

New **Ibogaine Outcome Study** Begins Enrollment

By Thomas Kingsley Brown, Ph.D., and Valerie Mojeiko

MAPS' newest ibogaine outcome study, headed by MAPS Deputy Director Valerie Mojeiko, has been underway for about three months. On September 27, Co-Investigator Tom Kingsley Brown, Ph.D., went to the Pangea Biomedics clinic in Playas de Tijuana, Mexico to enroll the first two subjects into the study. The study will ultimately enroll 30 subjects whose opiate usage will be tracked for one year. Anecdotal evidence for ibogaine's efficacy for interrupting addiction has been mounting steadily over the past few decades. Over this time, a number of people have died during or as a result of ibogaine administration, often due to improper screening or medical monitoring. Patients need more information on long term outcomes so they can accurately weigh risk against benefit.

This is the third ibogaine outcome protocol on which MAPS has collaborated, and it builds upon our prior study designs. John Harrison, Psy.D. candidate, has ended the data collection phase from the last study. We realize now that it is time to conduct this study more like our clinical studies with rigorous data collection procedures, even though it is an observational study which is not under review by the FDA. For this reason, we have restarted a new phase of the study with a new team, a new protocol, and a new oversight structure.

Treatment at Pangea Biomedics is residential and takes ten days or more. The clinic offers several guest rooms with ocean views. A medical doctor screens patients to assess fitness for ibogaine prior to ibogaine administration. Patients who are not eligible for treatment will be asked to enroll in the study as pseudo-controls, an improvement on our prior study design which did not include a control group. At this clinic, ibogaine is typically administered to patients multiple times over the course of several days. After treatment, some clients will stay for an additional period at an aftercare house run by Sandi Hartman,

who was inspired to start the facility after her own successful treatment at Pangea Biomedics in 2009. Sandi's treatment ended a 12-year addiction to opiate analgesics that were first prescribed after she was severely injured in an automobile accident.

The outcome study had enrolled four subjects as of the end of October. To be eligible for the study, patients at Pangea Biomedics must be naïve to ibogaine and must seek ibogaine-assisted treatment primarily for opiate addiction. On the day of enrollment, Brown meets with the patients and administers the Subjective Opiate Withdrawal Scale (SOWS) and the study's primary outcomes measure, the Addiction Severity Index (ASI). Within a few days after treatment, subjects again complete the SOWS and also a 100-item States of Consciousness Questionnaire. The results of the latter survey will be used to determine whether the intensity of the ibogaine experience correlates with positive outcomes as measured by the ASI scores. Subjects are called for a follow-up ASI one month after the completion of treatment and then monthly for a full year after treatment for comparison with the baseline scores.

IRB approval for the study was conferred this past summer by the California Institute of Integral Studies. The proposal was submitted by CIIS student Rishi Karim Gargour under the supervision of Meg Jordan, Ph.D, R.N. Brown, who is on staff at UC San Diego, travels to the clinic to enroll patients and will conduct the follow-up calls. He earned his doctorate in Anthropology at UC San Diego with an emphasis on the study of religious conversion and altered states of consciousness.



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