ABSTRACT

Title of Dissertation: THE IMPACT OF EXHALED CARBON MONOXIDE TESTING AND COUNSELING AND ADULT SMOKERS' IMPROVED MOTIVATION TO ENROLL IN TOBACCO CESSATION INTERVENTIONS

Gia Grier, Dr.P.H., December 2019

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While the overall rate of smoking has declined in the general U.S. adult population since the first U.S. Surgeon General's report on the dangers of smoking, current adult smoking rates vary greatly by socioeconomic status. Smokers in the most underserved communities are often the hardest to recruit into smoking cessation programs and face barriers to enrollment, including low motivation to quit. This investigation, which included 630 adult smokers in Baltimore City, had three aims: to examine whether or not enhancing a recruitment process with exhaled carbon monoxide (eCO) testing and education would, on average, increase the odds of enrollment in peer-led quit smoking classes; to explore, using a sub-sample of 279 smokers, whether or not there were differences in baseline characteristics between enrolled and non-enrolled smokers; and to determine whether the eCO intervention was moderated by motivation change ruler measures of importance, readiness, and confidence (IRC).

Study data was collected between May 2015 and March 2016 through the larger Phase IV investigation of the community based participatory research partnership, Communities Engaged and Advocating for a Smoke-free Environment (CEASE). The CEASE initiative trains former smokers to lead quit smoking classes and provides free nicotine replacement therapy to program enrollees in Southwest Baltimore and in neighborhoods within Morgan State University's Morgan Community Mile. Recruitment activities for the sample occurred through 72 community-based recruitment events in a variety of settings. Population-averaged generalized estimating equations, adjusted chi-squared and adjusted t-tests were used in the analysis to account for the clustered nature of data collection. On average, smokers that received the eCO intervention were 1.8 times more likely to enroll in CEASE programs than the average non-eCO participant (OR: 1.04-3.25). The intervention was more successful in institutional settings than public settings (OR, CI: 2.45, 1.21-4.93). The IRC measures did not moderate the eCO intervention, though there were significant baseline differences in enrollment groups for importance and readiness to change tobacco habits. There were also significant differences between enrollment groups for wanting any support in quitting, being comfortable with the use of nicotine replacement therapy, and Fagerstrom Test of Nicotine Dependence scores. There may be future implications for the incorporation of biomedical risk approaches in community-based smoking cessation program recruitment for low SES populations. Future studies exploring the role of risk perception and the specific roles that importance and readiness play in recruitment processes may also be warranted.

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by

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Finally, I want to thank the Peer Motivators of the CEASE for letting me into your universe. I was truly inspired by your determination to provide services to those who often go unreached. I can only hope to pay it forward in time.

DEDICATION

I want dedicate this to those who participated in this study and others who continue to battle with addiction on the path to better health.

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LIST OF ABBREVIATIONS

BCHD	Baltimore City Health Department
CO	Carbon Monoxide
CDC	Centers for Disease Control and Prevention
CAB	Community Action Board
CBPR	Community Based Participatory Research
CEASE	Communities Engaged and Advocating for Smoke-Free Environments
DARN	Desire, Ability, Reasons, and Need
eCO	Exhaled Carbon Monoxide
FTND	Fagerstrom Test of Nicotine Dependence
FDA	Food and Drug Administration
GEE	Generalized Estimating Equations
HPHC	Hazardous and Potentially Harmful Constituent
HBM	Health Belief Model
ICC	Intracluster Correlation Coefficient
IRC	Importance, Readiness, and Confidence
MCM	Morgan Community Mile
MI	Motivational Interviewing
NRT	Nicotine Replacement Therapy
QIC_u	Quasilikelihood Under the Independence Model Information Criterion
USDHHS	United States Department of Health and Human Services

Chapter 1: Introduction

Cigarette smoking remains the largest source of preventable death in the United States and is linked to approximately 480,000 deaths annually (United States Department of Health and Human Services [USDHHS], 2014). Tobacco use can be considered a chronic behavioral condition due to the common cycle of quitting followed by periods of relapse (Fiore, 2008). Smoking has been causally linked to cancers of the lung, liver, breast, pancreas, cervix, bladder, stomach, oralpharnyx, and colon as well as over 20 chronic illnesses, including respiratory illnesses, stroke, heart disease, and diabetes (USDHHS, 2014). Cigarette smoking has also cost the U.S. economy billions of dollars in recent years, with smoking-attributable cost estimates ranging from $289 to $332.5 billion dollars between 2009 and 2012. According to the Maryland Department of Health (2018), approximately $2.71 billion dollars a year is spent treating smoking attributable diseases. These costs include productivity losses due to premature deaths and work absenteeism, as well as direct medical costs (USDHHS, 2014; Center for Disease Control and Prevention [CDC], 2015). Unfortunately, the burdens of these costs have fallen disproportionately on minority and low socioeconomic communities.

While the overall rate of smoking has declined in the general U.S. adult population since the first U.S. Surgeon General's report on the dangers of smoking, current adult smoking rates vary greatly by socioeconomic status and race (USDHHS, 2014). Jamal et al. (2018) synthesized 2016 National Health Interview Survey data and found that while the prevalence of current adult smoking is 15.5%, there are differences by race and ethnicity. Approximately 16.6% of current smokers identified as white,

16.5% of smokers identified as African American, 10.7% identified as Latino or Hispanic, 31.8% identified as American Indian/Alaskan Native, and 9.0% identified as Asian. Jamal et al. also highlighted disparities by education level that are particularly notable, with 24.1% of current smokers age 18 and older having less than a high school diploma, 40.6% having a GED, 19.7% holding a high school diploma, 18.9% having completed some college and only approximately 7.7% of smokers holding a bachelor's degree. Disparities by employment status also vary with 13.6% of current adult smokers being employed, while over 33% of current smokers are unemployed (USDHHS, 2014).

Results from the Behavioral Risk Factor Surveillance System indicate that rate of adult smoking in the state of Maryland in 2017 was 13.8% (CDC, 2019). Unfortunately, Baltimore City's adult smoking rate is over twice that rate at 33%. There are also rate gaps within Baltimore's population, with an adult smoking rate gap of over 25% between those holding a college degree and those holding a high school equivalency or less, with lesser educated people having the higher rates of smoking (Baltimore City Health Department [BCHD], 2015). A 30% gap in the current adult smoking rate exists between those in the city with incomes of less than $15,000 a year and those with $50,000 to $75,000 a year, with lower income individuals having higher rates (BCHD, 2015). Targeting populations in Baltimore that are low SES are essential to the success of smoking cessation efforts in the city. Helping smokers quit remains a major challenge.

While approximately 68% of the nation's current adult smokers attempt to quit every year, only 10% are successful in quitting (Babb, Malarcher, Schauer, Asman, & Jamal, 2017). Low socioeconomic smokers tend to have significantly lower quit and

abstinence rates than their higher socioeconomic counterparts (Sheffer et al., 2012; Zhuang, Gamst, Cummins, Wolfson, & Shu-hong, 2015). This is due to the many barriers that this population faces in quitting.

Barriers to quitting for low socioeconomic populations encompass several dimensions: social/interpersonal, including lower levels of social support and normalized smoking behavior amongst peers; individual beliefs/attitudes, such as lower readiness and preparedness to quit, lower self-efficacy, and negative perceptions of the impacts of quitting; community/neighborhood factors, including easy access to cigarettes, pervasive tobacco marketing); and lifestyle factors, such as high stress levels and resource scarcity leading to lack of access to treatment services (Copeland et al., 2010; Rosenthal et al., 2013; Twyman, Bonevski, Paul, & Bryant, 2014). In addition, a lack of access to nicotine replacement and other medications was a frequently cited barrier for smokers with low educational attainment (Copeland et al., 2010). Low motivation and low self-efficacy are ultimately the most frequently cited barriers, and many low SES smokers are not prepared to quit (Copeland et al., 2010; Rosenthal et al., 2013; Twyman et al., 2014).

The U.S. Surgeon General has identified five key strategies for enhancing cessation outcomes for smokers, including improving access to treatment services (USDHHS, 2014). While more research on effective cessation program recruitment methods is needed, findings from a multi-state study as well as a systematic review suggest that tailored approaches that include interpersonal approaches as well as direct contact with smokers can be beneficial (Brodar et al., 2016; Marcano-Belisario, Bruggeling, Gunn, Brusamento, & Car, 2012). Once enrolled, cessation services that

operate through a community-based organization, that have flexible programmatic offerings, and that combine the use of nicotine replacement and behavioral support have been found to be effective for this population (Fiore, 2008; Murray, Bauld, Hackshaw, & McNeil, 2009; Stead, Koilpillai, Fanshawe, & Lancaster, 2016). Identifying motivational frameworks and tools to assist low SES populations in gaining access to these multi-faceted programs is an important step in improving cessation outcomes. Enhancing smoker's knowledge of the dangers of chemical exposures to tobacco smoke can be leveraged to enhance motivation.

Smoking's high rates of morbidity and mortality are linked to the chemical composition of cigarettes. Out of the 7,000 chemicals in cigarettes, 79 are considered carcinogenic (Rodgman & Perfetti, 2013). Carbon monoxide is a major component of cigarette smoke and outcompetes oxygen for its place in the bloodstream by attaching to blood cells in the body. The resulting oxygen depletion has been linked to health problems including shortness of breath, fatigue, dizziness, and increased risk of stroke (USDHHS, 2014).

Carbon monoxide is also one of the 93 chemicals in cigarettes identified by the Food and Drug Administration (FDA) as a hazardous and potentially harmful constituent (HPHC). The 2009 Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) added section 904 to the Federal Food, Drug, and Cosmetic Act, requiring that the FDA collect information on HPHCs from industry. Carbon monoxide was included on the list of 20 HPHCs industries must disclose information about (Kux, 2012). The FDA also must provide industrial chemical constituent information to the public in a

way that is easily understood (United States Congress House Committee on Energy and Commerce, 2009). This public disclosure element of the Tobacco Control Act has led to a line of health communication research around the public's knowledge of tobacco chemical constituents, including carbon monoxide, and its impact on health risk awareness (Brewer et al., 2016; Hall, Ribisl, & Brewer, 2013; Moracco et al., 2015). Carbon monoxide has also been used in another area of research utilizing biologically-derived data from smokers as a motivation tool.

Cessation programs have used exhaled carbon monoxide (eCO) tests as a tool for verifying smoking status for three decades. The eCO monitoring is accomplished by using small, inexpensive handheld devices that capture the breath of a smoker through a mouthpiece after a breath hold of a few seconds. The monitor produces a numerical score reflective of either percent carboxyhemoglobin in the blood or parts per million in the lungs (Deveci, Deveci, Acik, & Ozan, 2004; Jarvis, Belcher, Vesey, & Hutchinson, 1986). This testing has provided a positive reinforcement for smoking reduction and has been perceived as a reliable source of information for potential quitters in this programmatic context (Grant, Ashton, & Phillips, 2015).

These same eCO tests have been used as a motivational tool in smoking cessation studies, with mixed results. In this context, exhaled carbon monoxide testing is considered a form of biomedical risk assessment, which is the process of using biological data or messaging to help inform an individual of their personalized health risks. This biological data can include lung age, genetic markers or risk, spirometry measurements, and other processes (Bize, Mueller, Rège-Walther, & Cornuz, 2012; Clair et al., 2019).

Usually these biological assessments are accompanied by a brief educational discussion to relate the test results to an individual's risk of disease. Many studies using this form of assessment are randomized trials, where the personalized information is isolated to an experimental group (Bize et al., 2012; Clair et al., 2019). Previous reviews of this area of research found a lack of consistent study designs and a limited number of quality studies, leaving no definitive conclusion of the effectiveness of eCO and other forms of biomedical risk feedback on smoking cessation (Bize et al., 2012; Clair et al., 2019). Since the 1990's, several researchers have shifted the focus of their studies to examine the role of biomedical risk assessment approaches in promoting treatment seeking behaviors, enhancing smokers' quit intentions and cognitive impacts, and/or smoking reduction. Using eCO as an enhancement of a recruitment process is an area of research that has not been explored in depth.

Problem Statement

Given that low motivation and low self-efficacy have been documented as major barriers to quitting, particularly in low socioeconomic populations, motivation enhancing interventions are needed. Gaining access to treatment services that combine behavioral supports with the use of nicotine replacement therapies is a key strategy in improving quit rates, and discovering ways to reach, to motivate and to increase the number of smokers entering treatment programs is essential. Utilizing a community-based recruitment intervention that includes health messaging linked to results from exhaled carbon monoxide screening could enhance the enrollment rates of cessation services.

Purpose of the Study

This study analyzed data from the community based participatory research program, Communities Engaged and Advocating for a Smoke Free Environment (CEASE). CEASE launched in 2007 and trains former smokers who have abstained from smoking for at least one year (called Peer Motivators) to lead cessation programs, data collection activities, and community outreach efforts in mostly lower SES communities. The program had completed three previous phases of developing and refining their partnership processes and peer-led model, all of which included studies (Phases I-III). Figure 1 is an overview of their partnership processes, which included laying the foundation and infrastructure for the partnerhsip, identifying needs, looking at clinical outreach versus peer-driven outreach effectiveness, and refining the peer-led model. Phase IV was a final process that prepared the program for organizational sustainability beyond the initial research partnership.

The study conducted in Phase IV was designed to provide a final examination curricular formats and materials that could be ultimately described and disseminated in train-the-trainer materials. The Phase IV study included a baseline survey that recruited 843 smokers into various cessation program intervention arms and a self-quit control group from May 2015 through August 2016. This eCO study utilized data from Phase IV smokers from the beginning of the study through March 2016.

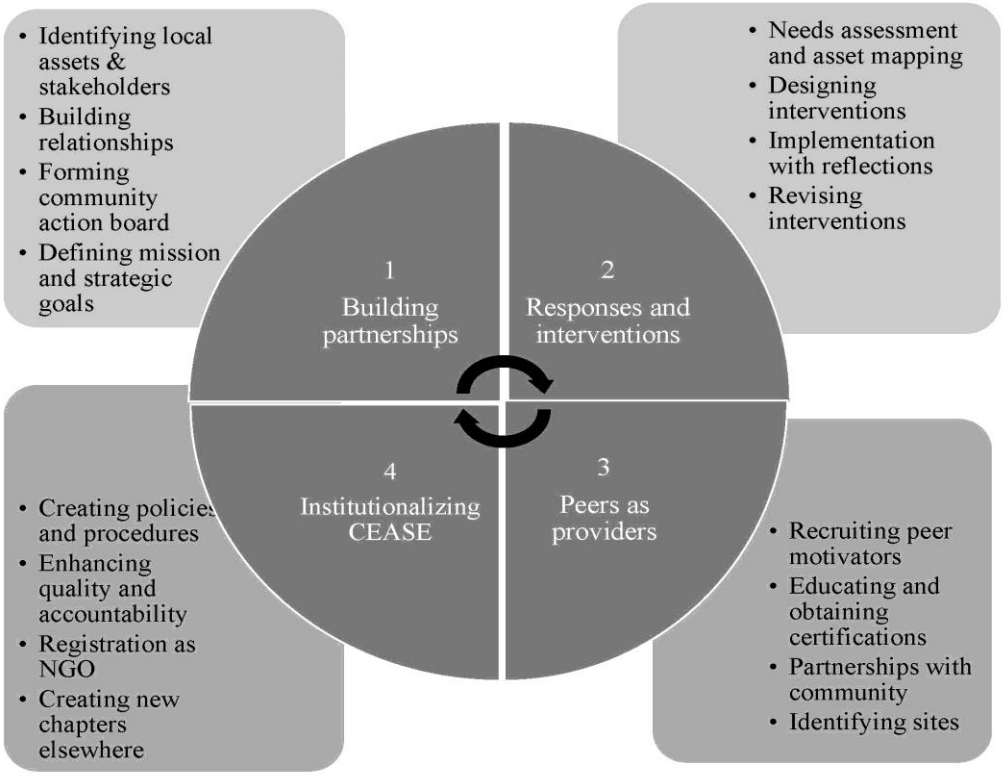

Figure 1. Overview of CEASE partnership processes. Reproduced with permission, CEASE Partnership, 2017.

The first aim of this study was to determine baseline enrollment predictors in a low SES population looking to enroll in a peer-led, community-based cessation program. The second aim was to examine the effectiveness of an eCO breath test and educational postcard on enhancing the likelihood of enrollment in those programs. A final aim was to determine if a participant's baseline motivation measures of importance, readiness, and confidence in changing their tobacco habit moderate the effectiveness of the eCO intervention.

Significance

Motivating smokers to take steps towards quitting is a critical issue, given the numerous negative health impacts of smoking and the high percentage of smokers who

wish to quit but who are not successful. Unfortunately, there is insufficient research on the effectiveness of exhaled carbon monoxide testing and counseling in motivating low SES smokers to enroll in cessation services. In addition, previous eCO motivation studies have been mixed in their results in general, have combined eCO testing with other forms of feedback (ex. spirometry), and have targeted middle class populations (Bize et al., 2012; Choi, Kim, & Lee, 2013; McClure, Grothaus, Pabinak, & Richards, 2010). Many motivational risk feedback studies are also conducted in university labs or in clinical or primary care settings (Bize et al., 2012). This study analyzed data from a proactive, community-based cessation program recruitment process that only included eCO feedback. It also sought to examine if an eCO enhancement could motivate a population that can be challenging to access, to motivate, and to recruit. There is also limited research exploring the motivational drivers that can explain why biomedical risk assessments are successful. Exploring whether or not measures of importance, readiness, and confidence can impact the effectiveness of an eCO testing and counseling intervention might help those designing eCO recruitment strategies for cessation programs in refining their target audience, fine tuning their recruitment channels, and in informing their materials development.

This study could also have implications for policy and public health practice. This study, conducted in partnership with a community-based organization, will add to the literature on the role that community-based organizations can play in conducting motivational tobacco studies that utilize personalized risk feedback. The intervention can also have policy implications in terms of identifying a simple method of explaining the

personalized health risks of a FDA-identified HPHC to lay audiences. Finally, depending on the outcome of the cessation intervention and the role that eCO plays, eCO monitoring could join the ranks of other high impact interventions that use personalized feedback in changing health behaviors, such as HIV testing and education. The eCO monitors are inexpensive, easy to operate, and portable for easy use in a community-based context. This eCO recruitment enhancement would be easy to replicate for even small-scale cessation programs.

Chapter 2: Literature Review

This chapter provides an overview of the literature. The chapter opens by describing effective enrollment strategies for low SES and African-American populations. An overview of community based participatory research is provided and includes a review of previous tobacco-related studies using the approach, including CEASE's Phase I-III studies. Core literature on public perception of chemicals in tobacco and the use of exhaled carbon monoxide in enhancing motivation and behavioral intention and exhaled carbon monoxide follows. The remaining sections of the chapter focus on the study's conceptual framework, the theoretical driver behind that framework, and variables used in the analysis.

Enrollment Strategies for Low SES and African-American Smokers

Enrollment, the primary dependent variable for the study, is merely the end result of successful health communication and engagement strategies. There are several studies that offer recommendations for reaching and recruiting African-American and low-socioeconomic smokers. Proactive (face-to-face) recruitment approaches have been found to be successful. Webb (2009) compared proactive, reactive (ex. media ads), and combination recruitment approaches for recruiting 240 African American smokers (47% considered low SES) into a randomized trial over an 8-month period. Results demonstrated that proactive approaches were most successful in attracting lower income smokers and those not ready to change their smoking habit.

A focus groups study of 67 Maryland-based African American adult smokers provided recommendations to engage smokers, including the need to use former smokers

in programming and offering smoking cessation programming at neighborhood versus city-wide levels (Wallen, Randolph, Carter-Pokras, Feldman, & Kanamori-Nishimura, 2014). A broader 10-year systematic review of recruitment processes of 165 public health trials targeting low SES and minority populations found that, in general, approximately 38% of studies incorporated community-based recruitment approaches. Only about 2.8% of those studies utilized the more intensive approach of community-based participatory research (Nicholson, Schwiran, & Groner, 2015).

Community-Based Participatory Research

Community-based participatory research (CBPR) is an approach that involves intensive collaboration between researchers and community partners (Israel, Schulz, Parker, & Becker, 1998). The guiding principles of CBPR call for research to be equitable, mutually beneficial, involve the co-generation and dissemination of knowledge, and involve long-term investments that might span across multiple studies. It also calls for efforts to be locally focused, but with an ecological approach that looks at several health determinants. The CBPR approach is meant to be a cyclical process, where partnerships and projects are assessed and refined overtime (Israel, Schulz, Parker, & Becker, 1998; Wallerstein & Duran, 2008). Another key feature of CBPR partnerships is the joint community-institutional decision making structures that form to help drive decision-making processes within a study. Many studies have Community Advisory or Action Boards (CABs) consisting of institutional researchers but also community residents and community based organizations (Coughlin, Smith, & Fernández, 2017).

The CEASE Partnership had a CAB and other internal structures that were instrumental to decision-making within the Phase IV study that will be described in Chapter 3.

There have been previous tobacco-related studies that have adopted a CBPR approach. Researchers conducting a randomized trial of 60 predominantly low-income African American adult smokers enhanced a 5-week cessation program with messaging about disproportionate tobacco industry targeting of African American communities, social justice messaging, and sessions delivered by former smokers in the community (Froelicher, Doolan, Yerger, McGruder, & Malone, 2009). The study found higher intervention group percentages of successful quitters at 6 months (13.6%) and 12 months (15.8%) as compared to the control group (11.5% at 6 months and 5.3% at 12 months). Community partners helped to recruit participants through community-based events, public service announcements, and outreach at neighborhood gathering spots (ex. barbershops and libraries). Community partners also co-developed the materials on the tobacco industry with researchers (Froelicher et al., 2009). The CEASE partnership's Phase I-III studies included a total of 965 participants (Sheikhattari et al., 2016). The program evolved its model by comparing a clinically-based quit smoking programming (Phase I, n = 404) to its current peer-led, community based quit smoking program (Phases II and III, combined n = 561).

The peer-led phases of CEASE involved the recruitment and training of the Peer Motivator, and data collection and outreach activities happened at community level for Phases II and III. Results from Phases I-III showed higher smoking quit and retention rates for Phases II and III as compared to Phase I (clinic-based), with a Phase I quit rate

of 9.4% and Phase II and III rates of 21.2% and 30.1%. The Phase I retention rate was 13.8% compared to Phase II and III rates of 51.9% and 67.9% (Sheikhattari et al., 2016). Phase IV, which continued with their peer-led approach and sought to examine curricular formats, is described in Chapter 3. Phase IV also incorporated exhaled carbon monoxide testing and counseling in the class recruitment process.

The Role of Tobacco Chemical Constituents in Health Communication

In response to the public disclosure requirement of the Tobacco Control Act, several studies have been conducted looking at the relationship between consumer knowledge of chemical constituents and an individual's risk perception of tobacco use. One health communication principle that multiple studies have identified is that chemicals that the general public can identify by name easily, such as carbon monoxide, tend to be more likely to heighten discouragement from smoking when used in messaging than chemical names that are lesser known (Brewer et al., 2016; Moracco et al., 2015). Researchers at the University of North Carolina, Chapel Hill conducted a phone study that included a national probability sample of adults (n = 5014) and an additional internet-based survey with a convenience sample of adults (n = 4137) that examined perceptions around 24 chemical constituents (Brewer et al., 2016). The study, which also included a sample of adolescents, asked participants to score constituents with perception of harm and discouragement scales of 1-4 (with 4 being perceived as the most harmful and the most discouraging from using tobacco products). The mean adult scores for carbon monoxide in terms of perceived harm were 2.77 (internet) and 3.12 (phone) and adult scores for discouragement were 3.04 (internet) and 3.46 (phone) (Brewer et al.,

2016). In another study of adult smokers, focus groups participants (n = 40) recognized that carbon monoxide could be harmful due to cigarette pack labelling as well as news reports of the dangers of indoor environmental carbon monoxide exposure from motor vehicles and household hazards (Moracco et al., 2015). Authors of these studies felt that future studies utilizing chemical constituents in health communication campaigns and tobacco control efforts were needed.

Exhaled Carbon Monoxide: Biomedical Risk Assessment as a Motivational Tool

This study's main enrollment predictor is the use of exhaled carbon monoxide testing and counseling as an enhancement to the CEASE Phase IV recruitment process. This section of the chapter contains a review of the literature of recent intervention studies that used exhaled carbon monoxide alone or in combination with other assessments. Studies were selected if they included eCO as an assessment method and if they examined enhancement of intentions to quit or other cognitive dimensions as one of their outcomes. Table 1 includes a summary matrix of the recent literature included in this chapter and shows the inconsistencies between studies in terms of varied population targets, desired outcomes, and length of follow-up period (ranging from four weeks to one year). It also outlines study settings, which were often lab or clinical-based.

Carbon monoxide only studies. Shahab, West, and McNeil (2011) conducted an exhaled carbon monoxide study with 160 members of the general public from the United Kingdom (UK), examining outcomes of threat and self-efficacy appraisals, quit intentions, and fear responses immediately post-intervention (T = 0) and at 6 months post intervention. It also explored differences in quit attempts 6 months post-intervention.

They found that eCO testing, paired with a standard pamphlet with quit advice, significantly enhanced health risk threat appraisals in the intervention group over the control group ($t(158) = 2.29$, $p = 0.023$). It also enhanced quit intentions to stop smoking in the next month in the eCO group, but only immediately post-assessment ($t(158) = 2.29$, $p = 0.004$). The study also included a mediation analysis for the intervention in relation to a smoker's post-intervention fear response and the impact on quit attempts. The results found that fear response was not a mediator (Shahab, West, & McNeil, 2011). A small UK pilot study (n = 10) by Beard and West (2011) found eCO to be a significant motivator when used to achieve smoking reduction outcomes after 2 and 6-week periods. Participants monitored and recorded their CO levels over two weeks. Eight of the study's participants were below their baseline daily average concentration of CO after two weeks, and after six weeks all participant's CO levels were below baseline (Beard &West, 2011).

Table 1

Synopsis of Smoking Recruitment and Cessation Studies Using Exhaled Carbon Monoxide

Author(s)	Setting/population, sample size	Feedback Method	Feedback Success (T=0)	Feedback Success, outcome (Follow-up)
McClure, Ludman, Grothaus, Pabinak,Richards, Mohelinsky (2009)	Lab-based; Mostly white, mostly college educated smokers across Washington state; n=523	eCO, FEV, FVC. lung age	yes (intentions only)	no, cessation, intentions, treatment sought (4 wks)
McClure, Ludman, Grothaus, Pabinak,Richards (2010)	Lab-based; Mostly white, mostly college educated smokers across Washington state; n=267	eCO, lung function,FEV and FVC;	N/A	yes[a] ,intention to quit, (6 mo.,12 mo.)
Shahab, West, McNeil (2011)	Lab-based; United Kingdom n=160	eCO	yes	no, intention to quit (6 mo.)
Beard and West (2012)	Group recruited after larger NRT study; United Kingdom; n=10	eCO	N/A	yes, smoking reduction, (over 2 wks and at 6 wks)
Brunette, Ferron, Drake, Devitt et. al (2013)	Large mental health facility;Chicago; mostly disadvantaged males with SMI/mood disorders; n=124	eCO	N/A	no, treatment sought, online educational tool enhancement (2 mo.)

[a] compared people with and without lung impairment that received feedback intervention; no non-feedback group

Another study by Brunette, Ferron, Drake, Devitt et al. (2013) examined the role of eCO in enhancing a computerized decisional support process in motivating 124 low-income smokers with mental health conditions in Chicago to seek treatment within a two-month period. The trial participants were randomized to either a control or experimental group. The control group received just a web-based program that provided information including the health risks of smoking and also provided testimonials about, and options

for, various cessation treatments. The experimental group received the same program with an additional three screens of information on the dangers of CO followed by the opportunity to take the CO test. After a two-month follow up period, there were no differences between study groups for initiating treatment based on results obtained using logistic regression modeling (difference in rate of initiation between groups = 15%; CI [-0.31, 0.01]). The researchers determined that their support system could stand on its own.

Mixed assessment methods (Get PHIT trial). Some studies combine eCO with other biomedical assessment approaches. McClure et al.'s (2009) Proactive Health Intervention for Tobacco Users trial (Get PHIT) used a comprehensive health risk assessment that included information about BMI and diet as well as the addition of an eCO test, Forced Expiratory Volume, and Forced Vital Capacity assessments for the intervention group (control group received generic health information). Results from the trial of 523 mostly college educated individuals found that the intervention group's motivation to enroll in phone counseling and use of self-help materials was not enhanced compared to the control group after 12 months' follow up (phone counseling OR = 0.88, $p = 0.15$ and self-help OR = 0.84, $p = 0.36$). The authors discussed the limitations of mixed assessment studies in terms of being able to determine the influence of each assessment method.

A separate study by McClure et al. (2010) used Get PHIT participant data (n = 367) to examine whether there would be differences in primary outcomes including the use of self-help cessation materials at 6 months' follow-up, enrollment in a phone

counseling service at and 12 months' follow-up, and their 7-day point prevalent abstinence. The results found that lung impaired individuals were more likely to enroll in counseling at 6 and 12 months (6 month OR = 1.46; CI [0.80, 2.70] and 12 month OR = 0.26; CI [0.71, 2.21]). They were also more likely to use self-help materials (6-month OR = 1.92; CI [1.06, 3.47] and 12 month OR=1.60; CI [0.94, 2.75]).

Exhaled carbon monoxide has been used in cessation and smoking reduction studies alone and with other assessment measures with mixed success. The studies are not often conducted with diverse populations and in lab or clinical settings. This study applied lessons learned from those studies and examined them alongside health behavior theories and constructs from the literature.

Study Conceptual Model and Additional Study Variables

Figure 2 is the study's conceptual model. The model depicts the health communication inputs that shaped the eCO testing and education materials. The health risk information, and eCO score, and information on eCO elimination were designed to serve as a motivational drivers and potential benefits that were used in the educational intervention for participants. It is hypothesized that the motivational measures of importance, readiness, and confidence may enhance the impact of the eCO testing and counseling. The study has a robust set of covariates that were examined alongside the eCO intervention in various study models. This chapter provides further explanation of the conceptual model, the health belief model as its theoretical frame, and a review of the remaining study variables.

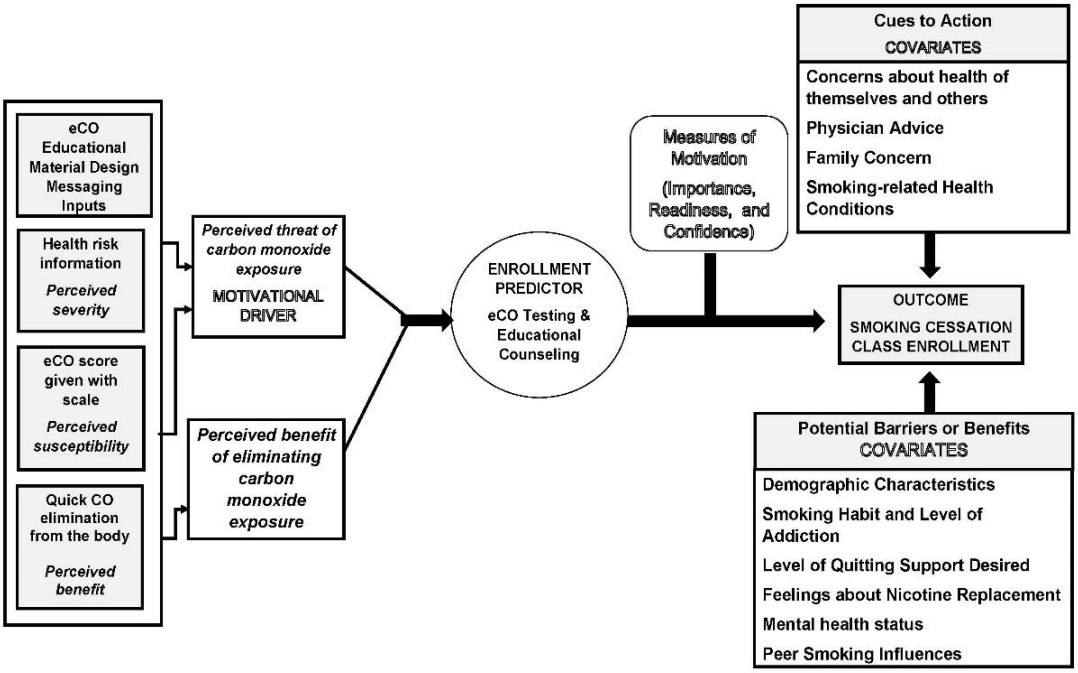

Figure 2. Study conceptual model incorporating constructs from the health belief model.

Constructs of the health belief model. The model outlines design elements of the eCO testing and counseling intervention, which incorporated the constructs and elements of perceived susceptibility, perceived severity, cues to action, and perceived benefits from the Health Belief Model (HBM). The HBM was developed by social psychologists Janz and Becker in the 1950's. It is an explanatory, individual level model that was originally designed to explain preventative health behaviors (Janz & Becker, 1984). The HBM posits that individuals will change behavior to reduce a health threat when they perceive that health threat to be both severe and highly likely to occur (Glanz, Rimer, & Viswanath, 2015). Perceived severity (belief of how serious the threat is) and perceived susceptibility (belief of how likely it is to occur in the individual) factor into perceived threat. These two constructs support the rationale for adding information on

the health risks of carbon monoxide exposure (to raise perceived severity) as well as providing smokers with their personalized CO score and relational scale (to heighten the sense of susceptibility). Rosenstock (1974) proposed that perceived threat is the motivational driver of the HBM.

The model also includes HBM's constructs of perceived benefits and perceived barriers, which are the pro's and con's that an individual considers in making a behavior change (Glanz, Rimer, & Viswanath, 2015). There are several covariates that will be examined that are potential barriers. The major perceived benefit that was featured in the eCO testing and counseling was the fact that carbon monoxide leaves the body quickly, providing an immediate result that could boost interest in enrollment. This model also utilizes HBM's construct of cues to action, which are things that heighten an individual's sense of urgency to take action (Glanz, Rimer, & Viswanath, 2015). The CEASE Phase IV community survey included several questions to gauge participants' attitudes on several possible cues (which are discussed further below).

The health belief model has been referred to as a risk learning model, as it emphasizes education around the severity and vulnerability of risks and what can be done to minimize risk via self-efficacy (Pechmann, 2001). It has been used in examining other testing and counseling and screening activities. Various components of HBM have been applied in research on HIV testing and counseling, including the role of counselor-participant communication as a cue to action in the process (Mattson, 1999), the role of perceived severity as it relates to the need for testing (Lin, Roy, Dam, & Coman, 2017), and the role of perceived benefits, barriers, and self-efficacy in the willingness to

participate in voluntary testing (de Paoli, Manongi, & Klepp, 2004). The HBM has also been used as a theoretical frame for risk perceptions of cancer screenings. A focus group study of 26 long-term smokers used the constructs of the HBM in their content analysis exploring smoker's risk beliefs around lung cancer and perceptions of risk screenings (for those screened and unscreened). They examined the perceived benefits of lung cancer screenings, which included the enhanced motivation to quit smoking, early detection, and providing a sense of relief. They also found that smokers had a low sense of perceived susceptibility around the long-term impact of smoking and the chances of developing lung cancer (Carter-Harris, Ceppa, Hanna, & Rawl, 2015). One noted limitation of the HBM is that while it imparts knowledge, additional frameworks are required to promote and sustain behavior change (Pechmann, 2001). It is this limitation, however, that potentially makes it an appropriate fit for an enrollment intervention, as enrollment in a smoking cessation program is a first step in a process of changing an individual's tobacco habit that is supported by the cessation program. The study model also includes motivation measures of importance, readiness, and confidence.

Motivation measures of importance, readiness, and confidence. The model incorporates motivation measures using tools employed in the field of motivational interviewing. Motivational interviewing (MI) is defined by Miller and Rollnick (2013) as a "collaborative conversation style" that seeks to enhance motivation and promote behavior change. This method was first introduced in the literature by Miller in the early 1980's and initially applied to substance abuse treatment (Miller, 1983). There is an element of MI that involves discussing "change talk." This conversation can be initiated

using a series of questions that prompt participants to respond using a ruler scale system that usually goes 0 to 10. In the initial development of the rulers, a measure of readiness was developed in clinical settings, where smokers were asked to place an "X" along a horizontal line to indicate their level of readiness. Eventually a second ruler for importance was developed through additional pilot testing (Rollnick, Butler, & Stott, 1997). Rulers of importance, readiness, and confidence (IRC) have been studied for their predictive validity and found to be comparable to the stages of change construct of the transtheoretical model of behavior change (Boudreaux et al., 2012).

Each of the IRC rulers is related to a different form of change talk that can either help an individual prepare for change or signal activation around making the change. This movement from language around preparing for change to language around taking action around change has been described as the Motivational Interview Hill, with preparation talk on one side of the hill and mobilization talk on the other side (Miller & Rollnick, 2013). Asking a participant about their readiness to change is on the mobilizing side of the hill versus language around confidence and importance to change, which are more preparation concepts (Miller & Rollnick, 2013).

In addition, linguist Paul Armheim developed a preparation language framework called DARN, which stands for Desire, Ability, Reasons, and Need. Collaborative research with psychologists working on MI discovered that the framework can map to MI change talk language (Amrhein, Miller, Yahne, Palmer, & Fulcher, 2003). The importance ruler attempts to gauge an individual's desire or need to change, while the

confidence ruler attempts to provide insight into a person's self-perceived ability to change (Miller & Rollnick, 2013).

Cues to action. This study included several variables that could be considered cues to action for smoking cessation program enrollment, including family and physician concerns, personal health status, and concerns for the health of others. In terms of personal health, there are several studies that demonstrate that having a smoking-related health condition can enhance motivation for making changes in smoking behavior. A study by Copeland (2016) examined pre-enrollment characteristics of 28 smokers engaged in a larger motivational biomedical risk assessment study and found that having a pre-existing smoking-related illness (cancer, respiratory, and cardiac illnesses) predicted a greater sense of readiness for smoking cessation (as measured by the stages of change) than individuals without them. A mixed methods study of African American, urban adult smokers (quantitative n = 253, qualitative n = 41) examined enrollment and attendance predictors of a multi-session hospital smoking cessation (Patterson et al., 2017). Authors found that 58 % of individuals who had chronic obstructive pulmonary disorder (COPD) enrolled in the program and that they were over 4.65 times more likely to attend sessions than non-COPD smokers. In addition, smokers with a mother that had cancer were 4.49 times more likely to attend sessions (Patterson et al., 2017).

Physician advice can also be a source of motivation. A study by Rosenthal et al. (2013) examined barriers and motivations in 1,205 low-income, urban adult smokers. Smokers who held a high school diploma/equivalency or less were 1.72 times as likely to endorse the support motivation of having an encouraging doctor and 1.52 times as likely

to endorse the motivation of having friends and family that are supportive. In a Baltimore-based study of 52 African-American smoking caregivers with asthmatic children in Head Start, physician support was also an often-cited reason for their motivation to quit (Hoehn, Riekert, Borrelli, Rand, & Eakin, 2016). The need for quitting with assistance can be another factor that can influence a smoker's motivation to enroll in a peer-led smoking cessation program.

Perceptions of quitting with support and the use of nicotine replacement. The Phase IV CEASE programs offered peer support in various formats. All format options also offered free access to nicotine replacement therapy. A potential participant's level of interest in quitting with support as well as their attitudes towards nicotine replacement could impact enrollment.

Social support. Social support is defined as "information from others that one is loved and cared for, esteemed and valued, and part of a network of communication and mutual obligations" (Taylor, 2018). Classic research on social support and smoking by Mermelstein et al. (1986) outlined three forms of support: role modeling behaviors (including social support networks), direct support for quitting behaviors (direct approval or disapproval of smoking habit), and indirect support (environmental influences). Low SES smokers tend to have lower levels of social support than higher SES counterparts in across multiple dimensions. A study of 2,739 diverse adult smokers in Arkansas that broke participants into 4 SES categories found that the lowest SES category was most likely to have workplaces that were not supportive of quitting, most likely to have smoking significant others, and most likely to let others smoke in the home (Sheffer et

al., 2012). Despite this, many low SES smokers are interested in receiving assistance in quitting.

Perceptions around nicotine replacement. There are several misconceptions around how nicotine replacement therapy works, including the belief that nicotine replacement therapies can be addictive. There are also concerns around financial costs and side effects (Carpenter, Ford, Cartmell, & Alberg, 2011; Lynam et al., 2012). Some perceptions of nicotine replacement differ across racial and ethnic groups. A focus groups study of 70 African American, white, and Hispanic smokers found that, compared to the other groups, African Americans tended to be more skeptical of pharmaceutical manufacturers, more comfortable with a "cold turkey" approach, and more prone to thinking that the overall negatives of NRT use outweigh the positives (Carpenter et al., 2011).

Mental health. A study published in utilizing nationally representative data from the National Survey of Drug Use and Health and the Medical Expenditure Panel Survey found that the rate of decline in smoking prevalence for adults with serious mental illness has been slower than the rate in the general population (Cook, Wayne, & Kafaili, 2014). Despite this, a review of 14 peer-reviewed studies examining readiness to quit amongst adult smokers with serious mental illness found that those smokers' level of motivation is similar to that of the general population (Siru, Hulse, & Tait, 2009). Special consideration are also needed for low-income, ethnically diverse populations with serious mental illness.

Nicotine dependence and smoking behaviors. Nicotine dependence is a function of several factors, including number of cigarettes per day, time to first cigarette, and general patterns of smoking behaviors (Heatherton, Kozlowski, & Fagerstrom, 1991). Nicotine dependence can impact a smoker's motivation to quit and seeking treatment. Dependence can also intersect with cultural differences, as African American, Asian American/Pacific Islander and Hispanic/Latino smokers are more likely to have lighter daily consumption of cigarettes than white smokers (Trinidad et al., 2009). Cox et al. (2014) examined baseline characteristics of 540 African American smokers that were recruited into a randomized trial designed to examine bupropion for light smokers (defined as smoking $\leq$10 cigarettes a day). They found that these smokers were highly motivated and confident in their ability to quit and had attempted to quit an average of 3.7 times over the past year. Despite this high level of interest, African American smokers tend to have a harder time quitting than white populations partially due to a disproportionate use of menthol and high tar cigarettes (Stahre, Okuyemi, Joseph, & Fu, 2010), slower rates of nicotine metabolism (Ho et al., 2009), and the barriers to cessation described earlier.

This study sought to explore various factors impacting a smoker's likelihood to enroll in quit smoking classes. The initial analysis involving the 279 standard enrollment participants sought to to explore possible differences in demographic and pre-enrollment characteristics between enrollment groups for the sample prior to the randomized trial analysis. Previous studies on the relationship between program enrollment and pre-enrollment participant charcteristics have explored several covariates, including

demographic characteristics, peer influences, smoking habit, and motivation measures (Dahm, Cook, Baugh, Wileyto, & Pinto, 2009; Mak, Lee, & Loke, 2015). This study included similar covariates.

Summary

Recruiting low SES smokers into smoking cessation programs requires proactive approaches. Many public health practitioners have used community-based methods in health outreach, but few utilize the intensive community-based participatory research design. The CEASE program has historically utilized a CBPR approach to explore the effectiveness of their peer-led program model. The program has undertaken a new area of research in examining the effectiveness of an eCO enhancement of their community-based recruitment efforts and the motivational characteristics that heighten the intervention.

There are several biomedical risk assessments that can be used in an educational intervention. Exhaled carbon monoxide was selected for this study as it is a hazardous and potentially harmful constituent that has wider recognition by the public than other chemicals found in tobacco smoke. It has also been found to have a greater impact in terms of enhancing perceptions of harm than lesser known chemicals based on previous health communication studies. There have been previous studies utilizing exhaled carbon monoxide that have sought the outcome of smoking cessation, abstinence, and/or reduction. Studies have also explored the impact of exhaled carbon monoxide on enhancing motivational drivers such as threat and risk perception. Unfortunately these studies have varied in their results and have often been ineffective for the outcome of

cessation. Using exhaled carbon monoxide to enhance a recruitment process was thus a novel use of a tool commonly used in smoking cessation programs.

This conceptual foundation of this study draws from constructs of the health belief model. Described as a risk learning model, the HBM has been used in other educational interventions, including HIV testing and counseling. The HBM leverages knowledge to promote the beginning steps of behavioral change, which was an appropriate fit for use in the design of materials used in an enrollment process. The study also utilized motivation rulers of importance, readiness, and confidence from Motivational Interviewing. This motivation measure is not used as often as the stages of change construct of the transtheoretical model, but is considered to have a comparable predictive validity. This study sought to examine whether these various measures could serve as moderators between the effect of the eCO testing and counseling and the outcome of enrollment.

The conceptual model for this study also calls for an examination of several covariates that can influence motivation to seek treatment in quitting. Some variables can be considered cues to action, a construct of the HBM that can enhance the motivation individuals to take action to make a health behavior change, including things like physician's advice, family concerns, and previous health conditions, among others. Other modifying variables include peer smoking influences, smoking behaviors, and mental health status. Additional variables that can influence motivation to enroll specifically in CEASE programs due to its format include perceptions around the

effectiveness and safety of nicotine replacement and desired levels of social support in quitting.

Research Questions

Bivariate and population averaged generalized estimating equations were estimated using CEASE Phase IV data and used to answer the following questions:

1. Are there significant dfferences in baseline characteristics between enrolled and non-enrolled participants, who only receive a standard enrollment procedure, for a study offering a peer-led, community-based cessation program with a combination of group counseling and nicotine replacement?
2. Will the average smoker who receives an eCO test and educational postcard at the time of recruitment be more likely to enroll in CEASE Phase IV cessation interventions than the average participant that does not receive the eCO testing and educational material?
3. Do motivation measures of importance, readiness, and confidence moderate the impact of the eCO intervention on the outcome of enrollment?

Chapter 3: Methodology

This chapter outlines the study hypothesis, design, participants, measures, study protocols, and sample size calculation. This randomized educational trial of 630 adult smokers, predominantly from North and Southwest Baltimore, was administered within the larger CEASE Phase IV study. The CEASE's Phase IV intervention study conducted a community baseline survey and recruitment process for trial arms between May 2015 and August 2016. The purpose of Phase IV was to determine which cessation support method, 4-session classes (one, 1.5-hour session per week for four weeks), 1-session classes, or a self-help control group would be most effective in enhancing smoking cessation rates after a six-month follow-up period. Non-smokers were also invited to complete portions of the baseline survey in the early phases of the study.

Figure 3 depicts an overview of this study. The eCO randomization period in Phase IV ran from May 2015 through mid-March 2016, as this was a time period where 72 recruitment events were randomized where all event participants were to receive either the standard CEASE recruitment procedure or one enhanced with the eCO testing and counseling enhancement. Phase IV data was collected in a clustered fashion due to outreach being conducted at several events and locations in the community, but the study was not designed to be a cluster randomized trial. Population averaged generalized estimating equations (GEE) were estimated to account for this clustering following a series of adjusted bivariate analyses by enrollment status (yes/no) and enrollment group (eCO/standard enrollment procedure). The balance of the number of recruitment events between treatment groups was reconfigured prior to the use of GEE by merging very

small clusters with larger clusters holding similar characteristics (ex. merging clusters with the same location and enrollment group assignment, just different dates) and dividing larger clusters into smaller clusters. This created an even number of clusters per study arm (n=30 per arm) and reducing extreme differences in cluster sizes to enhance the power of the analysis without the loss of any data. An additional GEE models was estimated for the randomized educational trial to include interaction terms for the motivation measures of importance, readiness, and confidence.

The exploration of differences in baseline characteristics between enrolled and non-enrolled participants that only received the standard enrollment procedure was conducted with just the non-eCO group (279 smokers). The purpose of this was to provide context into motivations to enroll in the absence of the eCO testing and counseling. An initial descriptive analysis by enrollment group was conducted utilizing the entire sample of 630 to provide an overview of the sample. Adjusted chi-square or adjusted t-tests, used to adjust for clustered data, were estimated to obtain all bivariate study results. In addition to the use of traditional analytical approaches, Phase IV, as well as this investigation, adopted a CBPR approach. This approach shaped certain study design processes, materials development, and decisions around recruitment strategies. These processes will be outlined early in this chapter.

Study Hypothesis Statements

The study's hypothesis statements are:

1. There will be significant differences between enrolled and non-enrolled participants (standard enrollment procedure recipients only) for baseline

enrollment characteristics, including wanting any level of support in quitting, being comfortable with using nicotine replacement products, and measures of readiness, confidence, and importance in changing tobacco habits.

2. On average, participants undergoing an eCO test will be more likely to enroll in CEASE Phase IV cessation interventions compared to the average non-eCO participant.
3. Measures of importance, confidence, and readiness to change will moderate the effect of the eCO testing and counseling intervention.

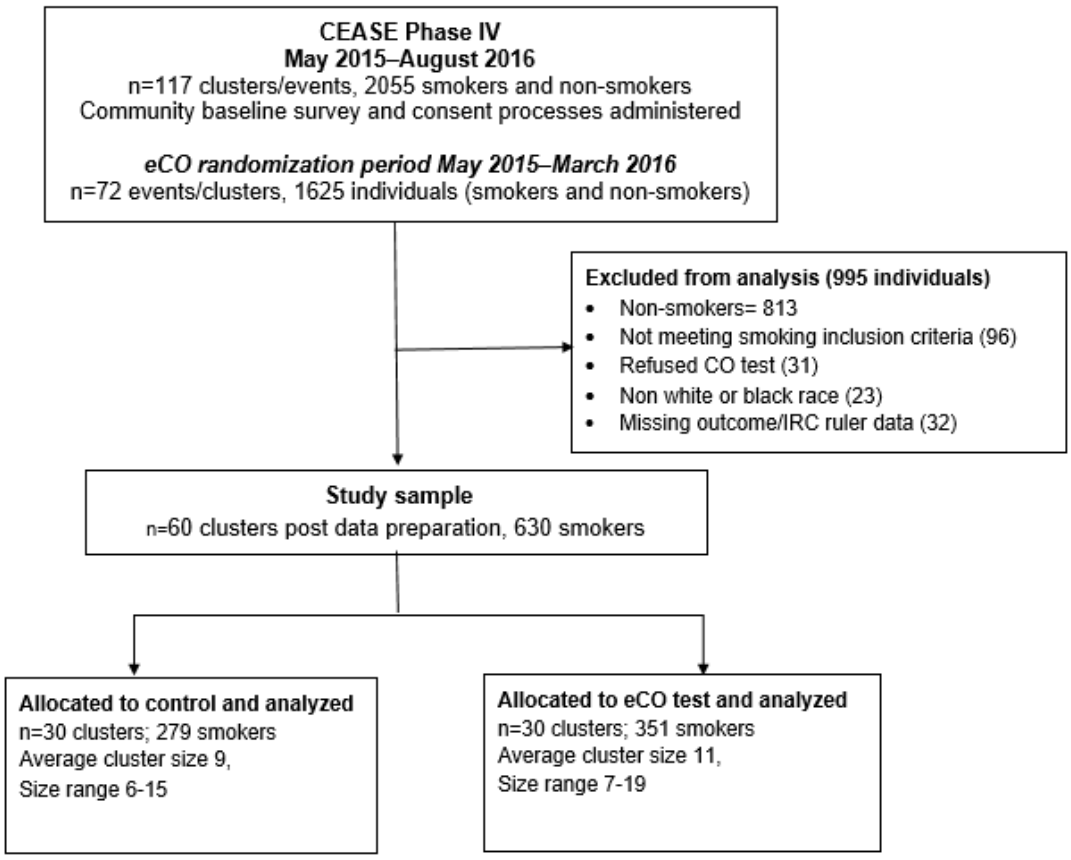

Figure 3. Study flow diagram depicting exclusion criteria, allocation of clusters, and the final sample.

The CEASE Partnership Infrastructure

The CEASE partnership included formal decision making structures and processes that served as the engine that drove study activities. These structures are outlined in Figure 4. The Community Action Board (CAB) was the overarching structure of the CEASE partnership and was composed of community partners, two representative Peer Motivators, and key Morgan State University researchers. This entity met quarterly or as needed to set key decision points for the partnership. Underneath the CAB were additional structures. The CORE team was a small group that met weekly or biweekly to make key decisions about Phase IV and overarching CEASE activities (including outreach projects, policy activities, and dissemination products). It included a Peer Motivator that also served as a study outreach coordinator as well key Morgan State researchers. The Peer Motivators also met weekly during baseline survey data collection and follow-up data collection periods to set shift schedules for CEASE office management and data collection for the upcoming week. Those weekly meetings were also designed to raise on the ground concerns about the study and also to discuss study recruitment goals. There was a continuous flow of information shared amongst the three structures.

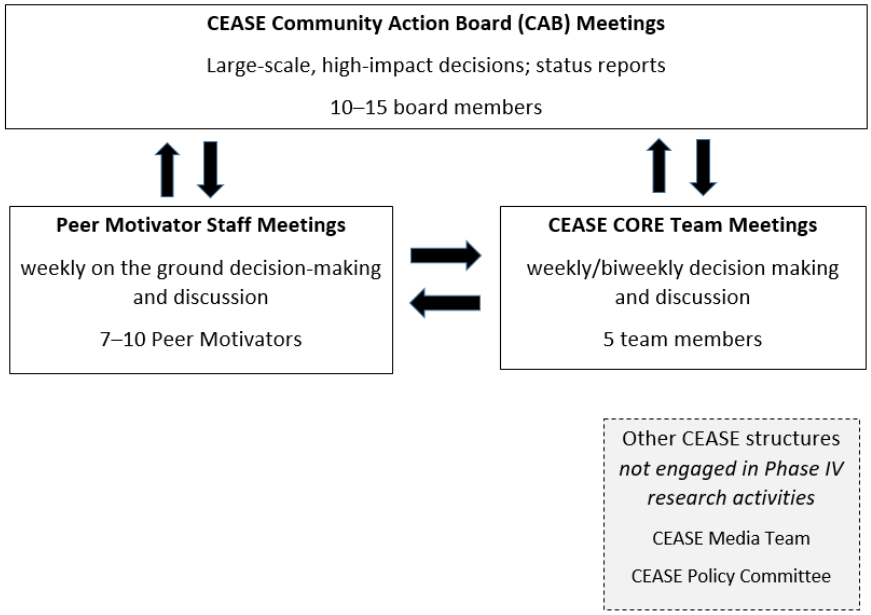

Figure 4. CEASE community-university structures for discussion and decision making.

The study investigator volunteered with CEASE for several months prior to the start of the study through CEASE's media team, which was a group charged with designing outreach materials and managing CEASE's monthly newsletter, website, and social media. The investigator sought initial permission to include the eCO study within Phase IV at a Phase IV kick-off retreat with participating CAB, CORE team, and Peer Motivators in February 2015. This retreat also included bigger discussions around outreach strategies and outlining the overall study goals. During Phase IV, the investigator attended over 35 meetings and discussions focused on study design and execution, not including data collection activities.

The investigator also had to work collaboratively with the CORE team and Peer Motivators to create the postcard for the eCO testing, and the initial draft developed by the investigator was shared with CEASE members for review and approval. This was the

same process for any overarching Phase IV study recruitment outreach flyers developed by the eCO study investigator during this timeframe. The final summer of Phase IV, the eCO study investigator served as the parent study's recruitment coordinator.

Phase IV Study Setting

Phase IV data collection activities took place in Southwest and Northeast Baltimore. These neighborhoods were selected due to CEASE's prior commitments to offering programs these neighborhoods. Southwest Baltimore is the original neighborhood home for CEASE programming and the target neighborhood for previous CEASE data collection activities (Phases I-III). Northeast Baltimore was added for Phase IV as a part of Morgan State University's commitment to the communities within a 12.2-square mile area near campus, which is an initiative called the Morgan Community Mile (MCM). Study events in Northeast Baltimore that occurred during the eCO randomization period were mostly located in the MCM neighborhoods of Waverly, Lauraville, and Greater Govans. Table 2 provides an overview of basic demographic information for those communities.

Table 2

Demographic, Economic, and Health Indicators for Neighborhoods where Phase IV Recruitment Events were Located Compared to City-wide Indicators

		Morgan Community Mile (North/North East Baltimore)			
Indicator	Southwest Baltimore	The Waverlies	Lauraville	Greater Govans	Baltimore City
Population size (n)	17,137	7,796	12,247	10,762	622,454
Demographic Data (%)					
Gender					
Female	47.5	55.5	50.2	53.9	47.1
Male	52.5	44.5	49.8	46.1	52.9
Percentage aged 25 years and older with a high school degree or less	65.6	50.1	39.9	52.2	47.2
Percent Unemployed	20.4	14.7	11.0	16.1	28.8
Age					
0-17	26.8	17.9	18.8	23.2	21.2
18-24	8.4	9.1	8.1	11.5	21.2
25-44	27.5	31.2	26.8	25.2	30.1
45-64	26.1	27.0	34.2	26.9	25.3
65+	11.2	14.8	12.1	13.2	12.1
Race					
African American	74.3	76.4	56.5	90.4	62.8
White	17.4	16.5	36.2	6.4	30.3
Asian	1.3	2.3	2.5	0.2	2.6
Hispanic or Latino	6.2	1.3	2.4	2.3	4.6
Two or More Races	4.5	1.7	2.6	2.6	2.3
Some other Race	2.5	3.2	2.2	0.3	2.0
Tobacco Store Density (per 10K residents)	44.7	24.5	10.6	15.9	20.9
Health (% Total Deaths)					
Drug and Alcohol Induced	7.1	4.3	4.6	3.1	4.5
Chronic Respiratory Disease	3.7	3.8	3.3	2.6	3.5
Diabetes	3.3	3.4	4.4	2.8	3.0
Heart Disease	21.2	24.1	22.5	23.7	24.4
Percent uninsured adults	18.5	14.7	10.8	11.6	11.7

Source: Baltimore City Neighborhood Health Profile, Baltimore City Health Department, June 2017

All target neighborhoods had higher than city averages for African American populations, with the exception of Lauraville. Southwest Baltimore also has a higher than city average of Hispanic and Latino populations. All neighborhoods except Lauraville had higher than city averages for percentages of adults aged 25 and older with a high school education or less. Southwest Baltimore and the Waverlies had the highest tobacco store densities. In terms of health outcomes, these neighborhoods also both had higher than city total death percentages for health outcomes like chronic respiratory disease. All neighborhoods except Greater Govans had higher than city total death percentages for diabetes. Lauraville and Southwest Baltimore had higher percentages for drug and alcohol induced percent of total deaths.

Study Sample and Inclusion Criteria

Baseline survey data collection and recruitment activities took place through a convenience sampling method at large-scale festivals, smaller-scale block parties, neighborhood meetings, as well as in pre-designated areas of social service agencies, educational entities, and behavioral health centers. Phase IV community baseline survey takers did not have to be smokers. Smokers did not have to indicate a willingness to quit smoking to take the baseline survey. There were inclusion criteria for both the 72 recruitment events and the individual participants. Inclusion criteria for the recruitment events were: being located within either the MCM or Southwest Baltimore neighborhoods and being hosted by organizations or event organizers that were willing to provide data collectors with a high traffic area and/or an event with the potential to reach a large audience. Public festivals and neighborhood events used as recruitment locations

often appealed to a broad audience, allowed resource tables or resource announcements at the event, and were often held during daytime hours on weekends or early evening hours during the week.

Inclusion criteria for participants were current adult smokers (adults 18+) that they smoked at least 21 cigarettes a week and 3 or more cigarettes per day. These were larger inclusion criteria for Phase IV class and self-help enrollees. The baseline survey utilized the National Health Interview Survey's definition of current smoker (NHIS, 2013) and was determined by two NHIS questions used in the baseline survey ("have you smoked at least 100 cigarettes in your lifetime" and "do you now smoke cigarettes every day, some days, or not at all?"). During data preparation, those that answered "yes" to the first question and "some days" or "every day" to the second question were considered for analysis. In addition, the community baseline survey asked whether or not participants had previously attended CEASE classes. Smokers who attended CEASE classes previously were not eligible for Phase IV CEASE classes, thus all study participants included in this study were new to the CEASE program.

Participant Adherence

A $5 incentive was offered to participants to take the baseline survey. In the bigger Phase IV study, smokers and non-smokers received the incentive. In addition, eligible smokers who were interested in enrolling in classes were told at the time of enrollment that they would receive an additional $10 per CEASE class plus an additional $25 for completing the 6-month follow-up survey.

Randomization and Treatment Allocation

During the randomization period, Phase IV participants were randomized to either a standard enrollment group or an eCO enhanced group using a block scheme generated using STATA 14 (StataCorp, 2015). A block scheme was selected as this method is known to ensure for balanced study groups (Efird, 2011). Randomization occurred at the event level, versus the individual level, for both administrative ease but also due to the public nature of the data collection. The investigator provided CEASE's Study Administrator with the treatment allocation scheme so recruitment events could be assigned to either the eCO education or the standard enrollment procedure as new events were identified. The trial was single-blind, as participants were not informed they were in a control or experimental group at the time of data collection.

Phase IV Community Baseline Survey Data Collection Overview

The Community Baseline Survey was administered electronically using IPad tablets and utilized Qualtrics© survey software (Qualtrics, 2015). All data collectors were trained on survey administration procedures prior to the start of the study, including several practice runs utilizing the tablet. Questions not answered were due to the decision branching that allowed the survey to terminate due to ineligibility. Most of the baseline survey questions were set as required questions. The average time for the completion of the survey and enrollment procedure was 15 minutes.

The survey included 40 questions leading up to the enrollment procedure, including an initial 24 questions on basic demographic and health conditions that were given to non-smokers (see Appendix A). These first set of questions ended with the

inclusion criteria questions. The survey ended for participants that did not meet these criteria. The middle section of questions asked participants about their tobacco habits, tobacco product usage, interest in using nicotine replacement, interest in quitting with support, quit attempts, and readiness in quitting smoking. The next seven questions related to the Fagerstrom Test for Nicotine Dependence. The baseline questions ended by asking participants their reasons to quit, if any.

The set up of recruitment varied by event type. Peer Motivators recruited participants at large-scale public events and farmer's markets with tables by asking passers-by if they would like to take a survey. Neighborhood event outreach was also done either via tabling or by walking through the event or free-standing at a corner or intersection with permission. Outreach through social service/health/educational agencies often involved the pre-designation of the organization of a room or lobby space where clients/members were informed where the data collectors would be.

Recruitment and Enrollment Protocol: Standard and eCO Enhanced

Participants were pre-randomized to either receive a standard recruitment and enrollment procedure or one enhanced with exhaled carbon monoxide testing and counseling by recruitment event. This section outlines the protocols for both treatment groups. The enrollment protocol begins at the end of the baseline survey.

Standard procedure. The standard procedure was for Peer Motivators to inform smokers that made it to the end of the baseline survey that they were eligible for "an additional phase of research." They then go over the following:

- The length of each CEASE class option

- That the class includes other people like themselves who are taught by former smokers
- That they will receive free nicotine replacement to use at least 24 hours before their class, during class, and two weeks after the class is over
- Details about survey completion incentives and follow-up survey completion incentives
- That they would get an enrollment packet that includes a quit plan worksheet with instructions, stop smoking resources, and a handout on how to use NRTs.
- During enrollment, participants were walked through and provided a copy of the consent form for the next phases of research along with their enrollment packetParticipants who were not interested in quitting were given basic stop smoking materials and a flyer for CEASE's drop-in program. They were given the $5 at the end of the process.

eCO testing and counseling enhancement. For the enhanced protocol, at the end of the baseline survey, eCO site participants were told that the last part of the process was to receive an eCO screening. Participants were also told what carbon monoxide was and that it could cause health problems. Participants were given the option to take the test or refuse. Those who agreed to take the test were told before the test began that they would be required to hold their breath for about 15 seconds then slowly blow into the straw attached to the handheld monitor. The Peer Motivator then inserted the disposable straw into the handheld monitor and asked the participant to begin the breath hold. The monitor signaled the end of the 15 second period and the participant was asked to blow

slowly into the monitor while the Peer Motivator held the monitor for them. After participants blew into the monitor, the eCO measurement appeared on the monitor screen. The Peer Motivator then referred to the eCO postcard. This postcard included common medical problems associated with increased exposure to carbon monoxide, a color-coded scale with a statement of nicotine dependence overlaid, and information on the short-lived presence of CO in the body. The postcard included a space for the Peer Motivator to insert the participant's score, and the participant was given the postcard to keep. Figure 5 is an image of the eCO education postcard. The front of the postcard provides an overview of potential personal health risks. The back provides the scale and additional information on how their score is determined. Directly following the eCO test, the standard protocol was utilized to complete either the enrollment process or survey closeout process (if non-enrolling).

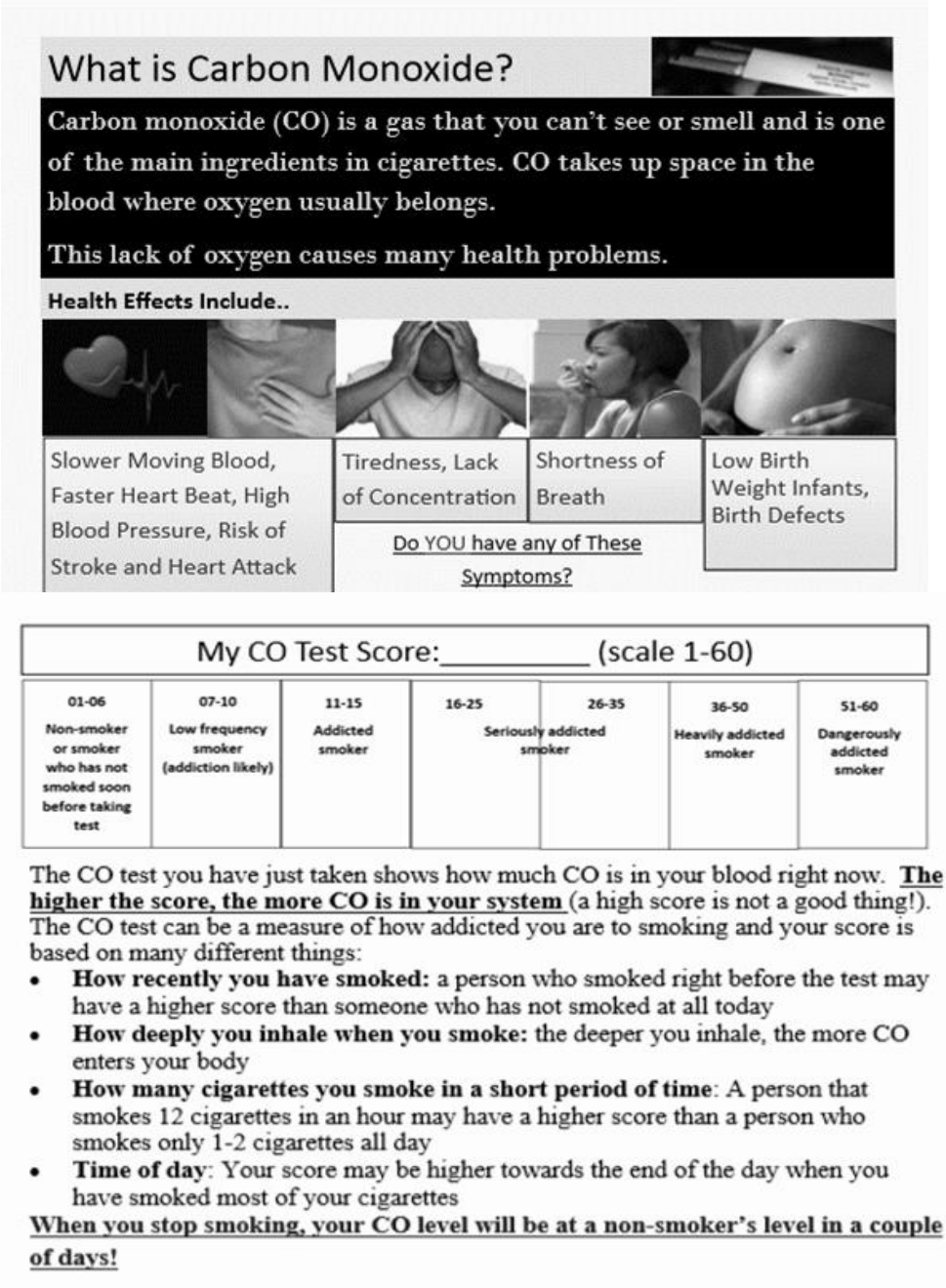

Figure 5. Front and back of the eCO testing and counseling postcard used in the testing and counseling procedure.

Human Subjects

Participants were told during the community survey that they could opt out of participation at any time. They were also given the option to refuse the CO test. Peer

Motivators eased concerns of participants by providing instructions to the participants beforehand and showing them the features of the monitor before asking them to use it. Participants were also given consent forms for class enrollment and the remainder of the surveys needed for Phase IV. Each participant was given a unique identification number at the start of the baseline survey to protect their identity that consisted of letters from their mother's maiden name and their birthdate. Participants referred to this unique ID for all the CEASE class and follow up surveys they completed.

Study Measures

The following section outlines the various measures used in the study. Numerous independent variables were included to ensure a thorough examination of motivational drivers for the baseline prediction model. These same independent variables were included in the subsequent eCO analysis.

Enrollment (outcome variable). Enrollment was recorded in the original dataset as a series of dummy variables broken down by type of class (or a self-help option). An enrollment dummy variable was created by merging the four and single session enrollees as a "yes" group, and then labelling non-enrollees as the "no" group. Self-help participants were not included in the analysis.

CO test allocation (exposure variable). The original dataset contained a variable indicating whether or not a recruitment event was a CO testing site (later re-named "cotest"). A second variable indicated whether a person accepted the offer of taking the CO test or whether they refused (later re-named "coaccept"). Participants in coaccept that were refusers (n = 31) were dropped from the sample. Coaccept was

replicated, then compared to the cotest variable to check for consistency between non-takers and non-co events, and then and recoded as a dummy variable that served as the exposure variable in the analysis.

Readiness rulers (potential moderators). The IRC ruler scores were recorded in the original data set as numerical values (scores of 0–10). This a scale that was adapted from Miller and Rollnick (2013). Participants were told during the baseline survey that 0 was equal to not ready/important/confident and that 10 was very ready/important/confident. The rulers were used as continuous variables.

Exhaled carbon monoxide score. Exhaled carbon monoxide was measured using the piCO+™ Smokerlyzer® breath carbon monoxide monitor. This was a hand-held monitor that was set to measure eCO in parts per million in the lung. The repeatability of the monitor was 2 ppm, the sensitivity of the monitor was 1 ppm, and the manufacturer's recommended cutoff to be considered a smoker was $\geq$6 ppm (Bedford Scientific, 2015).

Quit with support. A question asked right before the ruler items was one dealing with the amount of quitting support desired. The question, "how would you like to smoke when you are ready?" had three responses: "no support," "a little support," and "a lot of support." The responses for a little and a lot were merged in order to create the dichotomous variable that was used in the analysis.

Demographic measures. Race was given in the dataset as a series of eight dummy variables ("1's" for each racial category, including White, African American/black, Hispanic or Latino, Native American or Alaska Native, Native

Hawaiian or Other Pacific Islander, Asian, and more than one race). A new merged race variable was created initially with eight levels for an initial exploration of data. Once it was determined that there were only 23 participants that were not White or African American (less than 4 % of the sample), a final variable was created with just white and African American that was used in analysis (others were dropped from the analysis sample). Gender was given in the dataset as a dichotomous variable (Male/Female), which was retained and used in analysis. Marital status was given and used as a 3-level variable (married, single, or other). There were open-ended text responses for other and included options such as "widowed."

Socioeconomic status. The baseline survey did not include a specific question about household or personal income. Measures of employment and education were used as measures of socioeconomic status. Education was asked in the survey as the "highest grade or year of regular school" a participant had completed. Originally given as a 6-level variable, a new variable was created that collapsed it into three levels (some high school or less, high school graduate/GED equivalent, and at least one year of college or trade school or more) to still provide a sense of an educational obtainment gradient.

Smoking characteristics and attitudes towards nicotine replacement. The baseline survey asked several questions to determine a participant's baseline smoking habits, level of addiction, tobacco flavor preferences, and previous attempts to quit. The measure for level of addiction was the Fagerstrom Test for Nicotine Dependence (FTND), a commonly used instrument (Heatherton, Kozlowski, & Fagerstrom, 1991). The instrument uses six items. Appendix B includes the instrument's six questions. Each

question has a scoring system of either 0–2 or 0–3, depending on the question. The Qualtrics software was programmed to sum the individual scores from the 6 questions to produce the overall FTND score within the raw database.

In the dataset the individual items appeared as 2 to 4-level variables. In addition, there was a separate variable of the final score with a scale numbers between 0 and 10, with 0–4 being defined low dependence, 5 being defined as moderate dependence, 6–7 being high dependence, and 8–10 being defined as very high dependence (Heatherton, Kozlowski, & Fagerstrom, 1991). The continuous version of the variable was used for the analysis. In addition to the FTND question on number of cigarettes per day, the data collector administering the survey was prompted to enter an exact number of cigarettes into a text box. This became a continuous variable that was used as the primary measure for cigarettes smoked per day in all analyses.

The baseline survey also asked several questions about preferences of type of cigarette product as well as flavor preferences. The survey contained a question that asked, "what type of tobacco products do you use?" with options for menthol, regular, and flavored. In the original dataset, these were three dummy variables (one for each option). Only the variables for regular and menthol were used in analysis as very few participants indicated regular as an option.

Quit attempts were measured by a question found in the National Health and Nutrition Examination Survey's questionnaire for youth and adult smokers (CDC, 2013). The question, "during the past 12 months, have you stopped smoking for one day or longer because you quit smoking" had a yes/no response and was used as is in all models.

The survey also asked participants about their level of comfort using nicotine replacement therapy. The main question asked "Would you consider using nicotine replacement products (gum, patch, lozenge) to help you quit smoking?" The response options were yes, no, and not sure. In the analysis, no and not sure were collapsed as only 12 participants indicated they were unsure, and the new variable was described as whether or not they were comfortable with using NRTs.

Neighborhood of residence. Numerical zip code data from the baseline survey question, "what is the zip code where you live?" was initially coded into a six-level categorical variable initially by several Baltimore City neighborhood quadrants, then collapsed into a three-level variable (North/Northeast Baltimore, Southwest/West Baltimore, and an Other category) that was used in the analysis given the fact that there were two main neighborhoods where data was collected. Zip code boundaries and neighborhood quadrants were determined by using maps and lookup tools and maps from the US Postal Service and the Baltimore City Department of Planning (BCDP, 2016). Those not in the official boundaries in neighborhoods of North/Northeast or West/Southwest Baltimore were coded as "Other."

Study recruitment site type. Study recruitment locations were given in the data set as three digit codes (ex. Waverly Farmer's Market = WFM). A separate database containing the codes was developed by the CEASE Study Administrator and sent to the investigator post-data collection. An initial 5 categories were created to blanket fit the various types of study recruitment sites (farmer's and public markets, large-scale festivals, neighborhood-level events/block parties, health services, and educational and

social services). During an initial exploration of the non-CO group data, the cells for both non-enrolled, large-scale festivals and for educational/social services were found to be less than 25, and thus the large-scale festivals category was collapsed with neighborhood events, while health services was folded in with educational and social services.

Reasons to quit series. The baseline survey asked the question, "what are some reasons for you to quit smoking?" that featured 11 responses that were 2-level variables (Yes/No) in the dataset. The quit items that were used in analysis were financial costs, personal health, that it's a bad habit, family health, social pressure, family concern, the need to be a role model, a dislike of being addicted, and doctor's advice. These variables provide direct alternate motivational drivers and were thus included in both the baseline bivariate analysis and eCO analysis.

Health conditions and health status. All participants were asked, "in the past two years, has a doctor told you that you have the following health problems or conditions?" They were then presented with a series of 10 medical conditions, with response options of yes, no, or refused. The medical conditions were stroke, heart attack or any other heart disease, anxiety or depression, obesity, high blood pressure, drug addiction or abuse or dependence, alcohol abuse or dependence or other alcoholism problems, cancer, breathing problems such as asthma or emphysema, and diabetes or sugar diabetes. Given that no participant in the sample refused any of the questions, each variable was recoded as a dummy variable (Yes/No).

There were several variables for the baseline bivariate analysis that needed to be combined with others in order to achieve a proper sample size for analysis. This was ultimately due to the imbalance in enrollment groups, with a much smaller non-enrollment group (86 participants). The following combinations were created: diabetes or obesity and drug or alcohol dependence. There were variables that were not used in the bivariate analyses or the eCO analysis due to low overall numbers of individuals self-reporting those conditions. These conditions were cancer (n = 22), heart attack or any heart disease (n = 28), and stroke (n = 28). An attempt was made to combine heart attack and stroke, but the number of non-enrolled individuals in the sample with both conditions combined was only 7.

The baseline survey also asked participants to self-assess their current health status. This question was similar to a question found in the 2012–2013 National Adult Tobacco Survey (CDC & FDA, 2014) and asked "In general, would you say your health is excellent, good, fair, or poor?" Participants could respond "excellent," "good," "fair," or "poor." In the original dataset the variable contained 4-levels. For the analysis, those levels were collapsed down to two levels of "fair/poor" and "good/excellent" as responses were concentrated in the good and fair categories, with only 4% of the total sample indicating poor health.

Mental health. In addition to asking participants about their previous diagnosis of anxiety and depression, the baseline survey included three additional mental health questions. Two questions were from the Patient Health Questionnaire-2 (Kroenke, Spitzer, & Williamson, 2003) and one question stood alone. The items from the

questionnaire began with a parent question, “Over the past two weeks, how often have you been bothered by any of the following problems?” The items were “having little interest or little pleasure in doing things” and “feeling, down, depressed, or hopeless.” Participants were given the options of “not at all”, “1–7 days”, “8–13 days”, and “everyday.” The Cronbach alpha for the instrument was .89. The responses for both items were eventually collapsed down to a new variables that described whether or not participants had experience “any” times where they experienced those circumstances (yes/no), which was used in both sets of models. A third and separate question was asked in relation to perceived stress and was taken from an existing perceived stress scale (Cohen & Williamson, 1998). Participants were asked “how stressed have you felt in the last 7 days?” and were given four response options ranging from “not at all” to “I felt stressed every day.” All responses where a participant indicated feeling stressed were collapsed, and a dichotomous variable for whether or not participants felt any stress within the past 7 days was created for the analysis.

Peer influences. The baseline survey included a question, “Do other people around you smoke?” The responses were “at home,” “at my job,” “family members,” “friends,” and “no one.” In the original data set, each response type was its own dummy variable. All but the “no one” option was used in the analysis after seeing that over 90% of the sample had indicated having a smoking peer.

Data Management

The eCO study investigator was given the entire Phase IV uncleaned community baseline survey and enrollment registration dataset (2,042 participant entries) in an Excel

file, a key to map Qualtric column names to questions in the survey, as well as a copy of the baseline survey questions with response codes visible. This database had been previously stripped of participant names and enrollment registration addresses, phone numbers, and e-mail addresses. Zip codes obtained from an early baseline survey question where participants were asked their zip code of residence were retained as were all unique IDs. Non-smokers and all participants that were administered the survey after March 15, 2016 (the last date the treatment allocation was applied) were dropped from the Excel file. Duplicate unique IDs (in the data due to participants taking the survey at different events) were found using Excel's duplicate values tool. The earliest participant survey entry was retained and subsequent duplicate entries for the unique ID were removed. Columns with numbers with cell formats as designated as text format were changed to number format. The baseline survey did not ask participants directly for their age, only date of birth, so a column for age was created in Excel and populated via a cell formula that subtracted the participant birth year from the "baseline survey start date" year (either 2015 or 2016) column as a proxy. Column headings with survey question numbers were replaced with variable names that were more descriptive and of an appropriate length for STATA. An Excel file containing approximately 40 variables was imported into STATA 14 for further generation and transformation of variables, which is outlined in the following section on study measures.

Statistical Analysis

The clustered nature of the data collection (by recruitment event) required an analytical approach to account for the potential homogeneity that can occur within

clusters (Donner & Klar, 2000). This section outlines the process for the analytical approaches for the bivariate analysis of baseline enrollment characteristics and the bivariate analysis and GEE model building for the eCO randomized educational trial. Sample size calculations, including the selection of an initial intracluster correlation coefficient (ICC), and modifications to cluster sizes will also be presented.

Generalized estimating equations. The multivariate models for the eCO analysis are being estimated through the use of generalized estimating equations. Generalized estimating equations are used in the analysis of longitudinal or clustered data. Population-averaged generalized estimating equations (GEE), introduced by Liang and Zeger (1986), averages the effects over all clusters. It also models the average response for outcomes sharing the same covariates. This approach can be selected over multi-level modelling when research questions have population-level implications, when the number of clusters exceeds 50 and when clustering is considered a nuisance (Hardin & Hilbe, 2013; Hubbard et al., 2010). These models also incorporate a hypothesized structure for the potential correlation within clusters, called the working correlation matrix (Hardin & Hilbe, 2013). The exchangeable working correlation matrix was selected for the GEE analysis as participants were not followed overtime, and this was the only matrix structure that assumes that observations are not time dependent (Hardin & Hilbe, 2013). In addition to working correlation matrix, there are several parameters to select when developing GEE models that will vary depending on the form of the outcome data including: a model distribution family and a link function (a function that replaces the outcome variable with the mean of the outcome variable), and an estimator (Hardin &

Hilbe, 2013). The enrollment outcome variable in this study was binary, thus a logit link function and a binomial distribution were used in GEE models (Hardin & Hilbe, 2013). In addition, all GEE models utilized a robust variance estimator, which served as another way to adjust for clustering effects (Donner & Klar, 2000).

Analysis and model building procedure. STATA 14 software was used for the analysis. Adjusted chi-square tests and adjusted t-tests were used for the bivariate analysis of baseline characteristics and in the initial bivariate analyses that informed the eCO model construction. These adjusted methods are a modified approach for data that are clustered (Donner & Klar, 2000; Reed, 2004). The adjusted chi-square tests were performed on categorical measures. Adjusted t-tests were used for continuous variables such as FTND score, age, number of cigarettes per day, and continuous versions of the readiness rulers. In eCO model building, covariates that emerged from the bivariate analysis with a $p \leq 0.10$ were added to an initial GEE multivariate model that only included each covariate and just the cotest variable. Those variables that were significant in those precursor models were moved on for consideration in the final full model. In developing and evaluating GEE models, Pan (2001) developed a goodness of fit measure called the quasilikelihood under the independence model information criterion (QIC_u). The QIC_u can help guide decision making towards the optimal mix of covariates in a model after a bivariate exploration. In comparing several models, the one with the lowest QIC_u measure is considered most ideal at face value (Hardin & Hilbe, 2013). Several iterations of models were generated with additional covariates included for comparison, starting with a null model. A QIC_u measure was produced for each model, it and was a

key factor in determining the final base model selection (Hardin & Hilbe, 2013). A moderation model examining the relationship between eCO testing and continuous measures of confidence, importance, and readiness was also estimated and evaluated.

Sample weight construction for site type imbalance. During an initial exploration of the data, it was discovered that there was the eCO testing and education was disproportionately applied in the social service/educational/setting type. GEE models allow for the addition of weights, but at cluster/panel level. A weighting variable was constructed for the setting type variable to balance the influence of the setting types within the eCO and non-eCO groups. This involved a process where the actual probabilities for selection for each setting type were idenitfied within both the eCO and non-eCO groups and used as denominators under a numerator of ideal probabilities for selection (equal probabilities of selection for each setting type in both groups). These numerical values were used in the coding to create the sample weight variable in STATA (pwsitetype).

Sample size calculation. To achieve proper statistical power for a cluster design, an additional factor adjusting for the clustered nature of the data has to be considered, often resulting in a larger sample size requirement than that of a simple randomized design (Donner & Klar, 2000). This inflation factor is referred to as the design effect, $1+(m-1)\rho$, and is determined by the size of each cluster, *m* and ρ, the intracluster correlation coefficient (ICC). The ICC is a proportion that measures the variation in the responses within each individual cluster. Similar to the Pearson's correlation coefficient, an ICC of 1 would be interpreted as the occurrence of total statistical dependence

between two points in the same cluster, while an ICC of 0 would imply total statistical independence (Donner & Klar, 2000). Pre-determining the proper ICC for sample size calculations has been noted as being difficult to accurately estimate in advance and that a look at a wide range of ICCs for a similar outcome may be appropriate (Adams et al., 2004). Studies with clustered data and binary outcomes have used ICC values for sample size calculations ranging from 0.02 in non-primary care settings (Resnicow et al., 2010) to 0.05 in more clinical settings (Griffiths et al., 2004).

Another consideration for sample size with clustered data is when the number of individuals per cluster is not the same, which was the case for this study given the larger recruitment goals of Phase IV (since restricting the number recruited on-site to a fixed number was not practical). The coefficient of variation for cluster sizes (cv_c) also had to be considered and adjusted. The cv for cluster sizes was calculated by finding the standard deviation to mean ratio of the cluster sizes ($cv_c = s_c/m$) (Eldridge, Kerry, Grieve, & Ukoumunne, 2012). Cluster size coefficients of variation under 0.23 do not warrant the need to account for varied cluster sizes in the design effect formula (Eldridge, Ashby, & Kerry, 2006). The coefficient of variation for the original configuration of 72 clusters was 0.90 (range with a min=1 and a max=35, M = 8.5, SD = 8.3). Clusters with sizes of one or two were thus collapsed into clusters of a similar event type in the same neighborhood. Clusters over 20 were cut into smaller clusters. After collapsing clusters, the cv for the final 60 clusters was 0.21 (min= 6 and a max=19, M = 10.5, SD = 2.3). Stata's *power* function for two proportions allows for ICC and average cluster size parameters to be inputted, along with the success probabilities of the control and eCO

groups, to produce ideal arm sizes and overall sample size. Percent success inputs were based on examining the success of experimental and control groups of previous biofeedback studies (eCO but also spirometry) and selecting a mid-point. These success percentages varied widely, ranging from experimental group success rates from 17% to 51%, and control group success ranging from 5% to 44%. The margin of success between control and experimental groups in these studies ranged between 7% and 17% (Choi, Kim, & Lee, 2013; Shahab, West, & McNeil, 2011). The estimated number of clusters per arm for this study was 29, with 290 individuals in each arm. It is understood that this estimate is based largely off of best-guess estimates. The final parameters used for sample size estimation were:

Ha: $P_{CO=}$ 0.40, $P_{NCO=}$ 0.28, with alpha=0.05 and power=0.80 rho= 0.02 m=10 with

P_{CO}= the likelihood of eCO education participants enrolling in CEASE classes

and P_{NCO}= the likelihood of the standard enrollment group participants enrolling

rho= the ICC value (0.02 selected based on review of previous studies)

m= mean cluster size

Chapter 4: Results

This chapter outlines the results of the bivariate baseline characteristic analysis and randomized eCO randomized educational trial. The chapter starts with a description of the overall sample, followed by bivariate analysis results by enrollment status (yes/no) and by enrollment procedure group (standard/eCO). Multivariate GEE models follow to assist in model building for the final GEE model for enrollment in the presence of eCO testing and counseling. Results from estimating the QIC_u of various models will be presented. A GEE model with interaction terms for importance, readiness, and confidence will be provided. The chapter will conclude with a final summary of overall results.

Descriptive Statistics of the Overall Sample

Tables 3-6 provide an overview of sample characteristics. Table 3 shows various demographic characteristics. The total sample consisted of 630 adult smokers, with an average age of 47.2 (not shown). The sample was mostly male (57.1%), African-American (82.2%), unemployed (68.7%), and single (70.6%). Approximately half of the sample had graduated from high school or had a high school equivalency (48.1%).

A majority of the sample came from the targeted West or Southwest Baltimore (54.6%) or North or Northeast Baltimore (23.5%), while 21% of the sample came from other parts of the city. A large percentage of the sample was recruited through public events or markets (61.1%). It should be noted that while recruitment events were located primarily in two communities, study participants also lived in other parts of the city (likely from the city-wide appeal of certain large-scale public events).

Table 4 depicts descriptive statistics for smoking characteristics. Most of the sample was interested in quitting with support at any level (70.6%) and would consider using NRTs to quit (81.1%). A majority of participants had peers that smoke around them, including 65.4% that had a smoker in the household and 65.6% that had friends that smoke. Most of the sample were menthol cigarette smokers (88.7%). Very few participants had "very high" levels of nicotine dependence (10.2%), with about half of the sample having moderate to high levels (48.1%). A little over half of the sample made at least one previous attempt to quit in the past 12 months (52.1%) and the average number of cigarettes smoked per day was 12.5. The average importance, readiness, and confidence ruler scores were 8.39, 5.48, 6.85, respectively.

Table 5 provides a snapshot of the sample's indicated reasons to quit smoking. Over half the sample indicated that the cost of cigarettes (54.4%) and the fact that smoking was a bad habit (59.4%) was a reason to quit. Doctor's advice (48.9%) and not liking being addicted (49.7%) were reasons given by about half the sample. Reasons tied to societal pressures were the least popular reason selected, with only 14.4% of the sample indicated that option. While concerns for the health of their family was a reason for about 41% of the sample, the most popular reason to quit provided was a concern for their personal health (90.0%).

The final descriptives table, Table 6, shows variables around physical and mental health. Approximately 77% of the entire sample indicated that they had at least one health condition diagnosed by a physician in the past two years (not shown), but only 42.1% self-reported having overall fair or poor health. High blood pressure was the most

commonly cited condition (41.1%) along with anxiety or depression (41.0%). In terms of mental health, a majority of the sample indicated feeling down, depressed, and hopeless with any level of frequency (53.2%), and approximately 18.1% indicated feeling that way most days or every day (not shown). Approximately 51.8% indicated having little pleasure or interest in doing things at any level of frequency in the past two weeks. Approximately 21.6% felt stressed most or every day in that timeframe (not shown).

A majority of baseline survey participants enrolled in CEASE classes (74.1%). Out of the total number of enrollees (467 individuals), 55.7 % were recipients of the eCO testing and counseling as compared to the standard enrollment group (44.3%). The average CO score for those who received the eCO testing and counseling (351 individuals) was approximately 25, with scores ranging from 6 to 60 (not shown). Following a similar pattern as the FTND scores of the larger sample, a smaller percentage of the sample fell in the eCO postcard's "heavily addicted" or "dangerously addicted" smoker part of the scale (21.6%) and about half fell in their more moderate category of "seriously addicted smoker" (50.1%; not shown).

Table 3

Descriptive Statistics of the Study Variables, CEASE Phase IV Adult Smokers, May 2015-March 2016, Demographic Characteristics

Variable	n	%
Gender (n=630)		
Male	360	57.1
Female	270	42.9
Age (n=630)		
18–39	169	26.8
40–49	154	24.4
50+	307	48.7
Race (n=630)		
White	112	17.8
Black	518	82.2
Education level (n=630)		
Some high school	182	28.9
Graduated from high school	303	48.1
≥1 year of college or trade school	145	23.0
Employment (n=630)		
Unemployed	433	68.7
Employed	197	31.3
Marital Status (n=630)		
Single	445	70.6
Married	99	15.7
Other	86	13.7
Neighborhood of Residence (n=630)		
W/SWB	344	54.6
N/NE	148	23.5
Other Baltimore City	138	21.9
Recruitment Setting (n=630)		
Public events and markets	388	61.6
Health, social service, educational	242	38.1
Exposure variable (n=630)		
Received eCO testing and counseling		
No	279	44.3
Yes	351	55.7

Table 4

Descriptive Statistics of the Study Variables, CEASE Phase IV Adult Smokers, May 2015-March 2016, Smoking Characteristics

Variable	n	%	Mean	SD	Min	Max
Desire to Quit with Any Support						
Yes	445	70.6				
No	185	29.4				
Would Consider using NRTs to Quit						
Yes	511	81.1				
No	119	18.9				
Any Quit Attempt, Past 12 mo.						
Yes	301	47.9				
No	329	52.1				
Tobacco Flavor						
Menthol						
Yes	559	88.7				
No	71	12.4				
Regular						
Yes	78	12.4				
No	552	87.6				
Peer Smoking Influences (n=630)						
Smokers in the Home						
Yes	412	65.4				
No	218	34.6				
Smokers on the Job						
Yes	130	20.6				
No	500	79.4				
Friends that Smoke						
Yes	426	67.6				
No	204	32.4				
Family that Smoke						
Yes	351	44.3				
No	279	55.7				
FTND Score (scale 1-10)						
1-4 (Low dependence)	263	41.8				
5-7 (Moderate dependence)	303	48.0				
8-10 (High dependence)	64	10.2				
Change Ruler Scores						
Importance	630	100.0	8.39	2.63	0	10
Readiness	630	100.0	5.48	2.98	0	10
Confidence	630	100.0	6.85	2.98	0	10
Number of cigarettes a day	630	100.0	12.48	7.67	3	60

Table 5

Descriptive Statistics of the Study Variables, CEASE Phase IV Adult Smokers, May 2015-March 2016, Reasons to Quit Smoking

Variable	n	%
Reasons to Quit Smoking *(n=630)*		
Doctor's advice		
Yes	308	48.9
No	322	51.1
Family concern		
Yes	258	41.0
No	372	59.1
Cost of cigarettes		
Yes	343	54.4
No	287	45.6
Personal health		
Yes	567	90.0
No	63	10.0
Family's health		
Yes	259	41.1
No	371	58.9
Bad habit		
Yes	374	59.4
No	256	40.6
Social pressure		
Yes	91	14.4
No	539	85.6
Role model		
Yes	240	38.1
No	390	61.9
Don't like addiction		
Yes	313	49.7
No	317	50.3

Table 6

Descriptive Statistics of the Study Variables, CEASE Phase IV Adult Smokers, May 2015-March 2016, Self- reported Medical Conditions and Mental Health

Variable	n	%
Physician Diagnosed Health Conditions (Past 2 years, Self reported) (n=630)		
Alcohol Abuse		
Yes	89	14.1
No	541	85.9
Airway disease		
Yes	177	28.1
No	453	71.9
Drug dependence		
Yes	152	24.1
No	478	75.9
Anxiety or Depression		
Yes	258	41.0
No	372	59.0
High blood pressure		
Yes	261	41.4
No	366	58.6
Heart attack or stroke		
Yes	58	9.2
No	572	90.8
Diabetes		
Yes	85	13.5
No	545	86.5
Self-reported health status (n=630)		
Excellent or Good	365	57.9
Fair or Poor	265	42.1
Mental Health (n=630)		
PHQ-2: Feeling down, depressed, helpless (anytime, past 2 weeks)		
Yes	335	53.2
No	295	46.8
PHQ-2: Having little interest or little pleasure in doing things (anytime, past 2 weeks)		
Yes	326	51.8
No	304	48.2
Perceived Stress (any, past 7 days)		
Yes	454	72.1
No	176	27.9

Hypothesis 1: Baseline Enrollment Characteristics, Bivariate Analysis

The following section provides results for the bivariate analysis of baseline characteristics of enrollment that just examined the non eCO group (n = 279). A bivariate analysis assessing whether or not there was a difference between groups in terms of data collectors (style of peer motivator delivery) found that there was not a significant difference in enrollment groups, which compared the two peer motivators that collected data in the highest volume during eCO data collection period and a third "other collectors" group ($\chi 2(3) = 2.70$, $p = 0.441$). This variable (not shown) was not carried forward in further analysis as it was used mostly as a data collection quality control measure. Table 7 provides results for the adjusted chi-square analysis for participant demographics and neighborhood characteristics. There were no significant differences between enrollment groups for any variable. Table 8 provides an overview of smoking characteristics by enrollment group. There was a significant difference in enrollment groups for wanting to quit with any support ($\chi 2(1) = 10.50$, $p = < 0.001$). Approximately 79% of participants that said they wanted support in quitting enrolled, while those that said no/not sure were split more evenly across enrollment groups (approximately 51.5% enrolled and 48.5% did not enroll).

There were also significant differences between those indicating a willingness to use nicotine replacement therapy ($\chi 2(1) = 9.08$, $p = <0.002$). The differences between groups were not extreme, with approximately 72.4% of those who said they would consider using NRTs to quit enrolled, while approximately 65.7% of those who said they would not consider the use of NRTs also enrolled. Finally, FTND scores were

significantly different between groups, with enrolled participants having a higher average score (M = 5.1, SE = 0.27) than non-enrolled participants (M = 4.4, SE = 0.19), $t(54)$= -2.15, p = 0.03.

Table 7

Bivariate Associations between Independent Variables and Enrollment in CEASE Phase IV Smoking Cessation Classes, Demographic and Neighborhood Characteristics

	Enrolled						
	No (n=86)		Yes (n=193)				
Variable	n	%	n	%	total	Adj Chi-square	p-value
Gender						0.14	0.798
Female	35	32.1	74	67.9	109		
Male	51	30.0	119	70.0	170		
Age						3.34	0.187
18-39	33	42.3	45	57.7	78		
40-49	16	23.5	52	76.5	68		
50+	37	27.8	96	72.2	133		
High School Grad.						3.34	0.067
Yes	68	34.0	132	66.0	200		
No	18	22.8	61	77.2	79		
Race						4.27	0.233
White	21	39.6	32	60.4	53		
Black	65	28.8	161	71.2	226		
Employment						1.73	0.188
Unemployed	53	27.3	141	72.7	194		
Employed	33	38.8	52	61.2	85		
Marital Status						0.72	0.697
Yes	16	39.0	25	61.0	41		
No	70	29.4	168	70.6	238		
Neighborhood of Residence						0.88	0.393
W/SWB	41	27.3	109	72.7	150		
N/NE	23	35.4	42	64.6	65		
Other	22	34.3	42	65.6	64		
Recruitment Setting						1.01	0.315
Health, social service, educational	76	32.6	157	67.4	233		
Public events and markets	10	21.7	36	78.3	46		

Table 8

Bivariate Associations between Independent Variables and Enrollment in CEASE Phase IV Smoking Cessation Classes, Smoking Characteristics

	Enrolled						
	No (n=86)		Yes (n=193)				
Variable	n	%	n	%	total	Adj Chi-square	p-value
Any Quit Attempt, Past 12 mo.						0.70	0.402
Yes	40	27.6	105	72.4	145		
No	46	34.3	88	65.7	134		
Desire to Quit with Any Support						10.50	<0.001
Yes	38	21.1	142	78.9	180		
No/Not Sure	48	48.5	51	51.5	99		
Would Consider using NRTs						9.08	0.002
Yes	40	27.5	105	72.4	145		
No	46	34.3	88	65.7	134		
Tobacco Flavor							
Menthol						0.49	0.482
Yes	75	29.9	176	70.1	251		
No	11	39.3	17	60.7	28		
Regular						0.61	0.435
Yes	13	39.4	173	70.3	33		
No	73	29.7	20	60.6	246		
Peer Smoking Influences							
Smokers in the Home						1.95	0.336
Yes	50	27.9	64	64.0	179		
No	36	36.0	129	72.1	100		
Smokers on the Job						0.09	0.761
Yes	15	28.3	38	71.7	53		
No	71	31.4	155	68.5	226		
Family that Smokes						1.03	0.309
Yes	39	26.9	87	64.9	145		
No	47	35.7	106	73.1	134		
Friends that Smoke						0.09	0.761
Yes	51	27.9	132	72.1	183		
No	35	36.5	61	63.5	96		

(continued)

Table 8 (continued)

Bivariate associations between independent variables and enrollment in CEASE Phase IV smoking cessation classes, smoking characteristics

	Enrolled					
	No (n=86)		Yes (n=193)			
Variable	M	95%CI	M	95%CI	t	p-value
Cigarettes per day	11.6	[9.84, 13.35]	12.8	[11.66, 13.99]	-1.19	0.238
FTND Score	4.4	[3.87, 5.01]	5.1	[4.77, 5.54]	-2.15	0.035

Tables 9 and 10 provide bivariate results for a series of self-reported physical and mental health conditions. While a majority of the overall sample indicated personal health as being a reason to quit, there were no significant difference between enrollment groups on any physical or mental health dimensions.

Table 11 provides the bivariate results for the series of questions where participants were asked about reasons to quit smoking. Similar to the health dimensions there were no variables in the reason to quit series that were significantly different between enrollment groups.

Table 9

Bivariate Associations between Independent Variables and Enrollment in CEASE Phase IV Smoking Cessation Classes, Self-reported Health Conditions (past two years)

	Enrolled						
	No (n=86)		Yes (n=193)				
Variable	n	%	n	%	total	Adj Chi-square	p-value
High blood pressure						3.04	0.081
Yes	27	22.7	92	77.3	119		
No	59	36.8	101	63.1	160		
Drug or Alcohol Abuse						1.97	0.160
Yes	31	24.6	95	75.4	126		
No	55	36.0	98	64.0	153		
Airway disease						0.55	0.456
Yes	20	26.0	57	74.0	77		
No	66	32.7	136	67.3	202		
Anxiety or Depression						0.65	0.421
Yes	31	27.0	84	73.0	115		
No	55	33.5	109	66.5	164		
Diabetes or Obesity						2.08	0.149
Yes	14	20.6	54	79.4	68		
No	72	34.1	139	65.8	211		
Self-reported health status						2.02	0.155
Excellent	56	35.9	100	64.1	156		
Fair or Poor	30	24.4	93	75.6	123		

Table 10

Bivariate Associations between Independent Variables and Enrollment in CEASE Phase IV Smoking Cessation Classes, Self-reported Mental Health

	Enrolled						
	No (n=86)		Yes (n=193)				
Variable	n	%	n	%	total	Adj Chi-square	p-value
Feeling Down, Depressed, Helpless*						2.03	0.153
Yes	37	26.1	105	73.9	137		
No	49	35.8	88	64.2	142		
Little Pleasure or Interest in Doing Things*						1.45	0.230
Yes	37	25.3	84	63.2	146		
No	49	36.8	109	74.7	133		
Perceived Stress (7 days)						0.05	0.807
Yes	65	31.4	142	68.6	207		
No	21	29.2	51	70.8	72		

*Measures from the PHQ-2 questionnaire (Kroenke, Spitzer, & Williamson, 2003). Timeframe is within the past two weeks.

Table 11

Bivariate Associations between Independent Variables and Enrollment in CEASE Phase IV Smoking Cessation Classes, Self-reported Reasons to Quit

	Enrolled						
	No (n=86)		Yes (n=193)				
Variable	n	%	n	%	total	Adj Chi-square	p-value
Doctor's Advice						3.63	0.056
Yes	27	22.1	95	77.9	122		
No	59	37.6	98	62.4	157		
Family Concern						1.01	0.314
Yes	26	25.5	117	66.1	177		
No	60	33.9	76	74.5	102		
Cost of Cigarettes						1.53	0.215
Yes	39	26.2	110	73.8	149		
No	47	36.2	83	63.9	130		
Personal Health						0.89	0.345
Yes	76	88.4	180	93.3	256		
No	10	11.6	13	6.7	23		
Family's Health						0.01	0.935
Yes	35	40.7	113	58.6	115		
No	51	59.3	80	41.5	164		
Social Pressure						1.24	0.444
Yes	15	38.5	24	61.5	39		
No	71	29.6	169	70.4	240		
Bad Habit						1.01	0.762
Yes	43	29.7	91	67.9	145		
No	43	32.1	102	70.4	134		
Role Model						0.11	0.737
Yes	32	32.7	127	70.2	181		
No	54	29.8	66	67.4	98		
Don't Like Addiction						0.00	0.965
Yes	36	31.0	80	69.0	116		
No	50	30.7	113	69.3	163		

Table 12 provides the results for the bivariate analysis for the three readiness rulers. Measures of confidence were not significantly different between groups. There was a significant difference between enrollment groups for the importance ruler, with those enrolling having a higher average score (M = 8.9, SE = 0.20) than the non-enrolled

group (M = 7.5, SE = 0.30), t(54)= -3.75, p = <0.001. There was also a significant difference between enrollment groups for the readiness to change ruler, with enrolled participants having a higher average readiness ruler score (M = 6.1, SE = 0.29) as compared to non-enrolled participants (M = 4.1, SE = 0.43), t(54)= -3.71, p = <0.001.

Table 12

Bivariate Associations between Motivation Rulers and Enrollment in CEASE Phase IV Smoking Cessation Casses

	Enrolled					
	No (n=86)		Yes (n=193)			
Variable	M	95%CI	M	95%CI	Adj t	p-value
Change ruler score						
Importance	7.5	[6.90, 8.15]	8.9	[8.47, 9.30]	-3.75	<0.001
Readiness	4.1	[5.46, 6.65]	6.1	[6.90, 8.14]	-3.71	<0.001
Confidence	6.9	[5.96, 7.77]	7.2	[6.54, 7.77]	-0.54	<0.590

Hypothesis 2: eCO Randomized Educational Trial, Bivariate Analysis

The tables in this section are an overview of the results of the initial bivariate analysis for the eCO randomized educational trial. There were no significant differences between enrollment treatment groups (eCO or standard enrollment procedure) for most independent variables. This ensured that most differences in enrollment that came out of GEE analysis results could be attributed to the effects of the eCO testing and counseling intervention. Table 13 displays the bivariate results for enrollment in CEASE Phase IV classes by treatment group. There was a significant difference in CEASE Phase IV class enrollment between the standard enrollment group and the eCO group ($\chi 2(1) = 4.42$, p <0.025), with approximately 78.1% of all eCO particpants enrolling in classes versus approximately 69.2% of non-eCO participantsenrolling in classes (a difference of approximately 8.9%). The ICC for enrollment by treatment group, the primary study

outcome, was 0.15. The class enrollment trends (singles session versus four session or non-enrollment) were not significantly different between treatment groups.

Table 13

Bivariate associations between independent variables and CEASE Phase IV participant treatment groups (eCO enhanced versus standard protocol, CEASE class enrollment.

	eCO Enhancement						
	No (n=279)		Yes (n=351)				
Variable	n	%	n	%	Adj Chi-square	p-value	ICC
Enrolled					4.42	0.025	0.15
Yes	193	69.2	274	78.1			
No	86	30.8	77	21.9			
Class Enrollment					4.35	0.113	0.12
Single Session	46	16.6	72	20.5			
Four-Session	144	51.4	205	58.4			
None	89	32.0	74	21.1			

Table 14 is the results of the adjusted chi-square tests for demographic and neighborhood characteristics. Recruitment event setting was the only variable that was statistically significant between groups ($\chi 2(1) = 6.27$, $p < 0.012$) and with a very large ICC (0.97) due to fact that clustering was at event level. Approximately 79% of participants recruited in health, social service, educational settings received the eCO test. The application of eCO testing was more balanced amongst the other setting type with approximately 44% of participants recruited in public events and markets receiving the eCO testing and counseling and 56% receiving the standard enrollment procedure. The sampling weight for setting type was applied in GEE models at panel level as a corrective measure.

Table 14

Bivariate Associations between Independent Variables and CEASE Phase IV Participant Treatment Groups (eCO enhanced versus standard protocol), Demographic and Neighborhood Characteristics

	eCO Enhancement							
	No (n=279)		Yes (n=351)					
Variable	n	%	n	%	total	Adj Chi-square	p-value	ICC
Gender						1.71	0.191	0.07
Female	109	40.4	161	59.6	270			
Male	170	47.2	190	52.8	360			
Age						0.16	0.919	0.11
18-39	78	46.2	91	53.9	169			
40-49	68	44.2	86	55.8	154			
50+	133	43.3	174	56.7	307			
Education level						0.77	0.856	0.06
Some High School	79	43.4	103	56. 6	182			
High School Grad.	135	44.6	168	55.5	303			
≥1+years of College or Trade School	65	44.8	80	55.2	145			
Race						0.51	0.475	0.15
White	53	47.3	59	52.7	112			
Black	226	43.6	292	56.4	518			
Employment						0.05	0.813	0.16
Unemployed	194	44.8	239	55.2	433			
Employed	85	43.2	112	56.9	197			
Marital Status						0.80	0.679	0.04
Single	203	45.6	242	54.4	445			
Married	41	41.4	58	58. 6	99			
Other	35	40.7	51	59.3	86			
Neighborhood of Residence						0.12	0.939	0.15
W/SWB	150	43.6	194	56.4	344			
N/NE	65	43.9	83	56.1	148			
Other	64	46.4	74	53.6	138			
Recruitment Setting						6.27	0.012	0.97
Health,social service, educational	46	21.4	169	78.6	215			
Public events and markets	233	56.1	182	43.9	415			

Table 15 are the adjusted chi-square and adjusted t-test test results for smoking characteristics by treatment group. Similar to the analysis of baseline characteristics,

having the desire to quit with support was significantly different between groups ($\chi 2(1) = 5.35$, $p = 0.020$). Approximately 60% of all participants that indicated that they wanted to quit with support were recruited through events assigned to use the eCO testing and counseling, as compared to 40% of participants that received the standard enrollment procedure. Unlike the bivariate analysis of baseline characteristics, there was no significant difference between treatment groups in terms of willingness to use NRTs to quit ($\chi 2(1) = 0.67$, $p = 0.411$) or FTND score $t(58) = 0.05$, $p = 0.961$.

Table 15

Bivariate Associations between Independent Variables and CEASE Phase IV Participant Enrollment Groups (eCO Enhanced Versus Standard Protocol), Smoking Characteristics

	eCO Enhancement							
	No (n=279)		Yes (n=351)					
Variable	n	%	n	%	total	Adj Chi-square	p-value	ICC
Any Quit Attempt, Past 12 mo.						0.01	0.925	0.04
Yes	145	44.1	184	55.9	329			
No	134	44.5	167	55.5	301			
Desire to Quit with Any Support						5.35	0.020	0.07
Yes	180	40.4	265	59.6	445			
No	99	53.5	86	46.5	185			
Would Consider using NRTs to Quit						0.67	0.411	0.14
Yes	220	43.0	291	57.0	511			
No	59	49.6	60	50.4	119			
Tobacco Flavor								
Menthol						0.27	0.603	0.18
Yes	251	44.9	308	55.1	559			
No	28	39.4	43	60.6	71			
Regular						0.05	0.815	0.15
Yes	33	42.3	45	57.7	78			
No	246	44.6	306	55.3	552			
Peer Smoking Influences								
Smokers in the Home						0.16	0.681	0.10
Yes	179	43.5	118	54.1	412			
No	100	45.9	233	56.6	218			
Smokers on the Job						0.44	0.504	0.08
Yes	53	40.8	77	59.2	130			
No	226	45.2	274	54.8	500			
Family that Smokes						1.91	0.167	0.05
Yes	145	41.3	206	58.7	279			
No	134	48.0	145	52.0	351			
Friends that Smoke						0.55	0.455	0.07
Yes	183	43.0	243	57.0	426			
No	96	47.1	108	52.9	204			

(continued)

Table 15 (continued)

Bivariate Associations between Independent Variables and CEASE Phase IV Participant Enrollment Groups (eCO Enhanced Versus Standard Protocol), Smoking Characteristics

	eCO Enhancement						
	No (n=279)		Yes (n=351)				
Variable	M	95%CI	M	95%CI	Adj t	p-value	ICC
Cigarettes per day	12.5	[11.35, 13.54]	12.5	[11.49, 13.50]	-0.0688	0.945	0.04
FTND Score	4.9	[4.51, 5.25]	4.8	[4.52, 5.22]	0.0481	0.961	0.07

Table 16 provides results for self-reported physician and mental health conditions. These conditions included seven acute and chronic medical conditions plus the variable for self-reported health status. Similar to the bivariate results by enrollment group, there were no significant differences between treatment groups around any health conditions.

Table 16

Bivariate Associations between Independent Variables and CEASE Phase IV Participant Treatment Groups (eCO enhanced versus standard protocol), Self-reported Physical and Mental Health Conditions, Past 2 Years

	eCO Enhancement							
	No (n=279)		Yes (n=351)					
Variable	n	%	n	%	total	Adj Chi-square	p-value	ICC
High Blood Pressure						0.166	0.683	0.08
Yes	119	45.6	142	54.4	261			
No	160	43.4	209	56.6	369			
Alcohol Abuse						0.194	0.659	0.06
Yes	37	41.6	52	58.4	89			
No	242	44.7	299	55.3	541			
Airway Disease						0.05	0.837	0.04
Yes	77	43.5	100	56.5	177			
No	202	44.6	251	55.4	453			
Drug Abuse						0.01	0.933	0.13
Yes	68	44.7	84	55.3	152			
No	211	44.1	267	55.9	478			
Anxiety or Depression						0.01	0.929	0.08
Yes	115	44.6	143	55.4	258			
No	164	44.9	208	55.1	372			
Obesity						0.53	0.453	0.03
Yes	29	47.5	32	52.4	61			
No	250	43.9	319	56.1	569			
Diabetes						3.55	0.060	0.01
Yes	68	44.7	84	55.3	152			
No	211	44.1	267	55.9	478			
Self-reported Health Status						0.59	0.442	0.04
Excellent	156	42.7	209	57.3	365			
Fair or Poor	123	46.1	142	53.9	265			

(continued)

Table 16 (continued)

Bivariate Associations between Independent Variables and CEASE Phase IV Participant Enrollment Groups (eCO enhanced versus standard protocol), Self-reported Physical and Mental Health Conditions, Past 2 Years

	eCO Enhancement							
	No (n=279)		Yes (n=351)					
Variable	n	%	n	%	total	Adj Chi-square	p-value	ICC
Down, depressed, helpless*						0.05	0.827	0.04
Yes	142	42.4	158	53.6	335			
No	137	46.4	193	54.9	295			
Little interest/little pleasure*						0.64	0.424	0.07
Yes	146	44.8	171	56.3	326			
No	133	43.8	180	55.2	304			
Perceived Stress (past 7 days)						0.68	0.407	0.06
Yes	207	45.6	247	54.4	454			
No	72	40.9	104	59.1	176			

*Measures from the PHQ-2 questionnaire (Kroenke, Spitzer, & Williamson, 2003). Timeframe is within the past two weeks.

Table 17 provides bivariate results for a number of reasons to quit. The reasons to quit for bad habit and not liking being addicted were not significant in the baseline characteristic bivariate analysis, but differed significantly by treatment group. There was a significant difference between treatment groups for thinking smoking was a bad habit ($\chi 2(1) = 4.39$, $p = 0.035$), with approximately 61% of all "yes" respondents being eCO testing and education recipients, as compared to approximately 38% of "yes" respondents who were in the standard enrollment group. There was also a significant difference between treatment groups for those indicating that a reason to quit was because they did not like being addicted to cigarettes ($\chi 2(1) = 5.69$, $p = 0.017$). Approximately 63% of all "yes" respondents were in the eCO treatment group, as opposed to 37% of all "yes" respondents, who were in the standard enrollment group.

Table 17

Bivariate Associations Between Independent Variables and CEASE Phase IV Participant Treatment Groups (eCO Enhanced Versus Standard Protocol), Self-reported Reasons to Quit Smoking

	eCO Enhancement							
	No (n=279)		Yes (n=351)					
Variable	n	%	n	%	total	Adj Chi-square	p-value	ICC
Doctor's Advice						2.54	0.103	0.09
Yes	122	39.6	186	60.4	308			
No	157	48.8	165	51.2	322			
Family Concern						2.35	0.125	0.07
Yes	102	39.5	156	60.5	258			
No	177	47.6	195	52.4	372			
Cost of Cigarettes						0.16	0.689	0.03
Yes	149	53.1	194	55.3	343			
No	130	46.9	157	44.7	287			
Personal Health						0.86	0.351	0.09
Yes	256	45.2	311	54.8	567			
No	23	36.5	40	63.5	63			
Family's Health						0.01	0.970	0.04
Yes	115	44.4	144	55.6	259			
No	164	44.2	207	55.8	371			
Social Pressure						0.03	0.842	0.12
Yes	39	42.8	52	57.1	91			
No	240	44.5	299	55.5	539			
Bad Habit						4.39	0.035	0.15
Yes	145	38.8	229	61.2	374			
No	134	52.3	122	47.7	256			
Role Model						0.90	0.343	0.11
Yes	98	40.8	142	59.2	240			
No	181	46.4	209	53.6	390			
Don't Like Addiction						5.69	0.017	0.12
Yes	116	37.1	197	62.9	317			
No	163	51.4	154	48.6	313			

Table 18 provides bivariate results for the readiness rulers. There were no significant differences in treatment groups for any of the rulers. This was unlike the bivariate analysis by enrollment group, which found significant differences between groups for importance and readiness (see Table 12).

Table 18

Bivariate Associations Between Independent Variables and CEASE Phase IV Participant Treatment Groups (eCO Enhanced Versus Standard Protocol), Readiness Rulers

	eCo Enhancement						
	No (n=279)		Yes (n=351)				
Variable	M	95%CI	M	95%CI	p-value	Adj t	ICC
Change Ruler							
Importance	8.5	[8.01, 8.92]	8.3	[7.88, 8.75]	0.641	0.47	0.11
Readiness	5.5	[4.94, 5.99]	5.5	[4.98, 5.98]	0.960	-0.05	0.11
Confidence	7.1	[6.54, 7.59]	6.7	[6.17, 7.17]	0.266	1.12	0.12

Hypothesis 2: eCO Randomized Trial, Pre-cursor GEE Models

In preparation for the QIC_u model comparisons, any covariates with a $p \leq 0.10$ coming out of the bivariate analysis, as well as the readiness rulers, were selected for a series of multivariate GEE enrollment models that included just each individual independent variable plus the main cotest exposure variable. The FTND score was also included both because it has been known to be a strong influence on motivation to quit, is similar to the interpretation of CO test scores (test scores are mapped to levels of addiction), and because it was significant in the baseline bivariate analysis. Table 19 shows the results of those multivariate GEE models.

Having a desire to quit with any support (OR = 1.50, p = <0.001), agreeing that doctor's advice is a reason to quit smoking (OR = 1.89, p = <0.001), and being recruited in a health, educational, or social service setting as compared to public events and farmer's markets (OR = 2.37, p = 0.015), were all significant in the presence of the eCO testing and counseling. The rulers of readiness (OR = 1.24, p = <0.001) and importance (OR = 1.78, p = <0.001) were also significant in the presence of the eCO test, but not

confidence (OR = 1.03, p = 0.303). FTND score was also significant in the presence of the eCO testing and counseling (OR = 1.11, p = 0.017).

Table 19

Odds Ratios and 95% Confidence Intervals of Generalized Estimating Equations Examining the Association Between the Outcome of Enrollment and Independent Variables Adjusted only for the Presence of eCO Testing and Counseling

Variable	Adjusted OR	95% CI	p-value
Desire to Quit with Any Support			
No/Not Sure	1.00		
Yes	1.50	[1.18, 1.87]	<0.001
Reasons to Quit			
Bad Habit			
No	1.00		
Yes	1.14	[0.81, 2.91]	0.434
Don't Like Addiction			
No	1.00		
Yes	0.94	[0.67, 1.31]	0.716
Doctor's Advice			
No	1.00		
Yes	1.89	[1.29, 2.56]	<0.001
Health condition: Diabetes			
No	1.00		
Yes	1.79	[1.00, 3.23]	0.049
Recruitment Setting*			
Public events and markets	1.00		
Health, social service, educational settings	2.37	[1.18, 4.72]	0.015
Readiness Rulers			
Importance	1.78	[1.71,1.87]	<0.001
Readiness	1.24	[1.17, 1.31]	<0.001
Confidence	1.03	[0.97, 1.17]	0.303
FTND Score	1.11	[1.01, 1.21]	0.017

*weight applied to panels to balance application of cotesting and education within setting type

Hypothesis 2 and 3: QIC_u Comparisons and Final eCO Model Selection

The final step in full model development was to undertake a comparison of QIC_u measures between various model. Table 20 shows the results for the QIC_u comparisons, where enrollment was the outcome variable for each one. The initial model developed

was simply the null model for enrollment (QIC_u = 722.42). The second model includes just the cotest (QIC_u = 718.53). In the subsequent model, only the readiness rulers (*ruleconf, ruleimp, rulechge*) were added (QIC_u = 647.23). Another model included the reason to quit, doctor, variable (*rqdoctor*), but, given that the QIC_u value was not the smallest and the fact that *rqdoctor* was insignificant in the model itself (not shown, OR = 1.45, p = 0.063), it was not selected. The ideal model based on comparing QIC_u values is one that included all the readiness rulers, the event setting variable (*surveyeventtype*), wanting to quit with support (*quitwsupport*), and FTND score (*FTNDscore*) (QIC_u = 623.639).

Table 20

QIC_u Measures for Enrollment Models Examining the Impact of eCO Testing and Counseling

Covariates	QIC_u
enroll only (null model)	722.42
cotest	718.53
cotest ruleimp ruleconf rulechge	647.23
cotest ruleimp ruleconf rulechge surveyeventtype	646.30
cotest ruleimp ruleconf rulechge surveyeventtype quitwsupport	626.31
cotest ruleimp ruleconf rulechge surveyeventtype quitwsupport FTNDscore (best fit model)	623.64
cotest ruleimp rulechge ruleconf quitwsupport FTNDscore rqdoctor surveyeventtype	628.52
cotest_ruleimp cotest_rulechge cotest_ruleconf surveyeventtype quitwsupport FTNDscore (moderation model)	654.03

Table 21 shows the results of that ideal model. In the prescence of these covariates, the average eCO test participant was 1.83 times more likely to enroll in CEASE Phase IV classes as compared to the average standard enrollment participant (p = 0.037). Quitting with support (OR = 1.53, p = <0.001) , the importance ruler (OR = 1.19,

p = <0.001) and readiness ruler (OR = 1.18, p = <0.001) were strong predictors of enrollment in the prescence of the eCO testing and counseling. The setting type of health, social service, and educational institutions was also significant as compared to public events and markets in the prescence of the eCO testing and counseling (OR = 2.45, p= 0.012). Finally, the FTND score was significant in the prescence of the eCO testing and counseling. On average, for every 1 unit increase in FTND score, the odds of enrollment for the average participant increased by 1.13 (p = 0.013). The QIC_u for the moderation model was 654.03 (see Table 22). It was thus not the ideal model at face value. In addition, none of the interaction terms between the cotesting and counseling and the readiness rulers were significant.

Table 21

Final GEE Multivariate Model for Enrollment, Adjusting for eCO Testing and Counseling and Other Covariates

Variable	AOR	95% CI	p-value
Received eCO Test			
No	1.00		
Yes	1.83	[1.04, 3.25]	0.037
Quit with any Support			
No	1.00		
Yes	1.53	[1.24, 1.90]	<0.001
IRC Rulers			
Importance	1.19	[1.11, 1.29]	<0.001
Readiness	1.18	[1.12, 1.26]	<0.001
Confidence	0.96	[0.89, 1.04]	0.316
FTND Score	1.13	[1.02, 1.24]	0.013
Recruitment Setting*			
Public events and markets	1.00		
Health, social service, educational	2.45	[1.21, 4.93]	0.012

*weight applied to panels to balance application of cotesting and education within setting type

Table 22

GEE Multivariate Model for Enrollment, Adjusting for eCO Testing and Education, other Covariates, and Potential eCO Testing and Counseling Moderators

Variable	AOR	95% CI	p-value
Received eCO Test			
No	1.00		
Yes	1.21	[0.25, 4.51]	0.801
IRC Rulers			
Importance	1.13	[1.04, 1.23]	0.009
Readiness	1.20	[1.10-1.30]	<0.001
Confidence	0.95	[0.85-1.05]	0.335
Interaction Terms			
cotest_ruleimp (importance)	1.09	[0.94, 1.27]	0.243
cotest_rulechge (readiness)	0.97	[0.85, 1.10]	0.673
cotest_ruleconf (confidence)	0.99	[0.84, 1.17]	0.956
Quit with any Support			
No	1.00		
Yes	1.58	[1.28, 1.94]	<0.001
FTND Score	1.13	[1.03, 1.24]	0.006
Recruitment Setting*			
Public events and markets	1.00		
Health, social service, educational	2.45	[1.21, 4.93]	0.012

*weight applied to panels to balance application of cotesting and education within setting type

Chapter 5: Discussion

This final chapter will summarize the results of the study, and compare and contrast those results with what is in the literature. This chapter also includes a discussion of study strengths and weaknesses. The chapter ends with public health implications and recommendations for future research.

The primary aim of this study was to examine whether or not a proactive enrollment process enhanced with exhaled carbon monoxide testing and counseling would, on average, make it more likely for the average adult smoker to enroll in classes that combine peer support with pharmacotherapy than the average adult smoker receiving a standard enrollment procedure. Another study aim was to examine any differences between enrollment groups in baseline characteristics of the same sample to have an understanding of the typical enrollment drivers for this population in the absence of the eCO intervention. A final study aim was to see if motivation measures of importance, readiness, and confidence moderated the effect of the eCO testing and counseling. The hypothesis that the average participant receiving the eCO testing and counseling procedure would be more likely to enroll in CEASE Phase IV classes than standard procedure participants was supported. Participants that received the enhanced eCO testing and counseling enrollment process were 1.83 times more likely to enroll than recipients of the standard procedure ($p = 0.037$).

The other significant covariates in this multivariate GEE model included the desire to quit with support (OR = 1.53, $p = <0.001$), the importance to change measure (OR = 1.19, $p = <0.001$), and the readiness to change measure (OR = 1.18, $p = <0.001$).

The FTND score was also significant, and for every 1-unit increase in FTND score, the odds of enrollment for the average participant increased by 1.15 (p = 0.013). Finally, in the presence of the eCO testing and counseling, the average participant recruited in the setting type of health, social service, and educational institutions was 2.45 times more likely to enroll than the average person recruited in public and farmer's market setting (p = 0.010). It should be noted that there were no significant differences between enrollment groups for setting type in the examination of baseline characteristics ($\chi 2(1)$ = 1.01, p = 0.310).

The hypothesis that importance, readiness, and confidence would have a moderating effect on the eCO testing and counseling was not supported, as none of the interaction terms using these measures in that multivariate GEE model were significant. The hypothesis around differences between enrollment groups in terms of baseline characteristics was partially supported. Quitting with support ($\chi 2(1)$ =10.5, p = <0.001), the importance in changing their tobacco habit (t(54) = -3.75, p = <0.001) and their readiness to change their habit (t(54)= -3.71, p = <0.001) differed significantly between enrollment groups, but confidence in changing was not significant. The variable would consider using NRTs to quit was also significantly different between enrollment groups ($\chi 2(1)$ = 9.08, p = 0.002). While a large percentage of the overall sample indicated being willing to consider using NRTs to quit (81%), it was not a significant factor for enrollment in the presence of the eCO testing and counseling.

Approximately 71% of the sample indicated wanting some level of support in quitting. Quitting with support was significant in both bivariate analyses and all GEE

models. This is similar to a mixed-methods study by Harris et al. (2016) that examined enrollment characteristics amongst 255 adult smokers found that, after an analysis of 644 open-ended comments, the desire to quit with assistance was among the top 4 reasons provided. They also found that those who indicated wanting to quit with assistance were more motivated to quit than those who did not indicate wanting assistance. Motivation was measured using 10-point scale responses in relation to questions about overall motivation to quit and confidence in quitting (Harris et al., 2016). A majority of this study's sample (65%) also indicated having a smoker in their home, and very few felt social pressure was a reason to quit (14%). This is a population in need of, and desiring, strong external support systems, which the CEASE classes provided in various formats.

In terms of recruitment setting, previous studies have examined the effectiveness of a variety of recruitment methods for low-income communities of color. A CBPR study in East Harlem, New York that ultimately enrolled 99 pre-diabetics into a peer-led diabetes prevention program examined the effectiveness of five different study recruitment methods: public event/neighborhood event outreach, clinician outreach (referrals), community partner-driven approaches (organizations recommend the best approach for reaching their members/clients), and health education-focused public events, and presentations to community organizations for their referral. They found that 68% of their enrollees were recruited via community partner-driven approaches as opposed to clinical or event-based methods (Horowitz, Brenner, Lachapelle, Amara, & Arniella, 2009). The partner-led approach involved letting the partners explain the process to their members/clients prior to researchers coming to site and then giving the

study access through a special arrangement. This approach was most similar to the communication strategy and dynamic that occurred at Phase IV sites located in behavioral health, educational, and social service settings where data collectors were given access to a room or table space in a lobby and that was pre-advertised prior to arrival. Phase IV public event outreach was often less structured, involved busier settings, and involved the coldest approaches. Previous studies have also examined the relationship between nicotine dependence and smoking program enrollment. Higher levels of nicotine dependence have been found to be a trial or program enrollment predictor in several studies. A study examining the enrollment characteristics of 3,890 proactively recruited smokers found that higher levels of nicotine dependence were 3.75 times more likely to enroll in a telephone counseling program than lower nicotine smokers (Mak, Lee, & Loke, 2015).

The measures of importance and readiness to change were significant in all models, while confidence was not significant in any models. The impact of these measures on motivation to initiate change and to change behavior has varied across the literature. Bordeaux et al. (2012), in their examination of the reliability and validity of the IRC rulers, also explored their influence on outcomes related to smoking change status. They included each ruler measure in multivariate models, both separately and combined. They found that the importance ruler, when alone, produced the largest significant odds ratio for the outcome of quit attempt with relapse compared to the other two rulers alone (OR=1.17, $p = < 0.01$). Readiness was next highest measure (OR=1.13, $p = < 0.01$). Unlike this study, confidence was also found to be significant, but had the

lowest odds ratio (OR=1.10, $p = < 0.05$) (Bordeaux et al., 2012). Confidence was the only readiness ruler to be significant in any model for their outcome of sustained behavior change (Bordeaux et al., 2012). These results may indicate that importance and readiness play more of a role in the initiation of change (such the decision to enroll in a quit-smoking class), while confidence may be more influential in the change maintenance that would happen after receiving initial support.

This study has demonstrated that the use of exhaled carbon monoxide testing and education can greatly enhance cessation program enrollment rates in a peer-led, community-based quit smoking program. This study was one of the few biomedical risk assessment studies to customize risk information for the purposes of enhancing a smoking cessation program recruitment process. It was also one of the first studies to use exhaled carbon monoxide, specifically. The testing and education intervention was designed to enhance perceived severity and perceived susceptibility. It sought to do this through providing health risk information and a personalized eCO score to ultimately increase threat perception of the dangers of exposure to the exhaled carbon monoxide found in cigarettes in a limited timeframe. The participants in this sample had a strong sense that smoking could impact their health at baseline. Approximately 90% of the sample indicated that a reason for them to quit was concern for their personal health. Approximately 77% of the sample had indicated having been diagnosed with at least one health condition and approximately 55% had at least one health condition that was identified on the educational postcard.

The postcard's visual depiction of health risks could have enhanced smoker's perception of threat, as that has occurred with previous studies involving graphic materials. Mead, Cohen, Kennedy, Gallo, and Latkin (2015) conducted a qualitative motivational study 25 of low-income, Baltimore based smokers that examined the impact of 4 different types of graphic warning label messages. The messages depicted both negative and positive messages about health risks to smokers and to others. They found that that the labels that depicted negative health impacts to smokers were most motivational, with reasons given during semi-structured interviews that included the concern over the impact smoking had on their own bodies (Mead et al., 2015). The images in the eCO educational postcard showed images representative of negative health impacts, including images of an asthmatic using an inhaler, a person holding their chest, and a distressed individual holding their head, symbolic of an individual suffering from cognitive impairments (lack of concentration).

Other health risk studies have focused on threat elevation linked to biomedical concepts in the context of recruitment processes. A study by Schnoll et al. (2011), found success in enhancing telephone-based recruitment process by providing a randomized group of adult smokers an additional recruitment message on the role of genetics and the increased risk of smoking. The enrollment rate for the genetic risk messaging plus generic health threat message group was 51.7 % compared to the standard generic health threat only group that enrolled at a rate of 37.7%, which is a difference of approximately 14% (Schnoll et al., 2011). The difference in enrollment rates between eCO and non-eCO recipients for this study was approximately 8.9%. Finally, the exhaled carbon

monoxide testing and counseling was embedded in a process that lasted 15 minutes on average and was effective in this limited timeframe. Other studies using feedback methods have demonstrated this temporal effect. Shahab, West, and McNeil's (2011) exploration of quit intention enhancement after the use of an exhaled carbon monoxide test with counseling found the intervention to be effective only immediately post-intervention. The study by McClure et al. (2009), which utilized eCO testing among multiple health risk assessment methods, similarly found only immediate post-intervention enhancement of quit intentions. While exhaled carbon monoxide has not been successful supporting long-term outcomes, shorter term applications may be more appropriate.

This study's conceptual model proposed that the design elements of the eCO testing and education materials, moderated by participant's pre-intervention levels of importance, readiness, and confidence, could enhance participant class enrollment rates as compared to participants receiving the standard enrollment procedure. Various cues to action, including concerns for their own health, were considered as well as several benefits and barriers to enrollment. The eCO testing and counseling provided health risk information that visually depicted the threats of carbon monoxde exposure, while offering the benefits of reducing their exposure to cabon monoxide. It also provided participants with a sense of the severity of risk by providing a real-time, personalized eCO score. Enrollment rates were enhanced in this sample of adults smokers that recognized personal health concerns as a reason for quitting in large numbers, held a strong sense of the importance of quitting and that had some readiness to quit.

Study Strengths

This study featured a rigorous randomized experimental design applied within a community-based setting. The effectiveness of the eCO testing and counseling was examined while controlling for numerous covariates. The model building process explored over 40 variables in the process of building the final multivariate GEE models, including nine reasons to quit, 10 physical health and medical conditions, smoking behaviors, peer influences, mental health measures, neighborhood of residence, and several demographic characteristics. In addition, this study examined potential moderators of importance, readiness, and confidence within multivariate models through the inclusion of interaction terms.

This study utilized a CBPR approach, thus the role of eCO testing and counseling was examined in a real-world setting with diverse perspectives and populations involved in the process, versus conducting the study in an artificially controlled setting and making inferences to a community-based setting. This translational strength of CBPR in smoking cessation studies has been previously noted (Wallerstein & Duran, 2003; Andrews, Newman, Heath, Williams & Tingen, 2012). At times during the study, the investigator was fully engaged with Peer Motivators in thinking through recruitment strategy (ex. places in the community to recruit, the right level of persuasion when getting someone to engage in the survey when on the street) and also found that they acted as the voice of balance in terms being motivated by the goal of bringing services to the community versus the more logisitical recruitment goals of Phase IV. The investigator may not have thought to develop these approaches as a community outsider or operating as a lone

researcher. Finally, the study's low SES population is one that is not often included in smoking trial studies, but that has been identified as being most vulnerable to the health risks of smoking. Study recruitment happened at times along neighborhood blocks or in community organizations where researchers and service providers had rarely travelled previously, providing access to services that would not otherwise reach those participants.

Study Limitations

The study had several limitations. The target population of the study consisted of participants that came largely, though not exclusively, from two Baltimore City neighborhoods, with over 50% coming from West and Southwest Baltimore. As a result, data from the study cannot be generalized to a broader geographic levels. There were several questions in the baseline community survey that resulted in self-reported responses. Health condition data was self-reported and framed around whether or not participants had received a physician's diagnosis. Some medical conditions were thus reported in numbers far lower than city and neighborhood averages, including heart disease. This may be due to limitations in access to medical care in this underserved population (the percent uninsured is especially higher than city average in Southwest Baltimore), and participants were told that their condition had to be medically diagnosed. Participants also had to recall details about their smoking habit, including how many cigarettes a day they smoked. They may or may not be accurate in recalling certain behaviors.

The baseline bivariate analysis had its limitations. The enrollment groups were imbalanced with a substantively smaller non-enrolled group, which made it challenging to use all of the variables due to small cell sizes. This imbalance also made it less practical to cultivate a full model for enrollment characteristics that could adjust for clustered data with the proper statistical power. The high-volume recruitment needs of the larger Phase IV study also made it difficult to collect data under conditions that are typically ideal for clustered data. The setting types and discrete locations varied greatly between recruitment event clusters which lead to the need to create large buckets for setting types. Keeping recruitment numbers at each event within a similar range was impractical in the larger Phase IV context, but would have made conditions more ideal for the analysis of clustered data.

While the treatment allocation was randomly applied to clusters, the eCO intervention was administered disproportionately in more health/social service settings, causing a need to weight the data to accommodate an imbalance in setting type. Though the weights calculated in this study were not extreme and the sample was large, weighting, in general, can reduce accuracy. The eCO study combined the eCO breath test with an educational postcard, but did not include ways of examining the influence of one component of the intervention over the other. Adding a third treatment group with one component or the other would have been ideal, but would have made for more complications amongst data collectors in the field. The high volume needs of Phase IV made it less practical to add additional questionnaires to the recruitment process, thus participants that received eCO testing and counseling were not given any questions

asking about their thoughts and feelings around threat perception directly following the intervention. This line of inquiry could have more concretely supported the specific role of perceived severity and susceptibility in the influence of the postcard and test result materials. Finally, there lacks a gold standard for success and consistency in results when it comes to the use of smoking cessation program recruitment and the use of exhaled carbon monoxide. There are especially few studies that leverage eCO by itself for the purposes of program recruitment. This makes it challenging to gauge the strength of this aspect of external validity.

Public Health Implications and Future Research

There are three broad implications for this study. The primary implication is its contribution to smoking cessation program recruitment. Having insight into the baseline characteristics of low-income smokers that are interested in a program that combines behavioral support and the use of nicotine replacement therapy will help program administrators in their outreach efforts. In addition, incorporating the use of exhaled carbon monoxide testing and counseling in outreach efforts can potentially boost enrollment in cessation programs. The eCO monitor is inexpensive (The piCO+™ Smokerlyzer® and its accessories cost $ 830) and the educational postcard is simple to produce, making the overall intervention easy for organizations to implement. Understanding that organization-led approaches to recruitment can be most impactful for this underserved population can also help direct future community-based recruitment efforts. The second implication is its contribution to risk communication around harmful and potentially harmful constituents in tobacco products. Carbon monoxide is a FDA-

designated HPHC that the general public easily recognizes, and this eCO testing and counseling could be a new way for smokers to learn about the potential health hazards and personal health risks tied to this chemical constituent. Finally, a third implication is for the CEASE Partnership's dissemination efforts as it seeks to share its materials with other communities. Being able to provide lessons learned on recruitment best practices will help those looking to replicate CEASE's model have "start-to-finish" guidance.

In terms of future research, conducting an eCO recruitment study that could be limited to just one type of partner-driven community-based setting and with an additional trial arm for just the eCO test would provide further insight into the reasons what element of the eCO testing and counseling was effective. Including pre and post enrollment questions around threat perception in surveys would provide a more direct measure of risk perception and the various testing and education components. Having participants use the IRC rulers immediately post-intervention would also provide a more direct point of comparison of the intervention's impact on readiness, importance, and confidence to change their tobacco habit. The average age of participants in this study was 47, with the sample skewing towards older ages. A future study could focus exclusively on youth or young adult populations to see if this tool is effective for ages 18-24 or younger. The setting types used in this study were also not ones where you might find younger adult smokers (ex. entertainment venues), so that would be one setting type of a future youth or young adult study. Finally, any future studies could broaden the geographic reach of recruitment events to city-wide to enhance the intervention's generalizability.

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Appendix A: CEASE Phase IV Community Baseline Survey

Enter the following information:

- ❍ Date mm/dd/yyyy (1)
- ❍ Survey Site (i.e. name/event/address) (2)
- ❍ Surveyor Initials (3)

Is this a randomized CO testing site?

- ❍ Yes (1)
- ❍ No (2)

{Greeting Script}

Hello (or other suitable greeting)! Would you like to make $5 for completing a 10 minute survey?

YES: Thank you. My name is _____. I work with CEASE and we are doing community research. Let's begin…

NO: Okay, Have a nice day.

{Unique ID Creation}

***To ensure confidentiality and protect your identity, we will now create a unique identification*:**

What is your mother's maiden name?
What is your birth month and birth day?

{Surveyor, convert to 4-digit number (for example March 8th would be 0308)}

{Surveyor, combine Question 1 and Question 2 to create participant's 7-character unique identification number. Use the first 3 letters of mothers maiden name; 2-digit birth month and 2-digit birth day (e.g. SMI0308). Enter below with NO spaces between any characters}

1. **Have you ever heard about CEASE?**

- ❍ Yes (1)
- ❍ No (2)

[Answer: If Have you ever heard about CEASE? Yes is Selected]

1a. Where did you hear about CEASE?

- ❍ Friend / Family (1)
- ❍ Flyer / Newsletter (2)
- ❍ Website (3)
- ❍ CEASE Conference (4)
- ❍ Community Event (5)
- ❍ Other agency or organization (please specify) (6) _____

2. Have you ever attended a CEASE Quit Smoking class?

- ❍ Yes (1)
- ❍ No (2)

[Answer If Have you ever attended a CEASE Quit Smoking class? Yes Is Selected]

3. Where was the CEASE Quit Smoking class?

- ❍ At the Open Gates Community Healthcare Center (1)
- ❍ Another place (please specify) (2) _____

[Answer If Where was the CEASE Quit Smoking class? Another place (please specify) Is Selected OR Is Not Empty]

Thank you for your time. Here is the $5 we promised you. Would you like some information about CEASE to share with your family and friends? (If yes, give info.) Ok, great. Have a good day.

[<u>SURVEY END</u>: If Thank you for your time Is Displayed, Then Skip To End of Survey]

4. What is your date of birth (mm/dd/yyyy)?

5. What is your gender?

- ❍ Male (1)
- ❍ Female (2)

[Answer If What is your gender? Female is Selected]

6. Are you pregnant now?

- ❍ Yes (1)
- ❍ No (2)

[Answer If What is Your gender? Female Is Selected]

7. Would you like to become pregnant within the next year?

- ❍ Yes (1)
- ❍ No (2)

8. What is your race/ethnicity? (may select more than one category)

- ❍ African American/Black (1)
- ❍ White (2)
- ❍ Hispanic or Latino (3)
- ❍ Native American or Alaska Native (4)
- ❍ Native Hawaiian or Other Pacific Islander (5)
- ❍ Asian (6)
- ❍ More than one race (7)
- ❍ Other: please specify (8) _____

9. **What is the zip code where you live? _____**

10**. Do you have a job?**

- ❍ Yes, full time (1)
- ❍ Yes, part time (2)
- ❍ No (3)

11. What is your marital status?

- ❍ Single (1)
- ❍ Married (2)
- ❍ Other:(please specify) (3) _____

12. What is the highest grade or year of regular school you have completed?

- ❍ Some high school or less (1)
- ❍ Graduated from high school/ GED (2)
- ❍ One or more years of college (3)
- ❍ Graduated from trade school (4)
- ❍ Graduated from college (5)
- ❍ More than a college degree (6)

13. Including you, how many people live in your house? _____

14. In general, would you say your health is excellent, good, fair, or poor?

- ❍ Excellent (1)

- ❍ Good (2)
- ❍ Fair (3)
- ❍ Poor (4)

15. In the past two years, has a doctor told you that you have any of the following health problems or conditions?

	Yes (1)	No (2)	Refused (3)
High blood pressure (1)	❍	❍	❍
Heart attack, or any other heart disease (2)	❍	❍	❍
Cancer (3)	❍	❍	❍
Stroke (4)	❍	❍	❍
Diabetes or sugar diabetes (5)	❍	❍	❍
Anxiety or depression (6)	❍	❍	❍
Obesity (7)	❍	❍	❍
Breathing problem, such as asthma or emphysema (8)	❍	❍	❍
Alcohol abuse or dependence, or alcoholism problems (9)	❍	❍	❍
Drug addiction, or abuse or dependence (10)	❍	❍	❍
Any other health problems (11)	❍	❍	❍

16. Are you taking any medication for any of these health problems or conditions?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Refused (3)

17. **How stressed have you felt in the last 7 days?**

- ❍ Not stressed at all (1)
- ❍ I felt stressed a few days (2)
- ❍ I felt stressed most days (3)
- ❍ I felt stressed every day (4)

18. During the past 2 weeks, how often have you been bothered by any of the following problems?

	Not at all (1)	1 - 7 days (2)	8 - 13 days (3)	Everyday (4)
Having little interest or little pleasure in doing things (1)	❍	❍	❍	❍
Feeling down, depressed, or hopeless (2)	❍	❍	❍	❍

19. Do other people around you smoke? (Please check all that apply)

- ❍ At home (1)
- ❍ At my job (2)
- ❍ Family members (3)
- ❍ Friends (4)
- ❍ No One (5)

20. Have you smoked at least 100 cigarettes in your lifetime?

- ❍ Yes (1)
- ❍ No (2)

21. Do you now use tobacco products everyday, some days, or not at all?

- ❍ Everyday (1)
- ❍ Some days (2)
- ❍ Not at all (3)

[<u>SURVEY END</u>: If Not at all is Selected, Then Skip To *Thank you for your time. Here is the $5*..]

[Answer If Do you now use tobacco products everyday, some days, or not at all? Everyday is Selected OR Some days is Selected]

21a. On the days when you do smoke, how many cigarettes do you smoke?

- ❍ 1- 2 cigarettes (1)
- ❍ 3 or more cigarettes (please specify) (2) _____
- ❍ I do not smoke cigarettes (3)

[<u>SURVEY END</u>: If 3 or more cigarettes is Is Not Selected, Then Skip To *Thank you for your time. Here is the $5*..]

[Answer If Do you now use tobacco products everyday, some days, or not at all? Some Days is Selected]

21b. Do you now smoke at least 21 cigarettes per week?

- ❍ Yes (please specify amount) (9) _____
- ❍ No (10)

[<u>SURVEY END</u>: If No is Selected, Then Skip To *Thank you for your time. Here is the $5…*]

21c. What type of tobacco products do you use? (Check all that apply)

- ❍ Cigarettes (1)
- ❍ Cigars (2)
- ❍ Little cigars / cigarillos (3)
- ❍ Electronic smoking devices (4)
- ❍ Dip/Snuff/Chew or dissolvable tobacco (5)
- ❍ Other (please specify) (6) _____

[Answer If What type of tobacco products do you use? (Check all that apply) Cigarettes Is Not Selected]

Thank you for your time. Here is the $5 we promised you. Would you like some information about CEASE to share with your family and friends? (If yes, give info.) Ok, great. Have a good day.

[<u>SURVEY END</u>: Skip To *Thank you for your time. Here is the $5…*]

21d. What type of tobacco products do you use? (Please check all that apply)

- ❍ Regular (1)
- ❍ Menthol (2)
- ❍ Flavored (please specify) (3) _____

21e. During the past 12 months, have you stopped smoking for one day or longer because you tried to quit?

- ❍ Yes (1)
- ❍ No (2)

22. Are you seriously thinking about quitting smoking? (Choose the best answer for you)

- ❍ Yes, within the next 30 days (1)
- ❍ Yes, within the next 6 months (2)
- ❍ Yes, but not within the next 6 months (3)
- ❍ No, I am not thinking of quitting smoking (4)
- ❍ Not sure (5)

23. How would you like to quit smoking when you are ready?

- ❍ On my own with no support (1)
- ❍ With just a little help (2)
- ❍ I will want a lot of support (3)
- ❍ I have not thought about it (4)

[Answer If you seriously thinking about quitting smoking? Yes, within the next 30 days Is Selected AND If yes, how do you intend to quit smoking? On my own with no support Is Selected]

{Self-Help Group and Control Group Enrollment Script}

Ok, great. Since you've indicated you want to quit in 30 days, we would like to follow up with you in 4 months, at which time we'll give you $25 to complete another survey. Would you be interested in this?

[YES:] *Great! You'll get a reminder call around (approximate four months from today), with information about where the survey will take place. If the time doesn't work we will reschedule for another date that does work for you. Let me get your contact information.*

[NO: CONTROL GROUP/Not Interested]: *Thank you for your time. Here is the $5 we promised you. Would you like some information about CEASE to share with your family and friends? (If yes, give info). Ok, great. Have a good day***. [Surveyor: Click Submit, then open contact info link and complete if YES.]**

- ❍ Enrolled (1)
- ❍ Not Enrolled (2)

[<u>SURVEY END</u>: If Not Enrolled Is Selected, Then Skip To End of Survey]

24. How ready you are at this time to change your tobacco habit? [ruler scale]

_____ Select (1)

25. How important it is to you to change your tobacco use? [ruler scale]

_____ Select (1)

26. How confident are you that you can change your tobacco use? [ruler scale]

_____ Select (1)

27. Would you consider using nicotine replacement products (gum, patch, lozenge) to help you quit smoking?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Not sure (3)

[If Yes Is Selected, Then Skip To How soon after waking do you smoke your first cigarette?]

28. Why would you NOT use NRTs? (check all that apply)

- ❍ I would not need it to help me because I have made up my mind to quit. (1)
- ❍ NRTs are too expensive. (2)
- ❍ I don't know enough about how to use NRTs properly. (3)
- ❍ NRTs are too hard to get. (4)
- ❍ NRTs might harm my health. (5)
- ❍ NRTs do not work. (6)
- ❍ Other (7) _____

29. How soon after waking do you smoke your 1st cigarette of the day?

- ❍ Within 5 minutes (1)
- ❍ 6-30 minutes (2)
- ❍ 31-60 minutes (3)
- ❍ After 60 minutes (4)

30. Do you find it difficult to refrain from smoking in places where it is not allowed or is forbidden, e.g., in church, at the library, at the movies, in the car with someone that doesn't allow smoking?

- ❍ Yes (1)

- ❍ No (2)

31. Which cigarette would you hate to give up more?

- ❍ First one in the morning (1)
- ❍ Any other (2)

31a. How many cigarettes per day do you smoke? _____

32. Surveyor, please select category of cigarettes smoked per day:

- ❍ 10 or less (1)
- ❍ 11-20 (2)
- ❍ 21-30 (3)
- ❍ 31 or more (4)

33. Do you smoke more frequently during the first hours after waking then during the rest of the day?

- ❍ Yes (1)
- ❍ No (2)

34. Do you smoke even if you are so ill you are in bed for most of the day?

- ❍ Yes (1)
- ❍ No (2)

35. **What are some reasons for you to quit using tobacco? (Check all that apply)**

- ❍ Health (1)
- ❍ Family health (2)
- ❍ Cost (3)
- ❍ It's a bad habit (4)
- ❍ Good role model (5)
- ❍ Other (6) _____
- ❍ I don't like being addicted (7)
- ❍ My family wants me to quit (8)
- ❍ Doctor's advice (9)
- ❍ I have no reason to quit (10)
- ❍ Social pressure (11)

[Answer If this is a randomized CO testing site? CO Test Site Is Selected]

{eCO Test Intro Script} *A final step in our survey is to take your carbon monoxide level. This is a simple breath test that will help us get a better picture of your smoking, as it is right now. In a minute I'm going to ask you to take in a deep breath and hold it for 15 seconds. Put the mouth piece in your mouth. The timer will beep when it is time to blow. Then you will slowly blow the breath into the mouthpiece. Don't take another breathe before you blow. If you can't hold your breath that long, don't worry- blow when you have to. After you have blown into the monitor, it will give us a score. I'll explain to you what your score means in a minute. Are you ready to start?*

[YES: Give CO test, then explanation of score]

[NO: Move on to the information about the classes]

- ❍ CO score (1) _____
- ❍ Refused (2)

[If To get you started in the process we'd like to take your carbon monoxide level. This is a simple..Refused Is Not Selected AND Is this a randomized CO testing site? CO Test Site is Selected]

{**CO Test Explanation Base Script}** *You scored a {ENTRY VALUE} . This is how much CO is in your system right now, and is based on how much you have smoked so far today, how recently you have smoked, and how deeply you inhale when you smoke. Unlike most tests, a higher score is NOT a good thing. CO takes up space in the blood where oxygen usually belongs. This lack of oxygen causes many health problems, such as shortness of breath, slower moving blood, faster heart beat, high blood pressure, risk of stroke and heart attack. Any questions?...*

{Enrollment Intro Script} *Thank you! Based on the answers you provided, you qualify for an additional phase of our research. We offer quit smoking classes with tools and resources to help people quit when they are ready. You could choose either a single-session or 4- session class, with a follow-up survey several months later. You would be compensated for your feedback which lets CEASE know if the program is providing effective help. Would you be interested in the single session or the 4 session class?*

[Surveyor, please enter the respondent's CEASE session selection below:]

- ❍ Single Session (1)
- ❍ 4 Session (2)
- ❍ Unsure or Not Interested (3)

{Single Session Script} *Great, so this group meets for 1 hour with people like you who also requested a single session. You will receive tools, resources and free Nicotine Replacement products. Everyone is encouraged to quit for this session. You will receive*

$10 for completing a survey at the end of the session. We will also give you a voucher so you can pick up additional NRTs two weeks after your class. We will also schedule a time for you to come back in 4 months for a follow-up where you will receive $25 for completing another survey. The group is meeting on these dates **[show flyer]**. *Which date and time works best for you?*

[Surveyor: circle class date respondent picked and enter date on the next screen].

Last thing...to get you started we have an enrollment packet for you to take home. The packet has two Nicotine Replacement patches and resources and tips to help you quit. We'd like you to use the patches the two days leading up to the class. There are step-by-step instructions on how and when to use them in the packet and a number to call should you have any questions about anything in the packet. Now we need your contact information and we need you to sign a consent form.

{Four Session Script} *Great! The 4 session group meets weekly for 1.5 hours. During these classes we will help you finalize a quit plan, give you some more in-depth information, and provide you with Nicotine Replacement products. We encourage everyone to quit on the first day. The following weeks will be for support and information to make your quit a success. You will receive $10 for completing a survey at the end of each session. Once the 4 weeks are over, we will also give you a voucher so you can pick up additional NRTs two weeks after your class. We will also schedule a time for you to come back in 3 months for a follow-up where you will receive $25 for completing another survey. We have groups starting on these dates* **[show flyer]**. *Which date and time works best for you?*

[Surveyor: circle class date respondent picked and enter date on the next screen.]

To get you started we have an enrollment packet for you to take home. The packet includes a worksheet to help you get started in writing your quit plan. You will need to bring that to class filled out. The packet also has two Nicotine Replacement patches and resources and tips to help you quit. We'd like you to use the patches the two days leading up to the class. There are step-by-step instructions on how and when to use them in the packet and a number to call should you have any questions about anything in the packet. Now we need your contact information and we need you to sign a consent form.

{ Not Sure Script} *Sure, I understand that you are not ready to commit right now.* **[SURVEYOR: Pick one or two of the following questions to engage the respondent in motivational counseling]** *Tell me, what would make you decide that NOW was a good time to stop smoking? What are some of the barriers stopping you from quitting? When do you think you might be ready to quit? What will it take for you to quit now?*

Well, thank you so much for your time. I did want to let you know that if you are interested we will contact you in four months to see how you are doing. We will give you

$25.00 for completing another survey at that time. Or, we have an open group that meets every week for people that aren't quite ready to quit. Here is a list of classes coming up **[show flyer]**. *Would you like to sign up for the 4-month follow-up or the open group?* **[If YES: Surveyor, select 4-month follow up or open group.]**

[If NO: Select 'Not Enrolled' option below.] *Thank you for your time. Here is the $5 we promised you. Would you like some information about CEASE to share with your family and friends? (If yes, give info.) Ok, great. Have a good day.*

- ❍ Open Group (Preparing to Quit) (1)
- ❍ 4-month follow-up (3)
- ❍ Not Enrolled (2)

{Enrollment Intake}

[Surveyor, please enter class date below (mm/dd/yyyy)]

- ❍ Select and enter class date (mm/dd/yyyy) (1) _____
- ❍ No - Not Enrolled (2)

[Surveyor, please give participant hard copy of informed consent for classes. Ask them to read/read to them and sign. Then give participant yellow copy and you keep the white copy.]

[Surveyor, please complete the following contact information below.]

First Name (1)
Last Name (2)
Address Line 1 (3)
Address Line 2 (4)
City (5)
State (6)
Zip Code (7)
Home Phone (xxx-xxx-xxxx) (8)
Mobile Phone (xxx-xxx-xxxx) (9)
Email (10)

Appendix B: Fagerstrom Test for Nicotine Dependence Questions

FTND Item	**Responses/Score Scale**
How soon after you wake up do you smoke your first cigarette?	Within 5 minutes/0 6–30 minutes/1 31–60 minutes/2 After 60 minutes/3
Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, at the movies, in the care with someone that doesn't allow smoking)?	Yes/1 No/0
Which cigarette would you hate to give up more?	First one in the morning/1 Any other/0
How many cigarettes per day you smoke?	10 or less/0 11–20/1 21–30/2 31 or more/3
Do you smoke more frequently during the first hours after waking than during the rest of the day?	Yes/1 No/0
Do you smoke when you are so ill that you are in bed most of the day? No FTND scale (# cigs/day, time to first cig, etc.)	Yes/1 No/0