

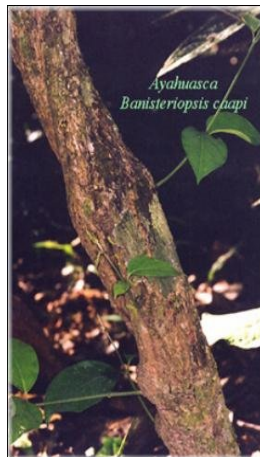


NATURALEZA, CIENCIA Y RELIGIÓN



...Debido a su ignorancia, a su vocación católica monoteísta y a sus pretensiones de Conquista, los españoles que llegaron prohibieron junto con el culto a los antiguos dioses, el consumo de las "plantas diabólicas del Nuevo Mundo". En 1638, una instrucción del Santo Oficio español sentencia:

«NOSOTROS, LOS INQUISIDORES, ABOCADOS A SUPRIMIR LA PERVERSIDAD HERÉTICA Y LA APOSTASÍA, POR VIRTUD DE LA AUTORIDAD APOSTÓLICA, DECLARAMOS CONDENADA ESTAS PRÁCTICAS, PUES CONSTITUYE UN ACTO DE SUPERSTICIÓN OPUESTO A LA PUREZA E INTEGRIDAD DE NUESTRA FE CATÓLICA».



La AYAHUASCA nos ofrece un enorme potencial, como una práctica ancestral, de SANACIÓN, CURACIÓN y de CRECIMIENTO INTERIOR que traspasa las fronteras de los modelos de tratamientos convencionales.

MOVIMIENTO PARA LA ALIANZA NACIONAL PERUANA

www.moanp.org

moanp@hotmail.com

AYAHUASCA

AS ALTERNATIVE TREATMENT FOR POST TRAUMATIC STRESS DISORDER (PTSD) (A PROPOSED PERUVIAN STUDY)

Information provided by: CENTRO PARA LA EVALUACIÓN DEL ESTRÉS
LIMA PERU

Purpose: This study is being conducted to find out if **AYAHUASCA** is safe and can help people with Post traumatic stress disorder (PTSD) arising from being a victim of a violent exposure (DSM IV)

Condition	Intervention	Phase
Posttraumatic Stress Disorder	AYAHUASCA BREW	Phase I

RELATED TOPICS: Post Traumatic Stress Disorder, Ayahuasca, Ethno Medicine,
Study Type: open-label
Study Design: Safety /Efficacy Study

OFFICIAL TITLE

Initial Clinical Trial Testing of the Safety and Efficacy of AYAHUASCA in Subjects with Chronic Posttraumatic Stress Disorder either related to crime victimization ,violence (terrorist attacks, combat related PTSD)

Study Details:

Primary Outcomes: Improvement in PTSD symptoms, measured by CAPS score.

Secondary Outcomes: Improvement in PTSD symptoms as assessed through other measures.

Expected Total Enrollment: 50 individuals, plus.

Study start: **PENDING** completion **PENDING**

Posttraumatic stress disorder (**PTSD**) occurs in response to a traumatic event or events. It is most likely to occur following an event involving perceived personal threat, such as physical assault, rape etc. PTSD is clearly a public health problem that causes a great deal of suffering and accounts for a significant portion of health care costs. This study will examine whether **AYAHUASCA** can be safely administered to participants with PTSD ,and will reduce PTSD symptoms either related to crime victimization or violent

exposure(,terrorism attacks, combat related); and has **not been treated at all**, (considering the socioeconomic status of the population to be investigated and taken account the medications cost specially antidepressants the possibility of comparing this modality of ayahuasca treatment over conventional ones (SSRI medications) will not be the primary focus of this study) or gotten better after psychotherapy and/or treatment with an SSRI (selective serotonin uptake inhibitor, such as Zoloft, Paxil etc)This preliminary open trial study, in this patient populations (50) will explore safety and efficacy in the treatment of PTSD and also will help to formulate hypotheses for testing (in a well-controlled investigation design) the use of the ayahuasca in the treatment of PTSD and other disorders.

BACKGROUND INFORMATION:

AYAHUASCA, is also known by the names Daime, Yaje', Natema, and Vegetal, is a psychotropic plant tea (hallucinogenic/visionary beverage) that is prominent in the ethno medicine of the Amazon Basin, used by shamans in traditional medicine, rites of passage, and magic-religious practices; . (Schultes and Hofmann, 1982; Dobkin de Rios, 1984) Ayahuasca is integrated into mestizo folk medicine in the Amazonian jungle of PERU COLOMBIA ECUADOR AND BRASIL,).where there use is LEGAL This ancient pattern of use has given way to a more widespread and frequent consumption by members of a number of modern Brazilian-based syncretic religious groups, mainly the Santo Daime and the Uniao do Vegetal, which have incorporated the use of the beverage in their rituals (Dobkin de Rios, 1996). In recent years, groups of followers of these Brazilian religions have become established in the United States and in several European countries, including Germany, Great Britain, Holland, France, and Spain, As a larger number of people have come into contact with ayahuasca, the tea has begun to attract the attention of biomedical researchers (Callaway et al., 1999; Riba et al., 2001b). Ayahuasca is obtained by infusing the pounded stems of the malpighiaceae vine *Banisteriopsis caapi* either alone or, more frequently, in combination with the leaves of *Psychotria viridis* (rubiacae) in Brazil, Peru, and Ecuador or *Diplopterys cabrerana* (malpighiaceae), used mainly in Ecuador and Colombia (Schultes and Hofmann, 1980; McKenna et al., 1984). *P. viridis* and *D. cabrerana* are rich in the psychedelic indole N, N-dimethyltryptamine (DMT; Rivier and Lindgren, 1972; Schultes and Hofmann, 1980), whereas *B. caapi* contains substantial amounts of carboline alkaloids, mainly harmine and tetrahydroharmine (THH), and to a lesser extent harmaline and traces of harmol and harmalol (Rivier and Lindgren, 1972; McKenna et al., 1984).

ISSUES IN DEVELOPING A CLINICAL PLAN

A Clinical Plan of the proposed study in humans to be conducted is to gather data on the drug's safety and efficacy of the use of ayahuasca in the treatment of Post traumatic stress disorder (PTSD). This proposed research project is preceded by previous studies among them **basic safety studies, involving healthy subjects**. ("the scientific investigation of ayahuasca 1998(Dennis j McKenna, PhD, JC Callaway PhD, Charles Grob MD UCLA). (Topographic pharmaco-EE mapping of the effect of South American psychoactive beverage in healthy Jodi riba et al.) **The pharmacokinetics of the active compounds and its metabolic effects** has been study (human pharmacology of ayahuasca: subjective and cardiovascular effects, Monoamine Metabolite Excretion, and

Jordi Riba Marta Valle Gloria Urbano Mercedes Iritia Adelaida Morte and Manuel barbanoj).

The ayahuasca brew has not substantial toxicity, with a very low risk profile its tolerability and the safety of the brew has been demonstrated and the administration of the beverage to patients, for whom the benefits may be obtained, we think, will offset the risks, at the doses administered by previous studies(0.6 and 0.85mg of DMT/kg of body weigh N,N-dimethyltryptamine (DMT), an orally labile psychedelic agent showing 5-hydroxytryptamine_{2A} agonist activity, with the monoamine oxidize (MAO)-inhibiting activity of the carboline alkaloids (harmine, harmaline, and tetrahydroharmine)

PHARMACOLOGY OF AYAHUASCA

(Jordi Riba)

AYAHUASCA, a brown-reddish drink with a strong taste and smell, is a shamanic drug originating in the Amazon. It is obtained from infusing the shredded stalk of the malpighiaceus plant *Banisteriopsis caapi* with the leaves of other plants; it is obtained from infusing the shredded stalk of the malpighiaceus plant *Banisteriopsis caapi* with the leaves of other plants, generally *Diplopterys cabrerana* or *Psychotria viridis*. During the cooking process, which may last for hours, a plethora of chemical compounds from these plants enter the infusion. *Banisteriopsis caapi*'s chief contribution is three alkaloids generically known as β -carbolines, namely harmine, tetrahydroharmine and to a lesser degree harmaline, while *Dyplopterys cabrerana* and *Psychotria viridis* contribute large quantities of N, N-dimethyltryptamine, or simply DMT. The final chemical compositions of ayahuasca infusions show great variability owing to fluctuations in the alkaloid contents of the plants used in its preparation, the differing extraction times and different practices with regard to the greater or lesser concentration of the infusions once obtained.

Of the four main alkaloids which the drink contains it is DMT which is chiefly responsible for its hallucinogenic effects. DMT is a potent ultra-short acting hallucinogen present in numerous species of plant growing in temperate and tropical regions. Before its presence in ayahuasca was discovered it had in fact been identified, along with other indole derivatives in *Anadenanthera* hallucinogenic snuffs which had been used in South America since before Columbus. The compound is remarkable within the hallucinogen family because of its pharmacological characteristics; when administered parenterally it produces extremely strong effects which are felt almost immediately (intravenously) or within around ten minutes (intramuscularly), to disappear within the space of about half an hour or forty-five minutes. Surprisingly, when the drug is administered orally it provokes no psychoactive effects whatsoever, even in doses as high as a gram, appearing to be entirely destroyed in the intestines and at hepatic level by monoamine oxidase (MAO), an enzyme which is widely distributed throughout the body, and thus prevented from reaching systemic circulation and the brain. Because of DMT's inactivity when taken orally several other methods of parenterally administration have been used; *Anadenanthera* and *Virola* snuffs are taken through the nose and synthetic DMT has circulated in a free base form for smoking.

On a molecular level DMT interacts equally with serotonin 5-HT_{1a} and 5-HT_{2a/2c} receptor sites, just like LSD does. Unlike LSD, however, repeated administration of DMT does not lead to tolerance of the subjective effects, or at least it has not done so in studies carried out to date. Furthermore, DMT does not show cross tolerance with this

classic hallucinogen; that is, an individual who has developed tolerance to the effects of LSD through repeatedly taking the drug will experience full hallucinogenic effects if administered a dose of DMT.

What is truly extraordinary about ayahuasca is that in a single preparation it combines DMT which is inactive when taken orally with the β -carbolines referred to above. These tricyclic compounds, to which proserotonergic and prodopaminergic properties are attributed, lack hallucinogenic activity but in vitro they display a potent inhibiting activity with respect to the MAO enzyme, or to be more precise, the isoenzyme MAO-A. In line with the generally accepted hypothesis the β -carbolines' inhibiting of this enzyme would prevent the oxidative deamination of the DMT, which could then reach and exercise its effects on the central nervous system. The experience which follows the ingestion of ayahuasca differs from the effects of parenterally administered DMT by being less intense and of greater duration; the onset of its effects is not instantaneous but occurs approximately an hour after ingestion and the effects usually last for a maximum of two hours, to disappear altogether after around three or four hours. In addition, adverse events such as nausea and vomiting, which are not observed in the parenterally administration of DMT and which are attributable to the action of the β -carbolines, frequently occur. The inhibiting of the MAO brings with it an increase in endogenous catecholamine and serotonin levels which would modulate the effects of the DMT, either reinforcing them or, as has also been postulated, reducing them given that the DMT now has to compete for the 5-HT₂ receptor with higher serotonin levels.>

Effects on the Central Nervous System

There are many problems inherent in studying the effects of hallucinogens on the central nervous system. Their eminently subjective nature hinders quantification makes it difficult for volunteers to undertake tasks or communicate with the evaluator. The evaluation of drugs' effects on the central nervous system is usually carried out via psychomotor performance tests and by using questionnaires to which the subject responds at regular intervals before and after taking the drug, given the alteration of consciousness experienced by the subject after a ayahuasca has been administered asking the subject to actively collaborate by completing these scales is not feasible and questionnaires will be completed once the drugs' effects have worn off, the following morning (HRS) and the other test (HARTMAN SCOR90 PCL) 2/3 days after the ayahuasca sessions. Other test like CAPS and « clinical global impression of change » will be administered every two months to asses the clinical response.

Subjective effects measures, the subjective effects will be studied through the use of scales which permit the ayahuasca effects to be quantified. However, the subjects will not respond to the questions until the effects of the ayahuasca have worn off. One of the scales for use is the [Hallucinogen Rating Scale HRS](#) developed by Rick J. Strassman, which has been translated in Spanish forms part of the study. The scale contains 100 items grouped according to six clinical factors which are characteristically affected by hallucinogens: **cognition, volition, somaesthesia, intensity, perception and affect**. According to its author, this scale describes the effects produced by DMT more accurately than pre-existing scales, which were compiled on the basis of data gathered after the administration of LSD.

This scale does not permit the time sequence of the drug's effects to be followed and it will not therefore be possible to establish correlations with plasma levels, but it does allow the overall quantification of these effects to obtain numerical values which in

principle will be in relation to the dose of the drug administered and will be an indirect methods of the ayahuasca psychophysiological effect (modified state of consciousness)

ANTHROPOLOGICAL PERSPECTIVE

Joseph M Fericgla Ph.D.

ENTHEOGENS refers to a psychoactive substance (most often some plant matter) that induce enlightening spiritual or mystical experience, In a broader sense, the word “entheogen” refers to artificial as well as natural substances that induce alteration of consciousness (**modified states of consciousness**) similar to those documented for ritual ingestion of traditional shamanic inebriants, even if it is used in a secular context. (The term “**Entheogens**” was coined in 1979 by a group of ethno botanists and scholars of mythology (Carl A. P. Ruck, Jeremy Bigwood, Danny Staples, Richard Evans Schultes, Jonathan Ott and R. Gordon Wasson). The term was coined as a replacement for the terms “hallucinogen Ruck et al. argued that the term “hallucinogen” was inappropriate due to its etymological relationship to words relating to delirium and insanity.)

Entheobotany, Shamanic Plants Science ([Visionary substances and emotional training](#))

In anthropology, the emotions are the basic field over which the web of social connections and practices are created. And these, in turn, become our cultural systems and our cultural content. **Emotions are the matrix over which our social live move**, basic types of relational behavior supporting the communication necessary to the creation of our different cultural worlds.

Cultures that fail to encourage the recognition of others, in their existential reality, are not loving cultures. Our culture is a good example in which, the individual, in its fullest essence is not recognized. For our governments, each one of us is only two numbers: a possible vote and a source of tax and no more. For large corporations that have more power than many governments, we are also only a number: the potential sum we spend in their products. The individual is not recognized. And to be recognized does not just mean to be friendly. One can recognize one’s self or another as an enemy, but in the final analysis it is **the recognition that counts**.

There is also a very important area in the study of consciousness and the emotions: **modified states of consciousness** and its long relationship with **art, religions, healing** and the **history**, and especially, the emotional world of each society.

And the modified states of consciousness are equally as interesting whether reached chemically or through bio-mechanical methods such as special breathing, sensory deprivation or ecstatic dances.

The emotions propel and form our reactions to stimuli, especially from other humans. At the same time, the emotions deeply influence our perceptions and cognitive process. They affect the memory, relational ability and the discriminatory process. The emotions condition the way each person establishes relations with others, and with themselves. We can say the emotions are the basis of the world in which we live immersed. **The lack of emotional equilibrium** is one of the few signs recognized by all cultures as being abnormal and anomalous.

The emotions should feel good in the body as if they were at home. And that isn’t a bad way to describe it. Science confirms the idea in psychobiology and neuro-anatomy. The emotions live throughout the body, just as peptides are found throughout organs and tissue. The whole body responds to the chemical language of the emotions. **The body lives the emotions**, not only the mind.

As well as this, there is another big anatomical and functional error that appears in almost all specialized publications. It supposes that the brain is a conglomeration of neurons fed by the glial cells. This is a very wide spread error, even amongst researchers. Really, there are two cerebral systems: the neuronal and the **glial**. The brain has an abundance of glial cells, such as **microglials, astrocities** and others whose function is still little understood. But recent researches have shown that these cells have a central role in certain functions like **memory and learning**. And both these functions are much related with the emotions and states of consciousness.

A person can change their mind in an instant if they are convinced by a consistent argument, but they can't change their feelings about someone in half a second, even if they discover they were mistaken in their feeling. We need more time.

The same happens with consciousness. Isn't possible to change from one state into another in an instant.

In spite of this knowledge, current psychopharmacological studies, financed by giant pharmaceutical corporations, only bother to discriminate between repulsion and attraction to a stimulus. Measuring only the number of automatic blinks, hard bits and other biological variables, they determine the efficacy of certain medications for our souls.

The labs have simplified our emotions, substituting them for a limited number of somatic reactions. In this sense, although we know the essential importance of the emotions, we are still a long way from understanding exactly **what they are and where they come from**. And farther still from understanding to what degree **we are formed** by our **emotions** and how much **our emotions are conditioned by culture**.

We know that emotions and different types of consciousness play a basic role in our cultural life. Every day, each person passes through hundreds of **different states of consciousness**. The question is that each culture trains us to recognize, use and understand only some of all these different states of mind. For example, we just say "sleep" but really between the moment we start and finish sleeping, we have passed through four different states of consciousness: **hipnagogic, dreaming sleep** or rapid eyes movement, **deep sleep**, or without dreams, and **hypnopompic estate**, previous to wake up. And neurons work different in each one of these four estates. Some societies nourish the dream conscious, other the hipnagogic estates, called "ensoñacion" in Spanish and I think there isn't any specific English word relating to this mental estate, only to dream. Our society, and we, doesn't discriminate between one's and other different estate of consciousness during sleeping time, only psychoanalysts they do some discrimination.

In spite of this, there have been few attempts to classify cultures according to the way they treat the emotions. In till now, anthropology has not been interested in constructing a cultural theory of the emotions, even less so in elaborating a theory addressing the central role of the **entheogenic substances** in the web that underlies all of our History.

Entheogens -each one in a different way- acts as **an emotional amplifier**. Firstly, they amplify the present emotions. This is why it's important to be in a good mood before taking psychoactive substances, except, of course, if someone wants to explore the origin of their bad mood. For this reason, some therapists, mystics and people with real commitment on their personal growth speak about the benefits of a bad trip.

Secondly, entheogens can reveal old emotions, bringing emotions from the past into the present. This is something basic to all processes of self-discovery and psychotherapy.

Thirdly, psychoactive substances increase perception of setting, allowing as to penetrate deeply into the webs that's constitute the setting. Also, the emotions are felt more intensely.

So, since the emotions and inebriants walk hand in hand, a cultural theory of emotions must include an analysis of the role played by these strange yet intimate substances in our emotional History.

The thing that brings us closer to other humans isn't sharing the same language, social status or sharing the same territory, but living in a shared web of emotions and feelings. Culture is an almost closed matrix of conversations creating a reality of behavioral coordinates. The fact of living in a culture, conditions us to live according to certain determined emotions. Our experience of the world is cultural. We use our accumulated experience to explain our new experiences. So, as the oriental philosophers affirm, perception and illusion are indistinguishable.

The principle experience that entheogens produce is the amplification of the emotions and, as a consequence, can help the process of amplification of consciousness. It seems to me that inebriants induce amplification of the basic emotions and from this offer the possibility of the increase in consciousness. All the other experiences often called "emotions" are really feelings, and feelings are emotional impulses that have passed through the filter of culture and consciousness. We have only six basic and biological emotions and when they pass through the filter of culture and consciousness are transformed into hundreds of different feelings. For this reason each culture has its own way of codifying these feelings.

For this reason, human beings put the emotions through the filter of the culture and we convert them into feelings. The same as we do with the other biological impulses. Similarly to entheogens and their effects and expressions, the emotions and their manifestations as feelings are a very important field of study where Nature and culture are interlaced forming a unique system.

Now, general results of research carried out with the help of my collaborators in the last year. In this research we were looking at the **psychological changes occurring with a session with ayahuasca**. We used the **Hartman test as the tool of control**. It is one of the most profound tests that exists and which, in my opinion, should be used systematically in all investigations about visionary substances and psychotherapy or personal growth or change.

This test was carried out on small groups who attended various sessions of ayahuasca. The attendants came from very different cultural and economic backgrounds. The majority of these people are not habitual consumers of either ayahuasca or any other entheogen.

After analyzing the results from about one hundred people, we observed that certain significant changes took place in the majority of the volunteers. The following is the resume of those changes. In other words, these changes are related simply to the effect of the entheogen in a secure frame, without any process of psychotherapy or elaboration or explanation from our side.

I'm going to enumerate the observations of the most important changes.

In the tests taken before the session, there appears to be something very common among the people who attended, that generally they are very curious about "having experiences", in the analysis of the tests conducted after the ingestion and comparing them to the previous ones the following common results were observed:

A lot of emotional flow appears, **even after two days** of taking the entheogen. This is the variable which is modified the most. Keeping in mind that it is not easy to produce an emotional aperture which lasts, at least, a few days, this sole effect would make ayahuasca a very useful substance in many ways.

After a session with this powerful Amazonian psychoactive substance, objectivity about the structure of one's personality and objectivity about the internal experiences of each

individual becomes much better. In another words, the lens through which we see our internal world (what I feel in this moment, who am I, how do I react to this or that situation, my infant memories, etc.), is normally more or less unfocused. It depends on each individual, but it is always more or less unfocused. Consuming ayahuasca this lens gets adjusted. According to my collaborators, who are specialists in psychodynamics and clinical psychology, this effect is really very strange and difficult to obtain with other treatments. In its essence, the intake of this entheogen permits an increase in the objectivity of ones emotions and memories.

Consequently, the focus on the general personal situation becomes better and a lot of clarity is gained on whatever is happening in the social life of the subject.

We have also observed that ayahuasca makes the body more flexible. This change also appears repeatedly. Along with the body the psyche also becomes flexible, and the rigidity of pride is relaxed. As a result a person's vision of the universe, his position in it and his opinion of the world changes.

The consumption of ayahuasca produces a state of "open mind": which means that the person is more capable of recognizing his own personal internal reality starting with empathy for others. It generates a strong emotional empathy.

In fifth place, it gives rise to moral structure. The system of moral values and personal convictions becomes more firm. This means a major maturity in the individual. Nevertheless, it also entails a danger that I often observe in the regular consumers of this or any other entheogen: it is easy to excessively overvalue individual morals and to believe that one is in possession of the Great Truth, without knowing that this Great Truth move, does not exist as something unique. In this sense, ayahuasca produces seeds of madness by increasing narcissism. But it is very interesting because at the same time it opens the possibility of self-inspection. With this, it can be affirmed that even though there is a certain degrade of increased madness, a curative tendency which was not there before taking ayahuasca also appears.

It is also observed that the balance between the conscious and the unconscious becomes greater, with all that it implicates from many points of view, amongst which there is reduction of anxiety and a decrease in depression, if it is there. That is to say, ayahuasca itself does not produce an integration and resolution of psychological and emotional conflicts, but improves the vision that the subject has of himself and his symptoms. Under the effect of ayahuasca, one discovers what it is to suffer and what one suffers, even though it is not integrated. So it is a good medicine for neurosis.

In the seventh place, after a session of ayahuasca the capacity to love grows as one sees others more objectively. With this, possibilities of more profound interpersonal relations open up. It can be said that it increases the romantic sensibility.

It also increase what is called "contact with ones personal necessities". This is something that happens very seldom in therapy and it is very important. After a session with ayahuasca people connect better with their own necessities, which means, in a certain way, to be conscious of ones weaknesses, especially emotional ones.

It is noted that the capacity of expressing ones demands to others also becomes better. This attitude is very necessary to situate oneself fully in society and even though this same attitude of "asking to satisfy ones? necessities" can be excessive, it is good. If ones demands become excessive, the surroundings would take care of limiting them, but if one is incapable of demanding for one will die with ones real necessities unsatisfied. And I am not talking about childish necessities but the profound ones.

Another very important and surprising effect registered after a session of ayahuasca, is the geometric effect on the resolution of psychological conflicts. That is to say, the bigger the conflict before taking ayahuasca, the better the result after. For example: if

somebody had depression of level five and after the session it's a level 3, that's a reduction of 2 points. Somebody with a level 10 depression after the session has a level 5, that's a reduction of 5 points generates a creative aperture in the senses through the subject discovers he can find solutions to his problems. Consciousness of the "internal guide" increases a lot: the subject takes charge of himself, intuition and personal criteria grow. The bigger the previous blockage, the stronger the therapeutic effect. It also decreases maladjustment and increases responsibility of the subject for his life. As a consequence of this, sentiments of guilt are reduced.

Also with the experience of ayahuasca the capacity to love grows with this, possibilities of more profound interpersonal relations open up. It can be said that it increases the romantic sensibility.

Ayahuasca itself does not produce an integration and resolution of psychological and emotional conflicts, but improves the vision that the subject has of himself and his symptoms. This has an effect on the resolution of psychological conflicts. That is to say, the bigger the conflict before taking ayahuasca, the better the result after, with this, it can be affirmed that a curative tendency which was not there before taking ayahuasca. For this reason I like to call certain psychoactives "adaptogens" that stimulate the active adaptation to the world and life in the people and other animals.

These latest results complement my previous research that allowed me to observe that ayahuasca stimulates theta waves. These brain waves are related to memory, dreams and complex processes of adaptation in humans and other mammals. Through the latest techniques of cerebral analysis, shown that ayahuasca activates some of specific parts of the cortex, called anterior cingulate, and the hippocampus. These anatomic areas are associated to the memory and emotions. Today we have proof from different fields that ayahuasca stimulates the recovery of long term memory. And this is very, very important in order to use them in psychotherapy, education, intelligence stimulation strategies and mental health.

The relationship between the emotions, **entheogenic substances, social order and mental health are indisputable**. It is our generational responsibility to look for new ways of healthy socialization using inebriants and new frames through which to experience cathartic states with safety and responsibility. Just as humans have throughout History. But the way isn't elevating myths about the shamans and other exotic figures from distant and really unknown peoples. Amongst them there are some wise and learned shamans and also some charlatans and frauds. We need to have more critical and common sense.>

LEGAL STATUS: IN PERU THE PRACTICE OF AYAHUASCA IS LEGAL

The current legal status of ayahuasca or its source plants in the United States is unclear; although DMT is a Schedule I controlled substance, (USA DEA "criteria")

On February 21, 2006 the U.S. Supreme Court decided that members of the ayahuasca-using União do Vegetal (UDV) church must be allowed to continue using their DMT-containing brew until a final decision is reached in their case against the USA government. Although many news reports about the ruling seem to suggest that the decision is final, the case before the Supreme Court was simply a re-re-re-hearing on a "preliminary injunction" that the UDV requested to stop the DEA from seizing their psychoactive tea and arresting church members.

The decision was a unanimous 8-0 (Justice Alito did not participate in the decision because he was not yet on the Court at the time of the hearing). The Supreme Court

decided most of the points of contention in favor of the UDV, although the Supreme Court disagreed with the lower court, which said that the United Nation's International Convention on Psychotropic Substances did not control ayahuasca because it is derived from plants (see below for more on this).

Summary of the Opinion:

The Supreme Court held that the Religious Freedom Restoration Act, passed in the wake of the Supreme Court's decision in *Oregon v. Smith* (1990), clearly carved out the possibility for exemptions to the Controlled Substances Act for religious groups and that the Government had failed to show that there would be serious harm done to make such exceptions in this case. The Court wrote:

Before this Court, the Government's central submission is that it has a compelling interest in the uniform application of the Controlled Substances Act, such that no exception to the ban on use of the hallucinogen can be made to accommodate the sect's sincere religious practice. We conclude that the Government has not carried the burden expressly placed on it by Congress in the Religious Freedom Restoration Act, and affirm the grant of the preliminary injunction. [*Gonzales v. UDV*, 2006]

This decision is final, and cannot be appealed further. It allows the UDV to transport and use DMT-containing hoasca tea until the conclusion of the trial in the District Court (a US Federal trial court) looking at the actual religious freedom questions involved. This Supreme Court decision lends substantial weight to the UDV's case by dismissing some of the key arguments by the DEA and federal government against the use of the tea by the UDV.

"The Government's argument echoes the classic rejoinder of bureaucrats throughout history: If I make an exception for you, I'll have to make one for everybody, so no exceptions."

Justice Roberts, writing for the U.S. Supreme Court, *Gonzales v. UDV* (2006)

Major points in this decision include:

- The Religious Freedom Restoration Act is the controlling law for this matter.
- The Government must prove that it has a compelling interest in criminalizing the religious use of this tea for this specific instance.
- Just because the Government says that a drug is dangerous in legislation (DMT is Schedule I) does not relieve the government of its obligation to show that it is dangerous in this specific case.

MEDICAL PSYCHOLOGICAL EVALUATION

The 50 volunteers that will be enrolled in this study will come from individuals previously identified as having **PTSD** from a parallel epidemiological survey ("**STUDY OF THE POST TRAUMATIC STRESS IN THE POPULATION OF THE SOUTHERN CONE OF LIMA (VILLA MARIA DEL TRIUNFO and VILLA DEL SALVADOR)**) victims of the **VIOLENT TURMOIL** that affected Peruvian society during the decades of 80 and 90, those individuals which the study identify as having PTSD will receive information about **PTSD**, treatments and referral alternatives, and will be offer to participate voluntarily in this research study each of the participants will receive a basic physical examination, medical history, laboratory tests, ECG, and urinalysis and pregnancy test (for females in childbearing age); volunteers will be interviewed by a psychiatrist for identification those with a **major psychiatric disorders** (bipolar I schizophrenia etc) and **alcohol or other substance**

dependence, that if present will be reason for exclusion in this particular project, participants will complete the scor90, PCL test, clinical global impression of change) the volunteers will receive detailed information on the nature of ayahuasca brew and the general psychological effects of psychedelics and their possible adverse effects, as reported in the psychiatric literature.; The study will be conducted in accordance with the Declarations of Helsinki and Tokyo concerning experimentation on humans. All volunteers will give their written informed consent to participate.

AYAHUASCA BREW will be administered in scheduled sessions two to three weeks apart, the sessions will be carried out under the guide of an experienced SHAMAN (MAESTRO **AYAHUASQUERO**) who will conduct the **AYAHUASCA SESSIONS**, (a physician and medical assistance will be available if the need arise) on small groups 5 to 10 participants the sessions will be begin about 11pm and last till 2-3 am the attendants came from very different cultural and economic back grounds. In every session uniformity was maintained in the way ayahuasca was taken: 5 to 10 people were put in closed groups. In every session two doses per person were taken; the first one of 30 ml and after 90 minutes, the second one of 50 ml. almost all the time was spent in darkness, and long periods of silence will be broken by softly whistled shamanic songs (**ICAROS**). The sessions were closed with very soft, cradle maternal chants. After the **AYAHUASCA SESSION** are over (3-4 hours) all participants are required to stay at the ayahuasca center (**MALOCA CENTER**). till next morning when will be evaluated by the researchers; **HRS** test will be given and a sample of urine will be obtained (for toxicological analysis); sample the ayahuasca brew will be saved for HPLC analysis in a determined laboratory; an appointment will be given 48 hours after the session, (to avoid any direct registered effect of the entheogenic) to meet with the investigators at the main office of the “Centro Para la evaluacion del estres for follow up and complete the required tests (**HARTMAN, SCOR 90, PCL** test).

CAPS and the “**clinical global impression of change**” will be administered” every two months until the end of the study.

Participants in this open-label study will act as their own controls. The open-label study will lasts six months to a **NO INDIVIDUAL PSYCHOTHERAPY** will part of this study aside of the standard follow up tests (**SCOR90, PCL HRS, HARTMAN TEST, CAPS**). **PTSD** symptoms will be measured to see whether there are any changes in symptoms during the time of the study, as well as scales for global function and quality of life other **comorbid conditions** associated to **PTSD** such as alcohol an drug abuse an mood disorders are not the main focus of the present research project.

ELIGIBILITY

Ages Eligible for Study: 18 Years - 70 Years, Genders Eligible for Study:

CRITERIA:

INCLUSION CRITERIA

- Diagnosed with **PTSD** as a result of crime victimization or as a result of terrorist/combat exposure
- Must be willing and able to attend to the schedules sessions, and to take **AYAHUASCA BREW**.

- If been seeing by other clinicians, be willing to give the principal investigator permission to communicate with him or her.
- Must be willing to stop taking any psychiatric medications during the study period. Drugs will be tapered in an appropriate fashion to avoid withdrawal effects. Participants must not start any new psychotropic medications until after two weeks of terminating his or her participation in the study.
- Must be willing to remain overnight at the **MALOCA CENTER** after each AYAHUASCA session until the next morning. An attendant will be present to assist with personal needs if requested the attendant will be a physician and a nurse assistant of the same sex as the participant, and he or she will be trained for assisting in this study.
- Participants must be willing to be contacted via telephone on a daily basis by one of the investigators for a week after each session.
- Female participants of childbearing potential must have a negative pregnancy test and must agree to use an effective form of birth control.

EXCLUSION CRITERIA

Women who are pregnant or nursing, or who are able to get pregnant and are not practicing an effective means of birth control.

- People with a history of or current primary psychotic disorder or bipolar affective disorder type 1.
- People with dissociative identity disorder or an eating disorder with active purging, or borderline personality disorder.
- People with hypertension, peripheral vascular disease, hepatic disease (with or without abnormal liver enzymes), or.
- People with evidence or history of significant hematological, endocrine, cerebrovascular, cardiovascular, coronary, pulmonary, renal, gastrointestinal, immunocompromising, or neurological disease, including seizure disorder.
- Weighing less than 50 kg (110 lb) or more than 105 kg (230 lb).
- People who would present a serious suicide risk or who are likely to require hospitalization during the course of the study.
- People requiring ongoing concomitant treatment with psychotropic drugs.
- if the prospect HAS BEEN TAKEN SSRI antidepressants **MUST BE OFF** the medication for at least two weeks, and those taken PROZAC for five weeks. (avoiding the risk of SEROTONIN SYNDROME)
- People diagnosed with substance abuse or dependence for any substance, save caffeine or nicotine in the past 60 days.
- Any person who is not able to fill out a basic medical questionnaire and give adequate informed consent.

**CENTRO PARA LA EVALUACIÓN DEL ESTRÉS
LIMA PERÚ**

**CONSENT TO PARTICIPATE IN A RESEARCH PROJECT
STUDYING AYAHUASCA AS TREATMENT OF PTSD
(POST TRAUMATIC STRESS DISORDER)**

Please Read Carefully

This consent form provides information about your voluntary participation in a research study of the safety and efficacy of the Ayahuasca in the treatment of Post Traumatic Stress Disorder PTSD. The purpose of consent is to ensure that you are informed about the purpose and the potential risks of this study before you decide to participate. This is a scientific experiment. Consequently, there may be words, information, or tests that you may not be familiar with. We encourage you to ask to our member of the study team to explain any material that you do not clearly understand. After learning about the study and the tests it requires you will be asked to sign this form if you want to participate. Your choice to take part in this study is voluntary. This means that you are free to choose to involve yourself or not.

Purpose and Background

EL CENTRO PARA LA EVALUACIÓN DEL ESTRÉS and their associates are conducting a research project assessing the effects of Ayahuasca brew in the treatment of Post traumatic Stress Disorder (PTSD). **AYAHUASCA**, is also known by the names Daime, Yaje', Natema, and Vegetal, is a psychotropic plant tea (hallucinogenic/visionary beverage) that is prominent in the ethno medicine of the Amazon Basin, used by shamans in traditional medicine, The ayahuasca brew has not substantial toxicity, with a very low risk profile its tolerability and the safety of the brew has been demonstrated

It is obtained from infusing the shredded stalk of the malpighiaceae plant Banisteriopsis caapi with the leaves of other plants, Of the four main alkaloids which the drink contains it is DMT which is chiefly responsible for its hallucinogenic effects. You will be given about 50cc of Ayahuasca brew a brown-reddish drink with a strong taste and smell the effects of the beverage will start about 60 minutes from being ingested and last about 4 to 5 hours, the main effect will be about 90 minutes to 120 minutes after ingested.

The more frequent experiences are sensory such us: **Body feels different, increased skin sensitivity, Electric/tingling feeling, Change in salivation; perceptual visual changes: Visual effects, Visual images, Change in brightness of objects in room; auditory changes: Sounds in room sound different, changes in your consciousness: Dreamlike nature of the experiences, Change in rate of thinking. Changes in your mood state : Euphoria, Excited, Awe, amazement, you will be with other persons and under the guide of and experienced SHAMAN** and also will be a physician if you don't feel well, however initially a moderate nauseous sensation of nausea and mil vomiting is very common before the experiences start taking place.

You will be provided for your own information with a list of the more common experiences people have under the influence of Ayahuasca brew.

Before you are admitted to participate you will have to fill out a medical and psychological questionnaires and will be interviewed by a physician who will perform a regular physical examination and laboratory test including urine test for toxicological examinations also if you are a woman in child bearing age a negative pregnancy test is mandatory to be able to participate in the Ayahuasca experimental sessions also you will have an interview with the shaman (**MAESTRO AYAHUASQUERO**) who will be the guide in the Ayahuasca sessions; after the session is over you will have to stay overnight at the **MALOCA CENTER** and in the morning you will be able to go home after you complete a questionnaire about your experience, and a sample of urine is given for chemical analysis, an appointment will be given for the next 2 days, at the main CENTRO PARA LA EVALUACIÓN DEL ESTRÉS office so you can be evaluated by a research member and you can complete additional medical psychological questionnaires regarding your health and state of mind.

The length of this participation will be about six months and you are encouraged to participate and follow the research guides and rules.

You are being asked to volunteer because you are in average health and have limited experience (no use within the preceding three months) with illicit drugs

You are not to use any illegal drugs during the time of your participation if the urine test is positive for opioids, sedatives stimulants cocaine or other illicit drugs you will be terminated.

You are not to take any alcohol smoke or drink caffeinated drinks at least 24 hours before the Ayahuasca sessions

If you are female in a childbearing age you must use contraceptive methods to prevent becoming pregnant while you are in this experimental research study.

All the information regarding your health and your participations is confidential.

You have the right to terminate your participation in this study at any time

What is being measured?

The goal of this experiment is to evaluate the Ayahuasca as possible alternative of treatment in the condition PTSD (Post Traumatic Stress Disorder) you have been diagnosed to have; and the evaluating procedures, questionnaires and other test you will undergo will help to understand this proposed **Ayahuasca experimental treatment alternative**

Experimental Procedures: What Will Happen

After carefully reading this consent form and discussing it with the researchers, the following will occur if you agree to participate.

1. You will make an initial visit to the El Centro Para la Evaluación del Estrés where a number of questionnaires will need to be completed. You will have blood samples taken for screening tests. Additionally, if you are female, a pregnancy test will be done. Women who are pregnant will not be allowed to participate. If the results of the blood tests are within acceptable ranges you will then visit the Center a second time to have the study physician perform a physical examination. If the results of the laboratory test and the physical examination show that you are in acceptable physical and health the study physician will refer to a psychiatrist who will evaluate you and decide if you can participate in the research experiment. The experiment will be conducted at the

MALOCA CENTER (located at the TABLADAS DE LURIN, VILLA DEL SALVADOR) the main office is located at the MIRAFLORES, LIMA PERU where the medical examination and follow up will be done.

2. After completing the screening procedures, you will be schedule for an interview with the SHAMAN (**MAESTRO AYAHUASQUERO**) who will explain to you the general procedures in case you will not speak the native language of the SHAMAN a translator will be provided.

3. Sessions will occur about every two weeks until six months (12 sessions). Each session will be at MALOCA CENTER according to a schedule developed when you are admitted to this project...

4. Your participation in this experimental project will be every two weeks, after each session you will be given an appointment to the main office where you will be seen by a research team member, every two weeks you will be spent have a day in the main office for evaluation and follow up. On this day evaluation of your mental status and questionnaires will be completed.

5. Always will be a physician on call, and if the need arise; an emergency phone number will be given for you to call.

6. **The Tests to Be Made.** Several tests will be given to you initially regular blood and urine test, after each sessions at the **MALOCA CENTER** you will be given a questionnaire and a sample of your urine will be saved for analysis also 48 hours later you will go to the main office for additional examination and test to measure how you are doing and what other evaluation or referral are necessary These tests may include measures of blood pressure,, and body temp-erature. Frequent measures of drug sensations will be made by questionnaires. Samples of your urine will be tested for analysis of drugs of abuse.

7. **Pregnancy.** If you are female and of childbearing potential you must have a negative serum or urine pregnancy test prior to the first Ayahuasca experience and subsequent pregnancy tests every other week during time of the experimental Ayahuasca sessions In order to decrease the risk of pregnancy, you will be required to practice an effective method of birth control, an approved oral, inject able, or implantable contraceptive drug, intrauterine device, diaphragm, condom with spermicidal, or sexual abstinence, while you are taking study medications. No form of birth control is 100% effective. You will not be able to participate in this study if you are pregnant or breast-feeding. You will call the study doctor or coordinator if you are or think you might be pregnant immediately. If you become pregnant during the courses of this study, you will be discontinued from it...

8. A follow-up call will be made by the research team after each sessions to the number you provided us as your contact number to check and be sure that you are okay

Risks and Discomforts

1. Addiction.

AYAHUASCA DOES NOT PRODUCE OR INDUCE ADDICTION

2. **Adverse Effects of ayahuasca** Although rare Ayahuasca can produce unpleasant symptoms ranging from dis-turbed sleep and appetite, to mild increased heart rate, blood pressure ,during the sessions also difficulty breathing, mild mental confusion, can be sense as part of the experience the attending AYAHUASQUERO and if necessary the PHYSICIAN will be able to assist you . .

The researchers will be monitoring your psychological and physical functioning in order to detect any adverse effects as early as possible. Should any unpleasant or potentially dangerous effects occur, the experiment will be discontinued immediately, and if necessary your symptoms will be treated. ("bad trips") However, as is the case with almost any psychoactive drug, when some effects appear and you wish to discontinue the experiment, it will take a while for the drug effects to wear off.

Confidentiality

This research is CONFIDENTIAL as well as your medical records the results of test scores, details of past drug history, past medical history, etc., will be kept confidential. Since Ayahuasca use in PERU is legal there is not any violation of the law with this practices that are part of our TRADITIONAL MEDICINE.

Likewise, confidentiality must be maintained as strictly as possible for any information about other participants in this project. You should not discuss names or any information concerning other subjects with anyone outside of the research project. This may seem like a trivial consideration, but it is of importance for the protection of everyone concerned.

Research Not Treatment — the Importance of Honesty

These experiments are not part of a treatment program. The experiments are being done with you as a research participant. It is important for your protection from unknown health risks to give an accurate account of your recent and past illegal or medical drug use and general medical and psychiatric history. This is important to minimize the chance of exposing you to unnecessary risks.

Women who are or who may become pregnant during the series of experimental sessions should absolutely not participate since we don't know the effect that Ayahuasca may have on a fetus.

Benefits

You may benefit as a result of being in these ayahuasca research experiments. The benefits are both theoretical and practical.

Withdrawing From or Quitting the Study

YOU CAN WITHDRAW FROM ALL TEST PROCEDURES AT ANY TIME AND CAN REFUSE TO PARTICIPATE IN ANY PARTICULAR TEST PROCEDURE AT ANY TIME. HOWEVER, IN THE UNLIKELY EVENT OF SEVERE MENTAL CONFUSION FOLLOWING AYAHUASCA ADMINISTRATION, YOU WILL BE ASKED TO REMAIN UNDER OBSERVATION UNTIL IT IS THOUGHT TO BE SAFE AND IN YOUR BEST INTEREST TO LEAVE THE MALOCA CENTER. THE RESEARCHERS WILL MAKE THIS JUDGMENT OR, IF YOU DISAGREE WITH THEM, OTHER PHYSICIANS WILL BE ASKED TO EVALUATE YOU.

This might take a few hours. Thus, in that limited sense, you **cannot** completely withdraw from the experiment once that series Ayahuasca induced events has begun. This, of course, is characteristic of most drug effects; they cannot be turned off once they start.

There will be no penalty of any sort, should you decide to withdraw. In fact, the investigators encourage you, if you develop any concerns, to report them immediately, and to stop the study rather than to continue.

If you fail to follow the rules of the study, the researchers may decide to end your participation. While many of the tasks you will be asked to repeatedly perform may become boring or annoying, it is important that you perform them to the best of your abilities.

Additionally, the researchers reserve the right to terminate you from further participation in this study if participation may be contributing to the development of medical or psychological problems.

IF BECAUSE OF POSSESSION OF ILLICIT OR OTHER PSYCHOACTIVE DRUGS OR YOUR URINE TESTS GIVE EVIDENCE OF USING ILLICIT OR OTHER PSYCHOACTIVE DRUGS, YOU WILL BE ASKED TO LEAVE

New Findings

You will be told of any significant new findings developed during the course of this study which may relate to your willingness to continue your participation. You can ask for study results at its conclusion.

Subject's Statement

The material in this consent form and all other aspects of the experiment has been satisfactorily discussed with me by _____.

I have a copy of this consent form and a copy of the Experimental Subject's Bill of Rights to keep.

I VOLUNTARILY CONSENT TO PARTICIPATE IN THIS STUDY.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I can decline to be in this study or quit it at any time (but keeping in mind that drug effects cannot be quickly reversed). If I wish to participate, I should sign below.

Subject's Signature

Date

Signature of Person Reviewing and Discussing
This Form with Subject