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

NCT05029362

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Appendix D: Informed Consent (beta participants)

Please read this informed consent document carefully and answer all questions truthfully and to the best of your knowledge.

UTHealth
The University of Texas
Health Science Center at Houston

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: SmokefreeSGM - Aim 2 (HSC-SPH-20-0318)

Full Study Title: SmokefreeSGM, A Text-based Smoking Cessation Intervention for Sexual and Gender Minority Groups (Aim 2)

Study Sponsor: NIH/NCI (1K22CA 237639-01A1)

Principal Investigator: Irene Tami-Maury, DMD, MSc, DrPH, Assistant Professor, School of Public Health, UTHealth

Study Contact: Irene Tami-Maury, DMD, MSc, DrPH, Assistant Professor, [redacted]

The purpose of this study is to pretest the design of a personalized, interactive text-based smoking cessation intervention specifically designed for sexual and gender minority groups. If you choose to participate in this study, you will be asked to sign this consent form and will be invited to use a text-based program for smoking cessation. After then, you will be asked to answer some questions and participate in an individual interview. The total amount of time you will be in this study is 1 month after your quit date.

The risks of the study are considered minimal. The research staff will discuss these risks with you. This study may include risks that are unknown at this time. There is a possible risk of breach of confidentiality. You may get tired when we are asking you questions. You do not have to answer any questions you do not want to answer.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research 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), Memorial Hermann Healthcare System, or Harris Health System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this study is to see how well a text-based smoking cessation program works at helping LGB smokers with their quitting efforts. This study will test the feasibility of the text-based smoking cessation program.

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

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 a member of the lesbian, gay, or bisexual (LGB) community, you are 18 years or older, you smoke at least 5 cigarettes per day, you own a cellphone with an unlimited text messaging service, and you are interested in quitting smoking within the next 15 days. It is our intent to expand the program to include all sexual and gender minorities at a later time in the study.

Contact Name: Irene Tami-Maury
Telephone: [redacted]

This study is being conducted at UTHealth. About 16 individuals will take part in this part of the study in Texas.

What will happen if I take part in this study?
You have been pre-screened over the phone or through a telehealth platform. You will be asked to verify your smoking status with a saliva test to complete the screening procedure. To be eligible, the results of the saliva test should indicate you are a smoker.

Listed below are assessments, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

If you agree to take part in this study, you will be invited to use a text-based program for smoking cessation tailored for LGB populations:

Enrollment Assessment (Baseline)

- You will be asked demographic questions: contact information (name, email address, phone number), race/ethnicity, work status, education, marital status, number of children in household, and smoking characteristics (e.g., how many smokers in the household, cigarettes smoked/day, age of first cigarette use, past quit attempts)
- You will be asked to set up a quit day within the next 15 days.
- This interview will last about 7 minutes.
- You will be given 4-week supply of nicotine patches.
- You will be given a $15 gift card once this visit concludes.

Once you complete this assessment, you will be meet with the research staff for 1 additional follow-up assessment by telehealth session:

1-Month Assessment (4 weeks after the quit date)

- You will be asked again certain demographic questions (contact information), questions about sexual orientation and gender identity, smoking characteristics, nicotine patch use, and history of tobacco use (FTND test).
- You will be asked to participate in a structured qualitative interview.
- You will be given a $25 gift card once the visit concludes.
- You will be given either a 6-week or 4-week supply of nicotine patches depending on if you are identified as a heavy smoker (smoke > 10 cigarettes/day) or light smoker (smoke ≤ 10 cigarettes/day) during the screening process.

How long will you be in the study?
If you agree to take part, your participation will last for 1 month and will involve 2 assessments (at baseline and one month follow-up which includes an individual interview).

What choices do you have other than this study?

Contact Name: Irene Tami-Maury
Telephone: [redacted]

You may select other options than being in this research study. You can call the Texas Quitline 1-877-YES QUIT (1-877-937-7848) or visit the website www.yesquit.org . Quitline services offers 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 the study are considered minimal and there are benefits to taking part in this study.

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

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

Since you will receive either an 8 or 10-week supply of nicotine patches, you should be aware of the most common side effects associated with the use of nicotine patches:

- Headache.
- Nausea.
- Upset Stomach.
- Dizziness.
- Vivid Dreams.
- Skin Irritation.

Female (Sex at Birth):
If you are pregnant or breastfeeding, you are not able to take part in this study, as you will be given either 8 or 10-week supply of nicotine patches. 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 be in this study. It is very important that you check with your study 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 become pregnant while taking part in this study or if you have unprotected sex, you must inform your doctor immediately.

What are the benefits to taking part in this study?
You will have the support from a text-based program during your quitting efforts. By taking part in the study, you will help us to develop a text-messaging intervention that supports cessation efforts among sexual and gender minority smokers for ultimately reducing the burden of tobacco-related conditions in this vulnerable group.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Dr. Irene Tami-Maury at [redacted]

The principal investigator, the research staff, or the sponsor (NIH/NCI) can stop the study at any time. The principal investigator or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, the text-based messaging program for smoking cessation 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

in the study is stopped, the principal investigator or the research staff will discuss other options for assisting you with your quitting effort.

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

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

What happens if you are injured during the study?
If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury 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 community. You should report any such injury to Dr. Irene Tami-Maury at [redacted] You will not give up any of your legal rights by signing this consent form.

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

You will receive a $15 egift card after completing baseline and $25 for completing the 1-month assessments, respectively. You will be issued the gift card, following completion of each assessment. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

How will 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 not giving permission to UTHealth, Memorial Hermann Healthcare System, or Harris Health System to use and disclose (release) your health information.

Personal identifiers such as your name will be removed from the information and the saliva test run in this study. After we remove all identifiers, the information or saliva test results may be used for future research or shared with other researchers without your additional informed consent.

People who receive your research information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your research information and may share your information with others without your permission, if permitted by 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

Contact Name: Irene Tami-Maury
Telephone: [redacted]

- Representatives of the National Health Institutes/National Cancer Institute (NIH/NCI).

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System or Harris Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as 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 [redacted]

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

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the Dr. Irene Tami-Maury at [redacted] as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

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

Contact Name: Irene Tami-Maury
Telephone: [redacted]

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time

Contact Name: Irene Tami-Maury
Telephone: [redacted]

1)	Would you like to voluntarily participate in this survey? Please select one of the two options below:	◯ Yes, I voluntarily agree to participate in this research survey ◯ No, I do not agree to participate in this research survey
2)	Please print your name here. Note that this will serve as an electronic signature	_____ (First name Middle Initial Last Name)
3)	Today's date and time	_____