

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

NCT Number: NCT03289676

Date: 01/10/2018

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.