Protocol Title

Tobacco Cessation Tailored to Patients Living With HIV (PLWH) in Brazil

Study Protocol & Statistical Analysis Plan

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Isabel C. Scarinci, PhD, MPH, Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

Feasibility Testing – Research Protocol

We propose to develop and examine feasibility of a tobacco cessation intervention tailored to persons living with HIV in Brazil. We already conducted Phase I (development and pre-testing of the intervention) among 14 participants. Phase II (current amendment) consists of the first iteration of the feasibility testing of the intervention. We will pilot test the tobacco cessation program among 10 persons living with HIV and who meet the inclusion criteria. We anticipate additional changes and adaptations as we pilot test the intervention among 10 participants. We will make adaptations based on their feedback to move to Phase III. The specific components of the intervention, number of sessions, format, etc will be determined in the pretesting phase. However, we anticipate being a mix of in-person, telephone, and WhatsApp contacts. We also anticipate being a mix of cognitive behavior therapy strategies and pharmacological aids. Based on additional feedback obtained in Phase II, we will pilot test the final intervention among 40 participants (Phase III). The specific components will be determined based on results of Phases I and II. If no changes are needed we will proceed enrolling the additional 40 participants in Phase II and Phase III will not be needed.

The primary outcome will be a 7-day point prevalence abstinence (defined as no tobacco use in the past 7 days and verified through measurement of *salivary cotinine and exhaled carbon monoxide (CO) levels*) at 7-month follow-up (from baseline).

Feasibility Testing

The intervention that was developed with input from the target audience during the pretesting phase consists of an initial comprehensive assessment (counseling + pharmacologic) since patients tend to come prepared to spend the day at the reference center to get all the needed services. If they are committed to quitting they will proceed with consenting, visits with the Clinical Psychologist and Pulmonologist. The four visits with the Clinical Psychologist can be in person, video or phone based on patient's preferences. Each patient is different and some may require more visits. The Clinical Psychologist will also provide the participant with the opportunity to send and receive texts for support. We will deliver the active intervention following this pattern for three months given the high risk of relapse within the first three months. Then, participants will continue to be engaged for another three months and monthly "check-ins" with the Clinical Psychologist and Pulmonologist. Follow-up assessments will be implemented at 7 months. The **cognitive-behavioral** component is based on evidence-based strategies but tailored to PLWH based on findings of the formative assessments. The tobacco cessation manual is available in Portuguese upon request.

Pharmacological management will be consistent with the recommendations and aids available through the public health system in order to assure sustainability – nicotine replacement therapy (NRT) and bupropion (if needed). The optimal dose of NRT can be difficult to determine without evaluating tobacco use pattern, comorbidities, and context. Thus, the NRT dose will be determined based on this evaluation. For example, participants who smoke within 30 minutes of awakening or smoke more than 10 cigarettes daily may be offered a higher dose NRT. (61) Others will receive a lower dose therapy with the option of increasing the dosage if physical withdrawal symptoms persist at 2 weeks. Patches will be initiated one week prior to the quit date, will be administered for 8 weeks total and the dose will be either 21 mg (high dose) or 14 mg (low dose). The dose will not be tapered. Those with skin sensitivities will be offered the alternative of scheduled nicotine gum at 4mg or 2mg doses (which is also offered through the public health system). The appropriate course of treatment will be decided as a collaborative discussion between the participant and the Pulmonologist and the medication will be provided free of charge.

Recruitment and Retention Strategies

The inclusion criteria are: (a) PLWH (that is, patients with a confirmed HIV diagnosis) receiving care at the reference center in Londrina; (b) 18 years of age and older; (c) smoke at

least 5 cigarettes (industrialized or hand-rolled) per day; (d) smoked within the past seven days; and (e) no intent to move from the area served by reference center in Londrina within the next 12 months. Exclusion criteria are a history of hypertension, angina, asthma, or medication for depression.

Participants will be recruited at the reference center with the support from the nursing staff. That is, the nurse will approach the patient who are tobacco users during the visit and ask about their willingness to talk to the Clinical Psychologist to learn more about the program. If they agree, the Clinical Psychologist or Research Assistant will either talk to them that day or call them to explain the study, assure eligibility, and then enroll them the next time they come to the center. Additionally, the introduction brochure described above will also be available at the clinic with the Clinical Psychologist's phone number. In our past studies, we have not provided incentives for participants in a tobacco cessation program since the trial must resemble the real world as much as possible. We will reimburse participants for their expenses associated with transportation and meals for completing assessments (baseline, post-test, 7-month f/u – total R$150/R$50 each).

Assessments

Participants will be interviewer-administered baseline, post-test, and 7-month f/u assessments by the Research Assistant since the Clinical Psychologist will be delivering the intervention. Baseline measures will include (those with an * will also be administered at post-test and 7-month f/u): demographics (e.g., age, income, etc.), tobacco history (e.g., # cigarettes per day, previous attempts, etc.), nicotine dependence* (Fagerstrom Test for Nicotine Dependence), smoking self-efficacy* (Smoking Self-Efficacy Scale), depressive symptoms* (CES-D), and social support.* These measures have been translated into Portuguese. Exhaled CO levels will be recorded at baseline, post-test, and 7-month f/u. Salivary cotinine will only be assessed at 7-month follow-up.

Sample Size and Statistical Analysis

As this is a feasibility study, sample size is justified based on the measurement precision of parameters referable for larger study. We are estimating sample size based on the results of the meta-analysis of tobacco cessation among PLWH conducted by Pool et al. where cessation was 13% in the intervention group. For the second phase of feasibility testing with 32 participants, we will be 90% confident that true rate of 7-day point prevalence abstinence at 6-months will be between 3.2% and 22.8%. For 90% confidence interval of true mean, we will be able to estimate 0.3 standard deviation as margin of error with sample size of 32. With conservative consideration of 8% attrition rate over 6 months, the study will recruit 40 participants. Descriptive statistics will be presented for participants' characteristics at each time of measures.