Study Title: Smoking Cessation Intervention for Women Living with HIV
NCT NO: NCT02898597

January 31, 2017

Data Analysis Plan

Data will be reviewed prior to data entry and entered by a research coordinator, which will be double-checked for errors or completeness by a third person. Data will be analyzed using Stata 14 (Stata Corp LP, College Station, TX, USA). Intention-to-treat analytic strategy will be used for cessation outcomes with missing values. The primary outcome of the study will be a 6-month prolonged abstinence. Its secondary outcomes will include 7-day point prevalence abstinence at each follow-up (1, 3, and 6 months post-quit), time to the first lapse, time to relapse, recovery rates from smoking relapse as well as changes in self-efficacy, depressive symptoms, and anxiety symptoms between the two treatment conditions and over time (baseline and 3- and 6-month follow-ups).

Specific aim 1: test the feasibility and acceptability of a videoconferencing smoking cessation intervention for women with HIV.
Recruitment and retention rates will be recorded per month throughout the study period. Any barriers to the recruitment and retention will be explored. Reasons for those who are eligible but decline to participate in the study will be recorded. Attrition rates will be compared by intervention condition and abstinence status at each follow-up. All participants will be asked to complete an exit survey, rating their overall satisfaction with the intervention that they have received.

Specific aim 2: establish a preliminary effect size of the videoconferencing smoking cessation intervention on 6-month prolonged abstinence compared to the telephone-based smoking cessation intervention.
The balance of participants' baseline demographics and smoking behavior between the two treatment conditions (videoconferencing vs. telephone counseling) will be evaluated using Mann–Whitney U tests or independent two-sample t-tests for continuous variables and the $\chi 2$ tests for categorical variables. Contingency analysis with $\chi 2$ test will be used to examine differences in the 6-month prolonged and 7-day point prevalence abstinence at each follow-up between the two arms. Survival analyses will be conducted to examine the relationship between the two arms and abstinence using the Kaplan–Meier survival plot and Cox proportional hazards model for possible covariates such as nicotine dependence and self-efficacy. Based on the intention-to-treat analysis, those who are missing at follow-ups will be treated as smoking. Participants who self-report abstinence but yield a positive result (cotinine concentration $\geq$10 ng/mL) or refuse to do the salivary cotinine test for any reasons will be all treated as smoking. An effect size will be calculated by comparing the 6-month prolonged abstinence rates between the two arms.