



MAPS Doubles Ethnoracial Diversity in Trials Again

Re-Designing Systems of Care

McKenna Leighton and Charlotte Harrison

In the Health Equity Plan¹ published in December 2020, MAPS announced its dedication to providing safe and effective care to as many people as possible by designing programs to serve those who are most marginalized by society. One of the first material successes of this plan was the increase in ethnoracial diversity among participants in our Phase 3 clinical studies of MDMA-assisted therapy for the treatment of PTSD. In our second Phase 3 study (MAPP2), people of color constitute a majority of enrolled participants. This success was not the result of wishful thinking, but a dedication to addressing causes of health inequality in order to provide greater care.

Diversity and inclusion are familiar issues in clinical trials, and psychedelic-assisted studies face unique challenges to the enrollment of participants of color (Fortuna 2010, Williams 2019, Herzberg 2019). In MAPS' Phase 2 studies of MDMA-assisted therapy for the treatment of PTSD, only 12.4% of participants were people of color² – 35% less than demographic data published on the PTSD population in the United States³ (Mithoefer 2019, Roberts 2011).

We implemented solutions between Phases 2 and 3 which included establishing an advisory council, requiring therapists and independent raters to complete training on racial justice and preventing microaggressions, providing participant reimbursement at select study sites for study-related costs, and prioritizing interested volunteers who identified as POC. These interventions had a significant (but insufficient) effect in the first Phase 3 trial completed in 2020 (MAPP1), doubling representation of POC from 12% to 27%. But the study demographics were still far from representative of the PTSD patient population in the U.S. (Roberts 2011) and fell short of MAPS' health equity mission.

Over the course of the second Phase 3 trial (MAPP2⁴), the previous seeds of change and a renewed commitment to diversity blossomed. Enrollment of participants of color doubled again, from 27% to 53% – participants of color constituted a majority.

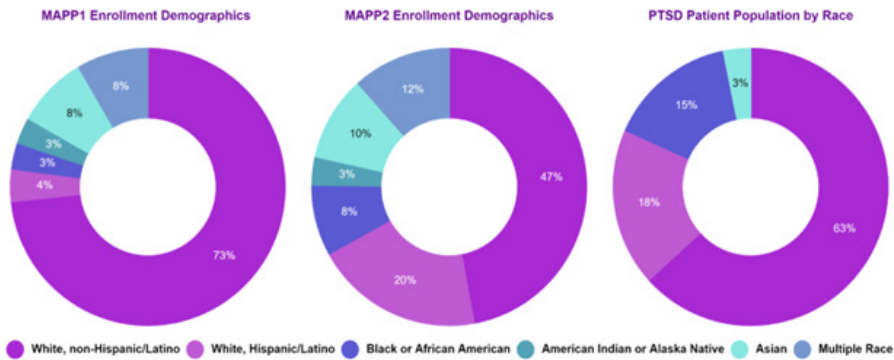
In this article, we will review some of the specific solutions we implemented in the second MAPS-sponsored Phase 3 study (MAPP2) to overcome systemic issues in clinical research and psychedelic science with the hopes that our efforts can illuminate a pathway for improving diversity and inclusion in both of these fields.

¹ Ginsberg, N., Ali, I., and Aggarwal, R. (2020), *Prioritizing Public Benefit Means Healing for All: Announcing MAPS' Health Equity Plan*. MAPS Bulletin. Published online December 2020.

² Per FDA guidance, clinical trial participants are asked to indicate their race according to the following options: White (which includes Middle Eastern and Jewish), African American/Black, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander. Participants are additionally asked to indicate whether they are 'Hispanic/Latino'. Participants are also given the opportunity to self-describe their race and ethnicity. For the purposes of this article, we use the FDA categories as will be required in the New Drug Application and other presentations of our data. In this article, "participants of color" includes all participants who identified with at least one race other than White/Caucasian and/or identified as "Hispanic". The authors acknowledge that these categories do not represent the beauty and complexity of our participants' racial and ethnic identities.

³ MAPS clinical trials consist of trial sites in multiple countries, including the U.S., Canada, and Israel. A majority of evaluable participants were from US sites; for simplicity, our data is compared to US population data.

⁴ MAPP2, the second Phase 3 study of MDMA-assisted therapy for the treatment of PTSD, finished enrolling in April 2022.



United States PTSD patient population data is provided by the nationally representative demographic study Roberts, A.L., et al., Race/ethnic differences in exposure to traumatic events, development of post-traumatic stress disorder, and treatment-seeking for post-traumatic stress disorder in the United States. *Psychol Med*, 2011. 41(1): p. 71-83. MAPP1 demographic data was published in *Nature Medicine*. MAPP2 demographic data represents our preliminary enrollment data. The demographics of our final enrollment, treated, and evaluable participants may differ.

Diversifying Psychedelic Clinical Research

Factors that contribute to racial health disparities are often described as “obstacles” toward health equity. The avoidance of these obstacles compounds years of neglect and underinvestment in the health and well-being of communities of color. In order to provide safe and equitable care to a racially diverse population in our clinical trials, it was critical to stop thinking about health disparity factors through this lens. These obstacles actually reveal political and economic realities that not only explain health disparities but also, and importantly, imply solutions.

Understanding structural causes of health inequity can unveil practices of collective liberation. Collective liberation, a framework that MAPS uses to address racial justice and equity, aims to free all people from systemic oppression and enable us to collaboratively imagine and build a new future. These practices must go beyond addressing the immediate needs of marginalized communities; they must also transform systems of power that currently manufacture inequality.

Clinical research, psychedelic-assisted therapy, and the healthcare industry are all fertile sites for these practices, in part because of the histories of violence which precede and contextualize our work. Racialized peoples have ample reason to mistrust a study involving a Schedule I substance — and sponsored by a novice clinical research organization — due to historic malpractice and harm in clinical research (Williams 2019, Scharff 2015); militarization and incarceration due to the racist War on Drugs (Williams 2019); and daily experiences of pathologization, abuse, and neglect in health care (Braunstein 2008, Jaiswal 2019).

The responsible practice is not to induce or coax the trust of racialized communities; the responsible practice is to be trustworthy. This requires education, attention, transparency, reflection, responsibility, and loyalty. In other words, it requires care. It requires a true commitment to the safety and well-being of participants of color. Without this care, the recruitment of POC makes these communities vulnerable to the same historic practices of exploitation, harm, and control. The stakes are even higher in clinical trials involving psychoactive substances that can induce the feeling of trust and safety (Smith 2022, Williams 2020).

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Becoming Trustworthy Critically Informed Interventions

The MAPS Diversity Working Group, formed in October 2020, consisted of internal and external members who could contribute meaningfully to the careful recruitment of participants of color. Some of the external members were or would become therapists on our studies, including Marcela Ot'alora G., M.A., L.P.C., Jennifer Jones, Ph.D., L.C.S.W., and Joseph McCowan, Psy.D.; others were prominent voices of color in the world of psychedelic medicine, including Kwasi Adusei, DNP, PMHNP, and Ritika Aggarwal, M.S., A.M.F.T. In general, the members were experienced and knowledgeable about the intersections of race, capitalism, and medicine and the systemic barriers to clinical mental healthcare. This group met monthly to identify factors preventing the successful inclusion of POC in our studies and determine solutions, some of which are detailed below.

Informed Consent: Building Trust

One of the first accomplishments of the Diversity Working Group was to revise the Informed Consent Form (ICF) provided to all study participants (and made available at clinicaltrials.gov after the trial concludes). POC may be more likely to underreport the severity of traumatic experiences and symptoms for a variety of reasons, including fear of punitive or social consequences and differences in the experience of trauma and safety (Malcoun 2015, Carpenter-Song 2010). We, therefore, felt that it was critical to the careful and successful enrollment of participants of color to improve our transparency regarding the purpose of study procedures, the uses of study data, data confidentiality, and the possibility of unwanted consequences related to study participation. The conversations that informed the revision of the ICF also informed guidance we issued to the clinical staff about establishing trust and rapport with participants of color. We believe this intervention increased our enrollment of POC and improved the quality of care.

The Burden of Expense

While participants did not have to pay to be screened or treated in the clinical trials, they may have incurred a study-related financial burden, including child and elderly care and transportation. Given that POC communities have historically been financially subjugated by state practices like slavery, forced segregation, discriminatory policing and incarceration, these personal expenses can be prohibitive to study participation. Partway through MAPP2, we added a \$100 stipend for screening activities and increased maximum reimbursement from \$350 to \$1,500 for study-related expenses. Site staff were

also empathetic and supportive of specific participant needs. These interventions protected the right of low-income people to participate in clinical research without incurring additional financial stress.

Addressing Schedule I Stigma

Due to the racist War on Drugs, the historic experimentation on Black Americans in clinical and military research, and the visible psychedelic movement in the U.S., we anticipated people of color would be hesitant to participate in our trials. Indeed, our clinicians reported that POC tended to have more concerns about the legality and safety of a clinical trial involving a Schedule I substance. They worried about participation impacting their job security or affecting their relationships. To address this concern, our clinical sites offered to speak with the families and employers of our participants to abate economic and social ramifications, with the participant's permission. This intervention was fundamentally a practice of care that again reduced race- and class-based burdens of participation.

Committing to Care: Racial Equity

Our most important intervention was to improve the diversity of clinical staff, particularly the therapists. This project was integrated with the MAPS MDMA Therapy Training Program, which has greatly increased the inclusion of clinicians of color in the MDMA-assisted therapy training program by [organizing programs](#)⁵ for clinicians of color and [offering scholarships](#)⁶ to reduce the financial burden for clinicians of color. We increased the number of therapists of color from 11% in MAPP1 to 28% in MAPP2 (unpublished data).

This was a significant intervention because clinicians of color are often better able to form therapeutic alliances with patients of color, in part due to shared experiences of marginalization and stigmatization (Smith 2022, Williams 2020), which could support an increase in quality of care. Increasing the diversity of clinical staff also guaranteed that there will be trained therapists of color who may be better situated to treat marginalized populations if the FDA approves this modality. Thus, the diversification of clinical staff served both goals of collective liberation practices: attending to inequalities in need and returning power to the communities from which it was stolen.

⁵ Carlin, S. (2020). MDMA Therapy Training for Communities of Color. MAPS Bulletin. Published online December 2020. <https://maps.org/news/bulletin/mdma-therapy-training-for-communities-of-color/>

⁶ MAPS. (2020). MDMA Therapy Training Program Update: January 2022. MAPS Update. Published online January 2022.



On March 11, 2022, psychedelic therapists Picolya McCall, Psy.D., and Joseph McCowan, Psy.D., made MAPS history by becoming the first Black co-therapy pair to conduct an experimental session within MAPS-sponsored clinical trials of MDMA-assisted therapy for PTSD.

A Final Note

These were just some of the many ways we carefully increased our inclusion of participants of color. Some of these solutions are reproducible and will certainly contribute to the successful recruitment of POC for other studies. But the crux of our success was a sincere commitment to protecting the right of POC to safely participate in clinical research. This required redesigning our processes to challenge the status quo of clinical research and health care practices that reproduce racialized inequality and harm. Diversity is not about metrics; our enrollment numbers were just a tool for measuring our progress toward a much greater goal: healing for all, racial justice, and collective liberation.

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