Biobehavioral Pathways Underlying Alcohol Use and Health

ClinicalTrials.gov Identifier: NCT05135767

Sponsor:

Brown University

Collaborators:

National Institute of General Medical Sciences (NIGMS)
Rhode Island Hospital

Information provided by (Responsible Party):

Brown University

STATISTICAL ANALYSIS PLAN

The primary goal of the research project is to demonstrate the feasibility of enrolling ALD patients in a brief psychosocial AUD treatment integrated with medical care. The intervention will include personalized feedback from biomarkers of liver function, drinking patterns, and EMA self-monitoring of craving and negative affect. We hypothesize the ability to reach the following primary targets:

1. Feasibility of recruitment, measured as number enrolled per month. Target: 2 per month.
2. Feasibility of enrollment, measured as proportion of screen eligible who enroll. Target: ≥ 60% of screen eligible.
3. Retention, measured as overall retention and treatment-specific retention rates. Target: ≥ 70%.
4. Acceptability of study procedures, measured as overall rate of individuals who withdraw from the study and treatment-specific withdrawal rates. Target: ≤ 20%.
5. Treatment adherence, measured as rates of adherence to protocol overall and for each group. Target: ≥ 80%.
6. Ecological momentary assessment (EMA) compliance, measured as proportion of planned assessments that are completed overall and for each group. Target ≥ 80%.

We will also evaluate our assessment process via calculating the mean, standard deviation, and range of responses for measures at all assessment points. Piloting the assessment process will either justify or inform revision of our protocol for a subsequent R01 submission. Importantly, this pilot study is used to generate pilot data and is not a hypothesis testing study (please see Leon, Davis, and Kraemer, 2011, for a detailed justification). Therefore, sample size determination can be based on the pragmatics of recruitment and necessary targets for examining feasibility.

The secondary goal is to test whether endophenotypes associated with alcohol-use outcomes in clinical trials are more resistant to change during AUD treatment in ALD/AUD patients vs. those with AUD only. This will be achieved through leveraging an ecological momentary assessment (EMA) and human laboratory (HLAB) paradigm. We hypothesize that ALD patients, as compared to an AUD-only comparison group, will demonstrate higher levels of:

1. Alcohol-cued craving in the natural environment using EMA.
2. Alcohol-cued craving in the HLAB using a validated and controlled *in vivo* cue reactivity paradigm.