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Research Involvement
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REVIEW **Open Access**

A meta-review of patient engagement, shared decision-making, and factors influencing equity-deserving populations' participation in clinical trials

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Abstract

Background Many equity-deserving populations, including those facing structural health inequities, lack support to participate in clinical trials while facing barriers to participation. Two approaches—patient engagement (PE) and shared decision-making (SDM)—can help trialists better understand and address such barriers. PE can improve the relevance of trials to silenced communities while SDM can align participation decisions among socially disadvantaged groups with their values, needs, and preferences, which may help overcome health inequities. Further, Indigenous community engagement is vital to address the effects of colonialism and promote Indigenous self-determination and health equity. The extent to which existing reviews have identified common barriers, enablers, and strategies across equity-deserving groups and discussed PE and SDM concepts is unclear.

Purpose (1) To describe which equity-deserving populations have been the focus of reviews on clinical trial participation and which barriers, enablers, and strategies are relevant to them (2) to explore the extent to which PE and SDM are discussed in these reviews.

Methods We searched for English-language reviews (including any study design) summarizing trial participation barriers, enablers, and/or strategies among equity-deserving populations in five peer-reviewed databases. We coded data on the (1) equity-deserving population(s) of focus, (2) barriers, enablers, or interventions/strategies mentioned, (3) PE reported, (4) Indigenous community engagement reported, and (5) SDM outcomes discussed.

Results Findings from 100 reviews showed that some equity-deserving populations have been represented more than others (e.g., 76% on racially, ethnically, culturally, or linguistically diverse populations; 29% on sex and gender populations; 2% on educationally disadvantaged populations). More reviews described barriers (84%) than enablers (31%) or strategies to improve participation (69%). Forty-five reviews (45%) reported PE while 11 (11%) reported

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Indigenous community engagement. Many reviews (74%) mentioned SDM outcomes (i.e., 9/11 [81.8%] outcomes from Gillies et al.'s internationally agreed core outcome set); however, few reviews (29%) discussed SDM outcomes in detail.

Conclusions Our findings suggest that PE and SDM could be more broadly applied among multiple equity-deserving groups to better serve disadvantaged communities. We advocate for an expanded focus on less-researched equity-deserving groups, improved PE reporting, prioritization of patient outcomes, and engagement with patients and Indigenous communities.

Plain English summary

Background Many equity-deserving groups, such as people who experience structural barriers to health, face challenges with participating in clinical trials. These challenges can come from different levels, like personal, organizational, or system-wide barriers. Two approaches to support more inclusive participation are patient engagement (PE), i.e., working in partnership with patients and communities throughout the research process, and shared decision-making (SDM), i.e., helping people make informed choices that reflect their values and needs.

Methods We conducted a review of reviews about equity-deserving groups participating in trials. We searched five scientific databases for published reviews in English. We coded data from the reviews using several established frameworks to see what helps or prevents equity-deserving groups from joining trials and how often PE and SDM were part of those studies.

Results Of 100 reviews examined, most focused on racial, ethnic, cultural, or language diversity (76%) and sex or gender (29%). Few focused on education level (2%). Many reviews described barriers (84%), but fewer mentioned enablers (31%) or strategies (69%) to improve participation. Under half of reviews (45%) mentioned PE, 11 (11%) mentioned Indigenous community engagement. Many reviews mentioned SDM (74%), but few went into detail (29%).

Conclusions Our results shows that some equity-deserving groups have been included in research about trial participation more than others. We recommend future research incorporate patient and community engagement, report it better, and focus on SDM to make trials even more inclusive.

Keywords Patient and public involvement, Community engagement, Indigenous engagement, Equity, Diversity, Inclusion, Underserved population, Equity-deserving population, Barriers, Enablers, Strategies, Shared decision-making

Background

For clinical trial evidence to generalize to the population broadly and advance health equity, participation by diverse individuals is needed [1]. However, research has generally established that clinical trials do not adequately support participation among many equity-deserving populations [2–4]. Equity-deserving populations are those who face structural health inequities, have been historically marginalized, or are at risk for social disadvantage based on their membership in one or more social group, including sexual and gender diverse persons, racialized groups, and persons with disabilities [5]. Research has reported common barriers to trial participation among equity-deserving populations, such as never being asked to participate among Black and Latinx persons [6, 7] and rigid or conflated language around sex and gender variables among sexual and gender diverse persons [8]. In two systematic reviews, less than 5% of clinical trials were found to report any engagement with patients (referred to as consumers in some parts of the world), caregivers, or families in designing or conducting the trial [9, 10]. Trial inclusivity has been named as one of the top 10 priorities in trial recruitment [11], with many reviews highlighting trial participation challenges among equity-deserving populations [12–14]. Some reviews have also described social factors influencing health equity [15] or have assessed the positive impact of considering patient and community priorities on recruitment and retention [12, 13]. However, we currently lack a broader sense of the factors relating to a range of equity-deserving populations and how their input, preferences, needs, and values can be better inform trial design and conduct.

Understanding whose perspectives have been highlighted in the literature can help clarify what evidence has accrued and where further evidence is needed. Trial participation among equity-deserving groups is complex due to intersectionality, where one's various social characteristics (e.g., age, race, gender) overlap, which creates unique experiences of disadvantage and inequity [16]. Equity-deserving populations face a range of barriers and enablers to participating in trials, and these exist at multiple levels (e.g., individual, organizational, systemic) [16, 17]. Examining these complex, multi-level factors among different equity-deserving populations, and what strategies have been used to support their participation, can guide efforts to advance equity, diversity, and inclusion

(EDI) in clinical trials broadly compared to investigating a single equity-deserving population.

Three other areas have been shown to help advance EDI considerations in clinical trials and other areas (e.g., community-academic partnerships [18]). First, patient engagement (PE) is the meaningful and ongoing collaboration with individuals who have personal experience with a health issue, as well as caregivers, families, and friends throughout all research stages as research partners rather than as research participants [19] (also sometimes termed patient and public involvement [20], consumer engagement [21], or community-based participatory research [12]). PE has been shown to improve the feasibility, acceptability, relevance, and transparency of clinical trials and health care decision-making for patients and communities, with growing evidence supporting these outcomes [22, 23]. Meta-analyses show that PE significantly increases the odds of clinical trial enrollment compared to no PE, including among equity-deserving populations such as Black and Latinx communities [24]. Including diverse perspectives, via engaging with a diversity of equity-deserving individuals and lived experiences, is central to PE [25]. Equity-deserving populations face poorer health outcomes and greater gaps in care than less socially disadvantaged populations [26] yet are consistently underrepresented in trials, limiting that the applicability of evidence that informs health care policy, medical treatments, and clinical decision-making to the entire population [27]. Given equity-deserving populations are excluded from these important health care decisions that heavily impact their care, PE may be a crucial tool in redistributing power and promoting equity in trials [23, 28].

Second, one equity-deserving population of particular importance to engage with in trials to improve health equity is Indigenous peoples. Engaging with the Indigenous communities who will be implicated by the research emphasizes relationship-building, respect for communities' self-determination and governance, and the aim of addressing disparities in social determinants of health, health outcomes, and trauma that Indigenous peoples experience as a result of the effects of colonialism [29, 30]. It is essential that engagement with Indigenous communities follow a participatory approach (e.g., Participatory Action Research, Community Based Participatory Research) where a partnership is created before the research begins, to identify or co-identify research priorities that matter to them and culturally appropriate methods, and endures throughout the research, to integrate the community's feedback and ensure the research benefits the community [29].

Third, shared decision-making (SDM) is a person-centered approach created to support people to make health care decisions that align with their values, needs, and preferences by deliberatively weighing the pros and cons, matching choices to preferred outcomes, and examining all the relevant information [31]. While originating from the context of care decisions, the SDM literature can inform trial participation issues by supporting potential trial participants in making evidence-informed, values-based decisions about participation and measuring the impact of good decision-making practices [32, 33]. Two reviews have supported that patient decision aids, a SDM tool, can increase patient's autonomy, agreement between their values and decision, satisfaction with their decision, accuracy of risk perceptions, and knowledge, and can decrease patients' decisional conflict in decisions about treatment and screening options [31] or participating in a clinical trial [34]. Among socially disadvantaged populations, a meta-analysis has supported that SDM interventions can similarly enhance knowledge, communication, and lead to informed choices, and decrease decisional conflict and the amount of uncertainty in decisions [35]. Trial recruitment conversations with socially disadvantaged populations tend to be shorter, less detailed, and contain fewer opportunities to ask questions than recruitment conversations with more socially advantaged populations, which could hinder informed decisions about whether or not to participate in a trial [36]. Thus, there may be a greater relevance and need for SDM approaches among equity-deserving populations who are considering trial participation to ensure they receive all the necessary information required to support good-quality participation decisions that align with the values, needs, and preferences important to them.

Many published reviews have summarized factors that influence clinical trial participation among equity-deserving populations. However, there has been a lack of research examining common barriers, enablers, and strategies for inclusive trial participation across a range of equity-deserving groups and the extent to which PE, Indigenous community engagement, and SDM have been used to optimize trial participation among equity-deserving groups is unknown. Synthesizing review evidence can identify which equity-deserving populations have been the focus of existing reviews, the range of barriers and enablers proposed to influence their participation, what strategies can improve their participation, and whether or how PE and SDM have been considered in this context.

Purpose

This meta-review aimed to: (1) describe which equity-deserving populations have been the focus of reviews summarizing their participation in clinical trials, and which barriers, enablers, and strategies are relevant to them, and (2) explore the extent to which concepts from

PE and SDM are discussed in reviews of equity-deserving populations' participation in clinical trials.

Methods

Study design

We conducted a scoping review of reviews (meta-review) guided by the updated JBI (formerly Joanna Briggs Institute) methodology for scoping reviews [37] and recommendations by Levac and colleagues [38]. Reporting follows the PRISMA Extension for Scoping Reviews (PRISMA-ScR) [39] and PRISMA-Equity Extension: Reporting Guidelines for Systematic Reviews with a Focus on Health Equity (Supplemental File 1) [40]. We developed but did not publish a protocol for this review.

Author positionality

We conducted this review in partnership with Clinical Trials Ontario (CTO), an independent, not-for-profit organization based in Ontario, Canada that strives to enhance efficiency, cost-effectiveness, and patient and public involvement in clinical trials. One benefit of this partnership was engaging with members of CTO's College of Lived Experience, a group of patients, caregivers, and members of the public who inform CTO's projects and provide insights to trial sponsors and investigators on lived experiences of clinical trial participation and/or PE [41]. The College members bring a diversity of lived experiences related to clinical trials and research in general, diseases and conditions, age, education, and more backgrounds. The first author is a female, cis-gendered postdoctoral researcher with an invisible disability and kinesiology background. Other co-authors include researchers, executives, and students with diverse gender identities, ages, lived experiences of chronic disease, cultural backgrounds (predominantly European), and education (undergraduate to postdoctoral level). Aspects of these identities were relevant to equity in trial participation and shaped our analyses and interpretations of research access, PE, and health system barriers. The interdisciplinarity of the co-author team, comprising psychology, sociology, epidemiology, patient and public engagement, health equity, ethics, clinical trials, and qualitative and quantitative research experience, also informed a reflexive consideration of multiple perspectives during analysis and interpretation. Considering our positions, discussions were held throughout to ensure the conclusions in our review were grounded in the evidence.

Data sources and search strategy

An initial informal search of Google Scholar and the Online Resource for Research in Clinical triAls (ORRCA) database [42] was undertaken in December 2023 to identify 15 target reviews, which informed the primary search strategy. Search terms were adapted for each database and based on keywords and index terms in the titles and abstracts of these 15 reviews (Supplemental File 2). We searched across five peer-reviewed databases for reviews on clinical trial participation among equity-deserving populations that were written in English and published from 1946 to May 16, 2024: (1) MedLine (Ovid), (2) EMBASE (Ovid), (3) PsycINFO (Ovid), (4) CINAHL (EBSCO), and (5) Scopus. 'Equity-deserving populations' were defined those experiencing structural inequities, marginalization, social disadvantage, or discrimination affecting their access to clinical trials based on one or more characteristic within the PROGRESS-Plus acronym (definition below) [5]. All searches were performed by a professional librarian with expertise in systematic reviews in the health domain and using the Peer Review of Electronic Search Strategies (PRESS) guidance [43].

Eligibility criteria and screening

Included studies had to (i) be a review (systematic, scoping, meta-analysis, narrative, umbrella, rapid, or a qualitative evidence synthesis) that included primary studies of any study design, (ii) summarize factors (i.e., barriers, enablers, and/or strategies) that help or prevent participation in clinical trials (i.e., not research in general), and (iii) primarily focus on one or more equity-deserving populations and/or their caregivers (i.e., the population of interest in the study was either completely or primarily comprised of persons experiencing structural inequities, marginalization, or social disadvantage). Reviews that mentioned an equity-deserving group implicitly or only as part of ancillary findings or a secondary discussion, and where the main findings did not relate to groups facing inequity or disadvantage, were deemed as *not primarily focusing* on an equity-deserving population. Studies also needed to be written in English as there were no resources available for translation. No restrictions were placed on the geographic area of studies; however, studies were excluded if they were written in the form of a commentary, opinion piece, brief report, or literature review chapter of a dissertation or thesis.

Two independent reviewers (TLM, MM) piloted the inclusion and exclusion criteria using the 15 target reviews from the initial search and first 50 references from the formal search. Subsequently, the reviewers independently screened the titles and abstracts of all identified studies using Covidence [44]. The full texts of the studies of interest were then retrieved and independently evaluated by TLM and MM against the inclusion and exclusion criteria, which were piloted individually by the two reviewers using the first 15 articles that passed title and abstract screening. Reasons for exclusion at the full text stage are reported in the PRISMA flow diagram (Fig. 1). Discrepancies between reviewers were resolved through discussion with a third reviewer (JCB).

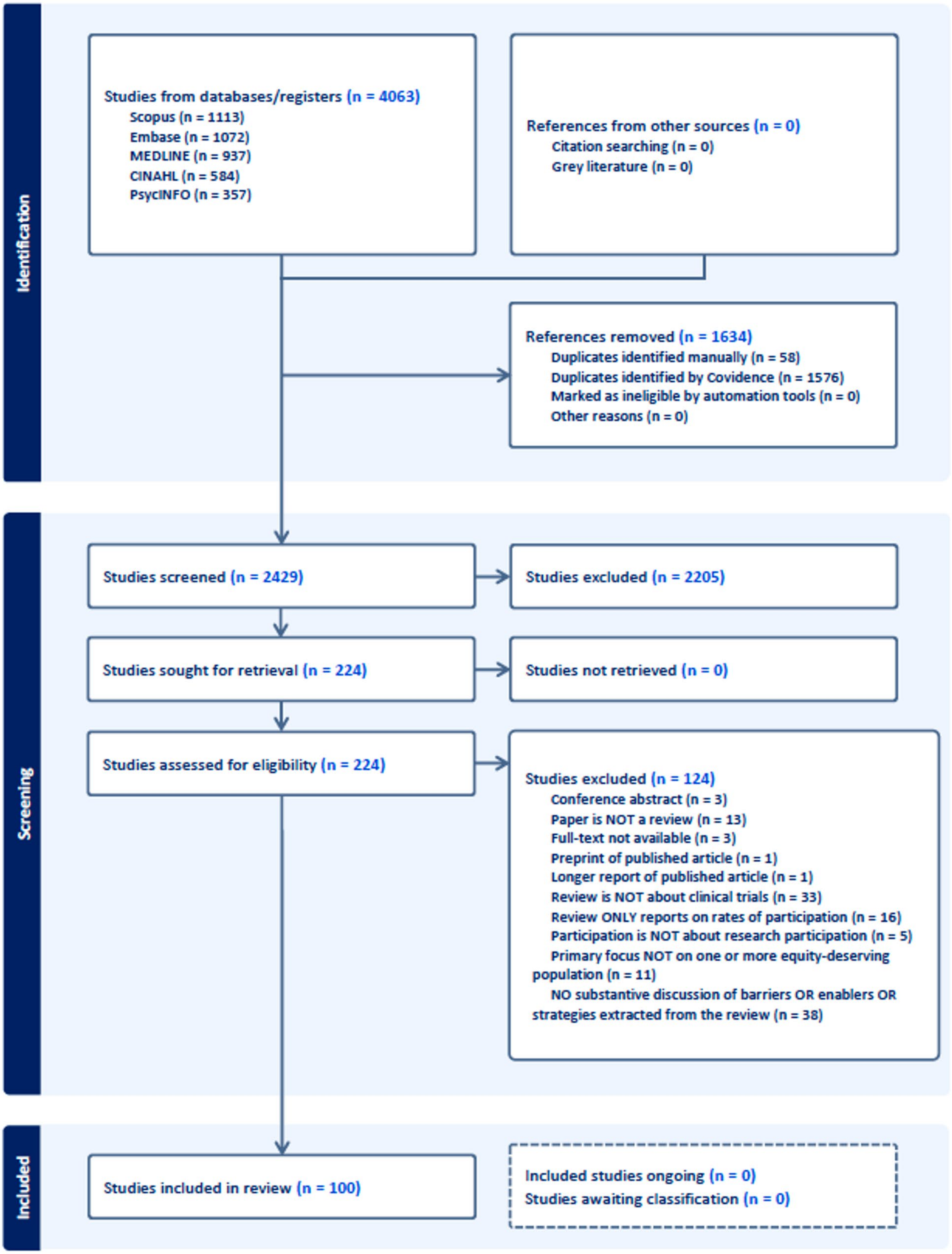

Fig. 1 PRISMA flow diagram

Data extraction and synthesis

The data extraction form was piloted by three reviewers (TLM, KC, JCB) prior to data extraction and adjusted as needed. Data were extracted on the (1) equity-deserving population(s) of focus in the review [5], (2) barriers, enablers, or interventions/strategies mentioned [17], (3) patient engagement reported in reviews about the primary studies [45], (4) Indigenous community engagement reported in reviews about the primary studies [46], and (5) SDM outcomes [32] reported in reviews about the primary studies. Methodological and study design information was also extracted, including the first author's name, publication year, title of review, country where the research was conducted, review design, number of studies in the review, reporting of databases and search criteria, presence of study flow diagram, reporting guidance followed, presence of quality appraisal, study design of included studies in the review, and clinical area of focus (e.g., rheumatology).

Several frameworks guided our extraction. First, the PROGRESS-Plus acronym was used to classify which equity-deserving populations were the focus of included reviews by considering a range of social identities that may be at risk of inequities [5]. PROGRESS-Plus stands for **P**lace of residence, **R**ace, ethnicity, culture, and language, **O**ccupation, **G**ender and sex, **R**eligion, **E**ducation, **S**ocioeconomic status, and **S**ocial capital, "plus" contextual factors including (i) personal characteristics linked to discrimination, like age and disability, (ii) relationship features, like social inclusion or exclusion, and (iii) time-dependent factors, like commuting time to a study site [5]. An 'other' category was added to capture any population who may experience discrimination or disadvantage not otherwise mentioned. We also expanded our definition of 'gender and sex' to include diverse sexual and gender identities, which are not explicitly stated as part of the framework. For reviews focusing on populations within the gender and sex category, we extracted data on whether binary gender or sex terminology was used and whether gender and sex concepts were distinguished and used correctly based on the International Council for Medical Journal Editors recommendations [47].

The Patient-Oriented Research Level of Engagement Tool (PORLET 2.0) and the Indigenous Research Level of Engagement Tool (IRLET) were used to code use of PE or Indigenous community engagement among the primary studies, respectively [45, 46]. The PORLET 2.0's five domains are: patient partners, patient-identified priorities, outcomes important to patients, knowledge into practice, and multi-disciplinary teams. The IRLET's four domains are: partnerships with Indigenous communities, knowledge into practice, strengths-based approaches, and Indigenous ways of knowing. Extracted data within PORLET 2.0 and IRLET domains were then coded per which level of the International Association for Public Participation (IAP2) Spectrum of Public Participation the PE occurred at: *inform*, *consult*, *involve*, *collaborate*, or *empower* [48]. Definitions of each level are provided in Table 4.

Next, we operationalized an internationally agreed core outcome set developed by Gillies and colleagues for the evaluation of interventions that aim to improve how people make trial participation decisions [32] to apply to trial participation decisions among equity-deserving groups. SDM outcomes were coded at the level of detail provided: 'no mention', where the outcome was not reported at all; 'limited mention', where the outcome was mentioned with little elaboration or explanation; and 'detailed discussion', where the outcome was described in detail. Finally, barriers, enablers, and strategies reported in the included reviews were extracted verbatim as free text.

Data synthesis

Pairs of reviewers (TLM with KC, NH, or AW) independently categorized extracted text on each barrier, enabler, and strategy into one of the five Social Ecological Model levels (i.e., individual, interpersonal, community, organizational/structural, or policy/systemic) they were deemed to operate at [17]. Any discrepancies were deliberated between the reviewer pairs. Tables of frequencies, percentages, and example quotations were used to synthesize and report data on equity-deserving populations of focus, PE, SDM, and barriers, enablers, and strategies.

Risk of bias

As the aim of this meta-review was to explore PE, SDM, and factors influencing equity-deserving populations' participation in clinical trials, and no quantitative outcomes were collected, a risk of bias assessment was deemed unnecessary [49].

Patient engagement in this review

We engaged in discussions with members of the CTO College of Lived Experience about the project overview, guiding frameworks, data extraction and analyses and interpretation of findings. College members also provided feedback on this manuscript. These discussions occurred from the early stages of data extraction to manuscript writing and consisted of several 90-120-minute Zoom meetings and online correspondence. The goal of this engagement was to hear CTO College members' thoughts about our extraction form and procedure and whether or not our findings resonated with lived experiences of clinical trial participation. College members were offered financial compensation for their time and co-authorship on this publication. Our PE is reported using the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Form (Supplemental File 3) [50].

Results

In total, 4063 studies were identified by our searches. Following de-duplication in Covidence, 2429 studies were screened at the title and abstract stage. Of these, 224 full texts were assessed for eligibility, of which 100 were included in our meta-review (references provided in Supplemental File 4). Figure 1 shows the PRISMA diagram.

Study characteristics

Table 1 lists the characteristics of included reviews. Most were labelled by authors as systematic reviews without meta-analyses (*n* = 34; 34%) or literature reviews/'reviews' (*n* = 28; 28%). Most reviews also reported which bibliographic databases were searched (*n* = 81; 81%); however, 47 (47%) reviews did not clearly describe the criteria or terms used in the searches. Just over half included a study flow diagram (*n* = 57; 57%). Reporting guidance for reviews was cited in 37 (37%) studies (i.e., PRISMA, *n* = 35 [35%]; PRISMA-Equity, *n* = 1 [1%]; both, *n* = 1 [1%]). Seventy reviews (70%) were conducted by authors based in the United States (US), followed by the United Kingdom (UK; *n* = 12; 12%), Australia (*n* = 7; 7%), and Canada (*n* = 7; 7%). Oncology was the most common clinical area (*n* = 38; 38%), followed by mental health and illness, HIV/AIDS, and diabetes (each *n* = 8; 8%).

Equity, diversity and inclusion (EDI)

Table 2 shows the equity-deserving populations of focus, use of binary sex and gender terminologies, and correct use and distinction of sex and gender terms among included reviews. The equity-deserving populations of focus in prior reviews encompassed all PROGRESS-Plus categories except occupation; however, some groups were more frequently researched than others. Seventy-six (76%) reviews focused on populations within the 'race, ethnicity, culture, and language' category, including persons with diverse racial, ethnic, and/or cultural backgrounds (e.g., Black, Latinx, Middle Eastern, South Asian, Chinese, Indian, Asian-American, African-American, and African-Caribbean people), limited-English proficiency, or Indigenous identity (e.g., Pacific Islanders, Māori, First Nations, Alaska Native). Seventy of these 76 reviews (92.1%) focused on racially and/or ethnically diverse populations (we were unable to separate race and ethnicity due to reporting issues), while 14 (18.4%) reviews focused on populations based on language, six (7.9%) focused on culturally diverse populations, and 24 (31.6%) focused on one or more populations Indigenous to several areas including the US (*n* = 17; 70.8%), Canada (*n* = 5; 20.8%), Australia (*n* = 2; 8.3%), and New Zealand and the UK (each *n* = 1; 4.2%). Within the subsets of reviews reporting PE and Indigenous community engagement (PE alone *n=39;* Indigenous engagement alone *n*=5; both *n*=6 combined; 50%) or SDM (*n* = 74; 74%), the focus on populations within the 'race, ethnicity, culture, and language' category was higher, at 44 (88.0%) papers within the PE subset and 58 (78.4%) papers within the SDM subset. Other categories (e.g., age, sex and gender, and relationship features) received less attention within the subsets of reviews reporting PE and SDM (see Table 2 for a full breakdown).

Populations within the gender and sex (*n* = 29; 29%; e.g., women) and age (*n* = 29; 29%; e.g., children, older adults) categories were the next most common, followed by place of residence (*n* = 17; 17%; e.g., rural residents) socioeconomic status (*n* = 17; 17%; e.g., uninsured individuals), disability (*n* = 16; 16%; e.g., persons with spinal cord injury), and relationship features (*n* = 12; 12%; e.g., caregivers, parents of children participating in trials). Of the 29 reviews focusing on gender and sex, 25 (86.2%) focused on one gender (women), four (13.8%) focused on sexual and/or gender diverse persons (including transgender and non-binary persons, lesbian, gay, bisexual, queer, and "other LGBTQ" persons), and two (6.9%) explicitly used binary terminology (one of which was published in 2006 and the other in 2021). In 22 (29%) of the 29 reviews, authors did not define or distinguish sex and gender terms, which could either indicate conflation of the two terms (as tends to be most common) or that definitions and distinction between the terms were not made explicit in the manuscript. For instance, some reviews only ever discussed one of the two concepts (e.g., gender) but never used other gender-based (e.g., woman) or sex-based (e.g., female) terms.

Most often, reviews only focused on one (*n* = 49; 49%) or two (*n* = 28; 28%) PROGRESS-Plus categories. Fewer reviews focused on three (*n* = 6; 6%) or four (*n* = 11; 11%) categories. Only one to two reviews mentioned five or more categories (5 or 6 categories, each *n* = 2; 2%; 7 or 9 categories, each *n* = 1; 1%).

Barriers, enablers, strategies

Table 3 lists examples of common barriers, enablers, and strategies at each Social Ecological Model level. Barriers to participation were more frequently reported (*n* = 84; 84%) than enablers (*n* = 31; 31%) and interventions/strategies to enhance participation (*n* = 69; 69%). Barriers and strategies were most often reported together (*n* = 38; 38%), followed by barriers and enablers (*n* = 16; 16%), just barriers (*n* = 16; 16%), just strategies (*n* = 15; 15%), barriers, enablers, and strategies (*n* = 14; 14%), and just enablers (*n* = 1; 1%).

In the 84 reviews referring to barriers, most operated at the individual level (*n* = 78, 92.9%). Common individual barriers included mistrust of clinical trials or the trial

Table 1 Descriptive characteristics of included studies ($N = 100$)

Characteristics	*n* (%)
Type of review (as self-identified by review authors)	
Systematic review (without meta-analysis)	34 (34)
Scoping review	19 (19)
Narrative review	12 (12)
Meta-analysis	1 (1)
Rapid review	1 (1)
Other [a]	33 (33)
Reporting of databases used	81 (81)
Reporting of search strategy	
Full search strategy reported	25 (25)
Partial description of search strategy	28 (28)
No clear description of search or criteria	47 (47)
Study flow diagram included	57 (57)
Reporting guidance used and cited[a]	
Review reporting guidance (e.g., PRISMA)	36 (36)
Review reporting guidance with equity extension (e.g., PRISMA-Equity)	2 (2)
No reporting guidance used or cited	63 (63)
Quality appraisal of included studies conducted	20 (20)
Study design of the primary studies included in the review [b]	
Randomized controlled trial	31 (31)
Qualitative	16 (16)
Cross-sectional	15 (15)
Review	11 (11)
Cohort study	10 (10)
Non-randomized controlled trial	8 (8)
Quasi-randomized controlled trial	5 (5)
Longitudinal study	5 (5)
Case study	4 (4)
Not specified	1 (1)
Other (e.g., surveys [unspecified], mixed methods research [unspecified], case-control, descriptive, database/registry review, secondary analysis)	39 (39)
Clinical area mentioned in the review [a]	
Oncology	38 (38)
Mental health/mental illness	8 (8)
HIV/AIDS	8 (8)
Diabetes	8 (8)
Cardiology/cardiovascular disease	7 (7)
Alzheimer's disease	7 (7)
Maternity, pregnancy, peripartum, menopause	5 (5)
Substance use, addiction	4 (4)
Hypertension	4 (4)
Parkinson's disease	3 (3)
Pediatrics	3 (3)
Reproductive/sexual health, family/parenting	3 (3)
Other areas mentioned only once or twice[c]	24 (24)
Not mentioned	26 (26)
Year of publication	
≥ 2020	54 (54)
2015–2019	16 (16)
2010–2014	17 (17)
2005–2009	9 (9)
2000–2004	2 (2)
1995–1999	2 (2)

Table 1 (continued)

Characteristics	***n* (%)**
Country of first author's affiliation	
United States	70 (70)
United Kingdom	12 (12)
Australia	7 (7)
Canada	7 (7)
India	1 (1)
Italy	1 (1)
New Zealand	1 (1)
Singapore	1 (1)
	Mean (range)
Number of primary studies included in reviews	81.01 (5-2710)

[a] Other types of reviews mentioned included literature reviews or 'reviews' unspecified ($n=28$; 28%), book chapter ($n=1$; 1%), research review ($n=1$; 1%), realist review ($n=1$; 1%), evidence map ($n=1$; 1%), and critical review ($n=1$; 1%)

[b] Sum exceeds total N due to option to select multiple responses

[c] Other clinical areas mentioned twice included dementia, cognitive impairment, pain/chronic pain, genetic-related conditions, diet and lifestyle, smoking, kidney disease, osteoporosis, and behavioural health. Other clinical areas mentioned once included hormonal therapies, sexually transmitted infections, rheumatology, musculoskeletal disorders, Multiple Sclerosis, palliative care, stroke, internal medicine, vaccination, asthma, arthritis, dermatology, nutrient-related disorders, eating disorders, physical health, behavioural health, spousal abuse, epilepsy, prevention, amyotrophic lateral sclerosis, chronic disease (not specified), acute conditions (not specified), health care service use, and peripheral artery disease

team (when framed as an individual barrier, compared to systemic mistrust due to systemic oppression), limited resources (in terms of time, money, and travel requirements), and negative attitudes (e.g., patient's fear of harm, clinician bias). Interpersonal barriers ($n=54$, 64.3%) encompassed communication challenges (e.g., spoken language discordance between patients and clinicians) and lack of family support for participation. Community-level barriers ($n=33$, 39.3%) included stigma of the condition being studied, failure to meaningfully engage with the community (e.g., to explain, partner in, or disseminate the research), and cultural influences that do not align with participation (e.g., religious beliefs, social disapproval). Organizational barriers were more common ($n=71$, 84.5%), relating to restrictive eligibility criteria (namely regarding age, language, ability level, and presence of comorbidities), logistical issues (e.g., lack of culturally competent staff, translated resources, and cultural representation among trial teams), and trial design factors (e.g., complex research procedures, time requirements, inconvenient trial sites, technical language). The policy/systemic level contained the lowest proportion of barriers ($n=30$, 35.7%) but included systemic racism in the healthcare system and lack of funding and policies to support inclusive trials.

Among the 31 reviews referring to enablers, individual-level enablers ($n=28$, 90.3%) were most common, including having knowledge and awareness of clinical trials, perceived personal benefits (e.g., participation will lead to better care, free care, or greater access to healthcare providers), and positive attitudes (e.g., provider enthusiasm for the trial, beliefs that trials are helpful). All other levels except the policy/systemic level were close in frequency (interpersonal and community, each $n=26$, 83.9%; organizational, $n=25$, 80.6%). Common enablers at these levels included family support in involvement in decision-making (interpersonal), feelings of altruism (community), and participant-centred trial schedules and procedures (e.g., comfortable environment, presence of racially and ethnically matched staff, flexible and convenient designs [organizational]). The one policy/systemic-level enabler related to advocacy from ethics review boards for inclusive practices ($n=1$, 3.2%).

Of the 69 reviews referring to strategies, most operated at the organizational level ($n=62$, 89.9%) and described adapting trial materials and processes (e.g., informed consent documents, intervention resources, study designs), cultural competence training for trial staff, providing financial incentives to participants, and achieving language and ethnic concordance between participants and trial staff. Patient navigation, tailored recruitment and retention strategies (e.g., peer-led, at-home, frequent follow-up), and building a trusting patient-provider relationship were the most frequently reported interpersonal-level strategies, while community-based and community-engaged research approaches were by far the most discussed community-level strategy. Few individual-level strategies ($n=18$, 26.1%), including education for patients (e.g., on randomization, benefits of clinical trials) or clinicians (e.g., on referrals, addressing bias, understanding patient experiences), and policy-level strategies ($n=12$, 17.4%), such as increasing trial access among communities, implementing policy and systemic

Table 2 Frequency with which equity-deserving groups were the focus of included reviews, binary terminology was used, and gender and sex terms were used correctly and distinguished (*N* = 100)

PROGRESS-Plus category	**Equity-deserving populations mentioned**	**Full sample (*N* = 100)**	**Reviews reporting SDM (*n* = 74)**	**Reviews reporting PE (*n* = 45)**
		n* (%)	***n* (%)***	***n* (%)***
Race, ethnicity, culture, and language	African American, African, African-Caribbean, Hispanic, Latinx, Black, non-Hispanic Black, Chinese, Chinese American, Asian, Asian American, South Asian, Southeast Asian, Arab, Arab American and Chaldean, Pakistani, Bangladeshi, Indian, Turkish, Jewish, Middle Eastern, multiracial, and mixed backgrounds People with low English language proficiency or language barriers Non-English speaking persons Spanish-speaking persons Aboriginal and Torres Strait Islanders American Indian, Alaska Native, or Native Haiwaiian Indigenous Peoples of New Zealand, Australia, Canada, and the United States of America Culturally and Linguistically Diverse backgrounds	76 (76)	58 (78.4)	44 (88)
Gender and sex	Gay, lesbian, bisexual, and transgender persons Men who have sex with men, gay and bisexual men, transgender women Sexual or gender minority groups [lesbian, gay, bisexual, transgender, queer, and other, or LGBTQ] Black men Women Sexual and gender minority persons, transgender and non-binary patients	29 (29)	20 (27)	13 (26)
Age	Rural-dwelling older people Rural-dwelling chilren Older adults (60, 65, or 70 years of age and over) High-risk youth Children and adolescents Children with cancer Women of older ages Elderly persons People with advanced age Older adults with Alzheimer's Disease Older adults with cancer Older Chinese immigrants Ethnic minority older adults Hispanic/Latinx American older adults	29 (29)	20 (27)	9 (18)
Place of residence	Rural communities Rural, urban, or inner-city populations Rural cancer patients Rural pediatric populations People living in a low-income, rural, or disadvantaged area Geographically isolated populations People living outside trial encatchment areas	17 (17)	13 (17.6)	9 (18)
Socioeconomic status	Lower socioeconomic status due to low income, employment, insurance People from disadvantaged socioeconomic backgrounds or experiencing socioeconomic disadvantage Residents of a developing country	17 (17)	13 (17.6)	8 (16)
Disability	People with sensory, cognitive, neurological, behavioural, psychiatric, communication and language, physical, or developmental disabilities People with Alzheimer's Disease Individuals with chronic pain, depression, anxiety, mental illness, or poor mental health People with impaired decision-making capacity People with spinal cord injury	16 (16)	11 (14.9)	8 (16)
Relationship features	Power imbalances in physician-patient relationships Presence of risk factors in family history Survivors of partner violence Relationships with family members who prohibit participation Older adults with caregivers Older adults, children, and adolescents enrolled as part of a dyad Parents of children approached to participate in a trial	12 (12)	8 (10.8)	4 (8)

Table 2 (continued)

PROGRESS-Plus category	**Equity-deserving populations mentioned**	**Full sample ($N = 100$)**	**Reviews reporting SDM ($n = 74$)**	**Reviews reporting PE ($n = 45$)**
		n* (%)	***n* (%)***	***n* (%)***
Education	Lower levels of education that attributes to limited medical knowledge Lower educational attainment	2 (2)	1 (1.4)	0 (0)
Occupation	N/A	0 (0)	0 (0)	0 (0)
Religion	People with religious beliefs affecting participation (e.g., folk beliefs, faith in prayer and spirituality, religious holidays observed)	1 (1)	1 (1.4)	0 (0)
Social capital	People experiencing homelessness Socially disadvantaged groups	1 (1)	1 (1.4)	1 (2)
Time-dependent relationships	Time since diagnosis of peripheral arterial disease Time to upcoming revascularization Time since revascularization Time since participation in exercise programme Availability for duration of intervention	1 (1)	0 (0)	0 (0)
Other	High-risk populations, based on demographics and behavior	1 (1)	1 (1.4)	0 (0)
	Individuals with comorbidities	1 (1)	1 (1.4)	1 (2)
	Chinese American immigrants who are 60 years or older	1 (1)	1 (1.4)	0 (0)
	Female sex-workers	2 (2)	2 (2.7)	1 (2)
Gender and sex terminology (*n* = 29)	**Example**	***n*(%)**		
Was binary terminology used?	"[…] creating a representative population of both genders and of minority groups within a specific time frame and budget are different limiting factors during the recruitment process." (Cardenas et al., 2006)	2 (6.9)		
Were gender and/or sex terms distinguished and used correctly?				
Not distinguished and unable to evaluate if correct or incorrect	"The purpose of this review is to investigate barriers and facilitators that provide possible explanations for the low participation rate of women and minorities in clinical trials with a specific focus on the field of cancer research." (Shmotzer et al., 2012) *Authors never use sex-based terms or mention the word "gender"	10 (34.5)		
Not distinguished and incorrect	"female gender" (Trivedi et al., 2015)	9 (31)		
Distinguished and correct	"To assess sex and gender in adults, experts recommend a two-step approach, first assessing sex-at-birth (i.e., female, intersex, male) and then gender identity (i.e., woman, man, transgender, nonbinary, genderqueer […])." (Burnette et al., 2022)	6 (20.7)		
Not distinguished but correct	"In SCI [spinal cord injury] trials, the epidemiologic distribution of diverse populations, such as ethnic minorities, age, and gender, should be considered to maintain the generalizability […] Women, as participants, compose an important group of concern." (Cardenas et al., 2006)	3 (10.3)		
Distinguished but incorrect	""Sex" refers to the classification of living things as male or female according to their reproductive organs and functions assigned by chromosomal complement (e.g., XX versus XY), and "gender" refers to a person's self-representation as male or female or to how that person is responded to by social institutions on the basis of that presentation" (Olson et al., 2020)	1 (3.4)		

[*] Sums exceed total *N* due to option to select multiple responses

Table 3 Examples and frequencies of barriers, enablers, and strategies mentioned among the included reviews ($N = 100$)

Category	Examples	*n* (%)[a]
Barriers		**84 (84)**
Individual	Mistrust (i.e., fear of being a guinea pig, unethical research on African Americans, suspicion about services, legal documents, and profit motive of pharmaceutical companies, fear of physicians) (Brown et al., 2014) Lack of interest in clinical trials (Dreyfus et al., 2023)	78 (92.9)
Interpersonal	Concerns that trials will adversely impact doctor-patient relationship (Cardenas et al., 2006) Family issues or responsibilities, significant others suggesting cancer screening isn't necessary or recommended (DeVandry et al., 2011)	54 (64.3)
Community	HIV stigma among the community (Bass et al., 2020) Interventions not aligning with community needs, values, and beliefs (Bonevski et al., 2014)	33 (39.3)
Organizational	Overly rigorous eligibility criteria, e.g., non-English speaking, co-morbidities; lack of inclusive study designs, e.g., far trial location; trial protocols occurring during 'normal' work hours, lack of transportation, poor accessibility of trial setting, lack of information on trials (Beer et al., 2022)	71 (84.5)
Policy/systemic	Systemic racism (DeVandry et al., 2011) Government policies that lack a strategic plan to promote the inclusion of Black men (Esdaille et al., 2021)	30 (35.7)
Enablers		**31 (31)**
Individual	Belief that participation will lead to greater care and increased access to health care providers or diagnostic tests (Cardenas et al., 2006) Knowledge about trials, having enough time to participate (DeVandry et al., 2011)	28 (90.3)
Interpersonal	Existing trusted relationship with medical personnel (DeVandry et al., 2011)	26 (83.9)
Community	Research integrated within community agencies; altruism (Bass et al., 2020)	26 (83.9)
Organizational	Adequate description of clinical trial or associated risks; ethnic and gender concordance with physician or research staff (Dreyfus et al., 2023)	25 (80.6)
Policy/systemic	Involvement and advocacy for inclusive practice by ethics review boards (e.g., requiring sociodemographic justification); provision of additional resources to researchers by research bodies (Shariq et al., 2023)	1 (3.2)
Strategies		**69 (69)**
Individual	Using accessible/unintimidating terminology and wording, patient education materials (Bonevski et al., 2014) Strategies to improve patient e-health literacy (Bumanlag et al., 2021)	17 (24.6)
Interpersonal	Increasing research staff's availability to answer questions and use two-way and clear communication (Anuruang et al., 2015) Peer-driven educational intervention (Bass et al.) Patient navigation (Carthon et al., 2021)	49 (71.0)
Community	Community engagement (e.g., enlisting community opinion leaders early on, partnering with community organizations, Community-Based Participatory Research approaches, patient advocates) (Adrissi et al., 2022)	60 (86.9)
Organizational	Provider resources (i.e., letters to treating physicians and professional collaborations to stress the need for Black participant recruitment); focused research staff interventions (i.e., cultural competency training, racial and ethnic concordance between staff and participants) (Arring et al., 2022)	62 (89.9)
Policy/systemic	Journal requirements for reporting within- or between-group analyses for Phase III trials; for reporting comprehensive gender, sexual orientation, socioeconomic status, racial, and ethnic data; reviewer checklists to increase accountability and improve reporting in manuscripts (Burnette et al., 2022)	11 (15.9)

[a] Proportions of each socioecological level within barriers, enablers, and strategies are calculated using the total number of reviews reporting on barriers ($n = 84$), enablers ($n = 31$), and strategies ($n = 69$) as the denominator. Sums exceed total *N* due to option to select multiple responses

changes, and limiting the unnecessary exclusion of equity-deserving populations, were reported.

Patient engagement (PE)

Table 4 shows the areas and levels of PE and Indigenous community engagement with examples. Forty-five reviews (45%) reported PE coded per the PORLET 2.0. Engagement in line with the 'patient partners' domain ($n = 43$, 95.6%) was reported more often than 'knowledge into practice' ($n = 12$, 26.7%), 'patient-identified priorities' ($n = 9$, 20%), and 'multi-disciplinary team' ($n = 4$, 8.9%). No reviews mentioned PE in line with 'outcomes important to patients'. Overall, the most common IAP2 Spectrum level reported was *involve* ($n = 36$, 80%) followed by *collaborate* ($n = 31$; 68.9%). The *inform* level was less common ($n = 12$; 24.4%) and predominantly comprised of reviews coded within 'knowledge into practice' ($n = 12$; 75%).

Table 4 Frequency with which patient engagement and Indigenous community engagement were reported among the results of the primary studies discussed in the included reviews ($N=100$)

Framework	Examples	IAP2 Spectrum Level[a]	*n* (%)[b]
PORLET 2.0 domain			**45 (45)**
Patients are partners	"[…] only 2 involved the community at the "inform" level. Both studies utilized visual mediums as methods of recruitment, specifically TV ads in Kupfer's article and community presentations in Gold's article." (Brockman et al., 2023)	Inform	2 (4.4)
	"[…] another demonstrated the effectiveness of a focus group which helped inform the various aspects of the intervention including acceptability, marketing, content, and environment" (Brockman et al., 2023)	Consult	10 (22.2)
	"[…] using images of local residents in campaigns, employing community members to deliver the intervention, and using a professional social media marketer to tailor content." (Arring et al., 2022)	Involve	29 (64.4)
	"[…] including focus groups, community advisory boards, local residents as members of the research team […]" (Arring et al., 2022)	Collaborate	19 (42.2)
	"Co-leading is the driving principle regarding community personnel in only two studies." (Brockman et al., 2023)	Empower	2 (4.4)
Patient-identified priorities	N/A	Inform	0 (0)
	N/A	Consult	0 (0)
	"Community-based participatory research (CBPR) can be used to foster partnerships and infrastructure for academic researchers and communities to address research questions in mutually beneficial ways […]" (Adrissi et al., 2022)	Involve	4 (8.8)
	"The majority of studies reported community involvement in identifying study questions (63%) […]" (De Las Nueces et al., 2012)	Collaborate	6 (13.3)
		Empower	1 (2.2)
Outcomes important to patients	N/A	Inform	0 (0)
	N/A	Consult	0 (0)
	N/A	Involve	0 (0)
	N/A	Collaborate	0 (0)
	N/A	Empower	0 (0)
Knowledge into practice	"The UCHSC [University of Colorado Health Science Center] RCMAR [Resource Centers on Minority Aging Research] developed a newsletter mailed biannually to participants and community leaders to summarize project status and emerging results." (Moreno-John et al., 2004)	Inform	9 (20)
	"The RIC's [Recruitment Innovation Center] recently conducted Return of Value survey, which found that participants value more than just the return of personal results, can be consulted for ideas on which study results are most valuable to specific minority populations." (Kennedy et al., 2022)	Consult	1 (2.2)
	"Two articles mentioned the involvement of participant and community member engagement in results interpretation 3 articles provided final trial results to participants, and 2 engaged with partners around dissemination." (Goldstein et al., 2024)	Involve	1 (2.2)
	"[…] very few of the studies cited involvement of the community in the interpretation of either quantitative or qualitative research findings (21 and 37%, respectively) or in efforts to disseminate trial findings (47%)" (De Las Nueces et al., 2012)	Collaborate	3 (6.7)
	N/A	Empower	0 (0)
Multi-disciplinary team	N/A	Inform	0 (0)
	N/A	Consult	0 (0)
	"Proposed strategies to increase minority enrollment in clinical trials include a multifaceted approach enlisting early community opinion leaders to help with project design and recruitment […] (Adrissi et al., 2022)	Involve	2 (4.4)
	Proposed strategies to increase minority enrollment in clinical trials include […] intentional recruitment of a diverse, culturally competent research team" (Adrissi et al., 2022)	Collaborate	3 (6.7)
	N/A	Empower	0 (0)

Table 4 (continued)

Framework	Examples	IAP2 Spectrum Level[a]	*n* (%)[b]
PORLET 2.0 domain			**45 (45)**
IRLET domain			**11 (11)**
Partnerships with Indigenous communities	N/A	Inform	0 (0)
	"Involvement of community personnel ($n=46$), feedback ($n=22$), and customization of recruitment materials and processes in accordance with the characteristics of the community ($n=17$) were mentioned most frequently." (Brockman et al., 2023)	Consult	1 (9.1)
	"Hing et al. and Couzos et al. highlight the importance of involving local community partners in the development of research protocols and materials when working with Australian Indigenous communities and the importance of extensive pilot testing of materials." (Bonevski et al., 2014)	Involve	7 (63.6)
	"Active collaboration with Indigenous groups right from the outset in the early design phase of the study, with Indigenous groups guiding research, and research driven by needs identified by the community were all key facilitators." (Glover et al. 2014)	Collaborate	5 (45.5)
	"[…] the role of equitable partnerships was emphasized in these studies rather than the establishment of a study-specific CAB [community advisory board]. Recruitment was led by community partners through integration of local knowledge and community strengths/resources, often through a long-term community-based research and recruitment infrastructure." (Wieland et al., 2021)	Empower	2 (18.2)
Knowledge into practice	"The "sharing" of data provides a stimulus to engage Indigenous populations in future RCT" (Olson et al., 2020)	Inform	3 (27.3)
	N/A	Consult	0 (0)
	"The community's involvement in being informed of the results and subsequently aiding in the interpretation of the results to a larger audience were key mediation strategies to increase trust and facilitate participation among Native Hawaiians in Hawaii." (George et al., 2014)	Involve	2 (18.2)
	"[…] 35 (33.7%) and 44 (42.3%) of the studies had community partners work together to disseminate results and identify research questions, respectively. Twenty-five (24.0%) and 23 (22.1%) studies had community partners participating in qualitative or quantitative interpretations of research findings." (McFarlane et al., 2022)	Collaborate	1 (9.1)
	N/A	Empower	0 (0)
Strengths-based approaches	N/A	Inform	0 (0)
	N/A	Consult	0 (0)
	N/A	Involve	0 (0)
	N/A	Collaborate	0 (0)
	"[…] the role of equitable partnerships was emphasized in these studies rather than the establishment of a study-specific CAB [community advisory board]. Recruitment was led by community partners through integration of local knowledge and community strengths/resources, often through a long-term community-based research and recruitment infrastructure." (Wieland et al., 2021)	Empower	1 (9.1)
Indigenous ways of knowing	N/A	Inform	0 (0)
	"A number of strategies were used to ensure study material was culturally appropriate, including having Indigenous people edit research material or intervention resources, committee or community input on adapting research materials and deriving material from Indigenous models." (Glover et al., 2014)	Consult	1 (9.1)
	"Appropriate study design included drawing on Indigenous traditions, addressing language barriers, and modifying the method to suit participants' knowledge systems" (Glover et al., 2014)	Involve	1 (9.1)

Table 4 (continued)

Framework	Examples	IAP2 Spectrum Level[a]	*n* (%)[b]
PORLET 2.0 domain			**45 (45)**
	"Office staff [tribal] members let the UCHSC know when and how they could participate in tribal events such as rodeos, powwows, or health fairs." (Moreno-John et al., 2004)	Collaborate	2 (18.2)
	"[…] the role of equitable partnerships was emphasized in these studies rather than the establishment of a study-specific CAB. Recruitment was led by community partners through integration of local knowledge and community strengths/resources, often through a long-term community-based research and recruitment infrastructure." (Wieland et al., 2021)	Empower	1 (9.1)

IRLET = Indigenous Research Level of Engagement Tool; PORLET 2.0 = Patient Oriented Research Level of Engagement Tool

[a] Examples of each IAP2 Spectrum level: *inform* (i.e., patients are informed about trials, such as through newsletters or presentations), *consult* (i.e., patient or community groups provide feedback on one or more aspects of trials, such as through focus groups), *involve* (e.g., patients share ideas that are sometimes reflected in aspects of trials, such as through Community Advisory Boards who advise trial teams), *collaborate* (e.g., patients are equal team members who co-develop aspects of trials, such as with patient partners who are actively involved in strategic planning for trials), *empower* (e.g., patients and communities lead or co-lead aspects of trials, such as with patient co-investigators)

[b] Percentages for each PORLET 2.0 and IRLET domain are calculated out of the 45 reviews reporting PE

Indigenous community engagement

Only 11 reviews (11%) reported engagement with Indigenous communities coded per the IRLET. Engagement more often aligned with the 'partnerships' domain (*n* = 10, 90.9%), compared to 'knowledge into practice' (*n* = 6, 54.5%), 'Indigenous ways of knowing' (*n* = 3, 27.3%), and 'strengths-based approaches' (*n* = 1, 9.1%). The one review reporting strengths-based approaches [51] referenced a community-led recruitment intervention supported by a long-term, equitable partnership with the relevant Indigenous community, which extended beyond the study, helped build capacity within the community, and provided mutual benefit to researchers and community members. The most common IAP2 Spectrum level was *involve* (*n* = 10, 90.9%) followed by *collaborate* (*n* = 8, 72.7%). The 'Empower' level comprised a much larger proportion of reviews coded within the IRLET (*n* = 4; 36.4%) compared to the PORLET 2.0 (*n* = 3; 6.7%).

Shared decision-making (SDM) outcomes

Table 5 describes the frequency of discussions about SDM outcomes with examples. Nearly three-quarters of reviews (74%) discussed SDM outcomes [32] and nine (81.8%) of the 11 outcomes were mentioned. Of these 74 reviews, 29 discussed only a select few SDM outcomes in detail. The most detailed discussions related to patient-clinician communication (60% overall [60 studies; 21 detailed, 39 just mentioned]). The only other detailed discussions were around the values of equity-deserving populations (37% overall [37 studies; 11 detailed, 26 just mentioned]) and their knowledge about clinical trials (29% [29 studies; 2 detailed, 27 just mentioned]). The two outcomes not discussed pertained to helping equity-deserving populations understand the options and features of trials that matter most to them and measuring the proportion who are undecided about participating in a trial. The remaining six outcomes were mentioned in between one to 10 reviews (1–10%).

Discussion

This meta-review synthesized 100 reviews, half of which were published in 2020 or later (54%). Our findings revealed that past reviews have focused on a range of equity-deserving populations, with large variation in how frequently and to what extent PE and SDM concepts are reported.

Need for an intersectional lens

Existing reviews have focused on a relatively narrow range of equity-deserving populations in reported strategies to improve trial participation (i.e., 76% of reviews focused on race, ethnicity, culture, and/or language compared to 1–2% on education, occupation, religion, social capital, and time-dependent relationships). PE and SDM concepts were studied more extensively among some groups than others. We found 29 reviews on sex- and gender-related barriers and strategies to trial participation, which is not an insignificant number; however, they presented a limited perspective on factors that may be relevant to other sexual and gender identities who are considerably underrepresented in clinical trials. Similarly, while a sizeable proportion of many countries' population identifies as living with a disability (e.g., 27% of the population aged 15 and over in Canada), discussions of PE and SDM among persons with disabilities were minimal [52]. Given that persons with disabilities require and use more health care services, medications, and medical devices and have greater unmet health needs than persons without disabilities, it seems logical that a larger focus of research on clinical trial participation should be on how to make health care more accessible and relevant to these populations [53]. Finally, educational level is an

Table 5 Frequency with which shared decision-making outcomes were discussed among included reviews ($N = 100$)

Shared Decision-Making Outcome	Example	*n* (%)	
Whether equity-deserving populations have **accurate perceptions of risks**	“Many individuals were concerned that they would be placed in a placebo group and consequently derive no medical benefit from participation.45 On the other hand, if they did receive the trial medication there was fear that it would not work on them or that the new medication would lead to negative side effects, both short-term and long-term.” (Bass et al., 2020)	**Total**	**3 (3)**
		Detailed	0 (0)
		Just mentions	3 (3)
Whether equity-deserving populations feel **informed about participation options and their features**	“Providing patients with clear, easy-to-understand information and enhancing their decision-making process through decisional support aids, while facilitating care coordination and addressing common barriers to timely cancer care, fosters a sense of control and provides patients with the information and skills they need to make informed decisions regarding their treatment options and the resources to implement those decisions […]” (Ramirez et al., 2022)	**Total**	**5 (5)**
		Detailed	0 (0)
		Just mentions	5 (5)
Whether equity-deserving populations are assisted in **getting clear about the options and features that matter most**	N/A	**Total**	**0 (0)**
		Detailed	0 (0)
		Just mentions	0 (0)
Values of members of equity-deserving populations	“Indigenous self-determination, leadership, impact and value, sustainability and accountability are core ethical principles that underlie research done with and for Aboriginal and Torres Strait Islander populations in Australia. An understanding and respect of these core principles, as well as Aboriginal and Torres Strait Islander peoples’ histories and culture, is crucial in enabling research participation for this population” (Beer et al., 2022)	**Total**	**37 (37)**
		Detailed	11 (11)
		Just mentions	26 (26)
Patient-clinician **communication**	“[…] the content and quality of physicians’ discussions about clinical trials can affect parents’ perceptions and understanding of clinical trials, thus affecting the decision about trial participation” (Hauck et al., 2021)	**Total**	**60 (60)**
		Detailed	21 (21)
		Just mentions	39 (39)
Whether equity-deserving populations **participate in decision-making**	“In most cases, patients themselves make the final decision regarding clinical trial participation, and they “are most concerned with obtaining the best treatment for their disease” (Allison et al., 2022)	**Total**	**10 (10)**
		Detailed	0 (0)
		Just mentions	10 (10)
The proportion of members of equity-deserving populations who are **undecided about participating in a trial**	N/A	**Total**	**0 (0)**
		Detailed	0 (0)
		Just mentions	0 (0)
Equity-deserving populations’ **satisfaction with their choice**	"In fact the studies found high participant satisfaction with the study, better follow-up rates and reduced tracking efforts.” (Bonevski et al., 2014)	**Total**	**1 (1)**
		Detailed	0 (0)
		Just mentions	1 (1)
Equity-deserving populations’ **satisfaction with the decision-making process**	“[…] Tait and colleagues report that parents who were more satisfied with the clarity and quantity of trial information were more positive about the trial than parents who were dissatisfied with the information” (Shilling et al., 2009)	**Total**	**2 (2)**
		Detailed	0 (0)
		Just mentions	2 (2)
Equity-deserving populations’ **satisfaction with the preparation for decision-making**	“Improved outcomes for participant comprehension, for both immediate information recall and delayed recall, participant satisfaction (particularly regarding understanding), and reduced patient anxiety levels have all been attested in both systematic reviews and individual studies of multimedia approaches to consent procedures conducted with fluent English speakers.” (Hughson et al., 2016)	**Total**	**1 (1)**
		Detailed	0 (0)
		Just mentions	1 (1)
Whether equity-deserving populations have **knowledge about clinical trials**	“Many potential participants lacked any knowledge of clinical research (62%). […] potential participants believed that clinical trials were conducted when the prognosis was poor and doctors preferred not to pursue treatment. For example: “So, my feeling is that, when doctors mention a clinical trial, it seems like [they are] going to give up on you.”” (Limkakeng et al., 2013)	**Total**	**29 (29)**
		Detailed	2 (2)
		Just mentions	27 (27)

easily capturable characteristic, yet it was only the focus of two reviews.

The predominant focus on racially and ethnically diverse groups is merited given the prejudice and discrimination that still exists in our health care systems [54, 55]. Still, there is a need to better understand trial participation experiences among many other groups, including sexual and gender diverse persons, rural communities, economically disadvantaged populations, culturally and linguistically diverse groups, and Indigenous peoples. With few reviews considering multiple PROGRESS-Plus categories concurrently, apparently little attention has been given to various intersections of sociodemographic factors that influence trial participation. Only by considering uniquely layered experiences can we determine whether or where experiences of under-researched groups fit within the current body of evidence. Additionally, improving upon the often-incomplete reporting of sociodemographic characteristics by primary studies could inform a more intersectional perspective to trial participation challenges and solutions.

From identifying to solving trial participation issues

The literature on barriers to equity-deserving populations' participation in clinical trials is vast and speaks to the diverse contexts that strategies to improve participation must address. Barriers were more common than strategies, suggesting a greater focus has been placed on problems with, rather than solutions to, trial participation. It is possible that strategies could address multiple barriers at multiple levels, such as conducting community-led research, addressing both the community barriers of group mistrust and social stigma and the structural barriers of limited infrastructure, interpersonal barriers of poor communication, and individual barriers of low knowledge and awareness of trials. Most strategies being community- or organizational-level could signify a positive shift from the onus of poor participation being placed on equity-deserving populations rather than on the institutions and policies that uphold their exclusion. Similarly, strategies to enhance trial inclusivity (e.g., PE) could potentially minimize unintended harms to equity-deserving groups when they are the focus of research, such as being labelled as 'hard-to-reach' or defined primarily by disadvantage, which could reinforce existing stigma surrounding their social identities. The limited discussion of policy- and systemic-level barriers, enablers, and strategies may also reflect the difficulties of addressing systemic issues or implementing system changes. Many barriers and enablers in our meta-review resonate with research on barriers and enablers to trial participation in general [56]. However, we have raised nuances within the factors affecting equity-deserving populations, including those related to mistrust and social determinants of health, pointing to the importance of context.

Implementing strategies is nearly, if not always, context- or resource-dependent. For example, outside of countries where funding streams for patient navigation in trials exist, like the Canadian Cancer Clinical Trials Network navigator program and the National Cancer Institute Community Oncology Research Program in the US [57, 58], patient navigation may not be a viable strategy. Trial teams could consider which strategies address the most relevant barriers for the population(s) they intend to recruit that fit within resource limitations in their setting, as many other strategies have been deemed effective for improving trial participation among a range of equity-deserving groups. However, redistributing resources to better prioritize strategies to improve trial participation among equity-deserving populations would be needed for more meaningful change [59]. Some efforts are working toward this, including calls for implementation science projects to embed equity throughout organizations, sectors, systems, and policies and within outcome measures, models, strategies, and dissemination efforts [60].

Engaging with a diversity of lived experiences

One area in need of better resource distribution is PE [59]. Despite most included reviews being published in the last 5 years, reporting of PE was low. We also found a narrow range of lived experiences in PE activities. Most PE was coded at more engaged levels (i.e., involve and collaborate); however, few reviews mentioned any PE activities other than including patient partners on trial teams. We were surprised to find little to no discussion of patient-identified priorities or outcomes given the primary reason for discontinuation of trials is poor recruitment [61]. A systematic review by Fergusson et al. [62] identifying 371,159 published trials found that only 23 reported PE, nine of which (39.1%) involved equity-deserving populations (children in three and "minorities" in six). Thus, PE appears to be even more scarcely used among equity-deserving populations. Fergusson et al. [62] similarly found little reporting of PE in the development of the research question and selecting outcomes in their sample; thus, perhaps, some patients are not participating because the trial does not seem relevant to them. In contrast, PE in translating knowledge into practice was higher in our meta-review, suggesting PE may be seen as more important in the research dissemination stages when equity-deserving communities are involved. We argue, however, that addressing evidence-practice gaps should start with the co-selection of priorities and outcomes, and mechanisms to support these processes.

In line with a review on Torres Strait Islander engagement in cancer research [63], our findings also underscore a need for true partnership with Indigenous peoples to improve health outcomes. Although reviews generally did not report co-creating knowledge translation plans and research agreements with Indigenous communities, more reviews reported engagement at the 'empower' level with Indigenous communities compared to non-Indigenous communities. This difference may reflect a focus on Indigenous rights of self-determination and data sovereignty [63]. Reviews also lacked a discussion of strengths-based approaches, such as adopting Indigenous conceptualizations of health and wellness over Western worldviews. Research tends to over-emphasize Western views and adopt a deficits-based perspective. A paradigm shift that focuses on community strengths rather deficits could better highlight enabling factors to support their inclusion in trials [65].

Lack of discussion on quality participation decisions among equity-deserving populations

To understand how to better support equity-deserving populations in making informed participation decisions, researchers should measure whether trial participation decisions are consistent with people's values, needs, and preferences [31]. However, with the limited discussion of SDM outcomes among included reviews, it is difficult to understand the specific features that contribute to good-quality patient-clinician communication and how to consider the values of equity-deserving populations. Discussions of SDM outcomes were even more limited when considering populations beyond the 'race, ethnicity, culture, language' category of PROGRESS-Plus, emphasizing a need to explore SDM outcomes among a greater diversity of lived experiences. No reviews mentioned clarifying what aspects of trial participation matter most to equity-deserving populations and only five measured whether they felt informed about the different options available (i.e., to participate, to not participate, to receive standard of care, etc.)—two key components of good communication. Certainly, good-quality trial participation conversations can exist with or without the intentional use of all SDM constructs. However, given in-depth, two-way conversations between trial recruiters and equity-deserving patients occur less often than with patients in more socially advantaged patients [36], implementing SDM elements, particularly preferences and information about options, in trial recruitment conversations with equity-deserving populations may be even more important to achieve full informed decision-making about participation [66].

While communication, values, and knowledge about trials are important, other outcomes are likely also relevant to equity-deserving populations. Initiatives like the Core Outcome Measures in Effectiveness Trials (COMET) have begun actively involving patients in core outcome set development, including in trials among equity-deserving populations, and have shown that patient involvement leads to a greater reflection of the impact of trials on patients' lives in core outcome sets [67]. Similar work could be done to determine which SDM outcomes are particularly important among equity-deserving groups.

Strengths, limitations, and future directions

A major strength of this meta-review was our engagement with persons with lived experience. Particularly, in our discussions during data extraction, patients and persons with lived experience asked questions and shared ideas on how to examine or interpret the data, which subsequently informed our coding and analysis. In our discussions about the results, their input was instrumental in directing which findings were most interesting and how to best communicate them. The former discussions were more challenging than the latter, likely due to the length and complexity of our data extraction form and abstractness of ideas at this stage. However, creating space for members to both grasp and debate our extraction items could have partially contributed to the richness of our later discussions on our findings as the group had prior knowledge of how items were coded. Our use of comprehensive frameworks to extract and code the data helped us to consider a range of equity-deserving populations, conceptualize PE and Indigenous community engagement more broadly than with other PE tools [50], and reflect on other patient experience and quality outcomes. Our findings highlight areas to advance these frameworks, particularly PROGRESS-Plus, where we incorporated diverse sexual and gender identities into the 'gender and sex' category. Finally, our extraction and coding of barriers, enablers, and strategies laid the groundwork for future in-depth analyses of key trial participation determinants among mulitple equity-deserving populations, which has not yet been conducted at a meta-review level.

As for limitations, we did not include search terms related to PE and SDM but instead considered whether any reviews about clinical trial participation pertaining to one or more equity-deserving population discussed any PE or SDM concepts. Despite using the PROGRESS-Plus acronym, we could have missed relevant reviews focusing on other equity-deserving populations, such as persons with low health literacy, for whom PE and SDM may be highly valuable approaches to improve trial participation [68]. There may also be a geographic bias as 70% of the included reviews were conducted in the US. Thus, our findings may not reflect other contexts, including differences in conceptualizations of PE, available resources, and health care system structures. Finally, the low reporting of PE could be due to a lack of PE, poor reporting, or our search terms. Some trial teams may be doing PE, even doing PE well, but are not reporting it due to journal word count limitations or lack of explicit prompting from journals to fully report PE activities. Mandating PE statements in publications or trial databases regardless of whether PE occurred could bolster the value of PE in trials, help trial teams consider PE, and promote complete reporting of PE activities in trial publications and reports [50, 69–71].

Aside from more empirical research among relatively under-studied equity-deserving groups (e.g., sexual and gender diverse persons, educationally disadvantaged persons, and populations based on religion, occupation, social capital, relationships, time-dependent factors), we encourage groups to focus efforts on investigating why existing barriers remain unaddressed despite the presence of effective strategies (e.g., through a behavioural science approach) and to deprioritize reporting on existing barriers and strategies. Such efforts may lack consideration of the underlying reasons as to why strategies succeed or fail in real-world settings, which could be explored through qualitative studies. Researchers could apply frameworks, such as the Consolidated Framework for Implementation Research [72], to code implementation determinants of strategies to support equity-deserving groups' participation in trials. Conceptual mapping using other frameworks, such as the Implementation in Context Framework [73], could help gauge whether certain barriers, enablers, and strategies apply to select populations or generalize across contexts, such as whether the mechanisms explaining why PE improves trial diversity apply across different trial contexts [28, 74]. Community-driven research could also assess whether equity-deserving populations face the same unresolved barriers, whether barriers have changed over time, or whether some strategies may no longer be effective, which may require novel strategies co-developed with patients and communities. If the same barriers, enablers, and strategies are persisting with no change in trial participation or health outcomes among equity-deserving groups, these trends could help estimate the degree of research waste.

Conclusions

This meta-review of 100 reviews discussed a variety of factors that may inhibit or promote equity-deserving populations to participate in clinical trials. PE and SDM are important for ensuring that clinical trial design and conduct align with patient experiences, arguably even more so among equity-deserving populations. However, fewer than half of reviews described PE and even fewer described Indigenous community engagement. Similarly, few of the internationally agreed SDM outcomes were discussed in detail. When conducting research that aims to serve equity-deserving groups, one would hope that they are engaged and their values and preferences are prioritized. We highlight opportunities where the use of PE and SDM among equity-deserving groups who have received less attention in research can be better studied and reporting can be improved. Future research should be also conducted in more countries as 70% of included reviews were conducted in the US. We encourage trialists to better consider patient and community priorities, needs, preferences, and experiences to address these multiple present gaps by working with patients and communities.

Supplementary Information

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Supplementary Material 1

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Author contributions

TLM, JCB, SM, and DPR conceptualized the study. JCB, SM, DPR, KM, KG, CE, and JP provided guidance and content expertise throughout the project. TLM wrote and edited the manuscript. TLM and MM screened all articles. TLM, KC, AW, and NH extracted and coded the data. JCB acted as the third reviewer to resolve screening, extraction, and coding disagreements. DPR facilitated the patient engagement activities for the project. MG, MS, and MW provided input on the relevance and understandability of the data extraction, analysis, interpretation regarding patient and lived experiences, and this manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval

Not applicable.

Consent for publication

Not applicable.

Patient engagement

Engagement with patients and persons with lived experience occurred from the early data extraction phase of this meta-review to the writing stage to guide our approach to data analysis, data visualization, interpretation of findings, and manuscript writing/reporting. Several patients and persons with lived experience engaged throughout the project and are acknowledged above, while others were more deeply involved across the full project timeline, some of whom met co-authorship criteria and wished to be listed in the author list. See the Methods, Discussion, and Supplemental File 3 for further details.

Competing interests

DPR is a full-time employee of Five02 Labs, Inc., which is under contract to Clinical Trials Ontario to provide services related to patient and public engagement and is the volunteer Vice President of the Canadian Arthritis Patient Alliance, an organization which receives the majority of its funding through independent grants from pharmaceutical companies. All other co-authors declare no conflicts of interest.

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