

The Faces of Phase 3: Principal Investigators in MAPS' Clinical Trials of MDMA-Assisted Psychotherapy for PTSD

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OVER THE PAST FEW MONTHS, my colleagues and I traveled all over the United States to visit, set up, and train the study sites participating in our open-label lead-in protocol for MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD)—the first step in our Phase 3 clinical trial program. Beginning in Spring 2018, our Phase 3 trials will expand upon, and hopefully confirm, the findings from our Phase 2 trials. These study sites will include academic research institutions as well as private practices.

Every Drug Enforcement Administration inspection we pass, every Institutional Review Board approval letter we receive, every supply we purchase, and every contract we sign brings us one step closer to treating participants in these upcoming trials. Behind the transformations and symptom reductions many of our participants experience lie stacks of paperwork, disorienting spreadsheets, floods of emails, and hours upon hours of training for our researchers and therapists. Our study teams are dedicated to jumping the many hurdles involved in Schedule I drug research, and our recent Breakthrough Therapy Designation from the Food and Drug Administration gives us great hope and inspiration.

In clinical trials, Principal Investigators (PIs) are ultimately responsible for ensuring the accuracy and integrity of all data generated by their site, overseeing all site staff, reporting adverse events, and retaining study records, among many other duties. Running a clinical research site is no easy task! Our investigators have varied backgrounds, but all have spent their careers preparing for this challenge. Each has assembled excellent teams of therapists, physicians, and study coordinators to accomplish this research. We are thrilled to include the energy of newer psychedelic therapists alongside more experienced colleagues. In this edition of the *MAPS Bulletin*, we profile and present personal statements from a selection of our U.S.-based PIs, a highly regarded group with whom we are fortunate to collaborate. We'll profile our other PIs in future Bulletins.



Participants in MAPS' Phase 3 trials of MDMA-assisted psychotherapy for PTSD will spend time in quiet reflection in a treatment room similar to this one in Boulder, CO.

Boston, Massachusetts

Boston has quickly become the East Coast hub of MAPS, home not only to our founder and executive director Rick Doblin, but also to three full-time MAPS Public Benefit Corporation employees (myself included). Our city is also home to the Trauma Center, which upon its opening 40 years ago was one of the first clinics dedicated to elucidating the impact of trauma. Its founding Research and Medical Director, Dr. Bessel van der Kolk, will serve as our Boston site PI. Dr. van der Kolk worked on the first neuroimaging studies for PTSD and conducted the first National Institutes of Health (NIH)-funded research demonstrating the effects of fluoxetine (Prozac®), sertraline (Zoloft®), yoga, and Eye Movement Desensitization and Reprocessing (EMDR) on PTSD. In 2014, he published the *New*



York Times best-selling book, *The Body Keeps the Score: Brain, Mind, and Body in the Healing from Trauma*, a popular read among our therapists. From Dr. van der Kolk:

“In recent years I have been particularly interested in solutions for treatment-resistant PTSD sufferers, and in looking at interventions that can

change the neurological parameters that I and my colleagues have identified as being involved in keeping people stuck in their trauma. I have been following the results of the Phase 1 and 2 trials with MDMA closely and mentioned the early, very promising, outcomes of MDMA therapy in my book.”

Boulder, Colorado

Our Boulder PI, Marcela Ot’alora, M.A., L.P.C., is a psychologist and artist who has been working with MAPS for decades. She worked in Spain in 2000 on the world’s first study of MDMA-assisted psychotherapy for PTSD. The protocol studied women with trauma due to sexual assault, but unfortunately ended early due to political pressure. After moving to Boulder, she served as the PI on our (now completed) Phase 2 dose-response study. She has also mentored and prepared many therapists for Phase 3 through the MAPS Therapist Training Program and our therapy training protocol. From Marcela Ot’alora:



“What we have already seen from previous studies is that

MDMA-assisted psychotherapy can bring about remission from PTSD symptoms for individuals who have not been able to find relief from existing treatments. This possibility has been alive for me for over 30 years, and is the reason I became a therapist: never losing sight, that against all odds, we would one day be able to offer this treatment to those who need it and want it. Now that day seems more plausible than ever before. The desire to be free from pain is intrinsic to us all, and the opportunity to witness this freedom in another is a humbling experience.

My goal is to remain attentive and curious, and out of the way of my own conclusions. The result is a special interaction with another human being, who is also present and curious and willing to break open in front of another whom he or she barely knows. What I noticed time and again during our Phase 2 study in Boulder was how participants got to know themselves as a stranger who was waiting to be met and embodied. The insights they received came from within, illuminated their path, and continued teaching them about how to live life meaningfully.

Doug Chadwick, a scientist, once said that ‘science is an organized form of wonder.’ The research we are doing is science, and the participants contribute to the wonder through their journey. As researchers, we get to hold and honor both. What a gift.”

Charleston, South Carolina

Dr. Michael Mithoefer has served as the PI for the Charleston site for over a decade. As he takes on the role of Medical Monitor for our Phase 3 research, he passes the torch of Charleston site PI to Dr. Yevgeniy “Zhenya” Gelfand, his long-time mentee. Dr. Gelfand moved to Charleston for a combined Internal Medicine and Psychiatry residency at the Medical University of South Carolina. There he met Michael and Annie Mithoefer, subsequently volunteering many hours to MAPS as a therapy Adherence Rater and trainer. He is now the Medical Director of an intensive outpatient program for behavioral health, and an emergency psychiatrist with the Crisis Intervention Team at Trident Hospital. He is very interested in the mind-body connection and overall wellness. From Dr. Gelfand:



“What brings me to this work is my firm belief in the tremendous therapeutic potential of psychedelic medicines. I am honored and excited to be able to do this work, contribute to the psychedelic revival, and help bring healing to some folks along the way. I am endlessly grateful to Michael and Annie Mithoefer for their inspiration and support.”

Farmington, Connecticut

Dr. Monnica Williams is an accomplished clinical psychologist who will serve as PI for our site team at the University of Connecticut. She trained in PTSD treatment under Dr. Edna Foa, the developer of Prolonged Exposure therapy, and both were recently named as two of “25 Individuals of Influence” by *PTSD Journal*. At the University of Connecticut, she is an Associate Professor and Clinical Director of the Behavioral Wellness Clinic. She also recently served as the Director of the Center for Mental Health Disparities at the University of Louisville. Dr. Williams’ research focuses on African-American mental health, culture, and psychopathology, and she has published over 90 scientific articles on these topics. In addition to studying MDMA-assisted psychotherapy, she states she is “drawn to the study of racial trauma—in other words, how racism uniquely contributes to traumatization in people of color. This problem is larger than anyone realizes, but we are only now developing the tools to even study it.” She is researching improvements in cultural competence in the delivery of mental health services and interventions to reduce racism. She provides diversity trainings nationally for clinical psychology programs, scientific conferences, and community organizations. Her work has been featured in



several major media outlets, including NPR and *The New York Times*. From Dr. Williams:

“I was approached over two years ago by Natalie Ginsberg at MAPS after she’d read an interview I’d done with The New York Times about race-based trauma among people of color. Once I read the scientific research studies, met the team, and saw videos of the treatment process, I realized there

was an incredible untapped potential for helping people with PTSD who hadn’t been helped by anything else.

All currently available medications for PTSD are just addressing the symptoms and are not curative, thus psychiatrists are often taking stabs in the dark as they try to help their clients with the disorder. The most effective psychotherapies for PTSD are exposure-based, and these are not always well-tolerated by patients or even therapists. If we can bypass the iffy drug cocktails and frightening detailed and difficult exposure stories, and still get people better, I am all for it. MDMA-assisted psychotherapy is humane and effective, and I am excited to bring this treatment to people of color.”

Fort Collins, Colorado

Dr. Scott Shannon, a holistic physician, acupuncturist, and teacher, will serve as our Fort Collins PI at his clinic, Wholeness Center, which provides cross-disciplinary evaluation and care

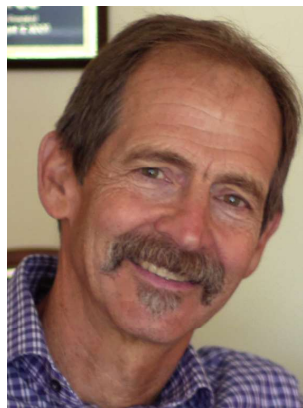


A welcoming view into the treatment room for Phase 3 trials of MDMA-assisted psychotherapy for PTSD at the University of Wisconsin at Madison, led by Principal Investigator Christopher Nicholas, Ph.D.

for mental health concerns. In 2001, Dr. Shannon published the first textbook on holistic medicine and continues to be published widely. His latest textbook for professionals, *Mental Health for the Whole Child*, was published in 2013, and his book for parents, *Parenting the Whole Child*, in 2014. Dr. Shannon believes that we can improve mental health care by embracing the concepts of health and the inner healer. He shares his knowledge as an Assistant Clinical Professor at the University of Colorado and through Psychiatry MasterClass, a program he was central

in creating that provides professionals with in-depth education in integrative mental health. From Dr. Shannon:

“For decades I have dreamed of giving MDMA to patients legally. In the early 1980s I often used MDMA legally in my practice to relieve suffering and heal relationships. The power of this medicine deeply moved and inspired me. Frustrated, I watched the DEA



place MDMA in Schedule I in 1984. My deepest joy involves facilitating as patients go inside and heal themselves after losing hope of ever finding peace. This molecule has the power to not only help heal trauma and relieve suffering in individuals, it can also inspire a deep and overdue transformation within the profession of psychiatry.”

Los Angeles, CA

Cole Marta, M.D., is the founder of New School Research and there will serve as our Los Angeles site PI. His interest in psychedelic research began during his psychiatry residency at the University of California Los Angeles, where he studied the relationships between psychedelics and mood, anxiety, substance abuse, and PTSD. In his private practice, he provides psychiatric care to adults, specializing in the use of ketamine for treatment-resistant depression. He is well-published in the field

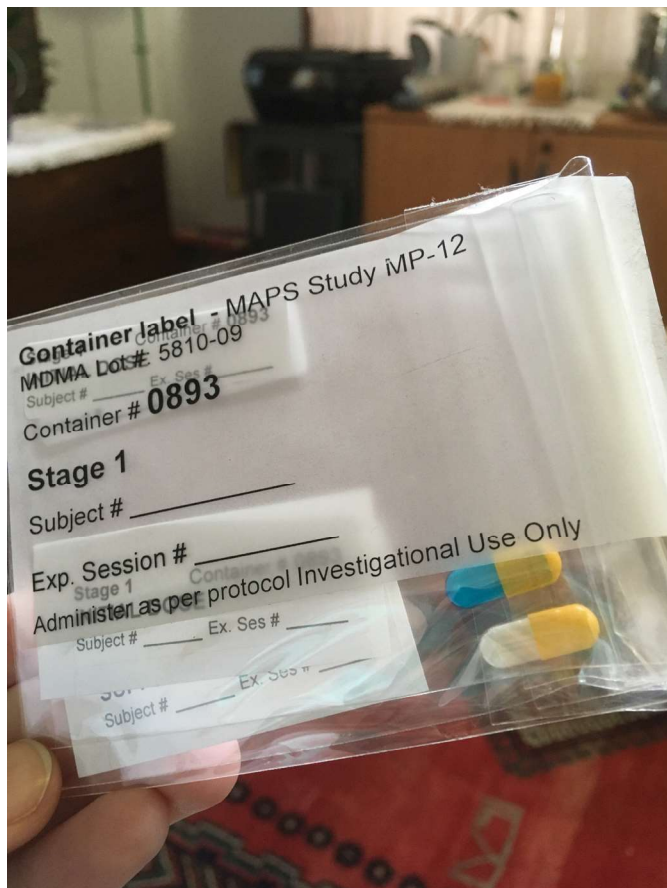


of psychedelic research with peer-reviewed articles and book chapters on ketamine, ibogaine, and MDMA. He enjoys educating the public about psychedelics at conferences and as a frequent guest on podcasts such as *The Duncan Trussell Family Hour*, *The Hount Tall Podcast with Moshe Kasher*, and *Here We Are with Shane Mauss*. He also serves as a supervisor and assists with

training of peer support services and psychedelic harm reduction with the Zendo Project.

Madison, Wisconsin

Clinical psychologist Christopher Nicholas, Ph.D., will be taking on the role of PI for the Phase 3 trials at the University of Wisconsin at Madison. He gained experience as a psychedelic



MDMA capsules will be administered to participants in MAPS' Phase 3 trials of MDMA-assisted psychotherapy for PTSD.



researcher as a study psychologist and guide on a pharmacokinetic study of escalating doses of psilocybin at the University of Wisconsin. He is also a consulting psychologist to Dane County District Attorney Witness Victim Services. He conducts research at the intersection of addiction, trauma, and aging, and recently started a clinical service for chronic pain patients with

comorbid psychiatric symptoms and substance abuse disorder. His academic research on the neurobiological underpinnings of self-awareness, episodic memory, and affective processing is relevant to our understanding and conceptualization of non-ordinary states of consciousness. From Dr. Nicholas:

“This work speaks to my personal interest and practice in using non-ordinary states of consciousness to promote insight, compassion, and healing for myself and others. Overall, this work is

fascinating in that it rests within the convergence of many nested domains of human experience and functioning, including neurobiology, psychopharmacology, psychology, consciousness, and spirituality.”

New Orleans, Louisiana

Dr. Ray Worthy, site PI in New Orleans, has a long history with MAPS. After earning a Ph.D. in Clinical Psychology from the California Institute for Integral Studies, he moved to Charleston and met Michael and Annie Mithoefer. Like Dr. Gelfand, he also spent hundreds of hours as an Adherence Rater for MAPS. He received his medical degree from Tulane in 2008, and now works at River Oaks Psychiatric Hospital, where he specializes in the treatment of PTSD. He has also served as Medical Director of a chemical dependency unit and an eating disorder unit. From Dr. Worthy:



tor of a chemical dependency unit and an eating disorder unit. From Dr. Worthy:

“The teachings and my teachers over the years had shown me the heart was always open to the suffering of the world, and lo and behold, could actually hold it all despite my usual instincts to run for the exits! Watching dozens/hundreds of hours of MDMA session tape

while working as a MAPS adherence rater enabled me to learn from the Mithoefers while also convincing me that MDMA could be a catalyst for healing that, like the heart, is within us all. I am proud to be a part of the New Orleans team and that this research will take place in a city that not only loves to celebrate but has also endured its share of trauma and hardship in recent years.”

New York, NY

At our New York private practice site, Ingmar Gorman, Ph.D., and Casey Paleos, M.D., are combining their strengths and sharing the role of PI.

Ingmar Gorman, Ph.D., is a clinical psychologist specializing in assisting people who have had experiences with psychedelics and other compounds. He directs the Psychedelic Education and Continuing Care Program at the Center for Optimal Living in New York City, leads groups and workshops, and provides individual therapy. He is also an NIH-funded post-doctoral fellow at New York University. Dr. Gorman has served MAPS as an adherence rater, supervisor, and researcher. From Dr. Gorman:

“I developed an interest in drug-assisted psychotherapy over ten years ago and dedicated my career to studying its potential. On this journey, I had the opportunity to study many hours of video-recorded MDMA-assisted psychotherapy sessions and witnessed tremendous transformations among the participants. I am fascinated by how these transformations take place and in what ways



these mechanisms are similar or distinct from those that take place in other forms of psychotherapy. What I hope to bring to this research is an empirically oriented mind with a keen eye for the psychotherapeutic process and a deep respect for each participant's intuition."

Dr. Casey Paleos is an attending psychiatrist and Clinical Assistant Professor at New York University Langone Medical Center. An experienced psychedelic researcher, at NYU he worked as a study therapist on a trial studying psilocybin's effect on anxiety due to cancer and as a co-PI on a ketamine study for depression. From Dr. Paleos:

"The inexorable, naïvely intrepid curiosity of late adolescence led me through a series of excursions into non-ordinary states of consciousness to the feet of something holy, something that defies description. There, trembling in the shadow of the terrifying, incomprehensible enormity of its faceless benevolence, I felt inside my chest the raucous clamor of teen spirit brought to gentle still-



ness and to quietude. Finally, I gathered enough courage to bring a handful of the infinite to my lips. Expecting something alien and indecipherable, its taste instead brought startling recognition: I knew it instantly as the very fluid that filled my lungs within the womb. Then the blinding flash faded, and flickering in my hand I found a small, delicate flower of flame, which I have

since guarded and nurtured into the blaze of lantern light that has illuminated my path to this extraordinary project where, with humility and deep gratitude, I have found a thousand other flames cupped in the hands of a thousand other seekers, divine rebels, and wounded healers. Together, we will transform psychiatry into a practice of true healing; in the process we very well might change the world."

San Francisco, California

Our San Francisco private practice site also benefits from two co-PIs, Gregory Wells, Ph.D., and Sylver Quevedo, M.D., MPH.

Gregory Wells, Ph.D., is a psychologist whose clinical focus is on treatment of anxiety and trauma. He also assists individuals addressing existential and psycho-spiritual growth issues, often through integration of psychedelic experiences and non-ordinary states of consciousness. He has worked at the

Veterans Affairs clinic in Oakland and consults in Silicon Valley on behavioral health issues in social media. He previously lived in New Orleans and completed a postdoctoral fellowship in Infant Mental Health and Treatment of Trauma at Louisiana

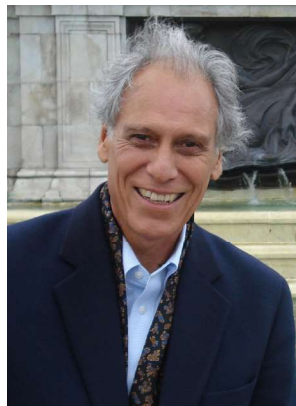


State University in the years following Hurricane Katrina. From Dr. Wells:

"My interest in psychedelics was piqued while working towards a degree in clinical psychopharmacology in 2009. I became aware of the incredible healing potential of psychedelic medicines which motivated me to become involved with MAPS. I diligently pestered Rick Doblin and Shannon

Carlín to become involved in the current study, and it eventually paid off. I'm thrilled and honored to be part of this groundbreaking research."

Sylver Quevedo, M.D., MPH, is an Associate Clinical Professor of Medicine at the University of California San Francisco and Director of Clinical Programs for the Osher Center for Integrative Medicine. At USCF, he is involved in the Global Health Sciences group and is involved in medical education reform, ambulatory care redesign, international health efforts,



and public-private partnerships in healthcare. Much of his medical career has been focused on nephrology; he has served as Associate Chief of Nephrology and Medical Director of the Artificial Kidney Center at the Santa Clara Medical Center. As a global educator, he has held visiting professorships in Kenya and Kyrgyzstan. 🌍

Charlotte Harrison is a Senior Clinical Research Associate at MAPS Public Benefit Corporation and is thrilled to be contributing to psychedelic research. Charlotte earned her B.A. in Greek and Latin at Tufts University while considering medical school. She decided her skills were better suited to clinical research after an exciting internship working on oncology trials at Clinical Assistance Programs. She has monitored and led multiple clinical trials in supportive cancer care, nephrology, dermatology, and cardiology. She is hopeful her interest in improving the quality of life of those suffering with mental illness and her determination to make scientific research more efficient will be beneficial to MAPS' important and necessary work. Outside of work, she enjoys yoga, board games, and her cats. She can be reached at charlotte@mapsbcorp.com.