TITLE: Integrating Financial Management Counseling and Smoking Cessation Counseling to Reduce Health and Economic Disparities in Low-Income and Immigrant Smokers

STUDY#: s16-02177

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1. ABSTRACT

Smoking is the leading preventable cause of death in New York City (NYC), and people with low income, including many immigrant populations, living in NYC are more likely to suffer from smoking-related mortality. However, there have been limited efforts to develop tobacco use programs specifically for low-income or immigrant populations. Prior research has found that low-income smokers face unique barriers to cessation, including financial distress, negative outcome expectancies, depressed mood, an externalized locus of control, and an increased focus on immediate needs at the expense of delayed goals. Financial counseling is effective at improving financial knowledge and outcomes, and offers the opportunity to reinforce the financial rewards of quitting while simultaneously improving the financial circumstances and associated barriers to abstinence in low-income smokers. We propose a pilot project that will evaluate an innovative program that integrates financial counseling with smoking cessation counseling for low-income and immigrant smokers at Bellevue Hospital Center and Lutheran Medical Center. The project will achieve the following specific aims: (1) Estimate the acceptability of the integrated program and its effect on participants' financial stress, mental wellness, quit attempts, and abstinence from cigarettes; (2) Estimate the per-patient cost of the integrated program; and (3) Identify barriers and facilitators toward wide-scale implementation of the program model. To accomplish these aims, we will conduct a two-arm randomized, wait-list control study. We will recruit 600 smokers to complete a 9-week intervention that integrates financial management and smoking cessation counseling. Participants will be randomized (300 per arm) to receive the intervention immediately after enrolling (Intervention Arm) or 6 months later (Waitlist Control Arm). Both arms will receive nicotine replacement therapy (NRT) for four weeks during their time in counseling. We will survey patients at baseline, 6 and 12 months to assess outcomes and their satisfaction with treatment. Additionally, we will recruit and interview hospital staff (N=5 per site, 10 total) to assess their perceptions regarding barriers and facilitators toward downstream implementation of the intervention.

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1 Background

Smoking is the leading preventable cause of death in New York City (NYC), and people with low-income, including many immigrant populations, living in NYC are more likely to suffer from smoking-related mortality. Further, immigrants in NYC – particularly those of Chinese, Dominican, Mexican, and Puerto Rican descent – often live in poverty, placing them at distinctly high risk for smoking, morbidity, and mortality. Indeed, previous research has found that rates of smoking among low-income households are three times higher than those among high-income households, and this income disparity in tobacco use has persisted over time. However, despite the chronic income disparity in tobacco use and high rates of smoking among immigrant populations, there have been limited efforts to develop tobacco use programs specifically for low-income or immigrant populations.

Prior research has found that low-income smokers face unique barriers to cessation, including financial distress, negative outcome expectancies, depressed mood, an externalized locus of control, and an increased focus on immediate needs at the expense of delayed goals. Of particular concern is that tobacco use can exacerbate financial strain by limiting funds to pay for other goods and services. In New York, smoking households spend approximately $1,100 year on tobacco – money that could otherwise be spent on household essentials such as food, clothing, and health care. Previous research has found that smoking households are more likely to experience food and housing insecurity and spend a larger proportion of their budget on tobacco than on health care. In NYC in particular, smokers living in the lowest income level can spend almost 30% of their budget on cigarettes. Our prior work has found that tobacco cessation is associated with reduced spending on alcohol and entertainment, and with increases in household savings. Thus, tobacco cessation can improve both the health and the financial well-being of low-income smokers.

Evidence supports the effectiveness of financial incentives to increase abstinence rates in low-income populations by providing reinforcement for quitting. However, providing cash payments for quitting may not produce sustained behavior change and raises ethical concerns over the exploitation of low-income populations' economic vulnerability without providing assistance with their underlying financial conditions. In contrast, financial counseling is effective at improving financial knowledge and outcomes, and offers the opportunity to reinforce the financial rewards of quitting while simultaneously improving the financial circumstances and associated barriers to abstinence in low-income smokers. Money management counseling has been shown to improve health and economic outcomes in patients using cocaine and/or alcohol. We aim to adapt this model by integrating money management counseling with smoking cessation counseling.

2.2 Aims

1. Estimate the acceptability of the integrated program and its effect on participants' disposable income, savings, financial stress, mental wellness, and abstinence from cigarettes.
2. Estimate the per-patient cost of the integrated program.
3. Identify barriers and facilitators toward wide-scale implementation of the program model.

2.3 Study Design

We will conduct a two-arm randomized, wait-list control study. We will recruit 610 participants total: 600 patient participants and 10 staff participants. We will recruit 600 smokers to complete a 9-week intervention that integrates financial management and smoking cessation counseling. Participants will be randomized (300 per arm, stratified by site) to receive the intervention immediately after enrolling (Intervention Arm) or 6 months later (Waitlist Control Arm). Both arms will receive nicotine replacement therapy (NRT) for four weeks as part of their time in integrative counseling. We will survey participants at baseline, 6 months and 12 months to assess outcomes and their satisfaction with treatment. The first 150 enrollees will complete an additional 2 month follow up survey. Additionally, we will recruit and interview hospital staff (N=5 per site, 10 total) to assess their perceptions regarding barriers and facilitators toward downstream implementation of the intervention.

2.4 Sites

The study will be conducted at two sites:

2.4.1 ***Bellevue Hospital Center*** is the largest public hospital system in the United States and is one of the New York City Health and Hospitals Corporation's member institutions. It is also the nation's oldest public hospital, established in 1736 as a 6-bed infirmary. The Adult Primary Care Center at Bellevue Hospital will serve as the site for recruitment from Bellevue. The Center provides over 60,000 continuity visits per year to approximately 28,000 active patients with a variety of chronic conditions.

2.4.2 ***Lutheran Medical Center*****,** Lutheran, which merged with NYULMC January 1, 2016, is the largest Federally-Qualified Health Center in NY State and 2nd largest in the US. Its 109 physicians, 43 NPs and PAs, 19 care managers and 4 community health workers care for >100,000 patients at 65 practice sites. As a level 3 patient-centered medical home, the Lutheran network offers a full range of health and dental care, including adult and family medicine, behavioral health, chronic disease management, comprehensive HIV/AIDS services, pediatrics and specialty services.

3. CHARACTERISTICS OF THE RESEARCH POPULATION

There are two groups of participants in the study: Patient participants and hospital staff participants.

3.1 Number of Subjects

We will recruit 610 participants total. 600 recruited participants will be smokers enrolled from any of our recruitment methods outlined in "Patient Participant Recruitment" below. Half of the enrolled participants (300 smokers) will receive the intervention immediately after consent, and the other 300 will receive the intervention after 6 months. Additionally, we will recruit 10 staff participants: 5 staff from Bellevue Hospital and 5 staff from NYU Lutheran.

3.2 Gender of Subjects

There are no enrollment restrictions based on gender.

3.3 Age of Subjects

Age ≥18 years

3.4 Racial and Ethnic Origin

There are no enrollment restrictions based on racial or ethnic origin.

3.5 Eligibility Criteria

3.5.1 Patient participants:

1) age ≥18 years
2) Has smoked a cigarette in the past 30 days, even a puff
3) Interested in receiving smoking and financial counseling
4) Self-reported income below 200% of the current federal poverty level for agiven household composition
5) New York City resident
6) English or Spanish language
7) Able to provide informed consent, and
8) Does not have a representative who manages his/her funds (to ensure the participant has the ability to manage household money). We will exclude participants who report being pregnant or breastfeeding (unable to receive NRT).

3.5.2 Hospital staff participants:

1) Must be current medical or non-medical provider or administrator at Bellevue Hospital or NYU Lutheran Medical Center

3.6 Vulnerable Population

We will recruit 5 employees from each location for the hospital staff interviews and ensure additional safeguards for these subjects. Employees' participation is completely voluntary and without undue influence. Participants will be assured that their employment will not be affected by their decision to participate or not. Any record of staff's participation will not be linked to any type of employee record. None of the study's primary investigators or study team members have any supervisory or management role for the participants in this group nor do they have any effect on employees' evaluation.

4. METHODS AND PROCEDURES

4.2 Patient Participant Recruitment

We will recruit patients using 5 methods. First, we will place flyers (Appendix A) in the waiting rooms of the primary care clinics and social work clinics at each hospital and at the elevator banks on each floor. We will also distribute flyer advertisements in the AM New York and Metro, two free local papers (Appendix Z) and El Especialito, a Spanish local paper (Appendix A). Flyers will describe the study, primary eligibility criteria, and a phone number to call. Patients who call will be screened for eligibility by a trained Research Assistant (RA) over the phone (Appendix C). The RA will schedule eligible participants for an in-person appointment to complete an IRB-approved informed consent process. Additionally, we will advertise on Facebook to English and Spanish speaking smokers located in New York City (Appendix A).

Second, this study will utilize NYUMC DataCore to use the Bellevue and NYU Lutheran's EMR data to identify patients who were screened as current tobacco users during a clinical visit in the

last 12 months. We will need patients' names, date they were screened to be a smoker, contact information (phone, address), preferred language, primary care provider name, and primary health insurance. DataCore will request a report in order to gather the data from EPIC/QuadraMed. We would like this query to be completed 4 times (3 months apart). Only the PI, Research Coordinator and Research Assistants will have access to the EMR search results. For patients assigned a primary care provider in the EHR, the RA will email each patient's primary care provider via secure institutional email (Appendix X) to notify the provider that we be contacting their patient(s) about the study and give the provider the opportunity to let us know not to contact a specific patient. We will wait 4 business days after sending the email to hear back from the provider. If a provider tells us not to contact a patient, we will remove the patient from our recruitment list (destroying his/her identifiers). To all patients on our list who are not identified by a provider as someone we should not contact, the RA will send a letter (Appendix B) and recruitment flyer (Appendix A). One week after mailing the materials, an RA will call the patients to discuss the study, screen interested patients for eligibility, and schedule eligible participants for an appointment to complete an IRB-approved informed consent process. Patients without a primary care provider assigned in the EHR will immediately receive the letter and recruitment flyer in the mail. One week after mailing the materials, an RA will call these patients to discuss the study. The RA will inform these patients of how we received their contact information and also let them know that they do not currently have a PCP listed in their electronic medical record. All identifiable screener data for patients who are deemed ineligible or who do not wish to participate in the study will be destroyed. We will only keep itemized screener data to report to the funding agency, though no PHI will be saved and we will only label participants with a pre-screening number.

Third, at the Bellevue site, we will receive referrals from the hospital's regular smoking cessation program. The smoking cessation program will let patients know about the study and give them the study flyer (Appendix A). The program will ask if they are interested in being referred to our study to learn more about the study. For patients who give permission to be referred, the Belleuve smoking cessation program will send our study team an NYUMC encrypted email with the name and preferred contact information. To all referred patients, a study RA will send a letter (Appendix B) and the recruitment flyer (Appendix A). Two weeks after mailing the materials, an RA will call the patients to discuss the study, screen interested patients for eligibility, and schedule eligible participants for an appointment to complete an IRB-approved informed consent process. All identifiable screener data for patients who are deemed ineligible or who do not wish to participate in the study will be destroyed. We will only keep itemized screener data to report to the funding agency, though no PHI will be saved and we will only label participants with a pre-screening number.

Fourth, we will work with medical center IT to set up a consult in EPIC that allows physicians to refer Lutheran patients to the program. Providers will be given an overview of the study and eligibility criteria prior to implementing the EPIC consult, so that they may filter some of the referrals received. If a patient is deemed eligible for referral, physicians will inform their patients that someone from the study team will contact them within the next two weeks to screen for study eligibility. Providers will also have copies of our study flyer (Appendix A) to hand out to patients who are interested, so the patient may also reach out directly to the research coordinator as directed by the flyer. Each day, a study team member will check EPIC for a list of patients referred by their providers. An RA will contact the patients to screen for eligibility. Those who are eligible will be scheduled for a consent appointment. Patients who are ineligible to participate in the study will be referred to the NY State Quitline. All identifiable screener data for patients who are deemed ineligible or who do not wish to participate in the study will be destroyed. We will only keep itemized screener data to report to the funding agency, though no

PHI will be saved and we will only label participants with a pre-screening number. We will also use EPIC to reach out to potential patients using MyChart. We will utilize EPIC's Slicer Dicer research tool to identify NYU Langone-Brooklyn adult patients that are listed as current smokers in EPIC. If a patient has opted in to being contacted about research studies through MyChart, we will send them a notification (Appendix V) about our study through their MyChart portal. Patients will be able to reach out to our study team directly for screening. Patients who are eligible will be scheduled for consent, and patients who are ineligible will be referred to the NY State Quitline.

Fifth, we will recruit participants in-person by approaching patients in primary care clinic waiting rooms. An RA will identify herself/himself as working on a quit smoking research study, ask if the patient would like to hear more, and then provide the patient with a screening questionnaire to assess eligibility, if interested. If the patient does not fit the eligibility criteria, the RA will thank them and move on to the next person waiting for their clinic appointment. If the person is eligible, the RA will describe the study further and ask if the patient would be interested in enrolling. If the patient is interested in enrolling, the RA will escort the patient to a private room, go through the consent process and baseline survey, and randomize the patient.

Participants will also be recruited through word of mouth referrals. Participants can earn a one-time $20 referral bonus for an eligible person referred and successfully randomized into this study. This referral process will be detailed in the patient's consent form and explained to participants during their in-person consent appointment.

4.3 Patient Participant Consent (Process and Documentation)

All participants will sign IRB-approved informed consent forms prior to completing any study procedures. The study coordinator and/or a trained research assistant will review the contents of the consent form and obtain consent from each of the participants, ensuring that each participant is fully informed of the details of the study and minor potential risks. The signed consent forms will be stored in a locked cabinet within a locked office on NYUMC campus. The research records of enrolled participants will be kept for at least six years after the study is over or as long as the sponsor requires them to be kept. All identifiable information from participants who are deemed ineligible or do not want to enroll in the study will be removed from any tracking or RedCap database.

4.4 Patient Participant Baseline Interview

After obtaining informed consent, a RA will administer a baseline survey (Appendix D) assessing sociodemographics, tobacco use, motivations and readiness to quit, income, financial stress, mood, household spending patterns and other intervention covariates or mechanisms.

4.5 Patient Participant Randomization

At the conclusion of the baseline survey, the RA will open a study database on a computer that he/she will have at the time of informed consent and enter a randomly assigned study ID number. The database will then use a random-number generator (developed under the supervision of the statistician) to assign the patient participant to one of the study arms. The database will store the randomization results and display the results on the screen for the RA, who will inform the participant of his/her group assignment, discuss the details of the assigned intervention, and schedule the patient participant for his/her intervention's first session and follow-up assessments.

4.6 Patient Participant Intervention Delivery

4.6.1 Intervention Arm: Integrated Smoking Cessation and Financial Counseling

Participants randomized to the Intervention Arm will receive counseling that integrates financial counseling and smoking cessation counseling immediately after enrolling in the study. The goal of the financial counseling will be presented to participants as helping them enroll in government assistance programs when needed and helping them manage their funds better to have more for things that make them happy and to improve their quality of life and well-being. The counseling content will be as follows:

Session 1: Session 1 will be in-person and will focus on a tobacco use intake and financial planning and will be comprised of three main components: (1) screening and referral for financial assistance programs, (2) money management counseling and (3) tobacco use and cessation overview. The designated study site-counselor will help the patient participant complete two online surveys assessing their eligibility for New York State and federal benefits. These assessments are provided free to the public through the www.mybenefits.ny.gov (state) and www.benefits.gov (federal) websites and take approximately 10 minutes each to complete. The websites will provide patients with a list of benefits to which they may be eligible with instructions on how to enroll. The counselor will also provide patients with an overview of programs available in New York City (e.g., financial empowerment counseling, housing assistance) and refer the patient to the program when appropriate. Patient participants will have the option to call the counselor in between sessions with follow-up questions or to request assistance in completing online applications for benefits.

Second, the counselor will initiate money management counseling. Dr. Rosen, a collaborator on the project, will train all study counselors in financial counseling prior to the first counseling sessions. Dr. Rosen will not have access to PHI, but will act as a consultant to the study team regarding any issues that pertain to the financial counseling aspect of the study. Participants will first describe their longer-term goals, and based on these longer-term goals, will be encouraged to set shorter-term financial goals for their money management. Next, participants will, assisted by a timeline follow-back calendar, complete an inventory describing their sources of income, expenditures (both monetary and in-kind), debts and asset balances. Based on this inventory, participants will be asked to make a budget based on smoking cessation at the time of their future quit date. This budget will list planned expenditures, with those made possible by smoking cessation highlighted and listed separately to increase their saliency and reward value.

Lastly, the counselor will complete a tobacco use intake and brief counseling (Appendix H) with the participant. Topics covered will include: 1) Assessment of smoking and quitting history, 2) Assessment of current readiness to quit through ratings of "importance" and "confidence", 3) Strategies to raise importance and confidence ratings, 4) Preparations for quitting, 5) Identification of top barriers toward quitting and smoking triggers, as well as coping strategies to address each trigger, 6) NRT use and barriers to use, and 7) Setting a quit date in the next 30 days. Participants will receive a flyer (Appendix Q) on how to use NRT and its possible risks and side effects.

Session 2 (See Appendix H, p. 17): Session 2 will be completed in-person and will begin with follow-up on the prior session's financial counseling to assess short-term goals (e.g., enroll in benefits) and challenges, and then will transition to focus on smoking cessation. Topics covered will again include: 1) Assessment of smoking and quitting history, 2) Assessment of current readiness to quit through ratings of "importance" and "confidence", 3) Strategies to raise importance and confidence ratings, 4) Preparations for quitting, 5) Identification of top barriers toward quitting and smoking triggers, as well as coping

strategies to address each trigger, 6) NRT use and barriers to use, and 7) Setting a quit date in the next 30 days.

Sessions 3 – 9 (See Appendix H, p. 23): Sessions 3-9 can be either in-person or over the phone (depending on patient preference). The counselor will deliver financial counseling prior to the smoking cessation counseling in order to motivate participants to attend to the quitting. Participants will track their progress towards adhering to the budget by reviewing financial transactions during the preceding week, and adjusting their budgets if the original budgets proved to be unrealistic. Tobacco expenditures and savings will be highlighted and tracked separately to increase their saliency and reward or cost value.[64] The composition of the tobacco cessation counseling during these later sessions will depend on each patient's individual quit progress.

4.6.2 Control Arm: Waitlisted Integrated Smoking Cessation and Financial Counseling

Six months after enrolling, participants randomized to the Control Group will receive all of the services described in the Intervention Group section above. Starting 3 weeks before their 6-month time point, study staff will call patients to schedule a counseling appointment (Appendix I). Patients in the control arm will not receive any procedures or counseling in the first six months.

4.6.3 Both Arms: Nicotine Replacement Therapy (NRT)

Participants in both arms will be eligible to receive a free four-week supply of NRT. Following the US Public Health Service guidelines for the treatment of persons who smoke ≥10 cigarettes per day, participants will receive combination NRT (patch plus gum or patch plus lozenge, depending on patient preference).[50] As we have done on other studies, we will order participants' NRT from drugstore.com after obtaining the participants' NRT preference during counseling. Drugstore.com will mail the NRT to our study office before the first counseling session. Counselors will provide the NRT and review proper use during the first session.

4.6.4 Both Arms: Patient Participant Follow-up Surveys

We will conduct a telephone follow-up survey 6 months (Appendix F) and 12 months (Appendix G) after enrollment with all participants. A study team member will make 10 attempts over 4 weeks to complete the survey (Appendix J). We will mail a hard copy or email the survey if participants do not want to complete the survey over the phone. The surveys will re-assess participant behavior and characteristic assessed at baseline, and a short series of close-ended and open-ended questions about satisfaction with the interventions. The first 150 participants will complete an additional 2 month follow up survey (Appendix E) in order to obtain preliminary data. After the first 150 enrollments, the 2 month survey will be retired and the remainder of the 450 enrollments will only complete surveys at baseline, 6 months and 12 months. All enrollees that signed a consent form indicating the additional 2 month survey will be eligible to participate in that survey and will be compensated accordingly. Participants will be paid $15 as reimbursement for their time completing the surveys. The additional follow-up survey (Appendix S) to gain feedback from participants who are NYCHA-residents on their smoking cessation needs will be conducted via phone. Patients being contacted are already enrolled in the study.

4.6.5 Patient Participant Administrative Data

We will obtain written patient consent and HIPAA authorization to conduct review of their medical record to abstract data on health care utilization during the study. This will include total number of outpatient visits and total number of inpatient visits in the 12 months before and after their study enrollment. Staff will also check the EMR for updated contact info.

4.7 Staff Participant Interview Recruitment

Staff recruitment procedures were created to minimize staff burden and to ensure we obtain a representative staff sample. We will use two methods of identifying and recruiting potential staff participants:

(a) Email and phone recruitment: We will request a list of relevant staff (e.g., nurse, physicians at) at each site from clinic and administrative managers. We will send all staff on the list a mass email (Appendix K) to their institutional email address notifying them of the study. The email will include a phone number and email address to contact if they would like to participate or to notify us that they do not want further contact from study staff. The email will inform staff that participation is voluntary and refusing to participate will not affect their employment. For staff who respond indicating they would like to participate, the study's project manager will email or call the staff member at their institutional email or institutional phone number to schedule a time to complete the verbal informed consent process and to conduct the interview. For staff who respond indicating they do not want further study contact, we will remove their name from our recruitment list.

We will send two additional follow ups via email for staff who do not respond to the initial email. The first follow up will be sent one week after the initial email, and the second follow up will be sent one week after the first follow up. Staff who would like to participate will be scheduled for a time to complete an informed consent process and the interview. Staff who refuse participation or whom we are unable to reach will be removed from our recruitment list.

4.8 Staff Participant Interview Consent (Process and Documentation)

We request a waiver of documentation of consent to obtain verbal consent from staff participants. The study coordinator and/or a trained research assistant will obtain verbal consent from each of the staff participants, ensuring that each participant is fully informed of the details of the study and minor potential risks (Appendix O). Additionally, staff will be reassured that their employment will not be affected by their decision to participate or not. Staff who do not wish to participate will have their contact information removed from the study database.

4.9 Staff Participant Interview Procedures

Interviews will be completed in a private room during business hours at a day and time preferred by the staff participant. Using a structured interview guide (Appendix M), the study PI, Dr. Rogers, will ask open-ended questions and follow-up probes that capture staff attitudes and beliefs about the intervention, their feedback on how to improve the intervention, and feedback on how to make it sustainable internally and within other organizations.

5. Data Analysis and Data Monitoring

5.1 Data Analysis

To evaluate the acceptability and feasibility of the integrated intervention, we will calculate the number of counseling sessions completed and satisfaction with treatment, which we will summarize descriptively using count and frequency statistics. We will calculate additional measures of study feasibility and acceptability, including the eligibility rate among people screened, enrollment rate among those eligible, reasons for ineligibility or refusal, and the proportion of participants who would recommend the intervention to other smokers. To estimate the effect of the integrated intervention on outcomes we will use generalized estimating equations (GEE) to model the main effects of time (baseline to 6 and 12 months)

and treatment group, and the interaction of time and treatment, on each outcome. GEE will allow us to determine whether intervention effects are present and whether they change over time.

We will also calculate and sum all time and costs of administering the interventions. Each intervention staff member will record their activity in a web-based intervention tracking system (using REDCap). Staff prospectively input detailed information for a 1-week sample of their activities and associated time required on a monthly basis. Those recording their time and activities have flexibility to add or tailor their entry form to match their exact activities. We will assign a dollar value for each unit of staff time based on the wage and fringe rate of those who perform the activity using regional labor rates from the US Bureau of Labor Statistics. We will also keep track of medications ordered and used by participants, which we will assign a dollar value to using Red Book, a wholesale pharmaceutical pricing index. Once all costs are compiled and summed, they will be adjusted to constant dollars using the medical care component of the Consumer Price Index.

5.2 Data Monitoring Plan

This study will not have an external data monitoring board. The PI will monitor treatment fidelity on a weekly basis by holding meetings with the study counselors to review active patients. Counselors will also keep standardized, electronic documentation of every counseling session in a REDCAp database created for the study, which will be reviewed weekly with the PI. To ensure accuracy of survey data, all paper surveys will be entered twice into study databases, and the two entries will be compared for consistency. Inconsistencies in data entry will be resolved by a third review of the paper survey records. The study team (PI, Co-Is, Research Coordinator) will monitor the quality of patient survey data on a quarterly basis by running data reports showing survey responses rates, as well as missing or invalid values. In addition, to allow for monitoring of adherence to survey procedures, the RAs will use a REDCap database created for the study to document all patient contacts and procedures completed with a patient. The PI and Research Coordinator will monitor adherence to data collection procedures by reviewing monthly REDCap procedure reports. Protocol deviations (either counseling or survey data collection deviations) will be reported to the NYU IRB as per the reporting requirements.

Study staff will document adverse events in a REDCap database created for the study. Adverse events will be monitored daily by the PI. Any adverse event (AE) identified by a study team member (e.g., counselor, RA,) will be reported to the PI within 24 hours. The PI will determine whether the event is a) serious or non-serious; b) anticipated or unanticipated, and c) related to the study or unrelated to the study. The PI will ensure that any necessary actions are taken immediately to address the current patient situation, and then will decide if the team needs to make any changes in the protocol and/or consent forms to prevent future occurrences or better inform future participants. We will report the event to the NYU IRB as per the reporting requirements. Violations of patient privacy/confidentiality will be treated as an AE related to the study and will be addressed immediately as appropriate.

5.2 Data Storage

All participants will be assigned a unique code number that does not identify him or her as an individual. Electronic data will be stored in RedCap and password protected files on NYUMC servers. Paper records will be stored in locked filing cabinets within locked offices at each site. All data will be stored separately from signed consent forms. These study procedures have minimized risk of confidentiality breach in past studies.

5.3 Confidentiality

All study personnel have already taken or will take the mandatory HIPAA and Patient Privacy/Confidentiality training modules required by our institutional IRBs, to ensure that they are aware of the importance of patient confidentiality and all appropriate laws regarding protection against privacy breaches. Procedures will be in place to ensure that all files containing subject information will be kept in locked filing cabinets or password-protected electronic databases on a secure server. The majority of study data and all interview transcripts will be maintained in electronic files with no patient identifiers other than a study ID number; there will be one file maintained separately, with its own password protection, that links study ID numbers to patient identifying information. De-identified data will be stored indefinitely.

No identifiable information about study participants will be disclosed to individuals outside those approved by the IRB to be on the study protocol. No publications that result from the study will identify individual participants. Identifiable staff participant interview data will not be shared with interviewees' coworkers or supervisors, even those working on the protocol.

6. RISK/BENEFIT ASSESSMENT

6.1 Risks

Participants are expected to encounter no more than minimal risk, as the study will only be providing evidence-based tobacco cessation treatments. Participants who quit smoking during the study may experience nicotine withdrawal. These may include craving, anxiety, problems concentrating, impatience, depression, irritability, restlessness, and weight gain. This risk is expected as part of the quitting process and minimal.

There may also be a slight risk of breach of confidentiality associated with the survey as researchers will have access to participant contact information. This risk is also expected to be minimal and infrequent and contact information will be stored separately from participant responses.

6.2 Protection Against Risks

All study personnel have already taken or will take the mandatory HIPAA and Patient Privacy/Confidentiality training modules required by our institutional IRBs, to ensure that they are aware of the importance of patient confidentiality and all appropriate laws regarding protection against privacy breaches. Procedures will be in place to ensure that all files containing subject information will be kept in locked filing cabinets or password-protected electronic databases.

Additionally, all study data, including any participant identifiers, will be stored on NYUMC password protected computers, and can only be accessed by study staff. Please see Section 5.2 above for more details about how data will be stored. To address risks related to the possibility of physical or psychological distress, participants will have the option of withdrawing from the study without loss of benefit. Additionally all health information will be protected.

Any adverse event (AE) that the research staff thinks may be related to study participation will be reported to the site PI within 24 hours. The PI will determine whether the event is a) serious or non-serious; b) anticipated or unanticipated, and c) related to the study or unrelated to the study. The PI will ensure that any necessary actions are taken immediately to address the current patient situation, and then will decide if the team needs to make any changes in the protocol and/or consent forms to prevent future occurrences or better inform future participants. We will report the event to the NYU IRB as per the reporting requirements. Violations of patient

privacy/confidentiality will be treated as an AE related to the study and will be addressed immediately as appropriate.

6.3 Benefits

We do not anticipate that participants will receive any direct benefit from participating. However, possible benefits from quitting smoking may include improvement in health.

7. Costs to the Subject

Participants will not incur any costs as a result of participating in the study.

8. Payment for Participation

Patient participants will be compensated $15 for each of the three survey completed during the study. Payment can be in cash or check. Additionally, patient participants will be reimbursed by Metrocard for the travel to and from counseling appointments.

9. Contacting Participants for Follow-Up Feedback Survey

Participants who are enrolled in the study and are current English-speaking NYCHA-residents will be called to complete a voluntary phone survey to gain their feedback on their smoking cessation needs. All patients who will be contacted for the feedback survey have already been previously enrolled in the study.

10. REFERENCES

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