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

NCT05645354

Version Date: 07/25/2023

Protocol Title:	SmokefreeSGM, A Text-based Smoking Cessation Feasibility Trial for Sexual and Gender Minority Groups
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Co-Investigators:	N/A
Study Coordinator:	N/A
Population:	100 LGBTQ+ smokers living in the United States
Number of Sites:	Single site. Data collected in the field.
Study Duration:	September 2022 to December 2023
Subject Duration:	Individual's participation will end approx. 8 months after their enrollment
Funding Agency:	NIH/NCI (1K22CA 237639)
Short Title:	SmokefreeSGM – Feasibility Trial

GENERAL INFORMATION

Smoking among sexual and gender minority (SGM) groups, which include lesbian, gay, bisexual, and transgender (LGBT) individuals, has been reported as highly prevalent. Nearly 1 in 4 SGM adults smoke cigarettes compared with about 1 in 6 heterosexual adults. Therefore, this population is at an increased risk for tobacco-related health conditions. Text messaging programs have been found to be effective for smoking cessation and appeal to traditionally hard-to-reach populations, such as SGM smokers. This protocol proposes a randomized controlled trial among 100 SGM smokers randomized to the original SmokefreeTXT program (control arm) developed by the National Institutes of Health/National Cancer Institute (NIH/NCI) for the general population or our SmokefreeSGM program (intervention arm), an SGM-tailored smoking cessation intervention developed by our research team for smokers who self-identified as SGM individuals. We will determine the feasibility and acceptability of both programs among SGM smokers through an analysis of recruitment, retention, and smoking abstinence rates at 1-,

3-, and 6-month assessments and the completion of qualitative interviews among 32 study participants. Findings from this research will help reduce tobacco-related health disparities among SGM smokers.

BACKGROUND INFORMATION

Cigarette smoking among sexual and gender minority (SGM) groups in the United States is higher than heterosexual and cisgender individuals [1]. The National Institutes of Health (NIH) define SGM as an umbrella term that includes individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. It also includes individuals with same-sex or -gender attractions or sexual behaviors and those with a difference in sex development, as well as those whose sexual orientation, gender identity or expression, or sex development is characterized by non-binary constructs [2]. The high rate of cigarette smoking among SGM groups is attributed to several factors, including stress due to stigmatization and discrimination, as well as targeted tobacco marketing [3]. Therefore, this population is at an increased risk for developing tobacco-related health conditions such as 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 [4,5]. 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 [6-9]. Mobile health (mHealth) programs that use text messaging have been found effective for smoking cessation and other behavioral change interventions. These programs are appealing to marginalized groups who experience barriers to smoking cessation interventions and who have high rates of mobile phone and text messaging use because they allow for self-management and discretion [10-13]. Although the number of people enrolled in text messaging programs for smoking cessation is increasing, no study has

evaluated their feasibility among SGM smokers.

SmokefreeTXT is an automated, personalized, and interactive mHealth program for smoking cessation developed by the National Cancer Institute (NCI) that sends text messages 2 weeks before and up to 6 weeks after a smoker's quit date. Similar programs have been found to be effective and SmokefreeTXT has been tested among the general population as well as subgroups (i.e., pregnant smokers) [10,14-16]. However, theoretically-based smoking cessation treatments delivered via text messaging and focused on the specific needs of SGM smokers are needed.

The rapid increase in the number of people, including SGM individuals, owning a mobile telephone has led to the development of new applications in the self-management of behavioral change interventions [17]. The proposed text-based smoking cessation intervention will include motivational messages or content specifically tailored to SGM participant characteristics to distract from cravings and will be sent based on participants' needs. While there is strong evidence that text-based tobacco cessation interventions help smokers quit smoking, no similar intervention has been conducted specifically for lesbian, gay, bisexual, and/or transgender smokers [18-20]. Reducing smoking prevalence among SGM individuals by implementing a cost-effective and tailored text-based smoking cessation intervention is a powerful cancer prevention strategy for this population.

OBJECTIVE

The objective of this study is to test the feasibility and acceptability of SmokefreeSGM, an SGM-tailored version of the SmokefreeTXT text messaging program developed by our research team.

STUDY DESIGN

We will conduct a randomized controlled trial among 100 SGM smokers living in the United States randomized to the original SmokefreeTXT program (control arm = 50) or the SmokefreeSGM program (intervention arm = 50). Data collected will be used to examine recruitment, retention, and smoking abstinence rates at 1-, 3-, and 6-months follow-up. Additionally, qualitative interviews will be conducted with 32 participants (control arm = 16, intervention arm = 16) to evaluate the acceptability of both programs among SGM smokers.

RESEARCH METHODS

Inclusion Criteria.

1) Age ≥ 18 years

2) Self-identify as an LGBTQ+ individual

3) Currently live in the United States

4) Have smoked at least 100 cigarettes in their lifetime, smoke every day, and smoke ≥ 5 cigarettes a day

5) Are willing to quit smoking in the next 15 days

6) Have a cell phone number with an unlimited short message service (SMS) plan

7) Have a positive cotinine saliva test to indicate their smoking status

Exclusion Criteria.

1) Have a prepaid cell phone plan (pay-as-you-go plan)

2) Have a cell phone number that does not work and/or is registered to someone else

3) Have inadequate equipment/devices (i.e., webcam, speakers, mic) for participating in telehealth sessions via Microsoft Teams, Webex, or Zoom AND cannot meet in-person

4) Pregnant or breastfeeding persons (nicotine patches are not generally recommended to this groups since nicotine can affect fetal and neonatal brain development)

5) Contraindication for nicotine patches. Absolute contraindications include: severe eczema

or serious skin conditions, allergy to nicotine patches, pregnancy, breastfeeding, heart attack in the past 2 months, ongoing angina, peptic ulcer disease, arrhythmia, or uncontrolled blood pressure. Potential contraindications include: stroke in the past 6 months, insulin therapy, and a current diagnosis of liver, kidney, or heart disease. Study participants reporting a potential contraindication will require approval from their primary care provider and/or other treating physician (e.g., psychiatrist) to use nicotine patches. If the request is denied or not returned in 2 weeks, potential study participants will be excluded from the study.

6) Current use of tobacco cessation medications

7) Enrollment in another smoking cessation study

8) Non-English speakers

Study Procedures.

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 health care facilities working for SGM groups. We will also advertise through the Health Equity Research Group's (HERG) social media accounts (i.e., Twitter and Facebook).

Screening Part A and B

Interested individuals will contact the research team. The screening process will take place over the phone, through telehealth (i.e., Microsoft Teams, Webex, or Zoom), or in-person, and will be divided into two parts. Part A of the screening will collect demographic information in addition to an assessment of the inclusion and exclusion criteria (Appendix C). Study participants who are

eligible to participate will be invited to complete Part B of the screening (through telehealth or in-person) at a later date and time where their self-reported smoking status will be verified by a saliva cotinine test. The informed consent (Appendix D) and an electronic copy of the saliva test instructions will be delivered electronically to study participants via email after they complete Part A of the screening. In an attempt to limit in-person visits, potential study participants will be mailed a saliva test kit (Alere or NICDetect) and a physical copy of the instructions in advance of their session. In-person visits will only be conducted for study participants with inadequate equipment/devices to participate in telehealth sessions. Study participants will conduct the saliva test by following the step-by-step instructions provided by the research team member. This procedure will be closely monitored by the research team member. The test results will be available when the colored band appears, which takes approximately 10 minutes.

While we are seeking to enroll 100 participants into this study, interested individuals that contact the research team after that time will be given the option to be enrolled in the SmokefreeSGM text-messaging program only. These individuals will not complete the screenings or assessments and will not be provided with nicotine patches or compensation.

Baseline Assessment

Immediately after confirming a person's eligibility to participate in the study, they will complete the Baseline Assessment (Appendix E), which will ask additional demographic and tobacco use questions: sexual orientation and gender identity, race/ethnicity, work status, marital status, number of children in household, and smoking behaviors (e.g., number of cigarettes smoked per day, past attempts to quit), among others.

Nicotine dependence will be measured using the Fagerstrom Test for Nicotine Dependence (FTND), which is a standard instrument for assessing the intensity of physical addiction to

nicotine related to cigarette smoking. It contains six questions that evaluate the quantity of cigarette consumption, the compulsion to use, and dependence. Yes/No items are scored from 0 to 1 and multiple-choice items are score from 0-3. The higher the total score, the more intense the study participant's physical dependence to nicotine. For study participants that also use electronic nicotine delivery systems (ENDS) also known as electronic cigarettes, vape pens, vapes, eHookahs, JUULS, etc; their dependence will be measured using the Penn State Electronic Cigarette Dependence Index, a 10-item scale with scores ranging from 0 to 20. The higher the total score, the more intense the study participant's dependence to ENDS.

The study participant will then set a quit date in 15 days and be enrolled in the text messaging program. Study participants will either be assigned to the control group (SmokefreeTXT) or intervention group (SmokefreeSGM) through the randomization function in REDCap. Following completion of the assessment, the study participant will be sent a $15 e-gift card via email and mailed a 6-week supply of nicotine patches. The dosage of nicotine patches will be dependent on whether the study participant identified as a light smoker (≤ 10 cigarettes/day) or a heavy smoker (smoke > 10 cigarettes/day). Light smokers will receive 3 boxes of 14 mg nicotine patches and heavy smokers will receive 3 boxes of 21 mg nicotine patches.

1-Month Assessment

Study participants will complete the 1-month assessment (Appendix F) via phone, telehealth, or in-person and be asked a series of demographic and tobacco use questions similar to the baseline screening: changes to contact information, sexual orientation and gender identity, smoking behaviors, and nicotine patch use. The research team member will conduct a FTND and/or Penn State Electronic Cigarette Dependence Index for those study participants that have not quit smoking. The research team member will also pose the question: "As an LGBTQ+ smoker, do you feel that the content of the text messages was tailored to your needs? Can you

explain why or why not?" Following completion of the assessment, the study participant will be sent a $15 e-gift card via email and mailed a 2- or 4-week supply of nicotine patches depending on if they identified as a light smoker (smoke ≤ 10 cigarettes/day) or a heavy smoker (smoke > 10 cigarettes/day) during the baseline assessment. Light smokers will receive 1 box of 7 mg nicotine patches and heavy smokers will receive 1 box of 14 mg and 1 box of 7 mg nicotine patches.

Individuals living in the Greater Houston Area will be given the opportunity to complete the 1-month assessment in-person at the University of Texas Health Science Center at Houston School of Public Health (RAS E515). In doing so, they will be able to complete an exhaled carbon monoxide (CO) test (coVita Smokerlyzer) for additional compensation ($30 gift card) and a voucher for parking in or public transportation to the Texas Medical Center. Unlike saliva cotinine tests, which will produce positive results for individuals who both smoke traditional cigarettes and use electronic nicotine delivery systems (ENDS), the CO test will only produce elevated results for traditional cigarette smokers. Implementing this procedure will also allow us to test its feasibility before launching a larger-scale efficacy trial for the SmokefreeSGM program.

3- and 6-Month Assessments

Study participants will complete the 3- and 6-month assessments (Appendix G & H) via telehealth and will conduct the saliva cotinine test to verify their smoking status. Individuals living in the Greater Houston Area will be given the opportunity to complete these assessments in-person at the University of Texas Health Science Center at Houston School of Public Health (RAS E515). In doing so, they will be able to complete an exhaled carbon monoxide (CO) test (coVita Smokerlyzer) for additional compensation ($30 gift card at each assessment) and a voucher for parking or public transportation to the Texas Medical Center.

Study participants will be asked a series of demographic and tobacco use questions similar to the 1-month assessment. If the saliva test results indicate that a study participant is still a smoker, a research team member will conduct a FTND and/or Penn State Electronic Cigarette Dependence Index. Following completion of the 3- and 6-month assessments, the study participant will be sent a $20 and $25 e-gift card via email respectively.

Semi-structured Interview

32 study participants, 16 from the control group and 16 from the intervention group, will be invited to participate in a semi-structured interview (Appendix I) to evaluate the acceptability of the programs and capture feedback that can be used to improve the design and functionality of SmokefreeSGM. We will ask the following questions:

1) In what ways did your participation in the text messaging program influence your current smoking behaviors (i.e., currently smoking or smokefree)?

2) Prior to your enrollment in the text messaging program, did you use electronic nicotine delivery systems (e.g., electronic cigarettes, vapes, e-Hookahs, mods)? If not, what are your thoughts about these products? If yes, do you currently use them and how has your participation in this program influenced your decision to do so?

3) What are some things that you liked about the text messaging program?

4) Were there specific text messages that you liked and still resonate with you? Which one(s) and why? It is okay if you do not remember the exact text message(s).

5) What are some things that you did not like about the text messaging program?

6) Were there specific text messages that you did not like and you believe should be modified or eliminated? It is okay if you do not remember the exact text message(s).

7) Were the response instructions in the text messages clear? Why or why not?

8) Did you find that the bidirectional text messages, meaning the two-way conversations

between you and the program, were satisfactory? Why or why not?

9) Was the content of the text messages clear? Why or why not?

10) After participating in this text messaging program, would you suggest it to other LGBTQ+ smokers interested in quitting? Why or why not?

11) Based on the text messages you received, do you believe that you were enrolled in the SmokefreeTXT program developed for the general population or the SmokefreeSGM program tailored to LGBTQ+ smokers? Why or why not?

12) Do you think that receiving text messages tailored to LGBTQ+ smokers helped or would have been helpful in your efforts to quit smoking? Why or why not?

13) Is there anything more you would like to share with me, whether about the text messaging program or the study?

Following completion of this interview, study participants will be sent a $30 e-gift card via email.

DATA SAFETY AND MONITORING

This is a minimal risk study. The risks of using either text-based platforms, completing the 1-, 3-, and 6-month assessments, and participating in the structured interview are minimal and may result in: (1) emotional discomfort due to discussion about sensitive issues, and (2) breach of confidentiality. Distress will be minimized by assuring study participants that they do not have to respond to texts and/or answer any questions during the assessments and the one-time individual interview that they do not feel comfortable answering and may withdraw from the study at any time without repercussion. Confidentiality will be maintained by numerically coding all data and password-protecting computer files. Data will be stored on a secure server with a firewall to protect the data and to prevent unauthorized access. Data on the server will also be password protected and only accessible to research team members who have met UTHealth IRB's requirements for training in Human Subjects' Protection. All study 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 United States.

For study participants that complete the exhaled carbon monoxide test (coVita Smokerlyzer) during the 1-, 3- and 6-month assessments, the device mouth pieces will be disposed of directly after use. No biological samples will be taken from the study participant. Results will be recorded from the device into the corresponding REDCap form. Additionally, the devices will be appropriately cleaned and disinfected before and after each use.

STATISTICS

Quantitative data collected via text messages will be downloaded from Mosio 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.

Recruitment rates will be defined by dividing the number of SGM smokers who consent and complete the baseline assessment by the number of SGM smokers who are approached and invited to participate in the text-based program. Retention rates will be defined by dividing the

number of SGM smokers who remained in the text-based cessation program and completed the 3- and 6-month assessments by the number of SGM smokers recruited. The recruitment and retention rates will be calculated along with confidence intervals (CIs) for specific arms and combined arms.

We will use t-test/Mann-Whitney or chi-squared/Fisher's exact test to compare baseline demographic variables between SGM smokers and those who refuse to participate or drop out from the study. Smoking abstinence outcomes will be defined as 7-day smoking abstinence along with negative saliva cotinine tests. Because abstinence is a binary variable (yes, no) the primary method of analysis will be a simple post-test analysis among SGM smokers with a generalized logistic mixed model, using a random intercept to incorporate the intra-subject correlation. Important covariates that will be used to adjust for potential baseline differences include age, level of education, biological sex, gender identity/sexual orientation, race/ethnicity, marital status, working status, years smoking, nicotine dependence, use of other tobacco products, and living with other household members who smoke. Odds ratio (OR) of smoking abstinence in the intervention group (SmokefreeSGM) relative to the control group (SmokefreeTXT) will be used to estimate effect size. Using logistic regression, abstinence will be regressed onto a dummy coded SmokefreeSGM vs. SmokefreeTXT group indicator, with the exponentiated coefficient of the group indicator yielding the OR.

Once the smoking cessation intervention concludes and in order to quantitatively assess engagement, a series of 32 individual interviews will be conducted with individuals previously enrolled in the feasibility trial. In this sense, the number of text messages a participant sends, including replies to the SmokefreeTXT and SmokefreeSGM programs and keywords used, will be totaled and averages will be calculated across participants. The total will not include use of the keyword STOP, which is used for unsubscribing from the program. The percentage of

participants who use this keyword will serve as an indicator of program disengagement. We will examine means and standard deviations of numbers of text messages over the course of the 6-month program in each arm. We will use t-test/Mann-Whitney to compare the average numbers of text messages between the two arms.

Qualitative data from each individual interview will be analyzed for assessing feasibility and acceptability. Audio recordings from the 1-month assessment and individual interviews will be transcribed. Data will be analyzed by the research team using a descriptive framework approach which will allow 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 throughout the study. Data analysis will be performed using computer software (ATLAS.ti or NVIVO).

ETHICS

This study involves no more than minimal risk to subjects. The risk of breach of confidentiality will be addressed by indicating to study participants that their involvement and data collected from them will be kept confidential to the extent of the law, and that while the findings of the study may be published, they will not be identified. Nevertheless, this study may benefit others since this work may contribute to a greater understanding of the 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 RECORDING KEEPING

Study participants will be assured that information collected will be kept confidential and that their name will not be used in presenting data in presentations and/or publications. All data collected through REDCap instruments will only be available to research team members who are knowledgeable of all human subjects' protection guidelines. Electronic datasets will be password protected on secure drives and only accessible to research team members.

QUALITY CONTROL AND ASSURANCE

Research team members involved in the study will be trained in human subjects' research and good clinical practice. Research team members will be available to answer any questions that the study participant may have via phone, email, or telehealth. Data collection instruments (e.g., screening forms) from each enrolled study participant will be checked to verify that inclusion and exclusion criteria have been respected.

PUBLICATION PLAN

The data collected from this study will help address the high prevalence of cigarette smoking and tobacco-related health disparities among SGM individuals. Additionally, our findings will help inform future text-based smoking cessation programs for SGM groups and other marginalized populations as well as contribute to the body of evidence for mHealth behavioral change interventions. At least one manuscript with findings from this randomized controlled trial is expected to be published in a peer-reviewed journal.

APPENDICES

- Appendix A: SmokefreeTXT and SmokefreeSGM text libraries
- Appendix B: Recruitment Flyers
- Appendix C: Screening Form Part A
- Appendix D: Informed Consent

- Appendix E: Screening Form Part B and Baseline Assessment
- Appendix F: 1-Month Assessment Form
- Appendix G: 3-Month Assessment Form
- Appendix H: 6-Month Assessment Form
- Appendix I: Semi-structured Interview Form

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