**Reporting and representation of race and ethnicity in 1683 RCTs of pharmacotherapy for mental disorders: a meta-analysis**

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# KEY POINTS

**Question**: How are race and ethnicity reported and represented across randomised controlled trials (RCTs) of pharmacotherapies for mental disorders?

**Findings**: Based on data from 1683 RCTs and using advanced meta-analytical techniques, we found significant under-reporting of race and ethnicity and under-representation of specific racial/ethnic groups, particularly in countries other than the USA and in small studies.

**Meaning**: The significant gaps in reporting race and ethnicity in RCTs of pharmacotherapies for mental disorders, as highlighted in our study, call for collaborative efforts among stakeholders and policymakers to develop international guidelines that promote equitable recruitment in clinical trials.

# ABSTRACT

**Importance:** Representation of race and ethnicity in randomised controlled trials (RCTs) is critical for understanding treatment efficacy across populations with different racial/ethnic backgrounds.

**Objective:** We conducted the first comprehensive overview of reviews of race and ethnicity representation and reporting across RCTs of pharmacotherapies for mental disorders.

**Data sources:** PubMed/Medline/Ovid-Embase/APA-PsycINFO/Web-of-Science were searched (March-01-2024), to retrieve the most updated and largest network meta-analyses (NMA) of RCTs of pharmacotherapies for ICD-10 mental disorders.

**Study selection:** From each NMA, we identified single-blind or double blind RCTs, quasi-RCTs, open label RCTs, and discontinuation/withdrawal design RCTs, recruiting people of any age with a diagnosis of mental disorder and testing the efficacy of any pharmacological intervention compared to any control arm.

**Data Extraction and Synthesis:** We used random-effects logit-transformed-proportion meta-analyses to: 1) estimate prevalence rates of race and ethnicity groups and their temporal trends across RCTs, and 2) compare US-RCT prevalence rates with US census data.

**Main Outcome Measures:** Reporting of data on race and ethnicity, and percentage of Asian, Black, Hispanic, Other/Multi-racial/Multi-ethnic, and White. Hispanic and White were operationalised as “White-including-Hispanic" and "Hispanic-among-White" to fit the categories used in the included RCTs. We also considered: year of publication, type of RCT, continent, age group, and sample size.

**Results:** We included 1683 RCTs (375,120 participants, 91.7% adults; USA=680, Europe=404, multiple continents=216). Race and ethnicity were reported in 39% of RCTs, reporting was the highest in USA-based RCTs (58.68%) and the lowest in Central and South America (8.70%) and Asia/Middle East (12.43%). 80.2% of participants [95% confidence interval=78.8-81.5] self-reported as White-including-Hispanic (of which 11.0% [9.1-13.3] as Hispanic-among-White), 9.0% [8.1-10.0] as Black, 5.8% [5.2-6.4] as Other/Mixed Ethnicity, and 2.7% [2.1-3.5] as Asian. We found better reporting of race and ethnicity in US-RCTs over time (log odds increase=0.066); and smaller improvement in non-US-RCTs (log odds increase=0.023). Larger RCTs were more likely to report race and ethnicity, albeit not in all continents. “Other/Mixed Ethnicity” was historically over-represented in US-RCTs, while “Black”, “Hispanic-among-White” and “Asian” were under-represented, with the latter two still currently under-represented.

**Conclusions and relevance:** Differences in reporting race and ethnicity across countries and under-representation of certain racial/ethnic groups in US-based RCTs highlight the need for international guidelines to ensure equitable recruitment in clinical trials.

**Keywords:** Ethnicity; Race; Mental Health; Randomised Controlled Trial; Reporting

**Funding:** No funding was obtained to conduct this study.

**Protocol:** [https://osf.io/wkh5a/?view\_only=d8138c80ddab4344a928108d6c20e4b9](about:blank)

# INTRODUCTION

Accurately describing the variability in response to pharmacotherapy among different racial/ethnic groups is crucial for advancing precision medicine, which aims to tailor treatments to the individual characteristics of each patient.1  In clinical practice, it is crucial to being able to interpret the results of individual randomised controlled trials (RCTs) and understand potential differences between racial/ethnic groups in terms of risk of developing various disorders and variability in treatment response. This approach is essential for better understanding the pathophysiology of disorders across individuals2 and differentiating between subgroups of individuals in terms of long-term outcomes.3 Indeed, while pharmacological treatment response might be affected by the interaction between genetic predisposition and environmental factors,4 race or ethnicity themselves are not valid genetic variables5.

As shown by studies in the field of general medicine,6 data about the racial and ethnic distribution of samples recruited in RCTs are often not reported. Furthermore, participants are often selectively sampled based on specific criteria that fail to represent the population the study results should be generalised to. This lack of information and poor representation may adversely impact science and clinical care, and potentially harm underrepresented populations.7 Race and ethnicity, along with other psycho-social factors (e.g., socio-economic background), are important contributors to mental health.8 Indeed, reduced access to healthcare systems or different standard of care for people from minoritised, marginalised and/or underrepresented communities, can exacerbate challenges associated with mental disorders.8 However, the extent to which information about race and ethnicity are reported in RCTs and prevalence rates reported in RCTs reflect population estimates, remains unclear. This is compounded by a lack of uniform international reporting standards, with inconsistent nomenclatures and lack of regular collection of information about race and ethnicity in some clinical or research settings.9,10

We conducted the first comprehensive overview of reviews and quantitative analysis of race and ethnicity representation and reporting across RCTs included in network meta-analyses (NMA), rather than searching for individual RCTs, which would have made our project unfeasible. We assessed: 1) what percentage of RCTs of pharmacotherapies for mental disorders do report race and ethnicity as sample characteristics; 2) any temporal trends and differences in reporting rates across diagnostic and age groups, and continents; and 3) considering the publicly available data on race and ethnicity prevalence rates in the USA, how the racial and ethnic distribution across US-RCTs (the most represented database in the present study) aligns with national census data.

# METHODS

Based on the protocol11 and following PRIOR guidelines (eTable 1), we systematically searched PubMed/Medline, Ovid Embase, APA PsycINFO and Web of Science (eTable 2), up to 1st March 2024, to retrieve the most updated and largest NMA of RCTs of pharmacological interventions for each of the following International Classification of Diseases (ICD-10)-defined mental disorders: Attention-Deficit/Hyperactivity Disorder (ADHD) or Hyperkinetic Disorder, Alcohol Use Disorder, Autism, Bipolar Disorder, Conduct Disorder and Oppositional Defiant Disorder, Dementia, Eating Disorder, Generalised Anxiety Disorder, Obsessive-Compulsive Disorder, Opioid Use Disorder, Panic Disorder, Personality Disorders, Post-Traumatic Stress Disorder, Recurrent Depressive Disorder, Schizophrenia, Social Phobia, Stimulant or Cocaine Use Disorder, and Tic Disorder or Tourette’s Syndrome. If several NMAs on the same disorder were retrieved, we included the largest one (i.e., with the highest number of studies included), and in case of tie, the most updated. A review investigating race and ethnicity reporting and representation in ADHD was recently published;12 we therefore updated the search performed in March 202212 and conducted analyses on newly retrieved RCTs only. No deviations occurred from the original protocol.

From each NMA, relevant RCTs were identified (by AC, AL, AR, AS, CM, DA, DTL, EM, MSL, SH, SO, VP, VR) – including single-blind or double-blind RCTs, quasi-RCTs, open-label-RCTs, and discontinuation/withdrawal-RCTs – recruiting people of any age who met Diagnostic and Statistical Manual of Mental Disorders (DSM) or ICD criteria (any edition) for any eligible mental disorder, and testing the efficacy of any pharmacological intervention compared to any control arm (e.g., placebo, waiting list, other medications). AB supervised and cross-checked study selection. At least two researchers (AL, AS, EM, MSL, SH, SO, VR) independently extracted data, cross-checked by AB. For each RCT (grouped by diagnosis), we extracted the following information: first author, year of publication, DOI, type of RCT (single-centre, multi-centre), continent (Africa, Asia/Middle-East, Canada, Central/South-America, Europe, Oceania, USA, multi-continental), age group (< or ≥ 18 years, or both), sample size, reporting of race and ethnicity, and – if the study reported such data – percentage of Asian, Black, Hispanic, and White. The category “Other/Multi-racial/Multi-ethnic” (hereon, referred to as “Other/Mixed”) was also used to include any race and ethnicity not included among these groups. “Race and ethnicity” refers to any information, reported in the included papers, which referred to the racial or ethnic background of study participants.

We observed that some studies reported the percentage of people with Hispanic ethnicity, while others did not. In RCTs not reporting the percentage of Hispanic participants, the percentage of White participants was 78%. Conversely, in RCTs reporting the percentage of Hispanic participants, the percentage of White participants was 67%, and the percentage of Hispanic participants was 11%. Thus, the sum of White and Hispanic participants in these RCTs was 78% – the same number as the percentage of White participants in RCTs not including "Hispanic" as a category, suggesting that, in RCTs only reporting White participants, Hispanic participants were considered White participants. To fit these varying definitions, we created the following operational categories: “White-including-Hispanic” (i.e., White for studies not reporting Hispanic participants, and the sum of White and Hispanic participants for studies reporting on people with Hispanic background) and “Hispanic-among-White” (meaning the proportion of Hispanic participants among the sum of White and Hispanic participants, only for studies reporting on people with Hispanic background).

We also noted that the proportion of individuals in each racial/ethnic group in the RCTs followed a zero-inflated binomial distribution (eFigure 1), i.e., RCTs could either include a racial/ethnic group or not and – if included – the proportion of individuals from that racial/ethnic group was variable. For this reason, we split the modelling into: 1) a Firth's logistic regression to model whether RCTs included the racial/ethnic group or not, and 2) a random-effects logit-transformed-proportion meta-analysis to model the proportion of individuals for a racial/ethnic group (in those RCTs including that racial/ethnic group). Both the logistic regression and the meta-analysis were weighted by the sample size of the RCTs, and the meta-analysis also considered cross-study heterogeneity (Q, I2 and Tau indices, which indicate if studies are homogenous in reporting effects, and if this variability is due to real differences and not chance). After fitting the logistic regression and the meta-analysis, we obtained the final estimate as the multiplication of the proportion of RCTs including the racial/ethnic group (from the logistic regression) by the proportion of individuals of the racial/ethnic group (from the meta-analysis), with its confidence intervals derived via Monte Carlo simulation.

In relation to the second aim of the study, we used [logistic regression](about:blank) (year of publication was the independent variable and percentage of studies reporting race and ethnicity was the outcome variable) across RCTs conducted in the USA and elsewhere, for both children/adolescents and adults, and plotted temporal trends. Data from the American Community Survey (ACS) – a demographics survey program conducted yearly by the US Census Bureau – were used (third aim) to compare the pooled racial/ethnic estimates generated by the meta-analyses to the prevalence rates reported in the ACS using 10-year sliding windows between 1958 and 2022 (linearly interpolating the missing years). “Hispanic” and “Other” were added as ACS categories only in 1970, but since then they have not changed, although some labels have changed over time. Whenever the 95% confidence interval from the meta-analytic estimates from the RCTs did not include the population proportion (p < 0.05), we concluded that the proportion reported in the RCTs was statistically significantly different from the proportion reported in the ACS. All calculations were conducted using the "*logistf*" and “*metafor*” R packages in R Studio 2024.09.0.

# RESULTS

After screening 6,125 records (Figure 1), we retrieved 24 NMAs, and 17 were included (eTable 3). We analysed data from 1683 RCTs (375,120 participants), of which 1363 were only on adults (92% of overall participants), 312 only on children and adolescents (8%), 8 on both. Altogether, 680 RCTs were conducted exclusively in the USA (36% of participants), 404 in Europe (17%), 51 in Oceania (10%), 177 in Asia/Middle-East (6%), 43 in Canada (0.9%), 23 in Central/South-America (0.3%), 12 in Africa (0.3%), and 293 across continents (30%). Overall, 51% of the included RCTs were multi-centre studies (n = 865), and 38% single centre studies (n = 639), while the number of centres was unspecified for 179 (11%) (Table 1).

Data on race and ethnicity were reported for 660 out of 1683 RCTs (39%), with similar figures for adults (40%) and children/adolescents (38%). The percentage of RCTs reporting such data was the highest for bipolar disorder in children (10/11 RCTs reporting data, conducted in the USA, with the oldest published in 2006), and the lowest for obsessive compulsive disorder in adults (19/132 RCTs reporting data, most conducted in Canada, with the oldest published in 1989). Indeed, there was high variability in reporting race and ethnicity between RCTs reporting on different diagnostic categories (see Table 1, column “Reporting race and ethnicity”). RCTs conducted in Central/South-America and Asia/Middle-East were less likely to report race and ethnicity (eTable 4). Conversely, amongst US-RCTs, race and ethnicity were reported in 63% of RCTs on children and adolescents and 60% of RCTs on adults. Additional details about the results of the meta-analyses, including heterogeneity metrics (Q, I2 and Tau), are reported in eTable 5.

Across RCTs reporting race and ethnicity, 2.7% of participants (95% confidence interval = 2.1-3.5) reported their race and ethnicity as Asian, 9.0% (8.1-10.0) Black, 5.8% (5.2-6.4) Other/Mixed Ethnicity, and 80.2% (78.8-81.5) White-including-Hispanic, of which 11.0% (9.1-13.3) Hispanic-among-White. Studies reporting race and ethnicity did not generally include larger sample sizes (mean sample size = 262 participants) compared to those not reporting such data (197 participants) (t = 1.7, p = 0.09). However, there were differences across continents; for example, RCTs reporting race and ethnicity in Africa, Asia and Middle East, and Europe (but not Oceania or the USA) included larger sample sizes compared to those not reporting (eTable 6).

Figure 2 shows the temporal trends in reporting race and ethnicity for RCTs conducted in the USA and elsewhere. The log odds of reporting race proportions increased by 0.038 (SE = 0.005, p < 0.001) across all RCTs each year. When focusing on data from the USA only, the log odds increased by 0.066 (SE = 0.008, p < 0.001). By contrast, when considering data from countries other than the USA, reporting only increased by 0.023 (SE = 0.009, p = 0.007) (difference 0.042, p < 0.001). The percentage of studies reporting Hispanic as a separate racial/ethnic group increased similarly in RCTs conducted in the US (yearly log odds increase 0.081, SE = 0.012, p < 0.001) and elsewhere (yearly log odds increase = 0.064, SE = 0.018, p < 0.001) (difference = 0.018, p = 0.863).

For US-RCTs, 1.1% of participants (0.9-1.4) reported their race and ethnicity as Asian, 11.9% (10.7-13.2) Black, 7.2% (6.4-8.2) Other/Mixed Ethnicity, and 79.1% (77.5-80.7) White-including-Hispanic –of which 13.2% (10.8-16.1) Hispanic-among-White. When comparing data from RCTs with US census data, for RCTs in adults, “White-including-Hispanic”, “Hispanic-among-White”, and “Asian” groups were under-represented (this was particularly evident since 2004 for “White-including-Hispanic”, in 1994-2021 for “Hispanic-among-White”, and since at least 1980 for “Asian”). Adults self-reporting as Black were under-represented until early 2010’s, while they have been over-represented for the last 10 years. The category “Other/Mixed” was overall over-represented, but only until about 5 years ago. Data in children/adolescents, available since 1994, showed that “Hispanic-among-White” and to a lesser extent “Asian” and “Black” groups were under-represented RCTs (particularly in the last 15 years), while the category “Other/Mixed” was overall over-represented since the early 2000’s. Rates of children/adolescents reported as “White-including-Hispanic” in RCTs were consistent with US census data, though slightly decreasing across years (1958-2022).

# DISCUSSION

Our study highlighted critical gaps in reporting and representation of race and ethnicity in RCTs of pharmacotherapy for mental disorders. Despite the established importance of race and ethnicity in influencing mental health outcomes,8 only 39% of the included 1683 RCTs reported such data, and White-including-Hispanic, Hispanic-among-White and Asian participants were under-represented in USA RCTs.

There were no significant differences in reporting race and ethnicity between studies involving only children/adolescents vs. only adults, suggesting potentially systemic barriers in reporting such information in RCTs. However, the variability across geographic regions and diagnostic categories was striking. Studies conducted in Central/South America, Asia/Middle East were less likely to report race and ethnicity, while USA-based studies exhibited the highest reporting rate. This may point to potential regional differences in the prioritization of race and ethnicity collection or reflect more racially/ethnically homogeneous cultures probably paying less attention to the collection and reporting of racial/ethnic data. Indeed, European countries and some Asian countries do not regularly collect race and/or ethnicity as demographic data (e.g., there are no minimum reporting standards available, as it is the case in the USA), but instead use “nationality/country of birth” to assess diversity of their populations.9 In other countries, the collection of race and ethnicity is heavily regulated and restricted, hence not commonly reported in RCTs.10 Conversely, some countries collect information on both race and ethnicity and indigenous identity, while others use general labels to refer to racial/ethnic groups.9 Of note, “Hispanic” is a definition used in the USA to indicate an ethnic group that spans across different racial groups, but it is not regularly used elsewhere. There is also heterogeneity in collecting race and ethnicity among African countries, with South African censuses collecting this data since early 1900’s – often aimed at creating ethnical division13 – and information about collection practices lacking in other countries.14

There were also notable discrepancies between studies focusing on different diagnostic categories, suggesting potential biases in the collection and the reporting of race and ethnicity based on clinical characteristics of the sample. Better understanding which specific factors are associated with under-reporting race and ethnicity across diagnostic categories is therefore crucial. We recommend researchers to work towards identifying such factors and addressing any associated biases, especially where race and ethnicity is less reported or less diverse, although this mandate applies to all countries and settings.

Our findings of higher reporting rates in larger RCTs suggest that researchers conducting smaller studies might decide not to collect/report race and ethnicity, at least in certain regional areas. This decision could stem from resource and time constraints, as larger studies are more likely to have funding bodies that may also mandate race and ethnicity reporting, but nonetheless perpetuates health disparities. Addressing this bias is therefore also essential.

While reporting of race and ethnicity has increased each year in the USA, it remained relatively stagnant or even declined in other parts of the world since the 1980s. This disparity suggests that USA-based researchers might have responded to regulatory bodies (e.g., Food and Drug Administration),15 funding bodies (e.g., National Institute of Mental Health),16 and societal calls for reporting on the representativeness of samples in clinical research, which have been lacking in other geographic regions.

The comparison of USA-based RCTs and census data revealed a complex pattern of findings. In adults, White-including-Hispanic, Hispanic-among-White, and Asian were under-represented; in children/adolescents, Hispanic-among-White, Asian, and Black groups were under-represented. Conversely, amongst adults, Black individuals were under-represented until early 2010’s and over-represented for the last 10 years. The “Other/Mixed” category was overall over-represented in adults and in children. There were no differences in rates of White-including-Hispanic children/adolescents between RCTs and US census data. It would be important to better understand how people belonging to different racial/ethnic groups perceive barriers to accessing healthcare services and RCTs, and what are the underlying factors. This could help improving inclusion and accessibility to clinical and research settings, especially for patients who are under-represented (e.g., Black children and Asian), whereby reason for underrepresentation – especially of Asian participants in RCTs of both children/adolescents and adults – requires further study.

The lack of consistent and comprehensive racial/ethnic data collection and reporting poses significant challenges for developing and testing inclusive, effective, and equitable treatments for people with mental disorders. Without such data, it is difficult to fully understand if and how different ethnic or racial subgroups respond to various interventions.6 The fact that, at least in Europe, research is more focused on disentangling genetic heterogeneity within populations rather than stratifying people based on race and ethnicity, could explain why studies conducted in Europe are less likely to report race and ethnicity compared to USA-based studies. However, tailoring treatments to individual patient characteristics needs race and ethnicity being collected in RCTs and reported in primary or secondary analyses. There is in fact strong evidence that removing or not measuring potentially discriminatory variables such as race and ethnicity does not remove the bias against a group but may make it worse, through the so-called principle “fairness through unawareness”, which assumes that if we are unaware of protected attributes while making decisions, our decisions will be fair.17 Conversely, carefully reporting and measuring racial/ethnic information is a more solid approach to account for the potential effects of systemic racism on treatment outcomes.18,19

Our study has some limitations. Considering we retrieved RCTs from the most updated and largest NMA for each mental disorder, we may have missed some RCTs not included in these evidence-synthesis studies. Furthermore, our temporal trend analyses were based on the date of article publication, rather than on the temporal period during which data were collected. Our choice of using generic labels to collate race and ethnicity was justified by the need to standardise data for the meta-analyses. However, this meant that other labels were collapsed into the category “Other/Multi-racial/Multi-ethnic”. Nevertheless, we are aware that the labels used to refer to race, ethnicity, or indigenous identity may have different connotations based on the country or the socio-cultural context,9,10 but it would have been impossible to conduct the current study using unstandardised labels. It is also important to note that it is common practice for RCT participants to self-report their race and ethnicity (however, RCTs usually inconsistently report whether race and ethnicity were self-reported or observed/inquired about). This introduces the possibility that a percentage of individuals recruited in RCTs identify with a different ethnicity than they might otherwise be categorized under. However, we note that this same self-reporting approach is used in the ACS. In addition, we could only compare RCT data with census data for USA-based studies, considering we could only obtain publicly available demographic data from the USA. Further studies are therefore needed, involving governmental and non-governmental organisations responsible for collecting demographic data in non-USA countries. We particularly recommend future studies to focus on investigating the potential role of other factors in under-reporting race and ethnicity, such as type of sponsor/funding, other socio-demographical variables, sex-assigned-at-birth, and self-reported gender.

In conclusion, it is urgently needed to work towards developing consensus guidelines and standardised international reporting protocols for easily collecting and transparently reporting race and ethnicity when presenting the main findings of RCTs for pharmacological treatments of mental disorders, but also in any other disease. This approach will ensure that RCTs are appropriately monitored, and researchers can be at least held accountable to better reflect and serve diverse populations globally, thereby mitigating biases and improving the generalizability of study findings. This task can only be accomplished by researchers, clinicians, patients, funders, research councils and foundations, policymakers, academic publishers, drug manufacturers, and regulatory agencies, working together towards this important goal.

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# DECLARATION OF INTERESTS

**Dr. Bellato** declares honoraria as Joint Editor of JCPP Advances. **Prof. Correll** has been a consultant and/or advisor to or has received honoraria from: AbbVie, Alkermes, Allergan, Angelini, Aristo, Boehringer-Ingelheim, Bristol-Meyers Squibb, Cardio Diagnostics, Cerevel, CNX Therapeutics, Compass Pathways, Darnitsa, Delpor, Denovo, Eli Lilly, Gedeon Richter, Hikma, Holmusk, IntraCellular Therapies, Jamjoom Pharma, Janssen/J&J, Karuna, LB Pharma, Lundbeck, MedInCell, MedLink, Merck, Mindpax, Mitsubishi Tanabe Pharma, Maplight, Mylan, Neumora Therapeutics, Neurocrine, Neurelis, Newron, Noven, Novo Nordisk, Otsuka, PPD Biotech, Recordati, Relmada, Reviva, Rovi, Saladax, Sanofi, Seqirus, Servier, Sumitomo Pharma America, Sunovion, Sun Pharma, Supernus, Tabuk, Takeda, Teva, Terran, Tolmar, Vertex, Viatris and Xenon Pharmaceuticals. Dr. Correll provided expert testimony for Janssen, Lundbeck and Otsuka; he served on a Data Safety Monitoring Board for Compass Pathways, IntraCellular Therapies, Relmada, Reviva, Rovi; he has received grant support from Boehringer-Ingelheim, Janssen and Takeda; he received royalties from UpToDate and is also a stock option holder of Cardio Diagnostics, Kuleon Biosciences, LB Pharma, Medlink, Mindpax, Quantic, and Terran. **Prof. Cortese**, NIHR Research Professor (NIHR303122), is funded by the NIHR for this research project. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR, NHS or the UK Department of Health and Social Care. Prof. Cortese is also supported by NIHR grants NIHR203684, NIHR203035, NIHR130077, NIHR128472, RP-PG-0618-20003 and by grant 101095568-HORIZONHLTH- 2022-DISEASE-07-03 from the European Research Executive Agency. Prof. Cortese has declared reimbursement for travel and accommodation expenses from the Association for Child and Adolescent Central Health (ACAMH) in relation to lectures delivered for ACAMH, the Canadian AADHD Alliance Resource, the British Association of Psychopharmacology, and from Healthcare Convention for educational activity on ADHD, and has received honoraria from Medice. **Prof. Fusar-Poli** has received grant support from Lundbeck and honoraria fees from Angelini, Menarini, and Lundbeck outside the current work. **Dr. Raduà** received CME honoraria from Inspira Networks for a machine learning course promoted by Adamed (outside the submitted work); his work is supported by the CERCA Program / Generalitat de Catalunya and Secretaria d’Universitats i Recerca del Departament d’Economia I Coneixement (2021 SGR 01128). **Dr. Solmi** received honoraria/has been a consultant for Angelini, AbbVie, Boehringer Ingelheim, Lundbeck, Otsuka. **All other authors** have no conflicts of interest to declare.

# DATA SHARING STATEMENT

Data are publicly available at the following link: <https://osf.io/wkh5a/?view_only=d8138c80ddab4344a928108d6c20e4b9>.

# FIGURE DESCRIPTION

**Figure 1.** Screening flowchart

**Figure 2.** Temporal trends in the reporting of race and ethnicity in RCTs of pharmacological treatments for mental disorders.

*Note:* the full line symbolizes the percentage of studies reporting race and ethnicity in general, while the dotted line represents the number of studies reporting Hispanic.

# TABLES

**Table 1. Characteristics of included studies, by age group and for each diagnostic category.**

|  | **N of RCTs** | **N of participants** | **Single-centre RCTs** | **Multi-centre RCTs** | **Reporting race and ethnicity** | **Reporting "Hispanic" as ethnicity** | **Asian** | **Black** | **Hispanic (among White)** | **Other** | **White (including Hispanic)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Overall | 1683 | 37,120 | 38% | 51% | 39% | 14% | 3% (2-4%) | 9% (8-10%) | 11% (9-13%) | 6% (5-6%) | 80% (79-82%) |
| **By age group** | | | | | | | | | | | |
| All diagnoses (<18 years old) | 312 | 31205 | 46% | 36% | 38% | 21% | 4% (3-6%) | 9% (7-11%) | 15% (11-19%) | 7% (6-8%) | 77% (74-80%) |
| All diagnoses (18+ years old) | 1363 | 343305 | 36% | 55% | 40% | 12% | 3% (2-3%) | 9% (8-10%) | 10% (8-13%) | 5% (5-6%) | 81% (79-82%) |
| **By disorder** | | | | | | | | | | | |
| ADHD (<18) | 23 | 7028 | 39% | 43% | 39% | 39% | 3% (1-7%) | 19% (10-31%) | 28% (19-38%) | 7% (4-12%) | 72% (58-83%) |
| ADHD (18+) | 12 | 3570 | 17% | 83% | 58% | 58% | 3% (2-4%) | 16% (10-24%) | 43% (9-76%) | 4% (2-7%) | 78% (71-84%) |
| Alcohol Use Disorder (18+) | 129 | 13644 | 64% | 17% | 29% | 5% | 0% (0-0%) | 4% (3-6%) | 14% (7-25%) | 4% (3-7%) | 90% (86-94%) |
| Anxiety Disorder (< 18) | 106 | 9693 | 60% | 34% | 50% | 26% | 4% (2-6%) | 5% (3-9%) | 10% (6-17%) | 8% (6-10%) | 83% (79-85%) |
| Autism (<18) | 149 | 9777 | 40% | 34% | 26% | 13% | 5% (3-6%) | 13% (10-16%) | 18% (11-28%) | 6% (4-9%) | 77% (70-83%) |
| Autism (18+) | 30 | 2292 | 43% | 37% | 27% | 23% | 7% (2-21%) | 7% (5-10%) | 8% (5-12%) | 3% (2-4%) | 80% (63-90%) |
| Bipolar Disorder (< 18) | 11 | 1845 | 36% | 64% | 91% | 27% | 1% (0-1%) | 13% (10-17%) | 20% (12-30%) | 9% (5-15%) | 77% (70-84%) |
| Bipolar Disorder (18+) | 181 | 39690 | 41% | 52% | 44% | 6% | 6% (3-11%) | 11% (8-13%) | 13% (9-19%) | 7% (6-10%) | 72% (68-75%) |
| Dementia (18+) | 63 | 10132 | 29% | 63% | 41% | 38% | 3% (0-18%) | 3% (2-4%) | 2% (1-4%) | 3% (1-5%) | 92% (89-94%) |
| Eating Disorders (18+) | 13 | 2261 | 31% | 46% | 69% | 62% | 1% (1-2%) | 12% (9-16%) | 0% (0-1%) | 8% (4-15%) | 84% (78-89%) |
| Generalised Anxiety Disorder (18+) | 67 | 24336 | 12% | 85% | 57% | 16% | 1% (1-1%) | 6% (4-8%) | 5% (3-10%) | 4% (3-6%) | 89% (85-92%) |
| Major Depressive Disorder (18+) | 226 | 66560 | 10% | 81% | 53% | 12% | 2% (1-6%) | 5% (4-7%) | 7% (4-10%) | 5% (4-6%) | 84% (82-86%) |
| Obsessive Compulsive Disorder (18+) | 132 | 9627 | 46% | 45% | 14% | 2% | 2% (1-4%) | 1% (1-1%) | 3% (1-7%) | 6% (4-9%) | 90% (87-93%) |
| Opioid Use Disorder (18+) | 74 | 74502 | 85% | 9% | 41% | 18% | 4% (0-15%) | 20% (13-29%) | 31% (15-53%) | 8% (4-14%) | 59% (48-69%) |
| Panic disorder (18+) | 84 | 14076 | 30% | 70% | 18% | 1% | 0% (0-0%) | 1% (1-2%) | 5% (3-9%) | 10% (6-16%) | 88% (84-91%) |
| Post-traumatic stress disorder (18+) | 53 | 6070 | 25% | 58% | 66% | 25% | 1% (0-4%) | 15% (11-19%) | 22% (12-37%) | 7% (5-10%) | 73% (67-78%) |
| Schizophrenia (< 18) | 2 | 276 | 50% | 50% | 50% | 0% | 17% (13-23%) | 6% (3-10%) | 0% (0-0%) | 1% (0-3%) | 76% (69-81%) |
| Schizophrenia (18+) | 221 | 64405 | 38% | 58% | 38% | 14% | 4% (2-6%) | 20% (16-25%) | 16% (9-26%) | 5% (3-6%) | 68% (62-74%) |
| Social Anxiety Disorder (18+) | 54 | 9914 | 22% | 59% | 46% | 13% | 1% (1-1%) | 5% (3-6%) | 12% (8-18%) | 7% (4-10%) | 88% (84-92%) |
| Stimulant or Cocaine Use Disorder (18+) | 22 | 2098 | 55% | 27% | 23% | 5% | 0% (0-1%) | 15% (9-23%) | 24% (16-35%) | 14% (7-28%) | 70% (62-76%) |
| Tourette's (<18) | 21 | 2586 | 29% | 33% | 38% | 19% | 54% (2-83%) | 1% (0-4%) | 8% (3-22%) | 3% (1-7%) | 37% (34-41%) |
| Tourette's (18+) | 2 | 128 | 0% | 50% | 50% | 0% | 2% (0-6%) | 4% (2-9%) | 0% (0-0%) | 5% (2-10%) | 89% (81-93%) |

Note: Percentages may not sum to 100% because each estimate used a separate meta-analysis with slight differences in study weighting.