

Outcome Inference in the Sensory Preconditioning Task in Opioid-Use Disorder

NCT03745339

Status	RECRUITING
Sponsor	National Institute on Drug Abuse (NIDA)
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (6)

- The enrollment target for the protocol is 120 (40 healthy controls, 40 patients on agonist maintenance, and 40 participants who have met DSM 5 criteria for OUD, but are now abstinent (for at least 3 weeks) and not on agonist maintenance).
- All Participants
- Age between 21 and 65 years inclusive. Rationale: objective olfactory impairment grows more prevalent with age; after age 53, the prevalence is 24.5%, increasing to 62.5 % in people aged 80-97 years.
- Willing to fast for at least 6 hours prior to the study session and be exposed to food odors. These will be assessed with the "019 Additional History Form" questionnaire.
- Additional Criteria for Abstinent OUD group
- ... and 1 more (see full listing online)

Exclusion (18)

- Additional Criteria for In-treatment OUD group
- Current enrollment in treatment for OUD with buprenorphine or methadone (>3 weeks on stable dose). Current use of illicit substances during treatment is permissible but not required. Rationale: Again, heterogeneity will be considerable, but what all enrollees will have in common is having sought treatment for their OUD and being currently maintained on an agonist that permits adaptive everyday functioning. Their heterogeneity in ongoing use of illicit substances will enable us to examine relationships between inferencing performance and treatment response.
- All participants
- Anosmia, dysosmia, or hyposmia (poor olfactory function), to be assessed via Sniffin Sticks threshold test <4 or via Sniffin Sticks odor identification test <10.
- History of any neurological condition resulting in inability to perform study task. Examples include but not limited to degenerative processes of the CNS (Parkinson disease, Alzheimer disease); other neurologic diseases (Huntington disease, multiple sclerosis, other motor-neuron diseases); inflammatory conditions (sarcoidosis, Wegener granulomatosis); or significant cerebrovascular disease including (but not limited to) epilepsy, stroke, or meningitis; traumatic brain injury (TBI) or major head trauma with sustained loss of consciousness (>30 min). To be assessed by history and physical and evaluation to sign screening consent. Eligibility will be determined based on MAI review of participants ability to perform study task. MAI will consider but is not limited to H and P results for mental status exam, language exam, and attention span exam. Rationale: any of these could impair task performance.
- ... and 13 more (see full listing online)

Locations (1 total)

National Institute on Drug Abuse, Baltimore, Maryland, United States

<https://clinicaltrials.gov/study/NCT03745339>

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