NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 1.00; 06-03-11

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*

2. Sex:*(DEGENDER)* ☐ Male ☐ Female ☐ Participant chooses not to answer

3. Ethnicity:*(DEETHNIC)* ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Participant chooses not to answer

4. Race:

American Indian or Alaska Native*(DEAMEIND)*	☐ No ☐ Yes
Asian*(DEASIAN)*	☐ No ☐ Yes
Black or African American*(DEBLACK)*	☐ No ☐ Yes
Native Hawaiian or Pacific Islander*(DEHAWAII)*	☐ No ☐ Yes
White*(DEWHITE)*	☐ No ☐ Yes
Other*(DEOTHER)*	☐ No ☐ Yes
If "Yes", specify:*(DEOTHRSP)*	_____

OR

Unknown*(DEUNKNOW)*	☐ Yes
Participant chooses not to provide their race*(DENORACE)*	☐ Yes

Comments:*(DEMCOMM)*

0037Z (ENR)

Web Version: 1.0; 1.02; 07-19-11

Eligibility

Date of assessment:*(R2ASMTDT)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

Check the appropriate response. If any of the inclusion criteria have been answered "No" or "Unknown," the participant is not eligible and cannot be enrolled or randomized into the study.

1. Male or female age 18-65:*(R2PTAGE)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
2. Admitted to residential setting and receiving substance use treatment: *(R2RESTRT)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
3. Ability to understand and willingness to provide written informed consent: *(R2INFCNS)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
4. Agree to remain in facility for authorized treatment of about 21-30 days:*(R2REMAIN)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
5. Agree to remain in facility for authorized treatment:*(R2REMAIN)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
6. Willing to provide contact information:*(R2CONTCT)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
7. Self-reported use of stimulant drug (cocaine, methamphetamine, amphetamine, or other stimulant, excluding caffeine and nicotine) within the 30 days prior to admission for treatment:*(R2STM30D)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
8. Meets DSM-IV criteria (per CIDI) for substance abuse or dependence for stimulants (cocaine, methamphetamine, amphetamine, or other stimulant, excluding caffeine and nicotine) within the last 12 months:*(R2STM6M)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
9. Medical clearance with protocol-defined stress testing (in accordance with American College of Sports Medicine (ACSM) guidelines) from protocol approved medical personnel:*(R2MEDCLR)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
10. Body mass index (BMI) ≤40 kg/m^2 or BMI >40 kg/m^2 and cleared by medical personnel to exercise:*(R2BMI)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
11. Able to comprehend and communicate in English:*(R2ENGLSH)*	☐ No	☐ Yes	☐ Unknown/Not Assessed

Exclusion Criteria

Check the appropriate response. If any of the exclusion criteria have been answered "Yes" or "Unknown," the participant is not eligible and cannot be enrolled or randomized into the study.

1. Evidence of general medical condition or other abnormality that contraindicates use of exercise, based on the Medical Screening Visit:*(R2MCNTRA)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
2. Current opiate dependence:*(R2OPIATE)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
3. Current opiate dependence (i.e., within the last 12 months):*(R2OPIATE)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
4. Currently considered a high suicide risk and/or high risk for being unable to complete the study due to the need for psychiatric hospitalization, suicide attempts or suicidality, significant self-mutilation, or other self-injurious or destructive behavior based on the judgment of the site PI, medical personnel, or designee:*(R2SUICID)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
5. Pregnancy:*(R2PREG)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
6. Significant physical activity, defined as aerobic exercise more than 3 times per week for 20 minutes or more, completed consistently for the three months prior to study enrollment:*(R2ACTIVE)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
7. Current psychotic disorder. Other comorbid psychiatric diagnosis that, in the investigator's judgment, will pose a safety issue or make it difficult for the participant to understand or complete the intervention:*(R2PSYCH)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
8. Concomitant treatments: beta blockers, methadone, buprenorphine or any other opioid replacement therapies:*(R2CONMED)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
9. Anticipated circumstances over the 9-month course of the trial that would render the participant unlikely to complete the study in the judgment of the site PI or designee:*(R2COMPLT)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
10. Anticipated living arrangements after the first month of the study that are likely to restrict exposure to substance use in the judgment of the site PI or designee: *(R2EXPOSE)*	☐ No	☐ Yes	☐ Unknown/Not Assessed
11. Any reason not listed herein yet, determined by the site PI, medical personnel, or designee that constitutes good clinical practice and that would in the opinion of the site PI, medical personnel, or designee make participation in the study hazardous:*(R2HAZARD)*	☐ No	☐ Yes	☐ Unknown/Not Assessed

Randomization

1. Is the participant eligible for the study?*(R2PTELIG)* ☐ No ☐ Yes
2. Is the participant eligible for the study and able to be randomized?*(R2PTRAND)* ☐ No ☐ Yes
   a. If "No", please specify:*(R2NORASP)* ☐ Dropped out of treatment ☐ Declined study participation ☐ Death ☐ Other
   b. If "Other", please specify:*(R2OTHRSP)* _____
3. What is the participant's score on the QIDS-C_{16}?*(R2DEPRES)* ☐ ≤10 ☐ ≥11
4. What is the quantity of the participant's stimulant use in the 30 days prior to admission for treatment?*(R2DRGSEV)* ☐ ≤18 days of use ☐ >18 days of use

Comments:*(R2COMM)*