Research Protocol

PURPOSE OF THE STUDY

Electronic nicotine delivery devices often referred to as e-cigarettes, are battery-powered devices that deliver vaporized nicotine when inhaled. Corresponding with the growth in media attention, marketing and promotion, awareness and use of e-cigarettes has increased dramatically. A large proportion of those using e-cigarettes use them to reduce the number of cigarettes they are smoking or to help them quit. Use of an e-cigarette by smokers unwilling or unable to stop smoking completely might be a good approach to reducing cigarette consumption as the e-cigarette imitates some behavioral aspects of cigarette smoking and contains nicotine. Moreover, the few existing studies on the effect of e-cigarettes on tobacco withdrawal and craving suggest promising potential to assist smokers in coping with smoking urges and decreasing cigarette use. The purpose of this study is to examine the feasibility of using e-cigarettes as a method for harm reduction and the effects of providing e-cigarettes (or placebo e-cigarettes) on smoking outcomes.

BACKGROUND

Most smokers want to quit and have made multiple quit attempts but the majority fail due to their dependence on nicotine and behavioral cues that reinforce their smoking behavior (Buckhalter 2005). Nicotine replacement therapy (NRT) is one of the most cost-effective treatments available to smokers who want to quit, but fewer than 20% of people quitting with NRT patch are abstinent at 12 months (Ronckers 2005, Stead 2012). This may be due to the fact that the NRT patch does not replace the behavioral ritual associated with cigarette use, nor deliver nicotine as rapidly as cigarettes (Le Houezec 2003, Walker 2011). It has been hypothesized that e-cigarettes could be a more effective way to help people reduce the harm of smoking through reductions in number of cigarettes smoked per day or to quit smoking completely by addressing both nicotine and behavioral dependence (Bullen 2010). A related question is the extent to which any quitting assistance provided by e-cigarettes might be attributable simply to the behavioral replacement they provide (Caponnetto 2011). This is relevant because some e-cigarettes are available with cartridges containing as little as 0mg of nicotine.

E-cigarette use appears to be growing and highest among young adults 18-24 years. A study conducted in Hawaii found that smokers who used e-cigarettes to try to quit were younger and had been smoking for fewer years than those who had not. Notably, the most recent analysis of trends in smoking in the US found that between 2005-2010 young adults had the lowest quit rates compared to other adult age groups (CDC 2014). These findings suggest a rationale for focusing on the young adult population in studying the potential use of e-cigarettes as a harm reduction strategy. There are an estimated 2.5 million e-cigarette users in the US with sales of $300 million a year (McCauley 2012). Many of these users are turning to e-cigarettes as a way to reduce or stop smoking. More research is needed to assess the effect of e-cigarette use on withdrawal symptoms, and its association with smoking reduction and abstinence.

The rationale for this harm reduction pilot study is based upon prior work demonstrating that pre-cessation nicotine replacement therapy (NRT) has been shown to increase the odds of reducing consumption of cigarettes per day (CPD by 50% or more compared to placebo) (Stead 2010). This prior work is especially noteworthy because smokers not interested in quitting made significant reductions in their smoking and maintained these reductions over time. Concern that pre-cessation NRT use will result in fewer quit attempts and impede cessation has not been supported by the literature. Among 19 relevant studies, none showed that pre-cessation NRT undermined future cessation. On the contrary it

appears that pre-cessation NRT is associated with smoking reduction which in turn increases the probability of future cessation (Hughes 2006).

METHODS

Primary research questions:

1) Is it feasible to recruit and retain young adult smokers in a pilot trial testing whether e-cigarette use can reduce the number of cigarettes smoked per day (CPD)?
2) To what extent do smokers reduce CPD when using e-cigarettes to displace cigarette use?
3) Are there differences in rates of reduction between two interventions arms (4.5% vs. 0 mg (placebo) e-cigarettes)?

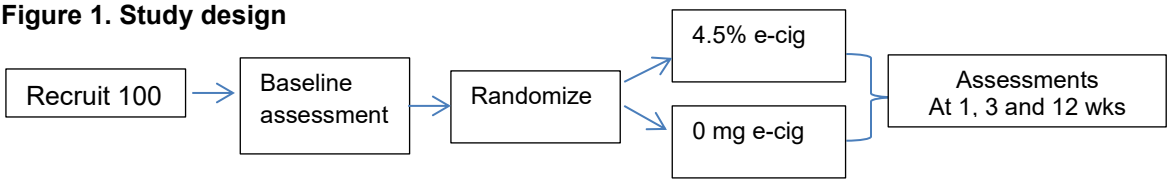
Study Aims

AIM 1: To evaluate the feasibility of recruiting and retaining young adult smokers in a harm reduction study using e-cigarettes to displace cigarette use;
AIM 2: To assess daily patterns of e-cigarette use (including dual use of combustible cigarettes), product satisfaction, and nicotine cravings with use of 4.5% vs 0 mg (placebo) e-cigarette; and
AIM 3: To compare the effect of nicotine e-cigarettes (4.5%) vs placebo e-cigarettes on smoking reduction at 1, 3 and 12 weeks post baseline assessment.

Study design

This pilot study will be a two-arm, randomized controlled trial. We will randomize 50 participants into each intervention arm. Participants will be recruited through advertisements placed in Craigslist and other social media as well as flyers placement in NYU venues and street distribution with contact details for how to get in touch with a Research Assistant. The randomization sequence will be prepared by the study statistician. Participants will be randomized to one of the two arms: e-cigarettes with nicotine cartridges or e-cigarettes with placebo cartridges (0mg). Participants and research assistants will be blind to the allocation of nicotine or placebo e-cigarettes as there are no difference in appearance or odor of the mist emitted from the e-cigarettes with and without nicotine containing cartridges.

Figure 1. Study design



Study participants

Inclusion criteria: ages 21-35 (must present proof of age), daily smoker, smokes at least 10 cigarettes a day (verified by a CO level of 8 ppm or above), interested in reducing CPDs, able to provide consent, uses a cell phone and is willing/ able to receive and respond to daily text messages regarding his/her cigarette use and e-cigarette use on his/her cell phone, and willing to use an e-cigarette for 3 weeks.

Exclusion criteria: Pregnant and/or breastfeeding (self-reported), current use of smoking cessation medications (including other forms of NRT, bupropion, or varenicline), enrolled in a smoking cessation program or another cessation trial. Other exclusion criteria include use of an e-cigarette in the past 14 days, use of any other tobacco products (pipe, cigar, cigarillos, snuff, chewing tobacco, or hookah/shisha) in the past 30 days, an Alcohol Use Disorders Identification Test (AUDIT C) score of $\geq$7

for men and ≥5 for women, a Drug Abuse Screening Test-10 (DAST) score of ≥5. Potential participants will also be excluded if they report having a history of asthma or other airways disease and heart disease.

Study Procedures

Potential participants will be screened for eligibility by telephone. Eligible participants will be invited to give informed consent and complete the baseline assessment in person at the first study visit. During this assessment, we will ask participants to practice using the e-cigarette and give them instructions to return with their used e-cigarettes at their next study visit. We will also train participates to use the text messaging system during the baseline visit. For the training, we will establish an interactive texting protocol that introduces participants to the messaging process and trains them how to respond. After being enrolled in the SMS program a sample of questions will be text messaged to the participants and responses will be solicited to establish an understanding of how data collection works. This protocol is based on Dr. Furberg's current research. (Furberg 2012, Harris 2013) The interactions will be fully automated and cover: 1) welcome to the intervention, 2) some example questions with practice answering them, and 3) information on how to contact project staff for additional support.

After the baseline assessment participants, will be asked to track their smoking behavior for three days prior to beginning to reduce. We will prompt participants to report cigarette use with a text message reminder 4 times a day at 4 hour intervals (e.g., how many cigarettes have you smoked in the past 4 hours). The first text message inquiry of the day will ask participants to report any cigarettes smoked since the last text message prompt. This is meant to capture any overnight cigarette or e-cigarette use. The time of day for delivering text messages will be tailored to the participant's schedule of waking and sleeping.

After tracking their cigarette use, all participants will receive a 20-30 minute behavioral counseling consultation with a trained tobacco counselor. The counseling session will be scheduled at the baseline visit. Counselors will review each participant's smoking pattern from the three days of tracking and offer tailored behavioral and environmental change strategies including specific smoking reduction strategy options, such as eliminating cigarettes at work, in the home, or least favorite or most favorite cigarettes of the day, carrying only those cigarettes needed for that day, dropping cigarettes associated with less intense triggers first, avoiding smoking triggers, using oral or manual replacements, and other strategies to manage urges. Since there is inadequate evidence that any one of these strategies was more effective than another, participants will be encouraged to choose those that are most appealing. Goal setting, and barriers identification will be used to help participants improve confidence in their ability to reduce the number of cigarettes they smoked (Josephs 2008).

In Summary, the baseline visit includes 1) completion of baseline survey, 2) registering subject on text messaging program, 3) have subject practice using the text message program, 4) proactive using e-cigarette 5) make appointment for counseling session and for returning to pick up e-cigarettes.

Participants will be encouraged to reduce the number of cigarettes smoked daily to at least 50% of the total number of cigarettes smoked per day at baseline. This level was selected a priori as a clinically significant measure of reduction and to be a substantial enough reduction to address partial compensatory smoking (Glasgow 2009). Participants will be encouraged to substitute the use of the e-cigarettes for each cigarette they eliminate in order to reduce nicotine withdrawal symptoms.

After the counseling session, they will return to 227 east 30th street to pick up their supply of disposable electronic cigarettes to last one week. They will be reimbursed for travel expenses. At the end of week

1 of ecig use, they will be asked to return to replenish the e-cigarettes for another 2 weeks and to complete a second in-person assessment. The final study visit will be 3 weeks post starting e-cigarettes. We will conduct in depth interviews with a random sample of 10 participants in each intervention arm at the week 1 and 3 study visits. The first visit will focus on a process evaluation of the data collection experience and satisfaction with e-cigarette use while Week 3 interviews will focus on gaining more in-depth understanding of their experience (ease of use, satisfaction) with the product over time, e-cigarette related outcome expectancies and norms and explore intentions to quit and/or continuing dual use of cigarettes and e-cigarettes.

Figure 2. Assessments and intervention period

Data collection and Measures

Baseline assessments: *Demographic information*: age, race/ethnicity, gender, years of education, employment, income; *Smoking history*: number of cigarettes smoked per day, number of years as regular smoker; use of other tobacco products or e-cigarettes, number of previous attempts in the past 12 months; *Other smoking related information*: self-rated importance and confidence to reduce and to quit, intention/readiness to quit using the readiness ladder, risk perceptions about e-cigarettes and combustible cigarettes, social norms related to using cigarettes and e-cigarettes, an assessment of urges to smoke using the QSU-Brief survey, other household members smoking at home; and the *Behavioral factors in smoking dependence scale* (Glover 2005*)*. We will also measure carbon monoxide and collect saliva for cotinine measurement at baseline and study visit 3.

Follow-up assessment study visits: At 1 and 3 weeks, we will assess withdrawal symptoms using the Minnesota Nicotine Withdrawal Scale (MNWS), e-cigarette use, cigarette use, quit attempts, and reduction in number of cigarettes used/day. Using Atkinson's treatment satisfaction scale, we will assess side effects associated with using the e-cigarette, convenience of use, perceived effectiveness, and global satisfaction with the product (Atkinson 2004). At the final study visit (week 3) we will also assess changes in baseline readiness to quit, intention to quit, norms related to smoking and using e-cigarettes, confidence in quitting and changes in intention to quit. At 12 weeks post starting e-cigarettes we will conduct follow up telephone surveys to assess current e-cigarette and cigarette use.

At each follow up assessment, RAs will complete a checklist for all of the activities including, completing surveys, and providing e-cigarettes. Note that we will schedule visits up to 4 times. If the subject misses all of those visits he/she will be considered lost to follow up. We will also attempt to contact subjects up to 10 times at different hours of the day and via text message to schedule or reschedule appointment to increase retention rates.

Table 1. In person survey assessments

Measures	**Screener**	**Baseline**	**Wk 1**	**Wk 3**	**Wk 12 telephone**
Socio demographics	X				
Smoking history and nicotine dependence		X			
Other tobacco products and marijuana use		X			
Readiness to quit		X		X	

Importance and confidence in quitting		X		X	
Smoking urges for traditional cigarettes (QSU-Brief)		X		X	
Self-efficacy questionnaire (SEQ12)		X		X	
Secondhand home policy and other smokers at home		X		X	
Risk perception (e-cigarettes)		X			
Social norms		X		X	
History of E-cigarette use		X		X	
Health status		X			
Behavioral dependence scale		X		X	
Current E-cigarettes use		X			
Treatment satisfaction scale (Side effects, Effectiveness, convenience related to e-cigarettes)			X	X	X
Minnesota Nicotine Withdrawal Scale			X	X	
Current cigarette use 1. Someday, every day, not at all 2. Number per day on days smoke (Self-report and CO and saliva validated abstinence		X	X	X	X
Quit attempt (24 hour) in past week			X	X	X
Acceptability and Receptivity to txt messages			X	X	X

Text message assessment:

We will send questions via text messages for a total of 24 days (3 days of baseline assessment of cigarette use and 21 days of dual use with e-cigarette). The first phase of data collection will include a three-day baseline assessment of the study participants' usual smoking pattern. This will begin the day after the baseline assessment. Participants will receive text messages approximately every 4 hours (4 times/day). The questions will only ask about cigarette use in the previous time period, mood and cravings (Table 2). We will wait until the study participant responds to the first message before sending each follow up message. Depending on the participant's answer to whether or not they have smoked a cigarette and/or E-cigarette in the previous time period, they might receive different combinations of questions. For example, there are 6 questions in the first message each day for the 3 day baseline assessment of cigarette use. However if the participant has not smoked any cigarettes in the previous time period, they will only receive 3 of the questions. Each question is sent to the participant only after the previous one receives a response.

During the intervention stage which will last 3 weeks, we will again send text messages 4 x/day. These messages will assess the following 1) number of cigarettes smoked in the previous time period, 2) use of e-cigarettes, 3) satisfaction with cigarettes and/or e-cigarette ("On a scale of 0-9 how pleasurable was the last [cigarette/E-cigarettes]?"), and 4) cravings (**"**On a scale from 0-9 how much do you want to smoke a CIGARETTE right now?"). The first text of the day will also ask how soon after waking participants smoked a cigarette and used an e-cigarette and if they used cigarettes, how much do they want to smoke fewer cigarettes than usual and how hard it would be to use E-cigs only. Questions about use of e-cigarettes will include the following: 1) how many separate times in the previous time period did you use your e-cigarette ("time" is defined as around 5 or more puffs or 5 or more minutes of use), 2) On average, how many puffs did you take with each use, and 3) How many minutes ago was your last E-cigarette puff? We will use numerical scales because our experience has demonstrated that this allows for more accurate data collection.

If subjects do not return any messages for a 24 hour period we will contact them by phone to assess if there is a problem with receiving the texts.

Table 2. Text messages and schedule

Rule (based on answer to the first question)	Text	3 days baseline tracking cig use				Intervention period			
		1st	2nd	3rd	4th	1st	2nd	3rd	4th
	Since your last report: Did you smoke a cigarette and/or E-cigarette? [no=0; cig=1; Ecig=2; both=3]	X	X	X	X	X	X	X	X
	Thinking about this morning, how many minutes after waking did you smoke your first cigarette? (Text 9999 if you did not smoke any cigarettes today)				X				X
	Thinking about this morning, how many minutes after waking did you use your first E-cig? (Text 9999 if you did not use any E-cigs today)								X
	Thinking about TODAY only: Do you want to smoke fewer cigarettes than usual? [0=Not at all ; 9=Very, Very Much]					X			
	Thinking about TODAY only: How hard would it be to use E-cigs ONLY? [0=Not at all ; 9=Extremely]					X			
If used cig	Since your last report: How many cigarettes did you smoked?	X	X	X	X	X	X	X	X
If used cig	How many minutes ago did you smoke a cigarette? [Text "0" if your are currently smoking]	X	X	X	X	X	X	X	X
If used cig only	On a scale of 0-9 how satisfying was your last cigarette? [0=Not at all – 9=Extremely Satisfying]	X	X	X	X	X	X	X	X
If used e-cig	Since your last report: How many separate times did you use an E-cigarette?					X	X	X	X
If used e-cig only	On average, how many puffs did you take with each use?					X	X	X	X
If used e-cig	How many minutes ago was your last E-cigarette puff? [Text "0" if you are currently using an E-cigarette]					X	X	X	X
If used e-cig	On a scale of 0-9 how satisfying was your last E-cigarette? [0=Not at all – 9=Extremely Satisfying]					X	X	X	X
	On a scale of 0-9, how much do you want to smoke a CIGARETTE right now? [0=Not at all – 9=Very, Very much]	X	X	X	X	X	X	X	X
	Thank you for completing the survey.	X	X	X	X	X	X	X	X

Primary outcome: For Aim 3, the primary outcome will be reduction in CPD and we will summarize this data as the proportion of participants who achieve 50% reduction in CPD at 3 weeks. Smoking reduction will be measured by a combination of self-report, text message data and changes in CO and saliva cotinine between baseline and end of treatment (3 weeks).

Secondary outcomes: We will assess potential side effects associated with e-cigarette use, additional use of other tobacco products and/or marijuana, satisfaction with the e-cigarettes, nicotine urges/cravings and withdrawal symptoms. An exploratory secondary aim includes assessing differences in the primary and secondary outcomes between the intervention arms.

Feasibility measures include: 1) Percentage of subjects screened who are eligible and enroll, 2) percentage retained at 3 and 12 weeks, 3) retention across study conditions, 4) consistency in tracking use of e-cigarettes and cigarettes, and 5) satisfaction with e-cigarettes.

Characteristics of the Research Population
Described above under the study participants section.

Number of Subjects
We expect to enroll 100 smokers total, 50 in each arm.

Gender of Subjects
We would ensure equitable inclusion of both men and women in this study.

Age of Subjects
All subjects will be 21-35. We are particularly interested in studying the effectiveness of e-cigarettes as a harm reduction strategy among young adults as this is an understudied population and one that has demonstrated exceptionally high rates of adoption of this product.

Racial and Ethnic Origin
We will recruit across all racial and ethnic groups.

Inclusion Criteria
All subjects must be between 21-35 years old, daily smokers, smoke at least 10 cigarettes per day, interested in reducing CPDs, able to provide consent, use a cell phone, are willing/able to receive and respond to daily text messages regarding their cigarette use and e-cigarette use on their cell phone, and are willing to use an e-cigarette for 3 weeks.

Exclusion Criteria
Subjects will be excluded if they are pregnant and/or breast feeding (self-reported), are currently using smoking cessation medications (including other forms of NRT, buproprion, or varenicline), are enrolled in a smoking cessation program or another cessation trial, have used an e-cigarette in the past 14 days, have used any other tobacco products (pipe, cigar, cigarillos, snuff, chewing tobacco, rolling tobacco, or hookah/shisha) in the past 30 days, score ≥7 (men) or ≥5 (women) on the Alcohol Use Disorders Identification Test (AUDIT-C), score ≥ 5 on the Drug Abuse Screening Test-10 (DAST), or report having a history of asthma, other airways diseases, or heart disease.

Data Analysis and Data Monitoring

All measures collected during study visits and by telephone at 12 weeks, will be summarized for each time point with standard descriptive statistics and frequency tables, as appropriate. Measures with significant baseline treatment group differences (assessed by analysis of variance or chi-squared as appropriate to the primary outcome measure) will be considered for inclusion as covariates in a generalized linear mixed model analysis.

In terms of the EMA data, as per Shiffman (2013), analysis of the EMA data will be handled through several different approaches depending on the research question. For example, if we want to assess differences between individuals with no reference to change over time we can ask if there is a correlation between cravings and e-cigarette use. Data would be collapsed over time, averaging craving ratings for each subject from all signal-contingent assessments in order to derive a single

craving score. Using simple Pearson correlation across subjects we can assess correlations between cravings and e-cigarette use. If we are interested in assessing how craving intensity changes with changes in cigarette use we would use a GEE model (Shiffman 2013).

We will assess multiple aspects of intervention feasibility including the eligibility rate (the proportion of smokers who were eligible for trial participation), the acceptance rate (the percentage of eligible individuals we recruited to the study) and reasons for study ineligibility and refusal. We will compare retention rates in the two study arms at each study visit (weeks 1,3, and 12). We will also assess consistency in tracking use of e-cigarettes and cigarettes, and satisfaction with e-cigarettes (see measures section). We will compute frequencies and percentages for categorical outcomes and means, standard deviations, medians, and interquartile range for continuous outcomes.
As part of our feasibility analysis, we will conduct qualitative interviews with 10 subjects in each arm at 1 and 3 weeks. Interview transcripts will be analyzed with Atlas.ti. A coding manual of core and secondary codes will be developed by Dr. Shelley and Dr. Krebs, both experienced qualitative researchers. Intercoder reliability will be assessed by examining rates of disagreement.

This study will be monitored by NYU School of Medicine's (NYUSOM) IRB in accordance with NIH guidelines on data safety and monitoring of clinical trials (http://cancertrials.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page2).

Data Storage and Confidentiality
This study represents no greater than minimal risk. All data entered into the research database will be protected by confidential entry codes. All participants will receive a permanent unique numerical study identifier (ID#), with no relationship to personally identifying information. In addition, computer records will be maintained in such a way that the patient's name or other obvious identifying factors is not accessible in the same file or using the same code. All computer systems are protected from possible external access. The data collected for this study will be used strictly for the purposes states in this grant application and will only be available to relevant research staff at NYU. We will output de-identified data from the research database to SAS for data analysis. Findings will be presented in aggregate form only with no references made to the individual patient's data.

The principal investigator will regularly monitor the Research Assistant's work over the course of the study and will meet weekly with study team for quality assurance and monitoring purposes, and to review problems or concerns that may arise.

Research Triangle Institute (RTI) will manage the text messaging system. They have extensive experience integrating mobile technology and behavioral research and have developed an onsite system to provide researchers with a gateway (Gateway Manager) for communicating via text with study participants. Prior to launching the system several quality assurance steps will be taken to ensure high quality standards are maintained throughout the implementation phase. These include: system verification prior to starting the study, use of a test device by RTI staff to receive a sample of outgoing messages during the intervention phase to monitor the health of the test gateway in real time, systematic and serial review of the gateway components, and contingency plans to ensure continued message delivery.

Participant cell phone numbers will be entered into the RTI messaging system along with the final database of potential text messages. The Gateway Manager will contain no other personal identifying information, medical or assessment data.

Access to the system will be password protected, employing Extended Validation SSL certificates that provide 256-bit encryption. Both RTI and NYUSM will execute business associate agreements which stipulate RTI's privacy guarantees. NYUSM will have access to messages both sent and received by study participants for process evaluation purposes, but these will only be identified by a PIN. Subjects may be at minimal risk of a breech of privacy if someone else gains access to their phone during the implementation phase. Therefore, we will inform participants of this risk during recruitment and encourage participants to mitigate this risk by 1) not sharing their phone with others, 2) password protect their mobile device, 3) deleting project-related text messages after reading them, and 4) in the event of loss, notifying the RA to terminate service to the device.

RTI International is one of the world's leading research institutes, providing research and technical services to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory testing and chemical analysis. They have an extensive security system in place covering three critical areas: physical security (e.g. limiting data center access to data center technicians, biometric scanning for controlled data center access, 24/7 on-site staff providing additional protection against unauthorized entry) operational security (e.g., using ISO17799-based policies and procedures, which are regularly reviewed as part of the SAS70 Type II audit process; training all employees on documented information security and privacy procedures; restricting access to confidential information to authorized personnel only; logging and tracking systems access for auditing purposes) and system security (e.g. using dedicated firewall and virtual private network (VPN) services to help block unauthorized system access; applying data protection with managed backups).

Risk/Benefit Assessment

Risk

This is a minimal risk study. Subjects may experience side effects from using an inhaled nicotine product including throat irritation, nausea, headache, however these side effects are rare. Of note, nicotine replacement products are available over the counter because of their excellent safety profile.

Protection Against Risks

We will use standard forms to assess side effects that may be associated with nicotine replacement therapies (NRT) and potential adverse events at each study contact. The PI will be on call to speak to the RA, if necessary, at the time of these study visits and will review all reports of side effects within 24 hours to determine if the side effect warrants discontinuing the medication. It is important to note, that our extensive experience with the use of NRT in clinical trials has demonstrated that most side effects can be addressed with additional explanation to patients regarding proper use of the intervention and reminders not to smoke while using nicotine replacement therapy. We will adhere to the NYU School of Medicine IRB policy for reporting adverse events and we will give patients a contact number to call if they experience side effects.

To protect against loss of confidentiality all data entered into the research database will be protected by confidential entry codes. Therefore there will no documents linking the patient's name or any other identifying information to the study data. When we are collecting identifying data, unique identifiers always replace names in the research database. Locked file cabinets will be used to store materials with identifying information (e.g., provider consent forms). All computer systems are protected from possible external access. No internet access is possible with the research systems. The data collected for this study will be used strictly for the purposes stated in this study and will only be available to

relevant research staff at NYU. IRB approval will be sought to any data collection involving human subjects.

All study participants enrolled in the pilot study may withdraw at any time. The PI will report any issues and/or problems identified through their ongoing review of standardized data summary reports which are used to monitor patient accruals, treatment, outcomes and adverse events (if any). The PI will regularly monitor RA's work over the course of the study and will meet weekly with research staff for quality assurance and monitoring purposes, and to review problems or concerns that may arise.

Potential Benefits to the Subjects
Participants will have the potential benefit of reducing the number of cigarettes smoked. Some patients may individually experience no benefit. In the long term, findings from this study will contribute to filling gaps in our knowledge about the most effective methods for helping smokers reduce and/or quit tobacco use.

Investigator's Qualification & Experience
Dr. Donna Shelley has considerable experience studying the implementation of tobacco use treatment guidelines in both medical and dental practices, and studying innovative interventions to increase smoking cessation among disparate populations.

All study staff is required to be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure the confidentiality in order to obtain Institutional Review Board (IRB) approval from NYU.

Consent
Trained research assistants will obtain consent. Participants will be recruited by placing a study ad on Craigslist or another similar venue where the research assistant's number will be placed. If interested they will call the number and be assessed to see if they meet study criteria. If eligible, participants will be asked to come to NYU to meet with study staff. Written consent will be obtained at that first visit. Subjects will be asked if they understand what has been read and if they have any questions. The consent will be read to all subjects. The informed consent process will be ongoing dialogue between the prospective research participants and the RAs.

Costs to the Subject and reimbursement
The subject will incur no costs as a result of participating in the study.

Payment for Participation
Participants will be paid $20 for each in person assessment totaling $60 and $10 for the 12 week follow up telephone survey. They will also receive $4/day (24 days) for each of the four times they receive messages per day and a $1 bonus each day if they answer all of the messages. Therefore each participant can receive up to $190. We propose to send 4-9 messages 4x per day (assessing not only use of e-cigarette and cigs but also craving and/or mood etc) for a total of 681 messages per subject.

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