

Cover Page for ClinicalTrials.gov

Document: Statistical Analysis Plan

Official Study Title: Project 2VIDA! COVID-19 Vaccine Intervention
Delivery for Adults in Southern California

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STATISTICAL DESIGN AND POWER CALCUATIONS

We will approach overall data analyses using a multivariate repeated measures design (i.e., doubly multivariate) to assess mean differences in treatment and control groups on our primary (acceptance of COVID-19 vaccine and vaccine series completion) and secondary outcome variables (increased knowledge of COVID-19 vaccine, increased access to COVID-19 vaccine, vaccine hesitancy). Additional measures at baseline and follow-up will be used as covariates (e.g., outreach and health communication, vaccine hesitancy or mistrust). Mean differences, both within and between treatment and control groups as well as group by treatment interaction effects will be analyzed. The targeted sample size is sufficient to detect a small effect size (.20) with power = .90 at alpha = .05 accounting for moderate participant attrition. Descriptive Statistics. To describe the overall sample regarding demographics, structural and individual barriers, and potential covariates of intervention effects at baseline, prevalence statistics and means and standard deviation will be provided for all baseline variables; Cronbach's alpha of .70 will be required to be considered reliable. Baseline Analyses to Detect Differences Between Treatment Groups. Chi-square analyses and paired t-tests will be used to detect differences in demographics, knowledge of COVID-19 vaccine, access to COVID-19 vaccine, acceptance of COVID-19 vaccine and series completion, COVID-19 resource-seeking behaviors and linkage into care between intervention and control groups. Demographic variables included in these analyses will be age, gender, race/ethnicity, household income, marital status, and having insurance. Those variables differing across treatment groups at the $p < .20$ level will be included in subsequent adjusted outcome analyses.