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Decídetexto: Mobile Cessation Support for Latino Smokers. Study Protocol for a Randomized Clinical Trial

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Abstract

Introduction: Latinos, the largest minority group in the U.S., experience tobacco-related disparities, including limited access to cessation resources. Evidence supports the efficacy of mobile interventions for smoking cessation, which may be greater among Latinos, the highest users of text messaging.

Objectives: To describe the methodology of a randomized clinical trial to evaluate the impact of *Decídetexto*, a culturally appropriate mobile smoking cessation intervention versus standard care on smoking abstinence (cotinine-verified 7-day point prevalence abstinence) at Month 6 among Latino smokers.

Methods: Latino smokers (N=618) will be randomized to one of two conditions: 1) *Decídetexto* or 2) standard of care. *Decídetexto* is a mobile smoking cessation intervention (available in English and Spanish) that incorporates 3 integrated components: 1) a tablet-based software that collects smoking-related information to develop an individualized quit plan, 2) a 24-week text messaging counseling program with interactive capabilities, and 3) pharmacotherapy support.

CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Decídetexto follows the Social Cognitive Theory as theoretical framework. Standard of care consists of printed smoking cessation materials along with referral to telephone quitline. Participants in both groups are given access to free pharmacotherapy (nicotine patches or gum) by calling study phone number. *Promotores de Salud* will rely on community-based approaches and clinical settings to recruit smokers into the study. All participants will complete follow-up assessments at Week 12 and Month 6.

Discussion: If successful, *Decídetexto* will be ready to be implemented in different community- and clinic-based settings to reduce tobacco-related disparities.

INTRODUCTION

Tobacco use remains the leading preventable cause of disease and death among Latinos, contributing to cancer, heart and lung disease, and stroke [1]. Latinos, the largest minority group in the U.S. [2], account for 17.4% of the current U.S. population and are projected to grow approximately 30% by 2060 [3]. Of the approximately 55 million Latinos that reside in the U.S. [2], over 6 million (11.2%) are current smokers [4]. Latinos are a heterogeneous population, with diversity related to many factors (e.g., country of origin, years living in the U.S., socioeconomic and immigration status, acculturation stressors, language, and cultural values) [5]. The majority of Latinos experience multiple barriers to healthcare access and treatment that result in tobacco-related disparities. Compared to non-Latino Blacks and Whites, Latinos are less likely to receive advice to quit, participate in smoking cessation programs, and use pharmacotherapy or smoking cessation quitlines [6–11]. Specific barriers in accessing smoking cessation resources include language, literacy, lack of trust in the health care system, and lacking knowledge of smoking cessation resources. Latinos also report a general lack of cultural sensitivity within existing Spanish-language resources [12–13]. Moreover, Latinos hold a number of misconceptions about smoking and smoking cessation, viewing smoking as a weakness rather than an addiction [13]. Some of these misconceptions may contribute to lower use of and adherence to pharmacotherapy and counseling to support a quit attempt. These findings highlight the need for specialized smoking cessation interventions for Latinos that provide skills-based counseling and encourage pharmacotherapy use in a manner that is culturally appropriate and fosters their engagement and trust. Although barriers to accessing smoking cessation resources exist, when provided with access, Latinos are interested in participating in smoking cessation programs and in using smoking cessation treatments to support quit attempts [10–11, 14–17]. One low-cost avenue with high reach for assisting Latino smokers is through mobile health interventions [18–19]. Studies have shown the effectiveness of smoking cessation interventions delivered via text messaging [20–21]. Developments in the sophistication of mobile technologies allow for flexible delivery of messages, with algorithms used to tailor content to individual motivational and behavioral needs for smoking cessation [21]. Furthermore, the potential for text messages to deliver smoking cessation treatment may be even greater among hard-to-reach, socioeconomically disadvantaged, and uninsured populations, such as Latinos [21]. However, implementation of mobile interventions among Latinos remains minimal despite the fact that Latinos are the highest users of text messaging technology [22]. Pilot studies that assessed the feasibility and acceptability of text messages for smoking cessation among Latinos resulted in high satisfaction, high text messaging

interactivity, high therapeutic alliance, and noteworthy cessation rates [16–17]. Given the promise of mobile interventions for smoking cessation among Latinos, there is a need to rigorously examine culturally and linguistically appropriate interventions designed for Latino smokers. This paper describes methodology of a randomized clinical trial to evaluate the impact of *Decídetexto*, a culturally appropriate mobile smoking cessation intervention versus standard care on smoking abstinence (cotinine-verified 7-day point prevalence abstinence) at Month 6 among Latino smokers.

METHODS

Study design.

This study is a randomized clinical trial (RCT) with a heterogeneous sample of 618 Latino smokers. Participants will be randomized to one of two conditions: 1) *Decídetexto*, a culturally appropriate mobile smoking cessation intervention, or 2) standard care (printed smoking cessation materials along with referral to telephone quitline). Participants in both groups will be given access to free pharmacotherapy (nicotine patches or gum) for up to 10 weeks, as recommended by clinical practice guidelines [23]. All participants will complete follow-up assessments at Week 12 and Month 6. The primary outcome will be cotinine-verified 7-day point prevalence abstinence at Month 6. We will also assess potential mediators (e.g., therapeutic alliance, pharmacotherapy utilization, and self-efficacy) of the presumed treatment effect. The study design and implementation were informed in collaboration with a Community Advisory Board. Study procedures were approved and monitored by Hackensack University Medical Center, University of Rochester Medical Center, and The University of Kansas Medical Center Institutional Review Boards.

Recruitment.

Recruitment will be led by multicultural and bilingual (English and Spanish) *Promotores de Salud* (Community Health Workers) using community-based approaches and clinical settings. Community-based methods include 1) advertisements via flyers, radio, television, church bulletins, and newspapers, 2) tabling at community-based organizations, school events, festivals, and health fairs, and 3) referrals from community-based organizations (CBOs). Financial incentives will be provided to CBOs that make a request. Clinic-based methods include contacting (calling and texting) Latino smokers from hospital patient registries to invite them to participate in the study and partnering with safety net clinics to refer Latino smokers to the study. Recruitment sites include Hackensack University Medical Center (New Jersey), The University of Rochester Medical Center (New York), and The University of Kansas Medical Center (Kansas).

Screening.

Eligibility assessment will be conducted by telephone or in-person. Trained research staff will provide individuals with detailed information about the study and offer screening for eligibility. Eligibility assessment will be conducted in the individual’s language of preference, either English or Spanish.

Participant Eligibility.

Eligible individuals will 1) self-identify as Hispanic or Latino, 2) know how to read and speak English and/or Spanish, 3) are at least 21 years old, 4) have smoked cigarettes for at least six months, 5) smoke cigarettes three or more days within a typical week, 6) report interest in quitting smoking in the next 30 days, 7) have an active cellphone with unlimited text messaging capability, 8) know how to send and read text messages, and 9) be willing to complete two study visits (at the beginning and 6 months) and at least one phone call between the visits (to complete the Week 12 assessment). Exclusion criteria include: 1) use of other tobacco products more than one day within a typical week, 2) current participation in any other smoking cessation program or use of any type of medication to quit smoking, 3) having a household member participating in the study, 4) being pregnant, breast-feeding, or planning to become pregnant in the next year, and 5) planning to move out of current residential address in the upcoming six months.

Consent and Enrollment.

Individuals who are eligible to participate in the study will be scheduled for an in-person appointment for enrollment. During the in-person appointment, research staff will guide eligible participants through the process of written informed consent, where they will discuss all aspects of study participation and confidentiality, and answer any questions. Individuals will be informed that they are free to decline study participation and end program participation at any time without negative consequences. After informed consent is completed, a baseline assessment will be conducted. Both the consent and baseline assessment will be conducted in the participant's language of preference.

Randomization.

After completion of the baseline assessment, participants will be randomly assigned 1:1 using computer-generated permuted blocks (block size of four) to either the *Decídetexto* intervention or Standard Care (control). Randomization will be stratified by site (Hackensack University Medical Center, The University of Rochester Medical Center, and The University of Kansas Medical Center). Study staff will provide each participant with the appropriate intervention right after randomization. Neither the participant nor study staff will know in advance the group assignment of each participant.

Intervention.

DECÍDETEXTO.—*Decídetexto* is a smoking cessation mobile intervention that encompasses three integrated components: 1) a tablet-based software that collects smoking-related information to support the development of an individualized smoking cessation quit plan and guides the ensuing text messages program; 2) a 24-week text messaging counseling program with interactive capabilities; and 3) pharmacotherapy support.

Decídetexto tablet-based software.

The tablet-based decision support tool was designed to help smokers create an individualized smoking cessation quit plan and to collect data that will tailor the text messages delivered over the ensuing 24 weeks. This tool was adapted from two smoking

cessation web-based, informed decision-making tools for Latinos in the United States [24], Mexico [25–26], and Brazil [27]. The tablet-based tool, available in English and Spanish, consists of interactive features that lead smokers through various steps in the quitting process. The tool includes a testimony from an ex-smoker and features short video clips and narrated graphics on the benefits of quitting while also describing how pharmacotherapy (NRT: nicotine replacement therapy) can support abstinence. The tool also collects participant smoking-related information, including number of cigarettes smoked per day, primary reason to quit smoking, top two smoking triggers and one strategy to manage each trigger. At the end of the 10- to 15-min tablet-based session, participants are prompted to request pharmacotherapy (nicotine patches or gum) and to select a quit date within a 30-day timeframe. Upon completion of the tool, participants are provided with a 1-page summary print-out of their individualized smoking cessation quit plan (e.g., the selected quit date and pharmacotherapy with the recommended dose and regimen). Participants will then automatically begin receiving the text messaging portion of the intervention.

Decídetexto Text Messaging

Development of the text messaging library was informed by Social Cognitive Theory [28]. Following the Cultural Accommodation Model [29], text message development was informed by literature reviews, feedback from key stakeholders and certified tobacco treatment specialists, focus groups with Latino smokers and ex-smokers, and results from pilot studies with Latino smokers [16–17]. Each message was developed in English and Spanish and was reduced to 140 characters and refined by a multidisciplinary Community Advisory Board (CAB), where each member represented different Latin American countries to ensure the cultural and linguistic congruency of each message. Readability scores averaged 3.9 (4th grade level) in English, and 77.4 (easy/very easy) in Spanish using the Flesch–Kincaid and Fernandez-Huerta tests for English and Spanish, respectively [30–32]. The text messaging intervention allows three levels of interactivity: 1) prescheduled standard messages, 2) keyword-triggered standard messages, and 3) counselor-personalized responses.

Prescheduled Standard Messages.—The text messaging library consists of 712 messages covering 10 themes: education, logistics, intra-treatment social support, coping with triggers, extra treatment social support, stimulus control, vicarious experience, relapse prevention, social norms, and reward. The text messaging system delivers these messages according to an algorithm based on fours sequential phases of the quitting process that support the personalized quit plan: 1) Pre-quit (30 days), 2) Quit-Day, 3) Post-quit Intensive (28 days), and 4) Post-quit Maintenance (20 weeks). The library also includes a Relapse track (8 days).

Keyword-Triggered Standard Messages.—These messages consist of automated immediate responses sent to participants who text one of the following keywords: 1) Stress, 2) Crave, 3) Family, 4) Patch and 5) Gum. In addition, throughout the 24-week program, participants will receive 11 response-triggered (YES or NO) messages to assess their smoking status (e.g., Have you smoked a cigarette (even a puff) in the last 7 days? Text YES or NO). If participants indicate that they are smoking, these automated messages encourage

them to select a new quit date. Participants can withdraw from the text message program at any moment by texting the keyword “Stop” (e.g., If you would ever like to stop receiving these messages, you can text STOP. However, we would prefer that you stay with us!).

Personalized Responses.—Taking advantage of the technological capability to recognize free texting (non-keyword) from participants, *Decídetexto* encourages participants to text any concerns, and/or questions to the program (e.g., on Day 1 of the text messaging intervention, participants will receive the following message: “Hi, I am Francisco, your counselor. Feel free to text me anytime - I am here to help you Monday through Friday from 8 AM to 6 PM. When you text me, I will reply as soon as possible”). Trained tobacco treatment specialists will answer these messages following standard protocols (e.g., answering questions on pharmacotherapy delivery, use, adherence, and side effects). The tobacco treatment specialists will monitor and triage queries daily, responding within 48 hours of receipt of text messages.

Pharmacotherapy: Nicotine Replacement Therapy

Given the limited access to primary care for many Latinos, non-prescription NRT increases the feasibility and reach of dissemination of treatment. Moreover, use of NRT was endorsed by the CAB due to issues of cost and access. The choice of pharmacotherapy follows the Clinical Practice Guidelines for Treatment of Tobacco Use [23]. NRT (nicotine patches or gum) will be offered to participants at no cost. Participants who smoke more than 10 cigarettes per day (CPD) will be offered 10 weeks of nicotine patches (21 mg nicotine patches to be used during the first 6 weeks, followed by 14 mg nicotine patches for 2 weeks, and 7 mg patches for the last 2 weeks). Participants who smoke between 6 and 10 CPD will be offered 8 weeks of nicotine patches (14 mg nicotine patches to be used during the first 6 weeks, followed by 7 mg patches for the last 2 weeks) or gum (2 mg nicotine gum). Participants who smoke 5 or less CPD will be offered 6 weeks of nicotine patches (7 mg nicotine patches) or gum (2 mg nicotine gum). Fruit chill, cinnamon, and mint flavored gum will be available. NRT will be provided in two phases. The first time a participant requests NRT, they will receive a 4-week supply via post mail. The second time a participant requests NRT refill, they will receive a 6-, 4-, or 2-week supply via post mail based on their baseline number of cigarettes per day. This approach is similar to some quitline programs in the U.S. and Canada [33–36]. Participants are prompted to start using their nicotine patches on their selected quit date.

Educational material

The educational material is a high quality printed 12-page booklet, available in English and Spanish, that was culturally and linguistically adapted in concert with the CAB. The educational material includes information about the health risks of smoking, short- and long-term health benefits of quitting, and reasons and strategies for quitting. Moreover, the educational material describes how NRT can support abstinence. Additionally, the educational material explains how to access NRT at no cost via a toll-free study number. Furthermore, the educational material explains how to avoid side effects associated with NRT and indicates to participants how to contact the study team to report and/or troubleshoot any potential side effects. Lastly, the educational material includes the national

quitline phone number for counseling. All participants are encouraged to use the quitline services.

STANDARD CARE.

In this study, Standard Care consists of the smoking cessation educational material described above and access to NRT via the study phone number provided within the educational materials. The choice of pharmacotherapy and delivery of NRT will be the same as the intervention group by calling study number. While we recognize this “Standard Care” control condition is beyond “usual care” for the majority of Latinos, the purpose of this control group is to provide a plausible alternative to our treatment condition that meets ethical standards of care by providing access/referral to quitline counseling and NRT.

Measures.

Week 12 and Month 6 Assessments.—Participants will be contacted at Week 12 and Month 6 following enrollment to complete a survey. The Week 12 survey will be conducted over the phone and the Month 6 survey will be conducted in person. A full list of the measures by time point is provided in Table 1.

Sociodemographics.—Baseline sociodemographic measures include participant age, gender, race, highest level of education, employment status, number of household members, number of children <18 years old in household, income and health insurance.

Overall health.—Baseline overall health measures include time of last routine checkup, comorbidities [diabetes, hypertension, high cholesterol levels, stroke (ischemic or hemorrhage), chronic lung disease such as asthma, emphysema, or chronic bronchitis, heart disease, cancer, depression, HIV/AIDS, etc.], depressed mood and anhedonia (measured by PHQ-2: Patient Health Questionnaire-2 [37]), generalized anxiety disorder (measured by GAD-2: Generalized Anxiety Disorder-2 (38)], and alcohol problem use (measured by AUDIT-C: The Alcohol Use Disorders Identification Test Consumption (39)].

Use of technology.—Baseline technology measures include cellphone carrier, type of mobile plan (prepaid, monthly contract, or long-term contract), cellphone’s capability to use Internet, type of mobile plan to access the Internet (limited or unlimited data), whether the participant share their cellphone with some else, and number of hours each day the participant has their cellphone with them. Specific questions related to the use of text messages include 1) number of text messages the participant send and receive daily, 2) if the participants has ever signed up to receive text message reminders for services (e.g., utilities, banking, health, education, news, smoking cessation, etc.), and 3) if the participant has concerns about privacy, SPAM, or receiving too many text messages when using text messages. Specific questions related to the use of cellphone’s Internet include whether participants use it for utilities, banking services, email, social media (e.g., Facebook, Twitter, Instagram, Snapchat, etc.), internet texting (e.g., WhatsApp, iMessage, Viber, etc.), buying things (e.g., Amazon, eBay, etc.), video calls (e.g., Skype, FaceTime, WhatsApp, etc.), playing games, and search health information. Moreover, participants are asked to list the three apps they use most frequently.

Smoking history.—Baseline assessment of smoking history includes the Timeline Follow-Back Instrument (TLFB, which quantifies days smoked in last 30 and number of cigarettes on days smoked [40]), Heaviness of Smoking Index (HSI, measured by number of cigarettes per day and time to first cigarette of the day [41]), Severity of Dependence Scale (SDS, a brief questionnaire used to assess psychological aspects of dependence [42]), age when started smoking regularly, type of cigarette smoked (menthol versus nonmenthol), preferred cigarette brand, use of flavored cigarettes, use of other tobacco products, and use of e-cigarettes.

Quitting history.—Baseline assessment of quitting history includes number of 24 hour quit attempts in the past 12 months. Follow-up assessments (Week 12 and Month 6) of quitting history include number of 24 hour quit attempts since the last study visit. Self-reported use of pharmacotherapy (e.g., nicotine patch, nicotine gum, nicotine lozenge, nicotine nasal spray, nicotine inhaler, Varenicline, and Bupropion) and resources (e.g., quitline, text messaging program, smartphone applications, websites, and healthcare providers) to quit smoking are assessed at Baseline and Follow-up visits.

Social influences on smoking.—Baseline assessment of social influences on smoking includes the number of five closest friends or family members who smoke, number of smokers in the home, partner smoking status, smoking rules at home [1) No one is allowed to smoke anywhere, 2) smoking is allowed in some places or at certain times, or 3) smoking is permitted anywhere; there are no rules] [43], and smoking rules at work [1) I do not work outside the home, 2) smoking is not allowed in any work areas, 3) smoking is allowed in some work areas, or 4) smoking is allowed in all work areas] [44].

Self-efficacy.—The Smoking Self-efficacy Questionnaire (SEQ-12) is a questionnaire measuring the confidence of current and former smokers in their ability to abstain from smoking in high-risk situations. The SEQ-12 consists of 12 items, and each item is rated on a 5-point Likert scale (1= Not at all sure, 2= not very sure, 3= more or less sure, 4= fairly sure, and 5= absolutely sure) [45]. Self-efficacy is assessed at Baseline and Follow-up visits (Week 12 and Month 6).

Therapeutic alliance.—The Working Alliance Inventory – Short Version (WAI-S) is a questionnaire measuring three key aspects of the therapeutic alliance: 1) agreement on the tasks of therapy, 2) agreement on the goals of therapy, and 3) development of an affective bond. The WAI-S consists of 12 items, and each item is rated on a 7-point Likert scale (1 = never, 2= rarely, 3= occasionally, 4= sometimes, 5= often, 6= very often, and 7= always) [46–47]. Therapeutic alliance is assessed at Week 12 and Month 6.

Social support.—The Partner Interaction Questionnaire (PIQ) is the most commonly used measure of spouse/partner support related to cessation [48]. We administer the modified version of the PIQ that measures the receipt of specific behaviors from the person who follows a participant's efforts to quit smoking most closely, not just a spouse/partner [49]. The modified version uses a 5-point Likert scale to assess how frequently the participant's support person exhibited positive and negative behaviors. Positive items include "express pleasure at your efforts to quit," "congratulate you for your decision to quit smoking," and

"express confidence in your ability to quit/remain quit." Negative items include "mention being bothered by smoke," "ask you to quit smoking," and "criticize your smoking." Response options are 0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, and 4 = very often. Social support is assessed at Month 6.

Acculturation.—Acculturation measures include country of birth, years living in the U.S., immigrant generation, and language of preference. For immigrant generation, "1st generation" refers to people who were born in their native country and emigrated to one of the 50 U.S. states. The "2nd generation" refers to the U.S.-born children of 1st generation immigrants. Acculturation measures are collected at baseline.

Hispanic stress inventory.—The Hispanic Stress Inventory Version 2 (HSI-2) is a questionnaire measuring psychosocial stress determined by demographic and political shifts affecting Latin American immigrants and later-generation Hispanics in the U.S [50]. The HIS-2 consists of 10 factors: 1) parental stress, 2) occupation and economic stress, 3) marital stress, 4) discrimination stress, 5) immigration-related stress, 6) marital acculturation gap stress, 7) health stress, 8) language-related stress, 9) pre-migration stress, and 10) family-related stress. For each item, participants indicate whether they had experienced the stressor (Yes or no) in the past 12 months. If participants report experiencing a stressor, then they rated how stressful the event was on a 5-point Likert scale (1= not at all worried/tense, 2= a little worried/tense, 3= moderately worried/tense, 4= very worried/tense, or 5= extremely worried/tense). The HSI-2 is assessed at Baseline.

Food insecurity.—The United States Department of Agriculture defines food insecurity as a household-level economic and social condition of limited or uncertain access to adequate food [51]. The Food Insecurity Screener is a two-item screener that ask two questions: 1) "We worried whether our food would run out before we got money to buy more" and 2) "The food that we bought just didn't last, and we didn't have money to get more". For each statement, participants respond whether the statement was often true, sometimes true, or never true for their household in the last 12 months. Food insecurity is assessed at Baseline.

Clinical trial awareness.—Clinical trial awareness measures include if participants have previously participated in a clinical trial, if they would consider participating in another clinical trial, and if we could contact them to see if they are interested in participating in another study.

Anthropometrics and biomarkers.—Exhaled carbon monoxide (CO) levels, height, and weight are measured at Baseline and Month 6.

Smoking abstinence.—The primary endpoint is cotinine-verified 7-day point prevalence smoking abstinence, defined as no cigarettes for the previous 7 days, at Month 6. The recommended cut-off of 15ng/ml for salivary cotinine will be used to differentiate smokers from non-smokers [52–53]. The secondary endpoint is self-reported 7-day point prevalence smoking abstinence at Week 12.

Retention and reimbursement.

Study staff will contact participants one week prior to each study visit via phone, text, and postcards. Participants will be given a $30 gift card at Baseline (Week 0), a $20 gift card at Week 12, and a $50 gift card at Month 6 in appreciation for their time and participation. Remuneration will not be based on smoking status.

Implementation fidelity.

All research staff will be trained by the Principal Investigator and Study Coordinator. The training will focus on recruitment, conducting study assessments, data entry, and data tracking. Moreover, the Principal Investigator and Study Coordinator will have weekly phone meetings with all study sites to ensure adherence to the study protocol, discuss participant accrual rates, and brainstorm methods to maximize enrollment and minimize attrition. Furthermore, tobacco treatment specialists managing the text messaging intervention will participate in weekly supervision meetings led by clinical psychologists with expertise in smoking cessation.

Coronavirus disease 2019 (COVID-19).

On March 11, 2020, the World Health Organization recognized the spread of COVID-19 as a pandemic [62]. In order to reduce the spread of COVID-19, study enrollment after March 11, 2020 will be completed in person practicing social distance guidelines (the study team and participant will stay at least six feet away from each other) and using personal protective equipment. Moreover, eligible smokers will only be scheduled for their baseline visit if they self-report they have not been exposed to COVID-19 in the last 14 days and show no signs of COVID-19 symptoms (e.g., fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea). Follow-up assessments (Week 12 and Month 6) will be completed over the phone. Participants who self-report cessation at Month 6 will be requested to provide the salivary sample via post mail for cotinine assessment.

Data analysis.

We will calculate frequencies for categorical variables and means and standard deviations for continuous variables. T-test will be used to examine difference between continuous outcomes. We will compare the cotinine verified 7-day point prevalence abstinence rates at Month 6 between *Decídetexto* and standard care arms using the Fisher's exact test. The primary analysis on cessation will be conducted using an intention-to-treat analysis, in which participants lost to follow-up are considered smokers. Multiple logistic regressions will be utilized to compare the 7-day point prevalence abstinence rates between the *Decídetexto* and standard of care arms adjusting for age, gender and baseline levels of smoking. We will examine both main effects and pairwise interaction effects and to determine if the expected differences between the two arms still exist in the presence of these other factors. Interactions not significant at the 0.10 level will be dropped from the model. The secondary analysis on potential mediators (e.g., therapeutic alliance, pharmacotherapy utilization, and self-efficacy) of the presumed treatment effect will be

conducted using complete case analysis, in which subjects with missing values in the outcome will not be included in the analysis. We will use the methods proposed by Baron and Kenney for assessing mediation [54].

Sample size and power analysis.

The primary outcome will be cotinine-verified 7-day point prevalence abstinence at Month 6. We expect a 20% and 10% cessation rate in the Decídetexto group and standard care group, respectively [16–17]. Using a two-tailed Fisher's exact test, a target sample size of 247 subjects in each group will give us 85% power to detect this difference with a type I error rate of 5%. According to pilot studies, we expect 20% attrition during the study [16–17]; therefore, we will recruit 309 subjects per group (618 total) to insure power for the proposed analyses.

DISCUSSION

Decídetexto is the first large-scale smoking cessation clinical trial to evaluate a culturally accommodated intervention for Latinos using mobile technology to deliver skills-based counseling and encourage pharmacotherapy use to promote abstinence. *Decídetexto* is a theoretically-based, culturally accommodated, mobile intervention consistent with evidence-based recommendations of the Clinical Practice Guidelines. The *Decídetexto* tablet-based software assesses smoking status, interest in quitting, key motivators and barriers, and advises smokers to quit. The tablet-based software assists smokers in developing an individualized smoking cessation quit plan including use of NRT if requested. The tablet data is transmitted to a software program that drives a text message follow-up system. Individualized skills-based counseling through automated and interactive text messages provides tailored motivational prompts, reminders of the participant's smoking cessation plan, and cues to promote use of NRT. The provision of NRT is key given few clinical trials have provided and tracked pharmacotherapy use for Latino smokers. Moreover, it is promising given that older studies have suggested limited interest in use of pharmacotherapy generally and NRT specifically among Latinos. An evidence-based mobile program that is clinically proven to better engage Latino smokers and increase use of pharmacotherapy and quitting outcomes, could be of significant interest to community- and clinic-based settings who serve a high proportion of Latinos and could have significant public health impact. As results from a myriad of cross-sectional and prospective correlational studies show that self-efficacy is a consistent predictor of smoking abstinence [55], the role of text messaging interventions to increase self-efficacy should be further evaluated. Greater working alliance predicts early engagement and positive outcomes in many studies on counseling for substance use disorder [56]. Although the role of therapeutic alliance has received some attention in the tobacco treatment literature [57–58], more research is needed to assess this counseling mechanism, especially in the context of mobile technologies. This study will assess therapeutic alliance and self-efficacy as mediators of the presumed treatment effect on smoking abstinence among Latino smokers using smoking cessation technologies.

We recognize that smoking among Latinos is complex and Latinos are a heterogeneous group differing by country of origin, years living in the U.S., socioeconomic and

immigration status, acculturation stressors, language, and cultural values. Prevalence of smoking is highest among Puerto Ricans (men 35.0%, women 32.6%) and Cubans (men 31.3%, women 21.9%), with particularly high smoking intensity as measured by pack/years and cigarettes/day among Cubans [59]. Dominicans have the lowest smoking prevalence among Latinos (men 11.0%, women 11.7%) [59]. Latinos of other national backgrounds have smoking prevalence that is in between the rates of these groups, and typically higher among men than women [59]. Non-daily smoking is common, particularly among Mexicans [59]. Moreover, smoking is more prevalent among U.S.-born Latinos compared to Latinos born outside the U.S., and is also more prevalent among those with higher levels of acculturation, particularly among women [59]. These differences justify the importance of implementing this randomized controlled trial in three states: New Jersey, New York, and Kansas. New Jersey has a very diverse, large, and rapidly-expanding Latino community that comprises 20.4% of the total population [2]. New Jersey has multiple municipalities with Hispanic-majority populations [2]. New Jersey has large Dominican, Puerto Rican, Cuban, Mexican, Peruvian, Colombian, and Ecuadorian communities [2]. New Jersey is also home to a large Brazilian population [2]. The sample from Rochester, New York will include rural and urban Latinos. The Rochester metropolitan area has approximately 80,000 Puerto Ricans and about 7,000 families moved to Rochester after Hurricane Maria [2, 60]. Moreover, the area surrounding Rochester has a high concentration of Mexican farmworkers that are brought to the U.S. with temporary VISAS [61]. The Latino population in the state of Kansas comprises 11.3% of the total population [2]. The sample from Kansas will include rural and Midwestern urban Latinos. Kansas has a predominantly Mexican immigrant community, yet there is also representation from Puerto Rico, Honduras, Guatemala, and Chile [2]. Moreover, Kansas has a history of multiple waves of Latino immigration in the 1900s, 1940s, and 1990s, resulting in 6th generation Latinos as well as new immigrants. Implementing the study in these three sites will allow us to recruit a diverse sample of Latinos. Our sociodemographic assessment will further strengthen the external validity of our findings. Future planned analyses including predictive modelling will examine subgroups (e.g., country of birth, immigrant generation) for whom efficacy differs.

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Table 1.

Measures at each time point

	Baseline	Week 12	Month 6
Sociodemographics			
Age	x	-	-
Gender	x	-	-
Sexual preference	x	-	-
Highest level of education	x	-	-
Race	x	-	-
Employment status	x	-	-
Marital status	x	-	-
Number of household members	x	-	-
Number of children <18 in household	x	-	-
Income	x	-	-
Health insurance	x	-	-
Use of technology	x	-	-
Health			
Last routine checkup	x	-	-
Chronic diseases	x	-	-
Depressed mood and anhedonia (PHQ-2)	x	-	-
Generalized anxiety disorder (GAD-2)	x	-	-
Alcohol use (AUDIT-C)	x	-	-
Smoking history			
Timeline followback (TLFB)	30 days	7 days	30 days
Heaviness of smoking index	x	-	-
Severity of dependence scale	x	-	-
Age of initiation	x	-	-
Use of menthol cigarettes	x	-	-
Cigarette brand	x	-	-
Use of flavored cigarettes	x	-	-
Use of other tobacco products	x	x	x
Use of e-cigarettes	x	x	x
Quitting history			
Number of 24 hour quit attempts in the past 12 months	x	-	-
Number of 24 hour quit attempts since last study visit	-	x	x
Use of pharmacotherapy to quit smoking	x	x	x
Use of resources to quit smoking	x	x	x
Use of e-cigarettes	x	x	x
Social influences			
Number of five closest friends/family members who smoke	x	-	-
Number of smokers in the home	x	-	-
Partner smoking status	x	-	-

	Baseline	Week 12	Month 6
Smoking rules at home	x	-	-
Smoking rules at work	x	-	-
Self-efficacy (SEQ-12)	x	x	x
Therapeutic alliance (WAI-S)	-	x	x
Social support			
Family, friends/colleagues, Decídetexto	-	-	x
Partner Interaction Questionnaire	-	-	x
Satisfaction	-	x	x
Acculturation			
Country of birth	x	-	-
Years living in the US	x	-	-
Immigrant generation	x	-	-
Language	x	-	-
Hispanic stress inventory (HSI-2)	x	-	-
Food insecurity (USDA short-version)	x	-	-
Clinical trial awareness	x	-	-
Anthropometrics and biomarkers			
Carbon monoxide (CO) levels	x	-	x
Height	x	-	-
Weight	x	-	x
Cotinine levels (saliva)	-	-	x