Trials ‘Still Largely White and Largely Male’ Due to Hidden Biases

By Deborah Borfitz

July 31, 2024 | Randomized clinical trials (RCTs) may need some serious revamping, based on mounting evidence of systemic biases afflicting the entire enterprise. Despite decades of efforts to realize equitable participation by marginalized groups, notably women and people of color, RCTs are “still largely white and largely male,” according to NiCole Buchanan, Ph.D., psychology professor at Michigan State University (MSU).

Up to now, most research on the topic has focused on problems with recruitment and simply “quantified the amount of under-inclusion” across a variety of physical and behavioral health issues, says Mallet Reid, a doctoral candidate in MSU’s department of psychology. As he learned firsthand while treating substance abuse disorders in New Mexico, the therapeutic tools at the disposal of clinical practitioners can be dishearteningly ineffective when tested on people who don’t map to the affected real-world populations.

Underlying problems exist in the way RCTs are constructed, implemented, and governed, as Reid and Buchanan covered in an intersectional analysis of co-occurring alcohol use disorder (AUD) and posttraumatic stress disorder (PTSD) recently published in the *Journal of Ethnicity in Substance Abuse* (DOI: 10.1080/15332640.2024.2367240). Both people of color and white women were found to be significantly under-included across 18 RCTs examining the co-occurring conditions over a 15-year period.

Since only five studies could be identified that solely focused PTSD and AUD, the remaining 13 explored PTSD, AUD, and other mental health issues (at least 50% of all participants in these studies had PTSD/AUD). The fact that PTSD/AUD has received little research attention is “deeply troubling,” says Reid, adding that the time to act is now since research in this field is just starting to take off.

“Statistically, we feel very confident in being able to draw some conclusions [about equality in trials] based on the methods used,” says Buchanan, adding that a more sophisticated analysis will be possible once more studies have been done. “But if we never get in there to interrupt the processes, then even when we have more studies, they will not be any more diverse and will only exacerbate the problems we found.”

The projects of any given researcher generally get funded for three to five years at a stretch, she explains, and “they have to do it with a similar population and similar methods.” But changes could be made over the short-term that could bring about substantive change—for example, expanding the definition of trauma in studies with military veterans to include not just combat-related trauma but also sexual trauma, which is especially common during combat taking place outside the continental United States.

Another simple but important corrective action researchers might take is to start indicating if their patient sample reflects prevalence rate differences within the broader population, adds Reid. In the latest analysis, “the vast majority of researchers never acknowledged that PTSD and AUD are issues that affects different groups of people at different rates.” The three researchers who made that acknowledgement “homogenized people of color as one group,” ignoring the nuanced differences within the racial category (e.g., Indigenous, Black, and Latine, male or female).

Context Matters

The latest study marks a shift from talking about equity and diversity in terms of potentially useful recruitment tactics to the broader issues impacting RCTs overall, says Buchanan. “Any one individual challenge is a one-off or can be dismissed as a one-off and what we’re showing is there are systemic problems in how we’re doing these clinical trials.”

For RCTs related to the treatment of substance abuse, including AUD, it’s helpful to remember that addictions are still stigmatizing conditions, Buchanan says. In the larger social context of the War on Drugs, the criminalization of drug use has hit communities of color disproportionately hard and that could impact their willingness to participate in studies.

As often referenced in work by her colleague, Monnica Williams, Ph.D., study protocols for psychedelic-assisted therapies need to offer would-be participants reassurance that they are not "clandestine police stings" whereby study enrollment is being used as an arrest mechanism, Buchanan continues. Before signing up for a drug-related study, communities of color need to believe it is a legitimate research project.
This is a genuine concern that can be a limiting factor in the ability to recruit participants, says Buchanan, but is also sometimes easily dismissed "regardless of the fact that there are ways to overcome it." If inclusion is truly the goal, communication efforts must allay fears that an RCT might involve a "carceral police presence."

Societal Implications
Buchanan has spent decades looking at ways to build a more equitable mental health and research equity ecosystem across multiple topics—from "the way we value researchers to the way we value marginalized research topics, to how we design our research, so we invite participation or not," she says. "Another factor we have to consider is that all of us pay our tax dollars into funding agencies that support this kind of work, and we all deserve to benefit from the outcomes of [that], as well as benefit from being participants... [and] knowing that the research involved people like us so that the research is applicable to people like us."

To do otherwise causes "detriment to all of society," she adds, not just black people. "Lower quality, less equitable research impacts all populations throughout the country."

In terms of trauma, it is important also to remember that it is not equally distributed across the population, and neither are the reasons for it, says Buchanan. When people can't get equitable access to care, they are "more likely to turn to substances to manage their symptoms."

As a clinical practitioner, Reid adds, "there is nothing worse than... trying to help somebody through their suffering and feeling as though what you have is inadequate." Patients of his back in New Mexico "lost trust that what I had could be helpful. The human element here that sometimes gets missed ... [is] ... people are suffering a lot."

For Reid, this about "trying to make right a legacy of wrongs" by alleviating the "largely invisible suffering of marginalized groups." Substance abuse was "levied" onto people of color during the Nixon and Reagan administrations due to institutional impoverishment, removal of beneficial resources, and racially fueled narratives about illicit drug use and mass incarcerations of blacks under the guise of the War on Drugs even as the Contra army's war effort in Nicaragua was being aided by cocaine drug sales in the U.S.

It is unusual for community psychologists to also be trained in conducting RCTs, notes Buchanan. But that unique combination is what will help in the pivot from ameliorating symptoms in individuals to preventing disease and promoting wellness across underserved populations of people.

Simple Changes
In the published review, Reid and Buchanan cite several corrective actions for countering systemic biases promoting the under-inclusion of marginalized groups in RCTs. Among these are changes to the design and implementation of studies so they're conducted in areas where more diverse populations can be found, followed by their purposeful recruitment.

The changes being suggested aren't particularly hard, says Buchanan. For example, trials will generally have greater diversity if recruitment is open to the larger community rather than limited to a single clinic.

Moreover, the journals publishing these studies could require statements about diversity, equity, and inclusion (DEI), she says. Among the 14 journals in their analysis, only four openly encouraged authors to consider DEI in their samples.

Particularly concerning was that researchers weren't acknowledging diversity within the prevalence of the issue that they were studying, says Reid. Author groups almost uniformly simplified the definition of prevalence of PTSD/AUD among the general or veteran population. In the one case where prevalence in the general population and women was detailed, variation among different groups of women was ignored and subsequently mostly White women were recruited despite women of color having higher rates of the disorder.

“Systematic under-inclusion of marginalized groups isn’t the fault of the researcher,” stresses Reid. “It’s not a person problem necessarily; I think on the whole researchers want to do this stuff well.”

Because the problem is systemic, it is hidden and “shapes our actions and behaviors without us necessarily recognizing it,” Ried says. Researchers can nonetheless take the simple steps suggested to help “unwind the knots within the system.” Systems science holds that “a system is perfectly designed to produce results that it is already producing”—in the case of RCTs, to under-include marginalized groups.

The likelihood of seeing needed changes enacted would be significantly enhanced if funding agencies were on board to “strengthen the consequences for grants,” says Buchanan. While the National Institutes of Health mandates the inclusion of women and members of racial and ethnic minority groups in all the clinical research it funds, the reality is that it has not made much difference.

As Buchanan sees it, the other major mechanism of change would be more rigorous reporting standards for RCTs. “We might know gender, we might know racial breakdown, but we don’t know how many women of color are included in studies, and we need to know there is systematic differences in the rates of certain types of traumas and in the rate of PTSD and substance abuse. We must start requiring that people give us accurate information... right now, almost everything is masked.”

DEI Pushback

Throughout her entire career, Buchanan says, she has encountered more disinterest than outright resistance to DEI efforts, but she is now witnessing a “sizeable backlash” against such initiatives across fields and domains. While DEI mandates are currently embedded in federal agencies, they are also at the center of heated political battles.

“I fear that we may just be at the cusp of how bad this will get, depending on what the next year looks like, and if we see doctrine that becomes codified in our federal systems where we are not allowed to talk and ask about race and gender differences,” says Buchanan. “If we’re not allowed to create equitable systems, then we are really going to be sending science back [at least] a number of decades ... and there is going to be a real cost to that.”

Untold numbers of women have already been lost because research of heart attacks and its symptoms was for many years done almost exclusively on men, she notes. “You can extrapolate that to virtually every disease and condition that exists because we have systematically excluded women and people of color from most studies.”

In several recent doctoral job interviews, Reid says, he observed that he didn’t get a call back until he changed his phraseology to the more familiar, less politically charged term “health equity” in lieu of “DEI.” This sort of word play has been a feature of public discourse ever since the start of the civil rights movement and, while unsurprising, he is “deeply concerned about the pushback that’s to come over the next four years.”

Generalizable Findings

As practitioners who treat people of color with PTSD and addiction, Reid says, he and Buchanan have been aware for some time that “research into treatments for these disorders often does not produce tools that are applicable to the needs and lives” of those they treat. “Largely, this has been because psychological research has primarily included white people... and mainly investigated issues relevant to their lives and experiences. Because the treatments we have been offered by research have often failed to fit with the lives of those people of color we work with, it was our suspicion that, like psychology research at large, research into treatments for PTSD and AUD likely primarily include white people and investigate issues relevant to their lives.”

The latest study confirms their clinical suspicions and “lays the groundwork for pushing forward a new agenda in PTSD/AUD research—one that includes people of color and centers [on] their needs,” says Reid. Moreover, the findings “highlight significant problems within the fabric of RCTs by revealing that the under-inclusion of people of color is a feature of how RCTs are implemented and governed.”

As Reid explains, researchers generally “conduct research within or near their university, and most universities are in predominately white locales. Further, there are no journals that have established

rules regarding research sample diversity in psychology. Indeed, many journals have implemented DEI statements, yet our study found that DEI statements in journals had no effect on the sample diversity of studies published in said journals."

Consequently, findings of the study can likely be extrapolated to reveal the "hidden elements promoting the broad under-inclusion of people of color in RCTs across disciplines," he says.

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