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Disparities in the burden of gastrointestinal diseases: a comprehensive analysis of data from randomized clinical trials from 2000-2023

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Abstract

Background Gastrointestinal (GI) conditions, such as inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), metabolic dysfunction-associated steatotic liver disease (MASLD), and gastroesophageal reflux disease (GERD) are major contributors to morbidity and the healthcare burden. Randomized controlled trials (RCTs) are essential for advancing evidence-based medicine, but disparities in participant recruitment often limit the generalizability of trial findings. This study aimed to investigate demographic disparities in GI-related clinical trials, comparing trial populations to real-world data in order to identify gaps in recruitment.

Methods A cross-sectional analysis was conducted using data from United States RCTs from 2000-2023 that focused on major GI conditions: IBD, IBS, MASLD, and GERD. Demographic variables, including age, sex, gender, race and ethnicity, were collected and compared to real-world data from national health surveys. Descriptive statistics summarized the demographic distribution within the trials and highlighted disparities.

Results The analysis revealed significant disparities in recruitment across multiple GI conditions. Despite the growing burden of chronic diseases in older populations, older adults were underrepresented across trials, as a majority of participants were aged between 18 and 65 years. Sex and gender disparities were also observed, with underrepresentation of females in IBD trials and overrepresentation in IBS and MASLD trials, and no representation of gender diverse individuals. White participants were mostly overrepresented, while Black, Asian, and Hispanic individuals were underrepresented in several trials.

Conclusion This study underscores the need for more inclusive recruitment strategies in clinical trials to ensure diverse representation across age, sex, gender, and race.

Keywords Disparities, gastrointestinal, randomized controlled trial, diversity

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Introduction

Gastrointestinal (GI) conditions are a major public health concern, contributing significantly to patient morbidity and the healthcare burden worldwide [1]. In the United States (US), GI conditions, including inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), metabolic dysfunction-associated steatotic liver disease (MASLD), and gastroesophageal reflux disease (GERD), account for substantial outpatient clinic visits, emergency room visits, hospitalizations and lost productivity [2-5]. Randomized controlled trials (RCTs) are critical in developing novel therapies and assessing their efficacy and safety to advance evidence-based approaches in treating GI conditions. However, disparities in patient

recruitment remain a significant challenge, limiting the generalizability of RCT results [6]. Recruitment in RCTs often fails to reflect the demographic and epidemiological diversity of the real-world population [7]. These disparities include underrepresentation by age, sex, gender, race, ethnicity, and socioeconomic background, which may bias clinical outcomes and result in unequal access to research [8].

The importance of addressing these disparities further underscores the growing prevalence of GI diseases across different demographic groups [9,10]. Conditions like IBS and GERD are highly prevalent in females, while other disorders, such as pancreatitis, are more common among certain racial and ethnic groups [11-13]. Therefore, inclusive recruitment is essential to ensure that clinical trial findings are applicable to all population groups affected by these conditions.

This study aimed to investigate the demographic disparities in patient recruitment for RCTs focused on GI conditions in the US. Using data from multiple GI-related RCTs, we assessed the age, sex, race and ethnicity distribution of participants across trials for key GI conditions. The goal was to provide insight into how well these trials align with the demographic profile of patients affected by these diseases in the real world, thereby identifying gaps in current recruitment practices. When trial demographics do not mirror those of the populations most affected by the disease, it undermines the relevance of the trial outcomes and may perpetuate ineffective or inequitable care. This manuscript presents a comprehensive analysis of disparities across key GI conditions, including IBD, IBS, MASLD, and GERD. We herein assess patient demographics across these diseases to highlight the extent of disparities in clinical trials and propose strategies to enhance inclusive research practices.

Materials and methods

We conducted a cross-sectional analysis of RCTs focused on GI diseases to investigate disparities in participant recruitment. Data were extracted from publicly accessible clinical trial registry: ClinicalTrials.gov. This study evaluated demographic trends across trials focusing on IBD, IBS, MASLD, and GERD. Although this study was not conducted as a formal systematic review, we implemented a structured and reproducible search strategy to identify relevant trials from ClinicalTrials.gov. We used disease-specific terms, including "gastrointestinal", "colorectal", "pancreatic", "hepatocellular", "gastric", "inflammatory bowel disease", "irritable bowel syndrome", "nonalcoholic fatty liver disease", "metabolic dysfunction-associated steatotic liver disease", and "gastroesophageal reflux disease". Eligible trials were limited to phase 2-4 studies that were either actively recruiting or completed between 2000 and 2023. Trials without available results or lacking demographic reporting were excluded. Variables such as trial phase, number of participating sites and industry sponsorship were not uniformly reported and were therefore not included in the final analysis.

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Study design

The analysis included RCTs that provided any demographic data, such as age, sex, race and ethnicity, to ensure comprehensive reporting. This approach allowed for an evaluation of participant representation across different GI diseases and recruitment trends during the study period. The inclusion of multiple GI conditions ensured that the findings could provide insights into a wide spectrum of diseases, each with its own unique demographic and clinical characteristics. Data management and handling adhered to privacy regulations, as no patient-identifiable information was included. Since only publicly available data were analyzed, institutional review board approval was not required.

Data sources and variables

The key variables collected from each trial included age, sex, race and ethnicity. Age was grouped into three categories: under 18 years, 18-65 years, and over 65 years, to reflect clinical relevance and differences in disease burden across the lifespan. The sex distribution of trial participants was reported as the proportion of male and female participants. Race was categorized into standard clinical classifications, including White, Black or African American, Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, multiple races, and other races. Ethnicity was recorded as Hispanic or Latino, non-Hispanic or Latino, or unknown.

Each trial was also identified by the specific GI disease studied, and the size of the recruited population, to explore whether certain diseases were associated with greater disparities in recruitment. Collecting detailed demographic data allowed us to identify patterns of underrepresentation, providing a comprehensive view of the inclusiveness of GI-focused RCTs.

Real-world data comparisons

We compared the demographic data from RCTs focused on IBD, IBS, MASLD, and GERD with real-world data sources to assess disparities in participant representation. For IBD, we utilized data from the National Health Interview Survey (NHIS) conducted in 2015 [14]. IBS demographics were compared with findings from the study titled: "Prevalence and Burden of Illness of Rome IV Irritable Bowel Syndrome in the United States: Results from a Nationwide Cross-Sectional Study" [15]. MASLD data were drawn from the National Health and Nutrition

Examination Survey (NHANES) 2017-2018 [16]. GERD data were compared with real-world data reported in the following study: "Prevalence of Gastroesophageal Reflux Disease and Proton Pump Inhibitor-Refractory Symptoms" [17]. This comparison allowed us to identify potential discrepancies in the demographic composition of clinical trial participants relative to the general population affected by these diseases. However, each comparator study had inherent limitations, including variability in sampling strategy, data collection methods and population representativeness. These limitations may have affected the precision and applicability of the comparisons drawn.

Statistical analysis

Descriptive statistical methods were employed to summarize the demographic characteristics of trial participants. Continuous variables, such as age, were presented as means, while categorical variables, such as sex, race and ethnicity, were reported as proportions. We intentionally focused on descriptive rather than inferential statistics, as our primary objective was to identify broad patterns and clinically meaningful disparities in demographic representation, rather than detect small differences that might be statistically significant yet clinically negligible. Highlighting clinically relevant disparities without overinterpreting marginal statistical variation aligned with our intent to inform future trial design. All statistical analyses were performed using JMP version 17 (SAS Institute Inc.).

Results

IBD

A total of 151 IBD trials conducted in the US were included, comprising 69 trials focused on Crohn's disease, 73 on ulcerative colitis, and 9 covering both conditions (Table 1). These trials enrolled 52,975 participants, with a mean age of 31.0 years across all trials, 13.3 years for pediatric-focused trials, and 35.7 years for adult-focused trials. Among those reporting age categories, 93% of participants were between 18 and 65 years, and 5.7% were above 65 years, compared to 26% of patients with IBD over 65 years in real-world data (Fig. 1A). Female participants made up 36.7% of the trial populations, compared to 57.4% in the general IBD population (Fig. 1B). In terms of race, 84.9% of participants were White compared to 88.8% in real-world data, 2.7% were Black compared to 5.1%, and the combined representation of Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, and individuals of multiple races was less than 1% (Fig. 1C). Regarding ethnicity, 86% of participants identified as non-Hispanic and 5% as Hispanic, compared to 12.8% in the general population, with the remaining participants having undocumented or unknown ethnicity (Fig. 1D).

Table 1 Age, sex, race and ethnicity distribution of GI conditions in RCTs localized in the US

Chronic disease	IBD	IBS	MASLD	GERD
Number of trials	151	79	72	85
Total participants	52975	28746	7816	22656
Age				
Mean age	35.7	43.1	50.2	39.9
<18, years (%)	1.3	0.5	14.5	36.9
18-65, years (%)	93.0	92.0	75.9	57.7
>65, years (%)	5.7	8.0	10.6	5.4
Sex (%)				
Female	37	77	54	55
Male	63	23	46	45
Race (%)				
White	84.0	75.0	84.9	84.1
Black	3.0	21.0	4.4	9.0
Asian	9.9	0.30	5.5	3.1
Native Hawaiian	0.01	0.1	0.3	0.1
American Indian	0.02	0.1	0.4	0.7
More than one race	0.2	0.4	0.5	1.3
Other race	0.2	1.5	0.5	0.9
Unknown race	3.9	0.3	0.5	0.7
Ethnicity (%)				
Hispanic	5.0	24.0	36.0	15.7
Non-Hispanic	86.0	76.0	64.1	83.4
Unknown	9.0	0	0	0.01

GI, gastrointestinal; RCTs, randomized controlled trials; IBD, inflammatory bowel disease; IBS, irritable bowel syndrome; MASLD, metabolic dysfunction-associated steatotic liver disease; GERD, gastroesophageal reflux disease

IBS

Seventy-nine IBS trials conducted in the US were included, enrolling 28,746 participants with a mean age of 43.1 years and a standard deviation of 12 years (Table 1). Among those reporting age categories, 92% of participants were between 18 and 65 years, and 8% were above 65 years, compared to 12% of patients with IBS over 60 years in real-world data (Fig. 2A). Female participants constituted 77% of the trial population, compared to 63% in real-world data, indicating a slight overrepresentation of females in trials (Fig. 2B). In terms of race, 75% of participants were White compared to 51% in real-world data, 21% were Black compared to 15%, and Asian participants represented only 0.3% in trials, far below the 16% in real-world data (Fig. 2C). Regarding ethnicity, 24% of trial participants identified as Hispanic compared to 21% in the general population, and 76% were non-Hispanic, noticeably higher than the 61% observed in real-world data (Fig. 2D).

MASLD

Seventy-two MASLD trials conducted in the US were included, enrolling 7816 participants with a mean age of 50.2 years and a standard deviation of 11 years (Table 1). Among those reporting age categories, 76% of participants were between 18 and 65 years, and 11% were above 65 years,

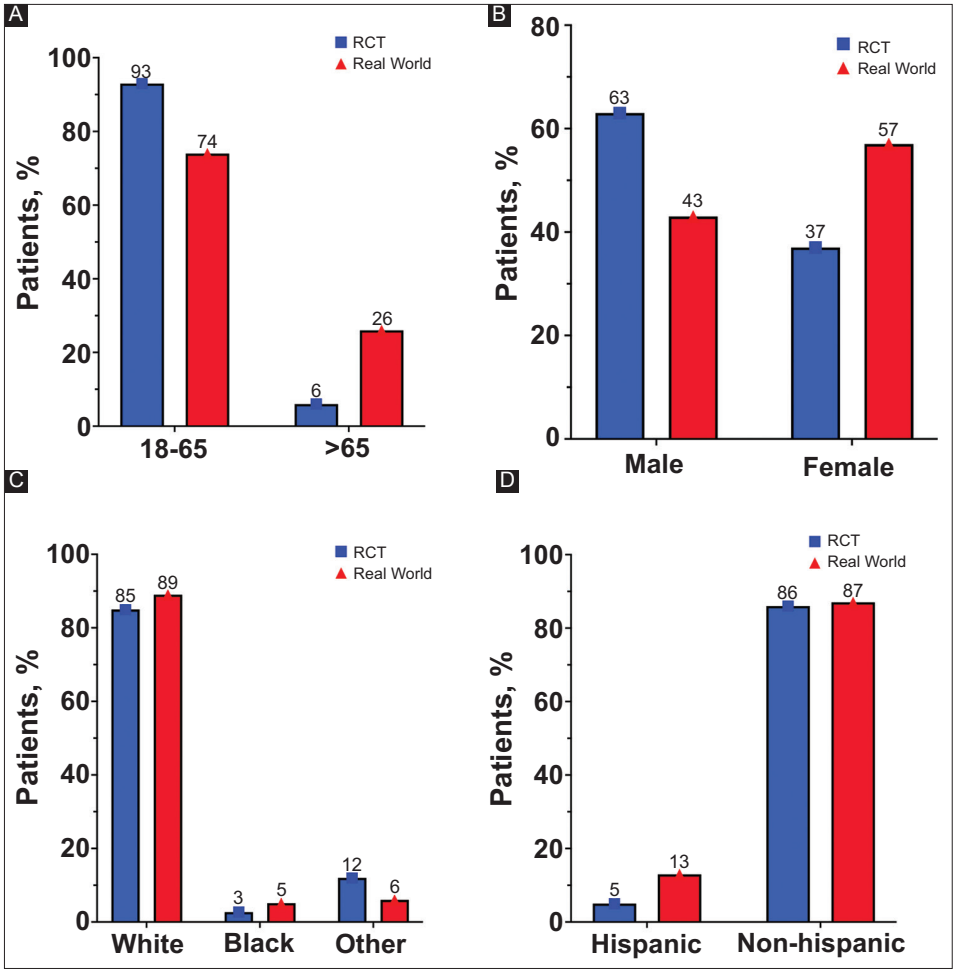

Figure 1 Demographic distribution of inflammatory bowel disease in randomized controlled trials (RCT) and real-world data

compared to 26% of patients with MASLD over 65 years in real-world data (Fig. 3A). Female participants constituted 54% of the trial populations, compared to 32% in the real-world data, indicating an overrepresentation of females in these trials (Fig. 3B). In terms of race, 85% of trial participants were White compared to 86% in the real-world data, 4% were Black compared to 8%, and 6% were Asian compared to 3% (Fig. 3C). Regarding ethnicity, 36% of participants in trials were Hispanic compared to 18.53% in real-world data, while 64.1% were non-Hispanic compared to 78.65% in real-world data (Fig. 3D).

GERD

Eighty-five GERD trials conducted in the US were included, enrolling 22,656 participants with a mean age of 39.9 years and a standard deviation of 9.9 years (Table 1). Real-world data for the <18 age group are not available, limiting direct comparison by age. Among those reporting age categories, 57.7% of trial participants were between 18 and 65 years, and 5% were above 65 years, compared to 82% and 18%, respectively, in real-world data (Fig. 4A). Female participants constituted 55% of the trial population, compared to 63% in real-world data (Fig. 4B). In terms of race, 84% of trial participants were White, compared to 77% in real-world data. Black participants made up 9% of trials compared to 6%, while Asian participants constituted 3% of trials, aligning closely with the 4% seen in real-world data. Other racial groups were 2.99% in real-world data compared to smaller proportions reported in trials (Fig. 4C). Regarding ethnicity, 16% of trial participants identified as Hispanic, compared to 11% in real-world data, while non-Hispanic participants constituted 83% in trials compared to 80% in real-world data (Fig. 4D).

Discussion

This study highlights significant disparities in demographic representation between clinical trials and real-world populations across multiple conditions: IBD, IBS, MASLD, and GERD. For example, MASLD disproportionately affects Hispanic adults and individuals with cardiometabolic risk factors, whereas IBS shows a female predominance. GERD is highly prevalent across all demographic groups, including older adults. Understanding these epidemiologic distinctions

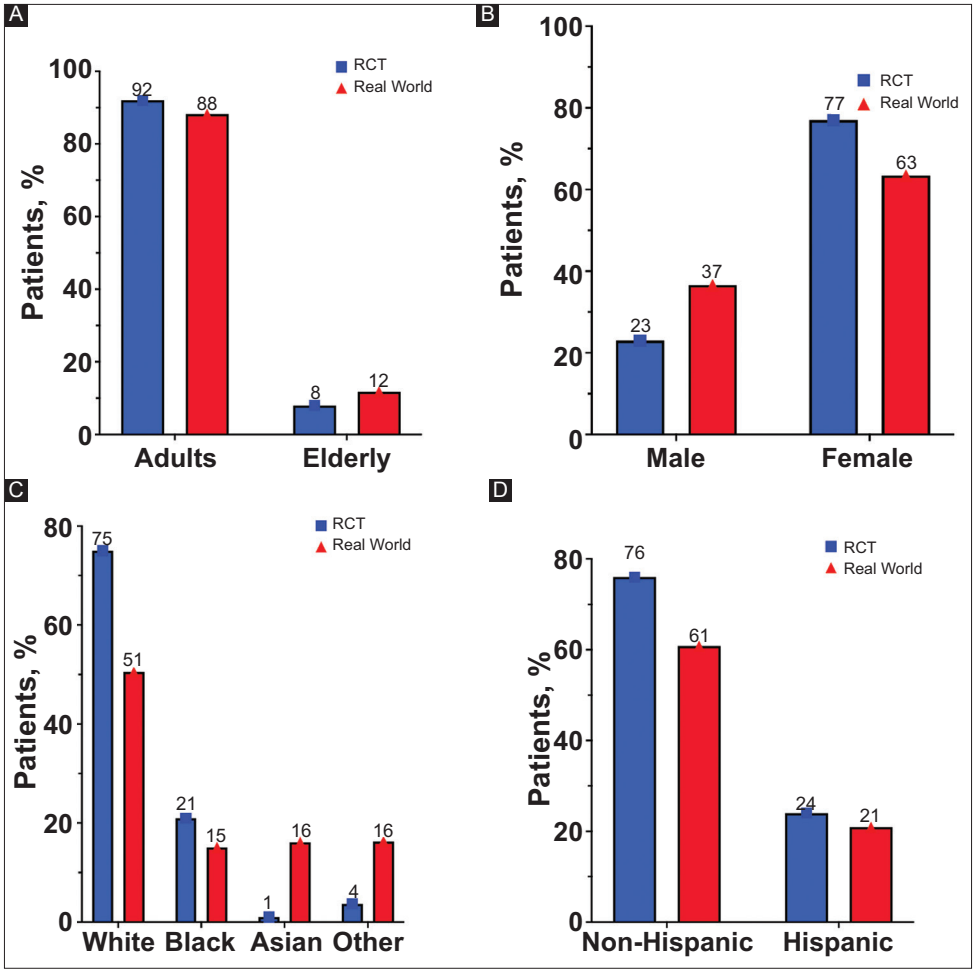

Figure 2 Demographic distribution of irritable bowel syndrome in randomized controlled trials (RCT) and real-world data

is critical when evaluating representativeness in clinical trials. Despite differences in disease characteristics, we observed several common trends: overrepresentation of younger adults and White participants, and inconsistent representation across sex and gender. These findings emphasize the need for condition-specific recruitment strategies that reflect real-world populations and disease patterns to improve generalizability of trial results.

Clinical trials across IBD, IBS, MASLD, and GERD reveal a consistent underrepresentation of older adults compared to real-world populations. This disparity is critical, as older adults often present with distinct disease trajectories, comorbidities and responses to treatment, which may not be fully captured in trial data [18-20]. The exclusion or limited enrollment of older individuals raises questions about the applicability of trial outcomes to a growing segment of the population. As chronic diseases become increasingly prevalent with age [21], ensuring adequate representation of older adults in clinical trials is essential to develop effective and inclusive treatment strategies. This is particularly concerning in GERD and MASLD, which are more prevalent in older populations, often accompanied by complex comorbidities and polypharmacy. Addressing these gaps requires deliberate recruitment efforts, including tailored eligibility criteria and targeted outreach, to ensure that research findings are both relevant and comprehensive for all age groups.

Sex disparities were apparent across the trials, with notable differences between trial populations and real-world data. Some trials, such as those for IBD, underrepresented female participants, suggesting possible recruitment barriers or eligibility criteria that may have contributed to the exclusion of females. By incorporating appropriate frameworks into trial designs, involving more females in leadership roles within clinical trial committees, and engaging female patients in discussions about trial planning, researchers will be better positioned to address some of the prevalent sex disparities [22]. In contrast, the conditions IBS and MASLD exhibited an overrepresentation of female participants, which may reflect either disease prevalence patterns or recruitment practices that favor females. These imbalances raise concerns about potential sex-related biases in clinical trial design and participant recruitment.

Additionally, RCTs rarely collect data on gender identity and sex assigned at birth. This results in a lack of representation of all genders in clinical trials. In consequence, we lack knowledge of the impact of certain therapies on individuals

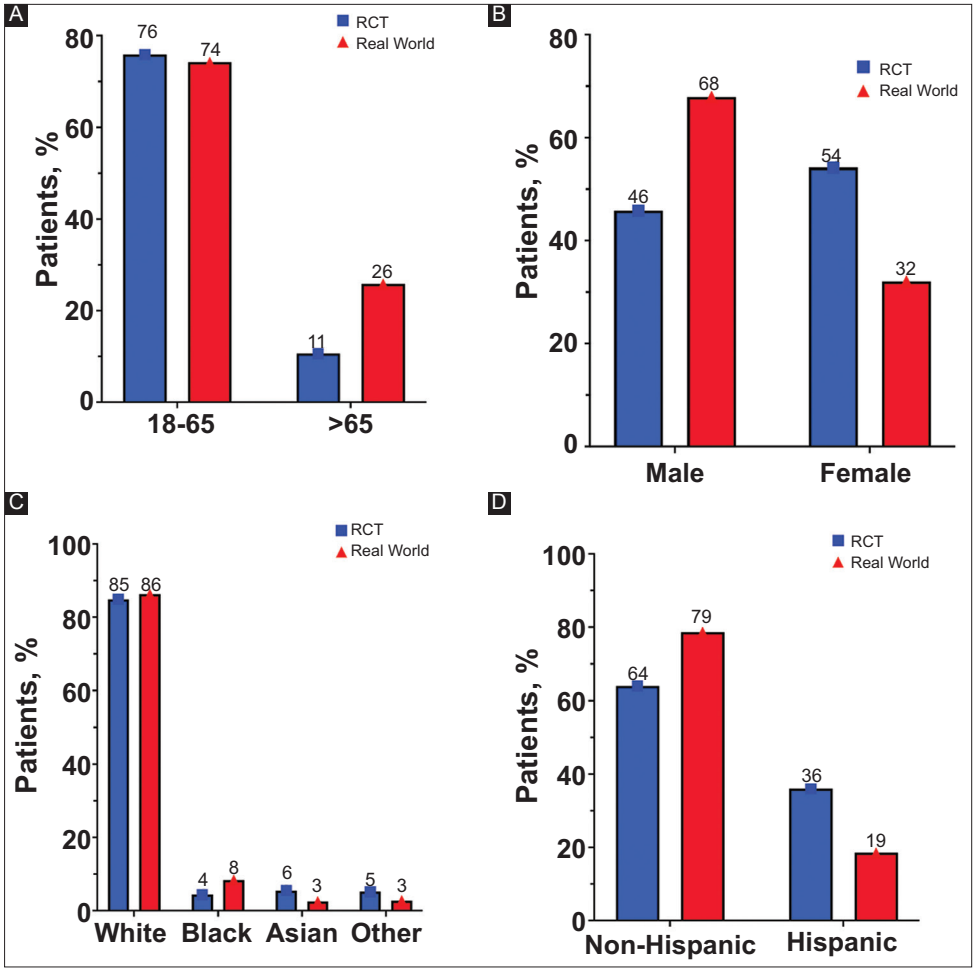

Figure 3 Demographic distribution of metabolic dysfunction-associated steatotic liver disease in randomized controlled trials (RCT) and real-world data

who are on gender affirming therapies, such as transgender and gender non-conforming individuals. Without balanced representation, the generalizability of findings to all genders may be limited, potentially leading to gaps in understanding gender-specific disease presentations, treatment responses and outcomes. Such disparities are not unique to these conditions, but have also been observed across other areas of medicine, highlighting a broader, systemic limitation in clinical trial design and execution [23-25]. Moving forward, clinical trials must adopt more inclusive recruitment strategies to ensure that all genders are adequately represented, providing more robust and applicable evidence for patient care.

Across all conditions examined, clinical trials mostly overrepresented White participants, while underrepresenting individuals from other racial and ethnic backgrounds. Black and Asian participants were particularly underrepresented, limiting the applicability of trial findings to these populations. Although Hispanic participation showed some variability, there were still notable gaps, especially for certain conditions, such as IBD. These disparities underscore the need to dismantle barriers to participation, such as mistrust in the medical system, logistical challenges, and restrictive eligibility criteria [26].

Strategies to improve the under-representation of the Hispanic population include deploying culturally tailored educational tools, such as patient videos and printed materials, to foster trust and enhance understanding among Hispanic communities [26]. Additionally, engaging with community stakeholders and developing social networks help facilitate outreach efforts by creating connections with minority organizations and healthcare providers; patient navigation programs, which offer personalized support and care coordination, have proven valuable in overcoming logistical and emotional barriers faced by Hispanic participants [26,27]. Incorporating social media and digital tools, such as targeted messaging through social media platforms, can further promote awareness and interest in RCTs among hard-to-reach populations [26]. Engaging healthcare providers and including Hispanic representatives within medical teams, also play a crucial role in addressing implicit biases and building patient trust [27].

To enhance Black and Asian participation in clinical trials, researchers should focus on cultural competence, ensuring staff are trained in culturally aware communication and able to engage participants respectfully [28,29]. Collaborating with trusted community leaders and organizations can

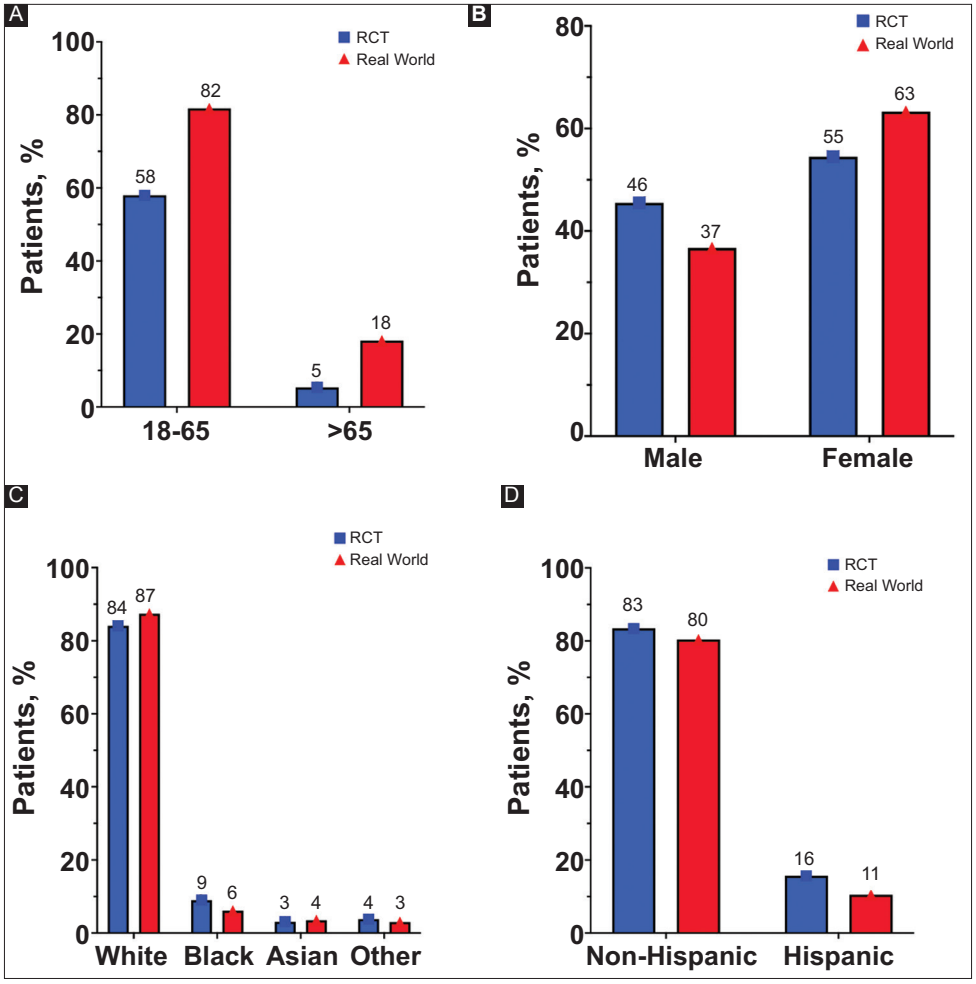

Figure 4 Demographic distribution of gastroesophageal reflux disease in randomized controlled trials (RCT) and real-world data

foster trust and facilitate outreach [28]. In case of language barriers, offering language support through bilingual staff or translated materials may be essential [28]. Providing practical support, such as transportation and covering expenses, along with involving community members in study design, ensures the research aligns with their needs and encourages participation [28,29].

This study offers a comprehensive examination of demographic disparities across a range of GI and metabolic conditions, drawing on both clinical trial and real-world data to highlight critical gaps in representation. However, relying solely on published trial data constrains the ability to investigate other influential factors, such as socioeconomic status, health literacy and comorbidities, which may impact trial participation and outcomes. Furthermore, incomplete reporting of demographic information across some trials introduces potential biases, limiting the depth and precision of the analysis. While real-world data help to bridge some of these gaps, missing data points and inconsistencies in data collection methods remain limitations. Additionally, while Crohn's disease and ulcerative colitis exhibit distinct demographic patterns, most RCTs in our dataset did not disaggregate participants by IBD subtype. Therefore, we retained IBD as a combined category. We recognize this as a valid limitation and highlight the need for future studies to examine Crohn's disease and ulcerative colitis separately. Similarly, while we collected age data in three categories (<18, 18-65, and >65 years), pediatric representation was minimal, and many included trials that either excluded pediatric populations or did not report them separately. For this reason, the <18 age group was not analyzed in depth. This exclusion limits the generalizability of our findings to pediatric populations. In addition, while the study aimed to capture trends over time in demographic representation, the lack of consistent year-by-year demographic reporting and inconsistent documentation of trial phases across published trials limited our ability to perform stratified temporal or phase-based analyses. Future research leveraging harmonized, or registry-level datasets may enable more granular assessments of how demographic inclusion has evolved over time.

In conclusion, this study highlights significant disparities in demographic representation between clinical trials and real-world populations across multiple GI and metabolic conditions. The underrepresentation of older adults, racial

and ethnic minorities, and, in some cases, females, limits the generalizability of trial findings. Addressing these gaps requires targeted recruitment strategies, inclusive eligibility criteria, and the integration of real-world data, to ensure that clinical research reflects the diversity of affected populations. Promoting more inclusive trials is essential for improving the applicability of evidence-based treatments and optimizing patient outcomes.

Summary Box

What is already known:

- Underrepresentation in gastrointestinal (GI) trials may bias outcomes and limit generalizability
- Prior studies have noted disparities in specific GI conditions, but comprehensive analysis is lacking
- Real-world demographic comparisons are critical to evaluating clinical trial inclusivity

What the new findings are:

- Older adults, racial and ethnic minorities, and gender-diverse individuals are underrepresented in GI randomized controlled trials
- Irritable bowel syndrome (IBS) and metabolic dysfunction-associated steatotic liver disease (MASLD) trials over-represent women, while inflammatory bowel disease (IBD) trials underrepresent them
- Black and Asian participants are markedly underrepresented across most GI trials studied
- This is the first study to systematically compare demographic data from GI trials to real-world data across IBD, IBS, MASLD, and gastroesophageal reflux disease

References

1. Chan JSH, Chao ACW, Cheung VCH, et al. Gastrointestinal disease burden and mortality: a public hospital-based study from 2005 to 2014. *J Gastroenterol Hepatol* 2019;**34**:124-131.
2. Buie MJ, Quan J, Windsor JW, et al; Global IBD Visualization of Epidemiology Studies in the 21st Century (GIVES-21) Research Group. Global hospitalization trends for Crohn's disease and ulcerative colitis in the 21st century: a systematic review with temporal analyses. *Clin Gastroenterol Hepatol* 2023;**21**:2211-2221.
3. Adejumo AC, Samuel GO, Adegbala OM, et al. Prevalence, trends, outcomes, and disparities in hospitalizations for nonalcoholic fatty liver disease in the United States. *Ann Gastroenterol* 2019;**32**:504-513.
4. Gross M, Beckenbauer U, Burkowitz J, Walther H, Brueggenjuergen B. Impact of gastro-oesophageal reflux disease on work productivity despite therapy with proton pump inhibitors in Germany. *Eur J Med Res* 2010;**15**:124-130.
5. Frändemark Å, Törnblom H, Jakobsson S, Simrén M. Work productivity and activity impairment in irritable bowel syndrome (IBS): a multifaceted problem. *Am J Gastroenterol* 2018;**113**:1540-1549.
6. Czwikla J, Herzberg A, Kapp S, et al. Generalizability and reach of a randomized controlled trial to improve oral health among home care recipients: comparing participants and nonparticipants at baseline and during follow-up. *Trials* 2022;**23**:560.
7. Ghusn W, Mosleh KA, Hage K, et al. A comprehensive analysis of health care Inequities in randomized clinical trials following bariatric surgeries. *Am J Surg* 2024;**237**:115796.
8. Stuart EA, Bradshaw CP, Leaf PJ. Assessing the generalizability of randomized trial results to target populations. *Prev Sci* 2015;**16**:475-485.
9. Sperber AD, Bangdiwala SI, Drossman DA, et al. Worldwide prevalence and burden of functional gastrointestinal disorders, results of Rome Foundation Global Study. *Gastroenterology* 2021;**160**:99-114.
10. Wang R, Li Z, Liu S, Zhang D. Global, regional, and national burden of 10 digestive diseases in 204 countries and territories from 1990 to 2019. *Front Public Health* 2023;**11**:1061453.
11. Lovell RM, Ford AC. Effect of gender on prevalence of irritable bowel syndrome in the community: systematic review and meta-analysis. *Am J Gastroenterol* 2012;**107**:991-1000.
12. Kim YS, Kim N, Kim GH. Sex and gender differences in gastroesophageal reflux disease. *J Neurogastroenterol Motil* 2016;**22**:575-588.
13. Wilcox CM, Sandhu BS, Singh V, et al. Racial differences in the clinical profile, causes, and outcome of chronic pancreatitis. *Am J Gastroenterol* 2016;**111**:1488-1496.
14. Dahlhamer JM, Zammitti EP, Ward BW, Wheaton AG, Croft JB. Prevalence of inflammatory bowel disease among adults aged ≥18 years - United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;**65**:1166-1169.
15. Almario CV, Sharabi E, Chey WD, Lauzon M, Higgins CS, Spiegel BMR. Prevalence and burden of illness of Rome IV irritable bowel syndrome in the United States: results from a nationwide cross-sectional study. *Gastroenterology* 2023;**165**:1475-1487.
16. Wang T, Xi Y, Raji A, et al. Overall and subgroup prevalence of non-alcoholic fatty liver disease and prevalence of advanced fibrosis in the United States: an updated national estimate in National Health and Nutrition Examination Survey (NHANES) 2011-2018. *Ann Hepatol* 2024;**29**:101154.
17. Delshad SD, Almario CV, Chey WD, Spiegel BMR. Prevalence of gastroesophageal reflux disease and proton pump inhibitor-refractory symptoms. *Gastroenterology* 2020;**158**:1250-1261.
18. Amblàs-Novellas J, Murray SA, Oller R, et al. Frailty degree and illness trajectories in older people towards the end-of-life: a prospective observational study. *BMJ Open* 2021;**11**:e042645.
19. Xiang Z, Wang H, Li H. Comorbidity risk and distribution characteristics of chronic diseases in the elderly population in China. *BMC Public Health* 2024;**24**:360.
20. Noble RE. Drug therapy in the elderly. *Metabolism* 2003;**52**:27-30.
21. Barrio-Cortes J, Castaño-Reguillo A, Beca-Martínez MT, Bandeira-de Oliveira M, López-Rodríguez C, Jaime-Sisó M. Chronic diseases in the geriatric population: morbidity and use of primary care services according to risk level. *BMC Geriatr* 2021;**21**:278.
22. van Diemen J, Verdonk P, Chieffo A, et al. The importance of achieving sex- and gender-based equity in clinical trials: a call to action. *Eur Heart J* 2021;**42**:2990-2994.
23. Dymanus KA, Butaney M, Magee DE, et al. Assessment of gender representation in clinical trials leading to FDA approval for oncology therapeutics between 2014 and 2019: A systematic review-based cohort study. *Cancer* 2021;**127**:3156-3162.
24. Cifuentes L, Ghusn W, Jijon D, et al. Tu1032 Examining demographic disparities in recruitment for clinical trials among adults with overweight and obesity treated with GLP-1 RA or

dual GIP and GLP-1 RA: a comprehensive systematic review. *Gastroenterology* 2024;166 Suppl: S-1230-S-1231.
25. Gala K, Ghusn W, Tariq R, Abu Dayyeh BK, Chedid V. Demographic disparities in recruitment for clinical trials focused on endoscopic bariatric therapies. *Obes Surg* 2023;**33**:3699-3702.
26. Ramirez AG, Chalela P. Equitable representation of Latinos in clinical research is needed to achieve health equity in cancer care. *JCO Oncol Pract* 2022;**18**:e797-e804.
27. Dreyfus B, Kuri L, Ferri M, et al. Understanding Hispanic/Latino participation in clinical trials and observational studies, and strategies to increase participation: a targeted literature review. *J Health Care Poor Underserved* 2023;**34**:399-424.
28. Farooqi A, Jutlla K, Raghavan R, et al. Developing a toolkit for increasing the participation of black, Asian and minority ethnic communities in health and social care research. *BMC Med Res Methodol* 2022;**22**:17.
29. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health* 2014;**104**:e16-e31.