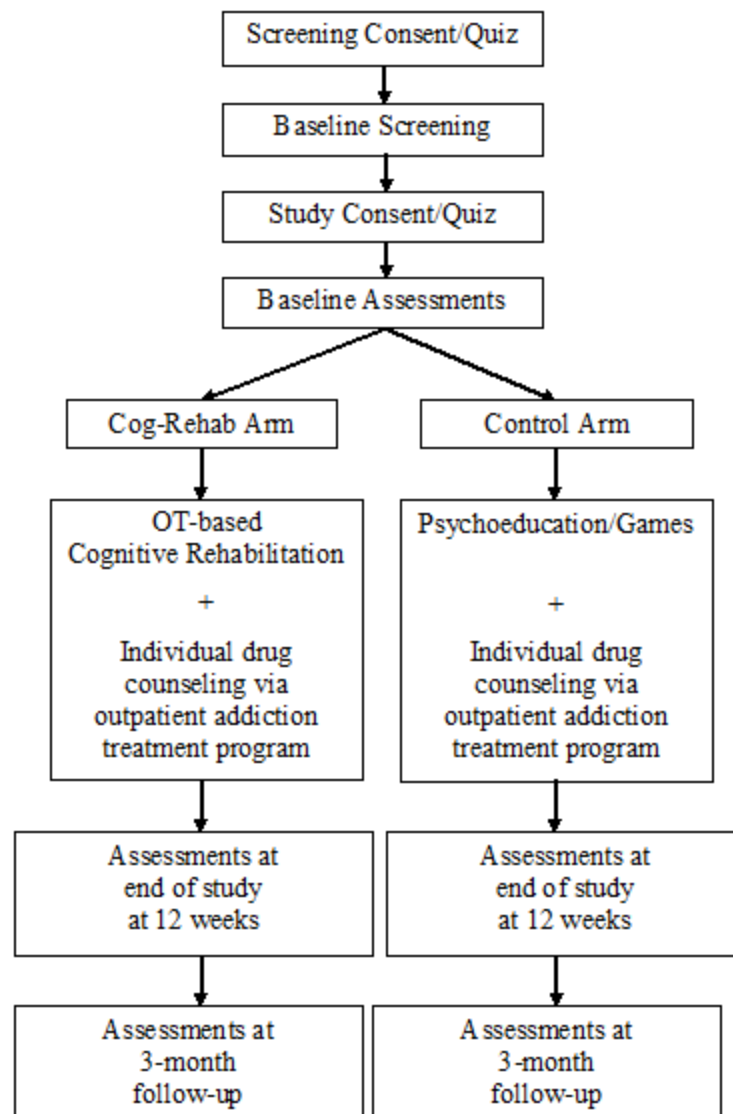




Overall Flow of the Study

Aim 1: Examine the improvement in cognition from OT-based cognitive rehabilitation.

Hypothesis 1: The Global Deficit Score, a valid neuropsychological test scoring method for detecting clinically significant cognitive impairment, will improve significantly more by study end (at 12 weeks) for participants in the “Cog-Rehab” arm, compared to those in the “Control” arm.

Aim 2: Examine the improvement in cocaine abstinence from OT-based cognitive rehabilitation.

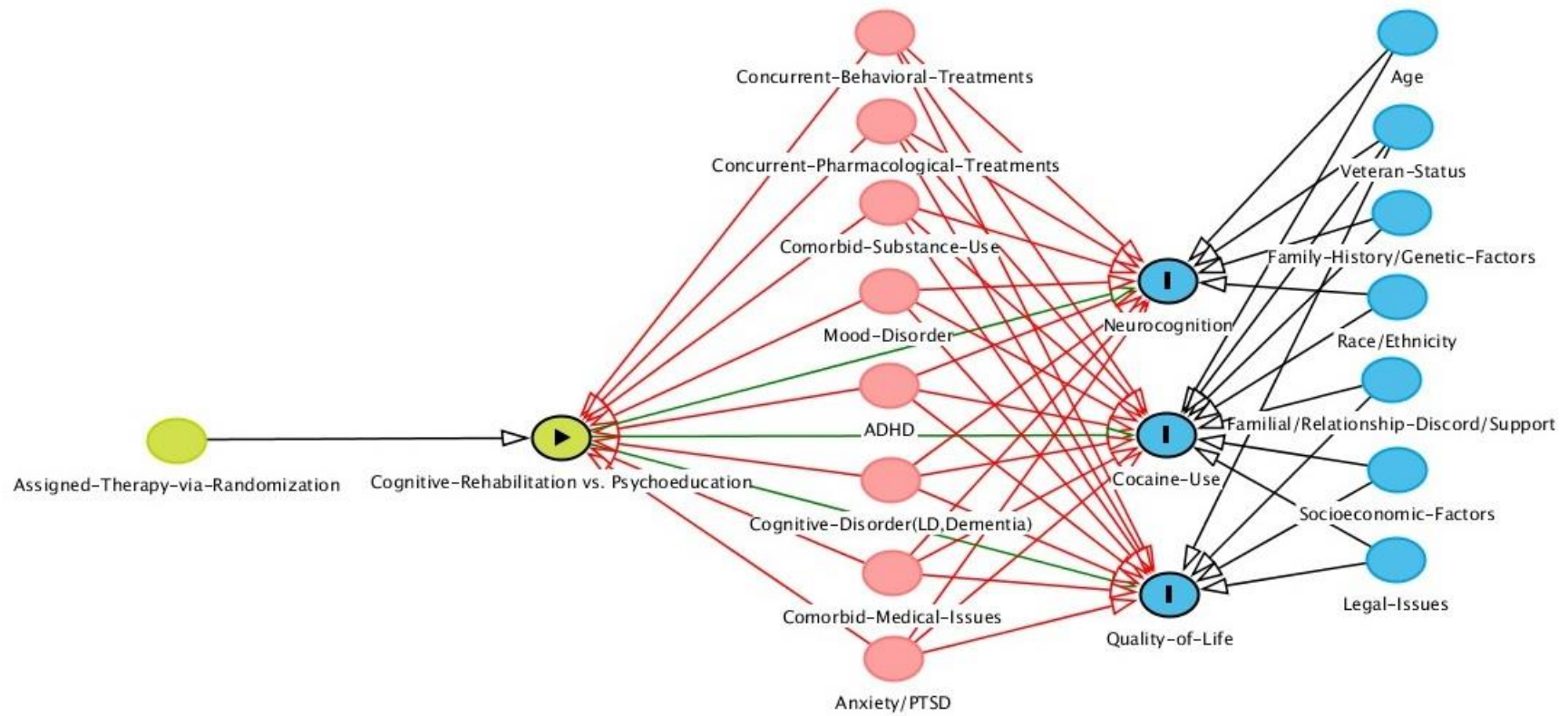
Hypothesis 2: The proportion of urine toxicologies negative for cocaine in the 12-week study period will be significantly greater for participants in the “Cog-Rehab” arm, compared to those in the “Control” arm.

Aim 3: Examine the improvement in daily quality of life/function from OT-based cognitive rehabilitation.

Hypothesis 3: The overall self-rating of quality of life score on the Drug User Quality of Life Scale, a valid measure for capturing the quality of life areas meaningful to substance abusers, will improve significantly more by study end (at 12 weeks) for participants in the “Cog-Rehab” arm, compared to those in the “Control” arm.

Inclusion Criteria
Age 18-65
Primary cocaine use disorder (based on DSM-5 criteria) and in at least 3 months of remission
At least mild cognitive impairment, defined as = or > 1.5 standard deviations impairment on any 2 performance-based neurocognitive measures
Needing to change quality of life, defined as self-identifying at least 2 life areas as needing to change on the Drug User Quality of Life Scale
A Veteran at the San Francisco Veterans Affairs Medical Center
Currently receiving weekly drug counseling (individual or group; at least 1 hour/week) through an outpatient substance use disorder treatment program

Exclusion Criteria
Inability to speak, read, write, and understand English
Inadequate hearing or vision
Concurrent substance use disorder (except tobacco or caffeine) not in at least 3 months of remission
A psychiatric disorder that will interfere with study participation or will make participation hazardous (e.g., psychosis, suicidal or homicidal ideations, severe anxiety)
A depressive disorder classified as severe, defined as a Beck Depression Inventory-II score >29
Current diagnosis of a bipolar disorder needing acute inpatient psychiatric hospitalization
Currently symptomatic from attention-deficit/hyperactivity disorder (DSM-5 criteria)
Any learning disorder, any type of dementia, any type of delirium, or an amnestic disorder due to any general medical condition
Wechsler Test of Adult Reading standard score <70
Mini-Mental State Examination score <24
Current use of scheduled (i.e., prescribed) regular (i.e., daily) psychotropics or other medicines with a high likelihood of sedation & cognitive impairment (e.g., benzodiazepines, clozapine, anticholinergics)
Currently prescribed stimulants (e.g., methylphenidate) or cognitive enhancers (e.g., donepezil, memantine)
Active medical illnesses – uncontrolled diabetes, uncontrolled hypertension, uncontrolled thyroid dysfunction, or uncontrolled B12/folate deficiency; central nervous system illness with potential cognitive aspects (Parkinson's, or Huntington's dementia); Cirrhosis with complications (e.g., ascites, encephalopathy, jaundice, gastrointestinal bleeding); Needing acute medical hospitalization from HIV sequelae, such as HIV-related opportunistic infection
Any history of any type of stroke or brain hemorrhage
Any history of traumatic brain injury, intracranial pathology (e.g., tumor), or brain surgery
Currently on probation or parole
Concurrent participation in another study that medically/administratively interferes with this study



ADHD 1 @-0.969,0.028
 Age 1 @-0.610,-0.217
 Anxiety%2FPTSD 1 @-0.966,0.217
 Assigned-Therapy-via-Randomization 1 @-1.461,0.066
 Cocaine-Use O @-0.777,0.062
 Cognitive-Disorder(LD%2CDementia) 1 @-0.968,0.093
 Cognitive-Rehabilitation%20vs.%20Psychoeducation E @-1.195,0.064
 Comorbid-Medical-Issues 1 @-0.967,0.158
 Comorbid-Substance-Use 1 @-0.969,-0.099
 Concurrent-Behavioral-Treatments 1 @-0.972,-0.217
 Concurrent-Pharmacological-Treatments 1 @-0.971,-0.156
 Familial%2FRelationship-Discord%2FSupport 1 @-0.621,0.024
 Family-History%2FGenetic-Factors 1 @-0.614,-0.092
 Legal-Issues 1 @-0.618,0.149
 Mood-Disorder 1 @-0.969,-0.038
 Neurocognition O @-0.776,-0.045
 Quality-of-Life O @-0.775,0.173
 Race%2FEthnicity 1 @-0.617,-0.034
 Socioeconomic-Factors 1 @-0.617,0.086
 Veteran-Status 1 @-0.613,-0.151

ADHD Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Age Cocaine-Use Neurocognition
 Anxiety%2FPTSD Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Assigned-Therapy-via-Randomization Cognitive-Rehabilitation%20vs.%20Psychoeducation
 Cognitive-Disorder(LD%2CDementia) Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Cognitive-Rehabilitation%20vs.%20Psychoeducation Cocaine-Use Neurocognition Quality-of-Life
 Comorbid-Medical-Issues Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Comorbid-Substance-Use Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Concurrent-Behavioral-Treatments Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
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 Family-History%2FGenetic-Factors Cocaine-Use Neurocognition
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 Mood-Disorder Cocaine-Use Cognitive-Rehabilitation%20vs.%20Psychoeducation Neurocognition Quality-of-Life
 Race%2FEthnicity Cocaine-Use Neurocognition
 Socioeconomic-Factors Cocaine-Use Quality-of-Life
 Veteran-Status Cocaine-Use Neurocognition Quality-of-Life

Questions:

1. **Aside from the obvious # of inclusion/exclusion criteria which limits external validity, are any of my inclusion/exclusion criteria inducing selection bias, are colliders, or unnecessary restrictors/confounders?**
2. **I'm restricting the range of outcomes upfront. Will this be a problem?**