Research Proposal

Protocol Number: I-OA3

Study Title: Observational study of the long-term efficacy of ibogaine-assisted treatment in participants with opiate addiction

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Introduction

The proposed research is an observational case series study of patients undergoing ibogaine-assisted treatment for opiate drug dependence using the Addiction Severity Index (ASI). Subjects will be drawn from patients treated independently for opiate drug dependence at one of two clinics in Mexico [redacted]. These clinics treat individuals--mostly from the United States although some from abroad--for addiction and other illnesses. Although many people have claimed benefits, the clinics have little information on the long-term effectiveness of their treatment. The sponsor has previously conducted a pilot study with a similar design that was terminated prematurely, with partial data obtained from 16 subjects (Harrison & Mojeiko 2010).

Study Aims, Background, and Design

Ibogaine is a naturally occurring indole alkaloid obtained from the root bark of the shrub *Tabernanthe iboga* with a history of use as a medicinal and ceremonial agent in West Central Africa and a complex pharmacological profile. It has been alleged to be effective in the treatment of chemical/substance dependence (Alper 2001). Evidence for ibogaine's effectiveness includes a substantial preclinical literature on reduced drug self-administration and withdrawal in animals and case reports in humans (Alper, Beal & Kaplan 2001).

Ibogaine has been termed an oneirophrenic; a substance that elicits "a dream phenomenon without loss of consciousness or change in the perception of the environment or any illusions or formal deterioration of thought and without depersonalization" (Goutarel, Gollnhofer & Sillans 1993).

Only a few case series and qualitative examinations have addressed the efficacy of ibogaine as a treatment for chemical dependency (Alper et al. 1999; Lotsof 1995; Mash et al. 2001), and there have been no systematic studies examining long-term efficacy of the treatment in reducing or eliminating problem substance use.

Commonly reported features of case reports describing ibogaine treatment (Sisko 1993; Mash et al 1998; Luciano 1998; Luciano, Della Sera & Jethmal 2000) are reductions in drug craving and opiate withdrawal signs and symptoms within 1 to 2 hours of ibogaine administration, and sustained, complete resolution of the opioid withdrawal syndrome after the ingestion of ibogaine. These case studies appear consistent with general descriptions of ibogaine treatment (Lotsof, 1995; DeRienzo & Beal 1997; Kaplan 1993).

Alper et al. (1999) summarized 33 cases treated for the indication of opioid detoxification in nonmedical settings under open label conditions. These cases are a subset of those presented at the NIDA Ibogaine Review Meeting held in March, 1995, focusing on symptoms of acute opiate withdrawal. The participants in this series of cases reported an

average daily use of heroin of 0.64 ± 0.50 g, primarily by the intravenous route, and received an average dose of ibogaine of 19.3 ± 6.9 mg/kg (range of 6 to 29 mg/kg). Resolution of the signs of opioid withdrawal without further drug seeking behavior was observed in 25 participants. Other outcomes included drug-seeking behavior without withdrawal signs (four participants), drug abstinence with attenuated withdrawal signs (two participants), drug seeking behavior with continued withdrawal signs (one participant), and one fatality, possibly involving surreptitious heroin use. Mash et al. (2001) reports having treated more than 150 participants for substance dependence in a clinic located in St. Kitts, West Indies. A subset of 32 of these participants was treated with a fixed dose of ibogaine of 800 mg for the indication of opioid withdrawal. Physician ratings utilizing structured instruments for signs and symptoms of opioid withdrawal indicated resolution of withdrawal signs and symptoms at time points corresponding to 12 hours following ibogaine administration and 24 hours after the last use of opiates, and at 24 hours following ibogaine administration and 36 hours after the last use of opiates. Mash and colleagues found that resolution of withdrawal signs and symptoms was sustained during subsequent observations over an interval of approximately one week following ibogaine administration. Depression scores and craving remained significantly reduced one month after treatment (Mash et al. 2000). The authors noted that ibogaine appeared to be equally efficacious in achieving detoxification from either methadone or heroin. The reported efficacy of ibogaine for the opioid withdrawal syndrome observed in the St. Kitts facility appears to confirm the earlier impressions of the case study literature (Alper, 1999; DeRienzo and Beal,1997; Lotsof, 1995; Sisko, 1993; Mash, 1998; Luciano, 1998; Luciano, 2000; Kaplan, 1993).

The aim of the currently proposed research is to study by observation over the long term (specifically, over a 12-month period post-treatment) the effect of ibogaine-assisted treatment on drug seeking and drug use behaviors and the associated impact of these behaviors, as compared to baseline, just after patients arrive at the clinic, in people seeking ibogaine-assisted treatment.

The clinics provide residential ibogaine-assisted treatment for drug dependence on a fee-for-service basis. This treatment consists of administration of ibogaine in the range of 15mg/kg (+/-5 mg/kg) under the supervision of clinic medical staff, followed by a residential stay. [redacted] utilizes a holistic approach and supplements ibogaine therapy with body work, energy work, and nutritional therapy. [redacted] has board-certified physicians who specialize in emergency medicine and registered nurses on site at all times while patients are in residence.

Thirty subjects will be recruited for this independent study. A total of 25 of these subjects will act as the experimental group and be drawn from people who undergo the ibogaine treatment at one of the clinics. A total of 5 of these subjects will act as the control group and be drawn from people who arrive at the clinic intending to undergo the ibogaine treatment, but who are denied the treatment by the clinic for medical safety reasons.

The primary objective of this study is:

1) to determine the effectiveness of ibogaine-assisted therapy in producing extended periods of opiate drug-use abstinence, in reducing opiate drug use, and in improving associated impacts of these behaviors as measured by the Addiction Severity Index composite scores over a period of 12 months following therapy.

Secondary objectives of this study are:

1) to investigate the correlation between Addiction Severity Index composite scores after treatment, and the subjective intensity of the peak and nadirs of the experience of the ibogaine-induced state of consciousness as measured by the Peak Experience Profile using a correlational analysis

2) to observe the severity of withdrawal symptoms accompanying opiate drug detoxification in patients receiving ibogaine using the Subjective Opiate Withdrawal Scale (SOWS)

3) to determine the effectiveness of ibogaine-assisted therapy in producing extended periods of relief from depression using the Beck Depression Inventory.

4.) to track changes in Emotional Intelligence (using the Trait Emotional Intelligence Questionnaire, Short Form (TEIQue-SF) to observe concomitants of possible relapse into substance use.

The pilot study previously conducted by this sponsor caused a robust decrease in drug-related ASI composite scores, with an effect size of 3.24 +/- 0.87 (N=16), which was in agreement with previously published results (Harrison & Mojeiko 2010). The ASI composite scores stayed low for the first three months after treatment for the majority of subjects who responded well to treatment. After this period, during the fourth month, a subset of subjects appear to have experienced long term benefit from the treatment, with ASI composite scores staying relatively constant. In contrast, a subset of subjects who were likely to have relapsed had higher ASI composite scores at the fourth month, with an effect size of 0.57 estimated from the ratio of average drug-related ASI composite scores.

The sponsor used Java applications created by Lenth to calculate estimated statistical power for this study based on preliminary results from the pilot study, assuming an effect size of 0.57 for the long-term follow-up portion of the study. According to a two sample independent T-test comparing a group of 25 who would receive ibogaine and 5 who would not, using the same standard deviations for the two groups observed in the original pilot study, the software calculated an estimated statistical power of 1, indicating the study should have sufficient statistical power.

Subject Population

Subjects will be drawn from patients who seek ibogaine-assisted treatment for drug dependence from one of two clinics: [redacted]

[redacted]ts receive such treatments on a fee-for-service basis, entirely independent of this proposed observational study. The ibogaine-assisted therapy is residential and lasts 5-10 days, sometimes longer. Subjects will be recruited sequentially after arrival at either clinic. The first five subjects were drawn from [redacted] for this study over a period of three months. Due to slow recruitment of patients from [redacted], an additional clinic is being added to the study.

Both clinics accept both men and women aged 18 years and older who are seeking treatment for chemical dependencies. Prior to treatment at the clinic applicants must undergo a thorough physical examination onsite with one of the staff physicians. This exam includes an Electrocardiogram (EKG), a cell blood count (CBC) with differential, and liver panels (AST/ALT).

[redacted] will treat patients with elevated liver enzymes (due to hepatitis) as long as the enzymes are not more than four times above normal. [redacted] may also still treat a person who has an abnormal EKG if the results of an additional 24-hour Holter test are satisfactory.

At [redacted], all test results must be within normal ranges in order for the individual to be accepted for treatment with ibogaine. Patients at [redacted] must also indicate to clinic staff that, prior to their arrival at the facility, they have sought and undergone other treatments for their opiate dependence.

All prospective subjects (those arriving and accepted for treatment at the clinic during the recruitment period and meeting the inclusion criteria outlined below) will be invited to participate in this voluntary study and will be shown the Informed Consent Form (ICF). Outcome observations on subjects who undergo ibogaine-assisted therapy will be made (using the measures specified below) for a period of 12 months after initial treatment.

A control group will be comprised of subjects who seek ibogaine-assisted therapy but are denied such treatment for medical reasons. Patients may be denied treatment if lab values described above are out of normal ranges or if the potential patient is unfit for any other reason according to the clinic physician. For the control group, outcome observations using the instruments specified below will be made monthly for 12 months following the onsite medical screening.

The recruitment period will continue until the research team has recruited 30 subjects (25 subjects undergoing ibogaine-assisted therapy and 5 subjects in the control group).

Inclusion Criteria:

1) Participants in this study must be participating on a voluntary basis and not coerced to participate.
2) Participants must be seeking treatment for a primary dependence on opiates.
3) Participants must already be planning to undertake ibogaine therapy at the specified clinic and must arrive at the clinic intending to undergo ibogaine treatment.

4) Participants must be able to communicate in English.
5) Participants must reside in the United States of America.
6) Participants must be able to provide at least one significant other (therapist, counselor, parent, spouse, close friend) who can be contacted regularly by the research team to verify information.
7) Participants must have a reliable method of communication by which the researchers may contact them during the study period.

Exclusion Criteria:

1) Persons whose primary motivation for seeking ibogaine-assisted therapy is for any reason other than opiate drug dependence.
2) Persons who have been treated with ibogaine in the past for any reason.
3) Persons who, in the opinion of the investigators, have any personal, health, situational, social or other problem that would prevent them from being able to fully comply with the requirements of this study.

Research Methods

This is an observational case series study consisting of interviews and questionnaires conducted both before and after administration of ibogaine. All questionnaires are included in this application. For each participant, baseline data will be gathered after the participant's arrival at the clinic and before the initial administration of ibogaine (if ibogaine is determined by the clinic safe to administer), and follow-up data will be gathered for one year post-treatment. Because most clients of the clinic reside far away and return home after their residential treatment is complete, most of the follow-up data will be gathered by telephone. All data will be gathered by an investigator who is certified in the administration of the Addiction Severity Index Lite (ASI Lite), the primary outcome measure. The other measures administered in this study are self-report and do not require certification.

Participants will provide the research team with contact information for at least one significant other (parent, spouse, close friends, therapist, counselor); a co-investigator will contact the significant others to independently verify information regarding the participant's substance use at the time of baseline assessment and at the time of each administration of the ASI Lite during the one-year-follow-up period. Significant others will also help to keep track of participants who may otherwise be lost to follow-up. During the time of baseline measures administration, one of the investigators will contact the significant others to verify their availability to participate by providing additional information on the study subject.

The Addiction Severity Index Lite (ASI) is the primary instrument that will be used to generate outcome data within the study. The ASI Lite will mainly be used to measure subjects' substance use patterns and will be administered before the initiation of ibogaine-assisted therapy and at monthly intervals for a period of one year post-treatment to measure changes in participants' substance use and lifestyle following the ibogaine treatment. The ASI is an assessment instrument designed to be administered as a semi-structured interview. An overall composite score of addiction severity can be derived

from the participants' responses during this interview. This score will be our primary measure of this variable. This score is derived from seven sub-scale scores: employment status, medical status, psychiatric status, family/social status, alcohol use, drug use, and legal status.

During baseline interview, subject will also be asked to report his/her last use of opiates, amount, type, and method of ingestion.

Other outcome measures include the States of Consciousness Questionnaire (SCQ), used to gauge the intensity and subjective quality of the peaks and nadirs of experience during the ibogaine treatment itself; the Subjective Opiate Withdrawal Scale (SOWS), a scale for grading the intensity of opioid withdrawal symptoms; the Beck Depression Inventory (Petrides & Furnham 1961) used to measure baseline depressive symptoms prior to treatment and to track changes after treatment; and the Trait Emotional Intelligence Questionnaire, Short Form (TEIQue-SF), used to observe changes in Emotional Intelligence (EI).

The Beck Depression Inventory (BDI) and the TEIQue-SF will both be administered once before initial treatment with ibogaine then again after treatment while the subject is still in residence at the clinic, and then at each monthly follow-up visit. Mash *et. al.* (2000) showed that subjects' BDI scores were significantly lower at discharge from treatment and at the 1 month follow-up as compared to pre-treatment scores. Low scores on Emotional Intelligence tests have been shown to predict a higher likelihood of substance-use problems (Riley and Schutte 2003)

The SOWS will be administered before initial treatment with ibogaine and then once following ibogaine treatment while the subject is still in residence at the clinic. The PEP will be administered just once: within a few days following initial treatment with ibogaine, while the subject is still in residence at the clinic. Subjects will also be given a blank piece of paper and writing or art utensils with instruction to briefly describe the ibogaine experience to the researchers. Control group subjects will not be asked to provide this brief description, or to fill out the PEP or the post-treatment SOWS.

In addition to these questionnaires and interviews, subjects will undergo either random urine drug testing or fixed hair testing to verify truthfulness of information gained in the ASI interview about drug use. Drug testing will be conducted by LabCorp, a nationwide drug testing service. LabCorp's SAMHSA-certified laboratories conduct urine drug analyses in accordance with Department of Health and Human Services (DHHS) requirements.

Subjects must have hair above the neck that is at least two inches long and must live within a reasonable distance of a hair testing facility in order to sign up for hair tests. A laboratory technician will directly observe the sampling of hair, and will take 30 strands of hair two inches in length. The hair test is able to detect drug use for six months prior to the test. If subject undergoes hair testing, he or she will be paid a stipend of $55 (in gift certificates) for each of two visits. Hair testing will be conducted twice, once within 2

weeks of Visit 9 and once within two weeks of Visit 14.

If subject does not meet the criteria for hair test, he or she may elect to sign up for random urine drug screening. At each monthly visit, the investigator will open an envelope associated with that visit that will tell whether the subject has been selected to undergo drug testing. If the subject is randomly selected for drug testing on that visit, the subject will have 24 hours from the time of being told about the test to report to the drug testing site. Participants will be compensated $35 (in gift certificates) for each urine drug test that they complete within the specified time window. To create the randomization list, the investigator will create 12 envelopes for each subject, numbered V3-V14, and will create 12 cards; 3 of these cards will say "Drug Test" and the other 8 will say "No Drug Test". The investigator will place these 12 cards in a box and then draw them out one at a time and place them in the envelopes. The envelopes will then be sealed.

Researcher will collect the following records from the clinic: dose of ibogaine administered and date/time of administration, and reason for refusal of ibogaine treatment if subject is refused ibogaine treatment.

Participants will be compensated $10 for each follow up visit/phone interview they complete upon leaving the clinic, up to a maximum of $120 for all 12 follow up visits/interviews, to be paid at quarterly intervals throughout the course of the study and in payments valued at up to $30 per quarterly payment, in the form of a gift certificate.

TIMEand EVENTS	At Clinic													
Visit number	V1	V2*	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14
Type of visit	Before Ibogaine Session	After Ibogaine Session	Month 1 Follow Up	Month 2 Follow up	Month 3 Follow up	Month 4 Follow up	Month 5 Follow up	Month 6 Follow up	Month 7 Follow up	Month 8 Follow up	Month 9 Follow up	Month 10 Follow up	Month 11 Follow up	Month 12 Follow up
Visit Timing and Windows (+/- number of days	before ibogaine is administered	may take place over multiple days	(-2/+3 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)	(-4/+5 days)
Amount of time to complete	2.5	1	1	1	1	1	1	1	1	1	1	1	1	1
Study Staff	Tom	Tom/Clinic Staff to Collect	Tom	Tom	Tom	Tom	Tom	Tom	Tom	Tom	Tom	Tom	Tom	Tom
ASI	X		X	X	X	X	X	X	X	X	X	X	X	X
PEP		X												
BDI	X	X	X	X	X	X	X	X	X	X	X	X	X	X
TIEQue-SF	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SOWS	X	X												
Brief Description		X												
SO Check	X		X	X	X	X	X	X	X	X	X	X	X	X
Random Drug Testing			X**	X**	X**	X**	X**	X**	X**	X**	X**	X**	X**	X**
Certificates Distributed					X			X			X			X
Termination														X
*This visit is for the experimental group only.														
**Actual drug test will happen on only three of these visits.														

Risks

Clinic staff provide information on the risks of ibogaine to their patients before administering it to them. There are no foreseeable physical risks to taking part in this observational study. However, there may be other types of risks, including possible psychological discomfort or distress and risks related to providing personal or sensitive information to other people.

Psychological Risks: In this study, patients will be talking about sensitive material such

as drug use and the effects of drug use on their lives; and may potentially talk about topics such as illegal drug use and other criminal activity. This might make patients feel more angry, upset, scared or depressed than usual. Thinking about past drug use and the negative effects it has had on a patient's life and relationships may also make the patient upset. The researcher conducting interviews is not a licensed healthcare professional, but he is an anthropologist who has experience and training in interviewing vulnerable and diverse populations in a sensitive and respectful manner. If the subject becomes upset or requests additional support, he will refer the subject to two referral source options: co-investigator Meg Jordan, Ph.D., R.N. and Simon Hodson, M.F.T. Dr. Jordan and Mr. Hodson will be available to facilitate referrals to consultants, other healthcare professionals, or therapists if such a need should arise. The subject will also be told of Dr. Jordan's and Mr. Hodson's roles during the consent process, and their contact information will be listed in the informed consent form. Dr. Jordan, a CIIS faculty member, is a clinical medical anthropologist and a registered nurse who specializes in behavioral health and integrative healthcare referrals. Mr. Hodson is a marriage and family therapist in private practice in California. He has received supplementary training materials from MAPS on assisting people who have undergone a difficult psychedelic experience. If the subject should need to use the referral, MAPS will pay for the first session. If the subject desires subsequent sessions, they will not be paid for by MAPS or the research team.

Women Able to become Pregnant: Women able to become pregnant, and women who are pregnant, can fill out the surveys and questionnaires and fully participate in the observational follow-up study. The clinic does not treat women who are pregnant.

Benefits

No direct benefit is guaranteed or implied by participation in this study. Subjects will be compensated $10 for each study follow up visit/interview they complete, up to a maximum of $120 for all 12 visits/interviews. Subjects will also be compensated either $55 for each of two hair drug test or $35 for each of three urine drug tests (up to $110 for hair tests or $105 for urine tests). This is a total compensation of up to $230 or $225 per subject. Information gained from this study may help the researchers better understand ibogaine therapy as a way of treating people with problem drug use, which could result in an additional treatment option for substance abuse.

Confidentiality

Every effort will be made on the part of the researchers to protect the patients' confidentiality. Subjects will be assigned a subject number and this number will be used, along with subject materials, on all interviews and questionnaires. A contact sheet identifying the full contact information for each subject will be kept in a separate location. The study interviewer will keep all original documents in a locked file cabinet in an office in San Diego, CA. Only the study researcher will have access to the contact sheet that contains identifying details. Name and identifying information (such as street address or phone number) will be removed from the records before they are shared with other members of the research team at the sponsor MAPS or the research team at CIIS.

After five years, (from the conclusion of the study) all personal records and identifying documents will be destroyed (shredded). The results of this research study may be presented at meetings or in publications but individuals' identities will not be disclosed. No audio or video recordings will be used in this study.

Subjects will be informed that their complete study records may be inspected at the study site by the Human Research Review Committee (HRRC) at CIIS to check the accuracy of study records. Subjects will also be informed of mandated reporting rules regarding harm to self or others, and suspected elder or child abuse.

Consent Process and Documentation

Participants will provide written consent indicating that they have been informed about the research and their part in it and that they have agreed to participate. Participants will be given adequate time to review the informed consent form, both alone and with one of the investigators, and to ask questions of the investigator before signing the form. Both the subject and one of the investigators must sign and date the consent form.

Consent Criteria

A copy of the informed consent form that includes all necessary elements is included in this proposal.

Human Subjects Bill of Rights

The 'Bill of Rights For Participants in Psychological Research' and 'Experimental Subjects Bill of Rights' will be delivered to subjects along with the written consent form.

Funding

This study is being fully funded by MAPS; 309 Cedar Street #2323; Santa Cruz, CA 95060, USA; 831-429-6362; www.maps.org.

Outside Institution

This study is being conducted at two privately owned and operated clinics in Mexico. Because these clinics are administering treatment, but not research, the clinics are not subject to IRB approval. A letter of authorization from the clinic director is included in this application. (Attached).

Cover Sheet Attached

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