

# Safety and Effectiveness of the BrainsWay Deep Transcranial Magnetic Stimulation (Deep TMS) for Treatment of Alcohol Use Disorder (AUD)

NCT07216872

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Brainsway
<b>Enrollment</b>	186 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Male or female subjects, 18-86 years old.
- Subjects diagnosed with AUD and who meet criteria for moderate (4-5 out of the 12 symptoms) to severe ( $\geq 6$  out of the 12 symptoms) AUD according to the DSM-5 diagnostic criteria as determined by a licensed clinician according to the DSM-5 criteria, and verified with the Mini International Neuropsychiatric Interview (Standard MINI version 7.0.2).
- Subjects who have a history of at least 24 heavy drinking days during the 90 days prior to screening (average  $\geq 8$  HDD/month), based on TLFB).
- Treatment seeking individuals with a treatment goal of achieving abstinence or reducing heavy drinking.
- Subjects able to understand and provide signed informed consent, and able to adhere to the requirements and restrictions of this protocol.

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

### Exclusion (27)

- Subjects diagnosed with schizophrenia or chronic psychotic disorder as determined by a licensed clinician according to the DSM-5 criteria, and verified with the Mini International Neuropsychiatric Interview (Standard MINI version 7.0.2).
- Subjects with present suicidal risk as assessed by the investigator or significant suicide risk based on MADRS item 10 score of 4 or 6, or a history of attempted suicide in the last year.
- Subjects who initiated treatment with any of the following medications which are known to effect alcohol consumption, within 30 days of the Screening visit: acamprosate, baclofen, buprenorphine, disulfiram, gabapentin, naltrexone, topiramate and varenicline.
- Subjects with a significant medical illness that is not well controlled (e.g., hepatic impairment, diabetes, hypertension, heart disease, septicemia, active tuberculosis, progressive neoplasm, frequent and severe migraine headaches, etc.).
- Subjects experiencing acute alcohol withdrawal. This will be determined using the Clinical Institute Withdrawal Assessment of Alcohol - revised (CIWA-Ar) wherein subjects with a value of  $\geq 7$  will not be permitted to receive TMS on that day to mitigate any potential risk of a seizure. Treatments may be rescheduled and CIWA-AR and alcohol breath tests may be reassessed, although if more than the allowed treatment sessions are missed, the subject will be withdrawn from the study.

... and 22 more (see full listing online)

## Locations (9 total)

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Alpha Neuron LLC, Tuscaloosa, Alabama, United States  
Kadima Neuropsychiatry, La Jolla, California, United States  
DTMS Center LLC, West Palm Beach, Florida, United States

... and 6 more locations

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<https://clinicaltrials.gov/study/NCT07216872>

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