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Editorial:

Enrollment and adherence of minorities in clinical trials for chronic pain

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Introduction

Clinical research provides scientific evidence to develop new treatments, diagnosis techniques and improve the quality of life of the world's population. However, historically in clinical trials, women and race-ethnic minorities are underrepresented compared to non-Hispanic white men in the United States of America (US) (Vasquez-Avila, et al., 2021). The lack of diversity must be considered when interpreting findings and generalizing them to the entire population because it could affect future studies and clinical decisions (Lee et al., 2016). Therefore, since 1993, NIH has required including women and minority groups in research studies to ensure their rights and gain better healthcare (Raz et al., 2012).

Over the last century, women and race-ethnic minorities have suffered from unethical clinical studies leading to mistrust in the medical community. For instance, in The Tuskegee Syphilis Study, approximately 400 African Americans infected by syphilis were left with no treatment. Also, in several countries, impoverished women were either submitted to compulsory sterilization or tested for contraceptive drugs without their full consent and understanding (Algahtani & Shirah, 2018; Killien et al., 2000). Moreover, for chronic pain management, studies have shown significant discrepancies in the clinical assessment and the prescription of drugs depending on the patient's gender, race, and ethnicity (Swift et al., 2019; Hoffman et al., 2016; Ghoshal et al., 2020). Consequently, some communities are skeptical about clinical studies, and researchers must be aware of this history of social injustice and discrimination before approaching these populations.

When we study patients who suffer from chronic pain conditions, evidence has identified barriers such as scarcity of effective treatments for their needs, lack of access to healthcare, and distrust in clinical trials (Heller et al., 2014). Nevertheless, it is pivotal for researchers to include different populations in their studies because previous data demonstrated that individuals with lower socioeconomic status have fewer treatment options available for managing pain; therefore, they are prone to be treated with opioid prescriptions (Atkins & Mukhida, 2022).

In 2020, a US cross-sectional survey of 481 patients with fibromyalgia, a chronic pain condition predominantly in women, showed that only 10% reported previous randomized clinical trial (RCT) participation, but 80% would likely participate in a future RCT (Cardenas-Rojas et al., 2021). This study also showed that the low-income category is the component of the underrepresented population that most influences participation; other factors include older age, clinical trial awareness from their physician, as well as having an emotional support system.

This review describes barriers and strategies for recruitment and adherence of gender, race, and ethnic minorities to RCTs. We performed a search in the PubMed database for randomized clinical trials in chronic pain with data on recruitment and adherence of minorities due to gender (>80% female) or race/ethnicity (>50% of the sample). We found 73 studies according to the search terms, including 11 eligible according to the criteria in the final table (Table 1).

Initiatives for recruitment

Addressing underrepresented populations is challenging because each community has its necessities and singularities. Bachour et al. (2016) demonstrated that mass mailing, including advertisements on the monthly bill and mailing to patients according to demographics described on research sites, was 13 times more effective in recruiting African American women than clinician referrals that were more effective for white women. This could be related to the lack of trust in the medical field, especially in sensitive conditions such as chronic pain in women with vulvodynia. Patients with fibromyalgia have been stigmatized, given the misunderstanding of the condition and the lack of diagnosis and treatment tools. These patients reported some barriers to recruitment, including the research center's privacy-confidentiality policies and the institution's reputation, while characteristics such as the research staff's friendliness and being able to give a result after their participation could be possible strategies (Cardenas-Rojas et al.; 2021). Therefore, understanding the condition and their needs, and providing an organized and safe environment are essential for minority women.

African American seniors still fear exploitation, and their social vulnerability and research mistrust are still obstacles to enrolling in studies. Strategies such as health care providers, whom patients can relate to and trust, can help with recruitment, as well as local clergy and senior centers, while newspaper advertisements and flyers do not seem to be an effective method (Groupp et al.; 2005). Moreover, tools such as focus groups to identify strategies for recruitment, a cultural adaptation of recruitment material, and providing services in a local community health center could be potential strategies (Janevic et al., 2022). Moreover, the number of sessions could be a potential barrier, as reported by Low et al. 2020 where an 8-week music therapy program had a better enrollment than a 12-week program but no changes in adherence (Low et al., 2020).

Ethnic minorities experience many obstacles when trying to enroll in a research study, such as not being English-native speakers, having a low level of education, and having a low income. The presence of multilingual and trust-worthy staff, the improvement of the researcher's communication skills to approach low-literacy and ethnically diverse patients, the management of a flexible schedule, and the accessibility of minority community centers are strategies to be considered (Anderson et al., 2015; Gardiner et al., 2019; Cardenas-Rojas et al., 2021; Janevic et al., 2022). Also, Damush et al. (2002), observed that despite low income, unemployment, and difficulties with transportation, patients were interested in participating in the trial for the treatment of low back pain. The authors stand that this population has less access to non-pharmacological therapies; therefore, they considered the study intervention more critical than those with more resources.

Table 1. Studies characteristics

Author	Cardenas-Rojas et al. 2021	Groupp et al. 2005(*), Haas M et al. 2005(**)	Joyce et al. 2022(*), Saper et al. 2017 (**)	Gardiner et al. 2019 (**)	Gardiner et al. 2019 (*)	Damush et al. 2005	Bachour et al. 2016	Low et al. 2020	Janevic et al. 2022
Population	Patients with fibromyalgia	Patients 60 or older with chronic low back pain	Patients with chronic non-specific low back pain	Patients with Chronic pain	Patients with Chronic pain	Patients with acute low back pain	Women with vulvodynia	Patients with chronic pain	Patients 60 or older with chronic pain
Site	MA, US	OR, US	MA, US	MA, US	MA, US	IN, US	TN, US	PA, US	MI, US
Groups	(1)aerobic exercise (AE) + tDCS, (2)non-aerobic exercise (nAE) +tDCS, (3)AE+ sham tDCS, (4) nAE+sham tDCS	(1) Chronic Disease Self-Management Program, (2) Waiting list	(1) Yoga, (2) Physical Therapy, (3) Pain education	(1) Integrative Medical Group Visits (IMGV), (2) Usual care	(1) Integrative Medical Group Visits (IMGV), (2) Usual care	(1) Acute low back pain self-management program, (2) Usual care	(1) Extended-release gabapentin, (2) Placebo	(1) Vocal Music therapy, (2) Waitlist-control group	(1) Home-based chronic pain self-management intervention, (2) Control group
Sample size	40 (21 for the survey)	109	320 (26 for the qualitative study)	155	205 eligible	211	219	43	46
Female (%)	87.50%	84.40%	62%	86%	85%	73%	100%	76.70%	89%
Age, mean (SD)	50.2 (11.3)	77.2 (7.7)	46.4 (10.7)	50.5 (12.3)	50 (11.9)	45.5	38.4 (12.8)	50 (13.7)	72.1 (7.2)
African American (%)	12.50%	14.70%	54%	56%	58%	60%	66%	79%	93%
Multi-racial (%)	6.60%		19%	6%				9%	7%
Other non-white race (%)	7.50%		6%	30%	23%			4%	
Hispanic/ Latino (%)	22.50%		14%	14%	15%	1%	1%		
Pain intensity at baseline	6.1 on a 0-10 scale	48.7 on a 100-point scale	7.2 on a 0-10 scale	7 on a 0-10 scale					6.2 on a 0-10 scale
Adherence (%)	62.5% of the randomized patients were adherent.	From the active group: 16% attended all classes, 68% attended at least 3.	44% of the yoga, 36% of the PT, and 44% of the education group adhered to the protocol. During the treatment phase, for the yoga group, a median of 7 classes was attended; for the PT group was seven appointments. Home practice was reported by 75% of yoga participants and 64% of PT participants.	11% did not complete the follow-up assessment at 9 weeks, and 10.5% at 21 weeks. 4 dropouts and 5 lost to follow-up on the active group. 17 control participants did not attend any PCP visits. Patients attended an average of 6 sessions.		28.3% attended at least 1 class, 62.3% received the intervention by mail/telephone/audiotape, and 9.4% received no intervention		77% completed the study. In the intervention group, 41% attended 9 or more sessions out of the 12 sessions. The treatment adherence was better in the pilot study with an 8-week vs. 12-week program (86% of the participants attended seven to eight sessions)	11% were lost-to-follow up or withdrew. Participants completed an average of 5.7 out of 7 sessions. 95% of the intervention group reported watching all the videos.

Table 2. Barriers and Strategies for Recruitment of Minorities in Randomized Clinical Trials

Author	Recruitment Barriers	Recruitment strategies
Janevic et al. 2022		Focus groups identified the most appealing positive activities. The materials included cultural adaptations (colloquial language, race-concordant videos), and cultural values (spirituality, community engagement). For recruitment, they used a registry list from a minority community center.
Joyce et al. 2022(*), Saper et al. 2017 (**)		Patients were recruited from community hospitals. Sources included clinician referrals, mailing letters to patients identified through electronic health records, and flyers in clinics and surrounding neighborhoods.
Low et al. 2020	Related to the protocol: The length of the program (12 weeks)	Participants were recruited from an urban nurse-managed health center in the inner-city with predominance of low-income African Americans.
Bachour et al. 2016	Less Hispanic population given unavailability of Spanish- speaking research staff and the geographic location of the research site	Best method: Mass mailing (paid target advertisement in a monthly bill and direct mailing according to demographic data). Other methods: clinician referrals, the media (fliers, advertisements, news, radio), and community outreach.
Damush et al. 2005		Recruitment strategies included: mailing a recruitment letter to potentially eligible patients with the study description and their physician's recommendation. The patients did not prefer a certain leader (physician, physical therapist, or anyone who had experienced back pain to lead the groups)
Gardiner et al. 2019 (*), Gardiner et al. 2019 (**)	36% scheduling concerns, 18% group activities, other: medical concerns, transportation, childcare, non-English speakers, not trusting personnel with health information, did not like the control group	Provider letters for older patients while younger through self-referral. Recruitment from two federally qualified community clinics covering minorities. The staff was trained to interview low-literacy and low-income racially diverse patients and reflected the study population. Demographic data was assessed monthly.
Groupp et al. 2005(*), Haas M et al. 2005(**)		Best strategy: endorsement of the program to trusted professionals (wellness/fitness directors of senior living facilities, senior centers, YWCA and the clergy). Other successful strategies: Public talks, health fair booths with brochures and a one-one interaction, arrangement of community-based classes, and presentations at program meetings. Unsuccessful: newspaper; Colorful flyers, Listservs.

Initiatives for retention

For a successful treatment, good adherence has always been crucial; however, retention can be affected by many factors such as availability, long distances, transportation, comorbidities, and non-English speakers, among others. Some practical and common ways to address these barriers are financial incentives, trustable and safe environments, multilingual staff, and the relationship with their physicians, who support their commitment to the trial. Historically these methods have been helpful overall in clinical research; thus, we need to consider the type of research being conducted, the disease studied, its epidemiology, and its predominance in the population (Janevic et al., 2017).

Research in chronic pain has limitations regarding adherence or retention, such as disability status, difficulties scheduling or attending sessions due to pain, transportation, other chronic conditions, and psychiatric comorbidities, e.g., depression, and anxiety, among others (Scheer et al., 2022). For example, Cardenas-Rojas et al. (2021) assessed the factors interfering with non-adherence of patients with fibromyalgia, where only 62.5% completed the protocol; they found that a score of 5 or more in the Anxiety visual analog scale, increase the hazard for non-adherence by 5 times; other significant factors included a lower Body Mass Index that could be related to the exercise intervention in the protocol. In another study, Scheer et al. expressed how people from racial and ethnic minorities, specifically black women, and non-Hispanic patients, have reported suffering from higher levels of pain and disability (Scheer et al., 2022), which makes them more prone to drop out from a study and consequently also increases the underrepresentation of minorities in pain studies. On the other hand, Damush et al. (2005) increased adherence to the pain program from 30% to 60% by mailing the materials for the missed classes and following up by phone calls. This supports that future clinical trials in chronic pain should consider a healthy environment, education of the patient, consideration of comorbidities, a flexible schedule, and other options for missed visits.

To address these evident barriers to achieving retention of patients in chronic pain research studies, strategies have been proposed by different authors, such as building a diverse, multilingual research team to establish a relationship between researchers and patients, providing training for research team members in cultural humility, implicit bias and communication strategies, adequate resources and logistics to assure accommodating hours, flexible schedules and transportation (Janevic et al., 2021; Damush et al., 2005).

Future recommendations

To recruit women and minorities in chronic pain, future studies should consider an approachable recruitment and assessment center in the target neighborhood, hiring a research staff that reflects the population, including a bilingual staff for non-English speakers. Also, alliances with community centers, community leaders, e.g., clergy, and participation from the physicians, are potential tools for recruitment and improving the trust in these communities. Some studies have shown that targeting patients according to their condition and demographics through mailing could be a potential tool; therefore, future studies should consider online recruitment tools, including the use of medical registries and emails compliant with privacy policies and new advertisement tools such as online and social media, e.g., GoogleAds, Facebook, Instagram, among others, targeting by the chronic pain condition and through locations as the zip-codes.

For adherence, creative ideas such as the usage of telemedicine, transparency, different types of incentives, not requiring having a citizenship confirmation, more inclusive and comprehensive materials for the subjects, and enabling self-identification via surveys should be revised and considered as well (Gerhards et al., 2011). Moreover, chronic pain could lead to disability and, therefore, lack of adherence to treatment and missing sessions; consequently, future studies should consider a flexible schedule as well as optional delivery modes such as online classes, sending the material to their location, phone calls or online surveys to collect data. However, these ideas still need to be adopted by more researchers and research institutions, clinics, and hospitals to achieve better recruitment and adherence in chronic pain clinical trials. To do so, more resources should be available, and more research needs to be conducted to identify the strategies that work best for this specific population. Furthermore, in this continuously evolving field, better efforts must take place to reassure access to research for women and race-ethnic minorities.

Table 3. Barriers and Strategies for Retention of Minorities in Randomized Clinical Trials

Author	Retention Barriers	Retention Strategies
Janevic et al. 2022	Scheduling sessions, difficulties accessing the website/videos, connectivity issues, and negative feedback on the organization. Non-adherents were younger, with higher pain intensity, worse physical functioning, worse social participation, lower pain self-efficacy, and lower resilience.	Participants received a financial incentive and the option to keep the activity tracker device
Joyce et al. 2022(*), Saper et al. 2017 (**)	For yoga: acceptability (their perceived stereotype of gender and body type), cost, access, or transportation. For the education group: lack of understanding of technical words, language barrier (non-English speakers).	
Low et al. 2020	Reasons for non-adherence or withdrawal: Medical Issues, schedule conflict and loss of contact. Reasons to miss a session included: childcare issues, family emergencies, bad weather, health issues, and travel	
Damush et al. 2005	Patients reported that they were unable to attend because of schedule conflicts and transportation problems. Patients indicated that they would attend a maximum of 4 classes. Patients who attended at least 1 intervention class were more likely to be older, low-income, and less likely to work for pay.	Best strategy: mail the class materials (tapes, handheld audiocassette players, and batteries) to absent patients and follow up by phone. Attend intervention classes at their neighborhood health centers rather than in church or community centers.
Gardiner et al. 2019 (*), Gardiner et al. 2019 (**)	Low-attendance participants had higher pain. Reasons for missing sessions: "too sick or "too much pain to come", lack of transportation, other: death of family/friends, work conflict, lack of child-care, weather, and doctor's appointments. In the control group, those who did not visit their PCP were younger and more depressed, with higher pain scores.	For any men randomized to the active group, the IMGV facilitators should acknowledge their participation in the first session.

(*) Study with the recruitment or retention data (**) Randomized clinical trial.

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