SmokefreeSGM, A Text-based Smoking Cessation Feasibility Trial for Sexual and Gender Minority Groups

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UTHealth Houston

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title:	SmokefreeSGM
Full Study Title:	SmokefreeSGM, A Text-based Smoking Cessation Feasibility Trial for Sexual and Gender Minority Groups
Study Sponsor:	NIH/NCI (1K22CA 237639)
Principal Investigator:	Irene Tami Maury, DMD, DrPH, MSc, Assistant Professor, School of Public Health, UTHealth
Study Contact:	Irene Tami-Maury, DMD, DrPH, MSc, Assistant Professor, (713) 500-9234

The purpose of this study is to test the feasibility and acceptability of a personalized, interactive text-based smoking cessation intervention designed for sexual and gender minority groups. If you choose to participate in this study, you will be required to sign this consent form. This study involves a baseline screening, baseline assessment, participation in a text-messaging program for 6 weeks, and additional assessments at 1-, 3-, and 6-months follow-up. You may also be asked to participate in a semi-structured interview after completing your participation in the feasibility trial.

The risks of participating in this study are considered minimal. The research staff will discuss these risks with you and answer any questions or concerns you may have. There is a possible risk of breach of confidentiality. You do not have to answer any questions that you do not wish to answer. This study may also include risks that are unknown at this time.

Participation in this study is voluntary. You may choose not to take part in this study or may choose to leave the study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth).

If you are interested in participating, please continue reading the information below.

What is the purpose of this research study?
The purpose of this study is to determine the extent to which a text-based program can help LGBTQ+ individuals in their efforts to quit smoking through a test of its feasibility.

The National Health Institutes/National Cancer Institute is paying UTHealth for their work on this study.

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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 website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?
You are being asked to take part in this study because you self-identified as LGBTQ+, are 18 years of age or older, currently live in the United States, smoke at least 5 cigarettes per day, own a cellphone with unlimited text messaging service, and are interested in quitting smoking within the next 15 days.

This study is being conducted at the University of Texas Health Science Center at Houston School of Public Health. Approximately 100 individuals will take part in this study.

What will happen if I take part in this study?
You have completed the prescreening and will now be asked to verify your smoking status with a saliva cotinine test before being enrolled in the study. To be considered eligible to participate, the results of your saliva test must be positive to indicate that you are a current smoker.

Listed below are the assessments and tests that you will take part in to monitor the effects of the study treatment as well as monitor your health and safety, which includes the prevention and management of possible side effects.

Enrollment (Baseline) Assessment (approx. 30 minutes)

- You will complete a saliva cotinine test to verify your smoking status.
- You will be asked a series of demographic and tobacco use questions: contact information (name, email address, phone number), sexual orientation and gender identity, race/ethnicity, education, work status, marital status, number of children in the household, and smoking characteristics (e.g., number of cigarettes smoked/day, past attempts to quit)
- You will be asked to set a quit date within the next 15 days before being enrolled in the text messaging program.
- Following completion of the assessment, you will be sent a $15 e-gift card via your email address and mailed a 6-week supply of nicotine patches.

1-Month Follow-Up Assessment (approx. 10-15 minutes)

- You will be asked a series of demographic and tobacco use questions similar to the baseline screening: changes to contact information, changes to sexual orientation and/or gender identity, smoking characteristics, and nicotine patch use.
- Following completion of the assessment, you will be sent a $15 e-gift card via your email address and mailed a 2- or 4-week supply of nicotine patches depending on if you identified as a heavy smoker (smoke > 10 cigarettes/day) or a light smoker (≤ 10 cigarettes/day) during the baseline assessment. You will also be mailed a saliva test kit to your home address about a week before your 3-month follow-up assessment.

- Individuals living in the Greater Houston Area will be invited to complete this assessment in person at the University of Texas Health Science Center at Houston School of Public Health. In addition to the saliva cotinine test, individuals will be given the opportunity to take an exhaled carbon monoxide test to verify their smoking status for additional compensation ($30 gift card) and voucher for parking in or public transportation to the Texas medical Center.

3-Month Follow-Up Assessment (approx. 10-15 minutes)

- You will complete a cotinine saliva cotinine test to verify your smoking status.
- You will be asked a series of demographic and tobacco use questions similar to the 1-month follow-up assessment.
- Following completion of the assessment, you will be sent a $20 e-gift card via your email address. You will also be mailed a saliva test kit to your home address about a week before your 6-month follow-up assessment.
- Individuals living in the Greater Houston Area will be invited to complete this assessment in person at the University of Texas Health Science Center at Houston School of Public Health. In addition to the saliva cotinine test, individuals will be given the opportunity to take an exhaled carbon monoxide test to verify their smoking status for additional compensation ($30 gift card).

6-Month Follow-Up Assessment (approx. 10-15 minutes)

- You will complete a cotinine saliva cotinine test to verify your smoking status.
- You will be asked a series of demographic and tobacco use questions similar to the previous two assessments.
- Following completion of the assessment, you will be sent a $25 e-gift card via your email address.
- Individuals living in the Greater Houston Area will be invited to complete this assessment in person at the University of Texas Health Science Center at Houston School of Public Health. In addition to the saliva cotinine test, individuals will be given the opportunity to take an exhaled carbon monoxide test to verify their smoking status for additional compensation ($30 gift card).

Semi-structured Interview (approx. 30 minutes)

- Following your completion in the study, you may be asked to participate in a semi-structured qualitative interview to get your feedback on the text-based smoking cessation program that you were enrolled in.
- Following completion of the interview, you will be sent a $30 e-gift via your email address.

If you agree to take part in this study, you will be "randomized" into one of the two groups described below. Randomization means that you are assigned to a group by chance. There is no

way to predict which group you will be assigned to, but you will have an equal chance of being placed in either group. Neither you nor the research staff can choose what group you will be in.

Group 1 (Intervention): If you are randomized to Group 1, you will be enrolled in a text-based smoking cessation program specifically designed to respond to the needs of LGBTQ+ smokers.

Group 2 (Control): If you are randomized to Group 2, you will be enrolled in a text-based smoking cessation program designed for the general population.

No matter which group you are assigned to, you will receive the same compensation (e-gift cards) and supply of nicotine patches.

How long will you be enrolled in this study?
If you agree to be enrolled in this study, your participation will last for approximately 6 months.

What choices do you have other than this study?
You may choose to take part in other smoking cessation interventions other than this study. You can call the Texas Quitline at 1 (877) YES-QUIT (1-877-937-7848) or visit www.yesquit.org. Quitline services offer free and confidential phone counseling services and resources, such as nicotine patches, gums, or lozenges to those who qualify.

What are the risks of taking part in this study?
The risks of participating in this study are considered minimal and there are no direct benefits.

If you choose to take part in this study, there is a risk that the LGBTQ+ tailored text messages may not be as successful as those created for the general population in helping you quit smoking.

There is also a risk that you could get tired when answering questions during assessments. You do not have to answer any questions you do not want to.

You will receive either and 8- or 10- week supply of nicotine patches, and therefore, should be aware of the most common side effects with their use:

- Headache
- Nausea
- Upset stomach
- Dizziness
- Vivid dreams
- Skin irritation

Female (sex assigned at birth): If you are pregnant or breastfeeding, you are not able to participate in this study, as you will be provided with nicotine patches. The nicotine patches used in this study could be harmful to an unborn baby. If you are sexually active, you must

agree to use a medically acceptable form of birth control in order to participate in this study. It is very important that you check with your doctor about what types of birth control or pregnancy prevention to use during the 8 or 10 weeks you will be using nicotine patches. If you have unprotected sex or become pregnant during this time, you must inform your doctor immediately.

Breach of Confidentiality
There is the risk that information about you may become known to people outside of this study.

Unknown Risks
There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?
You will have the support of a text-based program to help you quit smoking. Your participation will help us refine a text messaging intervention that supports smoking cessation efforts among sexual and gender minority (SGM) individuals to ultimately reduce the burden of tobacco-related health conditions among this marginalized group.

Can you stop taking part in this study?
You may decide to stop taking part in this study at any time. To withdraw from the study, please contact Dr. Irene Tami-Maury at (713) 500-9234.

The principal investigator, research staff, or sponsor (NIH/NCI) can stop this study at any time. The principal investigator or the sponsor may end your participation in the study if your condition worsens, the study is ended, the text messaging program is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation is ended, the principal investigator or research staff will discuss other options for assisting you with your efforts to quit smoking.

If you stop participating in this study, the information already collected about you will be used in our data analysis. However, no further information will be collected without your permission.

While taking part in this study, the research team will notify you of new information that may become available and could affect your willingness to remain in the study.

What happens if you are injured during the study?
In the event of injury resulting from this research, UTHealth Houston are not able to offer financial compensation nor to absorb the costs of medical treatment. If you suffer and injury as a result of taking part in this study, please understand that nothing has been arranged to provide you with free treatment or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general population. You or your insurance company will be billed for any treatment. You should

report any such injury to Dr. Irene Tami-Maury at (713) 500-9234. You will not give up any of your legal rights by signing this consent form.

What are the financial costs of taking part in this study?
There are no costs of taking part in this study.

Will you be paid for taking part in this study?
You will receive a $15 e-gift for completing the baseline and 1-month follow-up assessment, a $20 e-gift card for completing the 3-month follow-up assessment, and a $25 e-gift card for completing the 6-month follow-up assessment. If you are invited to complete the 1-, 3- and/or 6-month assessments in person to take an exhaled carbon monoxide test, you will receive an additional $30 gift card at each assessment. If you are invited to participate in the structured qualitative interview, you will receive a $30 e-gift card. You will be issued the e-gift cards via the email address you provided. All information of this nature will be stored on a secure and password-protected drive and will be deleted from our system once the study has been completed.

The University of Texas Health Science Center at Houston owns any data collected and the use of the data, results, treatments, or inventions that can be made from the research. The University's ownership includes the right to license or transfer the use or ownership to other parties including without limitation, commercial entities contracting with UTHealth. There are no plans to compensate you for any patents or discoveries that may result from your participation in this research study. You will not be paid for any use of your data, samples, or results.

How will your privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you are giving permission to UTHealth Houston to use and disclose (release) your health information. The health information that we may use or disclose for this research includes that self-reported during the screening process and follow-up assessments as well as the results of your saliva cotinine tests and exhaled carbon monoxide tests. However, no biological samples will be collected. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Personal identifiers such as your name will be removed from the information you provide us during this study. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.

If you are not comfortable with the use of your data or specimens in future research, you may not want to participate in this study.

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People who receive your research information may not be required by federal privacy laws (e.g. Privacy Rule) to protect your research information and may share your information with others without your permission if permitted by the laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records for the purposes of verifying study data:

- Representatives of UTHealth
- Representatives of the National Health Institutes/National Cancer Institute (NIH/NCI)
- Companies engaged with the UTHealth Houston for the commercialization of the results of the research study

Please note that you do not have to sign this authorization, but if you do not, you may not participate in this study. UTHealth Houston may not withhold or refuse treatment if you do not sign this authorization.

You may revoke this authorization at any time. Even if you revoke this authorization, researchers may still use or disclose health information that they have already obtained about you as deemed necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must contact Dr. Irene Tami-Maury in **writing** at 1200 Pressler Street, Suite E641, Houston, Texas 77030.

This authorization will expire 15 years after the end of the study.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

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Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Who to contact if you have any questions about the study?
If you have questions at any time about this study, please feel free to contact Dr. Irene Tami-Maury at (713) 500-9234. You can also contact the research team to discuss problems, voice concerns, report injuries, or obtain additional information at [redacted] or (713) 500-9174.

The Committee for the Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them with any questions about your rights as a research subject, and to discuss any concerns, comments or complaints about taking part in this study at (713) 500-7943.

SIGNATURES

Contact Name: Dr. Irene Tami-Maury DMD, DrPH, MSc
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Sign below only if you understand the information provided to you about this study and you choose to participate. Make sure that all your questions have been answered before signing. If you decide to take part in this study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date and Time

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date and Time

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