PACIFIC TREATMENT & RESEARCH IN PSYCHEDELICS (TRIP) PROGRAM

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The Pacific Treatment & Research in Psychedelics (TRIP) Program is dedicated to the development of psychedelic-assisted therapies and the scientific exploration of how altered states of consciousness can be harnessed to change behavior and improve brain health and quality of life.

MISSION OF THE PACIFIC TRIP PROGRAM

- To develop, safe, effective, and FDA-approved psychedelic-assisted therapies for anxiety, depression, addictions, PTSD, and other chronic conditions via clinical trials and research
- To advance the scientific understanding of the neurobiological and psychosocial mechanisms underlying the health benefits of psychedelics and expanded states of consciousness
- To advance the ethical and evidence-based practice of psychedelic and consciousness-based medicine to ensure that psychedelic treatments are accessible to patients in need

Given the enormity of behavioral health issues that remain inadequately treated worldwide and the modest effectiveness of existing treatments such as antidepressants and traditional psychotherapy approaches, there is an urgent need to develop more effective treatments for these conditions.

Early studies of psychedelic-assisted therapies for conditions including depression, alcoholism, smoking cessation, and end of life suffering have demonstrated much larger and durable effects compared to existing therapies suggesting that there is great potential for psychedelic-assisted treatments to revolutionize the treatment of mental health and behavioral disorders.

Despite this promise, government funding for research to develop the therapeutic potential of psychedelics is minimal and philanthropic support will be essential to help facilitate completion of the Phase 2 and 3 clinical trials required for FDA-approval of psychedelic-assisted therapies.

Our goal at PNI is to become one of the leading U.S. centers for psychedelic-assisted therapies research, clinical trials and ultimately delivery of these eventual FDA-approved therapies. We have already received seed funding from the Annenberg Foundation that has allowed us to assemble a world-class team of clinical investigators and a state-of-the-art clinical space for performing psychedelic-assisted therapies. We now need additional support to fully launch our treatment and research programs.

BACKGROUND

Psychedelic-assisted therapy is an innovative and groundbreaking approach that has the potential to revolutionize the treatment of behavioral health, mental health, and substance use disorders. Psychedelic-assisted therapy involves administering a psychedelic drug to a patient under clinical supervision with the purpose of triggering an altered state of consciousness or mystical

experience (Figure 1).

The potential for mystical experiences to produce rapid, profound, and sustained changes in



Fig. 1 Psychedelic-assisted therapy treatment room

insight, mood, behavior, and consciousness was recognized and first used by indigenous cultures in shamanic and other healing rituals.

Psychedelic-assisted therapies for treating behavioral health disorders was studied extensively and safely in approximately 40,000 patients in North America in the 1950's and 1960's. However, despite clear benefit for many patients, its use faded dramatically in the wake of the counter-culture movement and the Controlled Substances Act in 1970, which scheduled psychedelics as dangerous and illegal drugs. Fortunately, there is a renaissance in psychedelic-assisted therapies that has been quietly gaining momentum since the 1990's.

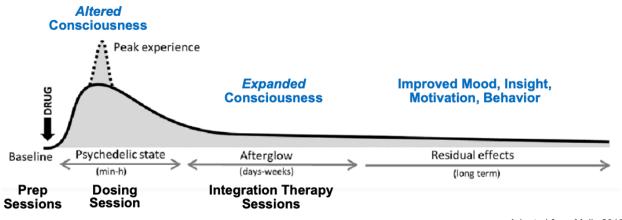


Fig. 2 Psychedelic-assisted therapy model and time-course

Adapted from Majic 2015

CURRENT PSYCHEDELIC RESEARCH

Today multiple clinical trials are underway testing a variety of psychedelic drugs including *psilocybin*, the active ingredient of "magic mushrooms," *MDMA* ("ecstasy"), and *ketamine*, for a diverse range of indications including major depression, Post-Traumatic Stress Disorder (PTSD), anxiety disorder, end-of-life and palliative care setting, as well as alcohol, nicotine and other substance use disorders.

Available treatments for depression, anxiety, and substance use disorders involve daily administration of a medication aimed at correction of neurochemical imbalances via action at specific receptors (e.g. serotonin, dopamine, mu opioid). In contrast, psychedelic-assisted therapy uses the drug to produce a short-lived but intense subjective experience—the mystical or peak experience—which triggers or elicits an afterglow, accompanied by a subsequent positive change in affect, insight, motivation, cognition, and behavior (Figure 2).

MYSTICAL EXPERIENCE

Qualities of the mystical experience as described by patients include a sense of unity, a noetic quality, sacredness, positive mood, transcendence of time and space, and ineffability. While the exact mechanism of psychedelic-assisted therapy remains an intense area of study, current thinking based on neuroimaging and clinical studies, suggests that a major mode of action may be a transient, but profound state of ego dissolution largely due to an impact on a cortical brain region referred to as the Default Mode Network (DMN). One of the most interesting potentials of psychedelic-assisted therapies is that a given compound such as psilocybin may have trans-diagnostic

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potential, meaning achieving a psilocybin-induced mystical state may lead to profound and sustained improvement across multiple disorders including depression, anxiety and addiction.

THE IMPORTANCE OF "SET AND SETTING"

The psychedelic experience is influenced not only by the choice of drug, but also by the set (the patient's mindset entering the experience) and the setting (the environment and surroundings). In psychedelic-assisted therapy, the drug is given within the context of a "set and setting" psychotherapy program. Prior to the psychedelic dosing session, patients meet with a team of therapists for several preparatory counseling sessions during which their medical and psychosocial history is reviewed, they are able to develop a rapport with the therapy team, and are educated and prepared for the psychedelic experience. The psychedelic dosing session is done in a special "trip room" designed to facilitate a safe and therapeutic experience for the patients. For safety reasons, the patient is monitored by two clinicians, typically a man and a woman. Patients lie on a comfortable couch, wear eyeshades, and listen to music through headphones to facilitate a focus on the internal experience. Afterward, patients complete a series of integration therapy sessions to assist them in harnessing the power of the mystical experience to make concrete and sustained changes in their lives.

USEFUL LINKS

"How to Change Your Mind" by Michael Pollan

<u>60 Minutes</u> story about psilocybin use to treat addiction, depression and anxiety



