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4.3 Statistical Design and Power

In Aim 1 we will refine the SAll intervention and pilot all research study protocols and procedures. Pilot participants will include members of our bilingual bicultural testing team (N = 5), followed by participants in ongoing testing and vaccination events we conduct via a partnership with the OHA (N = 20). Pilot data will not serve as a 'research' activity given the program development and refinement purpose of the activities, and that no individually identifiable data will be collected. The investigative team will examine the length of intervention delivery, any comprehension or translation challenges, and cultural appropriateness to iteratively refine the SAll protocols for the Latinx population before we begin the Aim 2 activities. We will iteratively discuss the pilot experiences with our CSAB and incorporate their input. The tailoring will first focus on producing a culturally competent adaptation of the brief SAll approach. Cultural adaptation of any evidence-based program, brief or intensive, requires systematic modification to consider language, behavioral traditions, and context that are compatible with and relevant to a focal population's shared values and beliefs. This primarily involves adequate translation and backtranslation for meaning and cultural acceptance. Secondly, it involves assuring culturally adequate administration protocols. In consultation with our established community partners and CSAB, we will then develop manualized protocols and train promotores to administer an oral version of SAll that does not require English language proficiency or literacy. In addition, we will train field staff and promotores on the use and distribution of SARS-CoV-2 rapid testing kits. Both the rapid testing distribution and the SAll will be examined for usability and acceptability using an adapted version of the System Usability Scale in Latinx research team members (N = 5) and in a sample of N = 20 Latinx community members attending the OHA events. The potential risks are minimal, but could include potential violation of confidentiality, mild psychological discomfort while responding to the research survey, and/or mild physical discomfort when self-collecting a rapid test and do not require specification of multivariate statistical analyses plans or power analyses.

Aim 2 study design is a clustered randomized control trial with randomization occurring at the event level.

General Analytical Approach

From a design standpoint, the multilevel clustering of data occurs with community participants being nested or clustered within a MC event site, analogous to designs with patients clustered within clinics. Standard normal theory general linear and generalized linear path analytic regression techniques will be used to test central effectiveness hypotheses using structural equation modeling (SEM). SEM is a maximum likelihood estimation latent variable regression technique that simultaneously combines factor analyses with path analyses. Aim 2 will evaluate intent to treat (ITT) effectiveness of the Promotores de Salud plus SAll versus the Promotores de Salud only. Analyses will be conducted in several steps starting with evaluation of psychometric properties, data reduction, and evaluation of missing data and differential attrition between the SAll and the Promotores control condition. As in SEM, the MLSEM model fit will be evaluated using recommended fit indices off a χ^2 minimization p value $> .05$, a comparative fit index (CFI) $> .95$, a chi-square ratio (χ^2/df) < 2 , and a root mean square error of approximation (RMSEA) $< .08$.

Data Reduction. We will first evaluate item level nonresponse, missing data patterns, and psychometric properties of validated scale scores. Next, we will conduct confirmatory factor analyses (CFA) for latent variables with multiple indicators comprising COVID-19 risk factors and health outcomes. Criteria will require internal consistency ($\alpha \geq .6$; item-total correlation $\geq .2$) and scale convergence in a CFA structural equation model (SEM) meeting acceptable fit criterion.

Missing Data. We will conduct standard attrition analyses to compare baseline characteristics between attritors and completers. Next, model data will be tested for missing completely at random (MCAR). If data are not MCAR, under assumptions of missing at random (MAR, i.e., data are not dependent on missing values of the intervention response variable), we will employ one of two recommended approaches full information maximum likelihood (FIML) or multiple imputation (MI). Although these approaches can be problematic when missingness is non-ignorable, they are still recommended with covariates associated with attrition.

Specific Aim 2 Analysis Plan for Hypotheses (a) and (b).

Aim 2 focuses on effectiveness of the SAll intervention enhancement on pre-post change (T1 to T2) in COVID-19-related health outcomes, including rapid testing and vaccine acceptance, mental health, and physical health. Example hypotheses are depicted in Figure 1, with paths from the health inequity risk factors of COVID-

19 related stressors and discrimination negatively impacting health outcomes. The path from the randomized SAIL condition is hypothesized to serve as an additive buffer (main effect) and as a moderating buffer, lessening the impact of risk factors on health outcomes (interaction effect). The hypotheses will be specified in multilevel SEM (MLSEM) to estimate the two-level models at the within person and between site levels (Heck & Thomas, 2015). The MLSEM growth model statistically addresses the nonindependence of the clustered data and partitions variance in participants' change across participants and any site level variation. For binary testing acceptance (yes/no) and counts of rapid testing kits we will specify generalized linear models in *Mplus* 8.8. For primary health outcomes, the Aim 2 within-participant mental health model, for example, is:

$T2 \text{ Mental Health}_{ij}$

$$= \eta_{0ij} + \eta_{1ij}T1 \text{ Mental Health}_{ij} + \eta_{2ij}\text{COVID19 related Risk}_{ij} + \eta_{3ij}\text{SAIL Condition}_{ij} + \eta_{4ij}\text{SAIL} \times \text{Risk}_{ij} + \eta_{5ij} \dots \eta_{nij}\text{Sociodemographic Characteristics}_{ij} + \varepsilon_{ij}$$

where Time 2 Mental Health (T2) is measured by the Broadband Psychopathology indicators and is a function of a random intercept (η_0) for participant i from site j ; the T1 Mental Health latent variable (η_1); the COVID-19 related risk (e.g., stress, discrimination) latent variables (η_2); the contrast of the randomized SAIL condition main effect (η_3), as well as the hypothesized test of the buffering effect of SAIL on the negative impact of COVID-19 risk factors (η_4), plus sociodemographic characteristics of participants including ethnicity, English proficiency, nativity, essential worker, age, and biological sex or self-identified gender.

Aim 2 Power. Multilevel SEM Monte Carlo simulations with 1000 replications were conducted for the Aim 2 effectiveness **hypothesis (a) main effect** specified above. A unique feature of the Monte Carlo approach is the ability to build in variation in cluster sizes and specific patterns of missingness for attrition over time. To estimate power for the proposed sample size, a baseline sample of 400 was specified to represent natural variation in event success in sample collection and testing comprised of 4 events with 25 individuals, 5 events with 20, and 20 events with 10; averaging 14 persons per event, roughly our MC estimates to date. The SAIL random assignment intervention contrast was a simulated dichotomous contrast with a mean of .50 and variance of .25 reflecting the randomized 50/50 allocation. A baseline COVID-19 Risk latent variable was specified with three indicators estimated with factor loadings of .70, a factor mean of 0, and a variance of 1, and residual variances of .5 for loadings. A Time 1 and Time 2 latent variable for a health outcome (e.g., testing acceptance, mental health, physical health) were specified with loadings of .70 at both time points, and autocorrelations of .4 for repeated measure indicators. The MSEM simulation model was powered .80 to minimally detect an effect of .32 for the SAIL contrast, powered .98 to detect a COVID-19 related Risk factor as small as .16, with ICCs for indicators ranging from .02 to .06. For **hypothesis (b)** the study is powered .88 to detect an SAIL buffering effect of -.30 in the simulation. Thus, the study is powered to detect moderate effect sizes consistent with SAIL literature reporting medium effects. We will help address nonresponse and generalizability using propensity score approaches for estimating a generalizability index using Phase I census tract indices as well as RADx CDCC county level indices for participating and non-participating counties.