

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

CHARLOTTE HARRISON



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THE MAPS PUBLIC BENEFIT CORPORATION (MPBC) has spent the last several months readying ourselves and our clinical trial sites for Phase 3 trials of MDMA-assisted psychotherapy for severe posttraumatic stress disorder (PTSD). In the US and Canada, sites have been enrolling and treating their first participants in our open-label lead-in studies—the training grounds in advance of Phase 3. Therapists are now in the process of receiving feedback from our experienced supervisors, and the sites are getting used to the high demands of our study protocols. We are gearing up to enroll our first Phase 3 participants this fall, which is a huge milestone in the journey towards approval of MDMA as a legal medicine.

In the Winter 2017 MAPS *Bulletin* (maps.org/bulletin), we introduced several of our investigators, and in this issue, we are following up to feature several more. The individuals below are saddled with the ultimate responsibility over the data generated from their study sites, participant safety and welfare, and research integrity. We feel incredibly lucky to be working with such qualified, dedicated, and experienced researchers, therapists, and doctors as our Clinical (Principal) Investigators.

Madison, WI

At the University of Wisconsin at Madison (UW), Dr. Christopher Nicholas, whom we featured in our last piece, shares the role of Clinical Investigator with Randy Brown, M.D., Ph.D. At UW, Dr. Brown serves as the Director of the Center for Addictive Disorders and is the Founding Director of the UW Addiction Medicine Fellowship Program. With a background in both family medicine and addiction, he also works as a consulting physician at the William S. Middleton Memorial Veterans Hospital, the UW Health Center HIV/AIDS Clinic, and Access Community Health Centers. He has been a prescriber of buprenorphine for opioid dependence since 2001. He is the Medical Director of the Overdose Prevention Program of the AIDS Resource Center of Wisconsin and a Director of the American Board of Addiction Medicine and the Addiction Medicine Foundation.



Dr. Brown's research focuses on the treatment and prevention of substance use disorders and their complications, including the preventing opioid misuse, supporting recovery through mobile technology, and promoting the prescription of medications to aid in alcohol and opioid use disorders in primary care settings. He has also worked on clinical trials using psilocybin. From Dr. Brown:

"I am excited by the possibilities of psychedelic-assisted therapies to improve outcomes for people struggling with complex mental health conditions and substance use disorders."

New York, NY

Dr. Michael Bogenschutz is an experienced psychedelic researcher at New York University (NYU). In addition to his role as Clinical Investigator for MAPS MDMA-assisted psychotherapy trials, he is currently conducting a Phase 2 randomized, double-blind, controlled trial of psilocybin-assisted treatment of alcohol use disorder. He is also conducting NIH-funded studies on the effects of cannabidiol and topiramate in the treatment of alcohol use disorder and the use of strengths-based case management to facilitate engagement of patients with opioid addiction into treatment. His research interests focus on developing novel combinations of pharmacologic and psychosocial therapies to improve outcomes for patients with alcohol and substance use disorders, integrating addiction treatment into medical settings, and treating co-occurring psychiatric and addiction disorders. He currently serves as a Research Professor at NYU Langone Medical Center. Prior to joining NYU in 2015, he served at the University of New Mexico Health Sciences Center as a Professor of Psychiatry and Psychology, Vice Chair and Division Director for Addiction Psychiatry, and Vice Chair for Clinical Research in the Department of Psychiatry. There he founded and directed the addiction psychiatry fellowship program and served as Principal Investigator of the Southwest Node of the National Institute for Drug Abuse Clinical Trials Network for 10 years. From Dr. Bogenschutz:



“Psychedelic-assisted treatments are, in my opinion, the most exciting and promising development in psychiatry in decades. The idea that one or a few discrete experiences, combined with appropriate therapy, can lead to lasting or permanent benefit has the potential to revolutionize psychiatry. I’ve been doing clinical research with psilocybin since 2011. MDMA is an

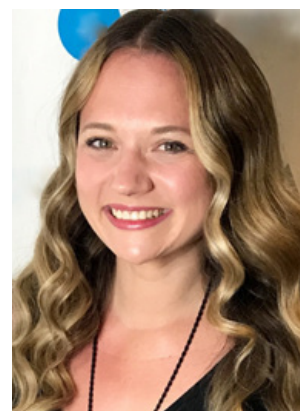
equally promising medication, which is very different from psilocybin but in some ways complementary in its clinical potential.

We are excited to be starting research with MDMA at NYU and hope this work will lead to clinical breakthroughs in treatment for PTSD and other psychiatric disorders.”

Montreal, QC, Canada

Dr. Emma Hapke is an attending psychiatrist at the Centre for Addiction and Mental Health in Toronto, Ontario, and a lecturer at the University of Toronto. Her specialty is in women’s mental health and the treatment of developmental trauma, sexual trauma, and complex PTSD. She has extensive training in multiple modalities of psychotherapy and has worked clinically with ketamine-assisted psychotherapy. She is joining the MAPS research team as the Clinical Investigator at the Montreal site for Phase 3 and in developing a study in Toronto combining Cognitive Processing Therapy (CPT) with MDMA. From Dr. Hapke:

“As Albert Einstein said, ‘We cannot solve our problems with the same thinking that created them’. The opportunity to access expanded and altered states of consciousness through psychedelics to facilitate deeper healing is one of the most promising developments in modern psychiatry. I’m honored to play my part in this paradigm shift from symptomatic management toward transformation and from the mind into the heart that is occurring in the field, in ourselves as individuals, and in our society as a whole.”



Dr. Simon Amar is a Sub-Investigator at his private practice in Montreal, where the study will be held. He specializes in integrative, psychodynamic, and mindfulness-based psychotherapy. His deep interest in the healing potential of psychedelics began at Psychedelic Science 2013. There, he attended Michael and Annie Mithoefer’s workshop on MDMA-assisted psychotherapy for PTSD, where he met his wife and co-therapist.



A view inside the study site in Montreal, Canada. Photo: Dr. Simon Amar



Since then, they have both passionately devoted themselves to becoming a part of MAPS research. From Dr. Amar:

“Unlike most psychiatric medications available to us today, this molecule provides a way of enhancing psychotherapy so that rather than just reducing symptoms, we are reaching a deeper level of

healing. I feel inspired by the profound transformations people have experienced.”

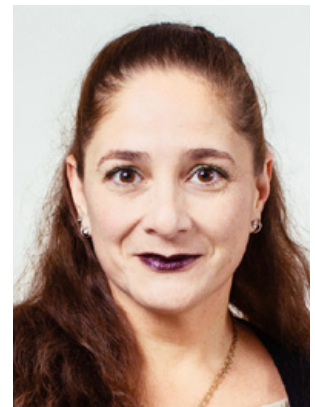
San Francisco, CA

For our research at the University of California at San Francisco (UCSF), two co-Clinical Investigators have teamed up to lead our studies: Jennifer Mitchell, PhD, and Josh Woolley, MD, PhD, two accomplished researchers in the field of mental health.

Dr. Jennifer Mitchell is a neuroscientist whose main research objective is innovation in the treatment of addiction and other mental health issues including PTSD, anxiety, depression, and impulsivity. At UCSF, she serves as an Associate Professor

in the Departments of Neurology and Psychiatry. Her research group studies the mechanisms of expression of behavioral disorders through the use of translational tools, such as behavioral pharmacology, genetics, functional magnetic resonance imaging (fMRI), and transcranial magnetic stimulation (TMS), in order to identify new potential treatments. From Dr. Mitchell:

“I am honored to be assisting MAPS in their quest to test and develop MDMA for PTSD; this is an all too common and debilitating condition for which better treatments need to be identified and rapidly disseminated.”



Co-Clinical Investigator Dr. Josh Woolley’s current research focuses on examining the mechanisms of social connection, which does not always come easy to people suffering from PTSD, substance use disorders, and schizophrenia. At UCSF, Dr. Woolley serves as an Assistant Professor in the Department of Psychiatry and the Principal Investigator for the Bonding and Attunement in Neuropsychiatric Disorders (BAND) Lab. He is also a Staff Psychiatrist at the San Francisco



VA Medical Center. From Dr. Woolley:

“My long-term goal is to develop and test novel interventions for various debilitating deficits commonly found in individuals with mental illness. To this end I have developed a program of research focused on investigating the underlying psychological, behavioral, physiological, and

neural mechanisms of these deficits and their treatment. Specifically, I have been examining the effects of intranasal oxytocin in schizophrenia, posttraumatic stress disorder, and substance use disorders. Recently, I have become intrigued by the therapeutic potential of MDMA combined with psychotherapy for difficult-to-treat psychiatric illnesses including PTSD. My multidisciplinary research group is currently conducting two studies that are centered around understanding the role of (1) intranasal oxytocin and (2) remote cognitive training on alleviating social cognitive deficits in PTSD as well as a pilot-study of psilocybin-enhanced group therapy for demoralization and complex trauma in long-term AIDS survivors. In the months and years to come, I am most

excited to be able to better understand the underlying mechanisms through which MDMA coupled with psychotherapy may be useful for treatment of PTSD. I cannot express my gratitude for the heroic effects of organizations like MAPS that allow dedicated scientists to pursue cutting edge research in psychedelic medicine. I sincerely hope that my lab’s work will help contribute to this impactful work.” 🌱

Charlotte Harrison earned her bachelor’s degree in Greek and Latin in 2012 from Tufts University while pursuing pre-medical studies. After an exciting internship working on oncology trials at Clinical Assistance Programs (CAP), she decided her skills were better suited to clinical research. She monitored and managed clinical trials in supportive cancer care, nephrology, dermatology, and cardiology at CAP, MedTrials, and Harvard Clinical Research Institute. At MPBC, Charlotte is currently serving as a Senior Clinical Research Associate, supporting the management of MDMA and marijuana studies. She supports, trains, and monitors multiple sites, ensuring quality research and compliance. She is hopeful that her passion for improving the quality of life for those suffering with mental illness and determination to make scientific research more efficient will be beneficial to MAPS’ important and necessary work. In her free time, Charlotte can be found doing yoga, snuggling her cats, or playing board games late into the night. She can be reached at charlotte@mapsbcorp.com.