

Official Title: Enhanced E-cigarette Coaching Intervention for Dual Users of Cigarettes and E-cigarettes

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# Phase 1 & 2 Project ENDSmoking Protocols

Quick link to Phase:

[Phase 1](#)

[Phase 2](#)

## PHASE 1:

Phase 1 recruitment was completed in May and June 2018. These participants are finishing out their study procedures using the below protocol (approved on 03.07.18). Based on learnings from Phase 1, we are submitting minor protocol changes for Phase 2 section below.

The goal of Phase 1 of the study is to pilot the tailored intervention for dual users of cigarettes and e-cigarettes with 10 tobacco helpline callers. The primary goal of the treatment is for participants to completely stop cigarette smoking. We will use the data and feedback we collect to make improvements to the treatment intervention and study procedures, if needed.

### **Recruitment, Consent, Baseline:**

We are requesting a Waiver of HIPAA Authorization to identify eligible participants among enrollees in the Oklahoma Tobacco Helpline. Research staff will contact eligible participants to invite them to join the study.

Interested and eligible participants will be screened, consented, and take a baseline questionnaire over the telephone. Participant responses will be recorded in password protected electronic systems. Because recruitment, intervention delivery, and follow-up is all conducted over the phone, electronically, or through mailed materials (no in person contact or materials that participants return to the study team), we are not collecting a signed consent or HIPAA Authorization.

- Recruitment, consent and baseline for Phase 1 of the Study will be conducted by the research staff (Grant Manager (GM) and Research Assistant (RA)).
- Participants will call into the Oklahoma Tobacco Helpline (OKHL) and enroll into the Helpline for Coaching Services.
- The Research Assistant (RA) will pull a report that will capture initial eligibility criteria based on standard information gathered during enrollment into the Oklahoma Tobacco Helpline and the initial coaching call.
  - Eligibility Criteria:
    - Requested Coaching Services
    - Currently using E-Cigarettes
    - English Speaking
    - 18+ years old
    - Not Pregnant
    - Not planning pregnancy in next 3 months
    - Currently using cigarettes
    - Enrolled in 5 Call OKHL program
    - Willing to quit cigarettes in the next 30 days
    - TCPA consented (consents to outbound telephone calls)

- Not enrolled via Proxy
- None of the following Use Exclusions (UEs) if screened for NRT during first coaching call (if not screened for NRT during first call and eligible the following questions will be asked in the additional screening questions):
  - No heart attack, stroke, or TIA within the past two weeks
  - No rapid or irregular heartbeat in the past 6 months that required a change in activities or medications to treat
  - No angina or heart pain in the past 6 months that a healthcare provider informed participant was serious or worsening
- Did not report a diagnosis of Schizophrenia
- Not previously screened for study
- The GM/RA will make up to 5 call attempts on different days to reach participants identified in the report to complete screening for Phase 1. After 5 attempts to reach the participant, the participant is considered ineligible for the study and will continue with the standard OKHL services they are already enrolled in.
- If a participant completes their second coaching call before the GM/RA is able to reach them to offer study participation, the participant will no longer be eligible for the study.
- For those who are reached, the RA/GM will offer the study via study invitation scripting (*see attachment A: Study invitations*) and ask additional screening questions (*see attachment B: Additional Screening Questions*). All participants who decline or screen out based on additional screening questions will continue with standard OKHL services and will not continue with the study.
- For those who accept the study invitation and are screened as eligible, the GM/RA will read verbal informed consent (*See Attachment C: Study Consent*) and record consent response. Those who decline consent will continue with standard OKHL services.
- For those who consent to the study, the GM/RA will ask the baseline survey questions (*see attachment D: Study Baseline*) and record their answers. They will then be considered enrolled into the ENDSmoking study.
- Once the Baseline survey is completed the GM/RA will attempt to transfer the participant to a study coach for their first study coaching call. If the participant does not have time or a coach is not currently available, the GM/RA will inform the participant that a study coach will be contacting them in the next 24-48 hours to complete their first study coaching call.
- RA will then send out a copy of the verbal consent form that was read to the study participant along with welcome letter (*see attachment G\_ Welcome Letters*) and send the participant a \$20 gift card for completing the baseline survey.
- The RA will also email the participant instructions for completing daily surveys. Participants will either (1) download a smartphone app which they will use to complete the daily survey, or (2) receive an email each day to complete their survey. The smartphone app may not be available for all Phase 1 participants. We will start using the app once our collaborators have successfully made it available in the app store (targeted for May 2018).

**Treatment Plan/Intervention:**

- All calls with participants will be completed by 2 Coaches that have been trained to deliver the study intervention.

- Each participant will receive their standard Oklahoma Tobacco Helpline Nicotine Replacement (NRT) benefit. This is based on insurance status information participants provided when they enrolled.
- The study is not providing any additional NRT. The study does not provide any e-cigarettes.
- Each participant will receive up to 5 outbound coaching calls. Participants can call in for additional support as needed.
- Each participant will be mailed 2 specialized E-Cigarette Quit Guides in addition to the standard OKHL quit guide.
- In every call, the Coach will:
  - (1) Assess participant's cigarette, e-cigarette, and quit medication use and habits.
  - (2) Provide tailored education and behavioral support for individuals who choose to use e-cigarettes while quitting smoking (*see Attachment E: Intervention Protocol Documents*).
- Coaches will receive training and will be guided by Intervention Protocol documents to determine what to cover in their calls with participants.

### **Daily Surveys:**

- Participants will complete daily surveys for a total of 12 weeks after they enroll in the study.
- Daily surveys will be sent via daily emails with a link to a Datstat survey where the participants will fill out the survey online.
- When the study app is available (targeted for May 2018) for participants to download. RA will email each participant with the link to the google store to download the app to their personal phones along with instructions. Participants will be given an option to complete daily surveys through the App or continue to receive daily emails. (see Phone App section below for more details on phone app)
- Participants will be sent 1 survey per day. Daily surveys will take about 1 minute to complete.
- Daily surveys will be sent for 12 weeks.
- Once per week, participants will be sent a slightly longer survey (~3 minutes to complete) to complete in addition to their daily questions.
- Participants will receive gift cards for completing daily surveys.
  - Participants will receive the following incentives for completing daily surveys:
    - \$5 per week for completing at least 5 of 7 daily surveys for the given week. Participants can also receive the \$5 for the week if they complete the longer weekly survey. Or, if participants complete the Timeline Follow-Back interview (see below), they can also receive \$5 for the week.
    - A total possible amount of \$60 can be earned by completing all 12 weeks of daily surveys
    - Participants will also receive a bonus gift card if the participant completes the following percentage of daily surveys:
      - \$50 – completes 80% or more of daily surveys
      - \$25 – completes 60% -79% of daily surveys
      - Those that complete less than 60% of daily surveys will not receive the bonus gift card.
  - Participants will be sent their gift card(s) for daily survey completion at the following times:
    - 7 week – includes surveys completed for weeks 1-6.

- 13 Week – includes surveys completed for weeks 7-12. This gift card will also include the \$50 or \$25 bonus based on the percentage of surveys completed, if earned.
- See Gift Card protocol for details on how Gift Cards will be delivered to participants.

**TimeLine Follow Back (TLFB) Interview:**

- Participants that do not complete (1) at least 5 of 7 daily surveys per week OR (2) the longer weekly diary will be contacted by the RA to complete a TLFB survey over the phone.
- The RA will make up to 3 attempts on different days to reach participants to complete the TLFB survey.
- See TLFB questions (*see attachment J: Study Measures*).

**Follow Up Surveys:**

Research staff will perform the following steps to complete follow up surveys with study participants:

1. Three days before their follow-up survey calls will start, Research Assistant (RA) will email participants to inform them that they will be called to complete the follow-up survey using **Email Reminder #1** (*See attachment H: Study Emails*). This email will include a link to complete the survey online.
2. RA will then begin to call out to participants to complete the survey over the phone at 7 weeks post enrollment for phase 1 and 11 weeks post enrollment for Phase 2.
  - a. If reached, RA will complete phone survey with participant and record responses.
    - i. For those who are selected to complete Qualitative interview:
      1. At the end of the survey RA will schedule with the participant when they will be contacted to complete their Qualitative interview.
    - b. If not reached, RA will make at least 4 more attempts to reach participant for a total of at least 5 attempts on different days. RA will leave a voicemail for participants to call the RA back.
3. If participant is not reached for the phone survey, the RA will email the participant using the **Email Reminder #2** email template (*See attachment H: Study Emails*). A link to complete the survey online will be included in the email.
4. If participant completes an online survey, the RA emails the study participant informing them that we have received their completed survey using the **Email Reminder #3** template (*See attachment H: Study Emails*).
  - a. RA will send gift card to participant.
  - b. If participant reports that they have quit smoking for 7+ days in Phase 2 and for all Phase 1 participants: RA will mail iCO monitor and include instructions on how to use the iCO monitor with the study phone app.
5. RA will check voicemails to see if any study participants have called back to complete survey over the phone.
6. If RA has still not received a completed online survey or phone survey from a participant after 1 month, the RA will send out **Email Reminder #4** (*See attachment H: Study Emails*), which includes a link to a shortened 3 question follow-up survey (see measures document) including only key outcomes of interest.

**Phone App:**

- We will use an android app created by the mHealth Core in the Oklahoma Tobacco Research Center at the University of Oklahoma Health Sciences Center.

- Research staff will program the diary questions into the study app.
  - The phone app will be designed for the following:
    - Ability to complete daily surveys.
    - Ability for participants to connect iCO Smokerlyzers to android smartphone.
      - The iCO Smokerlyzers will provide remote carbon monoxide readings for verification of quit status.
  - The phone App will be free for participants to use and only those enrolled into the Project ENDSmoking study will have access to the app.
- Not all phase 1 participants will begin the study using the phone app. The phone app will approximately be ready in the Google appstore for download in May 2018.
- For participants who enroll into the Phase 1 prior to the app being ready:
  - Research staff will call out to participants once the app is ready for download to introduce them to the phone app and inform them that they study would like them to download the app.
    - Staff will give the participant a choice on whether they would like to complete their daily surveys via the phone app or continue with the emailed surveys.
  - Research staff will then email the participant using Study App Email Instructions (for those who enrolled prior to appstore) template (*See attachment H: Study Emails*). This email will provide them the link to download the app and instructions on how to use the app.
- For participants who enroll into Phase 1 with the app ready for download:
  - Research staff will introduce participants to the phone app during their baseline.
  - After participants enroll in the study, research staff will send an email providing instructions for how to download and set up the app for completing daily surveys.
- After participants complete their follow-up survey, research staff will send an email with instructions on how use the iCO Smokerlyzer with their app and smartphone. The iCO Smokerlyzer will also be mailed to study participants with the instructions.

#### **iCO Monitors/Smokerlyzers®:**

- Research staff will purchase iCO™ Smokerlyzers® monitors from Bedfont Scientific Ltd. These will be used to test whether or not participants have quit smoking.
- All 10 participants in Phase 1 will be sent iCO™ Smokerlyzers® after they complete their follow up survey. All participants will receive the iCO™ Smokerlyzers® to pilot these procedures and receive more feedback from study participants in preparation for Phase 2.
- Participants will be sent instructions via email and mailed with the iCO Smokerlyzer on how to use the device and connect it to the study App.
- When participants receive the iCO Smokerlyzers they will be asked to attach the CO monitor the their phone jack and breath into the monitor several times to record a reading. They will be asked to do this for a total of 3 days to get a reliable assessment of participant’s current smoking status.

#### **Qualitative Interviews:**

- All 10 participants will be contacted to complete a qualitative interview. Findings will be used to improve the intervention development plan for Phase 2 (*see attachment J: Study Measures*)
- Interviews will be designed to collect the following from participants:
  1. ENDS, NRT, and nicotine beliefs (relative harm, safety, long-term use)
  2. Quit strategies used and how and why ENDS were used during the program,

3. Reactions to Shared Decision Making model for quit plan development,
4. Use of and reactions to print materials,
5. Reactions to coaching calls and education from quit coaches
6. Why/why not callers would recommend the program and recommendations for improvement
7. Diary completion experiences.

### **Gift Cards**

- Study Incentives:
  - Both Groups will have the opportunity to receive:
    - Completion of baseline survey - \$20
    - Completion of Daily Surveys - \$5 per week for completing at least 5 of 7 daily surveys per given week. For a total possible amount of \$60 for the 12 weeks
    - Bonus payment for completion of surveys during the 12 weeks:
      - 80% or more - \$50
      - 60-79% - \$25
    - Completion of follow-up survey - \$50
    - Completion of iCO™ Smokerlyzer® test - \$50
  - 10 participants in each phase (Phase 1 & 2) will complete Qualitative Interviews with Study Staff:
    - Qualitative Interview - \$50
  - In total, participants will have the opportunity to earn up to \$280.00 for completing study surveys.
- Participants will get paid by pre-loaded gift cards. During their baseline survey participants will choose which delivery method they would like all of their gift cards to be sent.
  - Delivery Options:
    - Electronic gift cards – sent via email
      - These gift cards are digital, and Participants can only use them online.
    - Mailed gift cards – sent through USPS postal mail
      - These cards are plastic can be used online or at a store.
- Gift Card Delivery Schedule:
  - \$5 week survey completion incentives:
    - Participants will be sent their \$5 week gift card for completing daily survey each week at week 7 and week 13. Gift cards will include both the a total earned for those two time frames:
      - Sent week 7: Weeks 1-6 surveys
      - Sent Week 13: Weeks 7-12 surveys
    - 12 Week Survey Bonus Incentives:
      - Participants will be sent their gift card for completing X% at the end of their 12 weeks.
    - Follow-Up and Qualitative:
      - Participants will be sent their gift card once the study staff completes or receives their respective survey/interview.
    - iCO Smokerlyzer test:
      - Participants will be sent their gift card once study staff receives their iCO results.
- Sending Gift cards:

- Study staff will use the email address or mailing address that was provided during participant's baseline survey for all gift cards.
- Participants are responsible and informed during baseline to call study staff in order to update their email address or mailing address.
- Study staff will send gift cards to participants in the delivery option participants selected during their baseline.
- Troubleshooting gift cards:
  - Participants who have issues with their gift cards can contact study staff or the contact number provided with their gift card.
  - Once gift cards are sent either digitally or mailed, study staff cannot re-issue a gift card.
  - Lost Electronic gift cards:
    - Study staff will assist participants by recommending that the participant search their inbox for their gift card.
  - Stolen Mailed Gift Cards:
    - Study staff will check in with the participant over the phone to see if they would like to provide a different mailing address for the study to use that may be more secure.

**Withdrawal Protocol:**

- If a participant informs the Quit Coach that they no longer wish to participate in the ENDSmoking Study, the Coach will first clarify if they want to withdraw from the study or the quitline treatment (not receive any more coaching calls; participant has the option to opt back in at a later date). If the participant says they want to withdraw from the quitline, but not the study, the Coach will place the participant's file on a status that will prevent the quitline from calling out to the participant, but the participant will still be eligible for study surveys and incentives.
- If the Participant states that they want to withdraw from the study, the Coach will explain that someone from the study will contact them to complete official withdrawal. The coach will also provide the contact information for the study team. Until the participant speaks to the study team to withdraw, they will still be considered part of the study.
- The study team will make five attempts on separate days to call out to participant(s) confirm that the participant wants to withdraw from the study and collect reasons for withdrawal. If the research team member reaches the participant, they will read the following Withdrawal Script (*see attachment 1: Withdrawal Script*).

**Phase 2:**

We are requesting a Waiver of HIPAA Authorization to identify eligible participants among enrollees in the Oklahoma Tobacco Helpline. When individuals call into the Oklahoma Tobacco Quitline (OKHL) and begin their enrollment they will be identified as eligible based on initial eligibility criteria that is collected during their standard OKHL enrollment process. Those who are identified as eligible will be read a brief study offer.

Interested and eligible participants will be screened, consented, and take a baseline questionnaire over the telephone. Participant responses will be recorded in password protected electronic systems. Because recruitment, intervention delivery, and follow-ups are all conducted over the phone,



electronically, or through mailed materials, we are not collecting a signed consent or HIPAA Authorization.

Phase 2 is a randomized pilot study where up to 130 dual users of cigarettes and e-cigarettes will be randomly assigned to receive OKHL treatment as usual or the study intervention treatment that has been tailored for users of e-cigarettes who want to quit smoking cigarettes. Our target is to have 50 callers in each group who engage in at least one session of treatment. Because this is a small sample pilot study where we want to examine the utility of the treatment for those who engage, if a caller does not complete their first treatment call after at least 5 attempts have been made to reach and complete Call 1, the participant will be withdrawn from the study and notified that they are no longer in the research study. These participants will receive coaching support from the OKHL.

### **Recruitment:**

- Participants who call into the Oklahoma Tobacco Helpline (OKHL) will be offered the initial study invitation (*see study scripts*) if they meet the following eligibility criteria:
  - Eligibility Criteria:
    - Requested Coaching Services
    - Reports using E-Cigarettes in the last 30 days
    - English Speaking
    - 18+ years old
    - Not Pregnant
    - Not planning pregnancy in next 3 months
    - Currently using cigarettes
    - Enrolled in 5 Call OKHL program
    - Willing to quit cigarettes in the next 30 days
    - TCPA consented (consents to outbound telephone calls)
    - Not enrolled via Proxy
    - Did not report a diagnosis of Schizophrenia
    - Not previously screened for study
- The OKHL uses a computerized participant record system. Application development work will be completed to display the study offer if an OKHL enrollee meets the above criteria. The study offer will be completed by a registration agent prior to finishing a participant's enrollment into the OKHL.
  - Participants who are not interested in the study will continue to be enrolled in the standard OKHL services.
- Participants who accept the study offer will be asked additional screening questions (*see Study scripts*) that will further determine eligibility into the study.
  - Participants who did not meet additional screening questions will be deemed ineligible for the study and continue with standard OKHL services.
- Those who are deemed eligible will be read the Final Study Invitation (*see Study scripts*) and their response will be collected.
  - Those who decline the study invitation will not continue with the study and instead be enrolled in standard OKHL services.
- Those who accept the study invitation will be transferred to a study-trained coach who will complete study consent, baseline and randomization to one of the two treatment groups.
  - Participants will be warm transferred to a study coach if one is available. If not, participants will be informed that a study coach will call them back to complete study enrollment.

- If participants do not connect with a study coach to complete study enrollment after at least 5 attempts have been made, they will no longer be eligible to continue in the study and will continue with standard OKHL services.

**Consent & Baseline:**

- Once the participant is on the phone with the Study Coach, the Coach will conduct informed consent (*see Study Consents*), confirm contact information, and complete the baseline survey with the participant (*see Study scripts and Study Measures (previously submitted)*).

**Randomization:**

- After consent and baseline, the participant will be randomized (*see Study scripts*) into the study at which time they will be considered enrolled into the study. Randomization will be stratified by gender so that equal proportions of males and females are randomized into each treatment arm.
- Following randomization, participants will complete their first coaching call with a coach trained for the group the participant was placed in.
  - If no coach is available, participant will be called back and 5 attempts to reach participant for their Call 1 will be made. If participant is not reached after 5 attempts they will be ineligible for the study and will continue with standard OKHL services.

**Treatment Plan/Intervention:**

**Group 1 – Control**

- Control group participants will receive 4 additional outbound coaching calls after they complete their initial coaching call, for a total of 5 calls. Participants can call in for additional support as needed. Participants may also be eligible for free nicotine replacement therapy through their standard OKHL benefits. Each participant will receive the standard OKHL quit guide.
- Coaches not trained in the study intervention will complete coaching calls with these participants.

**Group 2 – Experimental**

- Experimental group participants will receive 4 additional outbound coaching calls after they complete their initial coaching call, for a total of 5 calls. Participants can call in for additional support as needed. Participants may also be eligible for free nicotine replacement therapy through their standard OKHL benefits.
- All calls will be completed by a small team of coaches who have been trained to deliver the study intervention.
- Each participant will be mailed 2 specialized E-Cigarette Quit Guides in addition to the standard OKHL quitline quit guide.
- As in Phase 1, in every call, the Coach will:
  - (1) Assess participant’s cigarette, e-cigarette, and quit medication use and habits.
  - (2) Provide tailored education and behavioral support for individuals who choose to use e-cigarettes while quitting smoking
- Coaches will receive training and will be guided by Intervention Protocol documents to determine what to cover in their calls with participants.

### **Daily Surveys:**

- Participants will complete daily surveys for a total of 12 weeks after they enroll in the study.
- Daily surveys will be sent via phone app. Participants will complete all daily surveys via the phone app. In the event that there are problems with the app and participants are unable to complete their daily surveys, we will revert to the emailed online surveys via Datstat (as used during Phase 1).
  - Study coaches will introduce participants to the study phone app during consent and baseline, and let participants know that they will receive instructions for how to download the app after they complete their first coaching call. They will encourage participants to download the app as soon as possible once they receive the instructions.
  - After participants complete their first coaching call, study staff will send participants an email with instructions on how to download the free study phone app to their personal android smartphone.
  - Participants will have the first 3 days to download and set up the phone app.
    - Study staff will send a reminder email on Day 4 or the next business day if day 4 falls on a weekend to participants who have not yet set up the app. Participants will be asked to call the study staff if they are having issues downloading the study app to their phones.
    - If participants have not downloaded the app by Day 5 or the next business day if day 5 falls on a weekend study staff will call participants to determine what issues may be occurring.
- Participants will receive gift cards for completing daily surveys.
  - Participants will receive the following incentives for completing daily surveys:
    - \$5 per week for completing at least 5 of 7 daily surveys. Participants can also receive the \$5 for the week if they complete the longer weekly survey. Or, if participants complete the Timeline Follow-Back interview (see below), they can also receive \$5 for the week.
    - A total possible amount of \$60 can be earned for the 12 weeks.
    - Participants will also receive a bonus gift card if the participant completes the following percentage of daily surveys:
      - \$50 – completes 80% or more of daily surveys
      - \$25 – completes 60% -79% of daily surveys
      - Those that complete less than 60% of daily surveys will not receive the bonus gift card.
  - See *Gift Card* protocol section below for details on how Gift Cards will be delivered to participants.

### **TimeLine Follow Back (TLFB) Interview:**

- TLFB surveys will be completed for weeks 4 & 8.
- Participants that do not complete (1) at least 5 of 7 daily diaries per week OR (2) the longer weekly diary will be contacted by the RA to complete a TLFB survey over the phone.
- The RA will make up to 3 attempts on different days to reach participants to complete the TLFB survey.
- See TLFB questions (*see attachment J: Study Measures*).

### **Follow Up Surveys:**

Research staff will perform the following steps to complete follow up surveys with study participants:

1. Seven days before their follow-up survey calls will start, Research Assistant (RA) will email participants using **Outcome Survey Email #1** (See *Study Communications*) this email will inform the participant that it is time to complete their follow up survey. This email will include a link to complete the survey online and a note that study staff will call out to them in the next week if they have not completed the survey online. If the participant has not completed the online survey after 4 days the RA will send **Outcome Survey Email #1a Follow Up email** this email will continue to encourage participant to complete the survey online and remind them that they will be receiving a call to complete the survey over the phone in the next several days.
2. RA and/or survey specialists at Maryland Marketing Services (MMS) (both referred to as Study Surveyors in this section) will then begin to call out to participants to complete the survey over the phone at 12 weeks post enrollment for Phase 2. A total of at least 11 attempts will be made on different days to complete the outcome survey.
  - a. If reached, Study Surveyors will complete phone survey with participant and record responses.
    - i. For those who have quit smoking for 7+ days:
      1. At the end of the survey, the participant will be introduced to the iCO monitor and informed that they will be mailed out the device with instructions on how to complete the test using the phone app (see *Study Script*).
    - ii. For those who are selected to complete Qualitative interview:
      1. At the end of the survey RA will schedule with the participant when they will be contacted to complete their Qualitative interview.
  - b. If not reached, Study Surveyor will leave a voicemail (if able) for participants to call them back.
3. If participant is not reached for the phone survey after 5 attempts have been made, the participant will receive **Outcome Survey Email #2** email template (See *Study Communications*). A link to complete the survey online will be included in the email and a reminder that the participant will still receive phone attempts to complete the survey over the phone. After all phone attempts have been made, the participant will receive **Outcome Survey Emails #2a. Outcome Survey #2b** will be sent out to participant only if they have not completed their outcome survey via online or over the phone.
4. If participant completes an online survey, the RA emails the study participant informing them that we have received their completed survey using the Follow-Up Survey Completion Email template (See *Study Communications*).
  - a. If participant reports that they have quit smoking for 7+ days, RA will mail iCO monitor and include instructions on how to use the iCO monitor with the study phone app. If participant is selected to complete qualitative interview, RA will call out to schedule their qualitative interview.
5. If RA has still not received a completed online survey or phone survey from a participant after 1 month, the RA will send out the **Brief Outcome Survey Email** (See *Study communications*), which includes a link to a shortened follow-up survey (see *attachment J: Study measures*) including only key outcomes of interest.

#### Phone App:

- We will use an android app created by the mHealth Core in the Oklahoma Tobacco Research Center at the University of Oklahoma Health Sciences Center.
  - The phone app will be designed for the following:
    - Ability for participants to complete daily surveys.

- Ability for participants to connect iCO Smokerlyzers (if requested to complete) to android smartphone.
        - The iCO Smokerlyzers will provide remote carbon monoxide readings for verification of quit status among participants who report that they are quit from smoking for 7 + days on the end of treatment outcome survey (~3 months post-registration).
      - The phone App will be free for participants to use and only those enrolled into the Project ENDSmoking study will have access to the phone app
- All study participants will be asked to download the phone app after they complete their first call. Participants will also receive a study email with instructions on how to download the phone app from the android app store.
- Study staff will monitor whether participants download the app and start completing surveys. They will reach out to participants who do not download the app or start completing surveys to offer support and troubleshooting help.
- Participants who report being quit 7+ days during their follow-up survey will receive an email from study staff or a phone call with instructions on how to use the iCO Smokerlyzer.
  - Participants will also receive instructions when they receive their iCO Smokerlyzer in the mail. Study staff will be available to troubleshoot any problems participants have by phone.

#### **iCO Monitors/Smokerlyzers®:**

- Research staff will be purchasing iCO™ Smokerlyzers® CO monitors from Covita. These will be used to test whether or not participants have quit smoking.
- Only participants who report being quit 7+ days from cigarettes when completing their follow-up survey will be asked to complete a CO test and be sent smokerlyzer devices.
  - Participants will be sent instructions via email and mailed with the smokerlyzer on how to use the Smokerlyzer and connect the device to the study App.
  - When participants receive the iCO Smokerlyzers they will be asked to attach the monitor to their phone jack and breath into the monitor several times to record a reading. They will be asked to do this for a total of 3 days to get a reliable assessment of the participant's current smoking status.
  - RA will provide participants with support by phone, if needed.

#### **Qualitative Interviews:**

- 20% (N=10) of participants randomized to the experimental intervention will be selected to complete a qualitative interview *see attachment J: Study measures*.
- We will select participants to speak with individuals in the following groups:
  - Initially selected to use e-cigarettes as part of their quitplan
    - And successfully quit from cigarettes for 7+ days ( $n \sim 3$ )
    - And not successfully quit from cigarettes for 7+ days ( $n \sim 2$ )
  - Initially selected to use e-cigarettes and quit medications together as part of their quit plan
    - And successfully quit from cigarettes for 7+ days ( $n \sim 3$ )
    - And not successfully quit from cigarettes for 7+ days ( $n \sim 2$ )
- We will invite eligible participants who fall into the above groups until each of the group numbers are met. If it appears we will not have enough participants to meet the numbers in one of the groups, we will invite more participants in the other groups.

- Interviews will be designed to collect the following from participants:
  1. ENDS, NRT, and nicotine beliefs (relative harm, safety, long-term use)
  2. Quit strategies used and how and why ENDS were used during the program,
  3. Reactions to Shared Decision Making model for quit plan development,
  4. Use of and reactions to EEC print materials,
  5. Reactions to coaching calls and education from quit coaches
  6. Why/why not callers would recommend the program and recommendations for improvement
  7. Diary completion experiences.
- Interviews will be recorded and transcribed.

### **Gift Cards**

- Study Incentives:
  - Both Groups will have the opportunity to receive:
    - Completion of baseline survey - \$20
    - Completion of Daily Surveys - \$5 per week for completing at least 5 of 7 daily surveys per given week. For a total possible amount of \$60 for the 12 weeks
    - Bonus payment for completion of surveys during the 12 weeks:
      - 80% or more - \$50
      - 60-79% - \$25
    - Completion of follow-up survey - \$50
    - Completion of iCO™ Smokerlyzer® test - \$50
  - 10 participants in each phase (Phase 1 & 2) will complete Qualitative Interviews with Study Staff:
    - Qualitative Interview - \$50
  - In total, participants will have the opportunity to earn up to \$280.00 for completing study surveys.
- Participants will get paid by pre-loaded gift cards. During their baseline survey participants will choose which delivery method they would like all of their gift cards to be sent.
  - Delivery Options:
    - Electronic gift cards – sent via email
      - These gift cards are digital, and Participants can only use them online.
    - Mailed gift cards – sent through USPS postal mail
      - These cards are plastic can be used online or at a store.
- Gift Card Delivery Schedule:
  - Participants will be sent their gift card(s) for daily survey completion & Bonus incentive at the following Week intervals:
    - Weeks 7-8 – includes surveys completed for weeks 1-6.
    - Weeks 13-14 – includes surveys completed for weeks 7-12. This gift card will also include the \$50 or \$25 bonus based on the percentage of surveys completed, if earned.
  - Follow-Up and Qualitative:
    - Participants will be sent their gift card once the study staff completes or receives their respective survey/interview.
  - iCO Smokerlyzer test:
    - Participants will be sent their gift card once study staff receives their iCO results.

- Sending Gift cards:
  - Study staff will use the email address or mailing address that was provided during participant’s baseline survey for all gift cards.
  - Participants are responsible and informed during baseline to call study staff in order to update their email address or mailing address.
- Troubleshooting gift cards:
  - Participants who have issues with their gift cards can contact study staff or the contact number provided with their gift card.
  - Once gift cards are sent either digitally or mailed, study staff cannot re-issue a gift card.
  - Lost Electronic gift cards:
    - Study staff will assist participants by recommending that the participant search their inbox for their gift card.
  - Stolen Mailed Gift Cards:
    - Study staff will check in with the participant over the phone to see if they would like to provide a different mailing address for the study to use that may be more secure.

**Withdrawal Protocol:**

- If a participant informs the Quit Coach that they no longer wish to participate in the ENDSmoking Study, the Coach will first clarify if they want to withdraw from the study or the quitline treatment (not receive any more coaching calls; participant has the option to opt back in at a later date). If the participant says they want to withdraw from the quitline, but not the study, the Coach will place the participant’s file on a status that will prevent the quitline from calling out to the participant, but the participant will still be eligible for study surveys and incentives.
- If the Participant states that they want to withdraw from the study, the Coach will explain that someone from the study will contact them to complete official withdrawal. The coach will also provide the contact information for the study team. Until the participant speaks to the study team to withdraw, they will still be considered part of the study.
- The study team will make five attempts on separate days to call out to participant(s) confirm that the participant wants to withdrawal from the study and collect reasons for withdrawal. If the research team member reaches the participant, they will read the following Withdrawal Script (*see Study Scripts*).

## Study Monitoring Protocols

**Fidelity Coding**

- The research team will review all call recordings, code for treatment fidelity and collaborate with QC supervisors to review standard call quality metrics. Feedback will be provided to coaches.
- Study staff will review 20% of calls to ensure treatment adherence.

**Reporting Adverse Events**

- See Attachment M: DSMP

**List of staff with job descriptions**

- See Attachment N: List of Study Staff

**Data Safety and Monitoring**

- See Attachment M: DSMP