Development of a M-Health Smokeless Tobacco Cessation Intervention for Firefighters

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Purpose of the Study

The specific aims are:
Aim 1: In collaboration with the Professional Firefighters and Paramedics of North Carolina and our Advisory board of firefighters, develop a mHealth smokeless tobacco cessation intervention tailored to the specific needs of first responders such as firefighters and EMTs / paramedics. Using a co-facilitated user centered design approach and guided by the Spiral Technology Action Research Model (STAR) Model, we will work with firefighters & EMTS / paramedics to 1) identify and develop intervention content, messaging, and m-health modalities for delivery (e.g., text-messaging, text-chat); 2) refine the intervention; and 3) conduct usability testing. The outcome of Aim 1 will be a fully developed mHealth smokeless tobacco cessation intervention tailored to the unique needs of first responders (e.g., firefighters and EMTs) that is ready for pilot testing.
Aim 2: To assess the feasibility, acceptability, and preliminary efficacy of the tailored smokeless tobacco cessation intervention compared to a usual care control intervention in decreasing smokeless tobacco use. This aim will specifically address recruitment and retention to determine feasibility, acceptability as measured by the usefulness of the intervention received, and preliminary efficacy of the intervention in improving smokeless tobacco cessation at 30-days post intervention completion as measured by self-reported abstinence from smokeless tobacco use. This evaluation will be done with 50 firefighters & EMTs / paramedics who use smokeless tobacco who will be randomized to the tailored mHealth intervention (n=25) or the usual care control (n=25) of a self-help booklet. Both the intervention and control group will be given a 4 week supply of NRT lozenges with instructions of how to use.

Background & Significance

Firefighters are at high risk for cancer

Firefighters and other first responders such as EMTs / paramedics are the front line defense to fire, medical, and rescue emergencies and play a critical role in protecting lives and property in our communities. Occupational exposures put firefighters and other emergency medical personnel such as EMTs at increased risk for injury and disease. Firefighters are exposed to both known and suspected carcinogens during their work including acetaldehyde, formaldehyde, sulfur dioxide, benzene, toluene, and ethylbenzene. Firefighters are also exposed to flame retardants and plasticizers which have been shown to be harmful. Although exposure is often for short periods of time, exposure levels can be high. Occupational exposures put firefighters and paramedics / EMTs at increased risk of developing certain types of cancer compared to the general public. A number of studies have examined cancer incidence and mortality among firefighters. Results have been inconsistent, but generally indicating elevated risk for some cancer types including colon, lung, testicular and head and neck including thyroid. Lowering cancer risk among firefighters is essential to protect those who serve and protect others.

Smokeless tobacco use is a modifiable risk factor for cancer

It may not be possible for firefighters to avoid occupational exposures with carcinogenic agents; however, identifying and minimizing modifiable risk factors, such as tobacco use, has the potential to minimize cancer risk. Firefighters use smokeless tobacco at a rate that is higher than the general population and the military population. Our preliminary work surveying professional firefighters in

Central NC found that 14% of firefighters reported smokeless tobacco which far exceeds the general population norm in NC (4.5%). This high prevalence can in part be attributed to non-smoking policies in firehouses likely contributing to increased rates of smokeless tobacco use among firefighters. Even though smokeless tobacco does not have the level of toxicity found in combustible tobacco, it is not without risk as there are 28 known carcinogens. Smokeless tobacco has been linked to cancer of the mouth, esophagus, and pancreas. In addition, smokeless tobacco may increase the risk of mortality from heart disease and stroke. No data is available on the potentially synergistic effect of exposure to carcinogens in smokeless tobacco and occupational exposure to cancer-causing compounds. However, reducing rates of smokeless tobacco use among firefighters can reduce cancer risk in this vulnerable population.

Firefighters have unique contextual and occupational reasons for smokeless tobacco use

Smokeless tobacco use is widely accepted among firefighters and is often used on the job, perpetuating cultural norms around use in this population. Other unique attributes that may contribute to increased use in this population include job stress from dangerous work conditions, sleep deprivation and the pressure to stay physically fit. This stress leads to smokeless tobacco use being a form of stress reduction or means to mitigate stress among many firefighters. Cancer fatalism is also common which may impede cessation attempts. Many firefighters have adopted an attitude that whatever they do they will get cancer and therefore their motivation is low to change behaviors that are linked to cancer. Interventions tailored to these unique needs are needed to increase cessation rates in this population.

Existing smokeless tobacco cessation interventions may not address the specific needs of firefighters

To date, only one smokeless tobacco cessation intervention (Enough Snuff) has been empirically tested and found effective at helping smokeless tobacco users quit. Jitnarin et al recently beta tested QUIT SPIT, a culturally tailored version of the 54-page adaption of the Enough Snuff booklet specific for firefighters and found the intervention to be feasible and acceptable among those who wanted to quit. Firefighters indicated that delivery of the messages via an mHealth platform (app or website) may be preferable to the printed version, supporting the significance of our proposed study. Our current intervention is testing an mHealth intervention delivering scheduled gradual reduction (SGR) and supportive text messages to smokeless tobacco users interested in quitting. The SGR program has users reduce the number of dips per day over 6 weeks by lengthening the interval between dips based on a set algorithm. SGR helps mitigate withdrawal symptoms commonly experienced among highly dependent chewers by providing even spacing between dips. Further, SGR helps chewers self-regulate their behavior and practice restraint strategies in response to tobacco use cues during the reduction period prior to quitting. We have enrolled 12 firefighters in the parent EnufSnuff study to date. Initial reactions to the intervention are positive; however, delivery of SGR to participants who work in shifts such as firefighters and EMTs is problematic. Firefighters work a 10-day cycle with alternating 24-hours shifts for 6 days and then 4 days off. Other first responders also work in shifts. Their work also might remove the possibility to dip if they are out on an emergency call. This schedule may be a barrier to effective engagement with the SGR program. Through our preliminary work, we have also identified cultural norms regarding cancer risk and risk behaviors that could be addressed via supportive text messages. More research is needed to develop an mHealth intervention to meet the unique needs of first responders, such as firefighters and EMTs who are interested in quitting smokeless tobacco.

mHealth interventions have the potential to increase the reach and engagement of Firefighters in cessation interventions

mHealth interventions for tobacco cessation have potential to facilitate participant engagement and activation by reaching people in the real-world setting. Previous research indicates that features which promote engagement (e.g., interactive text messaging) are positively associated with quit rates. Following a user-centered design approach and getting input from the target audience is essential for developing mHealth interventions that are efficacious and usable. Many mHealth behavior change interventions are designed without users in mind thus limiting their potential efficacy. Our proposed study will engage firefighters throughout the development process to ensure that the intervention is developed to meet their cessation needs. Thus, the potential impact and reach of a user developed, mHealth intervention warrants investigation in helping firefighters quit.

Summary

First responders, such as firefighters and paramedics / EMTs, who use smokeless tobacco represent a group vulnerable for tobacco use. Despite their high risk for both tobacco-related and occupational-related cancers, this group of smokeless tobacco users has not been widely targeted for cessation intervention trials. There are very few interventions available tailored to the unique needs of firefighters, and there are currently no mHealth interventions that address smokeless tobacco cessation for this population. mHealth interventions have the potential to consistently reach and consistently engage many more firefighters who use smokeless tobacco given their varying work schedules, and this approach warrants testing in this population. Our proposed study will develop and pilot a mHealth intervention to address the unique cessation needs of firefighters who use smokeless tobacco. If successful, this pilot will serve as the basis for a larger to trial to test the efficacy of this intervention on a larger scale. The proposed study has public health relevance in that the goal is to decrease cancer risk among firefighters by increasing access and uptake of tobacco cessation interventions in an understudied group of tobacco users.

Design & Procedures

In aim 1, the focus was placed on smokeless tobacco cessation intervention with firefighters and EMTs / paramedics. We will then test its feasibility, acceptability, and preliminary efficacy. To assure the cultural and occupational appropriateness of the intervention, we will recruit n=30 smokeless tobacco users and using a participatory, user centered design approach, we will work with firefighters and EMTs to identify intervention components and various m-health modalities for delivery (e.g., text messaging, text-chat). We will employ a user-centered design guided by the Spiral Technology Action Research Model (STAR) Model 23 to develop and refine the intervention, after which we will conduct usability testing by observing users interacting with the mHealth intervention. Concurrent think aloud protocols and extensive field notes will guide this approach. We will gather feedback through semi-structured interviews immediately following use of the intervention program. To evaluate the feasibility and acceptability of the intervention we will then recruit 50 smokeless tobacco users and randomize them to either the mHealth intervention group (n=25) or the usual care control group (n=25) (Smokeless tobacco cessation booklet). We will survey participant's 30-days after intervention completion. The primary outcomes will be feasibility, as measured by the ability to recruit, retain, and engage firefighters in the

mHealth intervention, and acceptability as measured by self-report usefulness of the intervention. We will also assess preliminary efficacy as measured by self-reported abstinence from smokeless tobacco use.

Aim 1: In collaboration with the Professional Firefighters and Paramedics of North Carolina and our Community Advisory Board of firefighters, develop a mHealth smokeless tobacco cessation intervention tailored to the specific needs of firefighters and other first responders such as EMTs / paramedics. Objective: To create a customized smokeless tobacco cessation intervention informed by contextually and occupationally relevant data.

Methods and Strategy: We will recruit smokeless tobacco users from a collaborating Central North Carolina Fire Department that includes 29 individual fire stations and over 500 Firefighters (See Letter of Support). We will also recruit firefighters and EMTs through social media ads that will run nationally in the United States. Inclusion criteria is: 1) 18 years of age and older; 2) Employed as a firefighter or EMT / paramedic; 3) Have used smokeless tobacco for the last year and currently (past 30 days) uses smokeless tobacco daily; 4) Have access to a smartphone.

User-centered Design Workshops: To inform intervention development, we will conduct three user-centered design workshops of up to 10 smokeless tobacco users each at each Fire Department. Workshops will focus on: 1) Content development; 2) Content refinement; and 3) Usability testing. We will screen those interested in the study for eligibility and obtain contact info to schedule the workshops. At the time of the workshop, the study staff will meet with participants who are eligible and interested in participating and verbally consent them into the study. The workshop will last approximately 60 minutes. The workshop location will be at the firehouse in a private location and/or via zoom. When completed in person we will incentivize participants by providing some food before or after participation. After each workshop, we will present results to our Advisory Board.

We will use the STAR Model as a framework for developing our intervention during these workshops. The STAR model incorporates health promotion theory with systems design approaches using rapid-cycle change strategies adapted from the organizational improvement research. It involves 5 phases: listen, plan, do, study, and act that incorporates stakeholder feedback into technology design. We will start by gathering feedback on unique attributes of smokeless use for firefighters and EMTs / paramedics related to occupational factors as well as determine their needs and wants for a mHealth cessation intervention. For example, we will ask participants to provide feedback on specifications of how shift work contributes to their smokeless use habits and how this type of work may affect intervention engagement. We will identify what are salient benefits and barriers to quitting for first responders such as firefighters and EMTs. We will also present trigger materials, which include the content of messages of our current text-based smokeless tobacco cessation intervention to adapt previously successful messaging to the culture and context of smokeless tobacco use among firefighters. A moderator will help facilitate the meeting in partnership with one Community Advisory Board member from each firehouse. We will audio record each discussion and will transcribe them verbatim. We will analyze the transcripts using rapid content analysis to identify themes. We will use the resulting themes to inform the intervention development and adaptation using an intervention mapping process.

After gathering this feedback and incorporating it into the intervention design and content, we will present the updated intervention to the firefighters and EMTs in a second workshop to obtain their feedback on the design and content. We will use feedback to refine the intervention. We will then conduct usability testing during the third workshop. Usability testing will comprise: 1) observing smokeless tobacco users interacting with the intervention, guided by "concurrent think aloud" protocols, and taking field notes; and 2) gathering feedback through semi-structured interviews immediately following the use of the intervention. Overall usability of the intervention will be measured by adapting the System Usability Scale (SUS), a validated tool provided by the US Department of Health and Human Services, which consists of 10 items rated from "strongly disagree" to "strongly agree" (e.g., "I thought the intervention was easy to use" and "I felt very confident using the intervention").

Aim 2: To assess the feasibility, acceptability and preliminary efficacy of the mHealth intervention compared to a usual care control intervention in decreasing smokeless tobacco use.

Objective: To determine if the mHealth intervention is feasible and acceptable for smokeless tobacco cessation for first responders such as firefighters and EMTs. We will also evaluate preliminary efficacy of the intervention in decreasing smokeless tobacco use.

Methods and Strategy:
Recruitment and Data Collection: We will recruit 50 smokeless tobacco users from collaborating Central North Carolina Fire Stations, and from social media ads that will run nationally in the United States. Inclusion criteria: 1) 18 years of age and older; 2) Employed as a professional firefighter or EMT / paramedic; 3) Have used smokeless tobacco for the last year and current (past 30 days) smokeless tobacco daily use; 4) Have access to a smart cell phone.

Randomization: Eligible participants will be randomized to either the mHealth Intervention (N=25) or control (N=25) group. Computerized randomization will be used to deliver a permuted block randomization with block sizes of four that will be used to randomly assign participants to one of the two intervention groups. The randomization scheme generated by the study statistician will be administered using the REDCap system.

Intervention:
mHealth Intervention: Although the specific content, messaging and delivery strategy will be developed with firefighters and EMTs, the proposed mHealth intervention will incorporate evidenced-based strategies for cessation and theoretical constructs from the Social Cognitive Theory and the Health Belief Model that have been shown to support cessation. The intervention will contain key steps to quitting including: 1) supporting readiness and motivation to quit; 2) setting a quit date and constructing a quit plan; 3) dealing with withdrawal symptoms and triggers to use; and 4) maintaining quit status and avoiding relapse.

Participants will identify on the baseline survey with would prefer to quit by reduction or by abrupt cessation. All participants will receive support messages and NRT. All participants (including the control group) will receive an NRT lozenge guide (to provide to all participants to create a consistent use for all). This will be included when the NRT lozenges are sent out to each study participant.

Abrupt Cessation: Participants are asked to set a quit date within two-four weeks. This quit date is emailed to participants. Participants will receive 8 weeks of messages. Pre-quit messages will focus on health benefits of quitting, building confidence, and making a quit plan. Post-quit messages will focus on dealing with cravings and urges and relapse prevention.

Reduction Cessation: Participants will receive a text at the beginning of each week alerting them to their number of dips for each day that week. They will receive a message reminder in the morning: "Do your best to only dip X times today, limit dip in your mouth to 30 minutes." At the end of each day participants will be asked to report how many times they dipped that day.

Text-based Cessation Support Intervention: Participants will receive text-based support messages 2-3 times per day over ten weeks. The messages are based on constructs of Social Cognitive Theory the Health Belief Model and the Theory of Self-regulation. Messages were developed from our pilot work with firefighters and address salient features that are associated with smokeless tobacco use in this population such as stress. The text-based system with have interactive capabilities, participants can text the word CRAVE if they are having a craving and will receive a message to help them deal with the craving. Participants can also text the word SLIP if they have a slip after their quit date and will receive a message to get them back on track. Participants can text MOOD if they need a positive message to boost their mood. Finally, participants can text the word CALL, a feature that can be used to address the stress that is commonly felt post-call. Messages will focus around providing mindfulness and deep breathing activities to deescalate after participating in a call.

Nicotine Replacement Therapy: We will provide participants via mail nicotine replacement the nicotine lozenge at no cost. We will provide a 4 week supply of 4mg Lozenge (mirroring the dose and the length to similar studies with smokeless tobacco users) with instructions on how to use. Participants will be instructed via text to start their NRT on their quit date. Participants will be instructed to use the lozenges every day for 12 weeks. For the first 6 weeks, use 1 lozenge every 1-2 hours. For the next three weeks, use 1 lozenge every 2-4 hours. For the last three weeks, use 1 lozenge every 4-8 hours. They should not use more than 5 lozenges in 6 hours, or more than 20 lozenges total per day. For any side effects potentially related to use of the nicotine replacement, we will instruct participants to stop using the lozenge and contact the study phone number to speak to a registered nurse (PI is a registered nurse). We will explain side effects that include nausea, light-headedness, headache, poor sleep, mouth sores and heart palpitations. We will explain that severe side effects (vomiting, syncope, tachycardia) related to use of the nicotine replacement are rare; however, we will make participants aware of these and will instruct them to contact the PI (a registered nurse) if they occur.

Usual Care Control: The control arm will receive the Enough Snuff Cessation Booklet. The original Enough Snuff Booklet is a self-help cessation intervention endorsed by the NCI in their Research-Tested Intervention Programs (RTIPs). 6 The Enough Snuff program has been shown to be efficacious in promoting smokeless tobacco cessation in the general population with quit rates ranging from 16-18%.

The Enough Snuff Intervention is a self-help cessation booklet paired with two brief motivational phone counseling calls that occur one week after the cessation booklet is sent and the week of the set quit

date. The first call focuses on increasing motivation for quitting (e.g. reasons for quitting), setting a quit date, and choosing a quit method. The second call focuses on dealing with tough situations when quitting and following through on quit plans. The Enough Snuff program has been shown to be efficacious in promoting smokeless tobacco cessation with quit rates ranging from 16-18% and is an intervention endorsed by the NCI in their Research-Tested Intervention Programs (RTIPs). For the current study we are delivering the program as follows:

Enough Snuff Cessation Booklet: We will provide all control participants with the Enough Snuff Cessation Booklet developed by our consultant Dr. Herbert Severson. The manual is organized around four key steps to quitting: 1) evaluating readiness and motivation to quit; 2) setting a quit date and selecting a quit plan; 3) dealing with withdrawal symptoms; and 4) maintaining quit status. We will send all participants a link to the manual via text-message as well as mailed a hard-copy of the booklet.

Motivational Text-Messages: To deliver the most equivalent intervention to the original Enough Snuff Program, we will send participants motivational text messages that map to the content of the phone counseling sessions. One week after the cessation booklet is sent we will text participants twice a week for the next 10 weeks. These are separate texts than what the intervention group will receive and coincide with the Enuf Snuff booklet. We will model the messages after the phone content and messages will focus on: motivation to quit, setting a quit date, picking a quit plan, motivation to follow-through with plan and dealing with tough situations when quitting. Messages will refer to the Enough Snuff booklet ask for a response from participants. We chose to send text messages to participants instead of phone calls as texting is consistent with our mode of contact with participants, less expensive, expands our reach, and is highly acceptable according to our pilot work.

Nicotine Replacement Therapy: We will provide participants via mail nicotine replacement the nicotine lozenge at no cost. We will provide a 4 week supply of 4mg Lozenge (mirroring the dose and the length to similar studies with smokeless tobacco users) with instructions on how to use. Participants will be instructed via text to start their NRT on their quit date. Participants will be instructed to use the lozenges every day for 12 weeks. For the first 6 weeks, use 1 lozenge every 1-2 hours. For the next three weeks, use 1 lozenge every 2-4 hours. For the last three weeks, use 1 lozenge every 4-8 hours. They should not use more than 5 lozenges in 6 hours, or more than 20 lozenges total per day. For any side effects potentially related to use of the nicotine replacement, we will instruct participants to stop using the lozenge and contact the study phone number to speak to a registered nurse (PI is a registered nurse). We will explain side effects that include nausea, light-headedness, headache, poor sleep, mouth sores and heart palpitations. We will explain that severe side effects (vomiting, syncope, tachycardia) related to use of the nicotine replacement are rare; however, we will make participants aware of these and will instruct them to contact the PI (a registered nurse) if they occur.

Measures

Feasibility. The feasibility outcomes will be: (a) the number of smokeless tobacco users recruited and randomized during the 4-month recruitment period; (b) engagement in the intervention measured by the portion of responses to messages that require a response; (c) the retention rates in the mHealth intervention compared to the control group at 30-days post intervention completion. We will determine

the feasibility by: (a) ability to recruit and enroll 50 participants in 4-months; (b) engagement with the intervention by having participants respond to at least 75% of messages or engage with 75% of the content using both self-report and objective methods. To calculate the proportion of messages read per participant, we will use a 5-point Likert scale to ask participants the following questions: "What did you typically do when you received a message from the mHealth intervention?" (1= ignored it completely, 5= read it immediately), "On a typical day, did you read messages you received?" (1= Not at all, 5= read the entire message), and On a typical day, did you engage with the intervention you received?"(1= Not at all, 5= read the entire message); and (c) ability to retain 80% of the sample at the 30-days follow-up. All participants will be given the option to participate in a phone interview with a member of the study team to expand on these answers approximately 1 month after their intervention has completed.

Acceptability and Consumer Satisfaction. To determine acceptability, we will ask the following questions using a 5-point Likert scale tailored to each arm of the study: 1) How useful was the intervention in helping you to quit smokeless tobacco (1 - Not at all useful, 5 = Extremely useful); 2) whether the intervention will change their smokeless tobacco use (1= Will not change at all, 5 = Will change a lot); 3) Did the intervention make you think about quitting (1= Not at all; 5 = All the time); and 4) Would you recommend the program to a friend (1 = Definitely would not recommend, 5 = Definitely would recommend). We will deem the pilot "acceptable" if each question has a mean level of 4 or higher.

Preliminary Impact. We will measure 7-day point prevalence abstinence at 30-days post intervention. We will ask participants: "In the past 7 days, have you used any smokeless tobacco?" and the response will be code as no (0) or yes (1). We will also assess number of quit attempts and if they have been tobacco free for 7 days or more at any time during the intervention as secondary outcomes. Any participants that claim they have not used tobacco in 7 days will also be given the choice to opt into providing a saliva collection sample. Instructions to participants will be sent along with the sample collection kits. Samples will be discarded once the nicotine test has been performed.

Sample Characteristics and Other Explanatory Variables. In conjunction with the outcome measures, we will collect the following measures to describe the sample characteristics and obtain descriptive information regarding these concepts in this population. For this initial study, we want to explore the feasibility of obtaining these measures in this population and the current study design and examine the heterogeneity of the data.

Demographics. At baseline, we will assess age, gender, education, marital status, length of time as a firefighter or EMT and socioeconomic status (SES). Measures will be adapted from the study team's prior research.

Smokeless Tobacco Use History. At baseline participants will be asked about their smokeless tobacco use habit including: number dips/chews per day, age of initiation and number of past quit attempts and past use of other tobacco products including electronic cigarettes.

Nicotine Dependence-Smokeless Tobacco. At baseline we will assess nicotine dependence using the Severson Smokeless Tobacco Dependence Scale-Short Form (SSTDS). The SSTDS is a validated

questionnaire that has eight items with a range of scores from 0-19 with higher scores being most addicted to nicotine.

Readiness to Quit. At baseline participants will be asked to rate their readiness to quit using oral tobacco products. We will use an adaptation of the Contemplation Ladder for smokeless tobacco users that we have used extensively in our prior research, which are predictive of quitting tobacco. The participant uses a 1-10 scale to rate their readiness to quit, and we have found that a graphic ladder with anchors describing levels of readiness at several levels can be easily understood by participants.

Cessation Resources. Participants in both arms will be asked if they accessed government sponsored cessation support services, other support for cessation (physician support) or any pharmacotherapy use at the 30-day follow-up.

Selection of Subjects

Study Sample.

We will target professional firefighters and EMTs who are smokeless tobacco users who live in the United States. Inclusion criteria will include: Inclusion criteria is: 1) 18 years of age and older; 2) Employed as a professional firefighter (may include volunteer firefighters and EMTs to reach those professionals who live in rural areas that do not have paid professionals); 3) Have used smokeless tobacco for the last year and currently (past 30 days) uses smokeless tobacco daily; 4) Have access to a smartphone.

Projected Enrollment.

We plan to recruit all participants for the current study using established connections between the study team and the Professional Firefighters and Paramedics of North Carolina who have expressed interest in working with us on the proposed study. We will also include in social media recruitment firefighters and EMTs from states within the USA. We will initially target two fire departments in Central North Carolina. Should we find that recruitment is still an issue and we need to expand to other local Fire Departments we will rely on our Advisory Board to identify other potential local Fire Departments to participate. Given this project was developed from an expressed need of firefighters we anticipate we will be able to recruit the sample necessary for this study.

Recruitment.

We will recruit 50 firefighters / EMTs who are smokeless tobacco users who live in the USA. Inclusion criteria: 1) 18 years of age and older; 2) Employed as a professional firefighter or EMT (interviews may include some volunteers in order to capture very rural areas that do not have paid professionals); 3) Have used smokeless tobacco for the last year and current (past 30 days) smokeless tobacco daily use; 4) Have access to a smart cell phone.

Randomization: Eligible participants will be randomized to either the mHealth Intervention (N=25) or control (N=25) group. Computerized randomization will be used to deliver a permuted block randomization with block sizes of four that will be used to randomly assign participants to one of the two intervention groups. The randomization scheme generated by the study statistician will be administered using the REDCap system. We will also use a graded compensation for surveys with $15 for baseline and $20 for 30-days post end of program.

Risk/Benefit Assessment

This is a minimal risk study. The only risks are the potential for emotional distress in answering questions about smokeless tobacco use and the risk associated with smokeless tobacco use, and the potential loss of confidentiality. Every precaution will be taken to minimize these risks, including the ability to contact the PI for questions or concerns, and using encrypted devices to record PHI.

All participants may decline to be part of the study and may leave the study at any time without loss of benefit to which they are entitled.

The focus groups will be conducted in the firefighers' home station or individually via Zoom. Participants in focus groups will be familiar with each other and will be free to respond or not respond. Firefighters and EMTs will have the PI's email address and can message if they prefer to respond privately.

Intervention participants may choose the time and the place to take their surveys and respond or not respond to Mosio secure text messages. This will ensure their comfort with the privacy available to them. All study platforms will be secure and approved by Duke OIT, helping to ensure participant response confidentiality.

The potential benefits outweigh risks. Those who participate in the intervention have a high probability of benefitting if they decrease or cease using smokeless tobacco.

Data Analysis & Statistical Considerations

Descriptive statistics will be used to detail the baseline sample characteristic along with the feasibility, acceptability, and preliminary efficacy outcomes. The focus of the efficacy analyses will be on looking for a signal of intervention effect rather than statistical significance testing or effect size testing due to the small size and exploratory nature of this initial statistically underpowered pilot study. Non-directional statistical tests will be conducted, and the significance level will be set at 0.05 per test for this preliminary study. For the preliminary efficacy analyses, both intention-to-treat (ITT) and completers analyses will be conducted. The ITT analysis will include all participants randomized to an intervention group regardless of study or treatment completion, while the completer’s analyses will include only those who finish the 30-day post-intervention completion assessment. For the ITT analysis, those who do not complete the 30-day assessment will be considered non-quitters.

Sample Characteristics. Intervention group differences in baseline sample characteristics will be tested using Wilcoxon Two-Sample Tests for continuous measures and Fisher's Exact tests for categorical measures due to the small sample size per group.

Feasibility. We will describe recruitment, enrollment, and 30-day follow-up attrition rates, as well as engagement with the intervention.

Acceptability. Participants' ratings of (a) the usefulness of the intervention received; (b) extent to which the intervention received changed their smokeless tobacco use, (c) whether the intervention made them think about quitting, and (d) whether or not they would recommend the program to a friend. We will compare intervention group differences in the acceptability using Wilcoxon Two-Sample Tests or Fisher's Exact Tests if when the acceptability ratings are dichotomized.

Preliminary Efficacy. The ST cessation (quit) rate per intervention group at 30-days post-intervention will be determined for the ITT and completers analyses using Fisher's Exact Tests.

Power Analysis. Past ST cessation studies (both text and web-based) have yielded ITT quit rates in the 12%-20% range. We estimate that the mHealth intervention will yield similar quit rates. We expect that the quit rate for the control condition will likely be 5%-10%. Given the expected small to medium effect sizes (ORs: 1.44 to 2.47), a sample size of 50 (25/arm) will not provide 80% power to detect a statistically significant difference in quit rates with significance set at 0.05. Thus, the efficacy analyses will focus on looking for a signal of effect and that the intervention is trending in the right direction.