ISRCTN85247318 https://doi.org/10.1186/ISRCTN85247318

A study of brain stimulation in adults with attention deficit hyperactivity disorder

Submission date
18/09/2023

Recruitment status
No longer recruiting

Registration date
20/12/2023

Overall study status
Completed

Last Edited
03/11/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Attention-deficit/hyperactivity disorder (ADHD) is a widespread neurodevelopmental condition that affects many people worldwide. It is characterized by difficulties in paying attention, controlling impulses, and remembering things, which can make it challenging to focus and interact with others. There are different types of ADHD, but the most common include both inattention and hyperactivity. While medication helps some people with ADHD, it doesn't work for everyone. This can lead to problems in school, work, and daily life. ADHD has a big impact on society, costing a lot of money because of lower achievements in education and work. To tackle this issue, researchers are looking into non-invasive brain stimulation as a treatment. This involves using safe methods to stimulate specific parts of the brain responsible for ADHD symptoms, potentially offering new hope for those affected by the condition. This study aims to find out if a new treatment called transcranial random noise stimulation (tRNS), combined with computerised brain training tasks (CogT) can help reduce the severity of symptoms in people with ADHD, to make it easier for them to function in daily life, and improve their thinking abilities. The study also wants to understand how the brain may change in response to tRNS and CogT. To do this a technique called functional near-infrared spectroscopy (fNIRS). fNIRS is a safe and non-invasive brain imaging technology that uses light to track changes in brain activity, helping researchers understand how our brains work and how brain activity may relate to treatment.

Who can participate?
Adults aged between 18 and 35 years old, with ADHD, who have not taken stimulant and non-stimulant ADHD medications for at least 30 days, and who have a t-score >70 on the CAARS ADHD Index.

What does the study involve?
Participants will be randomly allocated to one of three groups: Group 1 will receive transcranial Random Noise Stimulation (tRNS) at a frequency randomly generated between 100-600 Hz with an amplitude of 0.75mA for 20 minutes; Group 2 will receive transcranial Random Noise Stimulation (tRNS) at a frequency randomly generated between 100-600 Hz (Berger et al., 2021) with an amplitude of 1.5mA for 20 minutes; Group 3 receives sham stimulation that feels real but does nothing.

On the first day of the study, all participants will complete a battery of cognitive and ADHD symptom assessments at Neurode Labs Study Facilities. Participants will then complete 20-minutes of cognitive training on their mobile phones while receiving either tRNS or sham stimulation. For the next 26 days, in their own homes, participants will complete cognitive training and tRNS/sham for 20-minutes per day on their personal phone while receiving tRNS /sham from the investigational device. On day 14, participants will receive an app-based notification asking them to complete a 10- minute questionnaire on a mobile app. On day 28, participants will come back to the Neurode Labs study facilities and repeat the same steps from day 1. They will return the investigational device on this day. On day 42, participants will receive an app-based notification asking them to complete a 10- minute follow-up questionnaire in the mobile app.

What are the possible benefits and risks of participating?
We cannot guarantee or promise that participants will receive any direct benefits from this research; however, they will be providing a valuable contribution to the scientific knowledge in this field. The indirect benefit of participating in this study is that they will be contributing to the potential development of a non-drug treatment for adult ADHD.
Medical treatments often cause side effects. Participants may have none, some or all of the effects listed below, and they may be mild or moderate. There may be side effects that the researchers do not expect. Most side effects go away shortly after treatment ends. However, sometimes side effects can be long-lasting.
The risks involved in use of the investigational device and mobile App include:
* Discomfort of wearing the investigational device headset,
* Adverse effects from completing cognitive tasks. These include mild headaches and occasional feelings of frustration.
* Participants may experience distress about the prospect of brain stimulation or while completing the online DASS questionnaire.
* The following adverse events are rare and range from mild to moderate in severity: headache, tingling sensation, itching, skin redness, minor burn, scalp pain, discomfort, sleepiness, mood change, difficulty concentrating, neck pain, flashes of light during stimulation, nausea, dizziness, stomach-ache, constipation, frequent urination, increased appetite, and teeth clenching.

Where is the study run from?
Neurode Labs Pty. Ltd. (Australia)

When is the study starting and how long is it expected to run for?
July 2023 to March 2024

Who is funding the study?
Neurode Labs Pty. Ltd. (Australia)

Who is the main contact?
Nathalie Gouailhardou (Co-founder and CEO), nathalie@neurode.com.au

Contact information

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Principal investigator

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Study information

Scientific Title
A double-blind randomised sham-controlled proof of concept study of non-invasive brain stimulation in adults with attention deficit hyperactivity disorder (PCBSADHD)

Acronym
PCBSADHD

Study objectives
1. It is hypothesised that both amplitudes of tRNS + cognitive training will improve symptom severity (primary outcome), functional impairment, and cognitive performance over sham stimulation + cognitive training.
2. We hypothesise a larger treatment effect for 1.5mA of tRNS + cognitive training than for 0.75 mA of tRNS + cognitive training.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/09/2023, Bellberry Human Research Ethics Committee (123 Glen Osmond Road, Eastwood, 5063, Australia; +61 8 8361 3222; bellberry@bellberry.com.au), ref: 2023-08-979

Study design
Interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Adult attention deficit hyperactivity disorder (ADHD)

Interventions
Participants with ADHD will be randomly assigned to one of three groups:

Group 1 will receive transcranial Random Noise Stimulation (tRNS) at a frequency randomly generated between 100-600 Hz with an amplitude of 0.75mA for 20-minutes on 28 consecutive days. Stimulation will occur over left dorsolateral prefrontal cortex and right dorsolateral prefrontal cortex.

Group 2 will receive transcranial Random Noise Stimulation (tRNS) at a frequency randomly generated between 100-600 Hz (Berger et al., 2021) with an amplitude of 1.5mA for 20-minutes on 28 consecutive days. Stimulation will occur over left dorsolateral prefrontal cortex and right dorsolateral prefrontal cortex.

Group 3 will receive sham stimulation, which involves brief activation (30-seconds ramp up immediately followed by 30-seconds ramp down) of the stimulator at the beginning of the 20-minute session, with no stimulation during the other 19 minutes, on 28 consecutive days. The brief activation will be delivered at 1.125mA (i.e., the midpoint of the two active conditions).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neurode Wave

Primary outcome(s)
ADHD symptom severity measured using the Conners Adult ADHD Rating Scales (CAARS) DSM-IV ADHD Symptoms Total score on Day 1, Day 14, Day 28, and Day 42.

Key secondary outcome(s))
1. CAARS DSM-IV Inattentive Symptoms score measured on Day 1, Day 14, Day 28, and Day 42.
2. CAARS DSM-IV Hyperactive-Impulsive Symptoms score measured on Day 1, Day 14, Day 28, and Day 42.
3. Cognitive function measured by the Tests of Variables of Attention and Digit Span on Day 1 and Day 28.
4. Performance on cognitive training tasks measured on Days 1-28.
5. Functional impairment measured with the Weiss Functional Impairment Rating Scale – Self Report (WFIRS-S) on Day 1, Day 14, Day 28, and Day 42.
6. Brain activity measured by the investigational device on Days 1-28.

7. Feasibility of the investigational device (inclusive of collection of adverse events) measured on Day 28.
8. Depression, anxiety, and stress as measured by the DASS-21 on Day 1, Day 14, Day 28, and Day 42.

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Male and Female adults aged between 18-35 years old.
2. Individuals with unmedicated ADHD, who have not taken stimulant and non-stimulant ADHD medications for at least 30 days, and have t-scores > 70 on the CAARS ADHD Index measured at screening.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Key exclusion criteria
1. CAARS ADHD index t-scores < 71.
2. English is not their primary language
3. Individuals who may be pregnant or are planning to become pregnant during the 42-day period of study
4. Individuals self-reporting any of the following conditions:
4.1. Acute psychiatric disorders (e.g., psychosis, schizophrenia)
4.2. Substance abuse disorder
4.3. Autism diagnosis
4.4. Anxiety disorders hindering participation in face-to-face activities involving wearing a clinical headset
4.5. History of unprovoked seizures, epilepsy diagnosis, or having a first-degree relative with such conditions
4.6. Traumatic brain injury, brain tumors, or brain lesions/skull abnormalities 3.7. Serious medical conditions, such as cancer
4.8. Current use of psychoactive medications

4.9. Presence of metallic implants in the body
4.10. Severe scalp or facial skin conditions, such as eczema

Date of first enrolment
02/11/2023

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
Australia

Study participating centre
Neurode Labs Pty. Ltd.
76 Windsor Street
Paddington
Australia
2021

Study participating centre
Neurode Labs Study Facilities
Bay 5-7 North, 2 Locomotive St
Eveleigh
Australia
2015

Sponsor information

Organisation
Neurode Labs Pty. Ltd.

Funder(s)

Funder type
Industry

Funder Name
Neurode Labs Pty. Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date