**Psychedelic-Assisted Therapy: Additional Information**

Bogenschutz, M. P., Ross, S., Bhatt, S., Baron, T., Forcehimes, A. A., Laska, E., Mennenga, S. E., O’Donnell, K., Owens, L. T., Podrebarac, S., Rotrosen, J., Tonigan, J. S., & Worth, L. (2022). Percentage of heavy drinking days following psilocybin-assisted psychotherapy vs placebo in the treatment of adult patients with alcohol use disorder. *JAMA Psychiatry, 79*(10), 953-62. [https://doi.org/10.1001/jamapsychiatry.2022.2096](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1001%2Fjamapsychiatry.2022.2096&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717431295%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=MVBSRYBNz0aK385AYlpuYaQ8dOdBhzeB6Xlh87dy1tM%3D&reserved=0)

Bogenschutz et al. (2022) studied the percentage of heavy drinking days following psilocybin-assisted psychotherapy versus placebo in the treatment of adult patients with alcohol use disorder. The study used a double-blind randomized clinical trial over 36 weeks that included two days of psilocybin or placebo. A total of 95 patients were included with 49 (51.6%) receiving psilocybin and 46 (48.4%) receiving placebo. The mean age was 45.8±11.6 years with 42(44.2%) female, 75(78.9%) Non-Hispanic White, 4(4.2%) Black, 3(3.2%) Asian, and 1(1.1%) American Indian/Alaska Native. The authors concluded that “psilocybin administered in combination with psychotherapy produced robust decreases in percentage of heavy drinking days over and above those produced by active placebo and psychotherapy” (p. 953)

Carhart-Harris, R., Giribaldi, B., Watts, R., Baker-Jones, M., Murphy-Beiner, A., Murphy, R., Martell, J., Blemings, A., Erritzoe, D., & Nutt, D. J. (2021). Trial of psilocybin versus Escitalopram for Depression. *The New England Journal of Medicine, 384*(15), 1402–1411. [https://doi.org/10.1056/NEJMoa2032994](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1056%2FNEJMoa2032994&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717443478%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=NZjretlNIXY%2B9EiWHFPl%2B9HS3XjPrkr7Pb6leH%2Fh0cg%3D&reserved=0)

Carhart-Harris et al (2021) studied the comparison of psilocybin versus escitalopram for depression. The study used a phase two, double-blind, randomized, controlled trial involving patients with long-standing, moderate-to-severe depressive disorder over six weeks with one group receiving 25mg of psilocybin in two separate sessions or 1mg of psilocybin in two separate sessions plus 6 weeks of daily oral escitalopram. A total of 59 individuals participated in this study with 11(37%) female, 48(81.4%) male, and 52(88.1%) Non-Hispanic White with no other culturally relevant information provided. The authors concluded that when comparing the two groups there were no statistically significant findings to indicate either medicine was better than the other. Both groups did show a similar decrease in depression scores yet when not compared to a control group, the statistical significance is inconclusive.

Davis, A. K., Barrett, F. S., May, D. G., Cosimano, M. P., Sepeda, N. D., Johnson, M. W., Finan, P. H., & Griffiths, R. R. (2021). Effects of psilocybin-assisted therapy on major depressive disorder: A randomized clinical trial. *JAMA Psychiatry, 78*(5), 481-489. <https://doi.org/10.1001/jamapsychiatry.2020.3285>

Davis et al (2021) completed a randomized, waiting list-controlled clinical trial to study the effects of psilocybin-assisted therapy on major depressive disorder. The study looked at the results of two separate psilocybin treatment sessions over four weeks and compared the results to a control group of waiting list participants over the same period. A total of 27 individuals began the study with 15(55.5%) receiving the psilocybin treatment and 12(44.4%) in the control group. Of those participants, 24 individuals completed the entire study requirements with 16(67%) women, 8(33%) men, a mean age of 39.8±12.2 years old, and 22(92%) Non-Hispanic White. No other cultural demographic information was included. The authors concluded that “the current study showed that clinically significant antidepressant response to psilocybin persisted for at least 4 weeks, with 71% of the participants continuing to show a clinically significant response at 4-week follow-up” (p.486) and “the present trial showed that psilocybin administered in the context of support psychotherapy produced large, rapid, and sustained antidepressant effects” (p. 487).

Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, A., Bennett, J. C., Malievskaia, E. (2022). Single-Dose psilocybin for a treatment-resistant episode of major depression. *The New England Journal of Medicine, 387*(18), 1637–1648. [https://doi.org/10.1056/NEJMoa2206443](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1056%2FNEJMoa2206443&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717458359%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=J8qPh90fogxhfD47kEGeRizBqUyYDJigUD90XzzYCcA%3D&reserved=0)

Goodwin et al. (2022) studied single-dose psilocybin for a treatment-resistant episode of major depression. The study was a phase two double-blind trial of randomly selected adults to receive a single dose of synthetic psilocybin with experimental groups receiving either 25mg or 10mg and a control group receiving 1mg along with psychological support. A total of 233 participants were separated into three groups with 79% (33.9%) in the 25mg group, 75(32.1%) in the 10mg group, and 79(33.9%) in the control group with a mean age of 39.8±12.2 years old and 215 (92%) Non-Hispanic White with no other culturally relevant demographic information provided. The authors concluded that the use of 25mg single dosing showed a statistically significant reduction in depression scores when compared to 10mg and 1mg groups and 10mg to 1mg group comparisons showed no statistical significance.

Hull, T. D., Malgaroli, M., Gazzaley, A., Akiki, T. J., Madan, A., Vando, L., Arden, K., Swain, J., Klotz, M., & Paleos, C. (2022). At-home, sublingual ketamine telehealth is a safe and effective treatment for moderate to severe anxiety and depression: Findings from a large, prospective, open-label effectiveness trial. *Journal of Affective Disorders, 314*, 59–67. <https://doi.org/10.1016/j.jad.2022.07.004>

Hull et al. (2022) studied the application of sublingual ketamine via telehealth for individuals with moderate to severe anxiety and depression. The study used a prospective approach of a large outpatient sample receiving ketamine-assisted therapy over four weeks by a telehealth provider. A sample of 1247 samples had completed treatment with sufficient data. Of those samples, 661 (54.6%) were women, 549 (45.4%) were men, ages between 19 and 79 with a mean of 40.0 (SD±9.1) and the only remaining demographic data provided was Urban living 1158 (95.0%) and Rural 61 (5.0%).The authors concluded “This is the largest study to date on real-world safety and effectiveness of any type of ketamine treatment…these data suggested that ketamine-assisted therapy offered clinically meaningful improvement and demonstrated a desirable safety and risk mitigation profile” (p. 63).

Sloshower, J., Skosnik, P. D., Safi-Aghdam, H., Pathania, S., Syed, S., Pittman, B., & D'Souza, D. C. (2023). Psilocybin-assisted therapy for major depressive disorder: An exploratory placebo-controlled, fixed-order trial. *Journal of Psychopharmacology, 37*(7), 698–706. [https://doi.org/10.1177/02698811231154852](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1177%2F02698811231154852&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717465034%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=4OPHXXZfi0cDKjz%2BtDUhB7fTTQlJ37dWt2whN%2F5u4m4%3D&reserved=0)

Sloshower et al. (2023) studied the effects of psilocybin on persisting depression and anxiety. Using an exploratory, placebo-controlled, within-subject, fixed-order study, the investigators provided a combination of psychotherapy, placebo, and psilocybin (0.3mg) over 16 weeks to patients meeting diagnostic criteria for Major Depressive Disorder for a mean of 20 years ± 12 years. A total of 19 participants completed stage 1- a placebo dosage- and 15 participants completed stage 2- a psilocybin dosage. Of those 19 participants, 13 (68.4%) were women, 6 (31.6%) were men, 16 (84.2%) were Caucasian, 2 (10.5%) were Black, 2 (10.5%) were Hispanic, and 1 (5.2%) were two or more races. The authors concluded “significant improvements in measures of both depression and anxiety following administration of both placebo and a moderate dose of psilocybin in combination with psychotherapy. While the degree of improvement post-psilocybin was not statistically significantly greater than placebo, several findings suggest the therapeutic potential of psilocybin-assisted therapy for depression is worthy of further study” (p. 703).

Straumann, I., Ley, L., Holze, F., Becker, A. M., Klaiber, A., Wey, K., Duthaler, U., Varghese, N., Eckert, A., & Liechti, M. E. (2023). Acute effects of MDMA and LSD co-administration in a double-blind placebo-controlled study in healthy participants. *Neuropsychopharmacology, 48*(13), 1840–1848. [https://doi.org/10.1038/s41386-023-01609-0](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1038%2Fs41386-023-01609-0&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717471670%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=INULNJoQ4BQRqkcBcg%2F%2F2IfB9sHg%2Bu4QmbWgrxIAYO0%3D&reserved=0)

Straumann et al. (2023) studied the acute subjective effects of combining LSD and MDMA to illicit a better drug effect that includes greater well-being, openness, and trust, and lower bad drug effects of anxiety compared to LSD administration alone. The study used a double-blind, placebo-controlled, within-subject comparison, crossover design with four 13-hour experimental test sessions to investigate responses to placebo, 100 mg MDMA alone, 100 mg LSD alone, and 100 mg LSD and 100 mg MDMA combined. A total of 24 participants were selected and included 12 (50%) men and 12 (50%) women with a mean age ± SD: 30±7 years, range 25-54 years. No other identifying demographic data were provided. The authors concluded “MDMA co-administration did not alter acute psychedelic effects of LSD. However, MDMA acted as a blocker for the metabolism of LSD to prolong its presence in the body and acute effects. The LSD+MDMA combination produced more autonomic effects compared to LSD alone. There is likely little benefit in combining MDMA and LSD in psychedelic-assisted therapy” (p. 1846).

Williams, M. T., Davis, A. K., Xin, Y., Sepeda, N. D., Colon Grigas, P., Sinnott, S., & Haeny, A. M. (2021). People of color in North America report improvements in racial trauma and mental health symptoms following psychedelic experiences. *Drugs: Education, Prevention and Policy, 28*(3), 215-226. [https://doi.org/10.1080/09687637.2020.1854688](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1080%2F09687637.2020.1854688&data=05%7C02%7CCharlie.Warstler%40ttu.edu%7C667517bd48174796aaeb08dc645f8ae1%7C178a51bf8b2049ffb65556245d5c173c%7C0%7C0%7C638495608717478271%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=krPHWhDekphg6zSLhcpwp6AjZtB4Bu1QbAYZOF9rTMQ%3D&reserved=0)

Williams et al. (2021) studied the effects of psychedelic experiences on people of color with a history of racial trauma and subsequent mental health symptoms. The study used a cross-sectional internet-based survey that included questions about experiences with racism, mental health systems, and acute and enduring psychedelic effects. A total of 313 participants were included in the study of which 43% were male, 57% were female, with a mean age of 33.1±11.2 years old, 47% were living in the United States, 53% living in Canada, 32% were of Black or African heritage, 29% were of Asian heritage, 19% of Hispanic heritage, 18% of Native American or Indigenous Canadian heritage, and 21% were Native Hawaiian, Pacific Islander or other. The authors concluded that participants experiencing racial trauma may benefit from the use of psychedelic medicines to alleviate long-term mental health symptoms. Further, research needs to include marginalized communities, considering the negative stigma psychedelics have with certain communities.