ANCILLARY REVIEWS

DO NOT DELETE. Submit the completed checklist below with your protocol.

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	*If yes…*	***Impact on IRB Review***
☐ **Yes** ☒ **No**	Include Gillette resources, staff or locations	*Gillette Scientific review and Gillette Research Administration approval is required. Contact: research@gillettechildrens.com*	**Required prior to IRB submission**
☐ **Yes** ☒ **No**	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned to your study by IRB staff Contact:* ancillaryreview@Fairview.org	**Approval must be received prior to IRB committee/ designated review.** **Consider seeking approval prior to IRB submission.**
☐ **Yes** ☒ **No**	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	*The regulatory ancillary review will be assigned to your study by IRB staff Contact: medreg@umn.edu* *See: https://policy.umn.edu/research/indide*	
☒ **Yes** ☐ **No**	Require Scientific Review? Not sure? See guidance in the Investigator Manual (HRP-103).	*Documentation of scientific merit must be provided. Contact: hrpp@umn.edu*	
☒ **Yes** ☐ **No**	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	*Complete the CPRC application process. Contact: ccprc@umn.edu*	
☐ **Yes** ☒ **No**	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	*Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee. Contact: barmstro@umn.edu*	**Approval from these committees must be received prior to IRB approval;** **These groups each have their own application process.**
☐ **Yes** ☒ **No**	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	*Complete the CMRR pre-IRB ancillary review Contact: ande2445@umn.edu*	
☐ **Yes** ☒ **No**	Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents?	*Complete the IBC application via eprotocol.umn.edu*	

☐ **Yes** ☒ **No**	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	*Contact OBAO for submission instructions and guidance*	
☐ **Yes** ☒ **No**	Include PHI or are you requesting a HIPAA waiver?	*If yes, HIPCO will conduct a review of this protocol.* *Contact: privacy@umn.edu*	
☐ **Yes** ☒ **No**	Use data from CTSI Best Practices Integrated Informatics Core? Formerly the AHC Information Exchange (IE)?	*The Information Exchange ancillary review will be assigned to your study by IRB staff* *Contact: bpic@umn.edu*	**Approval must be received prior to IRB approval.** **These groups do not have a separate application process but additional information from the study team may be required.**
☐ **Yes** ☒ **No**	Use the Biorepository and Laboratory Services to collect tissue for research?	*The BLS ancillary review will be assigned to your study by IRB staff.* *Contact: Jenny Pham* *Pham0435@umn.edu*	
☐ **Yes** ☒ **No**	Have a PI or study team member with a conflict of interest?	*The CoI ancillary review will be assigned to your study by IRB staff* *Contact: becca002@umn.edu*	
☐ **Yes** ☒ **No**	Need to be registered on clinicaltrials.gov?	*If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff* *Contact: kmmccorm@umn.edu*	
☒ **Yes** ☐ **No**	Require registration in OnCore?	*If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff* *Contact: oncore@umn.edu*	**Does not affect IRB approval.**

PROTOCOL COVER PAGE

Protocol Title	QuitGuide for American Indians: Aims 2 & 3
Principal Investigator/Faculty Advisor	Name: Dana Carroll
	Department: Public Health, Div. of Environmental Health Sciences
	Telephone Number: 612-624-0132
	Email Address: dcarroll@umn.edu
Scientific Assessment	Nationally-based, federal funding organizations
IND/IDE # (if applicable)	Not applicable
IND/IDE Holder	Not applicable
Investigational Drug Services # (if applicable)	Not applicable
Version Number/Date:	Version 6- November 16 2022

VERSION HISTORY

Version #	Version Date	Summary of Changes	Consent Change?
1	1/18/2022	N/A	N/A
There was a protocol version date of 3/10/2022 that was submitted to CPRC, and incorporated responses to CPRC stipulations and approved by CPRC but somehow the changes that were reflected in the 3/10/2022 version, were not included in future versions of the protocol (i.e., 5/5/2022 and 6/23/2022). *Therefore, the 8/22/2022 version includes these missing edits/line changes that were previously approved by CPRC and reflects the current protocol. We have also resent the 8/22/2022 version back to CPRC for review as an amendment.*			
2	5/5/2022	• HIPCO Review not required. Updating and removing references to HIPAA • Updated compensation structure • Clarified compensation for exit survey versus exit interview	N/A
3	6/23/2022	• Updating time window for full compensation for exit survey • Added a secondary outcome measure that was previously missing in error to align with our SAP.	Yes-consent was updated to version 6/13/2022 to reflect time widow update. No participants enrolled, (not yet IRB approved).
4	8/22/2022	-Updating consent and protocol to include Oklahoma State as study site -Updating Aim 2 to include only one wave of user testing --Adding protocol modifications that were reflected in a 3/10/2022 version of the protocol were inadvertently missing from the prior versions (5/5/2022 and 6/23/2022)	Yes to version 8-22-2022
5	10/20/2022	-dropping Oklahoma State as study site -updating order of baseline survey versus app download.	Yes to version 10-20-2022
6	11-16-2022	Dropping Aim 2 pilot run due to time restraints and going straight to Aim 3 which is now the focus of this protocol. Adding an exit interview/follow-up interview conducted among a subset of participants in the tailored arm only.	Yes to version 11-16-2022

Table of Contents

ABBREVIATIONS/DEFINITIONS

- AI: American Indian, referring to Native American individuals from the continental United States.
- Commercial tobacco: Tobacco products produced for commercial gain and containing chemical additives harmful to health. Examples include cigarettes and vaping liquid.
- Traditional tobacco: All-natural tobacco, which may or may not be ingested, that is grown and utilized for ceremonial purposes in various American Indian traditions.
- AICAF: American Indian Cancer Foundation

1.0 Objectives

1.1 Purpose:

This protocol is for a NIH funded study.

To test feasibility, acceptability, and preliminary efficacy of the tailored QuitGuide for smoking cessation among AIs. Our hypothesis is that the tailored QuitGuide will have higher ratings of feasibility and acceptability compared to the standard, publicly available QuitGuide among AI smokers. Additionally, we hypothesize that the tailored QuitGuide will have similar ratings of feasibility and acceptability among participants in OK compared with participants in MN/WI.

2.0 Background

2.1 Significance of Research Question/Purpose:

There is a need to better serve American Indian (AI) peoples in quitting commercial tobacco use. In many AI tribes, there is a long history of the use of tobacco for ceremonial and spiritual purposes. In the last century, however, the addictive use of commercially produced tobacco has increased dramatically among AI peoples. This disparity is particularly evident in the northern plains region of the U.S. in states such as Minnesota where an estimated 59% of AI adults identified as current smokers relative to 16% of the White population.[1] Consequently, and as shown in prior research by our team, AI peoples experience disproportionately higher rates of tobacco-related morbidity and mortality, such as lung cancer, as much as three-fold more that of White persons.[2-4] While the proportion of AI smokers who attempted to quit in the past year is similar to the general population (53% versus 56%), the percentage of AI ever smokers who are former smokers is roughly half that of the general population (29% versus 56%).[5,6]

Lower quitting among AI peoples is due to a number of factors, including poor engagement with available treatments. Many factors contribute to low quitting rates among AI peoples, including early age of smoking initiation which is associated with greater dependence,[7] infiltration of commercial cigarettes into ceremonies, funerals, and pow wows instead of traditional tobacco,[8] tobacco industry targeting of AIs as shown in our prior research,[9] stress and historical and contemporary trauma, socioeconomic challenges, and mistrust of health providers. Lack of access to or availability of culturally-tailored treatments is likely another important contributor.

2.2 Preliminary Data:

NCI's QuitGuide is a publicly available smartphone app for cessation. QuitGuide follows US Clinical Practice Guidelines which are the gold-standard in cessation treatment.[20] Guidelines call for tracking smoking status, offering quit planning, pharmacotherapy advice, tools to enhance motivation, and social support.[20] QuitGuide allows the user to track mood and cravings any time of the day, provides motivational messages and quit tips, and includes GPS technology which allows the user to mark a location as a trigger and then the app sends the user an alert and quit tip if they approach the location. QuitGuide was downloaded >100,000 times from 2015-2018 (personal communication w/Mr. Kendrick at Smokefree.gov; Smokefree.gov is managed by the

National Cancer Institute and the QuitGuide is a Smokefree.gov product). In testing of mainly White smokers without providing pharmacotherapy, QuitGuide was viewed as feasible and potentially efficacious as 8% quit (non-biochemically verified).[15] Although the QuitGuide's quit rate is lower than face-to-face studies that include pharmacotherapy,[21-23] the reach and therefore the absolute number of people quitting with QuitGuide is potentially far greater. Given prior studies like the aforementioned ANBL that observed numerically lower abstinence among AIs in the non-tailored versus culturally-tailored arm, **we hypothesize that the QuitGuide fails to maximize quitting among AIs, but can be improved if tailored**.

There are several avenues for tailoring the QuitGuide to better fit the culture and needs of AI smokers. QuitGuide uses conventional tobacco control messages that portray tobacco entirely negatively which may be offensive and ineffective among AI persons for whom ceremonial tobacco use is part of spiritual practice. This may be overcome by distinguishing commercial versus traditional tobacco use in the app and embedding previously developed content on traditional tobacco use to reframe how tobacco should be used. Such content may include resources on traditional tobacco use that are publicly available through the National Native Network Keep Tobacco Sacred website.[24] Additionally, while the QuitGuide provides guidance to triggers common to the general population such as drinking coffee , it does not include triggers unique to AI persons such as cigarette use at pow wows, funerals, ceremonies and in the home. Since smoking is pervasive in the environments of many AI persons, equipping AIs with how to combat triggers unique to their environment as well as triggers shared with the general population may be particularly effective. Another tailoring avenue is the inclusion of links to short videos on quit tips from AI persons themselves created by CDC's Tips from Former Smokers Campaign.[25] An additional avenue for tailoring may include emphasis on younger generations and communities at large to encourage quitting. This could be done through providing the option to upload family photos to the app.

Rigor of prior research and scientific premise of the proposed study:

- There is evidence from our team and others that there is a significant public health problem of commercial smoking among AIs[2-4] and while many AIs want to quit, lifetime quitting is lower among AI peoples compared to those from other racial/ethnic backgrounds.[5,6]
- While not reaching statistical significance, quit rates in face-to-face interventions such as ANBL were numerically higher if culturally-tailored to AIs.[10,11] This is also evidence that face-to-face delivery, even if culturally-tailored, suffers from low engagement due to participant barriers like transportation. [10,11]
- Smartphone-delivered interventions allow for immediate access to interactive, readily tailorable, treatment content;[15] therefore, these interventions have great potential for reaching and engaging AI smokers.
- QuitGuide is a smartphone app with evidence for cessation efficacy in predominately White smokers.[15] QuitGuide provides real-time guidance on how to navigate triggers resulting from the smoker's environment which could be particularly effective for AIs given the high prevalence of smoking in many AI communities. However, at present QuitGuide does not include guidance on triggers unique to AI persons such as cigarettes use at funerals, pow wows, and by others in the home. Additionally, the QuitGuide uses conventional messages that portray tobacco entirely negatively and does not address traditional tobacco. This is problematic because of our team's data showing that cultural references to traditional

tobacco in smoking cessation messages can positively affect message and cessation perceptions (AICAF unpublished data). The need for tailoring the QuitGuide to better fit the needs of AI persons is further supported by prior interventions that showed higher abstinence in groups receiving culturally tailored treatment.[10,11]

2.3 Existing Literature:

Evidence suggests that culturally-tailored interventions may increase cessation in AIs but face-to-face delivery is costly and hindered by lack of transportation among participants. Prior work by the American Indian Cancer Foundation (AICAF; subcontract on proposal), shows that references to traditional tobacco in cessation messages can positively affect self-efficacy to quit (unpublished data). To our knowledge, only two culturally-tailored cessation interventions for AI peoples exist that purposely engage AI voices throughout the research and utilized rigorous methodology (i.e., included a control group, biochemically confirmed abstinence). The first is the All Nations Breath of Life (ANBL) intervention which was created for AIs representing many tribes and included pharmacotherapy, in-person behavioral support led by AI facilitators, and culturally-tailored curriculum.[10] Biochemically confirmed abstinence was higher in the tailored versus standard group, though the difference between the groups was not statistically significant (11% vs 7%).[10] The second, a tribal-specific program which included pharmacotherapy, also observed higher, but non-significant, abstinence in the tailored versus standard group (23% vs 14%).[11] Both studies observed poor retention (~40% loss-to-follow-up) and lack of transportation was a major contributor. Innovative approaches that can reach AI smokers and, that overcome the barrier of travel to an intervention site are needed to address commercial smoking among AI people.

Mobile health (mHealth) interventions, can have broad reach, be delivered conveniently and efficiently, and can be tailored to be engaging and culturally appropriate for AI people, offer promise for overcoming obstacles to delivering the traditional modes of cessation treatment. Web-based and text messaging interventions have the advantage of convenience and may be well-suited for a cessation intervention due to cost effectiveness and scalability. A 2020 U.S. Surgeon General report concluded that these mHEALTH approaches increase cessation.[12] Two ongoing studies are using the web[13] or text-messaging[14] to deliver culturally-tailored cessation treatment to AIs. **However, the increasing use of smartphones offers a new mHEALTH platform known as smartphones applications ("apps")** that offer new intervention content modalities and extend elements of the web and texting to create more interactive and visually appealing content. Apps have several features that make them appealing for a smoking cessation intervention: (1) treatment content available at arm's reach, (2) tracking progress anywhere and anytime including tailored support to environments that trigger smoking cues (e.g., car, bar), (3) video/audio capabilities, (4) **after initial download, access without cellular or internet connection** which is particularly advantageous due to our prior research experience with AI persons who can lack minutes or internet connection, and (5) content sharable via social media.[15]

High smartphone ownership among AI peoples suggests potential high reach of a smartphone delivered cessation intervention in AI communities. Among U.S. adults in 2019, 81% owned a smartphone.[16] A prior study reported 86% of AI peoples owned a cellular device, but this study did not make the distinction between smartphone versus non-smartphone ownership.[17] However, it is likely that the majority (>60%) of AI peoples own a smartphone based on high ownership estimates regardless of rural (71%) or urban location (81%) and the lowest estimate

of ownership was at 66%, which was among persons of low education.[16] Additionally, a 2018 study reported 86% of AI peoples use a smartphone as their news source.[18] **Finally, apps for Indigenous language preservation and revitalization are being used by Tribes, which suggests that apps are a promising platform for delivery of other content to AI peoples**.[19]

For all of these reasons, we are now proposing to test the feasibility and acceptability of a culturally-tailored version of the QuitGuide, developed by our team, versus the standard QuitGuide among American Indian persons in MN and WI.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

The primary endpoint, which was used for power and sample size is the frequency of app use during the 5-week period.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

Secondary endpoints:

- Frequency of app use during the 1st week post-randomization
- Frequency of interactions with various app features (e.g. quit tips, trigger list) over the 5 weeks
- Study accrual relative to recruitment goal
- Study attrition measured as percentage of randomized participants that complete the survey at 5 weeks
- Frequency of returning saliva sample by 2 weeks post the week 5 survey (i.e., 7 weeks post randomization)
- Following measures at 5 weeks via exit survey
    - Usability of App Design measured using System Usability scale (SUS)[34] Acceptability of overall app (i.e., how likely would you be to recommend the app) and various app components (e.g. quit tips, trigger list) measured as Likert-scale responses

Fit of app with culture measured as Likert-scale responses
Exploratory endpoints:
Following measures at 5 weeks via exit survey

- Number of 24-hour quit attempts over the over the 5 week period
- Self-reported 24-hour abstinence at time of exit survey
- Self-reported 7-day abstinence at time of exit survey
- Self-reported 30-day abstinence at time of exit survey
- Nicotine replacement therapy and pharmacotherapy (e.g. Chantix) use over the 5 week period
- Other behavioral support (e.g. in-person, quitline) for smoking cessation over the 5 week period

- Saliva cotinine at 5 weeks for those with 7-day abstinence prior to this time point to biochemically confirm self-reported 7-day abstinence (saliva cotinine < 10 ng/mL)

4.0 Study Intervention(s)/Investigational Agent(s)

4.1 Description:

Participants will be randomized to either the tailored QuitGuide app or the standard version of the QuitGuide app for 5 weeks. Specifically, participants will be asked to use the assigned app for one week pre-quit and 4 weeks.

Tailored QuitGuide app
This is an app not available to the public. It was developed/tailored based on an app titled QuitGuide that is available to the public and can be downloaded. Screen shots of the publicly available version, referred to as the Standard QuitGuide app, are provided as an attachment. We have also included a document describing the changes and updates that were made to the Standard QuitGuide app to develop the Tailored QuitGuide app.

Standard QuitGuide app
This is an app titled QuitGuide that is available to the public and can be downloaded and screen shots are provided as an attachment. We will not provide all photos but several options are included in the IRB submission.

4.2 Drug/Device Handling:

This study does not use a drug. The study will not be providing any device to participants. They will be expected to use their own cell phone for accessing the QuitGuide app.

4.3 Biosafety:

No biosafety concerns or reviews required.

4.4 Stem Cells:

This study does not use stem cells.

4.5 Fetal Tissue:

This study does not use fetal tissue.

5.0 Procedures Involved

5.1 Study Design:

This is a two-arm randomized clinical trial of the tailored vs standard QuitGuide app conducted.

5.2 Study Procedures:

To test feasibility, acceptability, and preliminary efficacy of the tailored QuitGuide versus standard QuitGuide for smoking cessation among AI peoples.

1. **Telephone Screener**: We will recruit AI smokers interested in quitting. Individuals will be screened over the phone for eligibility.

2. **Phone-Based Baseline Interview**: If eligible, then consent will be completed. Then, participants will complete a REDCap survey (titled Baseline Survey—see below for measures). Participants will be randomized to either the *Tailored QuitGuide app* or the *Standard QuitGuide app*. Participants will be provided instruction on how to download the app to their smartphone. Upon download, all participants will be asked to provide a unique participant app ID in the app.

   Randomization: Participants will be randomized with equal probability to either a tailored version of the NCI QuitGuide or a standard version of the NCI QuitGuide. Randomization will be stratified by rural/urban clinic, male/female gender, and <50 years of age/50+ years of age. Randomization will be completed using permuted block randomization with random block sizes of 2 and 4. We anticipate no or minimal block effects in our data, and therefore, we will not account for block effects in our data analysis. The randomization schedules will be created in advance.

3. **App interaction**: Upon opening the app for the first time, participants will be asked to set a quit date. All participants will set their quit date for one week later to standardize pre- and post- quit times. If smoking relapse occurs, participants will be provided the option to reset the quit date as this flexibility is permitted in the QuitGuide. Each participant will be asked to use the app for 5 weeks. Participants will have the option to contact the research coordinator at any time to report issues. At week 4, participants will be mailed a letter reminding them of the exit survey and will provide routine saliva sample collection kit with instructions to provide the sample on the same day of their exit survey, and materials (e.g., pre-paid envelope) to return the sample to the University of Minnesota for analysis.

4. **Exit Survey:** At the end of the day on the last day of the 5 weeks of app use (i.e., 5 weeks + 1 day), an automated survey link from REDCap will be sent to participants email to assess self-report outcome measures. Participants will also be called and texted to remind them to complete the survey.

5. **Optional end of study interview:** Those randomized to the tailored QuitGuide may be asked to participate in a follow-up interview to get their feedback on using the app. We expect asking up to 10 people to complete this interview.

All measures are displayed in the table:

Baseline survey collected via REDCap: Demographics, America Indian Identity Measures, Internet and smartphone use, Traditional Tobacco Use, Commercial Tobacco History, Nicotine Dependence Scale, Contemplation Ladder, Environmental Smoke Exposures, Health Literacy Alcohol consumption, Financial Strain, Perceived Stress Scale, Brief Resilience Scale, Everyday Discrimination Scale
Data collected through using app and transferred from SmokeFree.gov: All app user data. Any and all interactions with the app including days and frequency of use each day and which app components are accessed.

Exit survey collected via REDCap: Contemplation Ladder TimeLine follow-back calendar to assess self-report CPD, use of any pharmacotherapy, 24-hour quit attempts, use of other cessation resources, Minnesota Nicotine Withdrawal Scale, Usability of App Design by System Usability Scale (SUS) Acceptability measures; plus open-ended responses on app
Audio recordings from the interviews among a subset of the participants
Saliva Sample

5.3 Study Duration:

- Individual participant duration is 5 weeks.
- The duration to enroll all study participants is 1.5 years.
- The duration for all data collection and analysis is 2.5 years.

5.4 Use of radiation*:*

The study does not use any radiation.

5.5 Use of Center for Magnetic Resonance Research*:*

The study does not use any CMMR resources.

6.0 Data and Specimen Banking

Not applicable

6.1 Storage and Access: Not applicable

6.2 Data: Not applicable

6.3 Release/Sharing: Not applicable

7.0 Sharing of Results with Participants

No study results will be shared with participants. Individual results on any collected specimens will not be shared.

8.0 Study Population

8.1 Inclusion Criteria:

- American Indian person based on self-report
- Age ≥ 18 years
- Interested in quitting smoking
- Smoke ≥ 3 commercial tobacco cigarette per day (CPD) in the past 30 days
    - Use of other commercial tobacco products (e.g., e-cigarettes) is permitted if they report cigarettes being their primary product
- Smartphone ownership with the ability to download applications and sufficient data to complete research procedures

8.2 Exclusion Criteria:

- New or change in pharmacotherapy for smoking cessation (includes: nicotine gum, patch, lozenge, inhaler OR medications Chantix/Wellbtrutin/Zyban/Bupropion) in past month

- Does not speak or read English

8.3 Screening:

Individuals are screened for eligibility by undergoing a phone screening interview with a research coordinator. The screening consists of questions about eligibility criteria. Participants who are eligible can then complete informed consent and enroll into the study—see informed consent section.

9.0 Vulnerable Populations

9.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be focus of the research (targeted), included, but not necessarily the focus or excluded from participation in the study.
Children	Excluded
Pregnant women/fetuses/neonates	included but not the focus
Prisoners	Excluded
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded
Non-English speakers	Excluded
Those unable to read (illiterate)	Excluded
Employees of the researcher	included but not the focus
Students of the researcher	included but not the focus
Undervalued or disenfranchised social group	included but not the focus
Active members of the military (service members), DoD personnel (including civilian employees)	included but not the focus

Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	included but not the focus
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	included but not the focus
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	included but not the focus
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	included but not the focus

9.2 Additional Safeguards, if any, to ensure inclusion is appropriate:

Individuals representing these vulnerable groups are not targeted for inclusion but may be included if the eligibility criteria is met. While this study is targeting American Indians, a historically disadvantaged population, members of this group should not be assumed to automatically have additional vulnerabilities.

9.3 If research includes potential for direct benefit to participants, provide rationale for any exclusions indicated in the table above:

There is potential for direct benefit of using a smoking cessation app. All exclusions listed above are related primarily to the smoking cessation app's requirements.

10.0 Local Number of Participants

10.1 Local Number of Participants to be Consented:

Up to 116 participants will be consented at the UMN/AICAF sites—all of these will be considered UMN accrual.

11.0 Local Recruitment Methods

11.1 Recruitment Process:

Recruitment will occur through social media and community events and news outlets. We also have recruited participants in one prior study (IRB: STUDY00012471: QuitGuide for American Indians: Aim 1 In STUDY00012471, we included a telephone screener form that specifically asks participants "Would you be interested in being contacted by us in the future if other research opportunities become available?". Those participants who responded "Yes" will be re-contacted by IRB approved study personnel on IRB: STUDY00012471 and reminded that they are being re-contacted due to their interest in future studies that was reported when they participated in IRB: STUDY00012471.

11.2 Identification of Potential Participants:

All participants will self-identify based on posted flyers and other recruitment materials OR recruited from IRB: STUDY00012471.

11.3 Recruitment Materials:

Pre-approved scripts and images will be used to develop flyers and postings.

11.4 Payment:

A ClinCard (Greenphire through UMN) gift card will be provided as a physical card mailed to the participant. Payment will be made as participant completes the following tasks:

Total possible compensation for all participants is $125. Those asked to participate in a follow-up survey can receive an additional $25.

1. Telephone Screener: No payment
2. Virtual Baseline Interview: $25 payment
3. App interaction: No payment
4. Exit survey: $25 if completed within 48 hours or else $10 if completed not within 48 hours
5. Returned saliva sample: $25 payment
6. Bonus for completing all study procedures: $50
7. Follow-up interview among a subset of participants, invite only: $25 additional.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances:

Participants can choose to withdraw themselves at any time for any reason. Participants may be withdrawn by the PI if they no longer meet eligibility criteria.

12.2 Withdrawal Procedures:

If a participant is withdrawn, they will be informed and data collection will stop. All data or specimens collected up to that point will continue to be used. Compensation to that point will be provided.

12.3 Termination Procedures:

If a participant is no longer eligible, they will be informed and data collection will stop. All data or specimens collected up to that point will continue to be used.

13.0 Risks to Participants

13.1 Foreseeable Risks:

The potential risks of this study are minimal and include the risks associated with the loss of confidentiality, boredom of participating, and adverse psychological events from smoking reduction/cessation due to nicotine withdrawal.

Nicotine withdrawal symptoms include sadness, difficultly sleeping, irritability, restlessness, anxiousness and are usually mild and fade with time. These symptoms present among smokers who quit in the real-world—not just exclusive to our study. The QuitGuide app has existing links to a 24-hour crisis center and information for participants to get help shall they need it as well as information on treatments (e.g., nicotine replacement therapy) to help reduce nicotine withdrawal. These resources will be maintained in the tailored version of the app. Nicotine withdrawal symptoms will be captured at the exit survey as part of an exploratory outcome via the Minnesota Nicotine Withdrawal Scale but will not be considered adverse events for this study.

Measures collected will be noninvasive and should present no psychological or medical risk to the participant. Participants will be told that they may refuse to answer any questions during baseline and follow-up surveys and they may decide to quit their participation at any time.

13.2 Reproduction Risks:

No risks to reproduction are expected with this study.

13.3 Risks to Others:

No risks to others are expected with this study.

14.0 Potential Benefits to Participants

14.1 Potential Benefits:

As the intervention involves using a smoking cessation app, participants could benefit from using the app and quitting smoking. This benefit is not guaranteed.

15.0 Statistical Considerations

15.1 Data Analysis Plan:

No blinding of the investigative team will occur.

General Approach

All statistical analyses will be performed using SAS (version 9.4) or R (latest version, R Core Team). All statistical tests will be two-sided and a significance level of 0.05 will be used. Proper transformation such as the logarithm transformation will be used to approximate normality for

the outcome variables. All analyses will be completed using intent-to-treat principle unless otherwise noted.

Describing the Study Population

Baseline characteristics will be summarized for all participants and by study arm to identify any treatment group imbalances post-randomization. This will include household income, education level, traditional tobacco use, cultural identity, multiple tobacco use, quit readiness, nicotine dependence and CPD. Continuous variables will be summarized using mean, standard deviation, median and range, and compared between study arms using Student's t-tests or Wilcoxon rank-sum tests, as appropriate. Categorical variables will be summarized using frequency and percentage, and compared between study arms using Chi-square or Fisher's exact tests, as appropriate.

Primary Endpoint Analysis

The primary endpoint is the frequency of app use initiated by the participant. The number of times the app is initiated per day will be measured using data from Smokefree.gov. If a participant does not use the app on a particular day, Smokefree.gov records this as non-use or 0 for that day. The total number of times will be summarized for analysis by totaling the number of times the app is initiated from randomization to 5 weeks post-randomization.

Primary Analysis

The objective of our primary analysis is to test the treatment effect on frequency of app initiated by the participant. Frequency of app initiated will be summarized by treatment group (tailored app vs standard app) using descriptive statistics, and analyzed using a Poisson regression model with covariates for treatment group and the three stratification factors (rural/urban clinic, male/female gender and <50 years of age/50+ years of age). Assumptions about mean and variance will be evaluated and if over-dispersion is present, negative binomial regression will be used. If data are zero-inflated, zero-inflated Poisson or negative binomial models may be considered.. This analysis will be performed using data for all participants who were randomized, while assuming non-use of app for those who did not complete the week 5 survey from the last day they launched the app.

Secondary Analysis

A secondary analysis of the primary endpoint will be performed that also adjusts for any other covariates that differ across treatment groups at baseline with a p-value less than 0.20 (covariates listed above). We acknowledge the limitations of this due to a small sample size and will take this into account when determining what additional covariates to adjust for. Additionally, a sensitivity analysis will be performed for all subjects who completed the week 5 survey.

Secondary and Exploratory Endpoint Analysis

Secondary and exploratory endpoints will be analyzed using the same approach as the primary endpoint. These endpoints will be analyzed using an appropriate regression framework (i.e. linear, logistic, Poisson etc.), adjusting only for baseline measurements of the endpoint, if available, and the three stratification factors (rural/urban clinic, male/female gender and <50 years of age/50+ years of age). Secondary analyses will consist of an adjusted analysis, as

described above. All analyses will utilize residual plots and other diagnostic statistics to evaluate all modeling assumptions.

Measures of the ability to abstain from smoking (self-reported 24-hour, 7-day and 30-day abstinence) will be analyzed using a similar approach to the primary and secondary/exploratory endpoints, and summarized using a binary endpoint. Continuous 7-day biochemically-verified abstinence (saliva cotinine < 10 ng/mL8) will be summarized for those who self-reported 7-day abstinence prior to the week 5 survey, and analyzed using logistic regression, with a main effect for treatment group and adjustment of the stratification factors (rural/urban clinic, male/female gender and <50 years of age/50+ years of age). Because traditional tobacco (depending on the method of use and plants used) and secondhand smoke can increase saliva cotinine, additional analyses may be performed to explore their impact on biochemically-confirmed abstinence. In addition, secondary analyses will consist of an adjusted analysis, as described in above.

Subgroup Analysis

No subgroup analyses will be performed due to small sample size.

Missing Data

An intent-to-treat analysis requires that subjects are analyzed according to their randomized treatment assignment, regardless of compliance to the study product, and that complete data are available on all study subjects. Every effort will be made to limit the amount of missing data in this trial, and study participants will be incentivized to partake in each study component, return the saliva sample, and complete all components.

We will compare subjects with and without missing data in order to identify baseline covariates associated with missing data. All observed data will be utilized in the analyses, with missing data being assumed to be missing at random. Sensitivity analyses of the secondary/exploratory endpoints using multiple imputation may be considered depending on the amount of missingness.

Interim Analyses

No planned interim analyses.

All statistical analyses will be performed by Katelyn Tessier from the Masonic Cancer Center, Biostatistics Core.

15.2 Power Analysis:

Our sample size is based on the primary outcome, frequency of app use initiated by the participant during the 5-week period. Using a two-sided, two-sample test for Poisson rates, a total of 116 participants (n=58 in the tailored group and n=58 in the non-tailored group) will allow us to achieve 80% power to detect a difference in frequency of app use between the groups of 3.15 assuming a rate of 35 (1 time per day over the 5 weeks) in the non-tailored group and an alpha of 0.05. This sample size is in alignment with other mHEALTH-related smoking cessation feasibility studies. [36, 50]

15.3 Statistical Analysis:

See above.

15.4 Data Integrity:

PI will periodically check for completeness as well as outliers or unusual values

16.0 Health Information and Privacy Compliance

16.1 Select which of the following is applicable to your research:

☒ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☐ I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

16.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☒ Other. Describe: Other source of data is from the app which is managed by Smokefree.gov. This data will be identified with a unique participant ID. Thus, only de-identified data will transferred.

16.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

NA

16.4 Approximate number of records required for review:

NA

16.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☒ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Communication will take place by phone/text, email, and virtually.

16.6 Explain how the research team has legitimate access to patients/potential participants:

All participants will sign a consent form.

16.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store☐ Analyze ☐ Share

☒ In REDCap (recap.ahc.umn.edu)

☒ Store☒ Analyze ☒ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store☐ Analyze ☐ Share

☒ In the University's Box Secure Storage (box.umn.edu)

☒ Store☒ Analyze ☒ Share

☒ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

cancer.ahc.umn.edu\cancer\CancerCenter\Biostat\CCSG\Carroll, D\R21-AI and NCI QuitGuide\Data

☒ Store ☒ Analyze ☐ Share

☒ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices: 20191709

☒ Store☐ Analyze ☐ Share

☒ Other. Describe:

Smokefree.gov will maintain de-identified participant app use data. This will be shared with the study team. Also, all de-identified saliva samples will be stored in a locked freezer overseen by the PI in Mayo 11th floor, Division of Environmental Health Sciences until shared with Masonic Cancer Center for analysis.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☒I will use a desktop or laptop not previously listed

EnHS-M-DCLAP (supported through Environmental health Sciences, School of Public Health); No device number

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

16.8 Consultants. Vendors. Third Parties.

We have a data use agreement with Smokefree.gov for collection and transfer of app user data. Please refer to the data use agreement included.

We will have de-identified audio recordings from the interviews among a subset of the participants transcribed by a third party.

16.9 Links to identifiable data:

All identifiable information will either be paper documents, locked in the PI or project coordinator's office in a locked cabinet, or in a folder on Box separate from study-related data. A link between the identifiable information and study-related data will be saved similarly.

16.10 Sharing of Data with Research Team Members.

All electronic data to be shared with research team will be identified by participant ID and/or app ID. Only those on the IRB or described in the consent form (i.e., Smokefree.gov) will have access to participant data.

16.11 Storage of Documents:

Participant saliva samples and electronic data will be stored until manuscripts are written.

16.12 Disposal of Documents: We will maintain all consent forms as well as REDCap documents and data transferred from Smokefree.gov for a total of 7 years per the

State of Minnesota. After that paper documents will be shredded in paper shredder and REDCap and Smokefree.gov data will be archived/stored indefinitely.

17.0 Confidentiality

17.1 Data Security:

All data is stored in one of the following secure systems: Box, REDCap, locked cabinet, locked freezer or the above mentioned AHC-IS supported biostat server.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants

18.1 Data Integrity Monitoring.

Oversight for quality control and adherence to protocol procedures will be conducted by Dr. Carroll. A start-up meeting with the investigative team and the research coordinator will occur prior to participant enrollment. During this meeting, Dr. Carroll will provide the research coordinator with training on the study protocol, standard operating procedures, equipment and data collection platforms. Dr. Carroll will closely monitor all procedures to be used in this study. Such monitoring will consist of frequent in-person discussion with the research coordinator to make sure that all protocol procedures are followed, and regular phone meetings to provide updates on study progress and review the data collection process, and other issues of concern.

Data will be collected in a consistent manner either through an interview with the research coordinator or via a REDCap survey that is completed by the participant.

18.2 Data Safety Monitoring.

N/A This study is considered not greater than minimal risk.

19.0 Provisions to Protect the Privacy Interests of Participants

19.1 Protecting Privacy:

The coordinator will first ask the participant if they are in a safe place to complete the interviews and will refuse to conduct any interview if it is known that the participant is in an unsafe location or environment (e.g., driving a vehicle).

All information from the study will be stored in a locked filing cabinet or password protected computer, and only the PI and key study personnel will have access. Participants will not be identified by name in any published report and will be given study specific numbers or false names. Participants will be told their participation will be strictly confidential that any identifying information will only be available to the research team. Participants will be told that tribal leaders and/or clinic leadership will determine if the Tribe/clinic is named or is anonymous in any publication or dissemination of the data.

Each participant will be assigned a unique participant ID. All interview or survey data will be de-identified and coded with their participant ID and stored in REDCap. The participants' returned saliva sample will also be de-identified and coded with the participant ID. The key linking participant names to their participant ID will be stored in password protected BOX folder, and only the PI and key study personnel will have access to this document.

An App ID (different from their participant ID) will be entered into the app upon login for the first time. The App ID will also be stored in password protected BOX folder with access only provided to the IRB approved study team. The file in BOX will be the only way to link the app ID and the participant ID together and these IDs with their contact information. Other than dates, no PHI is collected by the app. Data collected from the participant using the GPS function in the app includes no physical locations just that it is a function being utilized by the user.

19.2 Access to Participants*:*

Participants will sign a consent giving access to the study team.

20.0 Compensation for Research-Related Injury

20.1 Compensation for Research-Related Injury:

The study does not involve greater than minimal risk. However, the consent form includes standard not greater than minimal risk injury language.

20.2 Contract Language:

Not applicable. No contract.

21.0 Consent Process

21.1 Consent Process (when consent will be obtained):

The consenting process will take place at the baseline visit prior to any data collection and randomization. During the consent process, participants will be provided with an opportunity to have their questions and concerns addressed. We will use an electronic informed consent process through REDCap. There is no waiting period necessary between signing consent and collection of data.

21.2 Waiver or Alteration of Consent Process (when consent will not be obtained):

No Waiver or Alteration of the Consent Process will be used for this study.

21.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

No Waiver of Written/Signed Documentation of Consent will be used in this study.

21.4 Non-English Speaking Participants:

Participants who cannot speak or read English are excluded from the study because the QuitGuide app is currently only available in English.

21.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

This study will only enroll adults.

21.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

Individuals with cognitive impairments or with capacity to consent issues will not be enrolled.

21.7 Adults Unable to Consent:

All participants must be able to consent for themselves.

22.0 Setting

22.1 Research Sites:

The community partners include Native American Community Clinic (NACC), the Bad River Band Tribe in Wisconsin, and the American Indian Cancer Foundation (AICAF). See letters of support from NACC, Bad River Tribal leadership, and AICAF

Potential participants will be recruited from NACC and the Bad River Band Tribe communities and their networks. These two partners are to be considered Research Locations only.

AICAF will assist with study procedures and are to be considered a Research Site. All study-related interactions will take place virtually. The interviewer will be in a private room when interacting with the participant virtually. We will ask all interviewees to locate a private room or one that they find suitable for the interview.

Community partners helped develop the protocol. We will engage the communities through a Community Advisory Board (CAB) which includes community members (5-10) and stakeholders who are not participants.

22.2 International Research:

This is not international research.

23.0 Multi-Site Research

This study has two sites: University of Minnesota and AICAF. All sites will be submitted to the University of Minnesota as a single-IRB as required for federally-funded research.

23.1 Study-Wide Number of Participants:

Up to 126 will be consented.

23.2 Study-Wide Recruitment Methods:

All recruitment methods are as mentioned above.

23.3 Study-Wide Recruitment Materials:

All recruitment materials are as mentioned above.

23.4 Communication Among Sites:

Communications among sites will primarily take place by email but periodic meetings will also be scheduled as necessary. All currently-approved versions of documents will be available on Box and all site staff will have access to Box as a source-of-truth. All site staff will follow UMN's security policies and other applicable guidelines. All IRB submission and reporting requirements will be completed using UMN's IRB and communicated as necessary by UMN study staff.

23.5 Communication to Sites:

Communications to sites will primarily take place by email but periodic meetings will also be scheduled as necessary.

24.0 Coordinating Center Research

Not applicable. This is not Coordinating Center research only.

25.0 Resources Available

25.1 Resources Available:

We foresee the recruitment to be feasible based on previous studies within this population and with the same community partners.

This project is funded by the NCI and has sufficient funding to be accomplished. Any additional, unforeseen, funding required will be covered by Dr. Carroll.

Dr. Carroll, the PI, has sufficient resources to oversee this project and conduct human subjects procedures.

The American Indian Cancer Foundation staff will assist with the human subjects components. If any individual from the community partners, who does not have their own IRB, is involved in any human subjects research, this individual will complete appropriate training (CITI through UMN) and be added to the IRB submission as study staff.

26.0 References

1. Forster J. Cigarette Smoking Among Urban American Indian Adults—Hennepin and Ramsey Counties, Minnesota, 2011. *MMWR Morbidity and mortality weekly report.* 2016;65.
2. Martinez SA, Janitz AE, Erb-Alvarez J, Mowls DS, Campbell JE, Anderson T. Cancer among American Indians - Identifying Priority Areas in Oklahoma. *J Okla State Med Assoc.* 2016;109(7-8):374-384.
3. Mowls DS, Campbell JE, Beebe LA. Race and Gender Disparities in Lung Cancer Incidence Rates, 2001-2010. In. Oklahoma State Medical Association: Univeristy of Oklahoma Health Sciences Center; 2015.
4. American Cancer Society, the Minnesota Department of Health, Alliance. tMC. *Minnesota Cancer Facts & Figures 2015.* 2015.
5. U.S. Department of Health and Human Services. *Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General.* Atlanta, Georgia: U.S.: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health;1998.
6. Forster JL, Skjefte L. *Tribal Tobacco Use Project Survey Report: Findings from Minnesota American Indian Communities.* 2013.
7. Nez Henderson P, Kanekar S, Wen Y, et al. Patterns of cigarette smoking initiation in two culturally distinct American Indian tribes. *Am J Public Health.* 2009;99(11):2020-2025.
8. Burgess D, Fu SS, Joseph AM, Hatsukami DK, Solomon J, van Ryn M. Beliefs and experiences regarding smoking cessation among American Indians. *Nicotine Tob Res.* 2007;9 Suppl 1:S19-28.
9. Carroll DM, Soto C, Baezconde-Garbanati L, et al. Tobacco Industry Marketing Exposure and Commercial Tobacco Product Use Disparities among American Indians and Alaska Natives. *Substance use & misuse.* 2019:1-10.
10. Choi WS, Beebe LA, Nazir N, et al. All Nations Breath of Life: A Randomized Trial of Smoking Cessation for American Indians. *Am J Prev Med.* 2016;51(5):743-751.
11. Smith SS, Rouse LM, Caskey M, et al. Culturally-Tailored Smoking Cessation for Adult American Indian Smokers: A Clinical Trial. *Couns Psychol.* 2014;42(6):852-886.

12. U.S. Department of Health and Human Services. *Smoking Cessation: A Report of the Surgeon General—Executive Summary.* Atlanta, GA: U.S. : Department of Health and Human Services, Centers for Disease, Control and Prevention,National Center for Chronic Disease Prevention and Health Promotion,Office on Smoking and Health;2020.
13. Choi W. Development of a Web-Based Smoking Cessation Program for Tribal College Students. Society for Prevention Research 22nd Annual Meeting 2013.
14. Orr MF, Burduli E, Hirchak KA, et al. Culturally-tailored text-messaging intervention for smoking cessation in rural American Indian communities: Rationale, design, and methods. *Contemp Clin Trials Commun.* 2019;15:100363.
15. Bricker JB, Mull KE, Kientz JA, et al. Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy. *Drug and alcohol dependence.* 2014;143:87-94.
16. Center PR. Mobile Fact Sheet. https://www.pewresearch.org/internet/fact-sheet/mobile/. Published 2019. Accessed February 17, 2020.
17. Dotson JAW, Nelson LA, Young SL, Buchwald D, Roll J. Use of cell phones and computers for health promotion and tobacco cessation by American Indian college students in Montana. 2017.
18. Schlichting RJ. Common platforms and devices used to access news about Native Americans. 2016.
19. Post F. First Nations take to designing their own apps to preserve their languages and cultures. https://business.financialpost.com/entrepreneur/first-nations-take-to-designing-their-own-apps-to-preserve-their-languages-and-cultures. Published 2017. Accessed March 13, 2020.
20. Fiore MC JC, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* 2008/07/12 ed. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service; 2008.
21. Civljak M, Stead LF, Hartmann-Boyce J, Sheikh A, Car J. Internet-based interventions for smoking cessation. *Cochrane Database Syst Rev.* 2013(7):Cd007078.
22. Hutton HE, Wilson LM, Apelberg BJ, et al. A systematic review of randomized controlled trials: Web-based interventions for smoking cessation among adolescents, college students, and adults. *Nicotine Tob Res.* 2011;13(4):227-238.
23. Shahab L, McEwen A. Online support for smoking cessation: a systematic review of the literature. *Addiction.* 2009;104(11):1792-1804.
24. National Native Network. Keep It Sacred: Traditional Tobacco Use. https://keepitsacred.itcmi.org/tobacco-and-tradition/traditional-tobacco-use/. Accessed March 3, 2020.
25. Centers for Disease Control and Prevention. Tips from Former Smokers: Real Stories by Specific Group; American Indians/Alaska Natives https://www.cdc.gov/tobacco/campaign/tips/stories/michael.html#michaels-videos. Published 2019. Accessed March 3, 2020.
26. Institute NC. Making Health Communication Programs Work. https://www.cancer.gov/publications/health-communication/pink-book.pdf. Published 2004. Accessed February 23, 2020.
27. Centers for Disease Control and Prevention. The Health Communicator's Social Media Toolkit. https://www.cdc.gov/socialmedia/tools/guidelines/index.html. Published 2011. Accessed 2018, September 4.

28. University of Minnesota Program in Health Disparities Research. Research Partnership Checklist https://www.ctsi.umn.edu/sites/ctsi.umn.edu/files/research_partnership_checklist.pdf. Accessed March 10, 2020.
29. Krueger RA, Casey MA. *Focus groups: A practical guide for applied research.* Sage publications; 2014.
30. Carroll DM, Brame LS, Stephens LD, Wagener TL, Campbell JE, Beebe LA. Community-Based Study Recruitment of American Indian Cigarette Smokers and Electronic Cigarette Users. *Journal of Community Health.* 2017.
31. Tanner JA, Henderson JA, Buchwald D, Howard BV, Henderson PN, Tyndale RF. Relationships Between Smoking Behaviors and Cotinine Levels Among Two American Indian Populations With Distinct Smoking Patterns. *Nicotine Tob Res.* 2018;20(4):466-473.
32. Bernard HR. *Research methods in anthropology: Qualitative and quantitative approaches.* Rowman & Littlefield; 2017.
33. Glaser BG, Strauss AL. *Discovery of grounded theory: Strategies for qualitative research.* Routledge; 2017.
34. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. *International Journal of Human–Computer Interaction.* 2008;24(6):574-594.
35. Yen P-Y, Bakken S. Review of health information technology usability study methodologies. *Journal of the American Medical Informatics Association.* 2012;19(3):413-422.
36. Businelle MS, Ma P, Kendzor DE, Frank SG, Vidrine DJ, Wetter DW. An Ecological Momentary Intervention for Smoking Cessation: Evaluation of Feasibility and Effectiveness. *J Med Internet Res.* 2016;18(12):e321-e321.
37. Hébert ET, Ra CK, Alexander AC, et al. A Mobile Just-in-Time Adaptive Intervention for Smoking Cessation: Pilot Randomized Controlled Trial. *J Med Internet Res.* 2020;22(3):e16907.
38. Walters KL, Simoni JM, Evans-Campbell T. Substance use among American Indians and Alaska natives: incorporating culture in an "indigenist" stress-coping paradigm. *Public Health Rep.* 2002;117 Suppl 1:S104-117.
39. Walters KL. Urban American Indian identity attitudes and acculturation styles. *Journal of Human Behavior in the Social Environment.* 1999;2(1-2):163-178.
40. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict.* 1991;86(9):1119-1127.
41. Biener L, Abrams DB. The Contemplation Ladder: validation of a measure of readiness to consider smoking cessation. *Health Psychology.* 1991;10(5):360.
42. Robinson SM, Sobell LC, Sobell MB, Leo GI. Reliability of the Timeline Followback for cocaine, cannabis, and cigarette use. *Psychology of addictive behaviors.* 2014;28(1):154.
43. Sobell LC, Sobell MB. Timeline follow-back. In: *Measuring alcohol consumption.* Springer; 1992:41-72.
44. Abrams DB, Follick MJ, Biener L, Carey KB, Hitti J. Saliva cotinine as a measure of smoking status in field settings. *American journal of public health.* 1987;77(7):846-848.
45. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* 1983;24(4):385-396.
46. Cohen S, Williamson G. Perceived stress in a probability sample of the United States. The social psychology of health: Claremont Symposium on applied social psychology. Edited by: Spacapan S, Oskamp S. 1988. In: Newbury Park, CA: Sage; 1988.

47. Conger RD, Ge X, Elder GH, Jr., Lorenz FO, Simons RL. Economic stress, coercive family process, and developmental problems of adolescents. *Child Dev.* 1994;65(2 Spec No):541-561.
48. Williams DR, Mohammed SA. Discrimination and racial disparities in health: evidence and needed research. *Journal of Behavioral Medicine.* 2009;32(1):20-47.
49. Smith BW, Dalen J, Wiggins K, Tooley E, Christopher P, Bernard J. The brief resilience scale: assessing the ability to bounce back. *International journal of behavioral medicine.* 2008;15(3):194-200.
50. Sinicrope PS, Koller KR, Prochaska JJ, et al. Social Media Intervention to Promote Smoking Treatment Utilization and Cessation Among Alaska Native People Who Smoke: Protocol for the Connecting Alaska Native People to Quit Smoking (CAN Quit) Pilot Study. *JMIR Res Protoc.* 2019;8(11):e15155.