

# Non-invasive Vagal Nerve Stimulation as Novel Treatment to Improve Functional Outcomes in Veterans With Alcohol Use Disorder

NCT06399653

---

Status	RECRUITING
Phase	Not Applicable
Sponsor	VA Office of Research and Development
Enrollment	80 participants

## Plain Language Summary

---

This study is testing whether a non-invasive device that gently stimulates the vagus nerve (a major nerve connected to the brain) through the skin of the neck can help veterans with alcohol use disorder reduce cravings and improve brain function. This is a drug-free, wearable treatment approach.

**\*\*You may be eligible if...\*\***

- You are a veteran between 21 and 65 years old
- You have moderate or severe alcohol use disorder and drink heavily (5+ drinks for men, 4+ for women on the same occasion, 5+ days in the past month)
- You can safely go without alcohol for 12–24 hours
- You can speak and read English

**\*\*You may NOT be eligible if...\*\***

- You have had severe alcohol withdrawal symptoms (seizures, hallucinations, delirium) in the past 6 months
- You are in an abstinence-based treatment program
- You use other substances heavily
- You have a severe psychiatric disorder with psychosis or significant cognitive impairment
- You are at risk of suicide or violence
- You have a pacemaker or certain metal implants
- You currently use opioids or benzodiazepines

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

---

### Inclusion (6)

- Veterans between 21 and 65 years, any race or ethnicity.
- Meet current DSM-5 diagnosis of moderate or severe AUD (Structured Clinical Interview for DMS-5 (SCID) interview) with at least one functional disability due to alcohol use, current alcohol craving, and current heavy drinking ( $\geq 5$  drinks (men) /  $\geq 4$  drinks (women) on the same occasion, on 5 or more days in the past month) as defined by the Substance Abuse and Mental Health Services Administration (SAMHSA), and mild to moderate withdrawal symptoms during abstinence.
- Able to forgo consumption of alcohol for 12-24 hours without any serious discomfort or complications.
- Capable of complying with study schedule, procedures, and speaks English.
- Able to provide voluntary written informed consent prior to initiation of visit 1.

... and 1 more (see full listing online)

### Exclusion (13)

- Clinical Institute Withdrawal Assessment of Alcohol Scale (CIWA-Ar) score  $>10$  on the day of the scan (symptoms judged to be due to co-existing anxiety or headache disorders will not be counted toward the total).

<https://clinicaltrials.gov/study/NCT06399653>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Recent history past 6 months) of severe complications due to alcohol withdrawal (alcohol withdrawal seizures, hallucinations/illusions, delirium tremens).
  - Currently or recently (within last 90 days) enrolled in abstinence-based treatment program.
  - Evidence of a maladaptive pattern of substance use or abuse other than alcohol one month prior to screening visit.
  - Uncontrolled severe psychiatric disorder with psychotic symptoms or cognitive impairment. We will not exclude for PTSD.
- ... and 8 more (see full listing online)

## Locations (1 total)

---

VA San Diego Healthcare System, San Diego, CA, San Diego, California, United States

---

<https://clinicaltrials.gov/study/NCT06399653>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://ClinicalTrials.gov). Generated by [ClinicalTrialsFinder.org](https://ClinicalTrialsFinder.org).