Santo Daime study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21269

Source
NTR

Brief title
TBA

Health condition

N/A

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

The main study parameter is the drug induced change in brain activity and neurometabolite concentration when comparing ayahuasca to baseline.

Secondary outcome

The change in subjective state and cognitive flexibility will be assessed and correlated with the neurological effects. The modulatory effects of the ceremonial setting on these changes

will be evaluated through a controlled music paradigm.

Study description

Background summary

Ayahuasca, a South American psychotropic plant tea, has been traditionally used for centuries by indigenous and mestizo populations throughout the Amazon Basin for magical, ritual, and medicinal purposes. In the last few decades, there has also been an increase in the availability of the brew to non-Amazonian populations. Subsequently, there has been an increase of anecdotal reports from ayahuasca users regarding the acute and long-term effects of the substance, with many claiming that the substance has positive and therapeutic potential for psychosocial, emotional, and substance-related problems(Frecska, Bokor, & Winkelman, 2016). Ayahuasca contains the β-carboline alkaloids harmine, tetrahydroharmine, and harmaline, and the tryptamine N, N dimethyltryptamine (DMT), a hallucinogen that is structurally similar to serotonin (5-HT).
Similar to other serotonergic hallucinogens, 5-HT2A receptor activation is the suggested mechanism for the acute subjective effects of ayahuasca, which include perceptual modifications, increased rates of thinking when eyes are closed, and increased emotional lability. It is hypothesized that the effects of DMT can include brain network connectivity alterations, changes in neurometabolite concentrations, and cognitive changes such as enhancements in flexible (creative) thinking. Although interest into these mechanisms is high, the ability to perform controlled studies with ayahuasca is extremely difficult, due to a lack of availability of a GMP quality substance.
Observational studies have been proposed as an alternative to controlled studies with ayahuasca. Observational studies employ the fact that ayahuasca is used in ceremonial settings. Facilitators of these ceremonies have allowed researchers from our group to ‘observe’ and invite ceremony participants to participate in an academic research project. The present study will also employ an observational design, but in addition use functional imaging for assessing the neural correlates of the acute ayahuasca experience, in relation to subjective outcomes including ratings of substance intensity, well-being, and cognitive alterations. To study the facilitating effect of the ceremonial setting on subjective experiences, we will make use of a ritualistic music paradigm during the imaging. Furthermore, as it is likely that acute functional and behavioral changes induced by ayahuasca are accompanied by changes in neurochemistry, neurometabolite concentrations will be assessed.

Study objective

Ayahuasca significantly modulates high-level network functional connectivity and neurometabolite concentrations when compared to baseline.

Study design

Participants will be coming to the facilities on two occasions. On the first day, a baseline assessment of cognitive tests and questionnaires will be taken to get a baseline of subjective state and cognitive flexibility. Afterwards, a one-hour fMRI session will determine brain activity and neurometabolite concentrations. Participants will return for a second day during which the same measurements will be taken. This visit will occur after the cohort's usual ayahuasca ceremony, while participants are still under the influence.

Intervention

Ayahuasca, provided by Santo Daime.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
 Must be a member of the Santo Daime church, who volunteers to participate in the research project.
 Must be older than 18 years of age.

Exclusion criteria

 Medical devices and implants containing metal (e.g. pacemakers, copper birth control spirals, permanent jewelry, aneurysm clips, hearing aids).
 Permanent make-up and other large tattoos.
 Pregnancy or lactation.

 Use of (medicinal) substances in the past 24 hours which can interact with MAO inhibitors, including further MAO inhibitors (tranylcypromine, Parnate, Nardil, Aurorix, etc), all sympathomimetics (including amphetamine, cocaine, methylphenidate, ephedrine, metaraminol, certain asthma agents), certain medicines for cough, cold, hay fever, and allergies that are available without a prescription, such as Otrivin and dextromethorphan-containing agents (Dampo, VapoTab “Vicks”, Darolan and others) and antihistamines, diet medication (such as Ponderal), all antidepressants including SSRIs (citalopram, sertraline, etc) and trycyclic antidepresssents (clomipramine, etc), certain anti-asthma medications such as Berotec, Bricanyl, Ventolin, Salbutamol, Terbutaline, Pulmadil, or Serevent, blood pressure medication (beta blockers, methyldopa, thiazide diuretics, calcium antagonists, and ace inhibitors), antimicrobials or antibiotics, narcotic analgesices (including pethidine), or other substances like St. John’s wort, lithium, alprazolam, buspirone, L-tryptophan, L-DOPA, disulfiram, hydralazine (such as Apresoline), and carbamazepine (such as Tegretol).
 Use of Prozac in the past 2 weeks.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2020
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-09-2020
Application type:	First submission

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
NTR-new	NL8878
Other	METC az/UM : METC19-050

Study results