Modulating Amygdala and dACC activity during reward volatility in affective decision-making

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56892

Source
ToetsingOnline

Brief title
Modulating activity in affective decision-making

Condition

- Other condition

Synonym
normal brain function

Health condition

fundamenteel neurowetenschappelijk onderzoek in gezonde volwassenen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO

Intervention

Keyword: approach avoidance, computational modelling, Transcranial Ultrasonic Stimulation

Outcome measures

Primary outcome

During the task, participants' responses will control a joystick whose movements will be recorded. These behavioural responses will be categorised based on in-session conditions and between-session stimulation conditions. This allows us to compare the difference in behavioural responses between each condition.

Secondary outcome

Cortical changes in oxygen usage will be mapped using fMRI during task performance. With this, we can map oxygen usage in brain areas including the ones that were shown to be involved by previous studies such as the Amygdala, dACC. This activity can then be related to between-session stimulation conditions and within-session task conditions.

In addition to this, we will also use measures of autonomic arousal during the sessions such as respiratory activity, heart rate and electrodermal activity.

Study description

Background summary

Traditionally, only neuroimaging studies have been used to map the neural mechanisms of approach/avoidance behaviour. The limitations of these types of studies is that the correlations they find between neural activity and behaviour is purely correlational. We want to go one step further by stimulating network nodes found to be related to approach/avoidance behaviour by said studies using non-invasive brain stimulation. To be specific, we want to stimulate the Amygdala and dACC using Transcranial Ultrasonic Stimulation (TUS) to map what effects stimulating these areas has on both behavioural changes and cortical oxygen usage by having the participants complete an 'approach/avoidance' task in the functional Magnetic Resonance Imaging (fMRI) scanner. With this, we hope to provide causal neuromodulation evidence for the roles of the Amygdala and dACC in approach/avoidance behaviour.

Study objective

Our main goal is to clarify the behavioural and neurophysiological effects of short-term TUS on deep brain circuits in humans. We will compare the effects of Amygdala-TUS, dACC-TUS and sham-TUS to one-another using a behavioural task and fMRI. Our secondary objective is to map learning behaviour and tracking of the volatility of stimuli-outcome relations using computational modelling.

Study design

The study will be a four-visit, single-blind, randomised, crossover trial. During the first session, structural MRI scans will be obtained and the participants will practice the behavioural task in the scanner. The second, third, and fourth sessions are ultrasound intervention sessions. We will use a factorial design with stimulation (Amygdala-TUS, dACC-TUS, sham-TUS) as a within-subject factor.

Intervention

Participants will receive sham and verum TUS targeted at the amygdala/dACC.

Study burden and risks

Participants will receive no direct benefit from participating, though they often report enjoying their participation and the opportunity to experience MRI and TUS. Participants will receive a standard financial compensation where applicable (¤15/hour; ¤135 in total for all four sessions). Before participation, all subjects will be screened for contraindications with respect to non-invasive brain stimulation and MRI. The estimated risk for participating in MRI measurements and TUS-based interventions is minimal. The noise and the relatively confined space of the MRI scanner may cause discomfort to some subjects. TUS for human neuromodulation has never resulted in serious adverse events (Blackmore, Shrivastava, Sallet, Butler, & Cleveland, 2019; Pasquinelli,

Hanson, Siebner, Lee, & Thielscher, 2019; Sarica et al., 2022). Similar to applications of well-established biomedical ultrasound (ter Haar, 2010), the safety of study participants is ensured by adherence to internationally recognized practices and guidelines (e.g., from the U.S. Food and Drug Administration (2017)). In all cases, we will adhere to the recommendations of the International Expert Group on Transcranial Ultrasonic Stimulation Safety and Standards (ITRUSST, https://itrusst.com). Minor side effects of participating in a TUS experiment may include light transient headache and fatigue (Legon et al., 2020). To conclude, the risk and burden associated with participation are considered minimal, and we do not expect any (serious) adverse events during the project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Between 18-40 years of age;
- The ability and agreement to provide informed consent in sound body and mind, and the ability to fulfil the study*s requirements

Exclusion criteria

- Under 18 years of age;
- The consumption of more than four alcoholic units or any recreational psychoactive drugs within 24 hours before participation;
- A history of serious head trauma or brain surgery, or (close relatives with) epilepsy, convulsion, or seizure;
- Any current episodes of psychiatric or neurological disorders;
- Claustrophobia;
- Current pregnancy;
- Predisposition for fainting spells (syncope);
- Hearing problems or ringing in the ears;
- Implanted metal devices or large ferromagnetic fragments in the head or upper body (excluding dental wire), or jewellery/piercing that cannot be removed;
- Use of a medical plaster that cannot or may not be taken off (e.g., nicotine plaster);
- Use of (prescription) medication interacting with neuromodulation;
- Skin disease or sensitivity at intended stimulation sites;
- Calcifications in the brain in the acoustic path, see Chapter 6.4 of the C1 for a more elaborate explanation.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-11-2024
Enrollment:	64
Type:	Anticipated

Medical products/devices used

Generic name:	IGT driving system - low intensity transcranial ultrasonic stimulation
Registration:	No

Ethics review

Approved WMO Date:	01-08-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-01-2025
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86011.091.24