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A Systematic Review of Participant Diversity in Psychedelic-Assisted Psychotherapy Trials

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Abstract

A lack of diverse and representative participant samples in mental health intervention research perpetuates mental health disparities. This issue has become a salient concern in studies of psychedelic-assisted psychotherapy (PAT), which is emerging as a promising mental health intervention. This systematic review evaluates the reporting, representation, and analysis of participant sociodemographic characteristics in randomized controlled trials (RCTs) of PAT. A total of 21 RCTs of psilocybin- and 3,4-methylenedioxy methamphetamine (MDMA)-assisted therapies (N = 1034) are summarized. Participants' gender (100%) and race or ethnicity (76%) were frequently reported, with socioeconomic status (SES) sometimes (57%) reported using heterogeneous metrics. Sexual orientation (9.5%) and immigration status (4.8%) were rarely reported, and no studies reported gender identity. Compared to their representation in the US population and non-psychedelic clinical trials, Black/African-American participants (2.2%) and Hispanic/Latino participants (7.2%) were significantly underrepresented in PAT RCTs. MDMA trials enrolled more diverse participant samples than psilocybin trials. Analyses on treatment effects based on demographic variables were virtually nonexistent. These findings underscore the need for more inclusive recruitment strategies, along with more rigorous reporting, to improve the generalizability of PAT research.

Figure 1

PRISMA Flow Diagram of Article Identification and Screening

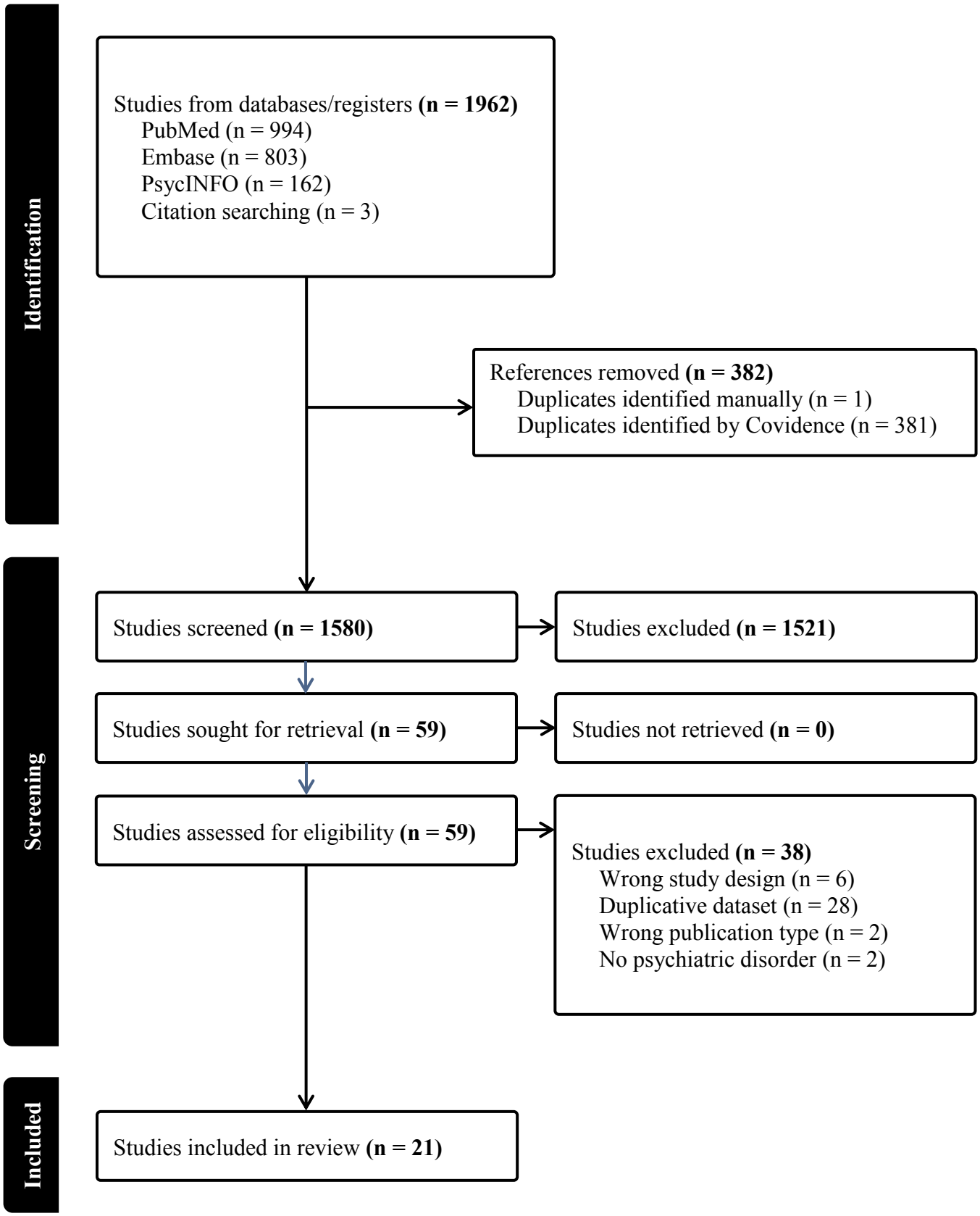


Figure 2

Number and Percentage of Psychedelic-assisted Psychoherapy RCTs Reporting Participant Sociodemographic Characteristics

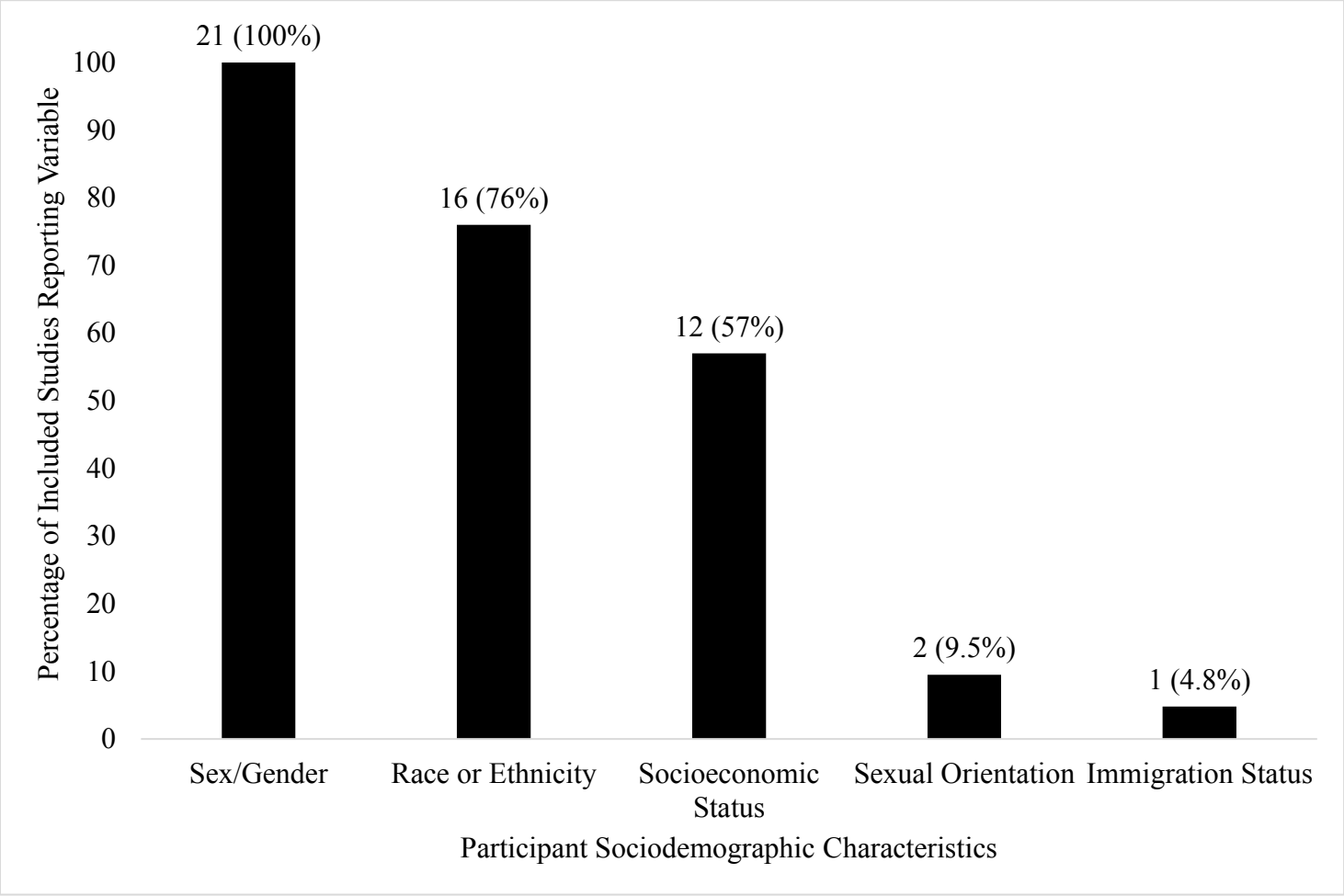
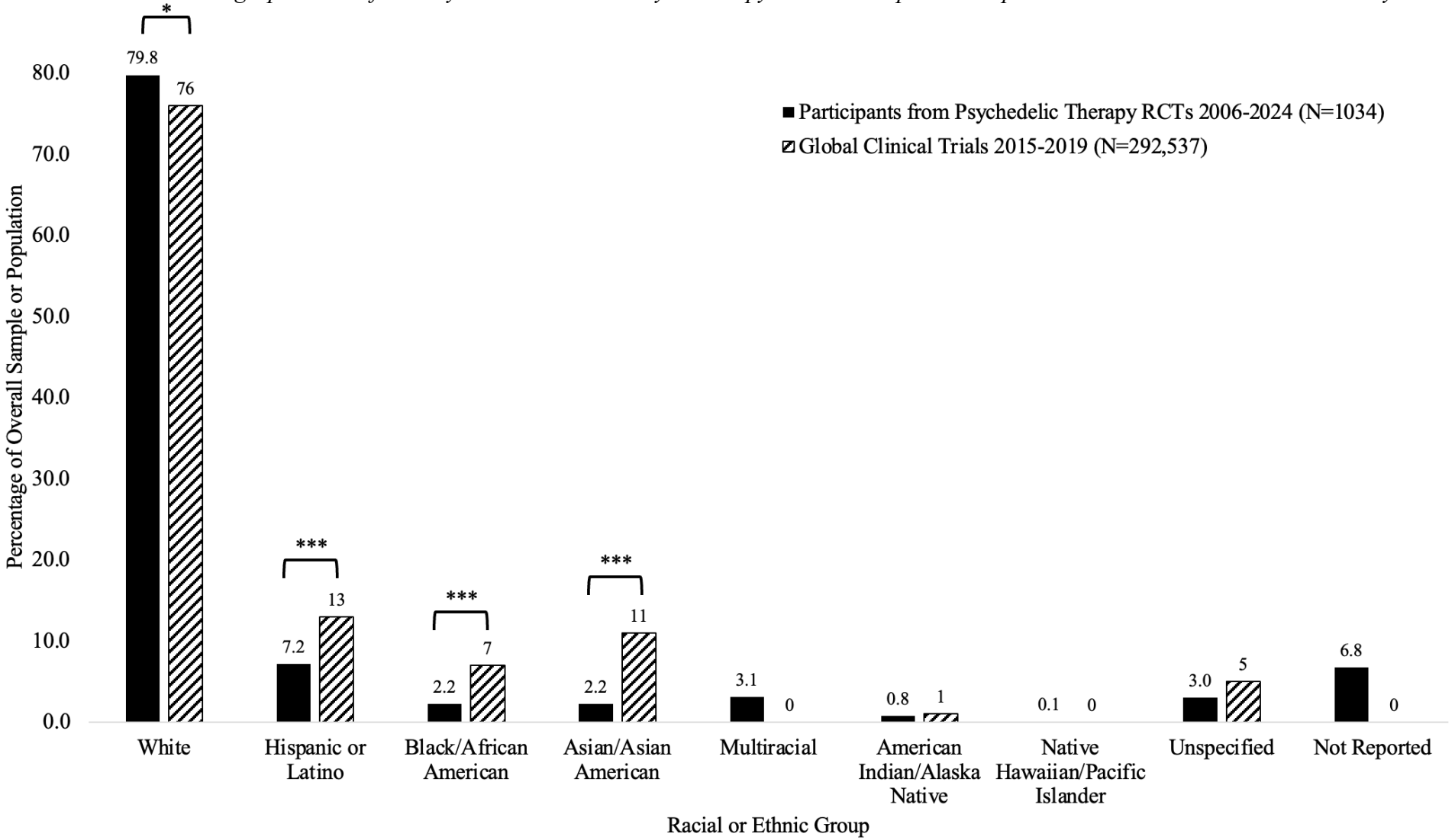


Figure 4

Racial and Ethnic Demographic Data from Psychedelic-assisted Psychoherapy Trial Participants Compared to Global Clinical Trial Summary Data

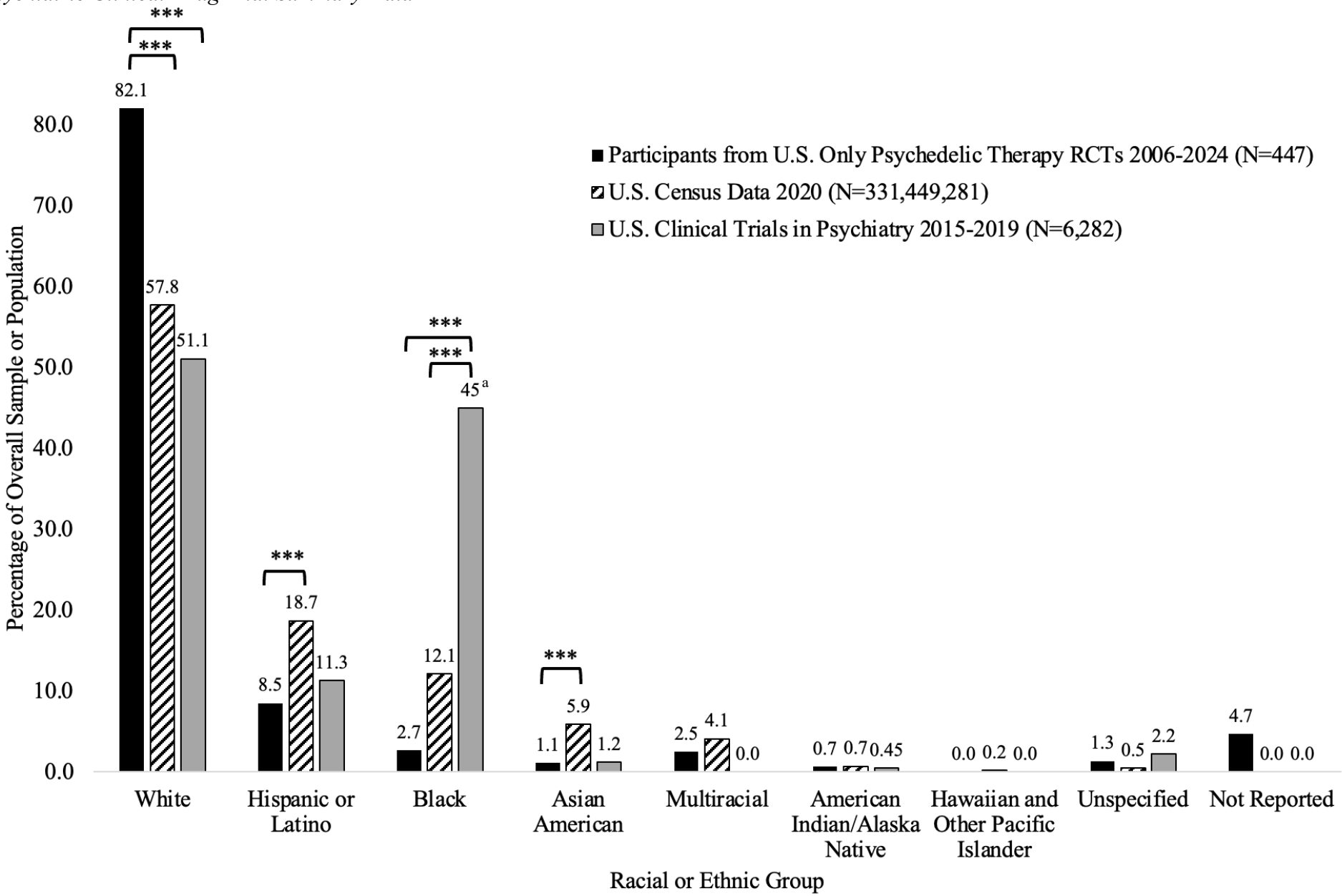


Note. The "Unspecified" category includes individuals described as "Non-White" or "Other" in U.S. Psychedelic Therapy RCTs, and includes individuals aggregated into a single category who identified as "Mixed Race", "Native Hawaiian," "Unknown", or "Other Race" in Global Clinical Trials 2015-2019.
Global clinical trial data (N=292,537) represents all therapeutic areas, since racial and ethnic data for psychiatry specifically was unavailable.

In three studies, race and ethnicity were reported separately. Therefore, the sum of proportions is greater than 100% due to multiple categories selected by participants in these studies.
*=statistically significant difference according to the Bonferroni-corrected *p*-value of .0125 in a one-proportion *Z*-test.
***=statistically significant difference according to the Bonferroni-corrected *p*-value of .00025 in a one-proportion *Z*-test.

Figure 3

Racial and Ethnic Demographic Data from U.S. Psychedelic-assisted Psychotherapy Trial Participants Compared to U.S. Census and U.S. Psychiatric Clinical Drug Trial Summary Data



Note. Participants from studies that did not report race or ethnicity were labeled as a "Not Reported" category. The "Unspecified" category includes individuals described as "Non-White" or "Other" in U.S. Psychedelic Therapy RCTs, includes individuals described as "Some other race" in U.S. Census Data 2020, and includes individuals aggregated into a single category who identified as "Mixed Race", "Native Hawaiian," "Unknown", or "Other Race" in U.S. Clinical Trials 2015-2019.
In three studies, race and ethnicity were reported separately. Therefore, the sum of proportions is greater than 100% due to multiple categories selected by participants in these studies.
***=statistically significant difference according to the Bonferroni-corrected *p*-value of .00025 in a one-proportion *Z*-test.
[a]=Upon further inspection of this FDA data, the representation of Black individuals in U.S. clinical trials in psychiatry is primarily driven by several large trials of medications for schizophrenia. Black individuals may have higher rates of psychotic disorders and inclusion in trials for schizophrenia due to a complex combination of factors, including historical misdiagnoses, racialized policing, and other systemic biases (Misra et al., 2022).

Table 1

Descriptive Characteristics of Studies Included in Review

MDMA-assisted Therapy Studies

First Author (Year of Publication)	*N*	Study Design	Countries	Diagnostic Groups	Gender or Sex (F=Female, M=Male)	Race and Ethnicity (% and Category As Reported)	Socioeconomic Status	Sexual Orientation	Immigrant Status
Bouso (2008)	6	Parallel Group	Spain	PTSD	100% F	NR	Education – Degree (50% Grade School, 16.7% High School, 16.7% College) Income (33.3% Low-Medium, 50% Medium, 16.7% Medium-High) Employment Status (66.7% Unemployed, 16.7% Teacher, 16.7% Housewife)	NR	NR
Danforth (2018)	12	Parallel Group	USA	SAD	16.7% F 83.3% M	50.0% White 16.7% Hispanic/Latino 8.3% Asian/Pacific Islander 8.3% Middle Eastern	Employment Status (33.3% Full-time, 33.3% Unemployed,	25.0% Non-heteronormative	NR

						8.3% Asian & Caucasian 8.3% Hispanic & Caucasian	16.7% Part-time, 16.7% Student)		
Mitchell (2021)	90	Parallel Group	Canada; Israel, USA	PTSD	65.6% F 34.4% M	76.7% White 8.9% Hispanic/Latino[a] 8.9% Multiple 7.8% Asian 3.3% American Indian or Native Alaskan 2.2% Black/African American	NR	96.0% Hetero sexual	NR
Mitchell (2023)	104	Parallel Group	USA; Israel	PTSD	71.1% F 28.9% M	66.3% White 26.9% Hispanic/Latino[a] 12.5% Multiple 10.6% Asian 7.7% Black/African American 1.9% American Indian/Alaska Native 1.0% Native Hawaiian/Pacific Islander	NR	NR	NR
Mithoefer (2010)	20	Parallel Group	USA	PTSD	85.0% F 15.0% M	100% Caucasian	NR	NR	NR
Mithoefer (2018)	26	Parallel Group	USA	PTSD	27.0% F 73.0% M	85% White 8% Latino/Hispanic 4% Native American 4% Native American & White	NR	NR	NR
Oehen (2013)	12	Parallel Group	Switzerland	PTSD	83.3% F 16.7% M	NR	Employment Status (42% On disability, 25% Limited employment,	NR	8.3% Foreign Born

							25% Full-time, 8% Retired)			
Ot'alora (2018)	28	Parallel Group	USA	PTSD	67.9% F 32.1% M	92.9% White 3.6% Latino/Hispanic 3.6% Native American	NR	NR	NR	
Wolfson (2020)	18	Parallel Group	USA	Life threatening illness anxiety	77.8% F 22.2% M	83.3% White 5.6% Black/African American 5.6% White/Native American 5.6% "Other"	NR	NR	NR	

Psilocybin-assisted Therapy Studies

First Author (Year of Publication)	*N*	Study Design	Countries	Diagnostic Groups	Gender or Sex (F=Female, M=Male)	Race and Ethnicity (% and Category As Reported)	Socioeconomic Status	Sexual Orientation	Immigrant Status
Bogenschutz (2022)	95	Parallel Group	USA	AUD	44.2% F 55.8% M	78.9% White 14.7% Hispanic[a] 4.2% Black 3.2% Asian 1.1% American Indian/Alaska Native	Income (Range: $3700-$4,000,000, Median: $100,000)	NR	NR
Carhart-Harris (2021)	59	Parallel Group; Within-Subjects	UK	MDD	33.9% F 66.1% M	88.1% White	Education – Years (76.3% University) Employment Status (71.2% Employed, 20.3% Unemployed, 8.5% Student)	NR	NR
Davis (2021)	24	Parallel Group;	USA	MDD	66.7% F 33.3% M	91.7% White	Education – Degree	NR	NR

		Within-Subjects					(58% Bachelor's, 17% Master's, 8% Advanced, 8% Associate's, 8% < College) Employment Status (63% Full-time, 21% Unemployed, 17% Part-time)		
Goodwin (2022)	233	Parallel Group	Canada; Czech Republic; Denmark	MDD	51.9% F 48.1% M	92.3% White	NR	NR	NR
Griffiths (2016)	51	Crossover	USA	Cancer-related anxiety and depression	49.0% F 51.0% M	94% White 4% Black/African American 4% Asian	Education – Degree (53% Post-graduate, 45% College, 2% High school)	NR	NR
Grob (2010)	12	Within-Subjects	USA	Cancer-related anxiety	91.7% F 3.8% M	NR	NR	NR	NR
Moreno (2006)	9	Within-Subjects	USA	OCD	22.2% F 77.8% M	NR	Employment Status (55.6% Unable to work, 33.3% Employed, 11.1% Housewife)	NR	NR
Raison (2023)	104	Parallel Group	USA	MDD	50.0% F 50.0% M	89.4% White 15.4% Hispanic/Latino[a] 5.8% Multiracial	Income – Annual (40.4% >$100k, 13.5% $75k-$99.9k, 7.7%	NR	NR

						2.9% Black/African American	$50k-$74.9k, 10.6% $25k-49.9k, 13.5% <$24.9k)		
Rosenblat (2024)	31	Crossover	Canada	MDD	38.7% F 61.3% M	NR	NR	NR	NR
Ross (2016)	29	Parallel Group; Crossover	USA	Cancer-related anxiety and depression	62.0% F 38.0% M	90% White 10% "Other"	Education – Degree (48% Graduate school, 31% 4-year college, 14% Part college, 3% High school, 3% Grade 7-12) Employment Status (41% Full-time, 21% Retired, 14% Part-time, 7% Self-employed, 7% Unemployed, 7% Long-term disability, 3% Student)	NR	NR
Sloshower (2023)	19	Within-Subjects	USA	MDD	68.4% F 31.6% M	84.2% White 10.5% Black 10.5% Hispanic[a] 5.2% Two or More Races	Education – Degree (57.8% College, 26.3% Masters, 10.5% High school, 5.2% Some college) Employment Status	NR	NR

							(47.8% Part-time, 36.8% Full-time, 15.7% Unemployed)		
von Rotz (2022)	52	Parallel Group	Switzerland	MDD	63.5% F 36.5% M	94.2% White 3.8% Arab 1.9% Black Caribbean	Education – Years (Mean: 14.7)	NR	NR

Note.
N=Participant sample size; NR = Not reported; AUD = Alcohol Use Disorder; PTSD = Posttraumatic Stress Disorder; SAD = Social Anxiety Disorder; MDD = Major Depressive Disorder.
[a]Indicates that Hispanic or Latino ethnicity were collected separately from racial categories, so percentages add up to more than 100%.

Table 2

Overall Participant Sex/Gender and Race and Ethnicity Across Psychedelic Therapy RCTs by Decade

	Overall (*k*=21, *n*=104)	**2006-2009 (*k*=2, *n*=15)**	**2010-2019 (*k*=8, *n*=190)**	**2020-2024 (*k*=11, *n*=829)**
Sex/Gender (%)				
Female	55.4	53.3	57.4	55.0
Male	44.6	46.7	42.6	45.0
Race and Ethnicity (%)				
White	79.8	-	77.9	81.7
Hispanic or Latino	7.2	-	3.2*	8.2*
Black or African American	2.2	-	1.1	2.5
Asian/Asian American	2.2	-	1.1	2.5
American Indian/Alaska Native	0.8	-	1.1	0.7
Hawaiian/Other Pacific Islander	0.1	-	0.0	0.1
Multiracial	3.1	-	1.6	3.5
Unspecified	3.0	-	1.6	3.4
Not Reported	6.8	100.0	12.6***	1.8***

*p<.05, ***p<.001 according to a two proportions Z-test comparing 2010-2019 to 2020-2024.

All authors have no competing interests to declare.

Stephanie L. Haft: Conceptualization, Methodology, Software, Validation, Formal analysis, Data Curation, Writing – Original Draft, Writing – Review & Editing, Visualization. **Amanda E. Downey:** Conceptualization, Methodology, Software, Validation, Formal analysis, Data Curation, Writing – Original Draft, Writing – Review & Editing, Visualization. **Marissa Raymond-Flesch:** Conceptualization, Writing – Original Draft, Writing – Review & Editing**. Gisele Fernandes-Osterhold:** Conceptualization, Writing – Original Draft, Writing – Review & Editing. **Ellen R. Bradley:** Conceptualization, Writing – Original Draft, Writing – Review & Editing. **Aoife O'Donovan:** Conceptualization, Writing – Original Draft, Writing – Review & Editing. **Joshua Woolley:** Conceptualization, Writing – Original Draft, Writing – Review & Editing, Supervision.

1. Introduction

Psychedelic-assisted psychotherapy (PAT) combines administration of a psychedelic compound with structured psychotherapy sessions, aiming to enhance therapeutic outcomes by leveraging the altered states of consciousness induced by the psychedelic. Randomized controlled trials (RCTs) exploring the safety and efficacy of PAT with psilocybin and 3,4-methylenedioxymethamphetamine (MDMA) yield promising outcome data (Ko et al., 2023; Wheeler & Dyer, 2020). However, these RCTs have limited generalizability due to inconsistent and incomplete demographic reporting and participant samples that do not represent the broader population in need. For example, between 1993 and 2017, 89.0% of participants in U.S. clinical psychedelic studies identified as non-Hispanic White (Michaels et al., 2018b), despite this group comprising only 51.1% of U.S. psychiatric clinical trial participants (Lolic et al., 2021) and 58% of the U.S. population (United States Census Bureau, 2020a).

Gaps in reporting of participant demographics exist across mental health RCTs: fewer than half of depression treatment RCTs report participant race or ethnicity (Polo et al., 2019), and less than 4% of suicide and self-injury treatment RCTs report sexual orientation (Maria Guzmán et al., 2024). Even when assessed, many trials fail to collect or report demographic data adequately and consistently, despite recent federal guidelines now offering clearer best practices (American Psychological Association, 2020; Moher et al., 2010; National Institute on Minority Health and Health Disparities, 2024; US Food and Drug Administration, 2022). Nevertheless, available data indicates individuals who are low-income or minoritized due to race, ethnicity, or sexual orientation are consistently underrepresented in RCTs for psychiatric conditions, including depression, post-traumatic stress disorder (PTSD), suicide, and eating disorders (Burnette et al., 2022a; Lolic et al., 2021; Madnick & Spokas, 2022b; Monahan et al., 2023). For example, multiracial individuals represented only 0.4% of participants in depression RCTs, despite comprising an estimated 4.9% of the U.S. population (Polo et al., 2019a; United States Census Bureau, 2020a). This underrepresentation is even more egregious considering that the prevalence of depression is highest among multiracial individuals compared to any other racial or ethnic group (13.9% vs. 8.3% in the overall population; National Institute of Mental Health, 2023).

While the issue of participant representation is therefore not unique to PAT trials, multiple factors likely contribute to severe underrepresentation of minoritized groups in PAT RCTs. First, these trials require large time commitments, effectively excluding individuals from low socioeconomic backgrounds who may lack the flexibility to participate (Garcia-Romeu & Richards, 2018). Second, the enduring impact of the War on Drugs (Williams et al., 2023) and past injustices in psychedelic research against people of color and sexual minorities have likely contributed to negative views of PAT in these communities (Strauss et al., 2022). Third, given differential policing policies, the ongoing criminalization of psychedelics in most jurisdictions may make many minoritized individuals less willing to participate (Ortiz et al., 2022).

Unrepresentative RCTs risk producing erroneous conclusions about safety and efficacy, as various groups may respond differently to the same treatment. For example, the efficacy of certain anticoagulant medications can vary by ancestry, leading to significant differences in dosing requirements. Early trials of certain anticoagulant medications that focused mainly on White populations failed to account for this variability, resulting in adverse outcomes for racial

and ethnic minoritized groups after U.S. Food and Drug Administration (FDA) approval until dosing modifications were made in 2013 (Bibbins-Domingo et al., 2022). Similarly, national cohort studies and meta-analyses suggest that other psychotherapeutic and pharmacological interventions for mental health disorders yield less favorable outcomes for minoritized racial, ethnic, and socioeconomic groups (Arundell et al., 2024; Barnett et al., 2023; Buckman et al., 2022; Elwadhi & Cohen, 2020; Olfson et al., 2023).

Lack of representation may be a particularly significant issue for PAT trials, as PAT outcomes are thought to depend on extra-pharmacological factors like participants' beliefs and mindset (Aday et al., 2022; Hartogsohn, 2016). Thus, historical and ongoing experiences of marginalization may shape how minoritized groups respond to PAT, much like how lived experiences of racism are linked to elevated cardiovascular risk and variations in treatment outcomes (Bibbins-Domingo et al., 2022). Similarly, prior psychedelic use influences familiarity with PAT, and rates of such use vary significantly across demographic groups (Krebs & Johansen, 2012; Viña & Stephens, 2023a). Consequently, individuals from different groups may experience systematic differences in their comfort with PAT, which could impact their responses to the treatment. Indeed, naturalistic studies have shown that the relationship between psychedelic usage and mental health outcomes differs by race, ethnicity, and socioeconomic status, with minoritized groups experiencing reduced benefits (G. Jones et al., 2025; G. M. Jones & Nock, 2022; Viña & Stephens, 2023). Despite the lack of RCT evidence, these findings suggest PAT outcomes may differ by demographic group, emphasizing the importance of accurate participant representation in PAT trials. Ensuring the inclusion of minoritized groups in PAT trials is particularly important as these groups often face higher rates of the conditions under study – for example, disproportionately higher PTSD rates and higher risk for suicidal thoughts and behaviors (Agency for Healthcare Research and Quality, 2022; Madnick & Spokas, 2022; Maria Guzmán et al., 2024; Mongelli et al., 2020). Overall, a lack of representative samples severely undermines the generalizability of PAT RCT findings, potentially exacerbating health disparities in underrepresented populations. Achieving representative study samples is critical so that the intervention is acceptable and generalizable across demographic groups.

As RCTs establish the evidence base for PAT and guide its development for safe and effective real-world implementation, ensuring adequate participant demographic representation is critically important at this stage. Accordingly, the objective of the present systematic review is to examine the reporting and representation of participant demographic characteristics in extant PAT RCTs – key elements for building generalizable evidence (Polo et al., 2019). The specific aims of this review are to: 1) uncover the extent of reporting on participant demographic variables and determine whether reporting practices have improved over time with implementation of federal guidelines and journal reporting standards, and 2) determine the demographic representativeness in PAT RCTs as compared to the general U.S. population and representation in U.S. clinical trials more broadly. Exploratory aims are to: 3) examine whether analyses of treatment effects based on participant demographic variables were conducted and summarize key findings; and 4) explore differences in reporting and representation based on the psychedelic substance studied (MDMA vs. psilocybin). The overall goal of this systematic review is to provide a detailed and comprehensive evaluation of participant representation in PAT RCTs, offering insights that can guide targeted recruitment efforts in future trials and help address persistent gaps in participant reporting and diversity.

Building on a 2018 review that examined the inclusion of people of color in PAT studies (Michaels et al., 2018), this review focuses exclusively on RCTs because they are the foundation for regulatory approvals and treatment guidelines but have historically faced more significant challenges with participant diversity and representation. This review also incorporates evidence from the past seven years (2017–2024) while including studies from 1993 onward to provide a comprehensive view of trends in participant representation and reporting. Including earlier studies ensures continuity with the previous review and allows for a direct comparison of how practices have evolved over time. Additionally, we expand the scope beyond racial and ethnic representation to include gender, socioeconomic status, sexual orientation, and immigration status, which was not previously analyzed (Michaels et al., 2018). These variables are widely recognized as critical social determinants of health that influence access to mental health care, outcomes, and treatment engagement (Braveman et al., 2011; Marmot & Wilkinson, 2005).

2. Methods

2.1. Inclusion and Exclusion Criteria

We included studies that: (a) were published in a peer-reviewed journal, (b) utilized a RCT design (either parallel or crossover design acceptable), (c) administered psilocybin or MDMA for therapeutic purposes, (d) included a psychotherapeutic element along with the psychedelic substance, and (e) enrolled participants with diagnosed or clinical levels of ICD-10 (International Classification of Diseases, Tenth Edition), DSM-5 (Diagnostic and Statistical Manual of Mental Disorders), or DSM-4 psychiatric mental disorders (ascertained through clinical interviews or symptom scores above clinical threshold). We excluded dissertations, theses, conference abstracts, registered protocols without participant data, and unpublished preprints. We focus on RCTs only given that these studies are gold standard for evaluating which treatments are considered "evidence-based" (Djulbegovic & Guyatt, 2017). We also excluded trials that administered psychedelics other than psilocybin or MDMA or administered psilocybin or MDMA with no psychotherapeutic component. These compounds were chosen to reflect the growing body of scientific research supporting their therapeutic potential in combination with psychotherapy as well as their U.S. Food and Drug Administration (FDA) breakthrough therapy designation. We excluded publications that were follow-up or subsample studies from original published RCTs to prevent sample overlap.

2.2. Search Strategy

The protocol used to conduct this systematic review follows the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) 2020 guidelines (Page et al., 2021). We systematically searched the following electronic databases for relevant articles: PubMed, Embase, and PsycINFO. Search terms used Boolean operators to combine concepts related to psychedelic compounds *("psychedelic", "hallucinogen*", "3,4-Methylenedioxy methamphetamine", "MDMA," "psilocybin"*), psychotherapy (*"psychedelic-assisted psychotherapy"*, *"-assisted psychotherapy"*, *"psychotherapy"*, *"mental health", "mental disorder*"*) and RCT design *("randomized controlled trial", "controlled trial", "controlled", "random*"*). Search terms found in the title and/or abstract fields of citation records were used in combination with relevant controlled vocabulary from databases (e.g. MeSH terms from PubMed, PsycINFO Index terms, and Emtree terms from Embase). The search was conducted

with a filter for articles published since January 1st, 1993, since studies conducted prior to the NIH Revitalization Act of 1993 do not meet current standards for methodological rigor or ethical practice guidelines (Johnson et al., 2008). "Back searching" was also conducted, whereby the bibliographies of relevant articles were searched to obtain additional articles. After search procedures, articles were imported into Covidence software where the two first authors proceeded with sequential stages of title/abstract screening, full-text screening, and data extraction. Authors conducted each stage independently, and resolved any discrepancies through discussion until consensus was reached. The initial search was conducted on 9/28/2023, with an updated search conducted on 5/5/2024. Figure 1 displays a PRISMA diagram of the search, screening, and selection process.

2.3. Data Extraction and Synthesis

Using Covidence software (Veritas Health Organization, 2024), the first authors extracted the following information from included articles: first author name, year of publication, study country or countries, RCT study design, psychedelic substance used, placebo or control used, recruitment methods, sample diagnoses, sample size, ages of sample. In terms of main study demographic variables, the first authors coded whether the following sample variables were reported: gender, sexual orientation, race, ethnicity, socioeconomic status, and immigration status. If the variable was reported, the authors extracted the sample characteristics and sample size within that variable. Finally, the first authors coded whether any analyses were conducted incorporating these demographic variables (e.g. as covariates, predictors, or moderators). Given the study aim to evaluate reporting in published articles, we did not contact study authors to obtain unreported or missing data. After finalization of data extraction, data were exported to R (Team, 2013) for computation of summary and frequency statistics as well as statistical tests of proportions. One proportion z-tests with Bonferroni-corrected significance levels were used to compare observed proportions of racial and ethnic participants in PAT RCTs to population estimates from census (United States Census Bureau, 2020b) and clinical trial data (U.S. Food & Drug Administration, 2020).

2.4. Ethics, Transparency, and Openness

As this review was an assessment of published studies, review by an ethics board was not necessary. Before the study selection process, the study's design protocol was preregistered on Open Science Framework, and associated materials are publicly available on this site: https://osf.io/js8q3/. The protocol was also registered on the international prospective register of systematic reviews (PROSPERO; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=468068).

3. Results

3.1. Study Characteristics

As detailed in the PRISMA flow diagram (Figure 1), our search strategy yielded a total of 1962 articles. After removal of duplicates and screening titles and abstracts for inclusion criteria, the co-first authors reviewed the full text versions of 59 articles. Ultimately, 21 of these articles, representing 1034 participants, met inclusion criteria and were included in the present review. Table 1 displays the study characteristics of included articles, which were published between the years of 2006 and 2024. Of these articles, 12 (57%) reported on trials involving psilocybin, while

nine (43%) reported on trials involving MDMA. Most of the articles (62%) reported results from RCTs conducted solely in the United States, while the remaining involved trials conducted in Switzerland (9%), Canada (5%), UK (5%), Spain (5%), or multiple countries (14%). These published RCTs were designed to test the effects of PAT for a range of mental health conditions, including major depressive disorder (33%), PTSD (33%), cancer-related anxiety or depression (14%), alcohol use disorder (5%), life-threatening illness anxiety (5%), social anxiety disorder (5%), and obsessive-compulsive disorder (5%).

3.2. Reporting of Demographic Characteristics in PAT Trials

Figure 2 displays the percentage of studies reporting on each participant demographic characteristic, and Table 1 displays which studies reported on individual characteristics.

3.2.1. Gender

All (100%) studies reported participant gender. No study clarified how participant gender was collected in terms of wording to participants or mentioned collection of gender identity. Therefore, it is unclear whether this variable represents participant biological sex-at-birth or gender identity across studies.

3.2.2. Race or Ethnicity

Of the included studies, 16 (76%) reported either participant race or ethnicity. Five (31%) of these studies included categories that reported race as "Other" or "Non-White". Three (19%) studies reported race and ethnicity together by including ethnic background (Hispanic or Latino origin) as a racial category. Five (31%) studies reported participants' race and ethnicity separately. The remaining eight (50%) studies that reported participant racial backgrounds did not enroll Hispanic or Latino participants, so separate reporting of ethnicity cannot be evaluated.

3.2.3. Socioeconomic Status

12 studies (57%) reported participant SES, with five (42%) of these reporting multiple metrics of SES. Of the 12 that reported SES, eight (67%) reported employment status, seven (58%) education (five reported degree attainment, two reported total years of education), two (17%) numerical income, and one (8%) categorical income (low, middle, high).

3.2.4. Sexual Orientation

Two (9.5%) studies reported participants' sexual orientation, with both reporting this as the percentage of participants who identified with a heterosexual or heteronormative sexual orientation.

3.2.5. Immigration Status

One (4.8%) study reported participants' immigrant background by reporting participants' aggregated countries of origin.

3.3. Representation of Demographic Groups in Psychedelic-assisted Psychotherapy Trials

3.3.1. Gender

Across studies and the total sample of 1034 participants, women comprised 55.4% of all RCT participants, and men comprised 44.6% of RCT participants. Almost all studies enrolled both male and female participants, except for one study that enrolled only female participants. No studies reported enrollment of nonbinary or transgender individuals.

3.3.2. Race or Ethnicity

Figure 3 shows the racial and ethnic representation of participants from PAT RCTs conducted in the U.S. (N=447) compared to both racial and ethnic representation of the U.S. population from 2020 U.S. Census data (United States Census Bureau, 2020b), as well as to U.S. clinical psychiatric drug trial representation conducted from 2015-2019 (Lolic et al., 2021). White participants represented the majority of U.S. PAT RCT samples (82.1%), which is a significantly higher proportion than White participants in U.S. psychiatric clinical drug trials from 2015-2019 (51.1%, p<.001), and is also significantly higher than is reflected by U.S. Census 2020 data (57.8% White, p<.001).

The proportion of Asian American participants in U.S. PAT RCTs (1.1%) did not significantly differ from U.S. psychiatric drug trials (1.2%) but was significantly lower than U.S. Census data (5.9% Asian, p<.001). The proportion of Hispanic or Latino participants in U.S. PAT RCTs (8.5%) did not significantly differ from U.S. psychiatric drug trials (11.3%) but was significantly lower than representation in U.S. Census data (18.7%, p<.001). The proportion of Black participants in U.S. PAT RCTs (2.7%) was significantly lower than that of both U.S. psychiatric drug trials (45%, p<.001) and U.S. Census data (12.1%, p<.001). The proportions of multiracial (2.5%), American Indian/Alaska Native (0.7%), Hawaiian/Other Pacific Islander (0.0%), and Unspecified (1.3%) participants were not significantly different from U.S. census data – because the FDA aggregates these racial categories, comparisons of these groups to U.S. psychiatric drug trials cannot be made.

Figure 4 displays the racial and ethnic representation of participants from all PAT RCTs globally compared to racial and ethnic representation of global clinical trials conducted from 2015-2019 for all therapeutic areas (U.S. Food & Drug Administration, 2020). White participants represented the majority of PAT RCT samples (79.8%), which was significantly higher than the proportion of White participants from global clinical trials from 2015-2019 (76%, p=.004). Several racial and ethnic minoritized groups were underrepresented in PAT RCTs compared to global clinical trials from 2015-2019, including those identifying as Hispanic or Latino (7.2% vs. 13%, p<.001), Black/African American (2.2% vs. 7%, p<.001), and Asian or Asian American (2.2% vs. 11%, p<.001). The proportions of multiracial (2.0%), American Indian/Alaska Native (0.6%), Hawaiian/Other Pacific Islander (0.0%), and Unspecified (3.3%) participants could not be compared to global clinical trials due to a lack of disaggregated clinical trial data.

3.3.3. Socioeconomic Status

Of the eight studies (n=168 participants) that reported employment status (62.5% U.S. studies), 64.3% of participants were employed (full- or part-time), 26.8% were unemployed, 4.8% were students, and 4.2% were retired. For only those studies conducted in the U.S. (n=150 participants), 69.3% of participants were employed (full- or part-time), 19.0% were unemployed, 4.8% were students, and 3.6% were retired. The employment rate across U.S. study participants (69.3%) is comparable to the average employment rate in the U.S. from the years 2006 to 2023

(59.8%; (Statista Research Department, 2024). Of the five studies (including 129 participants) that reported educational attainment (80% U.S. studies), 3.9% of participants did not complete high school or equivalent, 3.9% completed high school, 5.4% completed some college, 46.5% completed college (associate or bachelor's degree), and 40.3% completed an advanced degree such as a master's degree or doctoral degree. For only those studies conducted in the U.S. (n=123 participants), 0.8% of participants did not complete high school or equivalent, 3.1% completed high school, 5.4% completed some college, 45.7% completed college (associate or bachelor's degree), and 40.3% completed an advanced degree such as a master's degree or doctoral degree. The proportion of U.S. participants from PAT RCT studies with a college degree (45.7%) is significantly higher than the U.S. population age 25 or older with a college degree (23.5%; $p<.001$; United States Census Bureau, 2022). Similarly, the proportion of participants with an advanced degree (40.3%) is significantly higher when compared to the proportion of the U.S. population with an advanced degree (14.4%; $p<.001$). Due to a low proportion of PAT RCTs reporting participant income, participant representativeness in these domains cannot be evaluated.

3.3.4. Sexual Orientation

Of the two studies reporting participant sexual orientation ($n=36$), 83.3% of participants reported identification as heterosexual. One study was conducted in the U.S. and the other was conducted in the U.S., Canada, and Israel. According to U.S. Census Bureau estimates, 88.3% of the population identifies as heterosexual or straight (Anderson et al., 2021).

3.3.5. Immigrant Background

Because only one study reported participant immigrant background, representativeness in this domain could not be evaluated.

3.4. Time Trends of Reporting and Representation

We examined reporting on race and ethnicity in the time since ClinicalTrials.gov began requiring reporting of race and ethnicity information during results submission in April 2017. Of the seven articles published before this requirement, only three (42.9%) reported race or ethnicity. Of the 13 articles published after this requirement, 12 (92.3%) reported race or ethnicity. The proportion of participants with an unreported race or ethnicity significantly decreased from the decade 2010-2019 (12.6%) to the decade 2020-2024 (1.8%; $\chi^2(1)=46.29$, $p<.001$). Of the 12 studies that reported SES, half (50%) were published in the last five years, and nine (75%) were published in the last 10 years. Both articles reporting participant sexual orientation were published in the last five years, and the article reporting immigration status was published in the last 10 years.

Time trends for SES, sexual orientation, immigration status could not be evaluated due to infrequent reporting and heterogeneity. Overall, the sample makeup of PAT RCTs did not change substantially over time for sex/gender. In terms of race and ethnicity, the proportion of Hispanic or Latino participants significantly increased from the decade 2010-2019 (3.2%) to 2020-2024 (8.2%; $\chi^2(1)=5.11$, $p=.024$). There were no other statistically significant changes in other racial and ethnic categories.

3.5. Psychedelic Substance (MDMA vs. Psilocybin)

Overall, 316 participants came from MDMA-assisted therapy RCTs and 718 participants came from psilocybin-assisted therapy RCTs. There was a significant association between participant sex and psychedelic substance, with MDMA studies having a greater proportion of female participants (65.8%) compared to psilocybin studies (50.8%; $\chi^2(1)=19.35$, $p<.001$). MDMA studies were more racially diverse than psilocybin studies, enrolling a significantly greater proportion of participants who were American Indian/Alaska Native (2.2% vs. 0.1%, $p=.001$), Asian/Asian American (6.0% vs. 0.6%, $p<.001$), multiracial (7.9% vs. 1.0%; $p<.001$), Hispanic/Latino (13.3% vs. 4.5%; $p<.001$), and fewer participants who were White (71.8% vs. 83.2%; $p<.001$). The proportion of Black participants was not significantly different between MDMA studies (3.5%) and psilocybin studies (1.7%). Due to limited reporting, MDMA and psilocybin RCTs could not be meaningfully compared on SES, sexual orientation, or immigrant background.

3.6. Moderating Effects Across Demographic Subgroups

Four studies conducted analyses to examine the influence of demographic variable factored on treatment outcome, with all four specifically investigating the role of sex/gender. One study conducted between-group comparisons with gender and reported that gender did not influence primary outcome measures (Ross et al., 2016). Another study included gender as a covariate in exploratory analyses and found that gender did not interact with the treatment to influence primary endpoints (Mitchell et al., 2021). However, a separate study found that female sex assigned at birth was associated with improved outcomes in PTSD symptom reduction for both MDMA-assisted therapy and placebo groups (Mitchell et al., 2023). A fourth study controlled for sex in their main analyses of treatment effects (Raison et al., 2023), but did not report whether sex was a significant covariate.

4. Discussion

This systematic review identified several important issues related to reporting and representation in PAT RCTs: First, we found that important demographic characteristics like sexual orientation and socioeconomic status (educational attainment) were infrequently reported in PAT RCTs. Second, when reported, there was significant variability in reporting approaches in PAT RCTs. Third, we found significant overrepresentation of White participants (79.8% vs. 57.8% in U.S. population) and underrepresentation of Black participants (2.2% vs. 12.1% in U.S. population) in these trials. Fourth, PAT RCT samples are disproportionately comprised of individuals with higher education levels, which suggests greater participation from those of higher socioeconomic status. Finally, analyses of treatment effects based on participant demographic characteristics are virtually nonexistent (only 3 of 21 studies) and underpowered given the sample sizes of extant PAT RCTs. Taken together, these findings highlight the urgent need for PAT RCTs to systematically report demographic characteristics and to improve the representativeness of participant samples to enhance the generalizability of their results. These are necessary steps to draw conclusions about whether PAT effectively serves the populations it is designed to treat.

The first step in evaluating the extent to which PAT is generalizable across demographic groups is measuring and reporting relevant participant characteristics. Our results show that similar to RCTs of other mental health treatments (Burnette et al., 2022; Harned et al., 2022; Polo et al., 2019), gender was consistently reported across all studies. However, no RCTs reported non-cisgender identities, suggesting that sex and gender identity may be conflated in these studies, and only 10% (2 of 21) of RCTs reported sexual orientation. As sexual and gender minority groups are at heightened risk of suicide and other mental health disorders (Horwitz et al., 2020; Lund & Burgess, 2021; Ramchand et al., 2022), failure to report these variables, at minimum, means the impact of PAT on sexual and gender minority groups remains unknown. Although some researchers may fear that participants will find these questions too private to answer, research shows that participants are willing to provide this information when asked in a culturally sensitive manner (Ellis et al., 2017). Furthermore, the American Psychiatric Association, American Psychological Association, FDA, and National Institutes of Health all call for reporting of these demographic characteristics as a necessary first step to developing evidence-based mental health treatments for sexual and gender minority groups (American Psychological Association, 2021; Cabaj, 2024; National Academies of Sciences and Medicine, 2022; U.S. Food & Drug Administration, 2024). Click or tap here to enter text..

Reporting of racial and ethnic demographic information was similarly variable. While 76% (16 of 21) of the included RCTs reported either participants' race and/or ethnicity, one RCT published in within a year of this review did not report these variables and 31% (5 of 16) of the studies reported race only as "White" versus "Other" or "Non-White," which is both uninformative and problematic with centering of the White racial category (Flanagin et al., 2021). Additionally, the conflation of race and ethnicity in 19% (3 of 16) of these studies potentially obscures the identification of trends in inclusion of various racial and ethnic groups across studies and time. This heterogeneity in reporting is not unique to PAT RCTs – nomenclature on racial and ethnic categories has continued to evolve, with reporting standards and U.S. census categories shifting over time (Viano & Baker, 2020). Current U.S. federal guidelines recommend using a single combined race and ethnicity question that allows participants to select one or multiple categories (Office of Management and Budget, 2024). Transparent and consistent reporting of participant demographics improves tracking of trial representation and could eventually enable meta-analyses of subgroup differences across PAT RCTs.

Beyond issues with reporting, we found evidence of significant underrepresentation of minoritized groups in PAT RCTs. While PAT RCTs were generally gender balanced for women and men, other gender identities were not represented. Participants from the U.S. with higher levels of educational attainment were overrepresented in PAT RCTs compared to U.S. population data on educational attainment (e.g. 40.3% vs. 14.4% with an advanced degree), although this is based only on the five studies that measured and reported educational attainment. Nonetheless, this finding suggests that PAT RCTs may be less accessible to individuals from groups with lower educational attainment. Participants from more educated backgrounds may have increased familiarity with and trust in academic medical institutions, rendering them more likely to participate. Although not perfect, educational attainment is a widely used and appropriate proxy for socioeconomic status (Shavers, 2007), suggesting that individuals of a lower socioeconomic status may face barriers to participating in PAT RCTs. However, other

socioeconomic metrics, such as participant income, were too infrequently and inconsistently reported to identify more comprehensive patterns of socioeconomic representation across PAT RCTs.

In regard to racial and ethnic representation, White participants were significantly overrepresented compared to other racial groups (79.8% in PAT RCTs vs. 57.8% in U.S. population), with notably low inclusion of Black (2.2% vs. 12.1% in U.S. population) and Hispanic or Latino-identifying participants (7.2% vs 18.7% in U.S. population). This finding mirrors that of a prior review of 18 PAT studies (including non RCTs) from 1993 to 2017, which found that 82.3% of participants identified as White (Michaels et al., 2018), as well as a recent systematic review evaluating ethnoracial diversity in psychedelic studies since 2018 (Hughes & Garcia-Romeu, 2024). The low proportion of Black participants in PAT RCTs is particularly egregious in comparison to population data (i.e., 12.1% of US population) and data from U.S. RCTs for other psychiatric interventions, such as for self-injurious thoughts and behaviors (21.4% Black; Maria Guzmán et al., 2024), PTSD (20.4% Black; Madnick & Spokas, 2022), depression (10.1% Black; Polo et al., 2019), and anxiety (6.9% Black; Ong et al., 2024).

When comparing RCTs of MDMA vs. psilocybin, we found MDMA RCTs to have higher female representation and greater racial diversity compared to psilocybin RCTs, although White participants were still overrepresented (71.3% vs. 57.8% in U.S. population). The comparatively greater participant diversity in MDMA trials may reflect a 2020 initiative by the sponsor designed to increase demographic diversity among participants in a large Phase 3 clinical trial of MDMA-assisted therapy for PTSD, which successfully increased enrollment of non-White participants (McKenna Leighton & Charlotte Harrison, 2022; Mitchell et al., 2023). Differences in demographic representation between MDMA and psilocybin RCTs are also likely influenced by differences in the conditions studied with each compound. For example, MDMA RCTs have almost exclusively focused on PTSD, and women are twice as likely to suffer from PTSD compared to men, both in the U.S. and internationally (Kimerling et al., 2018; Maney, 2016). On the other hand, psilocybin RCTs have focused on depression and substance use disorders and there have been no RCTs focused on PTSD to date. Nevertheless, a concerted effort to ensure representative samples in all trials of PAT will help to elucidate conclusions surrounding its generalizability.

4.1. Recommendations

To improve representation in PAT RCTs, engaging voices from target demographic groups early in the research process – even before clinical trial design – can help address barriers to enrollment. Incorporating community advisory boards and qualitative studies can offer valuable insights into the experiences of individuals from minoritized backgrounds with PAT, supplementing RCT findings and guiding strategies for more inclusive trials. In addition, creating a diverse research team, especially study therapists, and featuring team members' photos and names in recruitment materials can help participants feel represented and understood (Williams et al., 2020). Diverse teams bring broader perspectives, enhancing cultural sensitivity and understanding of participants' experiences, which can improve recruitment strategies, foster trust, and increase participation among individuals from varied backgrounds (Does et al., 2018; Khuntia et al., 2022).

Several targeted efforts should be considered to increase representation for specific underrepresented groups. First, to enhance participation by individuals of low socioeconomic status, providing accessible transportation options, increasing compensation for participation (possibly through a need-based approach for reimbursement), and offering maximal flexibility in scheduling study visits are crucial steps. Additionally, compensation should be offered in forms that are convenient and inclusive, such as cash or gift cards, rather than checks, to accommodate individuals without bank accounts (Williams et al., 2020). To make participation inclusive of all education levels, researchers can use plain language and visual aids in consent forms and study materials and offer opportunities for participants to ask questions and gain clarity about procedures. Second, strategies to enhance participation of gender and sexual minorities include training staff on LGBTQ+ issues, using gender inclusive language, and ensuring privacy and confidentiality for participants. Third, to enhance participation by underrepresented and/or minoritized racial and ethnic communities, it is important to acknowledge and address the racialized history of psychedelics, and address misconceptions through psychoeducation. Supporting this approach, after receiving brief psychoeducation related to MDMA and PAT, Black American participants endorsed more interest and positivity towards PAT (Carter et al., 2023). This and other findings suggest that active outreach efforts that include accessible information about the research study and PAT broadly can rebuild trust among communities and researchers with the goal to increase diversity in PAT RCT samples. Consistent with the principles of intersectionality, enhancing the participation of one minoritized group is likely to increase the representation of others, given the overlap and co-occurrence of multiple minoritized statuses. For example, efforts to improve the inclusion of individuals with low socioeconomic status may also increase the participation of racial and ethnic minorities, as these identities often intersect. By implementing these strategies, PAT trials can become more inclusive and representative, resulting in more accurate and generalizable research outcomes.

4.2. Limitations

Results of this systematic review should be considered in the context of several limitations. First, investigators were not contacted for missing participant demographic information. This choice was intentional, as the study aimed to understand reporting practices in scientific dissemination. Demographic data may have been collected in these trials, though not reported. Second, most included studies were U.S.-based, prompting the use of U.S. Census and clinical trial data for comparison. Global data on many variables is limited or inconsistent due to differing racial and ethnic categories. Thus, our conclusions are most applicable to U.S. research, aligning with our goal to inform the U.S. context, where psilocybin and MDMA have FDA breakthrough status. As international trials expand, future reviews should examine regional representation. Third, we compared PAT RCT participant demographics to U.S. Census data and FDA psychiatry trial demographics. However, these comparisons overlook differences in disorder prevalence among demographic groups. Groups with higher disorder prevalence should ideally be overrepresented in RCTs to ensure findings are relevant to those most affected. As PAT trials expand, formalized methods for assessing demographic representativeness, similar to those used in other medical fields (Chen et al., 2024), will be essential.

4.3. Conclusion

This systematic review highlights significant gaps in demographic reporting and disparities in representation within modern PAT RCTs. Improving reporting and inclusion practices is critical to ensure that findings are generalizable, and reflect the treatment responses of groups disproportionately affected by the targeted mental health conditions. Community participatory research can promote equitable access through intentional recruitment, improved trial design, and trust-building with minoritized communities. These efforts are vital to generating robust, generalizable evidence for PAT to ultimately deliver safe and effective treatments that address mental health disparities.

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