

lsd research at the orenda institute

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ON MARCH 30, 1996 the Orenda Institute's Institutional Review Board (or IRB — the committee that oversees subjects' rights and ethics in research with human beings at the Orenda Institute) met and unanimously approved the study protocol, *THE RELATIONSHIP BETWEEN PEAK EXPERIENCE AND OUTCOME IN LSD-ASSISTED PSYCHOTHERAPY WITH SUBSTANCE ABUSERS, A DOUBLE-BLIND CONTROLLED STUDY*. The informed consent form was reviewed and amended and this amended form was given unanimous provisional approval pending the execution of changes requested. When the amended permission form is distributed to the IRB members and accepted as correctly amended, the last step in the arduous administrative approval process will be complete.

Approvals in place

This protocol was conceived eight years ago! Throughout this time we have been in negotiations with the IRS, the FDA, and the DEA as well as the state level regulatory agencies, in order to secure the necessary approvals for this work. Today, we stand at the threshold of finally beginning to work therapeutically with LSD again, returning to the clinical phase of research with human subjects (as opposed to animal studies or purely physiological human studies).

Study design

This outpatient study examines the relationship between the dose of LSD given during a therapy session, the quality of the psychedelic session content (the presence or absence of a peak or mystical experience), and outcome in the LSD-assisted psychotherapy of 60 people who have been diagnosed with a substance abuse disorder (as defined in the APA Diagnostic and Statistical Manual). Each person will be randomly assigned to one of three groups: Group 1 will receive 100 micrograms of LSD, Group 2, 200 micrograms, and Group 3, 400 micrograms. Neither the subject nor the therapist will know who has received which dose (double-blind). Each person may

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have up to five LSD sessions during which they will receive the same dose of LSD, in the context of a therapy relationship (up to 120 hours of therapy). Each session will be evaluated by the research team for the presence or absence of peak experience qualities. Subjects will be given different psychological measures before and after and outcome measurements (behavioral and functional ratings as well as random urine testing) will be done at specific time

intervals up to a year after the last therapy session. The hypothesis is that those people who have peak or mystical experiences that they are able to integrate into their lives will be motivated to decrease their abuse of substances and lead more satisfactory lives.

Outside source of LSD

In the past, LSD was available to us and other qualified researchers from the National Institute of Mental Health and the National Institute on Drug Abuse. However, at this time, we were unable to obtain supplies from the U.S. government. We have located another qualified source of LSD for human studies and soon will be ordering supplies for the study. The double blind packaging and labeling of the compound will be executed by an outside facility.

Inclusion criteria

When we obtain access to the LSD we will begin accepting applicants for the study. Subjects must be between 21 and 60 years of age, be a high school graduate (or equivalent), have a substance abuse disorder as diagnosed by the screening committee and have a local support network that includes a significant other. The significant other is a very important part of the treatment team. They will pick up the patient after LSD sessions and accompany them throughout the evening safeguarding their well being. The significant other must also be willing to participate by rating the patient's response to treatment at several points during the study and follow-up. Because of this requirement, initially we will only be accepting subjects from this geographic area.

There are many exciting new dimensions that we plan to add to research with psychedelics in the near future and we will continue to keep you informed. •

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