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

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This protocol describes both a pilot study and a feasibility study, which are registered as two separate records. Refer to pages 3-6, for the pilot study (aim 2) registered as ClinicalTrials.gov record NCT05645354.

Protocol Title:	SmokefreeSGM, A Text-based Smoking Cessation Intervention for Sexual and Gender Minority Groups.
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Co-Investigators:	Hongyu Miao, Associate Professor in Biostatistics.
Study Coordinator:	N/A
Population:	Total 96 study participants (Part 2 = 30 study participants; Part 3 = 80 study participants).
Number of Sites:	Single site. Data were collected in the field.
Study Duration:	July 2020 to December 2023.
Subject Duration:	Individual's participation will end 1 month after the smoking quit date (Part 2); Individual's participation will end 6 months after the smoking quit date (Part 3).
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Short Title:	SmokefreeSGM

GENERAL INFORMATION

Smoking among sexual and gender minority (SGM) groups, which include lesbian, gay, bisexual, and transgender (LGBT) individuals, has been reported from different sources as highly prevalent (46% for gay men and 48% for lesbians). Considering that the smoking rate within SGM groups is more than double that of the general population (19%) and that smoking accounts for at least 30% of all cancer deaths, it is clear that there is an increased risk for SGM individuals to suffer from this fatal condition. Text messaging programs are effective for smoking cessation and other health behaviors. They are appealing to traditionally hard-to-reach, at-risk populations who experience barriers to smoking cessation interventions, and who have high rates of mobile phone and text messaging use, which is the case for SGM users. SmokefreeTXT is a smoking cessation intervention that sends tailored, supportive texts to users based on self-selected smoking quit date. Although this program developed by the NIH National Cancer Institute (NCI) has been successfully evaluated with the general population, no study has evaluated its feasibility specifically among SGM smokers. This protocol proposes 3 specific aims or parts:

(1) To develop SmokefreeSGM, an SGM-tailored version of SmokefreeTXT, a text-based smoking cessation program.

(2) To pretest the design of SmokefreeSGM through a mixed-methods approach among 30 SGM adult smokers; and

(3) To examine recruitment, retention, and smoking abstinence rates at 1, 3, and 6 months of follow-up among 80 SGM smokers randomized to either the original SmokefreeTXT or SmokefreeSGM program arms. Engagement with the programs will be also measured by calculating the number of text message responses for each SGM participant from the system records. Additionally, we will use mixed-methods research among 32 SGM smokers completing their participation in the feasibility trial to better understand study participants' acceptability of the cessation interventions. Results will contribute to reducing tobacco-related health disparities among SGM groups.

BACKGROUND INFORMATION

Cigarette smoking among SGM groups in the United States (US) is higher than among heterosexual/straight individuals. Nearly 1 in 4 SGM adults smoke cigarettes compared with about 1 in 6 heterosexual/straight adults.[1] This high rate is attributed to several factors, including additional stress due to stigmatization and discrimination, as well as targeted tobacco marketing.[2] Four percent of adults in the US self-identify as SGM.[3] However, the US Census and other major federal surveys do not ask about sexual orientation. Therefore, the number could be substantially higher. Texas has the third-highest concentration of same-sex couples in the US, behind only California and New York.[4] Our study involving attendees of the 2014 Houston Pride Parade and Festival confirmed the alarmingly high prevalence of cigarette smoking in this vulnerable group (55%).[5] Considering that smoking accounts for at least 30% of all cancer deaths,[6] it is clear that there is an increased risk for SGM individuals to die of tobacco-related conditions, including cancer. It has been suggested that targeted and tailored interventions could be more effective among SGM smokers because they assure a safe, validating environment that enhances receptivity to cessation.[7,8] The few reported smoking cessation interventions for SGM smokers are minimally tailored, lack a control group, lack objective verification of self-reported quit rates, and/or are based on group interventions.[9-12] Mobile health (mHealth) programs that use text messaging are effective for smoking cessation and other health behaviors.[13-15] These programs are appealing to vulnerable groups who experience barriers to smoking cessation interventions[16-18] and who have high rates of mobile phone and text messaging use.[19] Although the number of people enrolled in text messaging programs for smoking cessation is increasing, no study has been conducted for evaluating its feasibility among SGM smokers. SmokefreeTXT is an automated, personalized, and interactive mHealth program for smoking cessation developed by the NCI that sends text messages 2 weeks before and up to 6 weeks after the quit date. Its efficacy was successfully evaluated with the general population in a randomized trial.[15,20,21] However, theoretically-based smoking cessation treatments delivered via text messaging and focused on enhancing treatment engagement and targeting the specific needs of SGM smokers are needed.

OBJECTIVE

The overall objective of the study is to develop SmokefreeSGM, a version of SmokefreeTXT that will be tailored and tested among SGM smokers. This protocol proposes 3 aims, each of them corresponding to Parts 1, 2, and 3 in this research study:

- Aim 1: Developing the design of SmokefreeSGM (Part 1).
- **Aim 2: Pretesting the design of SmokefreeSGM among 30 smokers (Part 2).**
- Aim 3: Feasibility trial to examine recruitment, retention, and smoking abstinence rates among SGM smokers. We will also assess program engagement and acceptability among SGM smokers who participated in the feasibility trial (Part 3).

NOTE: We are still enrolling study participants for all research activities related to Aim 2 (Pretesting). With this protocol amendment, we are seeking IRB approval to increase the sample size from 16 to 30 individuals, as several recruited study participants are lost in follow-up. Once activities with Aim 2 are completed, subsequent protocol amendments will be submitted for Aim 3.

OVERALL STUDY DESIGN. With this project, we propose to develop and test the feasibility of a personalized, interactive text-based smoking cessation program (SmokefreeSGM) specifically designed for SGM smokers. Ninety-six SGM smokers will be recruited for the entire study (n=96).

RESEARCH METHODS FOR PART 1

Procedures: In part 1, we will develop SmokefreeSGM, an SGM-tailored version of SmokefreeTXT, a text-based smoking cessation program for smoking cessation. SmokefreeTXT is an automated, personalized, and interactive mHealth program that sends bidirectional text messages timed around a participant's quit date over 3 months. It was developed by NCI. The text messages include pre-and post-quit educational messages, peer ex-smoker messages, NRT medication reminders, and relapse messages, as well as multiple opportunities for interaction. Messages are based on social cognitive theory[22, 23] and are consistent with the US Public Health Service Clinical Practice Guideline.[23] Messages are interactive and prompt users to track smoking, report cravings, and provide smoking status. Participants who report that they have not quit are routed into setting a new quit date. After enrollment, SmokefreeTXT offers both outgoing messages about quitting smoking and on-demand help through the use of keywords. Short Message Service (SMS) keywords include among others: CRAVE (study participants will get help with a craving by having a reminder of why the study participant should not smoke that cigarette, MOOD (participant will

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receive a positive message when having a difficult day, SLIP (user will receive extra encouragement to get back on track), and SMOKEFREE STATUS (which indicates if the study participant has smoked or not by the time he/she receives the text message).

SmokefreeSGM will be developed by Dr. Tami-Maury's research team with input and feedback from members of a Community Advisory Committee (CAB) composed of smoking cessation specialists, SGM former and current smokers, as well as scientists and community leaders with whom we have teamed up in previous research and advocacy efforts around SGM health disparities research. These CAB members should not be considered research participants. They will only provide feedback on the content and design of the SGM-tailored text-based platform. The CAB members will be compensated for completing a two-part survey ($15 eGift Card after completing each part). Further, we will solicit meetings with CAB members either individually or in a group via a telehealth platform (i.e., Zoom or Webex). After each meeting, which won't last more than 60 minutes, CAB members will receive a $15 eGift Card. CAB members will be requested to attend up to 4 meetings during the entire duration of the study.

Below are some of the SGM-tailored features we have anticipated for SmokefreeSGM:
o Messages originated from SmokefreeSGM will be sent by a fictitious peer ex-smoker SGM quit coach (Alex) who will offer evidence-based advice on quitting.
o The characteristics of, and messages sent by, the role model (Alex) will be based on real-life experiences of SGM ex-smokers who understand user's barriers and creates a welcoming environment.
o Modifying and tailoring of the NCI SmokefreeTXT text library (Appendix A) by adding 70 encouragement and motivational messages that address unique psychosocial stressors for SGM smokers such as elevated general stress (i.e., level of stress and number of stressful life events) and minority specific stress (i.e., internalized homophobia, sexual orientation concealment, discrimination events, stigma consciousness). The new keyword STRESS will prompt the additional set of text messages.

RESEARCH METHODS FOR PART 2

Study Design. In part 2, we will pretest the design of SmokefreeSGM using a mixed-methods approach among 30 SGM adult smokers.

Study Population.

- Aim 2: Pretesting the design of SmokefreeSGM (n=30). Once developed, SmokefreeSGM

will be beta-tested by 30 SGM adult smokers for 2 weeks before and 4 weeks after the quit date. Then, beta users will participate in individual interviews. The feedback provided by the study participants during the individual interviews will indicate if the messages were perceived as interesting and appropriate. Their thoughts and feedback will be critical for driving technical improvements of SmokefreeSGM's concept, design, and functionality before launching it during the feasibility trial (Part 3) targeting SGM smokers who have not participated in the above-mentioned beta-test.

Inclusion Criteria.

1) Self-identified as a lesbian, gay, or bisexual individual

2) Age ≥ 18 years

3) Smoke five or more cigarettes per day, has smoked at least 100 cigarettes in their lifetime and smokes everyday

4) Have an interest in quitting smoking in the next 15 days

5) Have a cellphone number with an unlimited short messaging service (SMS) plan

6) Have US mailing and email addresses

7) Positive cotinine saliva test results for current smoker status

Exclusion criteria.

1) Individuals who are found to have a prepaid cell phone (GoPhone or pay-as-you-go plan) will be excluded,

2) Individuals who are found to have a cellphone number that does not work or is registered to someone else will be disqualified,

3) Pregnant or breastfeeding women (nicotine patches are not generally recommended to this group as nicotine can affect fetal and neonatal brain development),

4) Contraindication for nicotine patch. Absolute contraindications included: severe eczema or serious skin conditions, allergy to nicotine patch, pregnancy, breastfeeding, heart attack in the past 2 months, ongoing angina, peptic ulcer disease, arrhythmia, or uncontrolled blood pressure. Potential contraindications included stroke in the past 6 months, insulin therapy, and a current diagnosis of

liver, kidney or heart disease. Participants reporting an absolute contraindication are ineligible for the study. A participant reporting a potential contraindication will require that his/her primary care provider and/or other treating physician (e.g. psychiatrist) approve the nicotine patches. If the request is denied or not returned in two weeks, potential participants will be excluded from the study;

5) Current use of tobacco cessation medications;

6) Enrolled in another smoking cessation study;

7) Non-English speakers. Although we recognize that excluding Spanish speakers (Hispanics represent 44% of the total population in Houston)[24] limits the potential generalizability and reach of our text-based smoking cessation program. We do not believe that developing and delivering an SGM- tailored intervention in 2 languages is feasible within the scope of this study.

8) Having inadequate equipment/device (i.e., webcam, speakers, mic) for participating in telehealth sessions via Webex or Zoom AND cannot meet for an in-person screening.

Study Procedures.

Once developed, SmokefreeSGM will be beta-tested by 30 SGM adult smokers for a period of 2 weeks before and 4 weeks after their quit date.

Recruitment procedures. Active efforts will be made to identify subjects who are suitable for enrollment into this part of the study. Flyers (Appendix B) offering help to SGM individuals interested in quitting smoking will be distributed at local community organizations and healthcare facilities working for SGM groups. We will also advertise the flyer at local newspapers, magazines, webpages, social media sites of local community organizations and healthcare facilities, and SGM-venues (e.g., bars, restaurants, etc.).

Interested individuals will contact the study team. The screening process will take place over the phone or through telehealth (e.g., Webex or a similar platform), or in person, and is divided into two parts. Part A of the screening (conducted over the phone, in person, or through telehealth) collects demographic information inaddition to an assessment of the inclusion/exclusion criteria (Appendix C). Participants who areeligible to participate in the study will be invited to complete part B of the screen (through telehealth, or in person) at a later date/time where self-reported smoking status will be verified by saliva. Informed consent will be

delivered electronically to participants via email after they complete part A of the screening and schedule their part B screen (Appendix D). In order to avoid in-person visits, the self-reported smoking status will be objectively verified by cotinine test (either Alere or NICDetect) during screening part B (Appendix E). However in-person visits will be conducted in the circumstances that videoconferencing technology or other barriers exist for screening. Potential study participants will be mailed in advance a saliva cotinine test with instructions (delivered electronically), or provided the test in-person. During part B of the screening process, participants will conduct the test at home or in person following the step-by-step instructions provided by the research staff. The test result will be available when the colored band appears, which takes around 10 minutes. The whole procedure of objectively verifying thesmoking status with the saliva test will be closely monitored during a second telehealth session.Potential study participants will be asked to show the result of the saliva test strip during the telehealth session or to the researcher in person. After enrolling into the study, participants will receive a 4-week supply of nicotine patches (NicodermCQ or CVS Health) that will be mailed to their physical address.

Baseline assessment. Immediately after confirming their eligibility and enrolling the participant into the study, additional questions will be asked to complete the baseline assessment.

Quantitative Measures. The following data will be collected: contact information (name, email address, phone number), demographic (race/ethnicity, work status, education, marital status, number of children in household), and smoking characteristics of participants (e.g., how many smokers in the household, cigarettes smoked/day, past quit attempts, age of first cigarette use). Nicotine dependence will be measured with the Fagerstrom Test for Nicotine Dependence (FTND) at baseline. The FTND is a standard instrument for assessing the intensity of physical addiction to nicotine. The test was designed to provide an ordinal measure of nicotine dependence related to cigarette smoking. It contains six questions that evaluate the quantity of cigarette consumption, the compulsion to use, and dependence. In scoring the FTND, yes/no items are scored from 0 to 1 and multiple-choice items are scored from 0 to 3. The items are summed to yield a total score of 0-10. The higher the total FTND score, the more intense is the study participant's physical dependence on nicotine. After completing the baseline assessment, participants will receive a $15 egift card, which will be distributed by email.

1- Month Follow-up assessment. Study participants will complete follow-up assessment via telehealth session 1 month after their quit date.

Quantitative Measures. This assessment will include the following items: contact information, sexual orientation, gender identity, living with one or more smokers in the household, cigarettes smoked/day, quitting attempts, nicotine patch use and FTND. We will also include the System Usability Scale (SUS) score which measures the usability of the SmokefreeSGM program (Appendix G). The SUS is a 10-item questionnaire with 5 response options ranging from Strongly Disagree (1) to Strongly Agree (5):

1. *I think that I would like to use this text-based smoking cessation program (SmokefreeSGM) frequently.*
2. *I found SmokefreeSGM unnecessarily complex.*
3. *I thought SmokefreeSGM was easy to use.*
4. *I think that I would need the support of a technical person to be able to use SmokefreeSGM.*
5. *I found the various functions in SmokefreeSGM were well integrated.*
6. *I thought there was too much inconsistency in SmokefreeSGM.*
7. *I would imagine that most people would learn to use SmokefreeSGM very quickly.*
8. *I found SmokefreeSGM very cumbersome to use.*
9. *I felt very confident using SmokefreeSGM.*
10. *I needed to learn a lot of things before I could get going with SmokefreeSGM.*

For completing the qualitative measurements during the 1-month assessment, participants will receive a $25 eGift card, which will be distributed by email.

Qualitative Approach. During the 1-month assessment, while participants are scoring the SUS items, an interviewer will be using probes (e.g., *Why do you think so?, What makes you feel that way?,* etc.) to elicit further information.

The entire 1-month follow-up assessment will last 45 to 60 minutes. A research staff member will act as a note-taker and will record the sessions. Findings from this mixed-method approach will indicate if the messages were perceived as interesting and appropriate. Their thoughts and feedback will be also critical for driving technical improvements of SmokefreeSGM's concept, design, and

functionality before launching it during the feasibility trial (Part 3, not presented in this protocol amendment) targeting SGM smokers who have not participated in the above-mentioned beta-test. Following completion of the 1-month assessment, participants will be mailed either a 6-week supply of nicotine patches (NicodermCQ or CVS Health) or a 4-week supply to their physical address, depending on if they are a heavy smoker (smoke > 10 cigarettes/day) or light smoker (smoke ≤ 10 cigarettes/day).

Data Safety and Monitoring. This is a minimal risk study. The risks of using the text-based platform, completing the 1-month assessment, and/or participating in the in-depth interviews are considered minimal and include 1) emotional discomfort due to discussions about sensitive issues, and 2) breach of confidentiality. Distress will be minimized by assurances that participants can stop texting or refuse to answer any questions during the individual interviews if they do not feel comfortable answering and may withdraw from the project at any time without repercussion. Confidentiality will be maintained by numerically coding all data and by password-protecting computer files. Data will be stored on a secure server with a firewall to protect the data and to prevent unauthorized access. Databases on the server are password protected and will be accessed only by members of the research staff who have met the UTHealth IRB's requirements for training in Human Subjects' Protection. All participants will be assigned a unique identification code that will be stored separately from identifying information. All electronic datasets will be saved in the institutional shared drive and only research team members will be able to access them. The text messaging program will be implemented by the vendor, Mosio. Mosio is hosted by Lightcrest, an established, trusted vendor with documented security and regulatory compliance through Equinix. For data protection redundancy, backups are hosted using AWS HIPAA eligible services in a geo-diverse location. All Production and backup data centers are located within the USA.

Statistics. Quantitative data collected via text messaging will be downloaded as an Excel, SPSS, R, SAS, or STATA dataset. These software packages will be used for analysis purposes. Study variables will be summarized using standard descriptive statistics. The distributional characteristics of relevant variables will be examined using box plots and histograms to ensure normality assumptions. Routine descriptive statistics, including proportions, means, and standard deviations as well as graphical methods will be reported to explore distributions for all variables. Engagement will be assessed among study participants' data by analyzing the received and sent text messages collected during the smoking cessation intervention. The number of text messages sent and received by study participants after enrollment will be assessed.

We will also compute the scores for the SUS scale which will allow our research team to analyze how well the study participants perform the tasks on the text-based platform, and how they find the entire experience. Participants will have ranked each of the SUS 10 questions from 1 to 5, based on their level of agreement (1 for Strongly Disagree to 5 for Strongly Agree).

- For each of the odd numbered questions, we will subtract 1 from the score.
- For each of the even numbered questions, we will subtract their value from 5.
- We will take these new values and add up the total score. Then, we will multiply this by 2.5. After computing the SUS score, we will convert it to percentile ranks. A percentile rank of 75% will indicate that SmokefreeSGM has a high perceived usability.

Qualitative data from each individual interview will be analyzed for assessing usability and acceptability. Audio recordings from the individual interviews will be transcribed. Data will be analyzed by the research team using a descriptive framework approach which allows for the exploration of a priori concepts and for new themes to emerge. Transcripts will be read and reread to gain familiarity with the subject. Analysis of the transcripts will be based on data grouping, creation of a code guide, and identification of themes from the narrative text. The coding guide will be drawn on the domains shaped by the discussion guide and themes that will emerge during the study. Data analysis will be performed using computer software (ATLAS.ti or NVivo). Results will inform the refinement of a smoking cessation text-based intervention focused on enhancing treatment engagement and targeting the specific needs of SGM smokers.

Ethics. This study involves no more than minimal risk to subjects. The risk of breach of confidentiality will be handled by indicating to participants that participation in the study and the information gathered from the study will be kept confidential to the extent of the law, and that the findings of the study may be published, but that participants will not be identified. No direct benefits to participating in this research are anticipated. Nevertheless, this research may benefit others since this work may contribute to a greater understanding of mechanisms underlying the acceptability of mobile health (mHealth) smoking cessation interventions among SGM groups. Results will contribute to the design of interventions targeting this underserved population of smokers.

Data handling and record keeping. Participants will be assured that assessment information will

be kept confidential, and no names will be used in presenting data in presentations and publications. All data collected through REDCap instruments (e.g., screening forms, baseline, and 1-month assessments, etc.) will be available only to the research personnel, who are knowledgeable of all human subjects' protection guidelines. Electronic datasets will be password protected and only accessed by research team members.

Quality control and assurance. Research team members involved in the study will be trained in human subjects' research. Team members will be available during data collection procedures respond via phone call or through telehealth to any question that study participants could have. Each research record (e.g., screening form) from each enrolled participant will be checked to verify that the inclusion/exclusion criteria have been respected.

Publication plan. No text-based smoking cessation intervention has been specifically tailored to SGM populations, incorporating text messages with SGM-specific information focusing on affirmative-based approaches and coping strategies for unique SGM psychosocial stressors (e.g., internalized homophobia, discrimination events, stigma consciousness), among others. Evaluating the design of SmokefreeSGM will provide an opportunity to enhance the usability of this SGM-tailored text-based cessation program before launching it in Aim 3. At least one manuscript with findings from Part 2 is expected to be published in a peer-reviewed journal.

Appendices.

- Appendix A: NCI SmokefreeTXT and SmokefreeSGM text libraries
- Appendix B: Flyer
- Appendix C: Screening form-Part A (Beta Testing: Part 2 of the Study)
- Appendix D: Informed Consent (Beta participants)
- Appendix E: Screening form-Part B, Cotinine Results, Baseline Assessment (Beta Testing: Part 2 of the Study)
- Appendix F: 1-Month assessment
- Appendix G: System Usability Scale and Structured interview guide (Beta Testing: Part 2 of the Study)

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