Outcomes from a Mobile Smoking Cessation Program During a Monitoring Period of 6 Months [redacted]

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Protocol Summary

Device Names	Carbon Monoxide Breath Sensor System (COBSS) and Pivot App
Protocol Title	Outcomes from a Mobile Smoking Cessation Program During a Monitoring Period of 6 Months [redacted]
Principal Investigators	[redacted]
Protocol Number	[redacted]
Protocol Version	[redacted]
Protocol Shorten Name	[redacted] 6-Month Outcomes of a Mobile Smoking Cessation Program
Study Design	Prospective, open label, single center clinical study enrolling up to 310 subjects (up to 50 run-in subjects, and 260 general subjects).. No medical decisions will be made related to test results.
Objective	We aim to assess a mobile smoking cessation program delivered through the Pivot Application ('App'). We will evaluate user engagement and retention in the program, attitude towards smoking and smoking behavior, quit rates, relapse rates, and quality of life over the study period, as well as user feedback on the program.
Potential Subjects	Up to 310 subjects who report daily smoking behavior (smokers).
Inclusion Criteria	● 18-65 years of age ● English speaking ● Smokes daily ● Smokes 5 or more cigarettes per day ● Owns and uses a smartphone (iPhone 5 and above, operating system iOS 9.0 and above, or, Android 4.4 and above, operating system Android 4.4 and above) ● Employed at least 20 hours per week ● Lives in the USA ● Understands and willing to sign the Informed Consent Form

Recruitment	Potential subjects will be identified via advertisement at outdoor locations (i.e. flea markets, outside of movie theaters, shopping malls, train stations, stores that sell cigarettes), print media (i.e., local newspapers, billboards), web media (i.e., Craigslist, Facebook, Survey Monkey, Instagram, Twitter, Google Ads, Reddit, smokefree.gov) and through clinical research recruiters.
Study Session	Potential participants will complete an online screening form. Eligible participants will be called to confirm eligibility, discuss the study, and have their questions about the study answered. Interested eligible participants will then be emailed the registration link, which includes the electronic informed consent. After providing electronic informed consent, subjects register online and receive the COBSS device. Baseline questionnaires (demographics, smoking history, and attitude towards smoking) are completed, and subjects then self-train to use the COBSS (which includes the CO Breath Sensor and Breath Sensor App, or BSA) and the Pivot App. The BSA is required for the breath sensor to communicate with the subject's smartphone and allows basic viewing of CO sample values. The Pivot App comprises 5 sequential phases (Explore, Build, Mobilize, Quit and Secure). The Pivot App provides the user with information about CO sample values and CO trends, as well as the ability to log cigarette events (when subject smokes), view cigarette consumption trends, view instructional videos, complete educational activities and challenges, and engage with a coach. During the registration process, subjects are paired with a live coach who will provide support using in-app text messaging during the study. During the study, subjects log their cigarette events in the Pivot App and submit breath samples using the CO Breath Sensor. They also complete short (2-8 minutes) activities in the Pivot App, create a quit plan, and periodically engage with their coach. The primary phase of the study, during which participants are using the Pivot program, is 14.5 to 18.5 weeks in duration, depending on participant relapse/exit/re-entry rates and navigation of the phases of the Pivot App journey (Build is self-guided and lasts 1-28 days). Three months after completing the primary phase of the study, participants are asked to complete a final exit questionnaire. Questionnaires assessing smoking behavior, attitude towards smoking, quality of life, engagement with the program and feedback on the program are conducted at baseline, at the end of each Pivot App phase and at 3 months after completing the primary phase of the study. In addition, more detailed user feedback on the experience is sought upon completion of the Secure phase of the Pivot App, or upon the end of the participant's engagement with the app, whichever occurs first. Upon return of the study device and completion of the questionnaire conducted 3 months after completing the primary phase of the study, the study is considered complete.

Endpoint and analysis	We will compare the following variables at entry, after completion of each Pivot App phase, and/or at exit. Engagement: ● Weeks of active engagement ● Phase completion ● Number of app opens Smoking Behavior: ● Number of cigarettes smoked per day ● Quit attempts ● Quit rates: 7-day, 30-day point prevalence ● Sustained quit (continuous days quit) ● Smoking reduction (in participants who do not quit) Responses to questionnaires: ● Measurements assessing attitude toward smoking ○ Readiness to quit ○ Goals related to smoking behavior ○ Confidence to quit ○ Difficulty maintaining quit ● Net Promoter Score (NPS) ● NPS, Coaching ● Nicotine Dependence ● Quality of Life

Schedule of Study Activities

	Screening	Day 0	Day 1	Pivot App - Explore (9 days)	Pivot App - Build (1 - 28 days)	Pivot App - Mobilize (7 days)	Pivot App - Quit (7 days)	Pivot App - Secure (11 weeks)	Exit - 3 mos after Secure or 3 mos after the end of participant's engagement with the app
Eligibility Confirmed	X								
Informed Consent		X							
Baseline Questions (demographics, thoughts about smoking)		X	X	X					
Receive COBSS*			X						
Cigarette Logging**				X	X	X	X	X	
Breath Sampling***				X	X	X	X	X	
Coach-Initiated Interactions				X	X	X	X	X	
Questionnaire			X	X	X	X	X	X	X
Questionnaire (thoughts about smoking and the experience of using the device)								X	
Exit questionnaire									X
Return Breath Sensor									X
Study Completion									X

* COBSS received by participant only after confirmation of eligibility and provision of informed consent
** Cigarette logging should stop at the beginning of the Quit phase of the Pivot App (assuming participant quits smoking), however, participants are asked to log all cigarettes, including those that occur during a lapse or relapse
*** Suggested breath sampling schedule varies from one phase to the next

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List of Abbreviations

CO	Carbon Monoxide
COBSS	Carbon Monoxide Breath Sensor System
CRF	Case Report Form
BSA	Breath Sensor Application
IRB	Institutional Review Board
ICF	Informed Consent Form
ppm	parts per million

1 Introduction

1.1 Background

The smoking of tobacco products is a leading cause of preventable morbidity and mortality, excess health care expenditure, and lost work productivity. [redacted]

We have developed a personal mobile CO breath sensor (study device, Carrot Sense) that communicates with a mobile app (BSA) on a smartphone to display the results to the user. The BSA is required for the breath sensor to communicate with the subject's smartphone and allows basic viewing of CO sample values. In addition, we have developed the Pivot App, which provides additional information about CO sample values and CO trends, as well as the ability to log cigarette events (when subject smokes), view cigarette consumption trends, complete educational modules and challenges, view instructional videos, create a quit plan, and interact with one's coach. Enabling a smoker to monitor and track the level of CO in their breath, while

logging the times of the cigarette consumption and participating in an educational program with coaching may lead to attitude changes, quit attempts, and/or smoking cessation.
This study aims to assess changes in smoker's behavior and attitudes toward smoking during and after using the Pivot mobile smoking cessation program.

1.2 Study Rationale

We will assess engagement, motivation, smoking behavior changes, nicotine dependence, smoking cessation rates, quality of life, retention and general feedback in smokers using the Pivot mobile smoking cessation program over a period of 3 months, with 3-month follow-up after program completion.

1.3 Potential Risks and Benefits

1.3.1 Known Potential Risks

There are no anticipated risks or harms to the subject. No medical decisions are made based on study data.

1.3.2 Known Potential Benefits

It is possible that some subjects may experience an increased awareness of their smoking behavior, decrease their smoking, or quit smoking altogether.

1.3.3 Risk Benefit Assessment

Given the non-invasive nature of the breath sampling and the data collection, there are no anticipated risks to subject safety. This study assesses a mobile smoking cessation program, which may help subjects decrease or quit smoking. No medical decisions are made based on study data.

2 Study Objective

We aim to assess the Pivot mobile smoking cessation program. We will assess participant engagement with and feedback of the program, as well as changes in attitude towards smoking and smoking behavior over the study period.

3 Device Descriptions

3.1 Carbon Monoxide Breath Sensor System (COBSS)

The Carbon Monoxide (CO) Breath Sensor System (COBSS) comprises a personal mobile breath sensor (CO Breath Sensor) capable of measuring the level of CO in exhaled breath and an app for smartphones which displays the exhaled breath CO value to the user.

3.1.1 CO Breath Sensor

The CO Breath Sensor (Figure 1) is portable, battery-powered, and small enough to be conveniently carried by the user throughout the day (pocket, purse, backpack). The CO Breath Sensor is rechargeable using a micro-USB cable. The LED pulses orange while charging and then solid green when fully charged.
The CO Breath Sensor pairs to the app (BSA) on the smartphone via low-energy Bluetooth. The user submits a breath sample by exhaling (blowing) into the CO Breath Sensor via a provided straw (polypropylene, reusable, cleaned with soap and water, replaced as necessary). In the study, a pack of 7 straws is provided with the CO Breath Sensor.

Figure 1. CO Breath Sensor

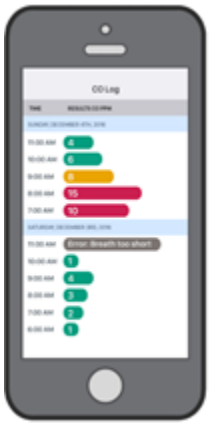

Figure 2. BSA CO Log

3.1.2 Breath Sensor App

The Breath Sensor App (BSA) for smartphones is required for the breath sensor to communicate with the subject's smartphone and allows basic viewing of CO sample values. The CO breath sample values are presented in parts per million (ppm) within color coded bars (see Figure 2). A low level in a smoker (CO value of 0-6 ppm, Green) does not mean it is safe to smoke. Likewise, a non-smoker may have CO levels higher than 6 ppm (Orange or Red) due to environmental exposure. These ranges are derived from many clinical studies using point measurements at various times of the day [redacted]. Should the subject submit a breath sample using improper technique, s/he will receive an error message in the CO Log.
The results in the app are stored in a secured database. Study personnel will be able to view these results as well as activity in the app.
The app has features to allow the subject to set reminders, vibration, volume, and other preferences.

3.2 Pivot App

Participants use the Pivot App as the main focus for study interactions. In the Pivot App, participants may perform the following main actions:

- View CO sample values, CO load, and CO trends
- Log cigarettes and see the associated data including cigarette trends
- Complete educational activities
- Complete challenges and practice quits related to the educational activities
- Set a Quit date, then build and revise the Quit Plan
- Read back all information entered in "My Story"
- In-app chat with the Pivot coach

More specifically, participants can see their individual CO sample values in the CO Log (as with BSA), and can also view CO load (area under the curve for CO exposure over 24 hours) and CO load trend day to day. Participants can also log cigarettes, view number of cigarettes smoked per day and trends in cigarette consumption. The participant's location at time of cigarette logging will be collected if the participant opts in for this feature.
In addition, activities are delivered and completed in the Pivot App. These are educational activities designed to increase participant's awareness of smoking risks and raise questions about the role of smoking in the participant's life. Some of these activities are combined with "challenges" that the participant can choose to accept or defer, which ask the participant to take particular actions related to the educational activity. These actions can range from thinking about a particular way smoking affects their life to attempting to replace smoking a cigarette with another activity of their choosing. Coaching provides human support and guidance, and is conducted via in-app chat in the Pivot App.

4 Study Design and Overview

4.1 Study Design

This is a prospective open-label clinical trial conducted with IRB approval in up to 310 subjects who report daily smoking (up to 50 run-in subjects, and 260 general subjects). Potential subjects will be recruited and prescreened as described in section 4.4

Potential participants will complete the Online Screening Form [redacted]. Each Online Screening Form submission will be reviewed by study staff. Eligible participants and those of uncertain eligibility (ex. potential participant's Online Screening Form was incomplete) will be contacted by phone by study staff or the clinical recruiter to confirm eligibility, provide more details about the study, and answer any questions the potential participant may have.

Eligible potential participants who remain interested in participation will be emailed the web registration link. This link, along with the phone call that occurred previously, will be used to verify the potential participant's identity. During the identity verification portion of the online registration process, the potential participant enters contact information and verifies their identity through a link sent to the email address they provide [redacted].

Every online submission from a potential participant will be reviewed by study staff and any discrepancies will be addressed through a phone call and/or possible videoconference with the potential participant (for example, more than one online submission with the same name, address, email address or phone number). Should a videoconference be pursued, such communication will occur in a private office setting with only necessary study staff present and the privacy of the potential participant protected (office door closed; screen not visible to anyone other than necessary study staff; headphones used if possible, if not possible, volume at the lowest level that allows for coherent dialogue).

After verification of eligibility and identity, potential participants will be asked to provide informed consent. Potential participants will have the opportunity to ask questions of the study investigator team during the informed consent process. Those who agree to participate will electronically sign the informed consent form [redacted].

Study staff must review the eligibility and identity criteria, document the resolution of any discrepancies from the identity verification process, answer any questions during the informed consent process, and confirm informed consent is signed before approving a participant for entry.

Upon approval for entry, study participants receive the study device. Upon receipt of the study device, participants will download the apps on their smartphone and use device labeling (User Manual [redacted], Quick Start Guide [redacted] Reference Card [redacted], Insert Card [redacted], Box Sleeve Label [redacted]) to set up and self-train on the device and apps.

Participants will have access to Customer Service and study staff as well if they need additional support. Participants are provided the study instructions during the online registration process:

the Pivot mobile smoking cessation program consists of 5 phases (Explore, Build, Mobilize, Quit, and Secure); during the study, participants provide breath samples using the CO Breath Sensor, log cigarettes in the Pivot app, complete daily activities in the Pivot App, and engage in coach-initiated interactions conducted through in-app text. [redacted]

Study participants will be asked to complete questionnaires (in-app and through email) at baseline, after each phase, and at exit. In addition, more detailed user feedback on the experience is sought upon completion of the Secure phase of the Pivot App, or upon the end of the participant's engagement with the app, whichever occurs first. Upon return of the study device and completion of the exit questionnaire (conducted 3 months after completing the primary phase of the study), the study is considered complete.

4.2 Study Endpoint

Primary endpoint:

- Phase completion - of those who started a phase, the proportion who completed that phase, assessed for each phase of the Pivot program.
    - Phase completion is defined as completing the last in-app activity from that phase
        - Exception: completion of Secure is defined as being in Secure for 11 weeks, and having engaged with the program at least once within Secure (app open, daily check-in, responds to coach, logs cig), and providing smoking status (cigarettes per day and 7-day point prevalence) in the end-of-Secure questionnaire

Additional endpoints include:

Engagement:

- Weeks of active engagement
- Number of app opens
- Phase completion - proportion of intention to treat (ITT) cohort that completes each phase
    - ITT cohort comprises participants who signed informed consent and completed onboarding in the Pivot app (i.e. downloaded the BSA and Pivot apps, completed device set-up, and completed the three guided breath tests, or GBTs)
- Program completion - proportion of intention to treat (ITT) cohort who have been in Secure for 11 weeks and have engaged with the program at least once (open app, or complete a daily check-in, or respond to coach, or log a cigarette), and, provides smoking status (cigarettes per day and 7-day point prevalence) in end-of-Secure Survey

Smoking Behavior:

- Number of cigarettes smoked per day
- Quit attempts (participant did not smoke for at least 24 hours)
- Quit rates: 7-day, 30-day point prevalence

    - Assessed in the ITT cohort
    - Assessed in the Per Protocol cohort (individuals who complete the end-of-phase survey in the phase during which the question is being asked or, complete the exit survey at the end of their engagement with the app, whichever occurs first)
- Sustained quit (continuous days quit)
    - Assessed in the ITT cohort
    - Assessed in the Per Protocol cohort
- Smoking reduction (in participants who do not quit smoking) - proportion who achieved 50% cigarettes per day (CPD) reduction or more at study exit

Responses to questionnaires:

- Measurements assessing attitude toward smoking
    - Readiness to quit
    - Goals related to smoking behavior
    - Confidence to quit
    - Difficulty maintaining quit
- Net Promoter Score (NPS)
- NPS, for coaching
- Nicotine Dependence
- Quality of Life

4.3 Eligibility Criteria

We will seek to enroll up to 310 participants (up to 50 run-in participants, and 260 general participants), with the aim of a balance between male and female participants. Potential participants will be classified as outlined below using self-reporting of smoking habits.

4.3.1 Criteria for All Participants

All participants must meet all inclusion criteria:

- 18-65 years of age
- English speaking
- Smokes daily
- Smokes 5 or more cigarettes per day
- Owns and uses a smartphone (iPhone 5 and above, operating system iOS 9.0 and above, or, Android 4.4 and above, operating system Android 4.4 and above)
- Employed at least 20 hours per week
- Lives in the USA
- Understands and willing to sign the Informed Consent Form

While pregnant women are not specifically sought in this study, pregnancy is not an exclusion criterion, and pregnant women would be eligible should they meet the inclusion criteria and wish to participate. Pregnant women would be considered eligible for the following reasons: the risk profile of the device, the fact that recording smoking in the study is by self-report and the

modest participant stipend is not linked to smoking in any way, and potential participants reach out to the study team if they are interested in participating (i.e. recruitment is passive and wholly at the initiation of potential participants, who the study team have no visibility to unless contacted by the potential participant). While participants are deemed eligible to enter the study based on their self-report of smoking at least 5 cigarettes a day, they are not required or asked to smoke any particular amount (or at all) over the course study. Participants are asked to provide breath samples in the CO Breath Sensor device throughout the day, as they are able.

The general study (n=260) will employ non-proportional quota sampling as follows to ensure the study population mirrors the expected initial intended user population:

Age	18-29 year olds ≤ 20 % of sample	30-60 year olds Remainder	61-65 year olds ≤ 10 % of sample
Cigarettes Per Day (CPD)	5-10 CPD ≤ 25 % of sample	11-30 CPD Remainder	> 30 CPD ≤ 10 % of sample
Stages of Change*	Quit 30 days ≥ 20% of sample	Quit 6 months ≥ 20% of sample	Not interested ≤ 20 % of sample
Sex	Male 40-60%	Female 40-60%	

*Stages of Change question and answer choices: Are you seriously thinking of quitting smoking? A. Yes, within the next 30 days B. Yes, within the next 6 months C. No, not thinking of quitting

4.4 Subject Recruitment and Screening

Potential subjects will be identified via advertisement at outdoor locations (i.e. flea markets, outside of movie theaters, shopping malls, train stations, stores that sell cigarettes), print media (i.e., local newspapers, billboards), web media (i.e., Craigslist, Facebook, Survey Monkey, Instagram, Twitter, Google Ads, Reddit, smokefree.gov) and through clinical research recruiters [redacted]. Respondents will be asked to provide contact information (phone number, email address), and answer questions on smartphone ownership, employment status and hours worked per week, and smoking behavior using the Online Screening Form [redacted] or through the clinical research recruiter, if applicable.

Study staff will review each potential participant's responses to the eligibility questions. Potential participants who meet eligibility criteria (or those for whom it is unclear if they meet eligibility criteria due to an incomplete Online Screening Form) and meet non-proportional sampling needs will be contacted by phone, informed of the study and screened further if necessary (for example, collecting complete screening information, or clarifying duplicate entries).

During this interaction, study personnel will inform the potential subject of the study details and will answer any questions. Potential participants will then determine if they would like to proceed with the study. Potential participants who would like to proceed will be emailed the online registration portal link, which includes the electronic informed consent [redacted].

All subjects will have ample time to read the informed consent and ask questions of the study investigator team before signing informed consent.

4.5 Subject Stipend

Subjects will be offered a stipend for the study. Payment structure will be described during the screening phone call and in the Informed Consent Form. Participant compensation is tied to completion of study questionnaires and returning the CO Breath Sensor at the end of the study. Participants will be emailed payment after completion of each study questionnaire. Payment will be in the form of a Visa e-card. Subjects who are not compliant with the protocol despite efforts by study personnel may be terminated from the study. Subjects who are not able to complete the study for any reason will be compensated for their completed participation.

4.6 IRB Oversight

This study will be conducted with IRB oversight.

4.7 Study Environment Description

The entire study, including participant data collection of breath samples, logging cigarettes, completing daily activities and interacting with the coach, will be conducted in an ambulatory environment, with participants living their daily lives however is typical for them (work, home, school, etc.).

4.8 Study Personnel

The study team members will be trained by reading the study protocol, informed consent form, and reviewing the participant-facing content (BSA app, Pivot app). The study team members will have full training on the operation of the study devices and protecting human research participants.

4.9 Study Site

Study staff and management is headquartered at the Carrot office: [redacted]. The entire study is conducted remotely; there are no study site visits for study participants.

4.10 Sample Size and Justification

Up to 50 participants will comprise the run-in group. The purpose of the run-in group is to provide baseline observations on the functioning of the BSA and Pivot app, and provide the opportunity to address unforeseen bugs or issues that arise prior to proceeding with the general study.

The target enrollment of 260 for the general study is estimated to yield 100 or more subjects completing the study at the last time point (3 months after the end of Secure). Based on power calculations, this will detect a 50% reduction in cigarettes, a mean change of 1 or greater in ratings assessing attitudes towards smoking, and will provide adequate confidence intervals to make historical comparisons.

5 Study Procedure and Schedule

5.1 Screening and Day 0

Study personnel will verify eligibility by reviewing the potential participant's responses to the Online Screening Form [redacted]; eligible participants (applies to both the run-in and general study participants) who meet non-proportional quota sampling needs (applies to general study participants) will then be called by study staff. During this call, any additional needed screening information is obtained, eligibility is confirmed, the study is described and the potential participant has the chance to ask questions. If the potential participant would like to proceed, the online registration form [redacted] is emailed to the potential participant. Potential participants will be provided an access code at this time to allow access to the website.

Verification of identity and informed consent is performed during the screening phone call and during the online registration process. At this time, potential participants create a user login and password. An email is then generated and sent to the email address provided by the potential participant. To confirm identity, the potential participant must access their email and confirm through the provided link. The potential participant then reviews the electronic informed consent form on their own timeline and is provided study staff contact information should they have any questions. If the potential participant would like to proceed, they electronically sign the informed consent form [redacted].

5.2 Day 1 Entry

After providing informed consent, participants complete baseline questions about demographics and smoking behavior. During the Pivot on-line registration process, the participant must access his/her email on their smartphone and click on a link to verify identity and further proceed in the registration process. The participant will then be emailed the links to download the BSA and Pivot apps, which they will do on their smartphone.

After completing the Pivot on-line registration, the participant will be mailed the COBSS. Labeling included with the COBSS includes the User Manual [redacted], Quick Start Guide [redacted] Reference Card [redacted], Insert Card [redacted] and Box Sleeve Label [redacted].

Participants will then self-train on how to set-up and use the COBSS [redacted] and Pivot app [redacted] using the available study device labeling. While they will be instructed to proceed with set-up on their own using the provided labeling, participants will ultimately have access to Customer Service and study staff should they need additional assistance.

During this self-led set-up and onboarding process, participants will be trained on how to provide a breath sample and log cigarettes, navigate the BSA and Pivot apps, and what to expect regarding coaching.

Participants who provide informed consent and complete the set-up and onboarding process (i.e. complete the 3 Guided Breath Tests) are considered enrolled (applies to run-in and general study participants) and comprise the intention-to-treat (ITT) cohort (applies to the general study participants).

5.3 Pivot Journey

After set-up and onboarding, participants start the Pivot program. The Pivot program consists of four primary components:

- Periodic breath sampling using the CO Breath Sensor
- Cigarette logging
- Daily activities and challenges
- Coaching using in-app chat

During the study, participants submit periodic breath samples (suggested frequency is phase-dependent) while awake. Participants are instructed to log each cigarette they smoke using the Pivot app.

Participants are also asked to complete the activities presented in the Pivot app. Pivot app activities are educational in nature and intended to facilitate exploration and understanding of one's smoking behavior and attitudes. In addition, Build (the second phase of the program) includes challenges associated with activities; these challenges enable participants to develop skills to assist with quitting [redacted]

In addition, participants will engage with a coach. The coach will initiate interactions with the participant by in-app chat throughout each phase of the study. The coach's primary role is to partner with the participant to explore how smoking impacts their time and financial resources, what purpose smoking serves in their life, their reasons for why they might want to quit, their interest and readiness in quitting, and provide support and encouragement during the quit process.

The Pivot program consists of 5 phases that are intended to be completed sequentially, with continuous engagement (i.e. no breaks in between). Acknowledging that challenging life events and circumstances occur, participants will be permitted to resume the Pivot program where they left off after up to two weeks of non-engagement/absence.

A summary of each Pivot phase is provided below [redacted]:

Explore	
Duration, pace, key components	● 9 days, time based, one activity unlocks each 24 hours
Intent	● "Open the Door" ● "Turn on the light bulb" ● Raise awareness and build motivation
Activity/content	● One activity is unlocked per 24h
Cigarette logging	● All cigs
Suggested breath CO sampling protocol	● Hourly samples (10) a day for 9 days
Coaching frequency	● 4 coach-initiated touch-points in 9 days
Study management	● If participant does not use the app at least once during the 2 days after onboarding (no cig logging, or CO sampling, or start/complete activity, or respond to coach outreach), study staff will call participant on days 3, 4 and 6

Build	
Duration, pace, key components	● 1 day to 4 weeks based on recommended daily pace. Can be longer if content is not consumed daily. ● Daily activity+challenge available
Intent	● For those ready to quit, make a quit plan ● For those not yet ready to quit, raise readiness and confidence, then make a quit plan

Activity/Content	● 28 activities and 28 associated challenges in 4 modules (7 activities and 7 challenges per):
	  ● Prep to Quit (PTQ)
	  ● Smoking & Health
	  ● Motivation Matters
	  ● Potential Pitfalls
	● User starts on a specific module based on their responses to final Activity (9) of Explore. Users whose responses indicate they are ready to quit (score of 8 or higher on each of 3 questions about readiness, confidence and perceived difficulty of quitting), go straight to PTQ. Otherwise another module is prioritized.
	● User must choose a quit date to unlock PTQ
	● User can spend 1 day to 4 weeks in Build, or longer if they do the activities slower than daily

Cigarette logging	● All cigs
Suggested breath CO sampling protocol	● Hourly samples throughout Build
Coaching frequency	● 3 to 4 touch-points per week ● If a user has not completed activities and/or hasn't had a coaching interaction within 3 days, the coach will reach out to the user to check in.
Study management	● If participant does not use the app at least once in 7 days (no cig logging, or CO sampling, or start/complete activity, or start/complete challenge, or complete daily check-in, or respond to coach outreach), study staff will email on day 9, text on day 10, call on day 11, and call on day 13

Mobilize	
Duration, pace, key components	● 7 days based on recommended daily pace
Intent	● Prepare for Quit Day
Activity/content	● 7 activities, daily pace recommended ● No time lock, but must finish all activities to move on ● User can finish faster or slower. Quit date must be set within 14 days, but user can push out quit date during Mobilize, and thus extend this phase of the program ● User prompted to change quit date if not all activities are completed ● User prompted to set earlier quit date if they finish all activities.
Cigarette logging	● All cigs
Suggested breath CO sampling protocol	● 2 days of "intensive" sampling (hourly) to benchmark – beginning and end of Mobilize ● Remaining days in between are 3 breaths a day: morning, mid-day, evening
Coaching frequency	● Intro touch point to Mobilize with two interactions on completion of specific activities that prepare users for quit day. ● Wrap-up touch point to review quit plan ● If a user has not completed activities, milestones and/or has not had a coaching interaction within the past 2 days, the coach will reach out to the user to check in.
Study management	● If participant does not use the app at least once in 7 days (no cig logging, or CO sampling, or start/complete activity, or start/complete challenge, or complete daily check-in, or respond to coach outreach), study staff will email on day 9, text on day 10, call on day 11, and call on day 13

Quit	
Duration, pace, key components	● 7 days from quit date, time based, activities are unlocked daily ● Daily check-in introduced ● Red 'guy' on Pivot app dashboard turns green, Crush-a-Craving button added
Intent	● Getting through the toughest week ● Lapse and relapse handling
Activity/content	● Daily check-in, must be completed to access rest of app ● One activity is unlocked per 24h
Cigarette logging	● Daily check-in asks if user smoked previous day, if so, then directs them to log cig
Suggested breath CO sampling protocol	Encourage light use to see progress ● 3 breaths a day, morning, mid-day, evening ● Plus every time user has a craving
Coaching frequency	● Intro touch point to Quit with two strategic interactions after completion of smoke-free milestones (Quit: 24 hours and 72 hours) ● Wrap-up touch point to review progress, celebrate smoke-free milestones and identify areas of the quit plan that may need to be adjusted going forward – guide to move to Secure. ● If a user has not completed activities, milestones and/or has not had a coaching interaction within the past 2 days, the coach will reach out to the user to check in.
Study management	● If participant does not use the app at least once in 7 days (no cig logging, or CO sampling, or start/complete activity, or start/complete challenge, or complete daily check-in, or respond to coach outreach), study staff will email on day 9, text on day 10, call on day 11, and call on day 13

Secure	
Duration, pace, key components	● 11 weeks from quit date ● Daily check-in
Intent	● Lapse and relapse handling
Activity/content	● Daily check-in with journaling
Cigarette logging	● Daily check-in asks if user smoked previous day, if so, then directs them to log cig.
Suggested breath CO sampling protocol	No explicit sensor use schedule, but sensor is incorporated as follows: ● Encourage people who find the 3 times a day useful to keep doing that. ● Allow users to set their own milestones, some can be sensor related. Pivot app also gives trophies for breath samples associated with abstinence to augment this. "Take a breath samples to celebrate your smoke-free success."
Coaching frequency	● 3-4 coach-initiated interactions per week for the first 3 weeks ● For users who achieve 30day PP at 3 weeks or 7 weeks in Secure, coaching frequency drops to once weekly, until/unless user indicates lapse or relapse.
Study management	● For the first 3 weeks: If participant does not use the app at least once in 7 days (no cig logging, or CO sampling, or start/complete activity, or start/complete challenge, or complete daily check-in, or respond to coach outreach), study staff will email on day 9, text on day 10, call on day 12, and call on day 14 ● For the remaining 7 weeks: If participant does not use the app at least once in 14 days (no cig logging, or CO sampling, or start/complete activity, or start/complete challenge, or complete daily check-in, or respond to coach outreach), study staff will email on day 16, text on day 17, call on day 19, and call on day 21

The following table details the different questions being asked of participants at specific time points over the course of the study. [redacted]

	Baseline	Explore	Build	Mobilize	Quit (1wk)	Secure - 1wk (2wk post Quit)	Secure - 3wk (1mo post Quit)	Secure - 7wk (2mo post Quit)	Secure - End (3mo post Quit)	Follow -up (6mo)
Cigarettes per day	X	X	X	X	X	X	X	X	X	X
Tobacco Forms Used	X		X		X		X	X	X	X
Readiness to Quit (1-10)	X	X	X	X						
Success, if were to quit (1-10)	X	X	X	X						
Difficulty staying quit, (1-10)	X	X	X	X						
Quitting Goal	X	X	X	X						
Nicotine Dependence		X		X						
7day Point Prevalence					X	X	X	X	X	X
30day Point Prevalence							X	X	X	X
Date of Last Cig					X	X	X	X	X	X
Longest Smoke-free Interval					X	X	X	X	X	X
Quit Attempts					X	X	X	X	X	X
NPS		X	X	X	X				X	
Coach NPS		X	X	X	X				X	
Quality of Life	X								X	X
Cessation Medications	X			X	X	X	X	X		X

Participants will receive an email, text or phone call from study staff to inform them they have a questionnaire to complete ([redacted]).

5.4 Exit

Three months after completing Secure or 3 months after the last engagement with the Pivot app (whichever comes first), the participant is asked to complete the final follow-up questionnaire [redacted] and return the CO Breath Sensor in the provided pre-paid package. Upon completion of the final survey and return of the CO Breath Sensor, the study will be considered complete.

6 Study Results

6.1 Data Collection and Confidentiality

Data collection will be electronically administered through participant input in the Pivot online registration form, BSA and Pivot apps, and online questionnaires. As it is entered by the participant, the study data directly populates a secure database. This database is user ID and password protected and will be accessible only by necessary study personnel. For analysis, this data is de-identified with participants assigned a study identification number [redacted]. The data will be kept for 5 years.

6.2 Data Analysis

Data from the run-in participants will be analyzed separately from the data from the general study participants. Both cohorts will be analyzed using the ITT and Per Protocol definitions, and endpoints described previously.
Changes in measurements from baseline, to the end of each phase, to exit will be assessed. Participants will serve as their own controls and comparisons will be made to no change. One sample t-test will be used for numerical data. Fisher's Exact or Chi square will be used for categorical data.
All deviations from the study protocol will be identified, recorded and analyzed.

6.3 Data Recording and Quality Assurance

Data forms will be completed electronically by the study participants. The study team will review these data forms in the database prior to completion of the study and seek completion/clarification from study participants as needed. Study data is kept in a secure database (PostgreSQL and Excel). This electronic file and database are user ID and password protected and will be accessible only by necessary study personnel.

6.4 Record Retention:

Record keeping is performed in accordance with the SOP Control of Quality Records, [redacted].

7 [redacted]

8 References

9 Document Revision History

Rev. A	Revision Date: Sept. 20, 2017	
Summary of Changes: · New protocol		
Rev. B	Revision Date: Sept. 29, 2017	
Summary of Changes: • Added a run-in group of up to 50 participants (general study continues to comprise 260 participants) o Informed consent reflects this change • Provided updated labeling • Added questions to the questionnaires (Baseline, end of Mobilize, end of Quit, Secure 1 week, Secure 3 weeks, Secure 7 weeks, Secure 11 weeks and Exit) about use of smoking cessation medications.		