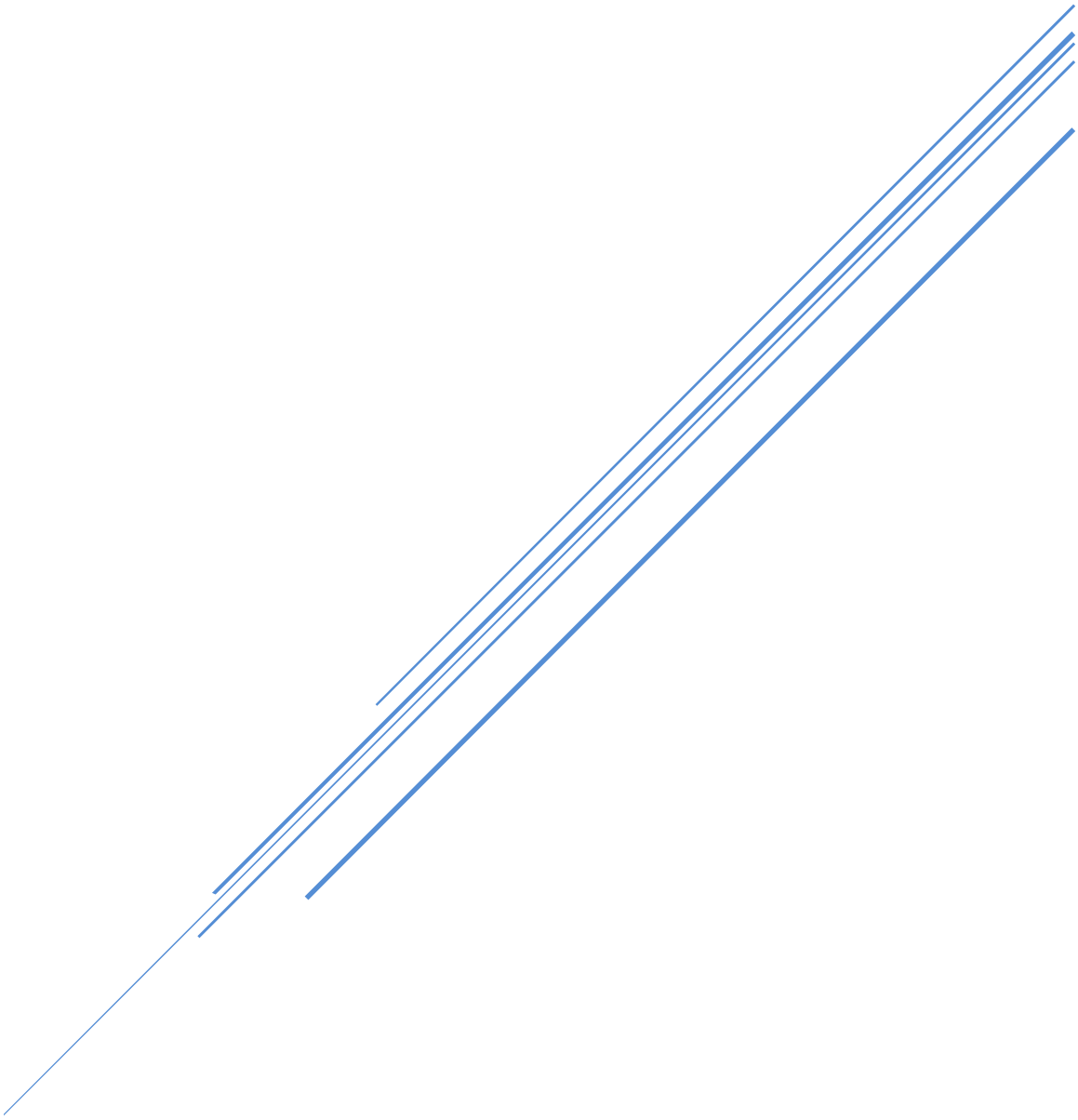
WEB-BASED SMOKING CESSATION PROGRAM FOR TRIBAL COLLEGE STUDENTS

STATISTICAL DESIGN AND POWER



NCT02050308
06/06/2019

This study will use a randomized control trial to examine the efficacy of a culturally tailored web-based smoking cessation program for AI (I-ANBL) versus a culturally tailored web-based heart healthy diet program (I-FV) in Tribal College students. Participants will be randomized either to the invention arm (I-ANBL) or the control arm (I-FV). The primary outcome will be salivary cotinine verified 7-day point prevalence abstinence at 6 months post-baseline.

Sample Size Calculation: The primary endpoint will be cotinine verified 7-day point prevalence abstinence at Month 6. Per preliminary findings, we expect a 30% cessation rate in the I-ANBL arm and a 15% cessation rate in the I-FV arm. Using the chi-square test, and the assumptions above, 121 participants in each group will give us 80% power to detect this difference with ah type I error rate of 5%. Given retention rates from our earlier studies, we expect attrition rates to be approximately 20% over the 6 month study period. Therefore, we anticipate needing to enroll 300 participants at baseline in order to have 242 active participants at 6 months.

Data Management: Data management activities will include data entry, data cleaning, conversion into proper format for data analysis and recoding. REDCap™ will be used for design, implementation and maintenance of the database. Data collection points for each participant will be calculated from his or her randomization date. Databases and the tracking system will be password protected for security and maintenance of confidentiality. Participant identifying information (name, address, telephone number) will be kept in separate records, subject to usual confidentiality protections. All data management activities will be supervised by Drs. Choi and Nazir.

Statistical Analyses:

Baseline Summary: We will summarize baseline characteristics globally and by arm. Categorical variables will be summarized by frequencies and percentages and quantitative by means and standard deviations.

Hypothesis Testing: We will first summarize all baseline measures globally and by treatment group. Categorical variables will be presented by frequencies and percentages within each of the possible categories and quantitative variables will be presented by means and standard deviations. Then, generalized linear modeling and mixed modeling will be applied to hypothesis testing for the primary and secondary aims (see below). In addition, for the exploratory purpose, we will evaluate potential covariates including smoking history and demographic, psychological, and sociocultural factors that may contribute to smoking abstinence. Interactions between intervention and these factors will also be investigated (i.e., moderation). All analyses will be conducted using SAS 9.2.82

Primary & Secondary Aims: To test the effectiveness of the I-ANBL compared to the I-FV on smoking cessation among tribal college smokers. We will compare the salivary cotinine verified prevalence abstinence rates at 6 months between the two groups using logistic regression. For our primary comparison, we will conduct per-protocol analyses on (a) only the participants who complete the study, as well as intent-to-treat analyses on (b) all subjects by imputing the dropouts as smokers and (c) all subjects by using the Markov Chain Monte Carlo (MCMC) imputation technique. In (c), the missing data related to attrition can be reasonably assumed to be missing due to known characteristics of our database (i.e., missing at random). We will create a large number of (e.g., 200) complete datasets via expectation-maximization algorithm as prior estimates for the MCMC procedure;83 and then combine the analysis outcomes from each complete dataset to make valid statistical inferences.84 To evaluate secondary endpoint, we will compare the salivary cotinine verified prevalence abstinence rates between the groups at Week 12 (end of pharmacotherapy). Finally, as we have no preliminary estimates of relapse based upon timeline follow-back, we will conduct explanatory, failure analyses to compare the time to relapse between the groups. We will calculate failure function (cumulative probability of smoking cessation as a function of time) and fit Cox regression models to the 6-month self-report data on smoking status.

Secondary Aims: To test the effects of the intervention on intermediate smoking variables including number of cigarettes smoked and number of quit attempts at 6 months following randomization. Mixed models for repeated measures will be used to examine the change in the number of cigarettes smoked over the 6-month study period. To evaluate group differences of reduced cigarette numbers, the models will examine the main effects of time, treatment, and the number of cigarettes smoked at baseline and their interactions. Estimated means at 6 months, which are adjusted for the baseline cigarette numbers, will be reported and compared between the groups. We will also, compare the number of quit attempts between the two groups using Poisson regression for count data. In the Secondary Aim 1 analyses, the dropouts will be handled by multiple imputation as described in Primary Aim.