Computer Based Training in CBT for Spanish-Speaking Alcohol Users

Clinical Trials.gov ID Number: NCT03474588

Statistical Analysis Plan

HIC Protocol 20000 20677

APPROVED BY THE YALE UNIVERSITY IRB

6/13/2019

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1. Determination of Treatment Outcomes

a. Data reduction: Primary outcome variables have been defined *a priori* to reduce the risk of Type I error. Preparatory analyses include evaluation of baseline equivalence of treatment groups on demographic and prognostic variables and comparability of rates of data availability across conditions.

b. Strategies for management of differential attrition: Data analyses will be conducted on the intent-to- treat sample and we will attempt to follow all participants regardless of their retention in treatment. We have established our ability to contact and follow participants who drop out of treatment and to conduct true intent-to-treat analyses [16, 208, 209], including supplemental analyses that account for whether data was collected before or after dropout/withdrawal[208]. While we anticipate that assertive efforts to locate and interview participants who drop out of treatment will result in low numbers of missing participants and minimal missing data in the final dataset, we will minimize the impact of missing data through the use of random effects regression modelling[251-253].

c. Evaluation of treatment effects at posttreatment and follow-up: The principal strategy for assessing the efficacy of the study treatments on outcome over time will be random effects regression models for continuously measured primary (e.g. percent days of abstinence by week) and secondary (e.g., acquisition of coping skills) outcome variables. The focus of the repeated measures analyses will be the 'contrast by time effects', which essentially evaluates whether the slopes, or rates of change, of one group differ from the slopes of another group. We have used these methods to evaluate main and interaction effects, with appropriate covariates (e.g., retention, compliance with treatment, time spent working with the CBT4CBT program) in multiple previous trials[14, 151, 160, 200, 201, 254]. Follow-up data will be analyzed using random-effects regression modeling [255] for our primary outcome measures across time, using the contrasts described above, with appropriate covariates (e.g., length of time in treatment, exposure to other treatment during follow-up). Random effects regression models have several advantages in

follow-up data from clinical trials of substance users where participants are unlikely to attend follow-up evaluations precisely at the desired fixed points, and are less vulnerable than traditional MANOVA approaches to missing data[208, 209, 251, 252]. As in our previous trials [16, 126], we estimate that our extensive efforts to track participants will yield a 90% follow-up rate.