Protocol

A Digital Health Communication Intervention to Reduce Nicotine and Tobacco Use Among Young Adults (Our Health Matters): Protocol for a Pilot Randomized Controlled Trial

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Abstract

Background: Dual use of nicotine vapes and combustible cigarettes is high among lesbian, gay, bisexual, transgender, and queer (LGBTQ+) young adults (YAs). Culturally targeted health communications interventions delivered via mobile multimedia messaging (ie, MMS) may support engagement and influence behavior, but optimal message framing and intervention feasibility are underexplored.

Objective: This protocol describes the rationale and design of a pilot randomized controlled trial (RCT) examining the feasibility, acceptability, and preliminary effectiveness of an MMS-delivered, culturally targeted health communications intervention to reduce dual use among LGBTQ+ YAs and inform a phase III trial.

Methods: This study describes a 3-arm, parallel-group RCT. Participants (target: n=300; n=240 after 20% expected attrition) were US adults, aged 18-35 years old, self-identified as LGBTQ+, were fluent in English, reported ever use of nicotine vapes and combustible cigarettes, and current use of at least one product, owned a US carrier mobile phone with MMS capability, and had internet or Zoom (Zoom Communications) access. Participants were randomized to standard risk (messages emphasizing harms of both products), comparative risk (messages contrasting cigarette harms relative to vapes), or sun safety control conditions. They received condition-specific communications three times weekly for 6 weeks, plus weekly engagement prompts. We conducted baseline, 6-week, and 12-week surveys assessing nicotine and tobacco use, and behavioral antecedents. We randomly selected 40 participants for postintervention interviews at 6 weeks. Feasibility (recruitment, retention, and engagement) and acceptability of the intervention are primary outcomes. The primary exploratory effectiveness outcome is smoking and vaping cessation at 12 weeks. To evaluate feasibility and scalability, we will calculate basic descriptive analyses for comparison with prespecified thresholds. We will apply generalized linear models (GLMs; identity link) for acceptability outcomes at 6 weeks (message and effects perceptions, relevance, and reactance) and estimate preliminary descriptive effect sizes for the exploratory cessation outcome using relative risk. Qualitative data will contextualize quantitative outcomes. Exploratory analyses include GLMs (logit link) for 12-week smoking cessation. With 240 completers, the trial would have ~95% power to detect a 17-percentage point difference in quit rates between an experimental arm and control (assuming 8% control quit rate; Bonferroni corrected α=.025).

Results: The parent study, which included formative research, was funded by the National Cancer Institute in August 2021. Data collection occurred between September 2024 and February 2026. Of 295 eligible individuals, 292 were enrolled and randomized to standard risk (n=99), comparative risk (n=98), and sun safety control (n=95) arms. At baseline, participants were mostly aged 26-35 years (n=165, 56.5%), cisgender female (n=128, 43.8%), and bisexual+ (n=157, 53.8%). Data analyses began in March 2026.

Conclusions: This protocol describes an MMS-delivered, culturally targeted health communications intervention to reduce tobacco use among LGBTQ+ YAs who smoke and vape. Findings will provide critical data to inform a phase 3 RCT.

Trial Registration: ClinicalTrials.gov NCT06644664; https://clinicaltrials.gov/study/NCT06644664

International Registered Report Identifier (IRRID): DERR1-10.2196/99627

JMIR Res Protoc 2026;15:e99627; doi: 10.2196/99627

Keywords: electronic nicotine delivery systems; cigarettes; health communication; text messaging; sexual and gender minorities; LGBTQ; dual use; lesbian, gay, bisexual, transgender, and queer

Introduction

Background

Despite progress in tobacco regulation and intervention leading to declines in combustible tobacco use, use of novel tobacco products, particularly nicotine vapes (henceforth, "vapes" or "vaping"), is on the rise [1,2]. Among lesbian, gay, bisexual, transgender, and queer (LGBTQ+) young adults (YAs), dual nicotine and tobacco use (henceforth, "dual use"), defined as the use of commercial combustible cigarettes (henceforth, "cigarettes" or "smoking") and nicotine vapes, is alarmingly high, with 22%-40% reporting use compared with 12%-21% of non-LGBTQ+ YAs [3-6]. This higher prevalence raises concerns, as many people engaged in dual use eventually transition to exclusive cigarette smoking [7,8]. Furthermore, both LGBTQ+ individuals [9] and those engaged in dual use [10-14] often underestimate the health risks associated with nicotine and tobacco, reinforcing continued use.

While the United States Food and Drug Administration (FDA) is mandated to educate the public about nicotine and tobacco health risks, effective communication strategies for LGBTQ+ YAs remain underexplored [15,16]. Tobacco public education campaigns [17,18] including "This Free Life," which engaged LGBTQ+ populations [19-21], have demonstrated some impact; however, research has yet to establish whether culturally targeted tobacco health education messages (ie, those designed to align with the shared cultural values, beliefs, and behaviors of a specific group, rather than the general population) are more engaging than nontargeted approaches.

Communications research establishes 2 levels of cultural targeting for message development [22,23]. Surface level targeting adapts visuals and language to match observable population characteristics to increase initial attention and receptivity. Deep (structural) targeting integrates core cultural values and psychosocial factors that drive behavior change, supporting message salience over time. Theoretically, the message impact framework [24] posits that message attributes influence individual reactions sequentially, starting with attention and emotional or cognitive reactions, which influence downstream beliefs, intentions, and behavior. Applied to cultural targeting, health communications can only shape behavior if they successfully engage viewer attention (ie, through surface targeting) and elicit cognitive and/or emotional responses consistent with the message (ie, through deep targeting).

The extended parallel processing model (EPPM) complements the message impact framework by providing specific strategies for framing health messages to affect behavior [25] via 4 key variables—perceived susceptibility, perceived severity, response efficacy, and self-efficacy [26]. The model predicts that health communications that cause high perceived threat and high efficacy will result in action (ie, quitting and switching). Evidence supports these theorized mechanisms; a meta-analysis [27] demonstrated that high-threat health communications were more effective when they included efficacy statements (95% CI 0.31-0.55) than not (95% CI 0.13-0.29).

Precise message framing is critical for addressing dual use. Many existing campaigns focus on standard, mono-product risk communications (eg, "*cigarette smoking leads to lung cancer*") to prevent uptake in never or experimental users, which may not effectively engage LGBTQ+ YAs engaged in dual use [28,29]. In qualitative studies, LGBTQ+ YAs who smoke and vape express a desire for pragmatic and nonjudgmental health communications that share facts about noncombusted nicotine and combustible tobacco products [30,31]. Accordingly, for LGBTQ+ YAs engaged in dual use, and especially those not ready to quit nicotine entirely, interventions focused on harm reduction via cessation of combustible tobacco and exclusive use of noncombusted products may be required.

Comparative risk communications (eg, "*cigarettes contain more cancer-causing chemicals than vapes*"), recognize the distinct health risks of noncombusted and combusted nicotine and tobacco products. The FDA describes these differences along a "continuum of risk" such that noncombusted products confer lower health risks while combustible cigarettes confer greater health risks [32,33]. Comparative risk communications that contrast the health risks of cigarettes and vapes demonstrate promise for reducing adult smokers' intentions to use cigarettes [34] while increasing intentions to purchase

vapes [35] or switch to vaping [34-36], making them uniquely suited for LGBTQ+ YAs engaged in dual use [34,36,37].

While the effectiveness of health risk messages is well-established [38,39], less is known about how to effectively frame corresponding efficacy messages required by the EPPM. While both self-efficacy (ie, belief one can perform a behavior) and response efficacy (ie, belief that the recommended behavior is a solution for the threat) are critical for influencing behavior change, evidence indicates that response efficacy must be established first [40,41]. In the case of dual use, if a person does not believe that quitting smoking and switching exclusively to vaping will reduce health risks (low response efficacy), they will not consider whether they can switch (self-efficacy). In qualitative studies, adults who smoke [42] and LGBTQ+ YAs engaged in dual use [31,37] respond positively to harm reduction messages about switching completely to vaping [31]. For LGBTQ+ YAs engaged in dual use, response efficacy messages focused on cessation of combustible tobacco and harm reduction represent a novel opportunity for supporting behavior change.

Study Objectives

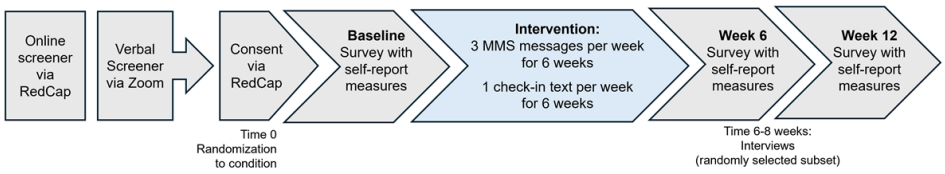
The protocol for this study was registered in ClinicalTrials.gov (NCT06644664) on October 15, 2024. Our goal is to investigate the optimal framing of health communications about nicotine vapes and cigarettes by integrating concepts from the message impact framework and EPPM to evaluate how exposure to standard and comparative risk and response efficacy messages can influence perceptions and reduce dual use. Through a multiarmed randomized control trial (RCT), we aim to (1) examine the feasibility of delivering health communications to LGBTQ+ YAs delivered via mobile multimedia messaging (MMS), and (2) estimate effect sizes of exposure to standard or comparative risk health communications delivered via MMS on tobacco use and risk perceptions over time.

Methods

Study Design

Our Health Matters is a phase 1/2, prospective, 3-arm, parallel-group RCT in which LGBTQ+ YAs who are susceptible to dual use of combustible cigarettes and nicotine vapes are randomized to a control group or 1 of 2 intervention groups for 6 weeks. The standard risk experimental group received health communications describing the shared health risks of vapes and cigarettes. The comparative risk experimental group received health communications describing the relative health risks of vapes compared to cigarettes. The control group received sun safety communications. The follow-up for the study period was 12 weeks, with assessments at baseline, 6 weeks, and 12 weeks. Figure 1 depicts the intervention flow.

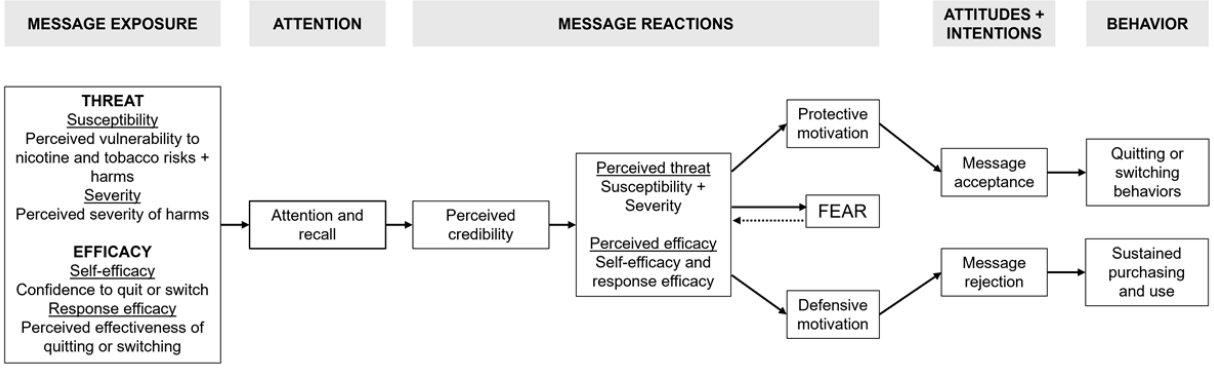
Figure 1. Flow diagram of intervention components.



Conceptual Model

A conceptual model based on the EPPM [43-45] and message impact framework [24] guides this intervention (Figure 2). Together they posit that, upon exposure to nicotine and tobacco health communications, a person proceeds through 3 steps—attention, reaction, and formation of attitudes and intentions. These steps determine whether a person engages in the behavior promoted in the message. The model predicts that messages which cause a high perceived threat and high efficacy will result in action (quitting all nicotine and tobacco, quitting smoking, and completely switching to vapes).

Figure 2. Conceptual model based on the extended parallel process model (1992) and message impact framework (2017).



Intervention Development

To develop culturally targeted, EPPM-informed health messages for this study, our team conducted formative research to establish the specific surface and deep targeting strategies, including risk and efficacy framing, that appeal to LGBTQ+ YAs who smoke and vape.

Initial Formative Work (Phase 1)

First, a mixed methods study including interviews, focus groups, and an online rating survey identified health messaging that resonated with LGBTQ+ YAs, including whether comparative messaging was acceptable to this population (ie, deep targeting) [37]. Findings suggested comparative messaging could be useful to lower dual-use intentions, although participants worried that some people might misinterpret comparative messages as promoting vaping as "risk-free." Notably, YAs responded positively to credible health harms that provided "novel" information, including those about cardiovascular disease risks.

Next, a focus group study identified strategies of LGBTQ+ cultural targeting used in advertising that LGBTQ+ YAs found engaging (ie, surface targeting) [46]. Overall, participants favored cultural targeting when they perceived it as "authentic" and without reductive LGBTQ+ stereotypes (eg, oversexualized, hypergroomed, monolithic, or White or Eurocentric models) and imagery (eg, rainbows, Pride parades, or parties).

Eye-Tracking Experiment (Phase 2)

Findings from phase 1 were applied to develop culturally targeted communications about smoking and vaping for experimental testing using eye-tracking [47]. After 1-week follow-up, LGBTQ+ YAs positively recalled culturally targeted imagery (ie, surface targeting) and content (ie, deep targeting) [47]. Critically, while visual attention to imagery was associated with increased perceived message relevance, visual attention to content about health risks of smoking and vaping was associated with effects perceptions (ie, perceived effectiveness of the message to influence smoking and vaping behavior) [47]. These findings support the message impact framework's structural pathways; surface cultural targeting is needed to elicit attention and positive reactions among LGBTQ+ YAs, but deep targeting (ie, values-aligned health risk messages) is critical for driving cognitive processing and influencing future behavior.

Stimuli Refinement (Phase 3)

We integrated empirical insights from phases 1 and 2 [37,46,47] to create the stimuli for this study. To ensure that content reflected current scientific evidence, the research team conducted weekly literature reviews on the harms of combustible cigarette smoking and vaping, as well as their comparative risks. Parallel literature reviews were conducted on UV radiation harms and sun-safety best practices.

We paired textual health messages for all conditions with licensed stock photos purchased from commercial databases (Shutterstock website, iStock website, and Canva website). Layouts were designed in Canva using standardized templates, which were systematically edited to highlight the target images and text. AI editing tools were used strictly for baseline photo modifications, such as extending or removing backgrounds from purchased stock images.

To align with established digital health frameworks, *Our Health Matters* leveraged automated SMS and MMS text-messaging, which has demonstrated consistent effectiveness for increasing smoking cessation [48-51]. Given that over 97% of YAs own a smartphone [52] and more than 75% use mobile devices to seek health information online and via social media [53], stimuli were optimized for MMS using integrated text and graphics to maximize user engagement. Text was assessed for readability using standard metrics (Flesch-Kincaid Grade Level, Flesch Reading Ease, and the SMOG Index; Multimedia Appendix 1). Grade level and SMOG scores were generally above recommended thresholds for public-facing health materials [54-56], reflecting the unavoidable use of polysyllabic terminology in tobacco risk communication (eg, nicotine, cigarettes, chemicals, dependence, and addiction). In contrast, reading ease scores were frequently at or above the recommended cutoff of 60, indicating that messages were written in short, direct sentences that reflect plain language standards. These findings suggest that messages may feel readable to audiences even when grade-level formulas classify them as more complex.

Stimuli were developed to fit a digital intervention architecture grounded in best practices for tobacco prevention and control. While evidence varies regarding the optimal intervention dose for SMS text message–based smoking cessation interventions [48,49,51,57-60], short-term digital campaigns (<3 months) [51] and fixed messaging schedules [48] appear more effective. With respect to message frequency, emerging evidence suggests that higher dose interventions (ie, multiple texts per day) do not improve abstinence rates at 6 months compared with lower dose interventions (eg, single text per day) [57,59].

Accordingly, our automated protocol applied a predetermined fixed message schedule; passive MMS delivered 3 times weekly (18 unique stimuli per condition) plus a 2-way SMS engagement prompt delivered once per week (6 unique prompts per condition). This dual component architecture satisfied 2 core digital health objectives. First, the 3-day passive delivery schedule optimized message dosing while reducing participant fatigue [57,59,60]. Second, the structured 2-way weekly engagement prompt enhanced participant retention and integrated participant self-monitoring, a behavior change technique associated with cessation effectiveness [59,61-63].

Once all stimuli were developed, they were evaluated by a scientific review panel (n=13) of LGBTQ+ community members, marketing and communication experts, and tobacco and LGBTQ+ health equity scientists. Through an online elicitation survey (Multimedia Appendix 2), the scientific review panel provided feedback on content (standard and comparative risk and efficacy statements), imagery (font, color, and photos), and layout. Panelists voted on the relative

effectiveness of each stimulus, allowing the research team to use highest-rated stimuli as templates to iteratively refine the lowest-rated stimuli. When panel feedback required clarification, members were contacted directly by the research team. Stimuli content, imagery, and layout were then adjusted by the research team. Scientific review panel members were given the option of receiving a US $20 online gift card for their contribution.

Study Setting and Eligibility Criteria

This study was conducted as a US-based, nationwide RCT. Study procedures—including recruitment, screening, consent, and data collection—were conducted remotely via secure, cloud-based technologies (Zoom [Zoom Communications], REDCap [Vanderbilt University], and Mosio). The study environment required participants to have a domestic US phone number linked to a cellular carrier capable of receiving MMS text messages, as the intervention was delivered through automated text messaging delivered to their personal mobile cellular devices.

Eligible individuals (1) were 18-35 years old, (2) spoke English fluently, (3) had ever used nicotine vapes and combustible cigarettes, (4) currently used at least 1 product, (5) self-identified as LGBTQ+, (6) resided in the United States, (7) had a mobile phone through a US carrier with MMS messaging and could send and receive SMS text messages for study participation, and (8) had access to the internet with Zoom capabilities. To ensure participants received MMS messages correctly and to prevent fraudulent activity, individuals were ineligible to participate if they used a landline or a Voice Over Internet Protocol (VOIP) phone number. We recruited most participants online via BuildClinical [64], a technology company that uses machine learning and data mining to identify specific and hard-to-reach participant groups (including LGBTQ+ YAs) across a multitude of platforms (eg, social media and health websites) and apply algorithms that lead participants to study enrollment platforms. Recruitment also occurred via word of mouth and former study participants who consented to being recontacted.

Procedures

Data collection occurred between September 2024 and February 2026. Potential participants recruited through BuildClinical completed a prescreener on BuildClinical's website. If found eligible in the prescreener, potential participants were routed to a screener in REDCap. Potential participants recruited through all other modes (eg, listserves and ResearchMatch) were directed immediately to the REDCap screener, which was reviewed by study staff to identify potentially eligible individuals.

To confirm eligibility and prevent fraudulent participation, research staff contacted eligible individuals to conduct a confirmatory verbal screener via Zoom. During the verbal screener, participants confirmed demographic information and showed a copy of photo identification (eg, driver's license, passport, or school or employee identification) to study staff for verification. Those confirmed eligible to participate were emailed a link to the consent form via REDCap.

Consented participants were randomized to either 1 of 2 experimental groups or the control group (refer to Randomization and Blinding section for details) and emailed a link to the baseline survey via REDCap. Upon completion of the baseline survey, participants began the intervention phase of the study. All text and MMS messages were sent directly to participants' devices using Mosio, a 2-way mobile messaging platform. Participants received MMS health communications specific to their condition 3 days per week for a total of 6 weeks (18 standard risk messages, 18 comparative risk messages, and 18 control [sun safety] messages; refer to Figures 3-5 for an example of an MMS health communication for each treatment group; refer to Multimedia Appendices 3-5 for all MMS health communications). To assess engagement and message effectiveness, participants received a weekly prompt via SMS (ie, text message). This 2-way prompt allowed participants to respond with a short message (eg, "Yes"), detailed response (ie, about how the messages they viewed that week influenced their attitudes or behavior), or tapback (ie, a quick, expressive reaction like a "thumbs up"). Refer to Multimedia Appendix 6 for the full texting schedule and engagement prompts. Participants were invited via REDCap to complete another survey at 6 weeks post baseline and a follow-up survey at 12 weeks post baseline.

Figure 3. Standard risk mobile multimedia messaging health communication.



Figure 4. Comparative risk mobile multimedia messaging health communication.



Figure 5. Sun safety mobile multimedia messaging health communication.



At 6 weeks post baseline, 40 participants were randomly selected (n=20 from each experimental treatment group) to participate in a qualitative interview. Interviews were approximately 30 minutes and assessed participants' unassisted recall of the MMS messages and their influence on quit intentions. Then, we assessed acceptability of culturally targeted messaging by presenting 6 randomly selected advertisements from their condition and asking participants to express their opinions of imagery and textual content. Refer to Multimedia Appendix 7 for the interview guide.

Randomization and Blinding

We randomized participants into 1 of the following 3 arms —experimental 1: standard risk messages (n=99), experimental 2: comparative risk messages (n=98), and control: sun safety messages (n=95). Standard risk messages described the shared health risks of cigarettes and vapes (eg, "cigarettes and vapes contain toxic chemicals that harm our bodies"), while comparative risk messages described the health risks of cigarettes in comparison to vapes (eg, "vapes aren't harmless, but they contain fewer toxic chemicals that harm our bodies").

The randomization schedule was created using the National Institutes of Health's Clinical Trial Randomization Tool [65] to apply asymptotic maximal randomization wherein the difference between any 2 arms never exceeded a maximum tolerated imbalance of 3. The predetermined randomization schedule was implemented via REDCap. Participants were blinded to their randomization category (standard risk, comparative risk, or control). The principal investigator (PI; JGP) and all team members except the research manager (ACE) and graduate research assistants (EJ and MS) were blinded to participants' assigned condition until all end point data was collected. No unblinding was planned or occurred during the trial.

Measures

Refer to Table 1 for all feasibility, acceptability, and exploratory effectiveness measures.

Table 1. Primary, secondary, and other outcome measures.

Outcome domains, types, and outcomes	Description	Time frame
Feasibility		
Primary		
Recruitment and retention	• Average number of participants randomized per month, screening-to-eligibility ratio, eligibility-to-randomization ratio. • Proportion of randomized participants who completed 12-week follow-up.	6 weeks post-baseline
Adherence to protocol	• Dose delivered: percentage of messages successfully sent via Mosio. • Dose received: percentage of messages successfully delivered to the participant's phone per the carrier network.	6 weeks post baseline
Engagement with intervention	6 items per study arm.	6 weeks post baseline

Outcome domains, types, and outcomes	Description	Time frame
	• Experimental arms 1 and 2: 6 Yes/No questions (1 per wk) checking for engagement with the study content, specifically regarding nicotine and tobacco use. • Control Group: 6 Yes/No questions (1 per wk) checking for engagement with the study content, specifically regarding sun safety.	
Secondary		
Interview qualitative assessment	• How did you find participating in a study with images sent via text message? How smoothly would you say it went?	6 weeks post baseline
Acceptability		
Primary		
Interview qualitative assessment	Qualitative interview questions included: • When you see this advertisement, what do you think? • What imagery do you like/not like? • What language do you like/not like? (see Multimedia Appendix 7 Interview Guide for all items)	6 weeks post-baseline
Secondary		
Survey qualitative assessment	Open-ended survey questions assessed unaided recall • What do you think was most memorable about the messaging on the advertisements? • What about the images or pictures that were in the advertisements, what was most memorable? • Have any of these advertisements made you quit, switch, or rethink your tobacco or nicotine use?	6 weeks post-baseline
Assisted recall	• Which of the following topics do you remember being included in the images you received as a part of this study? Please don't go back to look at the messages on your phone, we'd like to know which (if any) topics stuck out to you.	12 weeks post baseline
Effects perceptions	6 items on 5-point Likert Scale; 1=Strongly Disagree and 5=Strongly Agree • These messages discourage me from smoking cigarettes. • These messages make me concerned about the negative effects of smoking cigarettes. • These messages make smoking cigarettes seem unpleasant to me. • These messages discourage me from vaping nicotine. • These messages make me concerned about the negative effects of vaping nicotine. • These messages make vaping nicotine seem unpleasant to me.	6 weeks post-baseline
Other		
Reactance	3 items on 5-point Likert scale; 1=Strongly Disagree and 5=Strongly Agree. • These messages are trying to manipulate me. • These messages annoy me. • The health effects of these messages are overblown.	6 weeks post baseline
Message perceptions	6 items on 5-point Likert scale; 1=Not at all; 5=Very much • These messages … are worth remembering. grabbed my attention. are powerful. are convincing. are meaningful. are informative.	6 weeks post-baseline
Relevance	5 items on 5-point Likert scale; 1=Strongly Disagree and 5=Strongly Agree • These messages were… created just for me. created for people like me. relevant to me. of value to me. important to me.	6 weeks post-baseline
Preliminary effectiveness		
Primary		
Nicotine and tobacco cessation	2 items. Asks for current use of nicotine vapes and combustible cigarettes Every day, Some days, or Not at all. *Recoded to total cessation at 12-weeks post-baseline (Yes/No) defined for:* • Exclusive cigarette use at baseline*:* No current combustible cigarette use.	12-*weeks* post-baseline

Outcome domains, types, and outcomes	Description	Time frame
	• Exclusive vape use at baseline: No current vaping. • Dual use at baseline: No current use of either combustible cigarettes or vapes. • Participants who report abstinence from one product but use of the other will be classified as non-abstinent for the primary cessation outcome.	
Secondary		
Switching to exclusive vaping	• 2 items. Among those use cigarettes exclusively or dual use with vapes at baseline: Current use of nicotine vapes and combustible cigarettes: Every day, Some days, or Not at all.	6 and 12 weeks post-baseline
Behavioral intentions to quit	2 Items. 5 response options: Yes, within the next 30 days; Yes, within the next 6 months; Yes, within the next year; Yes, but not within the next year; No, not thinking of quitting. • Are you seriously thinking of quitting nicotine vapes? • Are you seriously thinking of quitting cigarettes?	Difference between baseline and at 6 and 12 weeks post baseline
Serious quit attempts	2 items. 5 response options: None; 1-2 times; 3-5 times; 6-10 times; More than 10 times • During the PAST 12 MONTHS, how many times have you stopped vaping nicotine for 1 day or longer because you were trying to quit? and • During the PAST 12 MONTHS, how many times have you stopped vaping nicotine for 1 day or longer because you were trying to quit?	Difference between baseline and at 6 and 12 weeks post-baseline
Self-efficacy (avoidance of vaping and smoking)	8 items on 5-point Likert scale; 0=Definitely will not and 4=Definitely will • How likely is it that, in the next 3 months, you will refrain from vaping nicotine… completely and permanently? when you get lonely? when you are with your friends who use them? when someone hands you a vape? • How likely is it that, in the next 3 months, you will refrain from smoking cigarettes… completely and permanently? when you get lonely? when you are with your friends who use them? When someone hands you a cigarette? • Definitely will not, Probably will not, Probably will, Definitely will	6 and 12 weeks post-baseline
Risk perceptions	2 items on a 5-point Likert scale where 1=Not at all harmful and 5=Extremely harmful. • How harmful do you think nicotine vapes, e-cigarettes, or other electronic products are to health? • How harmful do you think cigarettes are to health? • 1 item with 3 response options: Less harmful, About the same, More harmful. • Is using nicotine vapes, e-cigarettes or other electronic nicotine products less harmful, about the same, or more harmful than smoking cigarettes?	6 and 12 weeks postbaseline
Feelings about vaping and smoking	2 items. 7-point Likert Scale; 1=These messages made me feel much worse about vaping nicotine/smoking cigarettes and 7=These messages made me feel much better about vaping nicotine / smoking cigarettes. • Did these messages change how you feel about vaping nicotine? • Did these messages change how you feel about smoking combustible cigarettes?	6 weeks post-baseline

Feasibility Measures

Intervention feasibility was assessed with recruitment, enrollment, retention, delivery, and engagement statistics. Specifically, we tracked the number of individuals who completed screening, met eligibility criteria, and who were enrolled and randomized into the study. We assessed recruitment rates as the average number of participants randomized per month, enrollment rates as the proportion of eligible participants who completed informed consent, and retention as the proportion of randomized participants who completed 12-week follow-up. Consistent with the primary aim of this phase 1/2 trial, feasibility and scalability will be evaluated against a priori benchmarks. Systematic reviews of smoking cessation trials find considerable variation in feasibility metrics with enrollment rates ranging between 50% and 70% [66,67] and retention rates between 50% and 90% [66-68], with rates being lower when researchers did not have direct contact with potential participants during recruitment [66]. For this study, we will set thresholds at ≥60% enrollment and ≥70% retention at 12 weeks.

Adherence to protocol was operationalized as the dose delivered (ie, percentage of messages successfully sent), the dose received (ie, percentage of messages successfully delivered to the participant's phone per the carrier network), and percentage of participant responses to weekly SMS engagement texts. Read receipts are unavailable for MMS messages delivered through Mosio. For this study, we expect ≥80% message delivery fidelity and ≥60% engagement with weekly SMS prompts.

Among participants who were randomly selected for interviews at week 6, we assessed qualitative responses about intervention feasibility via the following interview questions: "How did you find participating in a study with images sent via text message? How smoothly would you say it went?"

Acceptability Measures

We assessed acceptability through the following message impact framework constructs: attention and recall (unassisted recall at 6 weeks post baseline; assisted recall at 12 weeks post baseline), perceived credibility (positive: message perceptions; negative: reactance), and attitudes (relevance and effects perceptions). All scales are summed and scored such that the higher score reflects a more favorable outcome with the exception of the reactance scale, for which lower scores reflect lower psychological reactance to the intervention. Follow-up interviews provided additional context by assessing participants' perceptions of thematic and visual content applied in experimental stimuli.

Exploratory Effectiveness Measures

Exploratory effectiveness outcomes of interest examine differences in nicotine and tobacco cessation, tailored to participants' baseline product use, as follows: (1) *Exclusive cigarette use at baseline*: no current combustible cigarette use, (2) *exclusive vape use at baseline*: no current vaping, and (3) *dual use at baseline*: no current use of either combustible cigarettes or vapes. Participants who reported abstinence from one product, but use of the other, were classified as nonabstinent for the primary cessation outcome. These effectiveness outcomes are exploratory and included to estimate preliminary effect sizes to inform the design of a future phase 3 trial.

Secondary exploratory outcomes measured at 6 and 12 weeks examine product-specific abstinence (eg, cigarette-only cessation, vape-only cessation), switching to exclusive vaping (yes or no), behavioral intentions to quit smoking or vaping (yes, within 6 months, or no), and serious quit attempts (difference in self-reported quit attempts between baseline and follow-up). Additional effectiveness outcomes include self-efficacy to avoid smoking and vaping, smoking and vaping risk perceptions, and feelings toward smoking and vaping.

Sociodemographic and Baseline Characteristics

We will collect standard demographic data (age, sexual orientation, gender, and race or ethnicity), tobacco use history (age of initiation, nicotine dependence, quit intentions, and quit attempts), substance use behaviors (alcohol use and marijuana use), and contextual factors associated with smoking and vaping among LGBTQ+ YAs [69,70] (discrimination experiences and perceived stress).

Statistical Methods

Feasibility and Acceptability

Quantitative Analysis

Baseline demographic variables will be summarized to describe the sample. Consistent with the primary aim of this phase 1/2 trial, feasibility and scalability outcomes will be evaluated against a priori progression criteria as follows: ≥60% retention at enrollment, ≥70% retention at 12 weeks, ≥80% message delivery fidelity, and ≥60% engagement with weekly SMS prompts. These thresholds will indicate whether the intervention is scalable for a phase 3 trial [71,72]. We will calculate descriptive statistics for all feasibility and acceptability measures, including frequency tables for categorical variables and means, SDs, and percentiles (25th, 50th, and 75th) for continuous variables. We will also use generalized linear models (GLMs) with an identity link to examine differences in acceptability measures between treatment groups (standard risk vs control, comparative risk vs control, and standard vs comparative risk) at 6-week follow-up. In cases where dropout (>10%), we will compare baseline characteristics between dropouts and complete cases and adjust models to account for sociodemographic differences.

Qualitative Analysis

We will conduct a reflexive thematic analysis following the framework by Braun and Clarke [73], incorporating a hybrid deductive-inductive coding approach, to evaluate feasibility and acceptability data from open-ended elicitation survey questions collected at 6 weeks from all participants and interview data from 40 participants randomly selected from the 2 experimental groups.

For interviews, Zoom-based audio recordings will be transcribed, reviewed, and deidentified by 2 members of the research team. Prior to commencing coding, we will develop an a priori codebook based on prior work on the acceptability of LGBTQ+ culturally targeted health communications [46,47]. Analysis will incorporate a hybrid, deductive-inductive approach. A senior researcher (ACE) and second coder will first independently code 5% of interview transcripts (n=2) using the a priori codebook to refine code definitions and identify emerging, data-driven codes. To ensure analytical rigor and enhance intercoder reliability, the 2 coders will then independently double-code a larger set of transcripts (~10%-15%; n=4-6). The coding team will meet weekly during this phase to resolve discrepancies via consensus-based discussion, with the PI (JGP) reconciling differences as needed. Once substantial agreement is reached (Cohen κ=0.61-0.80), the remaining transcripts will be randomly assigned to each coder for single coding. Coders will meet weekly to discuss and reconcile any questions during this period. The PI will meet with the coding team biweekly.

For open-ended elicitation survey questions, we will apply a hybrid deductive-inductive approach. We will begin with the same a priori codebook used for interview coding, allowing additional data-driven inductive codes to emerge. Two researchers will independently code a subset

of responses (~5%) to refine the codebook definitions and identify new codes. To ensure analytical rigor and enhance intercoder reliability, the 2 coders will systematically and independently double-code subsets of responses (~5%-10%). They will meet to resolve any coding discrepancies through collaborative consensus-based discussion. Unresolved discrepancies will be reconciled by a senior researcher (ACE), and the PI (JGP) will be queried if further interpretation is needed. Once substantial agreement is reached (Cohen $\varkappa$ 0.61-0.80), the remaining responses will be randomly assigned to the two coders for single coding. Coders will meet weekly with the senior researcher (ACE) to discuss and reconcile any questions. The PI will meet with the coding team biweekly.

We will apply criteria by Lincoln and Guba [74] to ensure rigor and trustworthiness, including credibility, dependability, and transferability. Credibility is supported through investigator triangulation that includes a coding team, a senior researcher, and the PI to offer multiple interpretive lenses. Dependability and confirmability are maintained through an audit trail, which includes an iterative codebook refinement phase, intercoder reliability testing, and weekly consensus-based reconciliation meetings.

To enhance credibility and confirmability, research team members will discuss their positionality, assumptions, and biases regarding LGBTQ+ health communications during weekly meetings. We will also leverage reflexive discussions to examine coding disagreements. For example, the coding team will consider whether disagreements stem from vague code definitions or the application of differing personal lenses to the data. This collective reflexive practice ensures that the final thematic framework is grounded in participant data rather than researchers' assumptions.

Data Triangulation

Qualitative data collected in this study captures the nuanced perceptions of participants who completed the 6-week survey elicitation questions, as well as a randomly selected subset of participants who were randomized to experimental groups and agreed to complete a follow-up interview. As qualitative inquiry, these descriptive findings are not intended for broad generalizability to all LGBTQ+ YAs. Instead, they offer conceptual generalizability and transferability, providing insights into the specific experiences of LGBTQ+ YAs susceptible to dual use of cigarettes and vapes.

To maximize the utility of these insights, we will use a triangulation protocol by Farmer et al [75] to integrate qualitative and quantitative findings describing intervention feasibility and acceptability. Following independent analysis of the qualitative and quantitative datasets, we will construct convergence matrices to systematically examine areas of convergence (ie, agreement), divergence (ie, disagreement), and silence (ie, content unique to 1 data source) between data sources. The PI (JGP) and senior researcher (ACE) will review triangulation findings and refine interpretations before they are shared with the PI's mentorship team (AKF, EGK, DM, MDS, and TW) for final synthesis.

Preliminary Effectiveness

Effectiveness outcomes are intended to estimate effect sizes that inform scalability and future trial design. Analyses will follow the intention-to-treat (ITT) principle, analyzing all randomized participants in the group to which they were initially assigned. This approach maintains the balance achieved by randomization [76] and provides an unbiased estimate of the treatment effectiveness. Consistent with early-phase cessation trials [77], missing outcome data for the primary exploratory outcome (total nicotine and tobacco cessation) will be handled by classifying participants with missing follow-up data as nonabstinent to include all randomized patients in the population set. A sensitivity per-protocol (PP) analysis will assess the robustness of findings. Participants will be excluded from the PP population if they did not receive the allocated intervention, if they experienced major protocol deviations, or did not complete the primary endpoint assessment.

Effect Size Estimation (Primary Effectiveness Outcome)

To support feasibility and scalability interpretation, we will estimate clinical effect sizes of the primary exploratory effectiveness outcome (self-reported nicotine or tobacco cessation at 12 weeks) using relative risk (RR). Because the study uses a 3-arm design, we will calculate independent RRs to contrast each experimental group against the control group (experimental 1 vs control and experimental 2 vs control).

$$RR = \frac{pExp}{pControl} = \frac{A/(A+B)}{C/(C+D)}$$

RRs will be calculated as the probability of cessation in the experimental group divided by the probability of cessation in the control group, where A and B represent participants in the experimental group who did and did not quit, respectively, and C and D represent participants in the control group who did and did not quit.

We will calculate 95% CIs using the SE of the log-transformed RR. RRs and corresponding CIs will be reported descriptively to provide context regarding preliminary intervention effectiveness and will not be used for formal hypothesis testing.

Exploratory Analyses of Primary Effectiveness Outcomes

GLMs using a logit link will be used to examine differences in total tobacco cessation (yes or no) between treatment groups (standard risk vs control, comparative risk vs control, and standard vs comparative risk) at 12-week follow-up. These models are exploratory and included to maintain fidelity to the prespecified National Cancer Institute–funded analysis plan.

Analysis of Secondary and Other Effectiveness Outcomes

Generalized linear multilevel models (GLMMs) will be fit for the repeated measures of tobacco risk perceptions, behavioral intentions, use, quit attempts, and self-efficacy to avoid future use across multiple visits. Fixed effects will account for condition and time (baseline, 6-week, and 12-week follow-up), and random effects will account for within-subject correlation. For all models, a logit link will be used for binary constructs, and an identity link will be used for linear constructs. In cases where dropout (>10%), we will compare baseline characteristics between dropouts and complete cases and adjust models to account for sociodemographic differences. These longitudinal models are exploratory and included to characterize patterns of change over time, consistent with the prespecified analysis plan. They are supplementary to, and do not replace, the primary feasibility and effect-size estimation objectives of this phase 1/2 trial.

Sample Size Justification

This phase 1/2 RCT will estimate key unknown parameters to inform a phase 3 RCT. Our primary feasibility objectives are to estimate recruitment, retention, fidelity, and engagement parameters to inform a phase 3 RCT. Cessation outcomes are exploratory and intended to provide preliminary estimates of effect sizes rather than to support definitive hypothesis testing. Prior studies of mobile-delivered health communications for cessation among single product users have evidenced 6%-20% absolute differences in quit rates [48-50]. Recommendations for phase 1 trials in which proportions are key outcomes suggest a sample size of 60-100 participants per group [78]. Assuming 20% attrition, enrollment of 300 participants (n=100/condition) is expected to yield 240 participants with complete follow-up data. Assuming an 8% control group quit rate and a Bonferroni-corrected type I error rate of 0.025, this sample size would provide approximately 95% power to detect a 17 percentage point difference in quit rates. These calculations are intended to contextualize the precision and operating characteristics of the proposed sample size and inform planning for a future phase 3 trial.

Ethical Considerations

Ethics Committee

The study was approved by the Ohio State University Institutional Review Board (IRB; 2021C0020; OSU-20427).

Consent Procedures

Once participant eligibility and interest were confirmed via REDCap and through the verbal eligibility screening, participants were sent a link to an electronic consent form administered via REDCap and encouraged to reach out with any further questions. After any questions were answered, participants were able to decline study participation or to provide their written informed consent, which was documented in REDCap. Participants automatically received a copy of the signed consent form via email. Once consented, participants were randomized to either one of two experimental groups or the control group using a pre-determined randomization model implemented within REDCap (see section on Randomization and Blinding).

Privacy and Confidentiality

Mosio

Mosio [79], a 2-way mobile messaging platform, was used for automated alerts, delivery of the MMS intervention, data collection, and 2-way texting. The web-based system allows researchers to use the Mosio dashboard while participants text from their mobile devices. Key functions included automated MMS delivery through storylines (3 times a week for 6 wk), weekly prompts (SMS single-question surveys), and shared links for informed consent and surveys via REDCap, all compliant with FDA 21 CFR Part 11.

Mosio is hosted by established vendors with documented security compliance verified through third-party audits, including HIPAA (Health Insurance Portability and Accountability Act). The platform uses industry best practices for data protection, including enterprise-level firewalls, virtual private networks (VPN), and intrusion detection systems. Data redundancy is ensured using HIPAA-eligible services in a geo-diverse location, with all production and backup data centers located within the United States.

Data Storage

To protect the privacy of study participants and to maintain data confidentiality, all datasets in this study were collected electronically in secure, password-protected, and encrypted servers. All survey data were securely stored in REDCap. To protect confidentiality, participants were assigned a personal identifier, which was maintained within REDCap. A limited number of IRB-approved research staff members have access to the full data sets in REDCap, and all data downloaded from REDCap are deidentified for participants' privacy. To disseminate the intervention, participants' identification numbers and phone numbers were stored in Mosio for automated MMS messages and weekly SMS prompts. Baseline, 6-week, and 12-week surveys were distributed via REDCap with survey links sent via Mosio. At the end of the study, all data stored in Mosio (eg, participant responses to SMS weekly prompts, records of successful MMS delivery per the carrier network) were deidentified and downloaded from Mosio and transferred to a secure, cloud-based server managed by The Ohio State University, which uses automated multi-factor authentication, network-level encryption, and restricted internal access permission.

Data Safety and Monitoring

The Ohio State University Comprehensive Cancer Center (OSUCCC) Data Safety Monitoring Committee (DSMC) oversees the study. The PI submits an annual summary report on the study's progress to the DSMC. No interim analyses or stopping guidelines were planned. During active data collection, investigators monitor participants for adverse events. No adverse events were recorded during data collection for this RCT and, thus, no protocol modifications or consent updates were needed due to adverse events.

Serious unanticipated events were not expected, and none occurred during active data collection. Generally, any serious unanticipated events are reviewed by the DSMC. Reportable serious adverse events must be reported within 48 hours to the IRB and relevant funding and regulatory agencies, along with a determination of their relation to the study. Adverse events exceeding expected frequency or severity must be reported to the National Cancer Institute (funding body).

The IRB conducts annual reviews of all open protocols, requiring investigators to report subject enrollment, adverse events, and findings affecting participant safety or trial ethics. Additionally, the PI provides an annual summary in progress reports to the National Cancer Institute. All data and safety monitoring complies with the OSUCCC's approved Data and Safety Monitoring Plan policies and procedures.

Participant Compensation

Participants received a US $30 online gift card for completing the baseline survey, a US $5 online gift card for each weekly SMS engagement text response (up to 6 texts total), a US $40 online gift card for completing the 6-week post-survey, and a US $50 online gift card for completing the 12-week follow-up survey. Participants who completed an interview received a US $50 online gift card. If selected for the interview, participants could receive up to US $200 for participation. Participants who were not selected for an interview could receive up to US $150.

Study Conditions

The primary objectives of this Phase 1/2 RCT were to evaluate the feasibility and scalability of *Our Health Matters* and test the effect of message framing (standard or comparative) on cessation and behavioral antecedents. Given the lack of proven effective, culturally targeted MMS interventions addressing dual use among LGBTQ+ YA, we chose an attention-matched, structurally equivalent, sun safety control group so that we could manage the time, format, and digital/human interaction afforded to participants, while still providing them with beneficial preventive health information. This design did not withhold standard care; participants in the sun-safety control group were not restricted from seeking standard tobacco cessation resources (such as national quitlines) during the study.

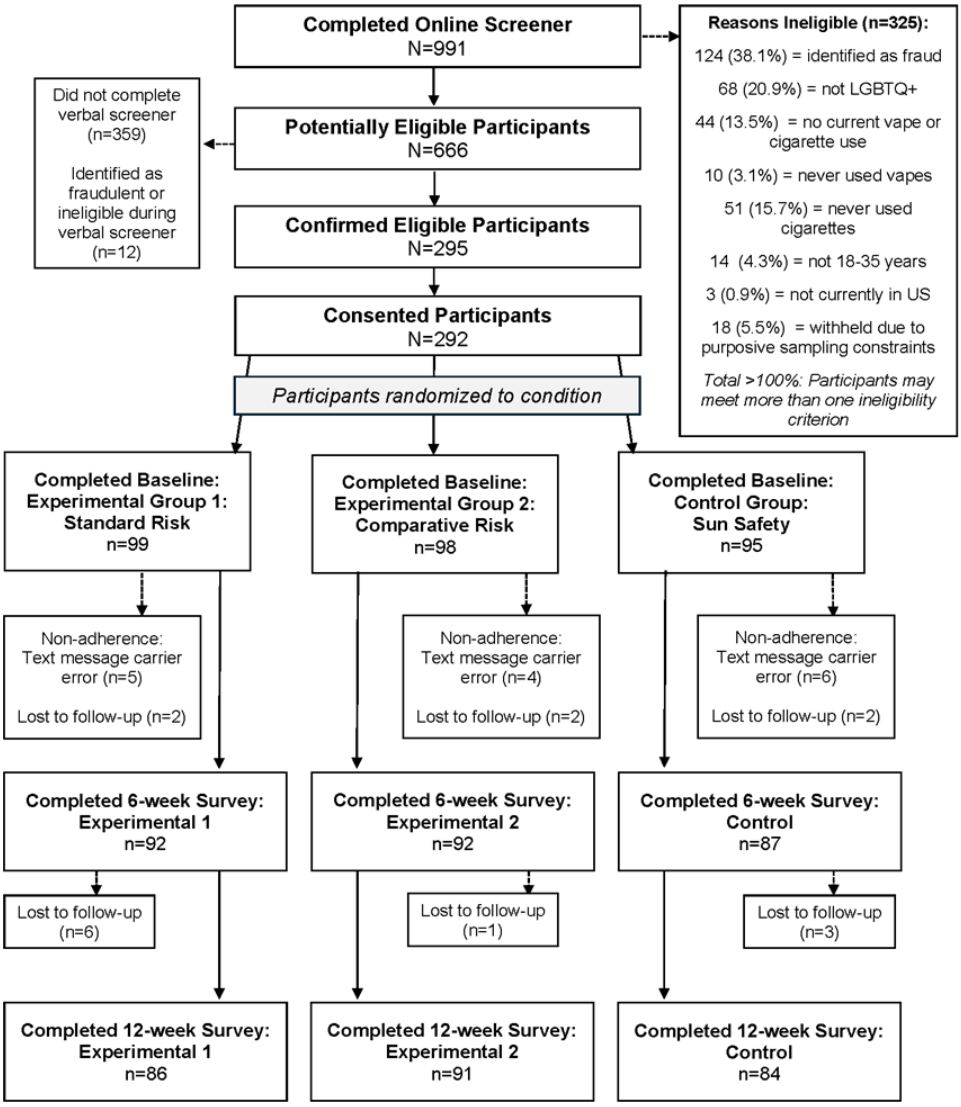
Dissemination

The study was registered with ClinicalTrials.gov (NCT06644664) and results will be made publicly available. The data that supports study findings are available from the corresponding author, JGP, upon reasonable request. We will disseminate the findings and accomplishments from this trial to the research community and the broader public through peer-reviewed publications and presentations at national conferences focused on tobacco control, public health, and medicine. Insights gained from this study may also inform the development of evidence-based standard and comparative risk communications for national public education campaigns.

Results

This study was funded in August 2021. Data collection began September 23, 2024 and ended February 2, 2026. See Figure 6 for the CONSORT (Consolidated Standards of Reporting Trials) flow diagram. A total of 991 individuals completed the online screener, of which 666 were invited to participate in a screening call via Zoom. Of 991, 295 were found to be eligible to participate after the screening call, and 292 participants consented to the study. Participants were evenly randomized into standard risk (n=99), comparative risk (n=98), and control (n=95) study arms. At baseline, 56.5% (n=165) were 26-35, 67.1% (n=196) identified as White, 12.3% (n=36) as Black, 3.8% (n=11) as Asian, 2.4% (n=7) as Native American or Alaska Native, and 15.7% (n=46) as Hispanic or Latinx. Regarding gender, 43.8% (n=128) identified as cisgender women, 20.9% (n=61) as cisgender men, 21.6% (n=63) as nonbinary or genderqueer, 8.9% (n=26) as transgender men, and 4.8% (n=14) as transgender women. Regarding sexual orientation, 53.8% (n=157) identified as bisexual or pansexual, 29.8% (n=87) identified as gay or lesbian, and 12.7% (n=37) identified as queer. Of all participants, 271 completed a postintervention survey (6 weeks after baseline), and 261 completed a 12-week follow-up survey. Analysis of primary outcomes will be conducted in 2026, with expected publication in 2027.

Figure 6. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. LGBTQ+: lesbian, gay, bisexual, transgender, and queer.



Discussion

Summary

Our research aims to reduce combustible tobacco use among LGBTQ+ YAs susceptible to dual cigarette and e-cigarette use. While prior studies [30,31] indicate that LGBTQ+ YAs are reluctant to quit all nicotine, they remain open to harm reduction behaviors. By testing a theory-based digital health communication intervention (*Our Health Matters*), this study advances research on optimization of health communications for high-risk LGBTQ+ populations [16,46,47,80,81] while collecting critical feasibility, acceptability, and preliminary effectiveness data. This randomized clinical trial uniquely integrates standard and comparative risk messages to understand how message framing influences dual use behaviors. Moreover, by building on iterative, mixed methods, and formative studies [46,47,82], this study bridges scientific rigor with user expertise to establish a foundation for scalable interventions tailored to LGBTQ+ young people engaged in dual use.

The delivery architecture of *Our Health Matters* was designed in response to extant evidence on methods for optimizing digital cessation interventions [48,49,51,57-60]. We applied a short-term (6-wk), structured message schedule with dosing limited to 3 passive MMS messages per week and one two-way engagement prompt. This structure also allowed us to standardize the frequency, timing, and dose of exposure across arms to reduce delivery-mode variance as a confounding variable and isolate the experimental message framing (comparative and standard risk vs control) as the primary mechanism of behavioral change. This approach also supports technological equity and scalability, as it relies on native mobile infrastructure available to most US YA [52] and does not require advanced digital literacy. However, our methods do not allow us to examine the effect of dosing on intervention feasibility, acceptability, or effectiveness. Future research is needed to test message architectures with differential dosing (messages per d/wk) and length (eg, 6 wk vs 12 wk; 6 wk plus a one-wk booster) to identify appropriate thresholds for participant engagement, message fatigue, and intervention effectiveness.

Future Research

The field of digital health is rapidly accelerating [83-85] from simple approaches, like *Our Health Matters*, to more complex personalized, multicomponent interventions. These advances raise opportunities for future adaptations; for example, leveraging geo-fencing or passive wearable sensing to deliver tailored health communications via just-in-time adaptive interventions (JITAI) in the exact moment of psychosocial risk or opportunity. Existing JITAI interventions demonstrate promise for increasing cessation success [86-88] and could theoretically be leveraged to support tobacco harm reduction behaviors.

Additionally, the expansion of generative AI has launched a new generation of digital cessation interventions [89-91] that integrate AI-driven chatbots to provide real-time, personalized, conversational smoking cessation guidance [92]. Early tests of large language model chatbots suggest that they vary widely in their adherence to evidence-based cessation guidance [93]. Across a test of 12 queries, each fielded to 3 chatbots, responses mostly recommended counseling (80%), social support (55.6%), and nicotine replacement therapy (52.7%) [93]. Critically, 22% of responses included misinformation, especially in response to queries about alternative quit methods (ie, not NRT) [93]. It is possible that integrating AI-driven bidirectional dialogue into *Our Health Matters* could increase participant engagement and effectiveness by tailoring messages to users' self-reported environmental, social, and psychological contexts. However, in emerging and highly nuanced public health domains—including tobacco harm reduction and comparative risk communication—generative AI models are susceptible to information hallucinations and data bias. Consequently, comprehensive training with strict guardrails and iterative validation would be needed to prevent harmful or inaccurate information.

Limitations

This study protocol is limited by the assessment of cigarette and vape use via self-report surveys. Integration of remote biochemical verification of smoking and abstinence may enhance rigor [94]; however, prior authors suggest caution given the risk for overburdening participants and introducing bias in remote trials [95-97]. To capture cessation, participants are followed for 6-weeks post intervention (ie, 12-wk post-baseline for this study); however, adding measures at 12-weeks post-intervention (ie, 18 wk post-baseline for this study) is recommended to assess sustained abstinence [98]. While we measure switching to exclusive vaping as a secondary outcome and indicator of harm reduction, we did not assess incremental reductions in cigarette or vape use (eg, cigarettes smoked per day). Future fully powered trials should include these secondary outcomes as critical indicators of harm reduction. Our study measures contextual factors associated with smoking and vaping among LGBTQ+ YA (discrimination experiences, perceived stress) [69,70]; however, in fully powered trials, more granular measurement of mental health issues commonly associated with tobacco use (eg, anxiety, depression) is critical for understanding potential moderators of intervention outcomes. Given that this intervention mimics exposure to health messages that participants may encounter via real-world digital mass-reach health communications, participants are not required to set a target quit date. As most meta-analyses assess sustained abstinence at 6 months post-target quit date [98], inclusion of this measure at baseline or post-intervention would facilitate comparisons with prior research. Future studies could also test how integrating a "quit or switch" date into *Our Health Matters'* baseline procedures and engagement prompts influences effectiveness. As this intervention is culturally targeted to LGBTQ+ populations, recruitment is limited to LGBTQ+ YA. Future research could broaden findings by including diverse stimuli to assess the impact of culturally inclusive, standard, and comparative risk health communications among YA generally. Despite these limitations, this study provides the first evidence of how digitally delivered standard and comparative risk messages affect dual use among a priority population, LGBTQ+ YA.

Conclusions

This Phase 1/2 RCT tests *Our Health Matters*, a digital health communication intervention, evaluating how standard and comparative risk message framing influences dual use behaviors. These findings will establish key parameters for a Phase 3 trial aimed at reducing dual use among LGBTQ+ YA. Ultimately, this research will guide scalable interventions to reduce dual use and its negative health consequences in the general young adult population, as well as adults who smoke.

Acknowledgments

We are grateful to all members of the Practice and Science for LGBTQ + Health Equity Collaborative (PI: JGP) who contributed to formative research that informed this study protocol, including (in alphabetical order): Elle Elson, Ashley Meadows, Maxwell Schoen, Sydney Galusha, Grace Turk.

Funding

Research reported in this publication was funded by the Office of The Director, National Institutes of Health (OD), National Cancer Institute (NCI) of the National Institutes of Health (NIH) and the US Food and Drug Administration (FDA) Center for Tobacco Products under Award Number K99CA260718 and R00CA260718 (PI: JGP). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration.

Data Availability

Data is available upon reasonable request from the corresponding author (JGP).

Authors' Contributions

JGP (lead), ACE, DM, EGK, MDS, TLW, and AF contributed to the study conception and design. JGP led funding acquisition and supervision of the research team. JGP (lead), ACE, EJ, and MS contributed to project administration. DM, EGK, MDS, TLW, and AF provided supervision (mentorship) to the PI (JGP). The first draft of the manuscript was written by WF and JGP, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Readability Metrics.
[DOCX File (Microsoft Word File), 76 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Expert Panel Survey.
[DOCX File (Microsoft Word File), 33 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Experimental Group 1: Standard Risk Messages.
[PDF File (Adobe File), 4405 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Experimental Group 2: Comparative Risk Messages.
[PDF File (Adobe File), 4527 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Control Group: Sun Safety Messages.
[PDF File (Adobe File), 11481 KB-Multimedia Appendix 5]

Multimedia Appendix 6

MMS Texting Schedule.
[DOCX File (Microsoft Word File), 36 KB-Multimedia Appendix 6]

Multimedia Appendix 7

Interview Guide.
[DOCX File (Microsoft Word File), 26 KB-Multimedia Appendix 7]

Checklist 1

SPIRIT Checklist.
[PDF File (Adobe File), 149 KB-Checklist 1]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
DSMC : Data Safety Monitoring Committee
EPPM: extended parallel processing model
FDA: US Food and Drug Administration
GLM: generalized linear model
GLMM: generalized linear multilevel model
HIPAA: Health Insurance Portability and Accountability Act
IRB: Institutional Review Board
ITT: intention-to-treat
JITAI: just-in-time adaptive intervention
LGBTQ+: lesbian, gay, bisexual, transgender, and queer
MMS: mobile multimedia messaging
OSUCCC: Ohio State University Comprehensive Cancer Center
PI : principal investigator
PP: per-protocol
RCT: Randomized control trial
RR: relative risk
SMOG: Simple Measure of Gobbledygook
VOIP: Voice Over Internet Protocol
VPN: virtual private network
YA: young adult

Edited by Amy Schwartz; peer-reviewed by Shweta Kulkarni, William Evans; submitted 27.Apr.2026; initial comments to author 03.Aug.2026; final revised version received 15.Sep.2026; accepted 23.Sep.2026; published 25.Nov.2026

Please cite as:
Patterson JG, Ennis AC, Figueroa W, Jankowski EE, Stanwick M, Mays D, Klein EG, Slater MD, Wagener TL, Ferketich AK
A Digital Health Communication Intervention to Reduce Nicotine and Tobacco Use Among Young Adults (Our Health Matters): Protocol for a Pilot Randomized Controlled Trial
JMIR Res Protoc 2026;15:e99627
URL: https://www.researchprotocols.org/2026/1/e99627
doi: 10.2196/99627

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