STATISTICAL ANALYSIS PLAN

PROJECT TITLE:

Team Science to Identify and Intervene on Metabolism- and Alcohol-Associated Liver Disease (MetALD)

PRINCIPAL INVESTIGATOR:

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To establish feasibility and acceptability of community-based screening for MetALD, a CONSORT flow diagram reflecting participants' progress through our screening and enrollment process will be created, including the number and percentage of individuals screened for self-reported weight and alcohol-use co-factors who were eligible for noninvasive liver screening (primary outcome measure) and the proportion of those eligible who agreed to non-invasive liver screening (primary outcome measure). These findings will inform how many individuals encountered through our proposed community recruitment efforts exhibit key biobehavioral co-factors for MetALD, the feasibility of reaching them in future studies and the feasibility of conducting noninvasive liver screening with them. To examine the acceptability of noninvasive liver screening, we will assess participant satisfaction with FibroScan® on a 100-point visual analogue scale following baseline procedures (primary outcome measure).

To test whether personalized feedback reduces alcohol-associated risk for MetALD, residualized multiple linear regression analyses will test whether participants receiving the enhanced intervention with personalized FibroScan® feedback report fewer heavy drinking days, fewer drinks per week, and more alcohol-free days than participants receiving the standard intervention (secondary outcome measure). Age, sex, ethnicity, and variables reflecting baseline levels of outcomes will be specified as a priori covariates. Including participants' baseline levels of outcomes will increase precision of the test of condition on follow-up outcomes and thus enhance statistical power. While not powered to test whether biological sex (assigned at birth) moderates the intervention, we will test for main effects of sex on outcomes and explore pre and post means separately by sex. The same approach will be utilized for ethnicity and age group. We will evaluate the residual distributions of drinking summary scores to ensure model assumptions are met. If the residual distributions do not approximate multivariate normal distributions, we will utilize appropriate other approaches. For example, we can pivot to evaluate standard drinks via a count regression model (e.g., negative binomial distribution). As another example, we can pivot to evaluate heavy-drinking days as complete absence of any heavy drinking vs. 1+ heavy drinking day via a logistic regression model (e.g., binary distribution).