

The purpose of this research study is to compare different ways of supporting people with HIV who smoke in quitting smoking.

This study is a randomized trial. That means that you will be randomly assigned to one of two groups. You have an equal chance of being assigned to each group. Each group will receive a different type of support for quitting smoking. Both types of support will include the use of a smartphone app; both groups will also be offered nicotine replacement therapy (NRT) patches (if desired). We will be comparing the experiences of participants assigned to the two groups to determine if one type of support works better than the other.

Who will take part in this research?

We are asking you to participate in this study, because you are a person with HIV who wants to quit smoking, and who is interested in using support materials to help you quit smoking. This study will involve 64 participants. The National Cancer Institute (NCI) is paying for the study to be done.

What will happen in this research study?

During the course of the study, we would ask you to undergo a quit attempt. You would receive smoking cessation support from us (i.e., smartphone app use for 8 weeks; staff support as you learn how to use the app; NRT patches provided by us, if you would like to use them), and engage in study assessments (i.e., 4 online surveys; 2 biochemical tests of smoking status). You would be paid for the study assessments (see later section), but not for the time and effort you spend on quitting smoking and using the smoking cessation support we provide.

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, 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. If you do not answer these items correctly, you may be deemed ineligible for the study. This survey takes about 30 minutes to complete.

2. Pass a biochemical test to confirm your smoking status. To confirm your smoking status, we will ask you for a sample of your exhaled breath and/or a saliva. This can be done in-person in our Boston office, or remotely using video-conference technology (i.e., Zoom; camera must be on).

Once you complete this survey, we will contact you to let you know if you are eligible to proceed. If you missed any check items, you will receive payment as described below, but will not be eligible to proceed with the study. If you completed the survey and completed all check-items correctly, we will set up the biochemical test with you to confirm your smoking status. This visit (remote or in-person) can also be your study enrollment visit.

Once you have enrolled in the study, we will ask you to:

- Give us permission to extract information from your medical record about your HIV status and clinical care (i.e., medications you use for treating HIV, CD4 count, presence of any HIV-related co-infections, and/or co-occurring health issues). This is information the National Cancer Institute, who is funding this research, asked us to keep track of for all participants partaking in HIV-related smoking cessation studies.

- Take time to talk with us about quitting smoking, including facts that are particularly relevant for people with HIV. This would happen during the same visit during which you enroll in this study.

- Show you how to use the smartphone app we are asking you to use during your quit attempt. This would happen during the same visit during which you enroll in this study.

- Give us permission to access the data you generate in using the smartphone app. The app we will 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. In a later section of this consent form, we will formally ask you for that permission.

- Use the smartphone app we give you for eight weeks.

- *(in one of the two groups)* Complete another visit with us (1 week before your chosen quit day; remote or in-person, 30min) to check in about your smartphone app use

- Complete 3 more online surveys (2 weeks, 6 weeks, and 3 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, as we will ask you specific questions about your experience with the quitting smoking materials. You will be compensated extra for this survey.

- Complete another biochemical test of smoking status (i.e., exhaled breath and/or saliva), in-person or remotely 3 months after your chosen quit day.

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's 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., become belligerent towards study staff).

Permission to access and use the data you generate in using the smartphone app we give you

As explained above, you will be asked to use a smartphone app to support you in quitting smoking. 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. The apps will not collect any identifying information like your phone number, name or location. When making text entries in this app, please do not include identifiable information (e.g., last names, phone numbers, etc.).

For research purposes, we want to look at your app usage data, and summarize them to describe how participants in this study interact with the smoking cessation apps. This information will provide insight to people designing smartphone apps.

Your specific app usage 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, I give permission to request my app usage data from the people responsible for the app I will be using as part of this study, using the ID code I will give you after installing the app
Initials	Date	
_____	_____	□ NO, I do not give you permission to request my app usage data from the people responsible for the app I will be using as part of this study

Initials Date

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.

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.

Permission to use text-messaging to communicate with you about this study

Text messages by mobile/cell phones are a common form of communication. Our study staff would be happy to send you text messages to communicate with you about this study (e.g., reminders to complete surveys or schedule study visits). Please be advised, however, that 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 Mass General Brigham 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 Mass General Brigham 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"

- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham 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.

_____ _____ □ YES, I give permission to communicate with me via messaging for this study
Initials Date

_____ _____ □ NO, I do not give you permission to use text-messaging to communicate with me for this study
Initials Date

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. For this reason, it is important to share data with other investigative teams, when possible. If you join this study, we may share your data for this purpose. Prior to doing so, however, we will remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

As part of this consent form (see further below), you can give us permission to reach out to you to share research findings from this study. This information will not announce your results or anyone else's, but it will tell you some information about what we learned through this study about supporting people with HIV in quitting smoking. If you give us permission to let you know about these findings, we will email you when we publish a paper in a scientific journal. Please note that the process from data collection to the publication of results is a lengthy process.

It may take 1 or more years. The data collection process itself may also take a long period of time.

If you give us permission to let you know about these findings, we will also email you when we publish the findings on *http://www.ClinicalTrials.gov,* as required by U.S. Law. You can also visit this website any time to get updates on the status of this study (e.g., to see if the data collection process is complete). The study's main findings will be published on this website no more than 1 year after data collection for the study is completed.

What are the risks and possible discomforts from being in 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.

What are the possible benefits from being in this research study?

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, particularly for people with HIV who want to quit smoking. This knowledge will guide the development of materials to help people with HIV quit smoking.

What other treatments or procedures are available for your condition?

You do not have to take part in this study to get support for quitting smoking. Smoking cessation support is broadly available, and include the Smokefree.gov website (https://smokefree.gov/quit-smoking) created and maintained by the National Cancer Institute. This website contains a lot of useful information about quitting, and let's you sign up for numerous technologies that can help you with quitting smoking, including text-messaging programs, smartphone apps, and social networking programs.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Yes. You will be remunerated up to a total of $175. 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.

Timepoint	Survey*	Saliva/Breath
Screening	$25	
Enrollment		$25
2-week	$25	
6-week	$50	
3-month	$25	$25
up to $175 per participant		
* $10 for a survey with missed check-item		

To get paid, you can choose one of two methods:

- Payment by check
- Payment via reloadable VISA gift card

For both methods, you would need to give us your US mailing address and your social security number (SSN). Here is why: we would need your address to mail you your check / VISA card.

We may be using an approved, outside vendor (Advarra) to make the payments to you via the reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. If you are paid by this system, you will be given a Participant Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will need to collect your Social Security number in order to make these payments. If you choose the gift card method, your social security number will be shared securely with the company that runs the card-based system.

We will need your social security number because payments like this are considered taxable income. you receive more than $600, the payment will be reported to the IRS as income by the hospital.

Payment via rechargeable VISA gift card is faster. If you are paid by the gift card system, you will be given a Participant Payments Visa card when you enroll in the study. After you receive it in the mail, you would need to confirm the card you received is the card we assigned to you. To do this, you would complete a Payment Card Acknowledgement Form online. Once the card is activated, the study team will add a payment after each paid visit

you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will mail you checks as soon as you complete each study assessment; we will combine the check for the 3-month follow-up assessments (i.e., survey and biochemical test of your smoking status). Payment via check is slower. Our study team needs to request the check to be sent by our hospital's Accounts Payable office. For the first check, it can take 10-16 business days for the check to be mailed out. For subsequent checks, it takes 5-8 business days. We can also set up an electronic check for you. You would need to complete a form in which you provide your banking information.

What will you have to pay for if you take part in this research study?

You will need to pay for your own transportation to participate in study visits, if you are attending in-person instead of completing visits remotely. Study funds will pay for NRT patches. We will also provide the smartphone app at no charge to you.

This study will not interact with your routine care. Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.
Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____

Print Name

_____

Subject Signature Date Time (optional)

Consent Form Version Date: 10/7/2024