Study Title: Storytelling Narrative Communication Intervention for Smoking Cessation in Women Living with HIV

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University of Massachusetts Boston Institutional Review Board Protocol

A. Title: Storytelling Narrative Communication Intervention for Smoking Cessation in Women Living with HIV

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PROJECT DESCRIPTION

HIV has transformed into a chronic illness due to the advent of effective treatments in the absence of a cure. As a result, the prevalence of non-AIDS defining cancers (NADCs), including lung cancer, has increased three-fold among people living with HIV. NADCs now account for 50% of all cancers among the people. Smoking is one of the major contributing factors to lung cancer and smoking prevalence is substantially higher in this population than the general U.S. population. Smoking prevalence does not differ by gender among people living with HIV. Women of color, particularly African American women represent the majority of women living with HIV (WLHIV) followed by Latinas. WLHIV smoke at a rate almost 3 times higher than that for the general U.S. female population (e.g., 42% vs. 16%). The proposed study has two phases: 1) the development of a storytelling narrative communication (SNC) intervention that will be added to an established HIV-tailored smoking cessation intervention and 2) a two-arm randomized controlled trial (RCT) of the HIV-tailored intervention plus the SNC Intervention compared with the HIV-tailored intervention only. We will develop narrative videos with three to five WLHIV who will be talking about their personal struggles with smoking and success in quitting. Our preliminary study revealed that the established HIV-tailored intervention was effective only for short-term (≤ 2 months) abstinence. Many relapsed to smoking between the 2nd and 6th month of quitting. We propose that the SNC intervention will be an effective strategy to sustain their quit efforts for long-term abstinence (≥ 6 months). A total of 60 WLHIV will be recruited and randomly assigned to either the experimental arm (a combination of HIV-tailored and SNC interventions) or the control arm (HIV-tailored intervention only).

STUDY AIMS

The Purposes of the study are to 1) Identify SNC intervention components that are rated high in transport and identification for use as an enhancement to an HIV-tailored smoking cessation intervention; 2) Determine the feasibility and acceptability of the SNC intervention for WLHIV by assessing the rate of recruitment and retention for feasibility and the degree of transport and identification for acceptability; and 3) Establish an effect size of HIV-tailored and SNC interventions for smoking cessation in comparison with the HIV-tailored smoking cessation intervention only for WLHIV, for subsequent grant applications.

SIGNIFICANCE OF THE STUDY

People living with HIV now live longer because of the use of highly active antiretroviral therapy.[1-3] However, the burden of non-AIDS related, especially, non-AIDS defining cancers (NADCs) has increased considerably and smoking is a profound cause of NADCs.[3-6] These cancers now account for 50% of all cancers among those with HIV, with lung cancer being the most common and deadliest cancer.[6-]People living with HIV smoke cigarettes at much higher rates than the general U.S. population i.e., 40-80% versus 19%.[1,7-9] There is no gender difference in smoking prevalence among people living with HIV. Women living with HIV (WLHIV) smoke at a rate almost three times higher than that for the general U.S. female population.[9] Given the strong association between smoking and the development of lung cancer, smoking cessation interventions that are tailored to the group are critical to decrease the morbidity and mortality associated with lung cancer.

Women of color, particularly, African American women in the United States represent the majority of WLHIV followed by Latinas.[10] Blacks bear a disproportionate share of cancer burden, having the highest death rate and shortest survival of any racial or ethnic group for most cancers.[11-13] Five-year relative survival is lower for Blacks than for Whites in most cancers at each stage of diagnosis.[11] The majority of participants in smoking

cessation studies for people living with HIV were males (> 80%) and studies conducted with WLHIV are very scarce.[14] Compared to men, women face more barriers to seeking treatment, including transportation and childcare issues.[15] A smoking cessation intervention that can be accessible at home may be an alternative strategies to reach WLHIV.

The effect of storytelling narrative communication (SNC) on an individual is largely determined by personal relevance, the perceived sensitivities to the risks and benefits that the stories effectively convey, identification with the storytellers, and the transformation of the individual from identification within the narrative.[16-22]This SNC intervention will relate one's personal story, which has culturally sensitive and gender-specific narratives to WLHIV for strong identification. The effect of the intervention is to increase emotional engagement and to break down cognitive resistance through absorption in the storyline and identification with characters in the narrative.[16-19] Another advantage of the narrative over alternative informational approaches includes its ability to more effectively reach audiences who have little knowledge of the health issues that may affect them. Storytelling, as a mode of narrative communication, is deeply rooted in African and Latino cultures and has been used to transmit ideas in education and history.[23-29] Recent studies indicate that narrative intervention is an effective, sustainable approach for changing health behavior, including medication adherence and cancer screening.[23-29]

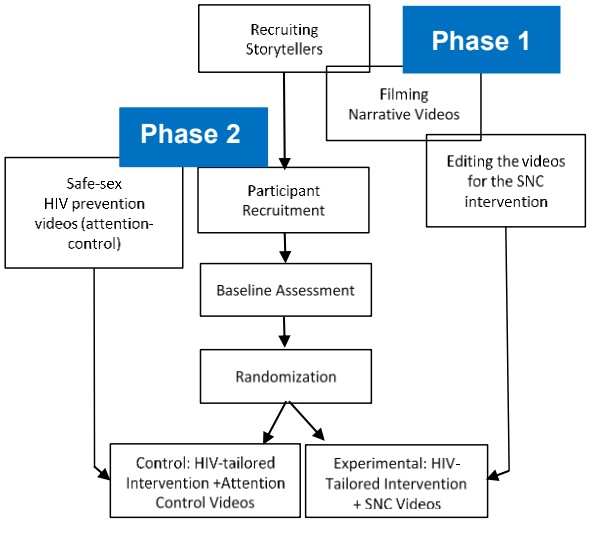
Video call counseling has the advantage of "eye contact" that promotes therapeutic alliance while avoiding transportation hassles among WLHIV. Especially, those who live in a resource-limited area can have virtual face-to-face counseling of an HIV-tailored smoking cessation intervention. Video call also enables researchers to monitor adherence to nicotine replacement therapy (NRT) during the session and validate self-reported abstinence by conducting a real-time saliva cotinine test. Despite these great advantages, video call smoking cessation interventions are very scarce. Contrary to the belief that individuals from low socio-economic classes and ethnic/racial minorities are less likely to use electronic devices such as computers and mobile phones, recent data suggest that individuals from these backgrounds have high rates of mobile phone and text messaging usage.[30,31] In our currently ongoing study with WLHIV, more than 80% of callers owned a smartphone. The proposed study is the first attempt to test the combined effect of video call counseling and the SNC intervention for smoking cessation in WLHIV.

RESEARCH DESIGN AND METHODS

Research Design: The proposed study has two phases.

a. Phase 1. Development of Narrative Video: We will first develop narrative videos in collaboration with community organizations of WLHIV in Boston. The video will be filmed in person at the University of Massachusetts Boston.
b. Phase 2. A Randomized Controlled Trial (RCT) of a Story Telling Narrative Communication Intervention: We will conduct a two-arm RCT assigning participants at a ratio of 1:1 to either one of the two arms (**Experimental:** HIV-tailored plus SNC interventions vs. **Control:** HIV-tailored plus attention-control interventions). Both arms will have eight weekly sessions of a 30-minute HIV-tailored cessation intervention (cognitive behavioral therapy plus nicotine patches). The experimental arm will receive three 5-minute SNC videos (testimonial stories about successful quitting), each per month between the first and third month of quitting, whereas the control arm receive three 5-minute attention control videos (women talking about being diagnosed with HIV) at the same monthly interval. However, participants in the control arm will also receive the SNC videos talking about successful stories of smoking cessation right after the last follow-up assessment (3-month follow-up post-quit). The overall flow of the study is illustrated in Figure 1. All research-related procedures will be conducted remotely.

Figure 1. The overall design of the study



Subjects: A total of 50 WLHIV will be recruited via online and offline advertisements and personal networks of community organizations and health care providers who work for people with HIV. To participate in the study, the following criteria must be met: women who 1) are able to speak English; 2) self-report HIV infection and submit a supplementary document if necessary; 3) are between the ages of 18 and 65; 4) have been smoking at least 5 cigarettes a day for the past 6 months; 5) own a mobile phone with an access to a video call application such as Skype, Imo, Tango, and Face Time; 6) are willing to quit smoking within the next 4 weeks from the baseline assessment; and 7) agree to use an approved form of birth control (e.g., oral medications, condoms, and intrauterine devices) during the study period. Individuals will be excluded if they: 1) are not able to speak English; 2) are pregnant or lactating; 3) have an active skin disease or serious alcohol use problems (≥ 26 on the Alcohol Use Disorders Identification Test [32]), 4) self-report currently receiving treatment for a serious mental illness (e.g., schizophrenia and bipolar disorder); or 5) currently use any illegal substances.

Recruitment and Retention Procedures: We will recruit participants via adwords.google.com, craigslist.com, and other offline advertisements such as advertisements on HIV/AIDS-related news magazines. We will first screen for eligibility and **the following screening interview script will be used:**

1. Can you speak English? Yes
2. Have you been diagnosed with HIV infection? Yes
3. What kind of medications are you currently taking for HIV infection? (This question is asked as a way to verify HIV infection)
4. How old are you? In between 18 and 65
5. How many cigarettes on average have you been smoking a day? 5 or more cigarettes per day
6. How long have you been smoking? At least for the past 6 months
7. Are you willing to quit smoking within the next four weeks? Yes
8. Are you willing to use nicotine patches? Yes
9. Do you have any active skin disease? No
10. Have you had emotional complications such as feeling anxious and depressed around quitting smoking? No. If the caller answers “yes” to this question, we will ask whether the quit attempt was made with or without assistance. We will also ask the severity of the complication(s). If the caller answers that the complications were so distressing and required treatment, she will be excluded from the study.
11. Do you currently receive treatments (counseling and pharmacotherapy) for any of these illnesses: Depression, Alcohol Dependence, Schizophrenia, Schizoaffective Disorder, and Bipolar Disorder? No
12. Do you currently use any illegal substances except marijuana (weed)? No
13. Are you pregnant? No
14. Are you currently using any method of birth control? Yes. We will then ask the caller to specify what type of birth control she is currently practicing. If no, we will ask whether the caller is willing to practice birth control during the intervention period (3 months). Only those who use or agree to use an approved form of birth control (e.g., oral medications, condoms, Depo Provera injection, and intrauterine devices) will be accepted into the study.
15. Are you currently breast-feeding? No
16. Do you agree to use birth control pills or devices during the study period? Yes
17. Do you have access to a telephone and an Internet-connected computer? Yes

Those who are determined to be eligible will receive an informed consent form as an image (the consent form). They will be asked to read the form and given an opportunity to ask questions if they have any. After all questions answered, they will be asked to send a text message by typing their full name and date if they want to participate in the study. The text message will be photographed and kept as a record. The participant then will be interviewed via telephone-based video call for baseline questionnaires, which will take 30 minutes on average. Upon completion of informed consent form and baseline questionnaires, participants will have eight weekly counseling sessions of a 30-minute HIV-tailored cessation intervention (cognitive behavioral therapy plus nicotine patches).

Study Procedures:

1. Phase 1. Development of Narrative Videos: A video divided into three sections, each section for 5-7 minutes will be produced by “Star” story tellers who are eloquent and have authentic personal experiences of quitting smoking. They will be WLHIV identified in collaboration with the community organization of WLHIV “Healing Our Community Collaborative”. Each woman will share her personal journey of quitting smoking focusing on (1) why she decided to quit smoking, (2) what helped her quit, (3) how she avoided smoking temptations, and (4) what changes she made to continue abstinence.

2. Phase 2. An RCT of a Storytelling Narrative Communication Intervention: Counseling contents will be primarily drawn from a cognitive behavioral therapy foundation, which is guided by Bandura's Social Cognitive Theory.[33,34] Within the theory, self-efficacy, that is, the conviction that one can successfully execute a behavior required to produce the outcome is viewed as the most influential determinant of the behavior and its appraisals are based on the following four: performance accomplishment, vicarious experience, verbal persuasion, and physiological state. Participants will have eight weekly counseling sessions and the duration of the sessions is approximately 200-240 minutes over 8 weeks. They will be counseled to enact small changes that are accomplishable, which will be the source of performance accomplishment. Both HIV-tailored and SNC interventions will augment self-efficacy via vicarious experience and verbal persuasion. The NRT will further increase self-efficacy by targeting physiological state. To prevent attrition, we will execute several strategies, including tracking subjects at least every month and providing incentives for follow-up tests. Counselors will proactively call participants prior to each therapy session and confirm the appointment a few hours before the session. A research assistant (RA) will conduct all follow-up assessments via telephone calls and video call for saliva cotinine tests. Regardless of smoking status, participants will receive a Visa gift card worth $25 at each follow-up assessment (post-quit 1, 2, and 3 months). Any participants who report abstinence at post-quit 3 months will be asked to do the salivary cotinine test via a video call on a smartphone and receive another Visa gift card worth $25 upon completion of the test. Those who complete all three follow-up assessments will receive one time bonus of a gift card worth $100.

   Individual counseling before the quit day. The main focus of the first session will be assessing each participant' readiness for smoking cessation and accordingly setting the target quit day. The day will be usually set between the third and fifth sessions. Pre-quit sessions will be focused on preparing participants for the quit day, which includes counseling to delay smoking the first cigarette at least 30 minutes after awakening and expanding smoking free areas inside the house until complete smoking ban is established at least a week before the target quit day. As a form of knowledge development, the effects of smoking on people with HIV will also be highlighted during the first session. The second session will be geared toward explaining neurobiological changes associated with nicotine addiction and immediate health benefits of quitting. The session (usually the third or fourth one) right before the quit day will be focused on explaining the underlying treatment mechanism of transdermal nicotine patches and gums. During the session, correct usage of nicotine patches and gums, their possible side effects, and how to manage the side effects will be educated. Skills training for situational smoking temptations will be provided with role plays so that participants can learn coping strategies that are known to be effective for avoiding lapses and relapses.

   Individual counseling after the quit day. Post-quit sessions will vary by individual needs depending on abstinence status and the severity of nicotine withdrawal symptoms. Thus, the number of cigarettes smoked for the past 7 days will be assessed at each post-quit session using the 7-day Timeline Follow-back Scale.[35] Minnesota Nicotine Withdrawal Scale will be assessed prior to counseling at each session and participants will be counseled accordingly depending on severity of nicotine withdrawal symptoms.[36] Participants will be counseled to utilize the 4D (Deep breathing, Drink Water, Distract, and Delay) behavioral strategies when they experience nicotine withdrawal symptoms.[37]

   Nicotine replacement therapy. Participants in both arms will receive a free supply of nicotine patches (Habitrol Patches, Novartis, Denmark) via post office mail at two separate occasions: first 4-week supplies of 21mg and then 2-week supplies of each 14mg and 7mg together. Those who smoke between 5-9 cigarettes will receive 14mg for 6 weeks and then 7mg for 2 weeks. Those who report difficulty using patches due to skin reactions and who earn a high score (≥ 7) on the Fagerstrom Test for Nicotine Dependence[38,39] will receive nicotine gums (2 or 4mg, Habitrol Gums, Novartis, Denmark). Adherence to nicotine patches and gums will be monitored asking number of patches and gums that they have used for the past 7 days. Prior to receiving nicotine patches and gums, participants will be instructed as to correct usage and possible side effects of the products, and which side effects that they should report immediately. Nicotine replacement products will be used in the study in accordance with their FDA approved labeling.

   Video Watching. Participants in both arm will be randomly assigned to either the SNC or attention-control interventions and accordingly receive the videos of either quitting smoking or being diagnosed with HIV infection, respectively. Participants in the control arm will also receive the SNC videos of quitting smoking right after the last data collection that is 3-month follow-up post-quit.

Saliva Cotinine Test. Participant who report abstinence at 3-month follow-up will receive two NicAlert™ test kits in 2-3 days via express mail. They will conduct the test at home and hence, there is no transportation of samples. Research staff will inform that participants should not open sealed test strips before the test. She/he will also inform them that they should not eat or drink for at least 30 minutes before the test. The staff person will assist them in testing by providing following step-by-step instructions.

1. Take out collection tube and funnel from the white vinyl bag.
2. Put the funnel in a collection tube.
3. Spit into the collection tube through the funnel until the tube is half full.
4. Discard the funnel and close the tube with a cap until you hear click.
5. Tear off the sealed white wrap and take out the test strip inside
6. Put the strip on the flat surface.
7. Squeeze the collection tube while holding it upside down
8. Have at least eight full drops of saliva drip from the tube onto the white padded area of the test strip (right below the three green arrows).

A research staff member will closely monitor the whole process via the video call. She/he will be blind to treatment condition. The person can read the result of the test when the blue line on top of the strip disappears, which usually takes 20-30 minutes. She/he will ask participants to take a photo of the strip right after the video call and send it to her/him. Then, the person will share the photo with other research staff to validate one's reading of the result.

Study Measures and Assessment Procedures: Baseline and three follow-up assessments will be conducted by telephone survey. All measures (see Table 1 below) have been tested and validated for use with WLHIV. Those who report abstinence will receive NicAlert® test kits at 3-month follow-up by a post office mail right before the follow-up assessments. As described above, participants will be guided step-by-step to perform the test while the whole process being closely monitored by research staff via a video call.

Table 1 Assessment schedule of study measures

Variables	Measure	Base	1M*	2 Ms*	3 Ms*
Demographics	Demographic Datasheet	✓			
History of HIV Infection	Year of the diagnosis, CD4 cell count, and viral load	✓			
HIV-medication Adherence	CASE Medication Adherence Scale [40]	✓			
History of Smoking and Quitting	Smoking and Quitting Datasheet	✓			
Stigma and Secrecy	HIV-related Stigma Scale [41]	✓			
Alcohol Use	Alcohol Use Disorders Identification Test (AUDIT) [32]	✓			
Depression	Patient Health Questionnaire-9 [42]	✓			✓
Anxiety	Generalized Anxiety Scale-7 [43]	✓			✓
Nicotine Dependence	Fagerström Test for Nicotine Dependence [37,38]	✓	✓	✓	✓
Self-Efficacy	Self-Efficacy Scale [44]	✓	✓	✓	✓
Nicotine Withdrawal	Minnesota Tobacco Withdrawal Scale [36]		✓	✓	✓
Narrative Engagement	The Measure of Narrative Engagement [19]			✓	✓
Program Evaluation	The Client Satisfaction Questionnaire [45]		✓	✓	✓
Abstinence or Cigarette Consumption	7-day Timeline Follow-back Smoking Behavior [35]		✓	✓	✓
	Saliva Cotinine Test (NicAlert®)				✓
Treatment Fidelity	Intervention Fidelity and Competence Scale (Kim, unpublished work)		✓	✓	✓

Power and Sample Size: This study aims to establish a preliminary effect size. In the currently ongoing study, abstinence rate for the video arm was 75.5% at post-quit 1 month but dropped to 20.0% at post-quit 3 months. For a two-sided test at a 5% significance level, 52 participants are required per arm to have 80% of power for abstinence rates 45.5% vs. 20%.[46] As a pilot study, we will recruit 50 subjects (25 per arm).

Data Analysis: Data analysis will be done in collaboration with the **U54 Research Design and Analysis Core**. Prior to data entry, data will be reviewed and double-checked for completeness and coding errors first by a research assistant and then by a data manager. An intention-to-treat analysis strategy will be used for cessation outcomes with missing values.

Specific Aim 1: Identify storytelling narrative communication (SNC) intervention components that are rated high in transport and identification* for use as an enhancement to an HIV-tailored smoking cessation intervention (*Narrative Understanding, Attentional Focus, Narrative Presence, and Emotional Engagement). Through two local networks of Black WLHIV in which Dr. DeMarco is a key collaborator, we will identify volunteers who have quit smoking and film them while they tell their story of quitting. We will ask them structured questions based on Bandura's Self-Efficacy Model to elicit the story components. When the film is edited effectively for clarity of content and length, it will be tested for acceptability using a mix-methods approach. Using focus groups the film will be shown and participants will be asked what they liked the most and the least about the film. These data will be analyzed for saturation through thematic analyses.

Specific Aim 2: Determine the feasibility and acceptability of an SNC intervention for smoking cessation for WLHIV by assessing 1) the rate of **recruitment** and **retention** for feasibility and 2) the degree of **transport** and **identification** for acceptability in the narrative enhancement. We will identify and describe the time to recruitment and any barriers. We will also describe reasons for study refusal and compare refusal rates by age ranges and number of cigarettes smoked per day, using χ^2 and t-tests. We will compare attrition rates at each follow-up by intervention condition and abstinence status, using Mann-Whitney tests. Subjects will complete an Exit Survey, rating their overall satisfaction with the intervention that they have. They will also rate their experience with the SNC videos, using a 7-point Likert-type scale.[45] In addition, the Measure of Narrative Engagement will be used as a quantitative indicator of 1) narrative understanding, 2) attentional focus, 3) narrative presence, and 4) emotional engagement.[19]

Specific Aim 3: Establish an effect size of HIV-tailored smoking cessation and SNC interventions in comparison with the HIV-tailored smoking cessation intervention only for WLHIV by comparing 30-day abstinence rates at 6-month follow-up. We will evaluate the balance of baseline demographics and smoking behavior between the two arms, using t-tests or Mann-Whitney tests for continuous variables and χ^2 tests for categorical variables. We will examine differences in continuous or 7-day point-prevalence abstinence rates between the two arms, using the χ^2 tests. Individuals who are not available at follow-up assessments or yield a cotinine test result higher than the cutoff level of 0 (cotinine level 0-30mg/ml) will be all treated as smoking. We will calculate an effect size by comparing 30-day abstinence rates at 6-month follow-up point between the two arms. We will also explore longitudinal logistic regression models under the framework of generalized linear mixed models to examine the relationships between abstinence status and intervention conditions over time.

PROTECTION OF HUMAN SUBJECTS

Consent Form: The consent process described pertains to RCT subjects in Phase 2. Dr. Kim or research assistant (from now they will be referred to as research personnel) will conduct a brief screening interview when a person makes an initial contact. If the person is not eligible, the research personnel will stop the interview and destroy the data. If the person is eligible, the research personnel will explain the purpose of the study and its procedure, including voluntary nature of study participation, and random assignment into one of two intervention conditions. The research personnel will then send five page photos of the consent and allow time for the caller to read and ask questions. After having answered all questions accordingly, the research personnel will ask the caller to text her full name and date if she agrees to participate in the study. Once the text message is received, the research personnel will make a video call and collect baseline data.

Potential Risks: This study constitutes minimal risks to subjects and interventions provided are accepted forms of treatment such as behavioral therapy and over-the-counter medications. Nevertheless, subjects may have the following potential risks. **First,** subjects may experience nicotine withdrawal symptoms after quitting. **Second,** they may also experience side-effects of nicotine patches and gums. Although nicotine patches and gums are FDA approved first-line cessation medications and relatively safe, some may experience side effects that require a medical attention. The most common adverse effect of nicotine patch is topical skin irritation ranging from mild erythema to a more generalized skin reaction, frequently in subjects with a history of eczematous dermatitis. The most common adverse effect of nicotine gum are diarrhea, dry mouth, jaw pain, muscle pain, nervousness, sweating, and weakness. Other potential side effects of nicotine patches and gums include hypertension, dizziness, insomnia, abnormal dreams, and abdominal discomfort. **Third,** subjects may feel uneasy and depressed when they talk about their smoking particularly after relapsing to smoking. **Fourth,** potential risk is loss of privacy or breach of confidentiality.

Protection against Risks: To prevent or minimize nicotine withdrawal symptoms, we will provide via secured post office mails nicotine patches to all subjects and gums to those who earn a high score (≥ 7) on the Fagerström Test for Nicotine Dependence.[38] Dr. Kim and students who are trained will counsel subjects, focusing on coping strategies that have been found effective in dealing with the withdrawal symptoms. For example, students will educate smokers a variety of behavioral strategies to manage the symptoms such 4Ds (Distract, Drink water, Deep breathe, and Discuss). Students will educate them about how and where to apply a nicotine patch, what to do if the patch comes off, how to handle common issues such as taking a shower, and how to dispose of a used patch. Students will also explain that they should chew nicotine gum slowly, until they feel a tingling sensation or a 'peppery' taste (usually after about 10 chews). Then rest it for one minute under their tongue, or between their cheek and teeth. This allows the nicotine to pass though the lining of their mouth. They should continue this 'chew - rest' sequence for 30 minutes, then throw away the gum. They should avoid eating and drinking 15 minutes before, and during, use of the gum (except for water). Acidic foods or drinks, such as orange juice, coffee, beer and soft drink, interfere with the amount of nicotine passing through the lining of their mouth from the gum.

During sessions, counselors will educate side effects of nicotine patches/gums and their proper managements. They will provide an emergency contact number (Dr. Kim's cell phone) to all subjects and instruct them to call the number if they experience any serious side effects of the medication such as nausea and vomiting. Counselors will monitor every subject weekly for the first four weeks of the medication and monthly thereafter during the remaining 4-weeks of the medication and at 1- and 3-month follow-ups. Nicotine intake during pregnancy is associated with an increased risk for spontaneous abortion, increased prenatal mortality, and with low infant birth weights. The safety of nicotine in nursing infants has not been clearly established. Thus, we will **exclude** pregnant women, nursing mothers, and women who are not using an acceptable form of birth control from the study.

Data and Safety Monitoring: Dr. Kim will document adverse events, and share copies of all forms and correspondences related to the adverse event with subjects' primary care provider if necessary after we obtain permission from subjects. Dr. Kim will *promptly* report to the IRB any unanticipated problems involving risks to subjects or others (i.e., events meeting the criteria described in section 1 of the UMB unanticipated problem report form. Dr. Kim will also periodically report a summary of the adverse events to the IRB or when we seek an annual re-approval of the protocol at a minimum. The summary will include the number of subjects enrolled in the study and a summary of graded adverse events to date. Dr. Kim will evaluate the frequency and severity of any adverse events and determine if modifications to the protocol or consent form are required.

Confidentiality: All study procedures will be in accordance with the approval by the UMB Institutional Review Board. To ensure confidentiality, each participant will be assigned a unique study ID code, collected data will only be linked through a code number to any identifying information such as name and telephone number. The file linking participants'' names and code numbers will be stored in a locked file cabinet in the office of Dr. Kim. All data obtained from participants will be kept confidential and only aggregated, combined results will be reported.

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