

Neurometabolites and functional brain connectivity in experienced ayahuasca users of the Santo Daime Church before and after drinking the psychedelic ayahuasca brew: an observational study

Published: 11-03-2020

Last updated: 10-04-2024

The current study will assess the neurocognitive effects of ayahuasca on brain activity and neurometabolite concentration, and how these effects correlate with various measures assessing subjective state and cognitive flexibility.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50144

Source

ToetsingOnline

Brief title

The effect of Ayahuasca on brain function and cognitive flexibility

Condition

- Other condition

Synonym

NA

Health condition

no condition

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ayahuasca, Functional connectivity, Neuroimaging

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

Additionally, the change in subjective state and cognitive flexibility will be assessed and correlated with the neurological effects. Lastly, we will evaluate the modulatory effects of the ceremonial setting on these changes 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. Ayahuasca contains the α -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-HT_{2A} 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

The current study will assess the neurocognitive effects of ayahuasca on brain activity and neurometabolite concentration, and how these effects correlate with various measures assessing subjective state and cognitive flexibility.

Study design

Observational study

Study burden and risks

Participants will visit the lab twice. Both testing days will include completion of questionnaires and cognitive tasks, as well as 1 hour in the MRI scanner. However, the second testing day will be performed after their regular church meeting, while individuals are under the influence of ayahuasca. On the second testing day a single small blood sample will be taken to measure drug concentrations. Throughout the whole procedure a Santo Daime facilitator will be present to ascertain the participant*s well-being.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion 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 tricyclic antidepressants (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 analgesics (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 invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-09-2020

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 11-03-2020

Application type: First submission

Review commission:

METC academisch ziekenhuis Maastricht/Universiteit
Maastricht, METC azM/UM (Maastricht)

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	NL70901.068.19