# A Mobile App Based Cognitive Dissonance Intervention for Smoking Cessation (CoQuit)

DP006495-01

Study Protocol and Analysis: 4/4/2019
Informed Consent: 5/5/2020

## A. SPECIFIC AIMS

Despite overall declines in the rate of tobacco use in the United States over the past 30 years, current daily smokers continue to be of great concern due to their extremely high risk for long-term health problems and death.[1,2] There has been extensive research evaluating a wide range of smoking cessation approaches over the past 40 years. Recent reviews note that there has been significant progress in the application of both clinical and public health interventions to help smokers quit. They also concluded that the overall success rate of smokers quitting had not significantly improved.[3] New and innovative, theory-driven approaches are needed to both increase the reach of effective interventions and to improve the overall abstinence and long-term quit rates. Individual, group and public health interventions, both with or without adjunctive aids such as nicotine replacement therapy, have generally used some combination of cognitive behavioral interventions in varying combinations, but there remains a need for novel, theory-driven approaches to enhance quit rates and increase reach and engagement, such as those offered via computer or mobile app.

One approach that has demonstrated preliminary success in improving smoking cessation rates is cognitive dissonance induction,[4-6] which is based on the premise that behavior change can be elicited through exposure to high levels of cognitive inconsistencies between their beliefs and behaviors.[7] For example, having an individual who smokes present a verbal argument to a young person, outlining specific reasons why he/she should avoid smoking initiation is a cognitive dissonance induction strategy that has been examined in prior studies.[4] Cognitive dissonance has been widely researched and applied in the physical and mental health arenas, and has been shown to be successful at treating obesity,[8] improving healthy eating,[9] reducing fears,[10,11] treating chronic illness,[12] improving safe sex practices,[13] and has been used as a preventive measure in the development of eating disorders.[14] In addition to its effectiveness in improving overall health, cognitive dissonance approaches have also shown success in treating substance use,[15,16] reducing the initiation of smoking,[17] and improving outcomes for smoking cessation.[6]

Computer-based and mobile app-based interventions have been successfully utilized for behavior change and for a number of physical and mental health problems,[18,19] as well as smoking and smokeless tobacco cessation.[20-22] Computer- and internet-based interventions offer increased accessibility and flexibility, as well as increased confidentiality and anonymity, all of which increase the number of individuals that can be treated.[23-25]

Given the preliminary success of cognitive dissonance approaches at treating tobacco and substance use, and other health-related problems, coupled with positive outcomes and increased accessibility of mobile-based app interventions, the current proposal is aimed at adapting and testing the feasibility of a cognitive dissonance intervention (CDI) delivered via a mobile app for current daily smokers that is based on a previously piloted computerized cognitive dissonance intervention for smoking cessation. Our group has a long history of developing and implementing successful interventions with high-risk, substance-using adults and youth, and testing successful tobacco cessation interventions.[26-28] Our group also has expertise in developing, implementing and testing successful cognitive dissonance intervention protocols,[4,29] and in developing and testing the use of mobile apps.[20,21] The proposed CDI mobile app will be based on the primary cognitive dissonance cessation components tested in our previous work with adult smokers, and on intervention components shown to be central to smoking cessation. Given the need for innovative, theory-driven approaches to augment current smoking cessation treatment, the potential public health impact of the proposed intervention is very high – especially given the use of a mobile app format that can reach high risk, underserved populations of smokers and can be broadly implemented at minimal expense.

Specific aims are as follows:

1. Design and create a prototype mobile app that uses a cognitive dissonance induction approach (CDI) that targets daily adult smokers who are interested in quitting. An iterative approach using focus groups of adult smokers will be used to inform the design and functionality of the first 3 modules of the CDI mobile app.
2. Assess program navigation and usability testing on the first 3 modules of the CDI mobile app with daily adult smokers, and prepare the final prototype for pilot testing and evaluation.
3. Evaluate the prototype app by having 60 daily adult smokers recruited through social media to complete the first 3 modules. Usability data, system log data on program use, and participant satisfaction data will also be analyzed. Input from participants will be gathered to incorporate additional features to be developed during Phase II. Significant changes in quit attempts, number of days without smoking (smokefree days) and changes in smoking attitudes and behavior will be used to determine the efficacy of the Phase I program and evidence for proceeding to Phase II development and evaluation.

## B. SIGNIFICANCE

### B.1. Importance of smoking cessation

Smoking is the leading cause of preventable death in the U.S.,[1,2] accounting for approximately 443,000 deaths, which is 20% of all deaths annually.[1,23] Despite overall declines in the rate of tobacco use in the United States over the past 30 years, improving quit rates among current smokers continues to be a significant public health focus given the high risk for long-term negative health outcomes.[2] There has been extensive research evaluating a wide range of smoking cessation approaches over the past 40 years, and the 2008 Clinical Practice Guideline for treatment of tobacco use and dependence summarized the efficacy of smoking cessation approaches based on more than 8700 research articles. Although there has been significant progress in the application of both clinical and public health interventions aimed at smoking cessation, researchers have concluded that the overall success rate of these interventions has not shown significant improvement.[3] New, innovative, theory-driven approaches are needed to both improve the overall abstinence and long-term quit rates, as well as to increase the reach of effective interventions.

### B.2. Cognitive Dissonance-based intervention approaches

One theory-driven approach that has shown promise as a basis for intervention development is cognitive dissonance induction. Cognitive dissonance theory is based on the premise that individuals strive toward consistency between their beliefs and behaviors.[7] When *inconsistencies* between attitudes, beliefs or behaviors occur, individuals tend to adjust their beliefs or behaviors in order to reduce the discomfort of the dissonance that is elicited by the inconsistency. Reducing cognitive dissonance can be achieved in one of three ways: 1) adjusting one or more attitudes or behaviors to make the relationship between the two consistent, 2) acquiring new information that offsets the dissonant belief, or 3) reducing the importance of the attitudes or beliefs so that the inconsistent behavior can continue.

Interventions that use cognitive dissonance to elicit behavior change do so through situations that create high levels of cognitive dissonance. Regardless of the behavior being targeted, there are several common concepts that are central to effective cognitive dissonance induction. First, participation in the induction activity must be voluntary. Voluntary participation requires the individual to attribute the inconsistency between beliefs and behaviors as existing within themselves, rather than being due to demands of a given situation.[7] Effortful involvement (i.e., actively engaging in treatment exercises) is also required, and is believed to result in greater dissonance and greater motivation for change.[30] And finally, public statements of beliefs (i.e., counter-attitudinal advocacy) are thought to elicit heightened dissonance responses.[31] In fact, Roehrig et al[32] have shown counter-attitudinal advocacy to be successful in isolation of the other dissonance-inducing components (voluntariness, effortful involvement). Counter-attitudinal advocacy activities that are often used to induce dissonance include preparing and delivering speeches or statements about personal beliefs, role-plays where individuals act out a particular behavior, or making public commitments. Given the central role that counter-attitudinal activities appear to play in eliciting cognitive dissonance, these activities are a core component of the proposed cognitive dissonance mobile app intervention (CDI).

Cognitive dissonance has been widely researched and applied in the physical and mental health arenas. In particular, increasing cognitive dissonance has been shown to be successful at treating obesity,[8] improving healthy eating,[9] reducing fears,[11,12] treating chronic illness,[13] improving safe sex practices,[14] and has been used as a preventive measure in the development of eating disorders.[10] In their study of eating disorders, Stice and colleagues[33] showed that participants in a cognitive dissonance induction intervention who voluntarily critique the thin beauty ideal in verbal, written, and behavioral exercises (voluntariness, counter-attitudinal advocacy) resulted in significant reductions in the thin-ideal internalization, which putatively decreased body dissatisfaction, unhealthy dietary behaviors, negative affect, and eating disorder symptoms.

Of particular relevance, cognitive dissonance approaches have also shown success in treating substance use,[15,16] reducing the initiation of smoking,[17] and improving short-term outcomes for smoking cessation.[4-6] In one study, Simmons et al.[4] demonstrated greater quit rates at one-month follow up for smokers who engaged in video-taped discussions of the consequences of smoking delivered via computer. Although prior study results are promising, no long-term significant outcomes have been found, which suggests that increased exposure to dissonance induction activities (dosage) and reach of cognitive dissonance induction approaches might yield improved smoking abstinence outcomes. Guided by prior research, the proposed CDI intervention specifically provides increased opportunity for exposure to cognitive dissonance by including dissonance induction activities in each of the proposed CDI modules. In particular, we propose to offer the participant multiple opportunities for counter-attitudinal activities and public statements. Additionally, the mobile app format allows for increased access and reach of the intervention. The CDI app will be based on prior cognitive

dissonance intervention activities that have demonstrated effectiveness and will specifically build on Consultant Simmons' prior work with cognitive dissonance induction via video-recorded tasks for smoking cessation.[4-6]

**B.3. Mobile behavioral health-based interventions**

The utilization of mobile applications for smoking cessation and other addictive behaviors has increased over the past several years due to the low cost, ease of use, and increased availability via smartphones. Smartphone use has grown considerably in recent years, with more than 90% of adults in the U.S. currently estimated to be relying on smartphones daily,[34] and as mobile phone data plans have become less costly, many of these individuals have turned to their mobile devices as their primary internet connection.[35] Use of mobile apps has continually increased over the past several years and it is currently estimated that US adults spend an average of nearly 3 hours per day doing non-voice related activities on their smartphones and have an average of 80 apps. In addition, within the past three years, watching and recording videos has become commonplace on mobile phones, with an estimated 75% of people using their smartphones to record and access video.[36]

One of the primary benefits of mobile app interventions is the ability to provide support for introducing new skills and for mobile content to be more readily delivered (pushed) to participants when and where they need it. Mobile interventions proactively *push* content to participants without requiring them to visit a computer.[37] The proactive outreach of mobile interventions is especially critical given the limited use (engagement) of websites found in tobacco cessation interventions.[38-40]

The term *mHealth* has even been coined to refer to programs that are delivered via mobile communication devices.[41,42] While the term "mobile" has come to describe portable technology devices, Beale has asserted that the *user* is mobile, not just the technology: "…it is about computing for users who are not in a single location, but are moving around…computing whilst on the go as well as when at their destinations."[43] We propose to use automated calls and text messaging to extend the reach and impact of the intervention.

Little research has been reported on the effects of mobile behavioral-health-based interventions for smoking cessation, but the results that are available have been promising.[44] Although NCI public health initiatives (e.g., QuitGuide, QuitSTART) are currently available, they have not been evaluated for efficacy. Given the increased reach of mobile-based interventions, coupled with evidence that internet-based delivery systems might be an effective method for delivering cognitive dissonance interventions, suggests that a cognitive dissonance mobile app for smoking cessation might be a feasible and novel treatment approach. It is important to note that even modest absolute abstinence rates can translate into very significant public health impact (reach X efficacy) given the large number of tobacco users who could be reached through mobile interventions.[45,46]

**B.4. Using technology-based delivery methods**

Overall, the high cost and labor-intensive nature of face-to-face interventions has made the development and testing of electronically-delivered treatments an attractive modality due to their affordability and potential for dissemination. Such interventions have been successfully utilized for behavior change and for the treatment of mental health problems, including depression,[19] fears,[47] healthy eating[18] and smoking cessation.[20-22] Computer and mobile app-based interventions offer increased accessibility and flexibility, as well as greater confidentiality and anonymity, all of which increase the number of individuals that can be treated.[24,25]

There is a growing body of reports and published studies that have described encouraging results for web-based interventions for smoking cessation[48-51] and a recent meta analysis of RCTs for smoking cessation concluded that there is sufficient clinical evidence to support the use of web- and computer-based smoking cessation programs for adult smokers.[52] Additionally, a number of computer-based cognitive dissonance interventions have been developed and tested. For example, in their study of female college students with body dissatisfaction, Stice, Durant, Rohde & Shaw[53] evaluated the use of an internet-based program for the prevention of eating disorders. This study found that the internet-based participants showed significant reductions in eating disorder risk factors and symptoms compared to the control conditions at 1- and 2-year follow-ups. More recently, Chithambo and Huey[54] developed and tested an eating disorder prevention intervention delivered in a web-based format. Results indicated that both of the internet-based interventions produced significantly greater reductions in body dissatisfaction, thin-ideal internalization, and depression compared to the no intervention control condition.

Although it is difficult to draw strong conclusions from the emerging research on electronically delivered interventions because of the limited number of studies and differences in methodologies – including the extent to which online programs were supplemented by counseling (in-person or phone calls) or pharmaceutical supplements – overall conclusions of these meta-analyses support the superiority of web-based interventions compared to non-web-based interventions across a broad range of health behaviors.[52,55] However, despite

positive preliminary evidence supporting computerized smoking cessation interventions, further research is needed. In fact, a recent Cochrane meta-analysis of web-based cessation studies concluded that "…more rigorous studies comparing the long-term effects of Internet interventions with non-Internet interventions or no intervention at all are needed in order to determine the true long-term effectiveness of the internet as a tool for smoking cessation."[56]

**B.5. Commercialization Potential of the Product**

The primary markets for the proposed CDI mobile app are entities that offer smoking cessation services to their customers. While there is a very large number of smokers in the United States estimated at more than 34 million adults, targeting smokers directly is challenging. We would focus our marketing to hospitals, clinics, VAs and other entities that could offer this efficacious intervention to smokers in their care. As part of our efforts in Phase I we will further assess the potential customer base and highlight the unique motivational aspects of the CDI intervention. We expect to license the use of the mobile app and charge fees based on the number of users for the licensee.

## C. INNOVATION

The proposed project is innovative in three primary ways. First, the proposed CDI mobile app will be the first dissonance induction-based mobile app for smoking cessation. Second, the proposed study focuses on both the initiation of quit attempts, as well as overall quit rates. The dual focus on increasing quit attempts and smoking cessation rates will help to inform the scientific knowledge of proximal outcomes that might inform intervention efforts aimed at more distal outcomes. And finally, the mobile app-based format – if shown to be successful at improving smoking quit rates – lends itself to improved accessibility across all classes of smokers. One significant limitation of existing face-to-face cognitive dissonance-based programs is cost and limited access to treatment for individuals without transportation. We believe that our program will be very attractive, as the mobile app-based format can greatly expand reach – both as a standalone program and as an adjunct to existing interventions. The mobile app intervention is also likely to appeal to underserved smokers and younger smokers who use their mobile phones for internet access and who frequently download apps for various personal interests and supports. Given the need for innovative smoking cessation programs that are low-cost and easy to access, the social impact of the proposed CDI intervention is high.

## D. APPROACH

**D.1. Overview**

The primary goal of the proposed Phase I project is to develop and evaluate a cognitive dissonance mobile app intervention for smoking cessation (CDI). The CDI app will build upon previous tobacco cessation treatment conducted by Co-I Severson and Consultant Simmons, on the substance abuse cessation and mobile-app treatment research conducted by PI Smith and Co-I Severson, and on the cognitive dissonance intervention research conducted by Co-I Yokum. Given our extensive experience developing and testing successful smoking cessation and cognitive dissonance interventions, as well as developing and testing mobile app interventions, we will focus our energy on effectively integrating these areas of study into an easy-to-administer mobile app intervention program that is attractive and engaging.

**D.2. Research and Development Team**

Dana K. Smith, PhD, Principal Investigator, is a Research Scientist at Oregon Research Institute and Oregon Research Behavioral Intervention Strategies. Dr. Smith's research has focused primarily on the development and treatment of co-occurring substance use and criminal behavior. Dr. Smith has taken the lead in developing three R01 interventions aimed at reducing co-occurring problems in substance-abusing participants. In addition, she and Dr. Severson have worked together to develop and test a mobile app for the treatment of substance use (see NIH biosketch).

Herb Severson, PhD, Co-Investigator, is a Senior Scientist at Oregon Research Institute and has developed and authored several interventions for tobacco cessation and other health-related interactive media programs. He has received national recognition for his work in health promotion and in research to practice activities and recently received the Research to Practice Award from the Society for Behavioral Medicine. Dr. Severson has been an investigator on more than 50 NIH funded research grants and has published more than 150 research reports in professional journals. A recent study was the development and evaluation of a mobile app for smoking cessation (Grant #R01CA172205) and he is recognized as an expert in tobacco cessation.

Sonja Yokum, PhD, Co-Investigator for this project, is a Research Scientist at the Oregon Research Institute. Her program of research focuses on the understanding of neural and biological risk- and maintenance factors for eating pathology and addictive behaviors. Dr. Yokum has conducted several randomized eating disorder and obesity treatment trials involving the development and testing of cognitive dissonance interventions.

Vani Simmons, PhD, Consultant for this project, is an Associate Member at the Moffitt Cancer Center and Professor at the University of South Florida, and has conducted successful RCTs of cognitive dissonance interventions for smoking cessation among young adults. In particular, she is focused on developing and testing experiential, theory-based, web-interventions for college smokers. Dr. Simmons has also conducted research on the development of culturally appropriate smoking prevention and intervention efforts.

Richard Brown, PhD, Consultant for this project, is an expert in tobacco cessation and has conducted extensive work in innovative smoking cessation studies. He has collaborated with Dr. Severson on several previous grants, including both web and mobile app programs for tobacco cessation.

**D.3. Contractors**

Twenty Ideas. Mike Biglan and the Twenty Ideas team have a successful history of developing computer- and mobile-app based interventions. Team members at Twenty Ideas have designed and built hundreds of web-based and mobile apps, including those funded by NIH, the Department of Education and the National Science Foundation. They have been involved in developing several health-related mobile apps, and have extensive experience utilizing the SBIR funding mechanism.

**D.4. Phase I SBIR Project Timeline, Benchmarks, and Procedures**

This Phase I SBIR will be conducted in two stages: 1) Product development and usability testing, and 2) pilot testing. Stage 1 and Stage 2 are outlined below and are expected to take approximately 6 months each.

**D.4.a. Stage 1: Product Development**

Our approach to developing the CDI mobile app is informed by three previous areas of our work: (1) the work of Drs. Smith and Severson in developing and testing innovative computer- and mobile-app based approaches for tobacco and substance cessation programs, (2) the prior research of Dr. Yokum in designing and examining cognitive dissonance interventions, and (3) the considerable prior work of Dr. Simmons in developing and assessing computerized cognitive dissonance interventions for tobacco cessation.

The proposed CDI intervention will consist of 9 modules that will be delivered via mobile app. During Stage 1, we plan to develop the initial 3 modules of the CDI app in order to examine the feasibility and usability of the app; the remaining 6 modules are proposed to be developed during a Phase II SBIR application. As outlined previously, three concepts are central to eliciting cognitive dissonance: voluntariness, effortful involvement, and counter-attitudinal advocacy. Building on the cognitive dissonance work by Co-I Yokum and Consultant Simmons, we have carefully integrated these concepts into the proposed session modules. We have included each of the three components into each module. Based on the strong relationship between counter-attitudinal advocacy and cognitive dissonance found in previous studies,[6,7] we included the need to make a public statement – either in letter format or verbal statements to family and friends – in each module as well. Given that Consultant Simmons found reduced smoking rates after one two-hour intervention with unmotivated smokers who made one public video statement of their negative beliefs of smoking, we believe that the proposed format of implementing all three components into each of nine modules will sufficiently increase the opportunity for dissonance induction. An overview of the core components and their relationship to dissonance induction is outlined in the Curriculum Table in Human Subjects.

Investigators will work with the technical team at Twenty Ideas, a trusted and experienced technology vendor who has a team that has developed previously-tested substance use cessation programs. Twenty Ideas will build a complete program with new infrastructure, logic, and information architecture using and JavaScript scripting combined with HTML and CSS. Animation and interactive content will use DHTML (Dynamic HTML). During development and deployment, the project database will be housed at a secure web facility on Amazon Web Services in a PostgreSQL database on a server running a Linux-based operating system. Data from the mobile app will interface with the project database through TLS (Transport Layer Security) encrypted by the server. Researchers will have secure access to project data—including participant reports and management utilities—through an administrative interface built on Node.js technologies. These fully automated, stand-alone, technology-based interventions will work appropriately on popular, modern Web browsers on both Macintosh and Windows computers.

In order to maximize reach with our intervention, we have structured the primary experience for the users to be on their mobile smartphone. A core piece of this experience is for a participant to watch a video, post it in a small public support group forum that we assign them to that includes approximately 8 participants, and then easily respond to their small group with encouraging and supportive comments. In addition, this model works well even if the group lives in various parts of the country and doesn't require geographically proximate groups. Groups of participants will be designated on a rolling basis, where a “group” will be assigned for every 8 participants enrolled. Twenty Ideas has extensive experience creating “work groups” and chat rooms for web- and mobile-app programs.

To implement the platform, Twenty Ideas has provided an architectural schematic that fits the necessary participant experience for the study, the data needs, as well as the budget submitted. With over fifteen years of experience designing and developing web and mobile applications, including numerous behavioral interventions, the Twenty Ideas team is confident with this approach. In addition, the team has experience in the development of video playback and recording solutions such as the Marco Polo video chat that works with millions of users. For this project, we plan to use the framework Ionic that works on both iOS (i.e. iPhones) as well as Android devices. To support easy video recording embedded into the App, our plan is to use the Ziggeo video recording Software Development Kit (SDK). Lastly, as participants use the App, their information will be stored off of the devices so we will use the Node.js framework and PostgreSQL database to collect, store, and make accessible key study data.

**D.4.1.a. Focus groups (N=20)**

We will incorporate an iterative formative process involving two focus groups of 10 participants each. The focus groups will be conducted at ORI by PI Smith and Co-I Severson. Because of our extensive experience in developing and testing cognitive dissonance and smoking cessation interventions, we have well-developed ideas for the “look and feel” of the program, which will aid in our initial mockups of the concepts, and graphics for the intervention modules. We will present these ideas and graphics to the initial focus group and use their feedback to refine the materials for a second focus group of participants that are representative of the target audience for the program.

Based on feedback from the first focus group, we will develop prototype versions of the program using Marvel, a design and rapid prototype development tool that yields functional mockups for users to interact with before any programming takes place. During an iterative process we will refine the mockups, present them to five test users, solicit their feedback, and continue to modify and refine the mockups until we arrive at an acceptable design and feature set. Session transcripts will be assessed both manually and using Atlast.ti,[57,58] a computer aided qualitative data analysis software program to identify themes. Next, we will finalize and create all the media assets for the app, including text and graphics, images, narration or other audio elements, and build all program screens and user controls. We will incorporate a simple user registration component to allow for tracking of app usage while also ensuring security of user-collected data. Throughout the development process, Twenty Ideas designers and programmers will create and iterate rapid prototypes of the app to make sure the content, functionality, and look and feel of the app conforms to the overall research goals of the project. Participants will receive a $30 gift card for their participation in focus groups or usability testing.

**D.4.1.b. Usability Testing (N=5)**

We will present the initial prototype to five test users for preliminary usability testing in which the participant will be observed using the program and then asked to talk aloud about their experience to help us better understand ease of navigation and program use. Observations and interviews with usability participants is a great help in discovering potential problems with program navigation comprehension of key concepts and interactive activities. Mobile app-based components will embody established usability standards and will adhere to their recently emerging usability guidelines. Individual test sessions will be held, with hands-on use of functioning program components. Based on our observations and interviews we will move on to conduct a more complete programming of the proposed intervention and prepare for pilot testing. One unique feature of the CDI program will be the use of video for making public statements about attitudes, beliefs and intentions. The usability testing will allow us to fully test the use of the video feature with adult participants who currently smoke. The program will be used by the participants on their own mobile devices to emulate the way that the program will be used in the evaluation study. The key features that need testing will be the video components that are recorded and posted by participants. We will test the ability of participants to upload video to the app and our ability to view and upload the video to their support group. The platform will allow us to view and monitor the video before it is shared with the support group of peers.

**D.4.2. Stage 2: Product Evaluation (N=60)**

We will conduct a pilot test of the CDI mobile app with 30 male and 30 female adult smokers (N=60). Feasibility, usability, participant satisfaction, and pre-/post- intervention outcomes of smoking will be evaluated in the pilot study. Data on: 1) frequency and duration of app use, 2) number of modules completed, 3) cognitive dissonance and motivation to quit, and 4) smoking attitudes and behavior, including motivation to quit, quit attempts, and number of days without smoking (smokefree days), will be examined pre- and post-intervention. Participants will be compensated using gift cards to Amazon in the following increments: $30 for the baseline assessment, $35 for the 1-month assessment, and $40 for the 3-month assessment.

**D.4.2.a. Participants.** Details regarding sample characteristics, eligibility criteria, recruitment and retention are described in the Human Subjects. Briefly, participants will include both male and female adult smokers recruited from the United States. We have a long history of successful recruitment of smokers, and have

extensive experience utilizing recruitment efforts to enroll smokers and tobacco users in mobile app-based intervention programs. Inclusion criteria will be as follows: 1) age 18 or older, 2) self-reported daily smoking, 3) having a valid home mailing address, 4) English-speaking, 5) access to a smartphone with video capability for the duration of the project, 6) not currently enrolled in or participating in any tobacco cessation programs, and
7) expressed desire to quit smoking.

**D.5. Data Collection Procedures**

**D.5.1. Overview and timeline for the pilot study.** In the proposed evaluation study, a total of 60 participants will be recruited and baseline assessed during Year 1. We anticipate that approximately 10-25% of these will fail to complete the study; however, we will employ an intent-to-treat analysis strategy, which will include all participants. We will conduct baseline assessments immediately after enrollment and consent; all measures completed at 1-, and 3-month follow-up assessments will be provided online.

The baseline assessment will primarily measure participant risk factors, as well as past and current cigarette and other tobacco use, readiness to quit, quit attempts and cessation in the past year, and will consist of questionnaires administered using Qualtrics; none of the assessments will be done via the mobile app.

The 1-month assessment will focus on usability, cognitive dissonance, motivation to quit, and short term outcomes such as making a quit attempt, use of the app (dosage), number of cigarettes smoked, and days abstinent from smoking. For the 3-month assessment, the focus will be on cessation outcomes, including both point prevalence (i.e., no smoking in the past 7 days; no smoking in the past 30 days) and sustained abstinence, which is defined as sustained abstinence between the 1- month and 3- month assessment. We will also assess quit attempts at each assessment. Non-responders to the request to complete a follow up assessment will be sent email and text messages to encourage completion of the assessment. We will continue to prompt completion for 14 days following the initial request for the one month assessment and there will be a 30 day window for completion of the 3-month assessment.

**D.5.2. Pilot Study Measures**. Program navigation and usability will be assessed during usability testing and for the evaluation participants over the one month of use, and will include reports of: 1) ease of use, 2) perceived benefits of using the app, and 3) suggestions for product development modifications. Participants will also provide ratings on product satisfaction and usability on a 7-point Likert Scale. Qualitative data gathered from the focus groups will be recorded and evaluated with the goal of identifying challenges to using the app, product satisfaction, and suggested modifications. This information will then be used to guide adaptations in a Phase II SBIR application. In addition to qualitative data, login tracking information from the app will be used to assess each participant's: 1) frequency and duration of app use, 2) number of modules completed, and 3) type and frequency of substance use. These data will be used to evaluate treatment engagement and adherence, as well as pre- and post- changes in tobacco use.

A full description of measures is included in the Human Subjects. Briefly, the following will be used to examine pre- and post- changes in smoking behavior, cognitive dissonance, and motivation to quit: 1) Nicotine Dependence, 2) Past and Current Tobacco Use, 3) Motivation to Quit, 4) Quit Attempts, and 5) Cognitive Dissonance. Nicotine dependence will be measured at baseline and at each follow-up assessment using the Fagerström Test for Nicotine Dependence[58] and items that assess withdrawal experiences. Past and current tobacco use will be assessed at each time point, including type, frequency, and duration of use. Motivation to quit will be assessed at baseline by asking participants if they want to quit within the next 30 days and at follow-up assessments in terms of stages of change.[59] We will also use an adaptation of the Contemplation Ladder[60] that we have used extensively in our prior research[40,61] and have found in predicting tobacco cessation.[61,62] Quit attempts will be measured by the number of intentional quit attempts that last at least 24 hours, duration of quitting, and use of pharmacological adjuncts at each time point. Cognitive dissonance will be measured using the Dissonance Thermometer.[63,64] Prior research[63] has shown that the 3- item discomfort factor of the Dissonance Thermometer represents the affective expression of cognitive dissonance.

**D.5.3. Statistical Design and Power Overview**.

This project will test the *promise o*f efficacy of the CDI mobile app with a pre-training, post-training, and 3- month follow-up non-experimental design with 60 adult daily smokers. We hypothesize that after use of the CDI mobile app participants will show increases in quit attempts and number of non-smoking days, and improvement in smoking attitudes and behaviors. We will use random effects growth models to test change in normally distributed outcomes and the Wilcoxon signed-rank test for non-normally distributed outcomes. We also propose ancillary analysis (e.g., dose-response) to bolster our confidence in the non-experimental design. Details of our analytic approach, approach to missing data, power analysis (power >.80 to detect medium effects (d=.39) for pre-post change), and feasibility benchmarks are provided in Statistical Design and Power in the Human Subjects.

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# Informed Consent for Participation

**Study Title:** CoQuit Study
**Principal Investigators:** Dana Smith, Ph.D. and Herb Severson, Ph.D.
**Sponsor:** NIH 1 R43DP006495-01-00

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You are invited to participate in a research study that will test a new program designed to provide support to adults who smoke and want to reduce or discontinue their use of cigarettes. This study is being conducted by Dana Smith, Ph.D., Herb Severson, Ph.D., and Sonja Yokum, Ph.D. of Influents Innovations in Eugene, Oregon and is funded by the National Institute of Health (NIH 1 R43DP006495-01-00). We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to participate in the study.

**What You Will Be Asked to Do**
If you decide to participate, you will be asked to complete a survey and use an app that is being developed as a tool to help adults decrease or stop smoking. This survey will take about 20 minutes and can be done on your phone or mobile device. The survey consists of questions about your past and current use of cigarettes and your motivation to stop smoking. There are also questions about you, such as your age, living situation, education and employment.

In the month following the first survey, you will be asked to use the CoQuit app and make an effort to reduce or discontinue your use of cigarettes. The app contains short videos of a narrator introducing online activities designed to help you stop smoking. As part of this program, you will be connected to an online group of about 8 other study participants. The study activities involve making and posting videos so that you can provide and receive support around reducing or discontinuing cigarettes. These videos can only be seen by study staff and other adults in your online support group. After each activity, there will be a brief survey that will take less than 5 minutes to complete. After 3 months, you will receive a link for the second survey about using and quitting cigarettes. This survey will take about 20 minutes to complete. You will be asked how much you liked the app and if you found it to be helpful. You can also share any ideas you have about improving it.

You will receive a check or Amazon gift card for completing surveys and study activities. You will get:

$30 for the first survey
$5 for each activity (there are 3 total)
$60 for the second survey

## Use of Video-recordings

One feature of this smoking cessation program is being part of an online group of adults who can support and encourage each other around their shared goal of reducing or stopping their use of cigarettes. You will be connected to about 8 other adults who are also in this study. Study activities include the group members making and sharing videos that focus on avoiding cigarettes. Study staff will control access to these groups and monitor activity for appropriateness and confidentiality. Videos must be appropriate for public viewing, may not contain any other people, and may not contain profanity or sexual references.

**Risks and What Will Be Done to Reduce the Risks**
There are some possible risks involved for participants. We will be asking you questions about your thoughts and actions related to tobacco use and asking you to share some of these thoughts and actions with other adults who are also working to reduce their tobacco use. We will also ask for your opinion about the app after you use it. You might feel a little embarrassed or uncomfortable sharing information about yourself or your opinions. Remember, you are not required to answer any questions or complete any activity.

We will be getting personal information from you. There is always the possibility that someone who is not authorized might see it. We take the following precautions to prevent any unauthorized person from having any access to the information you give us:

- Any information you give us will be kept strictly confidential. All information will be kept in locked electronic files. We will remove all names from all the information we get (except the Informed Consent). ID numbers will be assigned to the information you give us and only authorized staff will have access to the locked electronic file that links your name to your ID number.
- We will do all we can to protect your confidentiality. However, because you will be using your phone to answer questions, take videos and watch videos, others near you might be able to figure out that you are in a study related to substance use.
- We have a “Certificate of Confidentiality" which is a legal assurance from the federal government, which will help us protect your privacy even if the records are subpoenaed. We will not give any information about you to anyone, unless you give us your written permission to do so.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov . This website will not include information that can identify you. At most, the website will include a summary of the research results. At the very end of the project, we will post a study consent form to the same website. The consent form will not have names on it. You can search this website at any time.

**Storage & Future Use of Your Information**
We may keep information about you forever. We do not know what studies we might do in the future. We would like your permission now to use or share your personal information without having to ask you again in the future. We will only use your information in other studies about smoking cessation.
We will remove your name and any other information that identifies you before we use it in a new study. There is still a chance that someone could figure out that the information is about you.

**Benefits to You for Your Participation**
There are some benefits to you for taking part in this research project. You will contribute to the design of an app that will help efforts to reduce dependency on tobacco. Using this app may help you reduce or discontinue your use of cigarettes, which could have significant health benefits.

**Alternative Procedures**
There are other programs available to help you stop smoking. This study is testing a new program. You could explore other methods of reducing your use of tobacco instead of being in this study.

**Your Right to Withdraw from the Project**
Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits you might otherwise receive. If you decide to participate, you can stop participating any time without penalty. You will receive checks or gift cards for each survey that you complete.

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Holly Chedester or Erika James at 541-484-2123. If you have questions about your rights as a research subject and/or research-related injury, call the Office for the Protection of Human Subjects, Oregon Research Institute, 541-484-2123. ORI’s TDD number is 800-735-2900. You will receive a copy of this form to keep.

Your signature below indicates that you:
- have read and understand the information provided above
- willingly agree to participate
- may withdraw your consent at any time and stop participating at any time without penalty
- will receive a signed copy of this consent form via email

I understand the research project as described above and I agree to participate.

| _____ | _____ | __ __/__ __/__ __ |
|---|---|---|
| **Signature** | **Name (Please Print)** | **Date** |

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