Statistical Analysis Plan

Community-Centered Interventions for Improved Vaccine Uptake for COVID-19 (CIVIC): Getting to Yes, Michigan! (G2YMI)

NCT05096260

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Getting to Yes: Increasing COVID-19 vaccination in Michigan Community-Centered Interventions for Improved Vaccine Uptake for COVID-19 (CIVIC)

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Approved by IRB HUM00204174 DATA ANALYSIS

Analyses of vaccination status, a binary variable, will use chi-square for unadjusted analyses and a generalized linear mixed model with a logit link if covariates are needed. We will use an intent-to -treat analysis among all participants who complete the 6 month survey assessment. Patients missing at posttest will be considered as having not been vaccinated. The effect of the individual-level intervention on vaccine uptake will be quantified by crosstabs as well as the odds and confidence interval for vaccine uptake between Individually tailored vs. Standard Website/App. A priori interaction terms (intervention effect modifiers) that will include gender, income, education. For our secondary outcome of intention to get vaccinated we will use similar procedures.

Descriptive statistics will be tabulated and graphical methods will be used to characterize individuals. An intention-to-treat approach will be used to define the analysis populations: all participants randomized will be analyzed in the condition to which they were assigned. We will summarize the extent of missing data over time for the primary endpoints. Differences in participant demographics and baseline characteristics between those with and without missing follow-up data will be given overall and by intervention group. Two-sided p-value will be reported.