

REVIEW

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Patient engagement and shared decision-making in trial recruitment intervention studies: a systematic review

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Abstract

Background Supporting participation decisions and experiences in clinical trials is a persistent challenge that could be improved by two areas: patient engagement (PE), which involves actively collaborating with patients to enhance research relevance and value, and shared decision-making (SDM), which involves helping individuals make evidence-informed, values-based decisions about participation. The extent to which PE and SDM have informed trial recruitment interventions has not been synthesized.

Objectives We aimed to explore (1) how PE informed recruitment interventions, both in general and among equity-deserving populations, and whether demographic differences existed between studies using and not using PE, and (2) how SDM has informed recruitment interventions, both in general and among equity-deserving populations.

Methods We identified randomized and quasi-randomized recruitment intervention studies from a prior Cochrane review and the Online Resource for Research in Clinical triAls database. We assessed recruitment interventions for reporting of PE and coded the level at which PE occurred ('substantive engagement', 'limited engagement', 'both', 'unclear', or 'no engagement') and the areas in which PE occurred (development of the research question, intervention design, selecting outcomes, dissemination/implementation, or 'other'). We coded SDM across six domains: providing information about options, probabilities, clarifying outcomes, guidance in deliberation, using evidence, and disclosure and transparency.

Results Of the 122 recruitment intervention studies included, 37 (30.3%) reported PE, although limited engagement was most common ($n = 22$; 59.5%). PE was most often used in designing the recruitment intervention ($n = 32$; 86.5%) followed by 'other' ($n = 11$; 29.7%; e.g., PE supporting participant recruitment efforts), developing the research question ($n = 2$; 5.4%), selecting outcomes ($n = 3$; 8.1%), and dissemination/implementation ($n = 3$; 8.1%). SDM was occasionally reported ($n = 25$; 20.5%), most commonly as 'providing information about options' ($n = 11$; 9.0%). Equity-deserving populations were the focus of 24 studies (19.7%); 11 of these also used PE (9.0%).

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Conclusions Efforts to improve trial participation have not been informed by literature around patient lived experiences. Recruitment interventions infrequently reported any PE and occasionally mentioned SDM. When PE was mentioned, it was usually limited. These results hold among studies involving equity-deserving populations. Greater consideration of PE and SDM could enhance trial recruitment, research impact, trial participation experiences, and equity in trial recruitment.

Plain English abstract

Background Getting people to participate in clinical trials is challenging. Two approaches that can help are working closely with patients to ensure the research is important to them (called patient engagement, or PE) and helping them understand their options to make informed choices about whether to participate (called shared decision-making, or SDM).

Objectives We wanted to find out how PE and SDM are used when recruiting people for trials in general and when recruiting populations that are often left out of trials. We also wanted to find out the differences between studies that use PE and those that do not.

Methods We reviewed studies about how people are recruited into trials. We checked whether these studies used PE, how engaged patients were (ranging from very engaged to not engaged at all), and where they were engaged, such as helping to choose the research question or sharing results. We also reviewed how SDM was used, such as providing information about options or using evidence to help people decide.

Results Of 122 studies, only 37 mentioned PE, mostly at low levels of engagement. PE was mostly used to help design the recruitment strategy. Only 25 studies mentioned SDM, mainly by providing people with information. Only 24 studies focused on groups that are often overlooked, and only 11 of these used PE.

Conclusions Most efforts to ask people to join trials have not reflected patients' real-life experiences. Using PE and SDM more effectively could help more people participate and lead to fairer recruitment.

Keywords Patient engagement, Patient and public involvement, Patient partner, Shared decision making, Systematic review, Methodology review, Recruitment interventions, Clinical trial, Trial participation, Equity-deserving

Background

Recruitment in trials is a foundational element of scientific advancements in health care yet is a consistent challenge across nearly every branch of health care research [1–4]. Approximately 20% of National Cancer Institute-funded trials in the United States (US) were discontinued because of recruitment issues [5]. Further, 37% of trials funded by the United Kingdom (UK) National Institute for Health and Care Research between 1997 to 2020 failed to meet their recruitment targets, with some clinical areas experiencing lower recruitment rates (e.g., infectious disease, stroke) than others (e.g., obstetrics and gynecology) [6]. Low recruitment rates are associated with a wide range of financial and social costs such as wasted resources, delayed health care improvements, potentially biased or imprecise results, and ethical issues associated with exposing participants to risk without scientific gain [7].

Clinical trial participation is a human-centered term that can encompass many elements of clinical trials, including informed consent, recruitment, enrollment, retention, and post-study completion activities (or study-related terms), and thus relates to the overall experience of participating in a trial. Patient engagement (PE) and shared decision-making (SDM) are two complementary areas relevant to improving trial participation

experiences, as they each promote the inclusion of lived experiences and patient perspectives in trial design and conduct [8, 9]. PE is the term used in North America and differs from the UK terminology of 'patient and public involvement', or PPI; however, the two definitions align. The Strategy for Patient Oriented-Research (SPOR) in Canada and the Patient Centered Outcomes Research Institute (PCORI) in the US have defined PE as meaningfully involving patient partners and other interest-holders throughout research priority-setting, conduct, and dissemination/implementation [10, 11]. These definitions center on the including patient perspectives as complementary expertise to that of research teams. Relatedly, SDM centers on patient perspectives more directly, by enhancing the experiences of potential participants who are deciding whether to participate in trials [12]. Both PCORI and SPOR define 'patient partners' as people with lived and living experience who represent the population of interest and the families, caregivers, and organizations that represent them, all of whom are distinguished from patients who are enrolled as research participants [10, 11]. As much of the literature has previously focused on trial recruitment, we use this study-related term when reporting on past research, but we use the human-centered term 'trial participation' when focusing on patient perspectives within PE and SDM.

The area of PE could shed light on how to improve trial participation [13]. A growing body of literature has explored PE in health care research as an important and relatively untapped approach to enhancing health care research and interventions [13]. Related concepts such as *patient-oriented research* [14], *patient and public involvement (PPI)*, *patient-focused research*, *consumer involvement* [15], and *integrated knowledge translation* [16, 17] all highlight that wide-ranging benefits may stem from engaging with those who will be impacted by, or will use, the research findings. Specifically, PE can contribute to more pragmatic trial design, highlight participation issues that researchers may have missed, and foster trust, research literacy, and a sense of purpose among patients who are engaging with research teams [8].

PE can occur at multiple levels. For instance, the International Association of Public Participation (IAP2) Spectrum of Public Participation specifies five levels of PE, from informing patients of trial findings to consulting, involving, or collaborating on aspects of trials, to empowering patients in making final decisions (e.g., allowing patients to advocate for trials they have had positive experiences with). Given the ‘inform’ level describes a one-way transfer of knowledge, we conceptualize only the consult to empower levels as PE in this review. Other work has described how PE can occur in multiple areas, including developing research questions, selecting outcomes, delivering the intervention, and analyzing, interpreting, and disseminating trial results [18]. Across many areas of health care improvement, PE is being shown to enhance the uptake of research into practice, communication between interest-holder groups, relevance of research to patients, and overall capacity for health system improvement [16].

A second literature that could complement the use of PE in trials is SDM, which is a patient-oriented, theory-informed approach to supporting individuals in making deliberative, evidence-informed health decisions, including whether to participate in trials [19–21]. Key elements of SDM approaches comprise providing potential participants with balanced information about all options, ensuring understanding about what participation entails, assessing decision-making needs, clarifying values and outcome preferences, providing structured guidance, and developing decision-making and communication skills [20]. Employing SDM principles in trial recruitment has been found to improve patients’ trial experiences, particularly at the time of recruitment, by building rapport between patients and recruiters and helping patients increase their knowledge about trials and their conditions [12]. The extent to which SDM can improve recruitment rates remains largely untested. However, applying SDM alongside decisions about trial participation could facilitate more informed decisions about participation,

which could improve recruitment if the potential participant feels that participation aligns with their needs, preferences, and values.

Most research on PE in clinical trials has focused on overcoming issues with the informed consent process, such as burdensome consent documents [22, 23]. However, all aspects of trial design and implementation, from conception and design of the research question to publication and implementation of results, affects patient experiences [24, 25]. Therefore, using PE to solicit patients’ expertise on what makes a good (and bad) trial experience could help improve trial participation rates and experiences in ways that extend beyond documentation. Qualitative research has outlined how PE can facilitate trial recruitment, ranging from improving consent document terminology to providing broader input in steering group meetings [26]. Moreover, quantitative studies on the effectiveness of PE in improving recruitment have yielded modest but promising results [27, 28].

Further, a Cochrane systematic review comparing the use of a decision aid (a SDM tool) to usual care or alternative interventions among people facing treatment decisions reported that participants who received a decision aid were more knowledgeable, active in decision-making, and satisfied with their decision, had more accurate perceptions of risk, and had less decisional conflict [21]. Thus, SDM could also promote the rates and experiences of trial participation by helping patients play a more active role in participation decisions, improve their satisfaction with their decision, and achieve greater health outcomes, including taking treatment as prescribed [9].

While PE and SDM may support trial participation generally, they may have specific benefits in trials involving equity-deserving populations (i.e., any group that is underrepresented in health research or faces barriers to accessing health care due to systemic forms of discrimination, including but not limited to racism, ableism, transphobia, sexism, or ageism) [29]. Researchers have argued that PE can increase the impact of trial findings to society, redistribute privilege in the research enterprise, and enhance consideration of equity, inclusivity, diversity, and social justice in research, given the right people are involved [30, 31]. For instance, PE can help trialists address inequities in trial design by considering what logistical or systemic barriers individuals of equity-deserving communities face that hinder their full participation in trials [32]. Elements of SDM may also be relevant in interventions aiming to recruit individuals from equity-deserving populations or interventions testing the specific effects of PE on recruitment as it may help trialists better support inclusivity and the quality of participation decisions [31, 33]. In both scenarios, PE and SDM could arguably be more helpful in improving both trial participation and generalizability of trial results by

facilitating access to silenced communities, enhancing understandability of recruitment materials, and increasing the potential to participate by lessening barriers [34, 35].

There is considerable work evaluating interventions that aim to improve trial participation rates [36]. However, relatively few studies have focused on PE or SDM as the primary intervention under investigation, and the extent to which PE and SDM are a component of recruitment interventions has not been systematically explored. Therefore, the two aims of this review were to analyze existing interventions designed to increase trial recruitment to explore (1) whether and how PE has informed trial recruitment interventions, both in general and among equity-deserving populations, and whether demographic differences existed between studies using PE and studies not using PE, and (2) whether and how SDM has informed interventions, both in general and among equity-deserving populations.

Methods

Study design

We conducted a systematic review of the literature using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement to support complete reporting of this study (Appendix A) [37]. No protocol was published for this review.

Study selection

Study sources

As described elsewhere [38], we used two sources to identify relevant articles: (1) systematic searches from a Cochrane review of strategies to improve recruitment to randomized trials [36] and (2) the Online Resource for Research in Clinical trials (ORRCA) database [39]. Because our inclusion criteria resembled those of the Cochrane review, we retained all included articles from the Cochrane review (for details see Treweek et al., (2018) [36]). The ORRCA database collects and indexes publications relevant to the field of recruitment and retention research for clinical trials on an ongoing basis. We searched the recruitment ORRCA database on November 3rd, 2020, and again on August 11th, 2022 for English-language articles reporting on recruitment interventions that used randomized or quasi-randomized designs and nested randomized controlled trial methods, were published between 2015 and 2022, and included one or more outcomes of interest (i.e., number recruited, recruitment rate, willingness to participate, other, or unknown). Only host trials using randomized designs were of interest. We included only primary reports of recruitment interventions and did not search for protocols or supplementary materials.

Search results were de-duplicated and then screened at the abstract and full text level to ensure they met the inclusion criteria below. This screening was done by NH using the inclusion criteria from the Cochrane review [36]. Any unclear inclusion/exclusion decisions were discussed with KC, and if needed, were reviewed by JCB for a final decision.

Inclusion criteria

We included all published articles reporting on randomized or quasi-randomized recruitment interventions aimed at improving recruitment in a real or hypothetical host trial compared to either recruitment methods as usual or another intervention aimed at improving recruitment. Hypothetical trials were included as they can occur in advance of decisions to participate in real trials, and in some cases, participants are unaware that the trial in which consent is being sought for is not real. Thus, participation decisions made in studies about hypothetical trials can sometimes be indistinguishable from participation decisions for real trials and can provide additional insights on our topics of interest. Potential trial participants could be patients, caregivers, or representative community samples.

Exclusion criteria

We excluded any articles where the host study was a survey, observational cohort, or biobank study as these are generally considered lower risk for participants and may not present the same recruitment challenges as those recruiting to randomized trials.

Data extraction

Two of three raters (NH, KC, or SS) extracted and coded the data. Coders met regularly for consensus, with a fourth rater (JCB) resolving any discrepancies when consensus could not be reached. Coders extracted data into an Excel capture form developed by the authors. We used an initial set of six articles to pilot test and then revised this form for clarity and functionality.

Patient engagement (PE)

To address our first aim, coders assessed the presence of PE following guidance from the PCORI rubric [11] and previous work done by the study team [14]. PE was considered to be present when researchers reported engaging patients (or their family, caregivers, or organizations that represent them) on any aspect of the recruitment intervention study. PE was assessed categorically in line with the PCORI rubric [11], coded as 'substantive engagement', 'limited engagement', 'both', 'unclear', or 'none'. Studies were coded as 'substantive engagement' when there was evidence of levels of engagement more indicative of patient partnership (e.g., involve,

collaborate, empower [18]) and could have occurred with one to a few select individuals who had been involved in multiple areas of the study and who may have also been listed as a co-author or acknowledged by name. When available, we assessed contributor statements in the study manuscripts to clarify the extent of any PE. Studies were coded as 'limited engagement' when PE occurred in only one specific aspect of the study, such as in pilot testing informed consent documents, or occurred at levels of engagement (e.g., inform, consult [18]), and 'both' when there was evidence of both substantive engagement from one or a few individuals as well as limited engagement. Studies that gave some indication of PE, but where there was insufficient detail to distinguish between more substantive engagement and limited engagement, were coded as 'unclear' and studies that gave no indication of PE were coded as 'none'.

For studies reporting some form of PE, coders recorded the number of individuals involved, or listed studies as 'unclear' if no specific numbers or names of involved individuals were provided. Coders also extracted quotations where studies reported activities in line with PE. In some studies, the coders deemed PE to be integral to, or inseparable from, the intervention (i.e., an element of PE was the focus of study). Studies were coded as such if PE was the 'key ingredient' in improving recruitment. For instance, an intervention testing the impact of recruitment materials designed by patients versus standard materials would be coded as 'integral PE'. In contrast, PE that was not the focus of the intervention was not considered 'integral PE'. Examples of non-integral PE include interventions testing the impact of recruitment materials designed by the study team and only piloted by patients, or interventions where the PE is limited to reviewing the language and readability of recruitment materials.

We coded the areas in which patients were involved using items adapted from Fergusson et al. [14]: (1) developing research question for the recruitment intervention; (2) designing/developing the recruitment intervention; (3) selecting relevant recruitment outcomes; (4) planning, identifying, or participating in the dissemination or implementation of findings of the recruitment intervention into practice/health care; (5) other engagement not encompassed in the first four categories, such as engagement in the analysis and interpretation of findings). We categorized each area of engagement with a 'yes/no' response, with an additional open-ended response to capture details of engagement categorized as 'other'. Studies that provided insufficient detail to specify a clear area of engagement were coded as 'unclear'.

Shared decision-making (SDM)

To address our second aim, we assessed recruitment interventions for elements of SDM based on the six

domains from Brehaut et al. [40]. These domains were derived from the International Patient Decision Aids Standards Instrument [41] to evaluate whether informed consent documents for trials conform to patient decision aid standards. We coded whether recruitment interventions included elements of the six domains: (1) providing information about options, i.e., whether interventions explicitly described the intervention, health condition, advantages and disadvantages of participating, and side effects; (2) presenting probabilities, e.g., whether interventions provided quantitative information on the probabilities of advantages, disadvantages, and/or expected outcomes; (3) clarifying and expressing values, i.e., whether interventions described advantages/disadvantages in sufficient detail and asked participants to consider what matters most to them; (4) structured guidance in deliberation and communication, i.e., whether interventions included a tool and gave step-by-step guidance on deciding whether or not to participate; (5) using evidence, e.g., whether the scientific evidence used was cited; and (6) disclosure and transparency, e.g., whether the name and contact information of study personnel was provided. Domains were coded as either 'yes', where the domain was met to a greater degree in the intervention compared to the comparison arm, or 'no', where the domain was not met or was met to the same degree in all arms. Coders extracted quotations for all 'yes' or 'unclear' items to describe the presence of the relevant domain within each study.

Consideration of equity-deserving groups

We assessed for the inclusion of equity-deserving groups among recruitment interventions, whereby 'equity-deserving' populations were defined as any historically or currently underserved or silenced community that may face forms of systemic oppression such as, but not limited to, racism, sexism, transphobia, homophobia, classism, ageism, or stigma [29]. Coders extracted quotations or provided brief descriptions where studies clearly indicated that they were attempting to improve enrollment for such groups (e.g., interventions aiming to recruit African American participants). Coders also provided brief descriptions where studies did not make a clear indication that they were attempted to improve enrollment of equity-deserving groups, such as observed instances where participant groups were not representative of the population (e.g., 95% of the sample reported as non-Hispanic white participants).

Risk of bias

Risk of bias (RoB) was assessed by three independent coders in the larger review [38] using the 22-item Cochrane RoB 2 tool.

Data analysis

Data were imported into SPSS version 28 [42] to calculate frequencies for characteristics of included studies and use of PE and SDM. Frequencies and percentages of included studies were then represented in tables. Representative quotations from included studies were compiled to corroborate PE and SDM frequencies with authors' own descriptions of PE and SDM. Chi-squared (χ^2) analyses were run to assess for differences in demographic characteristics (i.e., publication year, country, real versus hypothetical decision, clinical specialty of trial, trial phase) between studies that reported using PE compared to studies that did not report PE.

Patient engagement in this review

Reporting of PE activities was guided by the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Form (Appendix B) [162]. Two patient partners engaged on this project by providing feedback on the grant proposal and manuscript. A group of patients and persons with lived experience of clinical trial participation also engaged in discussions about the manuscript, as members of the Clinical Trials Ontario College of Lived Experience. More details are provided in the PE section at the end of this manuscript.

Results

Figure 1 outlines the PRISMA flow diagram of study identification and inclusion. The search results have been described elsewhere [38]. In brief, the 68 papers from Treweek et al. (2018) [36] were automatically included and searching the ORRCA database [39] contributed 129 potential additional records. Following the removal of 24 duplicate records, further screening resulted in the exclusion of 57 records (further details provided in the larger review [38]). The final sample included 116 papers reporting on 122 individual recruitment intervention studies [43–158].

Of the 122 studies, 37 (30.3%) reported some level of PE. Table 1 describes the demographic features of these 37 studies. Most studies were published between 2010 to 2020 (86.5%), conducted in the USA (59.5%) or UK (35.1%), and pertained to recruitment into a real (versus hypothetical) host trial (56.8%). Among host trials, oncology was the most common clinical area (37.8%) and, unsurprisingly, Phase III (37.8%) was the most common type of trial. However, nearly half (45.9%) of studies could not be coded by trial phase due to a lack of reporting about the host trial or lack of fit with a phase category (e.g., screening trials). This demographic distribution resembles that of the larger review [38]. However, significant differences were observed between year of publication categories (χ^2 (3, 122) = 12.077, p = .007). A significantly greater proportion of studies reporting

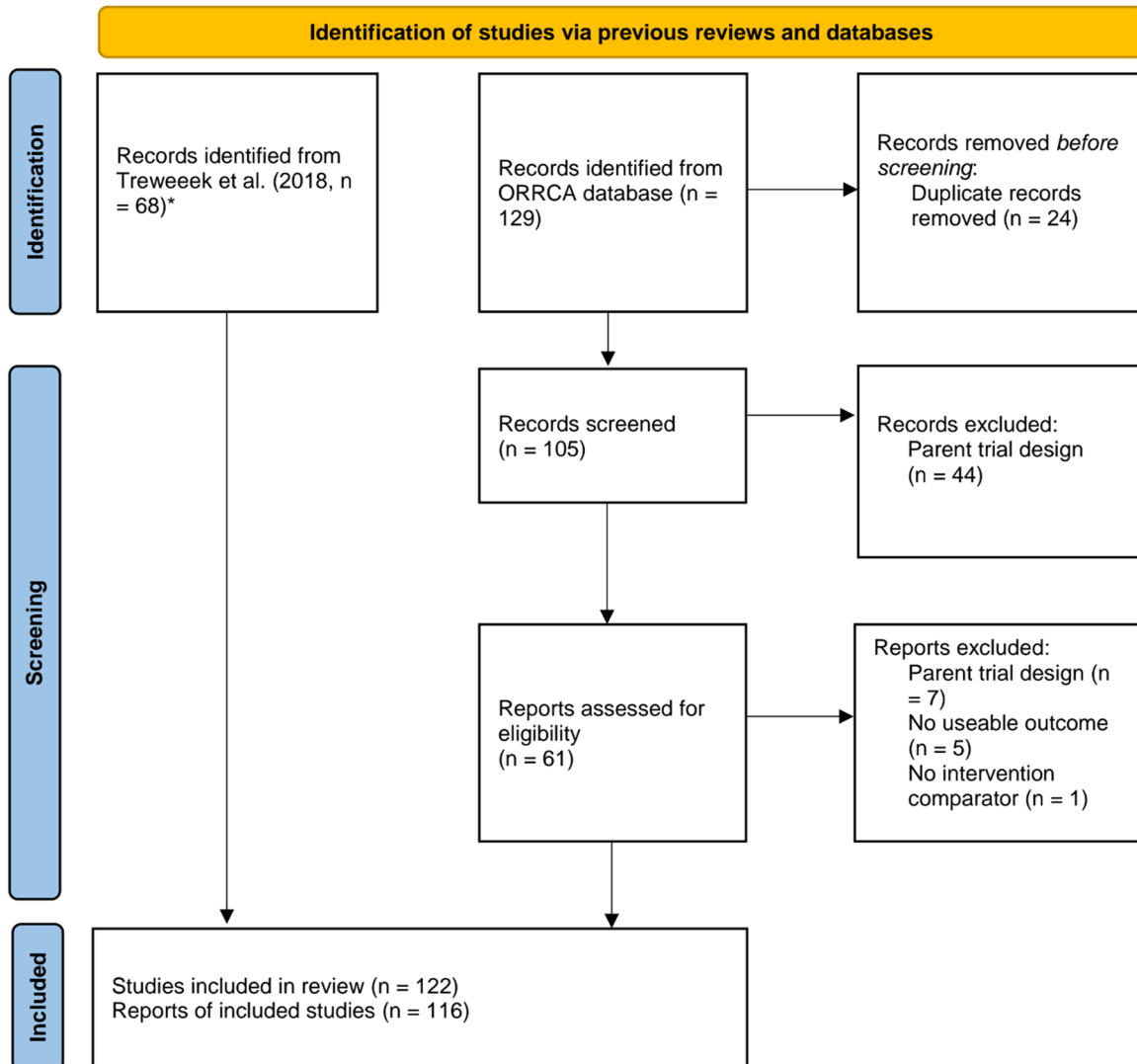
use of PE were published between 2010 and 2020 (86.5%) than in 2000–2009 (8.1%), with a similar but smaller difference observed in studies not reporting use of PE (54.1% published between 2010 to 2020 versus 34.1% between 2000 – 2009). No other statistically significant differences in demographic characteristics were found between studies that reported using PE compared to those that did not (see Table 1).

Patient engagement (PE)

Table 2 shows frequencies and examples of different types and areas of PE reported. Among the 37 studies (30.3%) that reported use of PE, most used limited engagement (n = 22; 59.5%), which typically involved a group of individuals assessing some element of documentation. For instance, Perry et al. interviewed patients to assess the acceptability and understandability of questions in a survey that was used to gather patients' preferences on the use of mobile technology in the recruitment intervention [150]. Combined use of substantive and limited engagement (n = 6; 16.2%) and substantive engagement alone (n = 2; 5.4%) was relatively rare. Seven studies (18.9%) were deemed to have 'unclear' PE due to insufficient description of PE activities in the study manuscript.

Most of the studies reporting PE (n = 28; 75.7%) involved patients in only one area of engagement, with engagement in the design of the recruitment intervention being the most common area (n = 32; 86.5%). For example, Jacobsen et al. [157] engaged patients in pretesting the modified recruitment materials and in evaluating the final version of the materials to ensure the intervention content was understandable and salient to their target audience. The second most common area of engagement was the 'other' category (n = 11; 29.7%), which included areas such as protocol review or approval, recruitment, or intervention delivery [2]. All other areas of engagement in the recruitment intervention study (i.e., research question formation, selecting outcomes, dissemination or implementation) occurred in less than 10% of studies. One study [152] used PE in three areas (i.e., research question, intervention design, and dissemination/implementation), demonstrating the feasibility of PE across the full range of trial recruitment intervention development activities.

The number of patients engaged ranged from one (2 studies, both using limited patient engagement [147, 148]) to 250 (one study, also using limited engagement [133]). Limited engagement typically encompassed less intense engagement and was more often used with larger numbers of patients, whereas substantive engagement typically encompassed engagement at more integrated levels, where patients were involved in decision-making across multiple or all aspects of a study, and was more often used among smaller numbers of patients. Studies

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only

* Records identified from Treweek et al. (2008) review were screened at the time of review and did not undergo additional screening for the current review since the same inclusion/exclusion criteria were used.

Modified from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

Fig. 1 PRISMA flow diagram

engaging fewer than the median number of patients (median = 21.5) were more likely to use both substantive and limited engagement ($n = 4$) or substantive engagement alone ($n = 1$) compared to limited engagement alone ($n = 2$), whereas studies engaging more than the median number of patients were more likely to use limited engagement alone ($n = 6$) compared to using both substantive and limited engagement ($n = 1$) or substantive engagement alone ($n = 1$).

In 13 of the 37 studies (35.1%), PE was integrated directly into the recruitment intervention. For instance,

the intervention by Larkey et al. [149] involved training and engaging Hispanic women who were already enrolled in their trial as *Embajadoras*, or Ambassadors, to advocate for other Hispanic women to participate in the trial. Among these PE-centric studies, limited engagement was the most common ($n = 8$, 61.5%), followed by using substantive engagement and limited engagement together ($n = 3$, 23.1%), substantive engagement alone ($n = 1$, 7.7%), and unclear ($n = 1$, 7.7%). The number of patients engaged among these 13 studies ranged from two to 118. Most often, PE was used in only one engagement area (n

Table 1 Descriptive characteristics of studies, including p-values from Chi-squared analyses ($N = 122$)

	Studies reporting use of PE ($n = 37$)	Studies not reporting use of PE ($n = 85$)	p-value
	Frequency (%)	Frequency (%)	
Year of publication			0.007
1980 to 1989	0 (0)	1 (1.2)	
1990 to 1999	2 (5.4)	9 (10.6)	
2000 to 2009	3 (8.1)	29 (34.1)	
2010 to 2020	32 (86.5)	46 (54.1)	
Country			0.125
USA	22 (59.5)	31 (36.5)	
UK	13 (35.1)	27 (31.8)	
Australia	1 (2.7)	10 (11.8)	
Canada	1 (2.7)	5 (5.9)	
France	0 (0)	2 (2.4)	
Italy	0 (0)	1 (1.2)	
International	0 (0)	2 (2.4)	
Other	0 (0)	7 (8.2)	
Trial participation decision			0.276
Real	21 (56.8)	57 (67.1)	
Hypothetical	16 (43.2)	28 (32.9)	
Clinical specialty of host trial			0.630
Oncology	14 (37.8)	22 (25.9)	
Psychiatry	3 (8.1)	2 (2.4)	
Pulmonology	3 (8.1)	1 (1.2)	
Cardiology	2 (5.4)	7 (8.2)	
Injury prevention	2 (5.4)	6 (7.1)	
Orthopedics	2 (5.4)	2 (2.4)	
Smoking cessation	1 (2.7)	4 (4.7)	
Gynecology	1 (2.7)	4 (4.7)	
Infectious disease	1 (2.7)	3 (3.5)	
Neurology	1 (2.7)	2 (2.4)	
Obstetrics	1 (2.7)	0 (0)	
Multiple specialties	1 (2.7)	8 (9.4)	
Non-specific	1 (2.7)	1 (1.2)	
Endocrinology	0 (0)	6 (7.1)	
Pediatrics	0 (0)	2 (2.4)	
Surgery	0 (0)	1 (1.2)	
Occupational health	0 (0)	1 (1.2)	
Geriatrics	0 (0)	1 (1.2)	
Bariatrics	0 (0)	1 (1.2)	
Rheumatology	0 (0)	1 (1.2)	
Palliative care	0 (0)	1 (1.2)	
Anesthesiology	0 (0)	1 (1.2)	
Gastroenterology	0 (0)	1 (1.2)	
Other	4 (10.8)	7 (8.2)	
Host trial phase			0.370
Phase IV	0 (0)	3 (3.5)	
Phase III	14 (37.8)	36 (42.4)	
Phase II	0 (0)	4 (4.7)	
Multiple trials/phases	6 (16.2)	17 (20.0)	
Other/Unclear	17 (45.9)	25 (29.4)	

PE = Patient engagement, USA = United States of America, UK = United Kingdom

= 6, 46.2%), followed by two areas ($n = 5$, 38.5%), then three areas ($n = 2$, 15.4%). The most common area of engagement was in the design of the recruitment intervention ($n = 12$, 92.3%), followed by other engagement ($n = 7$, 53.8%), selecting outcomes ($n = 2$, 15.4%) and dissemination/implementation ($n = 2$, 15.4%), and development of the research questions ($n = 1$, 7.7%). In 12 of the 13 studies, the recruitment intervention involved modifying trial information, in terms of who provides information about the trial and when, where, and how that information is provided.

Shared decision-making (SDM)

Table 3 shows how often and in which areas SDM domains were incorporated into the 122 recruitment intervention studies. The inclusion of any SDM element among the 37 papers using PE ($n = 8$; 21.6%) was proportional to the 85 papers not using PE ($n = 17$; 20.0%) and to the full sample of 122 papers ($n = 25$; 20.5%). Across the eight PE studies using SDM, the most common SDM domain was providing information about options ($n = 4$; 10.8%), followed by clarifying preferred outcomes ($n = 3$; 8.1%), guidance in deliberation ($n = 2$; 5.4%), using evidence ($n = 1$; 2.7%), and disclosure and transparency ($n = 1$; 2.7%). No PE studies included the SDM domain related to probabilities; however, four non-PE studies included information on probabilities. Elements of SDM were less than half as common in the integral PE subset as the 37 papers using PE and larger sample of 122 recruitment interventions.

Consideration of equity-deserving groups

Among the 122 studies, 65 studies reported the age (mean age = 51.1 years; age range = 14.2–77.7 years) and 81 reported the sex (mean percentage female = 61.7%) of recruitment intervention participants. Of these, 24 studies (19.7%) used binary sex terminology (i.e., only female, male) to describe participants, 32 (26.2%) used binary gender terminology (i.e., only woman, man), 26 (21.3%) did not specify whether sex or gender was used or were unclear, and 40 (32.8%) did not report sex or gender. A clear definition of sex and/or gender was only provided in one study (0.8%). While lack of reporting hindered a complete analysis of correct use of sex and gender terms, incorrect use was apparent. For instance, several studies included statements that data on gender was collected but used sex terms in their analyses. Of the 122 studies, 42 reported race and/or ethnicity data of participants (34.4%).

In 24 studies, authors clearly indicated that they were attempting to recruit and enroll persons of one or more equity-deserving groups (i.e., racially and ethnically diverse persons, $n = 19$; transgender persons, $n = 1$; older adults, $n = 2$; and persons with disabilities, $n = 2$;

Table 2 Level, area, and number of areas of patient engagement (PE) among studies using PE ($n = 37$)

Type of PE (Definition)	Example quotation	Frequency (%)
Limited engagement (Engaged patients during the study at a consultative level)	<i>"Easy-to-read consent statements were reviewed by the study's expert advisory panel and, in addition, by oncologists, research nurses, CRAs, and patient advocates before use."</i> [156]	22 (59.5%)
Substantive engagement (Actively engaged patients throughout the study at more involved, collaborative, or empowered levels)	<i>"Furthermore, 2 volunteers, with personal experience of back pain and clinical research, acted as patient advisors in this study. Research has shown that such "patient public involvement" in research can enhance the design and conduct of studies [36]. Both our volunteers participated in team meetings, which involved discussions and decision making around study design, procedures, and conduct."</i> [119]	2 (5.4%)
Both (Reported use of both substantive and limited forms of engagement)	<i>"The leaflet was piloted using a convenience sample (three women and two men), representing similar demographics as REFORM trial participants. This was discussed with the REFORM Patient and Public Involvement group to ascertain the readability and suitability of the language, design and information choices. Feedback from both groups was positive, and no changes to the leaflet were required."</i> [111]	6 (16.2%)
Unclear (Evidence of PE but unclear whether engagement was substantive or limited)	<i>"The other ('new sheet') minimised the use of the word 'falls' (including in the title) and instead emphasised maintenance of balance, health and wellbeing. The new wording was developed by the trial management group with advice from the local Older People's advisory group."</i> [114]	7 (18.9%)
Area of engagement^a(Definition)		
Research question (Patients engaged in identification/ development of recruitment intervention research topic)	<i>"Both PPIR members had active and ongoing involvement in EQUIP, one as a co-applicant and a member of the Trial Management Team; and both as part of the training team who delivered the user involvement training intervention to the host trial intervention clusters."</i> [152]	2 (5.4%)
Intervention design (Provide a clear description of the methods used for PE in the recruitment intervention)	<i>"The Authors' Informational Aid, named Culture Change in Research Participation Informational Aid (AIA; see a screenshot in Appendix A) was developed based on the literature on the significant barriers to clinical trial participation as well as data from formative focus group research studies."</i> [143]	32 (86.5%)
Selecting outcomes (Patients engaged in selection of relevant recruitment outcomes)	<i>"We employed a collaborative iterative design process, that included formative research with Shanti clients and navigators, and sought to develop an intervention that aligned with the Shanti model of care."</i> [140]	1 (2.7%)
Dissemination/ implementation (Patients engaged in planning dissemination efforts, participating in dissemination, identifying opportunities to present/share findings, or implementation of findings into practice/health care)	<i>"The patient advisors also helped to finalize recruitment materials and contributed to website design, for example, by providing feedback on prototypes of PoP. Of the 2 advisors, 1 advisor also chose to contribute to the process of writing up for publication."</i> [119]	3 (8.1%)
Other engagement (Patients engaged in any other way [see sub-categories below])	<i>"Patient and public involvement (PPI) forum members and qualitative experts developed study-specific components involving bespoke themes such as investigator details and benefits of participation. Generic information components included information on informed consent, randomisation, and confidentiality. Existing video clips of patients discussing their experiences of participation were edited for length and carefully matched to these components."</i> [129]	11 (29.7%)
<i>Acting in or providing feedback on videos used within intervention</i>		5 (13.5%)
<i>Pilot testing hypothetical scenarios</i>		1 (2.7%)
<i>Evaluating intervention components (e.g., surveys)</i>		2 (5.4%)
<i>Delivering the intervention</i>		1 (2.7%)
<i>Informed or conducted recruitment activities</i>		3 (8.1%)
<i>Unclear engagement in 'other' activities</i>		1 (2.7%)
Number of PE areas		
PE used in 1 area		28 (75.7%)
PE used in 2 areas		6 (16.2%)
PE used in 3+ areas		3 (8.1%)

^a Percentages exceed total number of studies due to some studies reporting engagement in more than one category

PE=patient engagement

Table 3 Frequency and areas in which SDM elements were used among recruitment intervention studies ($n = 122$).^a

Element of SDM (Definition)	Example quotation	Frequency (%)
Information about options (Does the intervention provide different/additional information about participant's options? e.g., describe more detailed advantages, disadvantages, health problem, side effects)	"All the scenarios included balanced information from both sides of the issue under consideration [...] Five topics directly related to different aspects of genetic research participation were selected for final inclusion: These were, duty to inform, duty to warn (family members), direct to consumer genetic testing, genetic discrimination and racial issues in genetically targeted care." [133]	11 (9.0) ^b
Probabilities (Does the intervention provide probabilities on information in multiple ways? e.g., probabilities of side effects, uncertainty, details on population, multiple frames presented)	N/A	5 (4.1)
Clarifying Preferred Outcomes (Does the intervention help participants clarify and express their preferred outcomes to a greater degree or a different way? e.g., provide more detail to show potential life impact, ask participants to think about which adv/dis matter most)	"A checkbox and additional white space was provided to the right of each question and response to enable patients to indicate that they did not understand a response and to write notes to discuss with the CRA or physician." [156]	7 (5.7)
Guidance in Deliberation (Does the intervention provide additional/different structured guidance to participants in deliberation and communication of their decision? e.g., tools to facilitate further discussion, step-by-step method to help decision process)	"The overall objective was to prepare patients for possible discussion and decision making about participation in a therapeutic clinical trial. [...] Patients and physicians served as spokespersons and provided recommendations that patients ask their physicians about clinical trials and, if eligible, consider carefully whether to participate." [157]	5 (4.1) ^c
Using Evidence (Does the intervention provide additional/different up-to-date evidence to participants? e.g., provide production dates, scientific citations, quality of evidence)	"Scripts provided factual content and sought to empower patients to ask questions and obtain additional information." [158]	1 (0.8)
Disclosure and Transparency (Is the overall study transparent for participants? e.g., provide name of PIs, contact info, name of REB, sources of funding)	"[Table 2] A section highlighting issues felt to be important to patients including: helping future patients, convenience, confidentiality, approval by a Research Ethics Committee. Quotation by EQUIP chief investigator about close working with PPIR members. Contained contact details of the study team." [152]	3 (2.5) ^d

^a Some studies reporting SDM in more than one category

^b Three papers in this category were 'unclear'

^c Two papers in this category were 'unclear'

^d One paper in this category was 'unclear'

SDM = shared decision-making

low education, $n = 2$; low income, $n = 1$; and limited English proficiency, $n = 1$). Of these studies, 11 also reported using PE (45.8%). In all 11, the recruitment intervention involved modifying trial information. Limited engagement was also the most often used form of PE among these 11 studies ($n = 7$, 63.6%): one study involved substantive engagement via a community advisory board [131], one used both substantive and limited engagement [140], and two were unclear. Use of PE in only one area was most common ($n = 6$, 46.2%), with engagement in the design of the recruitment intervention being the most used area of PE ($n = 10$, 90.1%). Four of these 11 studies reported the number of patients that were engaged (i.e., 3 [140], 16 [151], 27 [131], or 98 [149]); the remaining seven were unclear in how many were involved. In eight of these 11 studies, PE was an integral piece of the intervention [131, 140, 142, 149, 151, 153–155]. Five studies (20.8%) among the 24 that focused on equity-deserving populations included some element of SDM (i.e., information about options, $n = 2$; presenting probabilities, $n =$

1; clarifying preferred outcomes, $n = 2$; guidance in deliberation, $n = 2$; using evidence, $n = 1$).

Risk of bias

Figure 2 shows the RoB ratings by domain. A summary of RoB ratings is provided in the larger review [38].

Discussion

We explored the extent to which PE and SDM have been used in trial recruitment interventions. Despite the potential to improve participants' experience [12], PE and SDM have rarely informed efforts to optimize trial participation. Relatively few recruitment intervention studies reported using any form of PE, and when PE was used, it was typically limited and in only one area of the trial recruitment intervention. We also observed relatively little use of SDM approaches in studies seeking to enhance trial participation.

PE was used in less than one-third of the 122 recruitment intervention studies we explored, most commonly

Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Arundel, 2017	+	-	+	+	+	-
Bishop, 2019	+	+	+	+	+	+
Brierley, 2012	+	+	+	+	+	+
Chen, 2011b	+	+	+	+	+	+
Cockayne, 2017	+	+	+	+	+	+
Courtright, 2017	-	+	+	-	+	-
Coyne, 2003	X	+	+	+	+	X
Dear, 2012	+	+	X	-	+	X
Felicitas-Perkins, 2017	-	+	+	-	+	-
Free, 2010c	-	+	+	+	+	-
Frew, 2015	-	+	+	-	+	-
Fureman, 1997	-	+	-	+	-	-
Haynes, 2019b	+	+	+	+	+	+
Hughes-Morley, 2016	+	+	+	+	+	+
Jacobsen, 2012	+	+	+	+	+	+
Jolly, 2019	+	+	+	+	+	+
Kenerson, 2017	-	+	+	-	-	-
Kern-Goldberger, 2019	+	+	+	-	-	-
Kim, 2016	-	+	-	-	-	-
Kimmick, 2005	-	+	+	+	+	-
Krishnamurti, 2016	+	+	+	+	+	+
Larkey, 2002	-	+	+	-	-	-
Man, 2015a	+	+	+	+	+	+
Man, 2015b	+	+	+	+	+	+
Masset, 2017	+	+	-	+	-	-
Meropol, 2016	+	+	-	+	X	X
Mudano, 2013	X	+	-	+	+	X
Nickell, 2019	+	+	+	-	-	-
Ortiz, 2019	-	+	-	-	-	-
Parker, 2018	+	+	+	+	+	+
Peng, 2019	-	X	+	+	+	X
Perry, 2019	+	+	+	+	-	-
Skinner, 2019	+	+	X	-	+	X
Tilley, 2012	+	+	+	+	+	+
Wells, 2013	+	X	-	+	+	X
Weston, 1997	+	+	+	-	+	-
Witham, 2018	+	+	+	+	+	+

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
 High
 Some concerns
 Low

Fig. 2 Risk of bias ratings by domain

in the form of limited engagement, which suggests that a better understanding of the various PE approaches is warranted when developing recruitment interventions [22, 23]. A systematic review and meta-analysis by

Crocker et al. [28] on the impact of PE on clinical trial enrollment and retention also supports that community-based, community-led, and community-advised recruitment strategies led to significantly higher enrollment,

while support for trial participants from community health advisors led to significantly higher retention. While the present review did not report on recruitment or retention outcomes, our findings expand on those of Crocker et al. [28] as we found that PE can be applied in a multitude of ways across all aspects of trial design and conduct, from research question formation to dissemination of trial findings. We also found that limited engagement typically occurred with larger numbers of patients, while substantive engagement typically occurred with smaller numbers. Thus, different approaches (e.g., limited versus substantive PE) may be used for different aims. For instance, although it is possible for limited engagement to be unidirectional and allot decision-making power to researchers rather than patients, it may be beneficial as a starting point for those new to PE or may help in gathering a diversity of opinions to guide a trial [159]. Conversely, given substantive engagement can involve more bi-directional information sharing and greater collective decision-making with patient partners, it may have greater utility in emphasizing patient-identified priorities and building mutual trust and respect with communities [152, 160]. The low use of PE across trial recruitment interventions that we observed could stem from the many reported barriers to conducting PE in research [161]. Testing more PE approaches and techniques may thus help determine whether PE-informed recruitment strategies lead to better outcomes or different PE approaches are more effective in certain contexts. Here, reporting checklists like the GRIPP2 can be helpful to advance the transparency and quality of PE evidence [162].

About one-fifth of studies included any SDM element, suggesting there is potential to further explore how SDM in recruitment interventions can improve trial participation. The most common SDM domain was ‘providing information about options,’ which includes explaining all (dis)advantages of trial participation during the informed consent process. However, informed consent involves a process of decision-making that goes beyond simply reviewing participation (dis)advantages in informed consent documents [40, 163, 164]. Thus, it may be useful to explore whether other SDM domains help support these additional aspects of participation decisions. For instance, discussing probabilities could improve potential participants’ understanding of the risks of possible outcomes of participation, which is central to forming realistic expectations and informed decisions [165–167]. Moreover, providing structured guidance in deliberation could help avoid bias, decision traps, and uncertainty in decisions and ensure potential participants can clarify any misunderstanding before deciding [40]. The development of patient decision aids is one strategy to evoke more deliberative, values-based, and evidence-informed decision-making to ensure patients make explicit choices

about clearly defined options [21]. Decision aids are now also emerging to guide decisions related to engaging in PE and education to support inclusive PE [168]. Thus, adopting a range of SDM approaches could help trial teams both improve the process of participation decisions and support equitable partnerships moving forward [168, 169].

While PE and SDM may be potentially useful approaches to improve equity-deserving populations’ trial participation experiences, less than half of the 24 studies reporting on equity-deserving populations used PE, typically as limited engagement, and just over one-fifth used SDM. PE has been argued as crucial to recruitment efforts among equity-deserving populations [170] and to reduce health disparities [171]. More substantive engagement and consistent and expansive use of SDM could possibly enhance trial inclusivity and recruitment efforts by better integrating the perspectives of equity-deserving persons [172]. A recent report supports that limited knowledge and awareness of clinical trials may be common among some equity-deserving groups amidst other barriers such as language differences and lack of communication and trust with health care providers [173]. Providing detailed information about all participation options and helping people focus on what outcomes matter most to them could help support participation decisions in general, and regarding the historical and ongoing harms to equity-deserving groups made by the health care system and trials. However, trialists can take actions beyond simply providing information, such as initiating trust-building with communities and involving patients in trial governance [173]. Further, we found a binary use and conflation of sex and gender terms across recruitment interventions as only one study reported gender identity data, and no study reported sexual orientation data [174]. While most of the studies with equity-deserving populations in this review focused on racially and ethnically diverse populations, using inclusive terminology is relevant in any group as people hold multiple intersecting identities and variations in the therapeutic effects of interventions have been reported across sexual orientation and gender identities [174, 175]. Conducting PE with equity-deserving groups could help identify strategies to improve trial inclusivity and diversity, while SDM could help ensure trial participation decisions match the diverse values, needs, and preferences of equity-deserving individuals [21].

Finally, improved reporting of PE is needed to strengthen future evidence syntheses of PE and SDM in trial recruitment interventions and determine which kinds of PE and SDM most strongly influence participation outcomes [38]. Journals like *The BMJ* have started requiring authors to include PE statements in their manuscripts [176], including within manuscripts for

trials (e.g., the *Journal of Orthopaedic and Sports Physical Therapy*). However, few other journals have enforced PE reporting requirements. Guidelines have also been published to advance reporting practices for PE and equity considerations in trials, including GRIPP2, the Consolidated Standards of Reporting Trials (CONSORT) [177], and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [178]. Requiring explicit PE statements in journal publications, via requirements for authors to include the GRIPP2 or other PE reporting checklists for instance, could help gather a more robust account of PE and help capture when PE may be used, but not reported, by authors [179]. Journals could also promote the practice having patient partners report on their engagement in submitted manuscripts through the use of tools such as McMaster University's Patient and Public Engagement Evaluation Tool [180] or Patient Engagement in Research: A Toolkit for Patient Partners [181]. The findings of this review reveal the need for more consistent guidance on PE reporting, particularly in areas other than the design of the intervention, and how incorporating SDM can specifically improve trial participation experiences. Greater PE reporting guidance across health journals, for any study design, may increase the regularity and quality of PE and SDM reporting in trial publications, which in turn may inform clearer recommendations on optimizing trial participation.

Limitations

This review comes with several limitations. Our updated searches in the ORRCA database [39] were limited to articles published in 2022 or earlier and written in English. These criteria could have missed more recent papers or potentially produced biased results. Over 40% of included studies that used PE involved some element of hypothetical decision-making, which may impact real-world validity. However, assessments of the conditions under which hypothetical decision-making does and does not predict real-world decision-making is an underexplored area [182]. Further, it was not possible to contact the authors of the included studies to clarify items that we coded as 'unclear', which may have limited the amount of PE and SDM data we were able to code. Clarifying with authors could have helped us to determine whether the low prevalence of PE and SDM among included studies were due to a lack of PE and SDM use or reporting. The practice of reporting patient partners on authorship teams or in study acknowledgements is also imperfect and likely underestimates the PE activities that took place. Besides not being offered co-authorship, patient partners may choose not to be named as a co-author or acknowledged due to risks of stigmatization, discrimination, or other consequences based on being identifying publicly as a patient partner. In an upcoming

review, we plan to investigate reporting issues around PE by exploring reporting practices of when, how, and why, PE was used in trial recruitment interventions and the outcomes of PE. Future studies should similarly investigate when, how, and why SDM is used in recruitment interventions and SDM outcomes to accrue further guidance on applying SDM in trials. Finally, the International Committee of Medical Journal Editors (ICMJE) has published recommendations for the use, reporting, rationale, data collection methods, and analysis of sex and gender data when publishing in medical journals [183]; however, given the dearth of reporting on sex and gender data, we were unable to comment on the degree to which the included studies met each of these ICMJE recommendations. Enhancing the reporting of sex and gender data collection and analyses is an important future direction among trials and health research more broadly.

Conclusions

This review characterized the extent to which PE and SDM were used in recruitment intervention studies for clinical trials, overall and in studies among equity-deserving populations. Less than one-third of studies reported any PE, and most commonly involved limited engagement in only one aspect of the recruitment intervention. About one-fifth of papers reported SDM, usually in the form of providing more information about participation options. Few studies specifically aimed to recruit members of equity-deserving groups. There are key opportunities for recruitment intervention researchers to improve their use and evaluation of PE across different areas (e.g., research question development) and types (e.g., substantive engagement), and of their use and evaluation of SDM elements across different domains (e.g., clarifying values). Doing so may help optimize trial participation experiences, bolster patient-researcher relationships, support evidence-informed and values-based decisions about clear participation options and improve considerations for equity-deserving groups in trials [9, 28, 170, 172]. Journals adopting requirements for reporting PE and trialists routinely referencing existing guidance on PE and SDM in trial recruitment interventions could strengthen this evidence base.

Abbreviations

BMJ	British Medical Journal
CONSORT	Consolidated Standards of Reporting Trials
GRIPP2	Guidance for Reporting Involvement of Patients and the Public
IAP2	International Association of Public Participation
ICMJE	International Committee of Medical Journal Editors
ORRCA	Online Resource for Research in Clinical triAls
PCORI	Patient Centered Outcomes Research Institute
PE	Patient engagement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RoB	Risk of bias
SDM	Shared decision-making

SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPOR	Strategy for Patient Oriented-Research
UK	United Kingdom
US	United States

Supplementary Information

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Supplementary Material 1

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Author contributions

J.C.B., J.P., J.G., D.A.F., K.G., I.D.G., and M.T. conceptualized and provided guidance and content expertise throughout this project. N.H. drafted the initial manuscript and T.L.M. wrote and edited the final manuscript. N.H. and S.S. performed data extraction. N.H., T.L.M., and J.C.B. performed data analysis. N.H., K.C., and J.C.B. performed study screening. M.-L.Y. and J.I. contributed to grant writing for the larger project. All authors read and approved the final manuscript.

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Data availability

The dataset supporting the conclusions of this article is available on the Open Science Framework repository at <https://osf.io/ag3vj/>.

Declarations

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Patient engagement in this review

At the grant writing stage for this project, J.C.B. met with two patient partners (M.-L.Y. and J.I.) to discuss the proposed grant that would support this research and offer insight on what their partnership may look like. The patient partners contributed to the project by attending to online meetings to discuss the project, providing feedback on the grant proposal prior to submission, and providing feedback on this manuscript prior to submission. Additionally, one 90-minute online discussion was held with members of the Clinical Trials Ontario College of Lived Experience, including Heather Douglas, Christopher Fink, Kimberly Mitchell, Charlotte Munro, Maureen Smith, Murray Walz and others, to contextualize the study results within lived experiences of trial participation. This discussion was very helpful in shaping the manuscript as it resulted in several changes to the Introduction, Methods, and Discussion sections to clarify terms and definitions and better incorporate patient perspectives.

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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