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Psilocybin-Assisted Therapy for Mental Health Treatment: Effectiveness, Safety and Public Support for Legalization in the State of New Jersey

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Contents

Abstract

The *Psilocybin Behavioral Health Access and Services Act* (Bill S2283) was introduced to the New Jersey State Senate in January 2024. If passed in its current form, one of, but not the only, major policies of the bill would be to legalize the professionally supervised administration and use of psilocybin (the psychoactive compound in psychedelic "magic mushrooms") in licensed "psilocybin service centers" for the purposes of supporting mental health treatment. Based on a literature review of randomized clinical trials that have assessed the safety and effectiveness of psilocybin-assisted therapies used to treat clinical depression and anxiety, we summarize evidence that the professionally supervised administration of just one or two doses of psilocybin results in quick and long-lasting reductions in symptoms of depressive and anxiety disorders. Further, this review also provides evidence that professionally supervised use of psilocybin poses minimal physical and psychological safety risks. Based on an original public poll we conducted, we found, in what we believe to be the first-ever publicly published poll assessing public support in the state of New Jersey for the legalization of medicinal uses of psilocybin, that a slim majority (55%) of individuals support such legalization. Support for such legalization was stronger for individuals who are aware of the medicinal uses of psychedelic drugs for the purposes of treating mental health compared to individuals who are not aware of this, indicating that education about the scientific knowledge of the anti-depressant/anti-anxiety effects of professionally supervised psychedelic drug use is an important factor predicting support for this policy. Further, those who have used psychedelic drugs in the past were more likely to support this policy than individuals who have never used such drugs, indicating that personal experience in using psychedelic drugs is an important factor predicting support for this policy. As detailed in the report, support for the policy significantly varied by age, race/ethnicity, highest level of education, income, and political party affiliation, but did not significantly vary by the region of New Jersey the respondent resided in (North vs. South vs. Central) or gender. In sum, this report indicates that professionally supervised use of psilocybin for mental health treatment is an effective and safe practice whose legalization is seemingly supported by the majority of New Jersey adults. Such legalization seems like a

promising policy to pursue to achieve the objective of offering adults in the state an alternative strategy for treating the mental health problems they may experience.

Introduction

Potential Decriminalization and Legalization of Psilocybin in The State of New Jersey

In January 2024, the *Psilocybin Behavioral Health Access and Services Act* (Bill S2283)[1] was introduced to the New Jersey State Senate, sponsored by Senate President Nicholas P. Scutari (Democrat) and co-sponsored by Senators Andrew Zwicker (Democrat), Nilsa Cruz-Perez (Democrat) and Holly Schepisi (Republican). The bill would enact two major policy changes in New Jersey in relation to the production, distribution and use of psilocybin, the primary psychoactive compound found in "magic mushrooms" that is responsible for the psychedelic, or hallucinogenic, effects experienced by users when consumed in large doses[2].

First, the bill seeks to decriminalize the possession, storage, use and transport of small amounts of psilocybin for adults who are at least 21 years old and to expunge prior criminal offenses related to the drug.

Second, and most relevant to this report, the bill would permit the establishment of "psilocybin service centers". Such centers would be allowed to manufacture and sell psilocybin products that would only be permitted to be used at the center under the professional supervision of a "facilitator". Under the bill, clients interested in consuming psilocybin at a service center would first have to participate in a preparation session that partially involves screening for health and safety issues. After completing the preparation session, clients would consume the drug and be guided through the experience by the facilitator. At the conclusion of the experience, the facilitator would be available to lead the client through an "integration session" that is intended to help the client "process the results" of their experience.

The "facilitators" working at service centers would be required to receive specialized training and licensure. Training would teach facilitators how to guide clients through the experience in an affirming, nonjudgmental, culturally competent, and non-directive fashion. Further, facilitators would be trained to provide

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[1] *Psilocybin Behavioral Health Access and Services Act*, S2283, 221st Legislature, Session 2024-2025 (NJ 2024). https://www.njleg.state.nj.us/bill-search/2024/S2283/bill-text?f=S2500&n=2283_I1

[2] National Institute on Drug Abuse (2024). *Psilocybin (Magic Mushrooms)*. https://nida.nih.gov/research-topics/psilocybin-magic-mushrooms (accessed May 2024)

clients support while they are under the influence of the drug, with a focus on specialized skills to ensure a safe experience and how to guide clients with behavioral health disorders through the experience. After such training, an exam must be passed for an individual to earn the licensure required to work as a facilitator.

According to the language used in the bill, the intended purpose of establishing such service centers and permitting clients to use psilocybin under the supervision of a facilitator is to provide "opportunities for supported psilocybin experiences to alleviate distress, provide preventive behavioral health care, and foster wellness and personal growth…[the bill] seeks to improve the physical, mental, and social well-being of all residents of New Jersey, and to prevent and reduce the prevalence of behavioral health disorders in adults by providing for supported adult use of psilocybin under the supervision of trained and licensed psilocybin service facilitators". Thus, it is apparent that one of the major motivations of creating this bill is to provide the public with an alternative method for mental health care and treatment.

The New Jersey public and legislative debates concerning the support or opposition of this bill should be primarily focused on evaluating three major questions. First, how effective is professionally supervised psilocybin use in helping people cope with mental health problems? Second, how safe is the use of psilocybin under professional supervision? Third, to what degree does the New Jersey public support the state-wide legalization of professionally supervised psilocybin use for the purposes of improving mental health?

This report aims to evaluate the answers to these three critical questions. Through a review of the published research literature of clinical trials, we will summarize current knowledge concerning the effectiveness and safety of professionally supervised psilocybin use for the purposes of mental health treatment. To gauge current public opinion, we will report the results of an original poll we conducted in early 2024 that asked a representative sample of New Jersey residents to indicate their level of awareness and support for the professionally supervised use of psilocybin for mental health treatment.

As mentioned earlier, one of the main proposals of the bill is to decriminalize private recreational production and use of psilocybin. While an important aspect of this bill, this report does not focus on providing

information useful for public policy debate on this issue. Such a debate is complex and involves interdisciplinary discussions of issues relevant to criminal/social justice, politics, psychology, philosophy, public health, and economics that are outside the scope of this report. Thus, this report is exclusively focused on providing information that informs the debate concerning the portions of the bill that propose the establishment of service centers that provide professionally supervised opportunities for individuals to seek mental health care via the use of psilocybin products.

Effectiveness of Professionally Supervised Psilocybin Use for Treating Mental Health Problems

Multiple randomized clinical trials have been conducted to assess how effective professionally supervised psilocybin use is in helping reduce symptoms of mental health disorders. In these clinical trials, the effectiveness of psilocybin treatment is typically assessed in two complementary ways[3]. First, research subjects are initially assessed for symptoms of mental health disorders prior to psilocybin treatment ("baseline measures"). Then, subjects are randomly assigned to either experimental or control groups. Experimental groups are typically administered one or two moderate-to-high dosages of psilocybin (e.g. 10-30 mg/kg) under professional supervision. In contrast, control groups are typically administered either a placebo (e.g. niacin) or a very low dose of psilocybin (e.g. 1-3 mg/kg) under professional supervision. Finally, after the psilocybin/placebo sessions conclude, research subjects are reassessed for symptoms for mental health disorders at varying time periods, including immediately after the session concludes and days, weeks, months and years later.

The results of these studies assess the effectiveness of psilocybin for mental health treatment in two ways. First, significantly lower levels of mental health disorder symptoms after psilocybin sessions relative to baseline levels are typically interpreted as evidence of the effectiveness of psilocybin-assisted treatment.

[3] IsHak, W.W., Garcia, P., Pearl, R., Dang, J., William, C., Totlani, J. & Danovitch, I. (2023). The Impact of Psilocybin on Patients Experiencing Psychiatric Symptoms: A Systematic Review of Randomized Clinical Trials. *Innovations in Clinical Neuroscience, 20*, 39-48.

Second, observations of experimental groups having significantly lower levels of mental health disorder symptoms than control groups after psilocybin treatment also typically serves as evidence of the effectiveness of psilocybin-assisted treatment. To date, the most common and rigorously studied mental health disorders treated with psilocybin-assisted therapy in such clinical trials have been depression and anxiety. Thus, this section will primarily focus on summarizing the results of randomized clinical trials that have assessed psilocybin's effectiveness in treating these two disorders.

In 2016, one such clinical trial was published reporting the results of a study of 51 individuals diagnosed with anxiety and/or mood disorders that were related to their life-threatening cancer diagnosis[4]. After baseline measurements of depression and anxiety were made, subjects were initially randomly assigned to receive either a high dose (22-30mg/kg) or "placebo-like" low dose (1-3mg/kg) of psilocybin under professional supervision. Five weeks later, subjects were re-administered psilocybin under professional supervision, with them receiving the dose they did not receive in the initial session (e.g. if they received the high dose in the first session, then they received the low dose in the second session, and vice-versa).

Five weeks after the initial session, both the high and low dose groups reported significant reductions of depression and anxiety relative to baseline. Critically, the high dose group experienced a significantly larger reduction in depression and anxiety (relative to baseline) than the low-dose group did.

Five weeks after the second session, the high dose group (who initially had the low dose in the initial session) were observed to have further significant reductions in depression and anxiety relative to five weeks after the first session, whereas the low dose group (who initially had the high dose in the initial session) maintained their lower-levels of depression and anxiety that were observed 5 weeks after the initial session. Finally, the level of reduction in depressive and anxious symptoms that were observed 5 weeks after being

[4] Griffiths, R.R., Johnson, M.W., Carducci, M.A., Umbricht, A., Richards, W.A., Richards, B.D., Cosimano, M.P., & Klinedinst, M.A. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *Journal of Psychopharmacology, 30*, 1181-1197.

administered the high dose did not significantly change 6 months later, even though no further psilocybin-assisted therapy was administered in that 6-month period.

Another clinical trial performed around the same time by a different group of researchers employed a similar experimental method (e.g. two groups who were randomly assigned to receive, under professional supervision, a high dose 1st/low dose 2nd vs. low dose 1st/high dose 2nd) and studied a sample with similar characteristics (e.g. 29 individuals with life-threatening cancer alongside clinically diagnosed depression and/or anxiety). Results from this trial found similar results in that a high dose of psilocybin resulted in significant reductions in depression and anxiety (relative to baseline) that were sustained for 6 months after treatment[5]. A long-term follow-up to this clinical trial demonstrated that the reductions in depression and anxiety (relative to baseline) observed 6 months after being treated with psilocybin persisted for at least 4.5 years[6]. In sum, evidence from these two clinical trials indicate that the combination of one high-dose and one low-dose of psilocybin can result in lower levels of depression and anxiety for months and years after treatment in cancer patients with clinical depression and/or anxiety.

In another clinical trial studying a sample of 27 individuals diagnosed with moderate-to-severe major depressive disorder (but were otherwise healthy)[7], subjects were randomly assigned to either an experimental group who received two doses of psilocybin approximately 2 weeks apart under professional supervision (first dose was 20mg/70kg and second dose was 30mg/70kg) or to the control group who received no form of treatment at all during the study period[8]. Relative to their own baseline levels of depression measured before being administered psilocybin and relative to the control group's depression levels, the experimental group was observed to have significantly lower levels of depression at both 5 and 8 weeks after their second dose. Further,

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[5] Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., Mennenga, S.E., Belser, A., Kalliontzi, K., Babb, J., Su, Z., Corby, P., Schmidt, B.L. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. *Psychopharmacology, 30*, 1165 – 1180.

[6] Agin-Liebes, G.I., Malone, T., Yalch, M.M., Mennenga, S.E., Ponte, K.L., Guss, J., Bossis, A.P., Grigsby, J., Fischer, S. & Ross, S. (2020). Long-term follow-up of psilocybin-assisted psychotherapy for psychiatric and existential distress in patients with life-threatening cancer. *Journal of Psychopharmacology, 34*, 155-166.

[7] 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 for major depressive disorder: A randomized clinical trial. *JAMA Psychiatry, 78*, 481-489.

[8] Although, the no-treatment control group was administered psilocybin-assisted therapy after the study was conducted

a long-term follow-up for this clinical trial[9] reported that the significant reductions of depressive symptoms observed in the experimental group persisted for at least 12 months after their second dose.

In all the clinical trials summarized thus far, subjects receiving psilocybin-assisted therapy were assigned to receive two doses of psilocybin to assess effectiveness in treating depression and/or anxiety. More recently published clinical trials have investigated the effects of being administered a single dose of psilocybin under professional supervision for the treatment of these two mental health disorders. In one of these clinical trials[10], 233 individuals with a history of major depressive disorder were randomly assigned to receive either 25 mg/kg (high-dose) or 10mg/kg (low dose) or 1mg/kg (placebo dose) of psilocybin under professional supervision. Relative to baseline levels of depression, all three groups were observed to have significant reductions in depression for at least 12 weeks after being administered psilocybin. The high-dose group was further observed to have significantly lower levels of depression than the low-dose and placebo-dose groups for up to 9 weeks after being treated with psilocybin (at Week 12 post-treatment, there was a non-significant trend for the high-dose group to have a greater reduction in depression than the other two groups). At no point after treatment did the reduction in depressive symptoms significantly differ between the low-dose and placebo-dose groups, indicating that a single low dose of 10mg/kg is not effective (above and beyond placebo effects) in treating depression in a sample of clinically depressed individuals.

In another clinical trial investigating the effects of a single session of psilocybin-assisted treatment on depression[11], 52 individuals diagnosed with major depressive disorder were randomly assigned to receive either a single dose of psilocybin (16 mg/70 kg) or a placebo (mannitol, a non-psychoactive diuretic) under professional supervision. Relative to both their baseline levels of depression and to the level of depression of the

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[9] Gukasyan, N., Davis, A.K., Barrett, F.S., Cosimano, M.P., Sepeda, N.D., Johnson, M.W., & Griffiths, R.R. (2022). Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up. *Journal of Psychopharmacology*, 36(2), 151–158.

[10] Goodwin, G.M., et al. (2022). Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression. *New England Journal of Medicine, 387*, 1637-1648.

[11] von Rotz, R., Schgindowski, E.M., Jungwirth, J., Schuldt, A., Rieser, N.M., Zahoranszky, K., et al. (2023). Single-dose psilocybin-assisted therapy in major depressive disorder: a placebo-controlled, double-blind, randomised clinical trial. *eClinicalMedicine, 56*, 101809.

placebo group, the psilocybin group was observed to have significantly lower levels of depression at 2, 4 and 14 days after treatment. A different, but similar clinical trial studied a sample of 104 individuals diagnosed with major depressive disorder[12]. Subjects were randomly assigned to receive a single dose of either psilocybin (25 mg/kg) or a placebo (niacin, a non-psychoactive vitamin) under professional supervision. Relative to both their baseline and to the placebo group's depression levels, the psilocybin group had significantly lower depression levels for at least 43 days after treatment.

One question that the studies summarized above do not address is how the effectiveness of treating depression with psilocybin-assisted therapy compares to more traditional pharmaceutical approaches for treatment. In the only published study to date to compare the effects of psilocybin-assisted treatment versus traditional anti-depressant treatment on depression[13], 59 individuals diagnosed with major depressive disorder were randomly assigned to either receive two 25mg/kg doses of psilocybin (separated by 2 weeks) plus a 6-week daily course of a placebo vs. a 6-week daily course of escitalopram (also known as Lexapro, a selective serotonin reuptake inhibitor, or SSRI, antidepressant). The major result of this trial was that, overall, both groups showed lower levels of depression beginning 1 week after the start of treatment (the first timepoint that depression was assessed after the start of treatment) and persisting for at least 6 weeks after the start of treatment (relative to baseline levels of depression). Critically, the degree of reduction in depression did not significantly differ between the psilocybin and the escitalopram groups between 1-6 weeks after the start of treatment (although, there was a non-significant trend for the psilocybin group to have lower levels of depression than the escitalopram group between 1-6 weeks after treatment).

In addition to reports of individual clinical trials, there have been several meta-analyses (studies that review and statistically analyze the "average results" of multiple clinical trials) published assessing the general effect of psilocybin treatment on depression and anxiety. One meta-analysis focused on assessing the time-

[12] Raison C.L., et al. (2023). Single-Dose Psilocybin Treatment for Major Depressive Disorder: A Randomized Clinical Trial. *JAMA, 330,* 843-853.
[13] Carhart-Harris, R., et al. (2021). Trial of Psilocybin versus Escitalopram for Depression. *The New England Journal of Medicine, 384*, 1402-1411.

course of the anti-depressant effects that are produced by psilocybin-assisted treatment[14]. By reviewing 10 clinical trials published between 2011-2020 that studied a total of 208 subjects, the meta-analysis indicated that psilocybin-assisted treatment resulted in significant and large reductions in depression (relative to placebo groups' depression levels) at 1 day, 1 week, 1 month, 3 months, and 6 months after using psilocybin under professional supervision. Further, studies that administered larger doses of psilocybin (relative to studies administering smaller doses) and studies that administered two separate doses of psilocybin (relative to studies that administered just one dose) were observed to result in significantly greater reductions in depression.

Another meta-analysis reviewing nine randomized clinical trials[15] found that psilocybin-assisted treatment: (a) resulted in a 2.71 times greater chance of the subjects' depression going into remission compared to the remission rates of placebo treatments, (b) was more effective in reducing depression if the subject had a prior history of using psychedelic drugs and (c) had a stronger effect to reduce depression in older compared to younger subjects.

Finally, one meta-analysis reviewed four different trials that assessed the effects of psilocybin-assisted treatment on both depression and anxiety[16]. When compared to baseline measurements of both depression and anxiety, symptoms of both mental health disorders were significantly reduced after treatment for at least 6 months, and the effect size of the baseline-to-post treatment change was large. When comparing the psilocybin and placebo groups, the effect psilocybin had on reducing depression and anxiety was comparable in size to the effect that other psychological interventions (e.g. cognitive behavioral therapy) have on the symptoms of these two disorders (when compared to no-treatment conditions).

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[14] Yu, C.-L.; Liang, C.-S.; Yang, F.-C.; Tu, Y.-K.; Hsu, C.-W.; Carvalho, A.F.; Stubbs, B.; Thompson, T.; Tsai, C.-K.; Yeh, T.-C.; et al. (2022). Trajectory of Antidepressant Effects after Single- or Two-Dose Administration of Psilocybin: A Systematic Review and Multivariate Meta-Analysis. *Journal of Clinical Medicine, 11*, 938.

[15] Metaxa, A-M. & Clarke, M. (2024). Efficacy of psilocybin for treating symptoms of depression: systematic review and meta-analysis. *BMJ, 385*, e078084.

[16] Goldberg, S.B., Pace, B.T., Nicholas, C.R., Raison, C.L. & Hutson, P.R. (2020). The experimental effects of psilocybin on symptoms of anxiety and depression: A meta-analysis. *Psychiatry Research, 284*, 112749.

In sum, the research summarized above indicates that psilocybin-assisted treatment is a promising approach for treating depression and anxiety. Significant anti-depressant and anti-anxiety effects of psilocybin use under professional supervision is a consistent finding that has been replicated across multiple randomized clinical trials, as summarized above. Further, the anti-depressant effects of psilocybin treatment are comparable to the anti-depressant effects of more traditional pharmaceutical drugs used to treat depression, like SSRIs. In fact, the research summarized above suggests that there are some advantages to using psilocybin under professional supervision rather than using traditional anti-depressant drugs to pharmaceutically treat depression. For instance, it is widely known that traditional anti-depressant drugs must be taken daily, have numerous long-lasting side-effects (e.g. headaches, insomnia, sexual dysfunction, drowsiness, and in children and younger adults, an increased risk for suicidal thoughts and behaviors), are delayed in producing anti-depressant effects by weeks or months and the end of use must be carefully managed in order to reduce the chances of experiencing withdrawal symptoms. In contrast, the results of the psilocybin clinical trials summarized above indicate that only one-to-two administrations of psilocybin is sufficient to produce large and long-lasting anti-depressant effects (rather than needing to be taken daily), generally are not associated with long-lasting side-effects (more on this in the next section), have immediate effect (unlike the delayed onset of anti-depressant effects of drugs like SSRIs), and are not known to produce withdrawal symptoms when use is immediately discontinued[17].

Finally, although the effectiveness of psilocybin-assisted treatment has been most widely and rigorously studied in relation to the treatment of depression and anxiety, other studies using less rigorous methods and/or relatively small sample sizes have been published that have provided promising early results suggesting that psilocybin-assisted therapy may be useful for treating substance abuse disorders relating to the use of tobacco,

[17] O'Brien, C.P. (2006). Drug addiction and drug abuse. In Brunton, L.L., Lazo, J.S. & Parker, K.L. (Eds.), *Goodman & Gilman's The Pharmacological Basis of Therapeutics, 11th Edition* (pp. 607-627).

alcohol and opioids[18, 19, 20, 21, 22], eating disorders[23, 24, 25] and obsessive-compulsive disorder[26, 27]. With further research, we may find that psilocybin-assisted therapies can be used to treat a wider-array of mental health problems beyond just depression and anxiety.

Safety of Using Psilocybin to Treat Mental Health Disorders

In addition to assessing the effectiveness of treating depression and anxiety, the clinical trials summarized in the prior section also assessed the safety of psilocybin-assisted therapies. Overall, the results of such assessments indicate that psilocybin-assisted therapies pose minimal physiological and psychological risks for users. One of the most common observations relating to safety of research participants consuming psilocybin are non-clinically significant and temporary increases in blood-pressure and heart rate that did not

[18] Johnson, M.W., Garcia-Romeu, A., & Griffiths, R.R. (2017). Long-term follow-up of psilocybin-facilitated smoking cessation. *The American Journal of Drug and Alcohol Abuse*, *43*, 55-60.
[19] Hendricks, P., Clark, C., Johnson, M.W. (2014) Hallucinogen use predicts reduced recidivism among substance-involved offenders under community corrections supervision. *Journal of Psychopharmacology, 28*, 62-66.
[20] Garcia-Romeu, A., Griffiths, R. R., & Johnson, M. W. (2015). Psilocybin-occasioned mystical experiences in the treatment of tobacco addiction. *Current Drug Abuse Reviews, 7*, 157-164.
[21] Davis, A.K., Barsuglia, J.P., Windham-Herman, A., Lynch, M., & Polanco, M. (2017). Subjective effectiveness of ibogaine treatment for problematic opioid consumption: Short- and long-term outcomes and current psychological functioning. *Journal of Psychedelic Studies, 1*, 65-73.
[22] Bogenschutz MP, Ross S, Bhatt S, Baron T, Forcehimes AA, Laska E, Mennenga SE, O'Donnell K, Owens LT, Podrebarac S, Rotrosen J, Tonigan JS, Worth L. (2022). Percentage of Heavy Drinking Days Following Psilocybin-Assisted Psychotherapy vs Placebo in the Treatment of Adult Patients With Alcohol Use Disorder: A Randomized Clinical Trial. *JAMA Psychiatry, 79*, 953-962.
[23] Peck, S.K., Shao, S., Gruen, T., Yang, K., Babakanian, A., Trim, J., Finn, D. & Kaye, W.H. (2023). Psilocybin therapy for females with anorexia nervosa: a phase 1, open-label feasibility study. *Nature Medicine, 29*, 1947-1953.
[24] Gukasyan, N., Schreyer, C.C., Griffiths, R.R., & Guarda, A.S. (2022). Psychedelic-assisted therapy for people with eating disorders. *Current Psychiatry Reports, 24*, 767–775.
[25] Spriggs, M.J., Kettner, H. & Carhart-Harris, R.L. (2021). Positive effects of psychedelics on depression and wellbeing scores in individuals reporting an eating disorder. *Eating and Weight Disorders, 26*, 1265-1270.
[26] Kelmendi, B., et al. (2022). Single-dose psilocybin for treatment-resistant obsessive-compulsive disorder: A case report. *Heliyon, 8*, e12135.
[27] Moreno, F.A., Wiegand, C.B., Taitano, E.K. & Delgado, P.L. (2006). Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder. *Journal of Clinical Psychiatry, 67*, 1735-1740.

require medical intervention[28, 29, 30, 31]. A meta-analysis of 10 clinical trials estimated that the average increase in blood pressure for individuals using psilocybin was 13.58-24.41 mmHg (systolic blood pressure) and 5.18012.15 mmHg (diastolic blood pressure)[32]. Another common observation is that some psilocybin users in these trials experienced transient headaches and/or nausea that was experienced while under the influence of the drug[28, 29, 30, 31, 33]. One clinical trial observed that 32% of psilocybin users experienced "psychological discomfort", but this was minor and did not require psychiatric hospitalization[28]. No observations were made in any of these clinical trials of prolonged visual hallucinations or psychotic-like symptoms extending past the period of being under the influence of the drug[28, 29, 31], although one clinical trial observed that 7% of the psilocybin users experienced "transient psychotic-like symptoms"[29]. The most serious safety issue observed in these individual clinical trials was the observation in one clinical trial[30] that less than 5% of psilocybin users engaged in "suicidal behaviors" between 3 and 12 weeks after being treated with psilocybin. However, it is important to note that these three individuals reported experiencing suicidal ideation prior to treatment. Thus, it does not seem that individuals who do not experience suicidal ideation are at risk of developing suicidal ideation after using psilocybin.

A published review of safety issues and guidelines for psilocybin-assisted treatment of mental health disorders[34] further indicated that psilocybin is not a physiologically toxic substance, does not cause physical or psychological dependency or withdrawal symptoms and does not lead to addictive use. It was noted in this

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[28] Griffiths, R.R., Johnson, M.W., Carducci, M.A., Umbricht, A., Richards, W.A., Richards, B.D., Cosimano, M.P., & Klinedinst, M.A. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *Journal of Psychopharmacology, 30*, 1181-1197.

[29] Agin-Liebes, G.I., Malone, T., Yalch, M.M., Mennenga, S.E., Ponte, K.L., Guss, J., Bossis, A.P., Grigsby, J., Fischer, S. & Ross, S. (2020). Long-term follow-up of psilocybin-assisted psychotherapy for psychiatric and existential distress in patients with life-threatening cancer. *Journal of Psychopharmacology, 34*, 155-166.

[30] Goodwin, G.M., et al. (2022). Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression. *New England Journal of Medicine, 387*, 1637-1648.

[31] Sloshower J, Skosnik PD, Safi-Aghdam H, et al (2023). Psilocybin-assisted therapy for major depressive disorder: An exploratory placebo-controlled, fixed-order trial. *Journal of Psychopharmacology, 37*, 698-706.

[32] Yu, C.-L.; Liang, C.-S.; Yang, F.-C.; Tu, Y.-K.; Hsu, C.-W.; Carvalho, A.F.; Stubbs, B.; Thompson, T.; Tsai, C.-K.; Yeh, T.-C.; et al. (2022). Trajectory of Antidepressant Effects after Single- or Two-Dose Administration of Psilocybin: A Systematic Review and Multivariate Meta-Analysis. *Journal of Clinical Medicine, 11*, 938.

[33] Raison C.L., et al. (2023). Single-Dose Psilocybin Treatment for Major Depressive Disorder: A Randomized Clinical Trial. *JAMA, 330,* 843-853.

[34] Johnson, M.W., Richards, W.A., & Griffiths, R.R. (2008). Human hallucinogen research: guidelines for safety. *Journal of Psychopharmacology, 22,* 603-620.

review that the "most likely risk" associated with psilocybin use is the psychological discomfort (e.g. anxiety, paranoia, fear) that is experienced when users experience a "bad trip". However, it is noted that, under the carefully controlled environmental conditions of professionally supervised psilocybin experiences, experiencing such discomfort is a relatively infrequent occurrence.

In the attempt to create a set of safety guidelines relevant to the administration of psilocybin and other psychedelic drugs, the following ideas were proposed by clinical researchers experienced in overseeing professionally supervised uses of psilocybin[35]:

- Careful selection of individuals to be administered psilocybin to ensure that the user is in good general health, does not have high blood pressure (due to the increases in blood pressure typically observed due to psilocybin use), are not pregnant and not on birth control, and does not have any psychosis-related psychiatric conditions (e.g. schizophrenia) that may be exacerbated by psilocybin use (due to observations that a small minority of psilocybin users in some of the clinical trials summarized above experienced transient psychotic-like symptoms).
- Ensure that psilocybin experiences are directly supervised by at least two well-trained professionals. Such supervisors of the experience should remain in the room with the user for the entirety of the session, should be trained in how to recognize and react to cues indicating adverse reactions to taking the drug, and should be strong in empathy- and respect-based interpersonal skills needed to relate to a user under the influence of a hallucinogenic drug. A detailed description of the development of such a training program has been recently published[36].
- To promote psychological comfort during the experience, it should be ensured that the physical environment is as relaxing and comfortable as possible, as opposed to being overly "clinical" and

[35] Johnson, M.W., Richards, W.A., & Griffiths, R.R. (2008). Human hallucinogen research: guidelines for safety. *Journal of Psychopharmacology, 22,* 603-620

[36] Tai SJ, Nielson EM, Lennard-Jones M, Johanna Ajantaival R-L, Winzer R, Richards WA, Reinholdt F, Richards BD, Gasser P and Malievskaia E (2021) Development and Evaluation of a Therapist Training Program for Psilocybin Therapy for Treatment-Resistant Depression in Clinical Research. *Frontiers in Psychiatry, 12*, 586682.

"antiseptic" as is typically the case in the environment found in most doctors' offices or research laboratories. Examples of setting up such an environment include the use of comfortable furniture users can lay on, low lighting, the presence of aesthetically-pleasing art and music in the room, and the absence of cellphones that could distract users from the experience.

- Before being administered the drug, users should undergo a thorough "preparation session" that explains the range of experiences users can expect to have, the expected time-course of the drug's intoxicating effects, and a description of the potential physical and psychological risks associated with use of the drug. Further, the preparation session should allow the user to become familiar with the professionals who will later supervise their experience to build rapport and trust. A recommendation was made that the user should be in contact with the supervisors for at least 8 hours over 1 month prior to being administered the drug, and at least one of the meetings should occur in the room that psilocybin will be later administered in.
- After the drug's effects wear off, users should be provided an opportunity to have a post-drug session with a supervisor where any intense emotional reactions to the experience can be talked through and processed before the user leaves the facility.

In relation to the proposals found in the New Jersey Bill S2283, it is encouraging to note that many of the specific policies concerning psilocybin service centers follow most of these guidelines, including the requirements of: (a) trained and licensed facilitators to be present in the room with a client to supervise their experience while under the influence of the psilocybin, (b) clients being required to participate in "preparation sessions" before psilocybin is administered so that clients are screened and provided with information that allows them to understand what they can expect from the experience, and (c) clients being offered the opportunity to participate in an "integration session" immediately after the effects of psilocybin subside. Thus, it appears that the development of Bill S2283 followed evidence-based practices and adheres to safety guidelines established by experts in the field.

In sum, professionally supervised use of psilocybin in a well-controlled environment seems to pose minimal risks for physical and psychological harm. However, one limitation of our current knowledge is the safety risks posed by unsupervised use of psilocybin in uncontrolled, private settings given that most safety assessments have been performed in the context of clinical trials. Given that New Jersey Bill S2283 proposes decriminalizing personal, recreational and private use of psilocybin, future research should aim to assess safety risks and harm-reduction strategies pertaining to the non-clinical use of psilocybin in private settings.

Public Support in New Jersey for the Legalization of Professionally Supervised Use of Psilocybin

Given that the passage of New Jersey Bill S2283 requires a majority vote by either a legislature (if it is decided that the bill will be voted on by the state legislature) or by the New Jersey electorate (if it is decided that the bill will be voted on by public referendum during an election, like how the act that legalized marijuana in the state in 2020 was passed[37]), it is important to assess the level of public support in the state for legalizing professionally supervised psilocybin use for the purposes of mental health treatment.

To our knowledge, no poll has been conducted on a sample of New Jersey residents concerning their level of support for such a policy. Therefore, to determine, for the first time, the New Jersey public's current level of support for legalizing the professionally supervised use of psilocybin, we designed and conducted an original poll in collaboration with Stockton University's William J. Hughes Center for Public Policy. This poll assessed responses of a probability-based sample of 606 New Jersey adults that were at least 18 years old between February 20 – March 3, 2024 (see **Appendix A** for a detailed Methodology Statement).

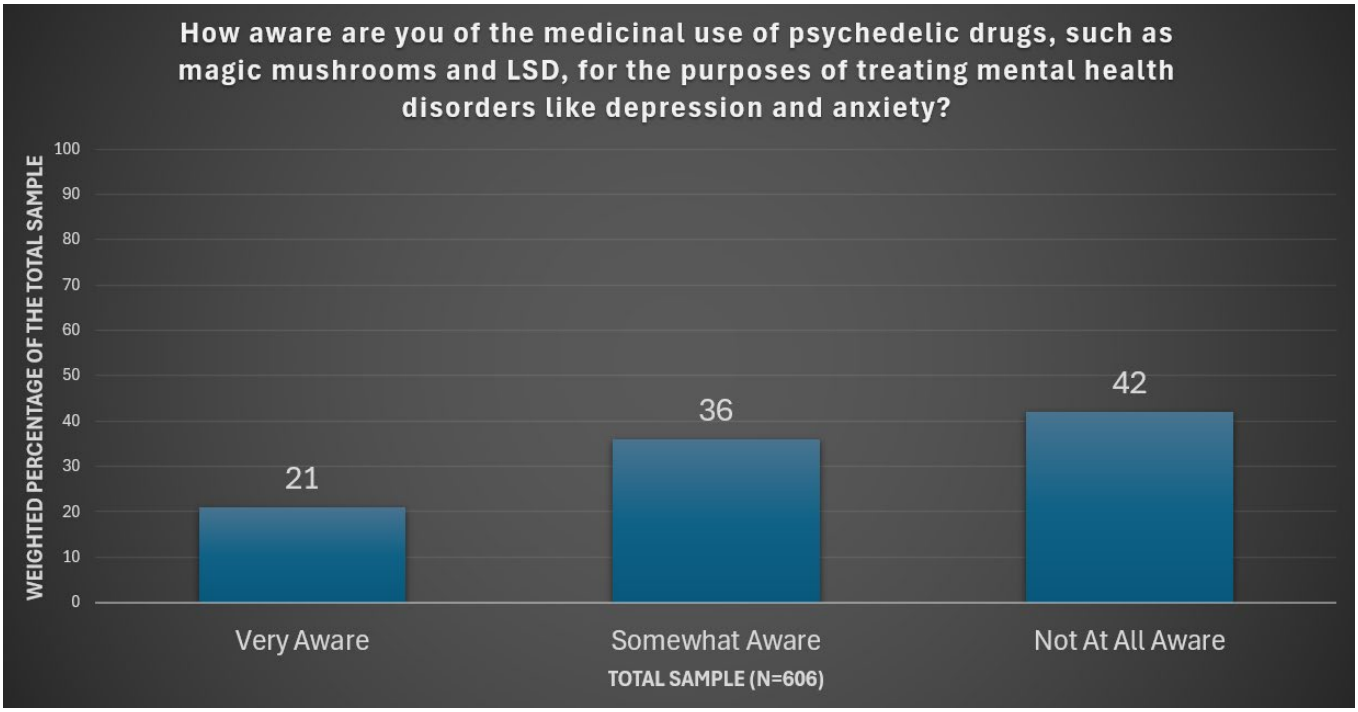
General Familiarity with and Opinion of Psychedelic Drugs

One thing we assessed was the New Jersey public's current level of familiarity with the medicinal uses of psychedelic drugs. As one can see in **Figure 1**, 57% of respondents indicated that they were either "Very

[37] Marijuana Policy Project (2023). New Jersey Becomes the 14th State to Legalize Cannabis, Raises Bar for Equity Efforts. (Accessed online May 2024). https://www.mpp.org/states/new-jersey/

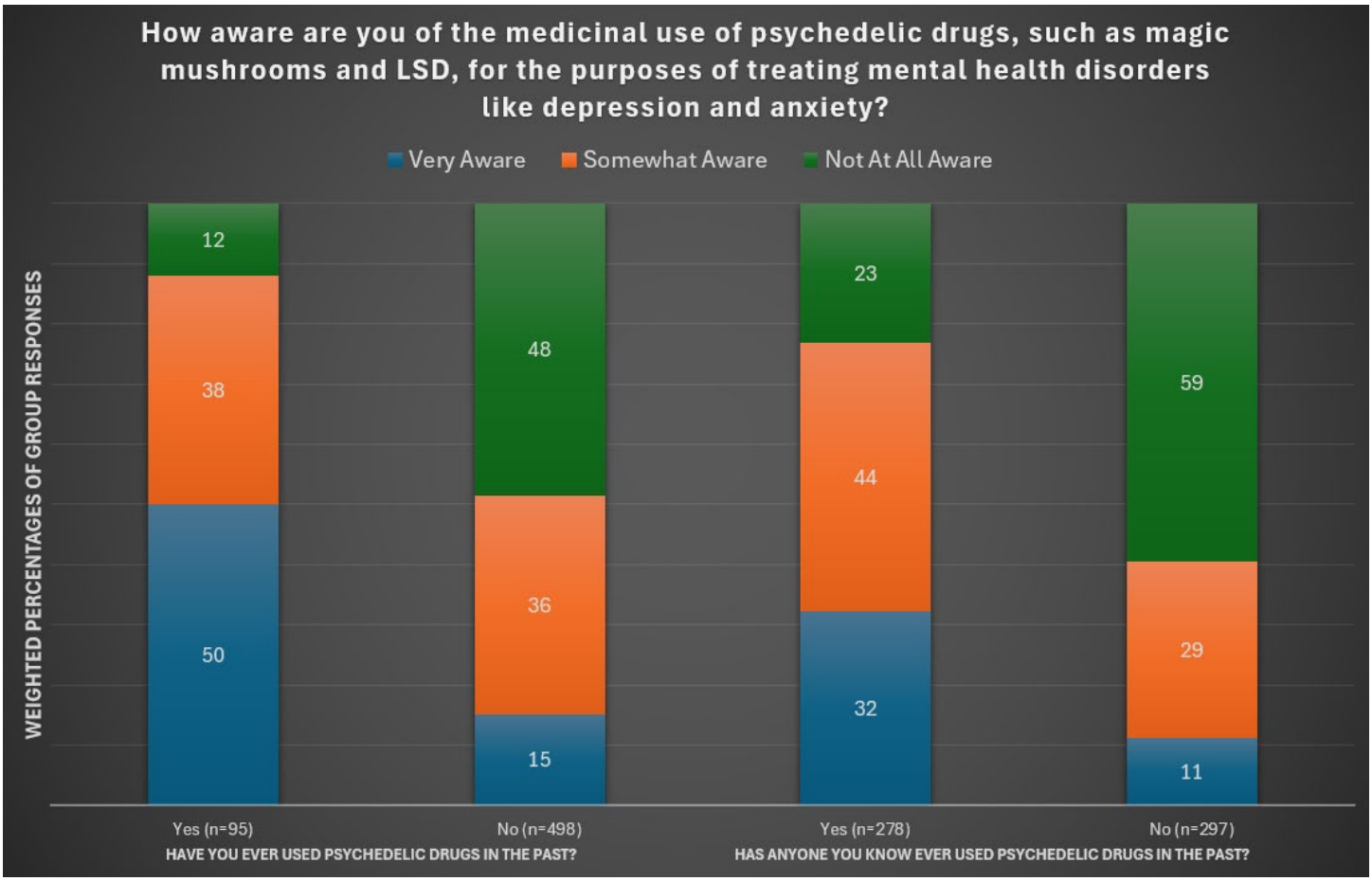
Aware" or "Somewhat Aware" of the medicinal use of psychedelics for the purposes of mental health treatment, whereas 42% indicated being "Not Aware at All". Further, 16% of the respondents indicated having a prior history of personally using psychedelic drugs and 46% indicated knowing someone in their personal life that have used such drugs.

Figure 1



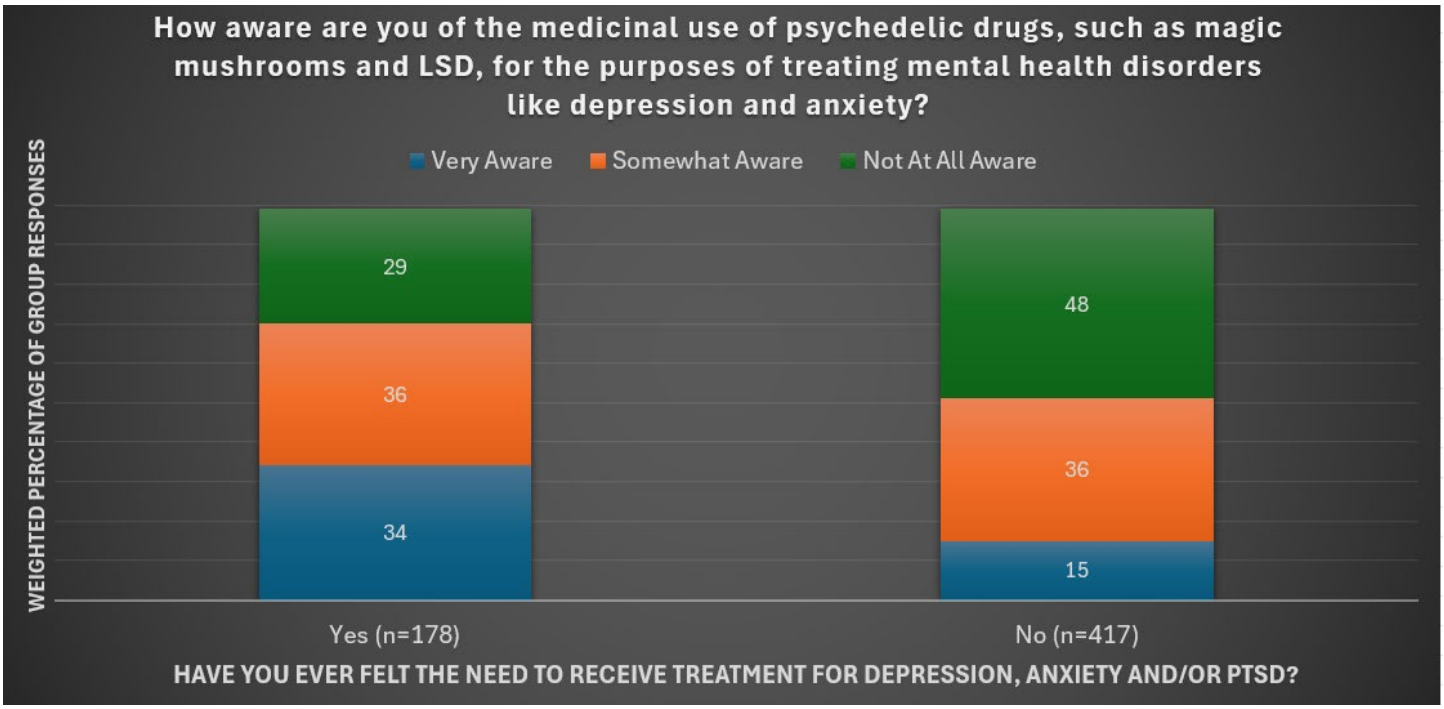
As can be seen in **Figure 2**, the level of awareness of the medicinal use of psychedelic drugs for mental health treatment significantly varied between individuals who have vs. have not used psychedelic drugs in the past, $\chi^2 = 72.06$, $p < .00001$, and between individuals who know vs. do not know someone in their personal life that has used psychedelic drugs in the past, $\chi^2 = 83.71$, $p < .00001$. These analyses indicate that significantly more individuals were "Very Aware" or "Somewhat Aware" of the medicinal use of psychedelic drugs for mental health treatment if they had previously used psychedelic drugs in the past (relative to those who have not) and those who know someone in their personal life who has used such drugs in the past (relative to those who do not).

Figure 2



As can be seen in **Figure 3**, the level of awareness of the medicinal use of psychedelic drugs for mental health treatment significantly varied between individuals who have vs. have not felt the need to receive treatment for depression, anxiety and/or PTSD, $\chi^2 = 31.54$, $p < .00001$. Significantly more individuals who have felt the need for such mental health treatment indicated being "Very Aware" or "Somewhat Aware" of the medicinal use of psychedelic drugs than individuals who have not felt the need for such treatment.

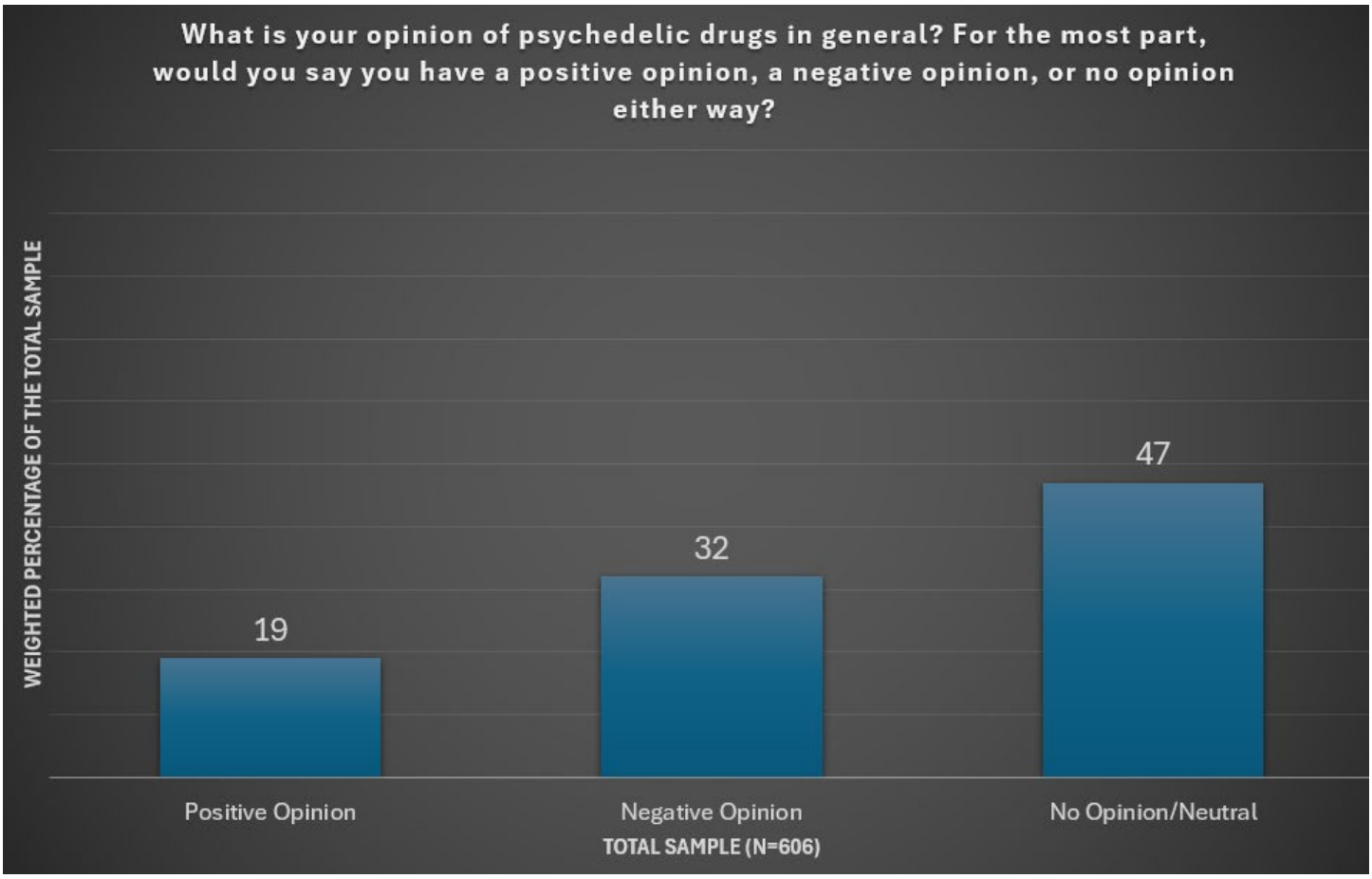
Figure 3



In sum, given that 42% of the sample indicated no awareness of the medicinal use of psychedelic drugs for mental health treatment and that only 16% of the sample has direct personal experience in using such drugs, there is a generally high prevalence of New Jersey adults lacking direct experience in using psychedelic drugs and knowledge about the potential mental health benefits of medicinal use.

In assessing general opinions on the use of psychedelic drugs (**Figure 4**), 19% of respondents indicated having a generally positive opinion, 32% indicated having a negative opinion and 47% indicated having no opinion/neutral opinion of the use of psychedelic drugs.

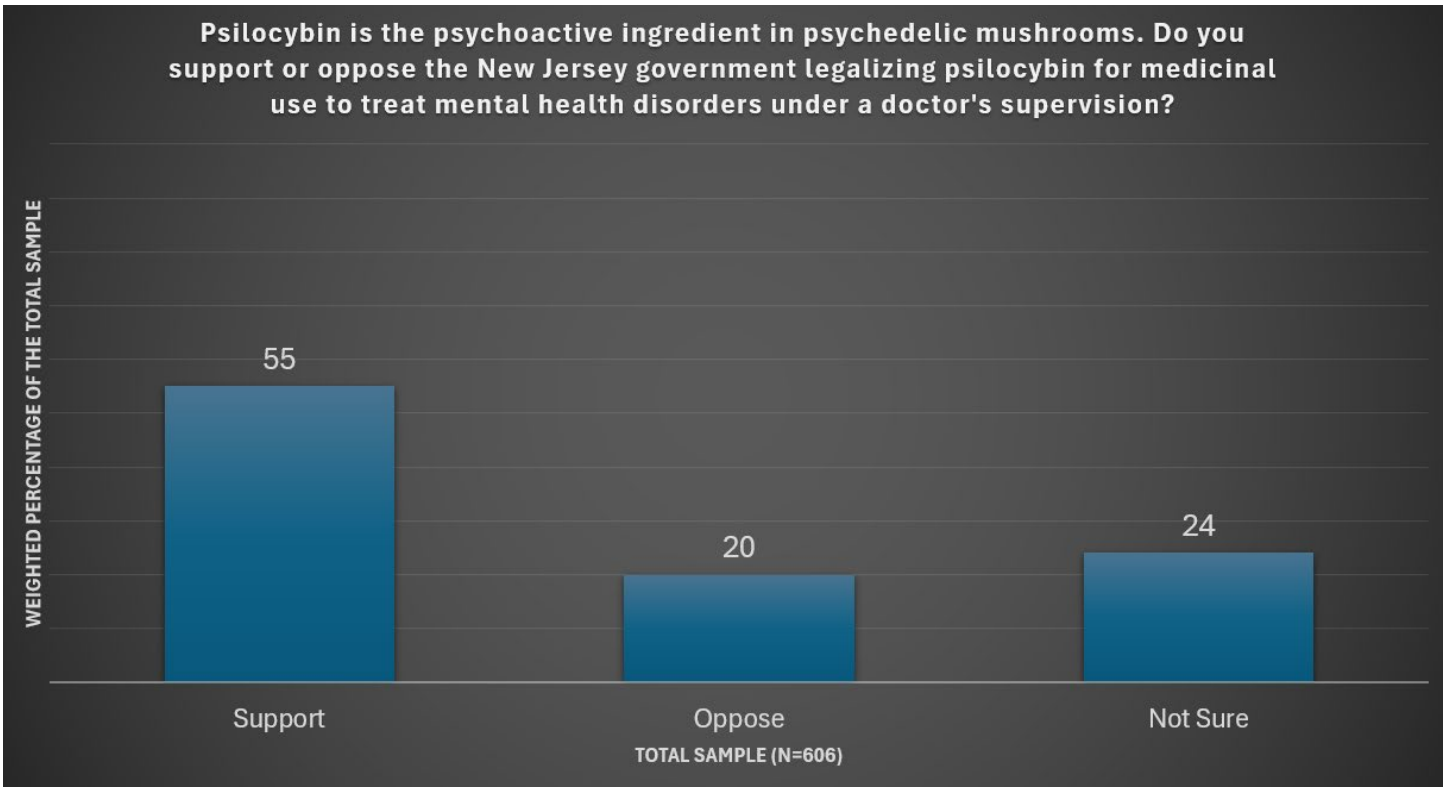
Figure 4



Level of Support in Legalizing Medicinal Psilocybin Use for the Purposes of Mental Health Treatment

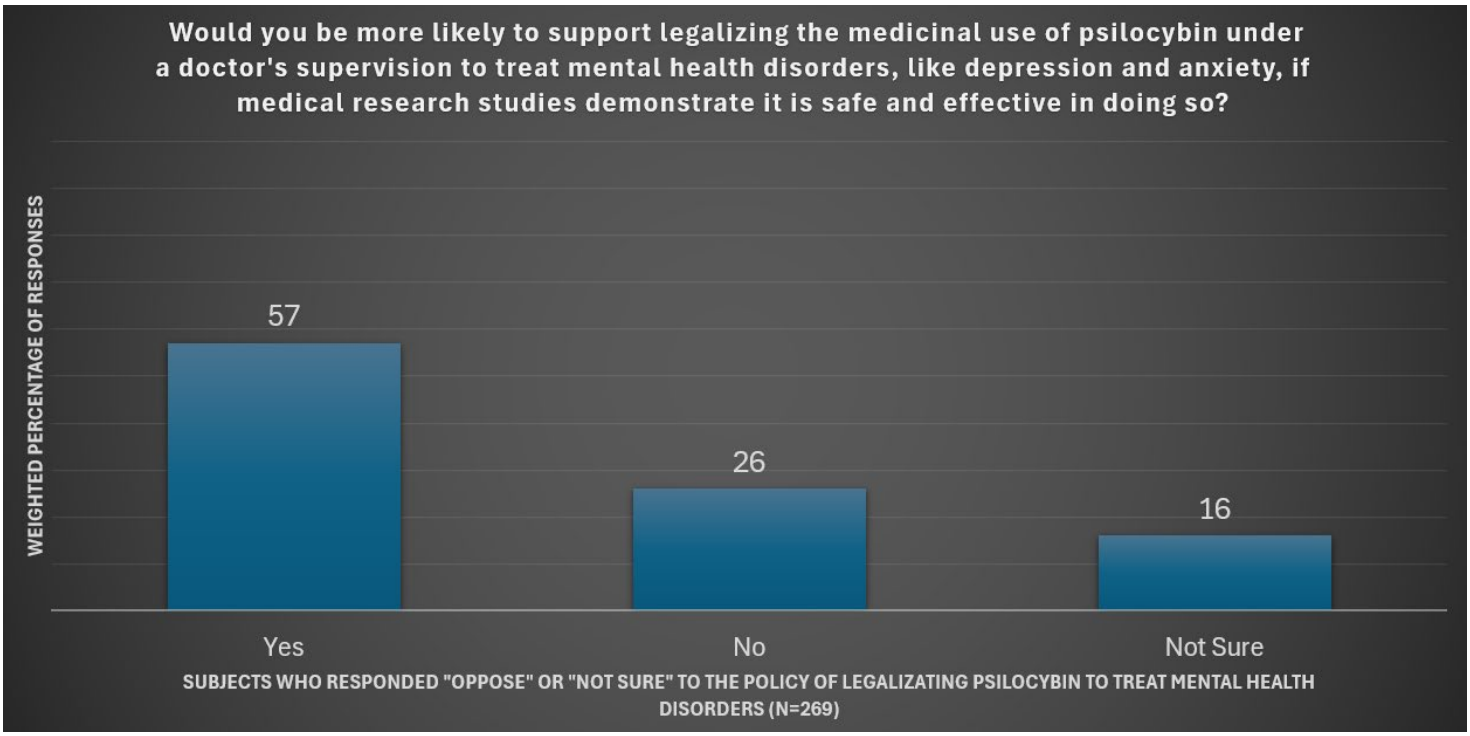
As can be seen in **Figure 5**, most respondents (55%) indicated that they support the legalization of professionally supervised use of psilocybin to treat mental health disorders. Only 20% indicated that they opposed such a policy and 24% indicated being uncertain about whether they support or oppose the policy.

Figure 5



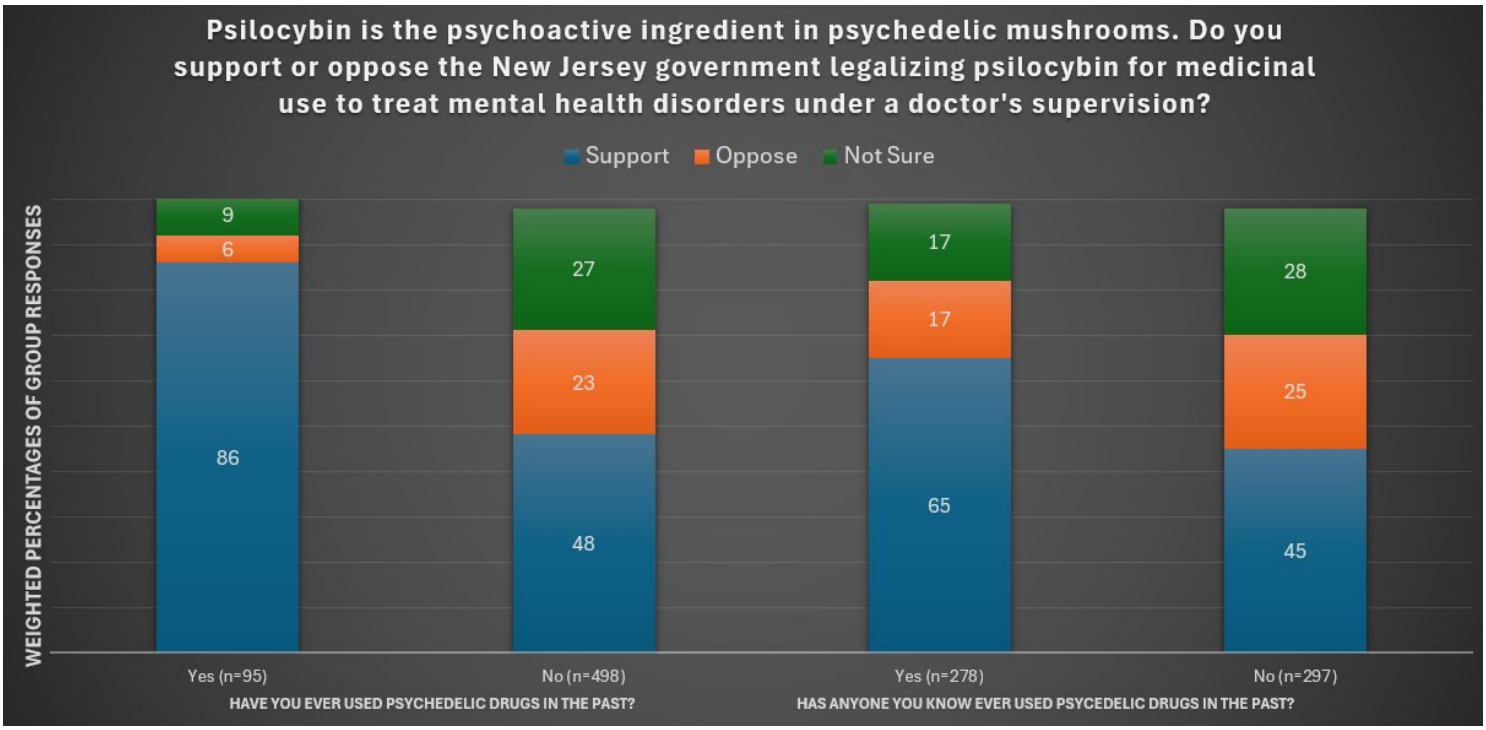
As can be seen in **Figure 6**, of the 44% of the sample who indicated opposing or not being sure about their support of the legalization of psilocybin for the purposes of mental health treatment, 57% of such individuals indicated that they would be more likely to support this policy if medical research studies demonstrated that the use of psilocybin for mental health treatment was effective and safe.

Figure 6



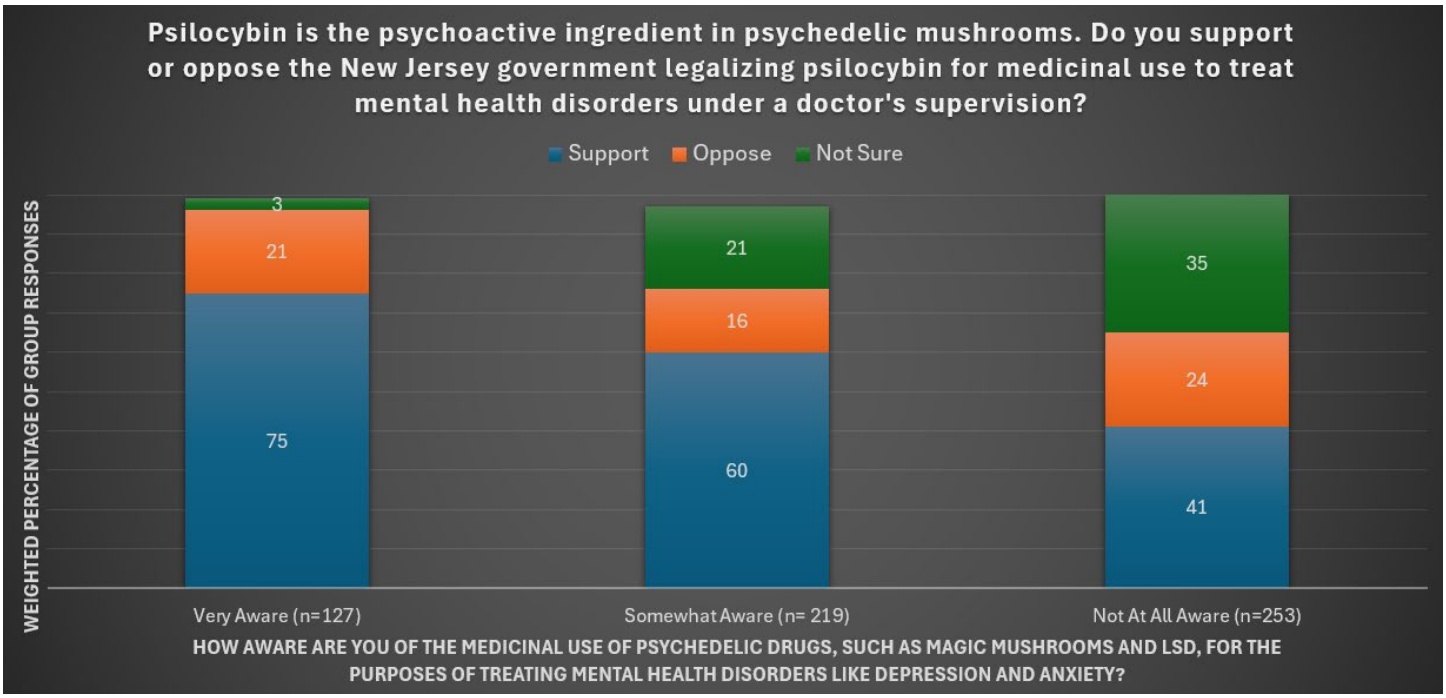
Support for this policy varied depending on the respondents' level of experience in using psychedelic drugs. As displayed in **Figure 7**, the percentage of individuals who have used psychedelic drugs in the past that supported legalization (86%) was significantly greater than the percentage of individuals supporting legalization who have not used such drugs (48%), $\chi^2 = 43.55$, $p < .00001$. Further, those who know someone in their personal life that has used psychedelic drugs were more likely to support legalization (65%) than those who do not know such a person (45%), $\chi^2 = 23.18$, $p < .00001$.

Figure 7



Additionally, the level of support for legalization differed depending on the respondent's level of awareness of the medicinal use of psychedelic drugs for mental health treatment. As can be seen in **Figure 8**, support for legalization was significantly greater in individuals who were "Very Aware" (75%) and "Somewhat Aware" (60%) of the medicinal use of psychedelic drugs for mental health treatment than in individuals "Not at All Aware" (41%), $\chi^2 = 37.34$, $p < .00001$. Interestingly, the level of opposition to legalization did not vary much between those who were "Very Aware" (21%), "Somewhat Aware" (16%) and "Not at All Aware" (24%) of the medicinal use of psychedelic drugs. Rather, being "Unsure" of legalization varied more between these three levels of awareness, where the greater levels of awareness were associated with lower rates of being uncertain about legalization, with only 3% of those "Very Aware" indicating that they were "Unsure" of legalization as compared to 35% of those "Not At All Aware" indicating that they were "Unsure" of legalization.

Figure 8



The results displayed in **Figure 9** indicate that the level of support for the legalization of the medicinal use of psilocybin significantly differed depending on whether the respondents have felt a need in the past for mental health treatment for depression, anxiety and/or PTSD, $\chi^2 = 7.12$, $p = .028$, with those who have felt the need for such treatment being more likely to support legalization (62%) than those who have not felt the need for such treatment (52%).

Perhaps unsurprisingly, support for legalization significantly varied depending on the general opinion respondents had about the use of psychedelic drugs, $\chi^2 = 158.32$, $p < .00001$. As can be seen in **Figure 10**, the percentage of respondents indicating support for legalization was significantly greater for those with a generally positive opinion concerning the use of psychedelic drugs (91%) as compared to those with a generally negative opinion concerning the use of these drugs (26%).

Figure 9

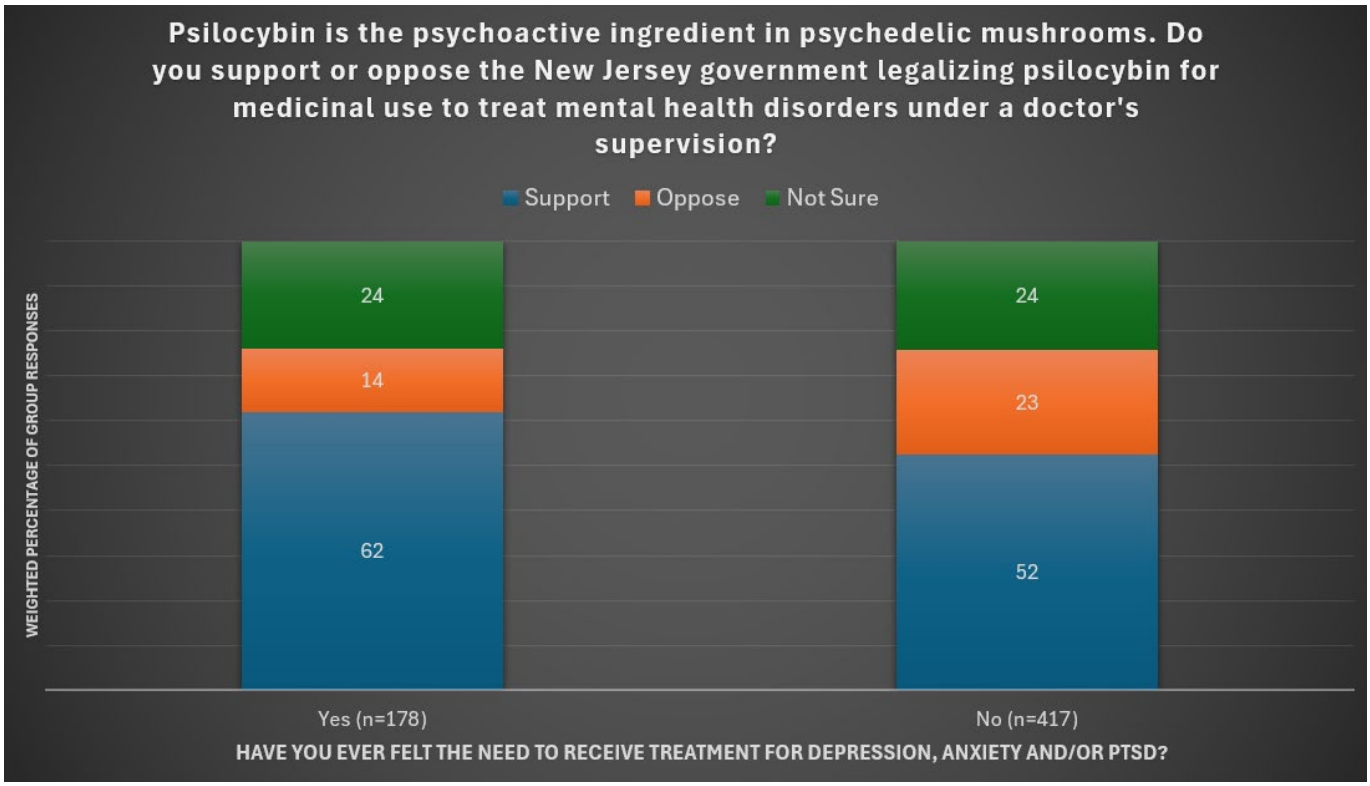
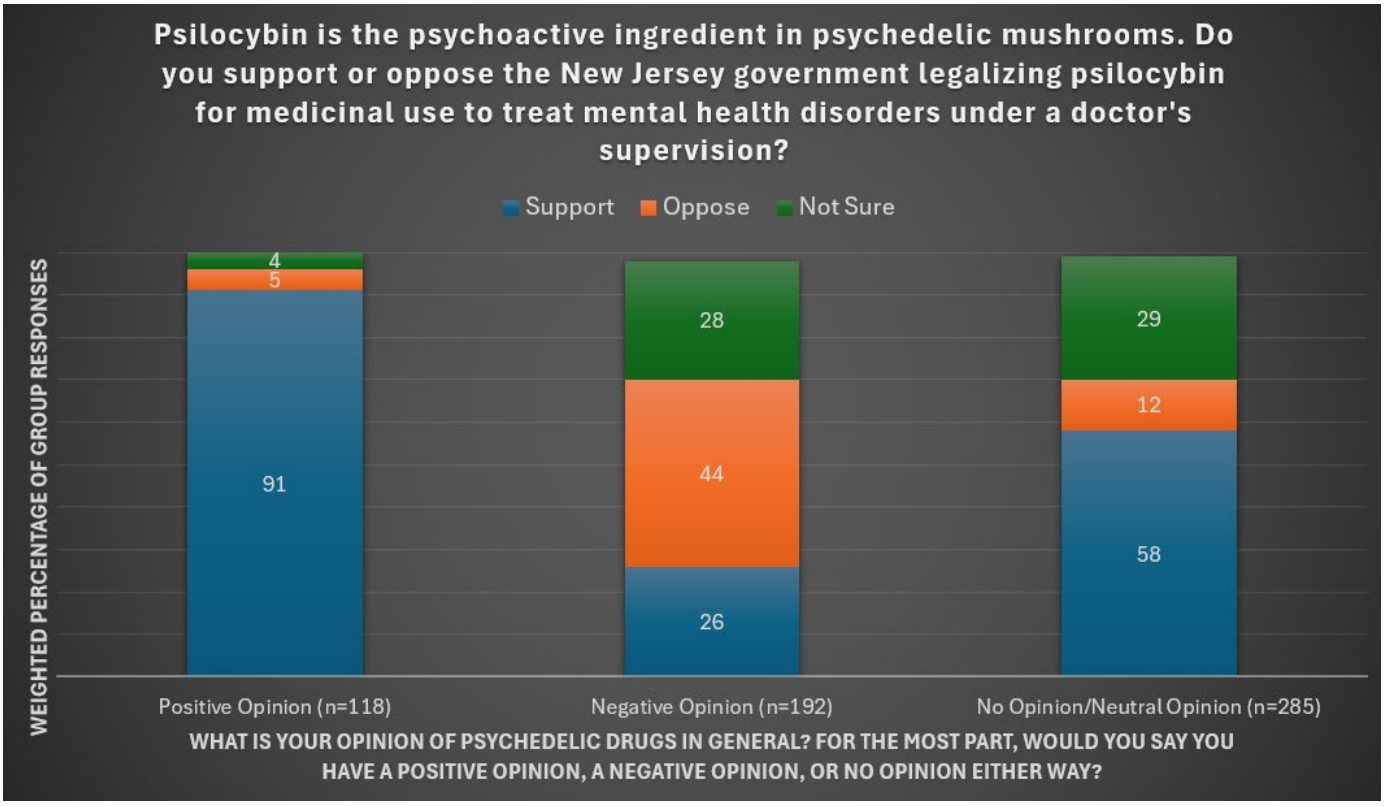
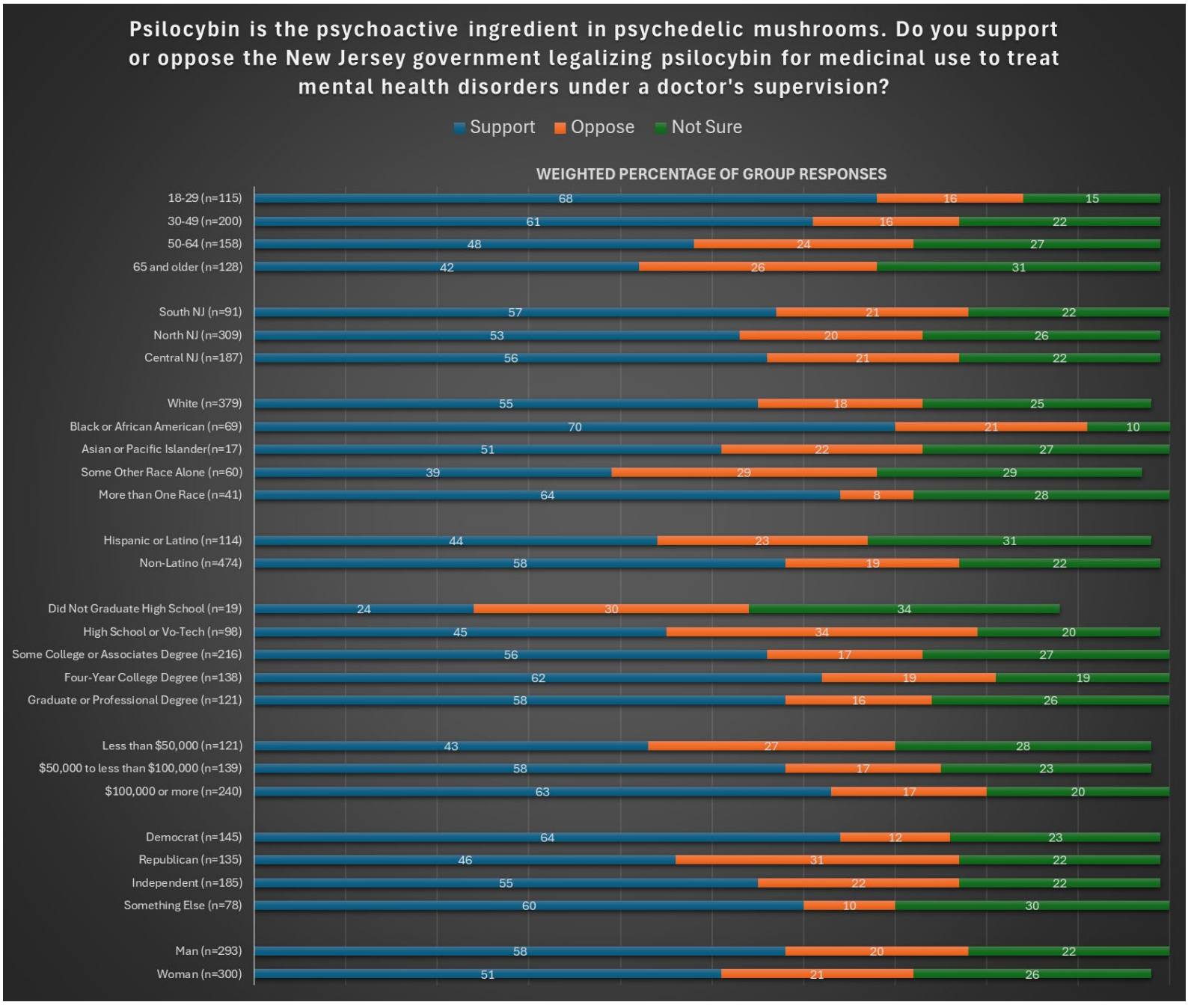


Figure 10



The level of support for legalizing medicinal psilocybin for the purposes of mental health treatment significantly varied across multiple demographic groups, as summarized in **Figure 11**.

Figure 11



Support for legalization significantly varied between different age groups, $\chi^2 = 22.86$, $p = .0008$, with younger age groups (61-68% support indicated by those aged between 18-49 years) being more likely to support legalization than older age groups (42-48% support indicated by those aged 50 or older).

Support for legalization did not significantly differ depending on whether the respondent lived in North vs. Central vs. South New Jersey regions, $\chi^2 = 4.82$, $p = .306$.

Legalization support significantly differed between race and ethnicity groups. Non-Hispanic respondents were more likely to indicate support for legalization (58%) than Hispanic respondents were (44%), $\chi^2 = 6.29$, $p = .0431$. Further, support for legalization significantly varied between race groups, $\chi^2 = 19.90$, $p = .011$, with the highest level of support found in Black/African American respondents (70%) and multi-racial respondents (64%). The lowest level of support was found among "Some Other Race" respondents (39%). White and Asian American/Pacific Islander American groups had similar levels of support ranging from 51-55%.

Support for legalization significantly varied across individuals of different education levels, $\chi^2 = 23.26$, $p = .0030$. Overall, higher levels of education were associated with greater support for legalization of professionally supervised psilocybin-assisted therapies. The percentage of respondents who indicated support for legalization were greater for those with some experience in higher education (56% support in those with some college or an associates degree, 62% support in those with a 4-year college degree and 58% support in those with a graduate or professional degree) compared to those without experience in higher education (24% support in those who did not graduate high school and 45% support in those who only graduated high school or a vo-tech school).

Level of support for legalization also significantly differed amongst groups with different annual income levels, $\chi^2 = 12.70$, $p = .013$, where individuals with a greater annual income were associated with higher levels of support for legalization than individuals with a lower annual income.

Political party affiliation differences were related to different levels of support for legalization, $\chi^2 = 22.42$, $p = .001$. Support for legalization was significantly more likely to be indicated by those identifying as Democrat (64%) and "Something Else" (60%) than those identifying as Republican (46%) and Independent (55%).

Finally, support for legalization did not significantly differ between men (58%) and women (51%), $\chi^2 = 2.00$, $p = .367$.

Summary

Two key observations were made by assessing the results of this poll. First, there is a generally high rate of New Jersey residents unaware of the medicinal use of psychedelic drugs for treating mental health problems (42%) (**Figure 1**) and an even higher rate of residents without any direct experience with personally using psychedelic drugs (82%). Second, there was a slim majority of respondents who expressed support for the legalization of professionally supervised psilocybin use for mental health treatment (55%) (**Figure 5**), although this percentage of support significantly varied along multiple factors (**Figures 7-11**).

Results from this poll indicate that education and increased familiarity with psychedelic drugs could be key to enhancing support for the legalization of psilocybin for mental health treatment in New Jersey. First, 57% of those who indicated opposing or being unsure of legalizing the medicinal use of psilocybin indicated that they would be more likely to support legalization if medical research studies demonstrate that such use of psilocybin was effective in treating mental health problems and was safe (**Figure 6**). Given that multiple clinical studies have been published over the last 15 years or so that have consistently demonstrated the effectiveness and general safety of the professionally supervised use of psilocybin to treat mental health problems, we interpret this to mean that a majority of those opposed or uncertain about such legalization are currently unaware of the published clinical research on this topic, and this lack of awareness is one main obstacle preventing these individuals from supporting such legalization (or, at least, from being more certain in their position on this proposed policy).

This idea is further supported by the observation that support for such legalization significantly varied across levels of awareness concerning the medicinal use of psychedelic drugs for the treatment of mental health disorders (**Figure 8**), where higher levels of awareness were associated with higher levels of support for

legalization (75% support for those Very Aware vs. 60% support for those Somewhat Aware vs. 41% support for those Not at All Aware). Further, levels of uncertainty about their support for/opposition to such legalization varied among these levels of awareness (**Figure 8**), where lower levels of awareness were associated with higher levels of uncertainty (3% uncertainty for those Very Aware vs. 21% uncertainty for those Somewhat Aware vs. 35% uncertainty for those Not at All Aware).

In addition to the level of awareness of the medicinal use of psychedelic drugs for mental health treatment being associated with level of support for legalization of medicinal uses of psilocybin, direct and indirect experience in using psychedelic drugs were associated with support levels for legalization (**Figure 7**), as support was more likely for those who have used psychedelic drugs in the past (86% support) compared to those who have never used such drugs (48% support), and support was more likely if the respondent knew someone in their personal life who has used psychedelic drugs in the past (65% support) as compared to individuals who do not know such an individual (45% support). Further, uncertainty in their opinion for supporting/opposing the legalization of medicinal psilocybin use varied among these two factors as well, where the percentage of individuals expressing such uncertainty was greater for those with no direct experience in using the drugs themselves (27% of those who never used such drugs expressed uncertainty as compared to just 9% of those who have) or indirect experience in knowing someone who has used the drugs (28% of those who do not know such a person expressed uncertainty as compared to 17% of those who do know such a person).

Thus, based on these observations, one may predict that higher levels of support (or, at least, lower levels of uncertainty in opinion) for the legalization of professionally supervised use of psilocybin for mental health treatment may be achieved if: (a) legislators, educators, media outlets and/or policy advocates focus more on educating a larger portion of the public about the science of using psilocybin for mental health care, (b) residents become more personally familiar with individuals who have used psychedelic drugs in the past, and (c) more individuals gain direct experience with psychedelic drugs through personal use of them (not that this report is specifically advocating use for those who have never used them before).

One major limitation to this analysis is that it is based on the only poll we are aware of that has been conducted to date that assesses public support in New Jersey for the legalization of the medicinal use of psilocybin, and thus, should be interpreted with caution. Since the results of polls are generally subject to sampling variability, additional polls must be performed in the future to get a more reliable, accurate assessment of the level of state-wide public support for this policy.

Conclusions

Through a review of published clinical trial reports and via the analysis of the original poll we conducted, our report indicates that the professionally supervised use of psilocybin to treat mental health disorders (particularly, depression and anxiety) is effective, safe and most New Jersey adults support the legalization of such use. Given these observations and that New Jersey Bill S2283 would require psychedelic service centers to administer psilocybin experiences following most, if not all, of the safety guidelines published by medical researchers[38], it can be argued that Bill S2283's specific policies regarding the legalization professionally supervised use of psilocybin for mental health care at service centers may serve as an effective and safe alternative method of mental health treatment.

However, as mentioned in the Introduction, another major policy proposed in Bill S2283 is the general legalization of unsupervised, recreational adult use in private settings. The research summarized in this report does not provide useful information to critically evaluate this aspect of the bill, and thus, we cannot offer an evidence-based perspective here useful for debating this specific policy found in the bill. Further, rigorous scientific studies of private, unsupervised psilocybin use are lacking in the published research literature, and thus, it is unclear how safe such use is (especially for individuals who are not carefully screened prior to use

[38] Johnson, M.W., Richards, W.A., & Griffiths, R.R. (2008). Human hallucinogen research: guidelines for safety. *Journal of Psychopharmacology, 22,* 603-620.

and/or individuals who are not carefully "prepared" for the experience prior to use, as is advocated for by safety guidelines[37]).

Further, as identified in the Introduction of this report, one of the objectives the bill is intended to achieve is to permit adults to use psilocybin to "…alleviate distress, provide preventive behavioral health care, and foster wellness and personal growth". One of the major limitations of the current state of research on psilocybin is a lack of rigorous scientific assessment of psilocybin's effect in non-clinical, "healthy" populations not suffering from a mental health disorder (as summarized earlier, the clinical trials conducted to date have exclusively studied samples of individuals who have been clinically diagnosed with depression and/or anxiety). As to whether supervised or unsupervised use of psilocybin provides an effective form of "preventative" mental health care for those not suffering from mental health problems has not been rigorously studied, and thus, remains unclear.

In sum, our report provides information that indicates that the sum of medical research conducted to date and current public opinion supports the New Jersey government's efforts to legalize professionally supervised use of psilocybin for the treatment of mental health disorders, particularly, depression and anxiety.

Appendix A – Methodology Statement for Original Poll

The poll was sponsored and conducted by the Stockton Polling Institute of the William J. Hughes Center for Public Policy at Stockton University. Data collection took place from February 20 to March 3, 2024. A probability-based random sample of 606 New Jersey residents ages 18 and older were interviewed. The poll was conducted via telephone by live interviewers in English. The survey instrument was developed by Hughes Center faculty associate Dr. Justin Ostrofsky, Hughes Center Research Associate Alyssa Maurice and Stockton University students Shayla Nagle, Morgan Seidman and Katherine Wilkinson. The full questionnaire can be found at Stockton.edu/HughesCenter.

Of the full sample, 27 respondents (4%) were reached via live call to a landline, 473 respondents (78%) were reached via live call to a cellphone number, and 106 respondents (18%) were reached via text message to a cellphone number, known as text-to-web. The live calls were conducted by an external vendor, Opinion Services based in Absecon, New Jersey. The respondents who received a text were sent a message by Stockton Polling Institute staff made up of Stockton students from the University's Galloway campus. The text message included a link to take the survey online.

New Jersey landline and cell samples were generated via random-digit-dialing and provided by Marketing Systems Group. Listed and unlisted have an equal probability of selection. Within-household selection is done by asking for the youngest adult. Adults without a telephone are excluded from the sample.

Weighting was done to balance the sample demographics to be representative of the target population. Data were weighted using iterative proportional fitting, also known as raking or random iterative method (RIM) weighting. Weights were based on U.S. Census Bureau American Community Survey 2022 data for New Jersey on variables of age, race, education level, and sex. The poll's margin of sampling error is +/- 4.0 percentage points at a 95% confidence level. The margin of sampling error is higher for subsets. Sampling error does not account for other potential sources of bias in polls such as measurement error or non-response.