

## Trials of alcohol use disorder treatments routinely exclude sex, gender, race, and ethnicity from consideration

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The manifestation of alcohol use disorder (AUD) and its social, health, and psychological implications depend in part on patient demographics. Yet researchers routinely exclude those demographics from analyses of



non-medicinal AUD treatment trials, a review of studies has found. Consequently, little is known about how sex, gender, race, and ethnicity influence the effectiveness of those treatments, or which treatments are indicated—or not—for specific patients and communities. This is despite the National Institutes of Health Revitalization Act in 1993 requiring that NIH-funded studies include diversity of sex/gender and race/ethnicity in their participant samples and analysis. Problematic alcohol use, which has high prevalence and low treatment rates, is a leading contributor to preventable death and disease. Nonpharmacological treatments include cognitive behavioral therapy (CBT), motivational interviewing (MI), contingency management, twelve-step programs, and more. Inequalities in healthcare experienced by women and people of color contribute to substantial disparities in outcomes; this includes varying effectiveness of non-medicinal treatments for other mental health conditions across demographic groups. It is not known how demographic factors influence treatment outcomes in AUD.

For the meta-epidemiological review in *Alcoholism: Clinical & Experimental Research*, researchers at the University of Rhode Island examined articles focusing on the effectiveness of non-pharmacological AUD treatments for compliance with NIH guidelines on inclusion and reporting for sex, gender, race, and ethnicity. They scoured online databases for empirical articles reporting randomized, controlled trials of non-medicinal AUD treatments published in English from 1994 onward, identifying 155 articles representing 59,000 study participants. They reviewed the articles for funding source, treatment of focus, and inclusion of sex, gender, race, and ethnicity in the participant sample, analysis of outcomes, and discussion.

More than eight out of ten of the reported trials had received NIH funding. Most articles included at least some information about participants' sex, gender, race, and ethnicity. However, diverse participants were not routinely or representatively included in <u>clinical</u>



trials, which appeared dominated by White men. Of the 155 articles, only 37% fully reported the sex/gender and race/ethnicity of their participants. Only two examined treatment effectiveness by both sex/gender and race/ethnicity, and only 10 mentioned inclusion and diversity with regard to outcomes. Eight articles acknowledged a lack of "diversity" as a limitation of their findings but did not elaborate. Only two articles reported subgroup analyses of effectiveness based on sex/gender, and none reported participants who were intersex, transgender, or otherwise nonbinary. Only 16% fully reported on the race/ethnicity of participants. Nearly one in five reported "predominantly White" or similar samples; references to "other," "minorities," and "non-White" were common. Only one reported subgroup analyses across racial and ethnic groups. The handling of sex, gender, race, and ethnicity barely improved over time.

The limitations in inclusion and reporting have persisted despite growing awareness of issues related to diversity, equity, and inclusion, and notwithstanding evidence of differential effectiveness of non-medicinal AUD treatments. The reviewers called for a substantial effort by the scientific community to include women and members of minority racial and ethnic groups in trials, analyses, and reports. Aggregating results across demographic groups fails to consider differences in context and experiences that might influence responses to treatment, and is a barrier to personalized, patient-centered medical care. The researchers recommended samples proportionate to AUD prevalence among demographic groups, and precise measurement of racial categories and non-binary sex and gender, among other necessary changes.

**More information:** Melissa R. Schick et al, Inclusion and reporting of sex, gender, and race/ethnicity in randomized controlled trials of nonpharmacological treatments for alcohol use disorder: A meta-epidemiologic review, *Alcoholism: Clinical and Experimental Research* (2022). DOI: 10.1111/acer.14850



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