Journal of Clinical Epidemiology 181 (2025) 111715

Journal of Clinical Epidemiology

ORIGINAL RESEARCH

Lack of data collection in clinical trials prevents us from evaluating inclusion of people with disabilities

Shauna Cunningham[a,b], Amy M. Russell[c], Emma Lidington[d], Frances Shiely[a,b,*]

[a]*TRAMS (Trials Research and Methodologies Unit), Trial Forge, HRB Clinical Research Facility, University College Cork, Cork, Ireland*
[b]*School of Public Health, University College Cork, Cork, Ireland*
[c]*Leeds Institute of Health Sciences, School of Medicine, University of Leeds, Leeds, United Kingdom*
[d]*Cancer Prevention Trials Unit, Queen Mary University of London, London, United Kingdom*

Accepted 1 February 2025; Published online 7 February 2025

Abstract

Objectives: Improving clinical trial inclusivity for diverse populations, including people with disabilities, is crucial. Ethical considerations emphasize the need for trial enrollment to mirror the potential trial users' diversity, yet underrepresentation persists due to direct and indirect exclusions. The purpose of our study was to determine if trial teams collect data on people with disabilities for diversity monitoring purposes. We also examined how they collect disability and report it.

Study Design and Setting: We reviewed trial reports for randomized controlled trials published in the UK National Institute of Health Research library from 2016 to 2021. We extracted data on disability, including if, how and when it was collected, who collected it, the measurements used, and the results presented.

Results: We extracted data from 407 trial reports. Disability was not collected as a demographic characteristic in any trial. 27% (109/407) collected some disability data for other purposes, eg, eligibility, a measure of functional outcome or serious adverse events. Disability was most commonly assessed through questionnaires (65%; 71/109), clinical assessment (17%; 19/109), and interviews (8%; 9/109). A variety of measures were used to collect disability information. In 109 trial reports, the most common was a measure of cognitive function, the Mini Mental State Examination, which accounted for 15% overall.

Conclusion: Disability is not just under recorded or underreported, it is ignored, in trials. As disability is not collected as a demographic characteristic, people with disabilities remain underserved in trials. Given 16% of the global population live with a disability, it is a threat to the generalizability of all trials and risks exacerbating health inequalities of people with a disability.

Keywords: Inclusivity; Diversity; Disability; Randomised controlled trials

1. Introduction

Improving inclusivity in clinical trials to ensure that findings apply to the whole population for which the intervention is intended, including those who are traditionally underserved in health and social care, is a priority for trialists and funders [1]. People with disabilities are one such group [2,3]. Arguments that trials require a homogenous sample to avoid confounding have been challenged [4]. We now understand that ethically, as well as for generalizability and implementation, clinical trial enrollment should reflect the diversity of the target population to ensure trial findings apply once implemented in practice [5,6]. Despite this, research shows that certain populations are directly and indirectly excluded from trials [2,7]. For example, cardiovascular trials consistently include fewer women despite

Funding: Shauna Cunningham was funded by HRB-TMRN 2023 Summer Scholarship. Amy M. Russell is supported by a Welcome Trust Fellowship 219754/Z/19/Z. Emma Lidington is supported by the CRUK Clinical Trials Unit Core Funding Grant CTUQQR-Dec 22/100005. These funding bodies did not have a role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Ethics statement: Ethical approval was not required for this study.

Consent for publication: All authors consent to the publication of this research.

* Corresponding author. TRAMS (Trials Research and Methodologies Unit), HRB Clinical Research Facility and School of Public Health, University College Cork, College Road, Cork, Ireland T12 XF62.

E-mail address: f.shiely@ucc.ie (F. Shiely).

https://doi.org/10.1016/j.jclinepi.2025.111715

What is new?

Key Findings

- Of 407 trial reports, none recorded or reported disability for diversity monitoring.
- 109 (27%) collected disability for other purposes such as eligibility, as an outcome measure, or for serious adverse events.

What this adds to what is known?

- Making trials more inclusive is a priority for the trial community. The collection of demographic data for diversity monitoring is essential to understand who is included and excluded from underserved groups. We are unable to assess whether people with disabilities are adequately included in research as this data is not collected.

What is the implication and what should change now?

- Trial teams need to actively consider the diversity of their participants and consider all potential underserved groups that may benefit from the intervention, including people with disabilities. Recording and reporting this demographic data is essential so we can continue to monitor progress in this area and ensure underserved groups, including those with disabilities, are part of trials and metaresearch studies.

known sex differences across a range of risk factors, preventative measures, treatment strategies and overall outcomes [8]. Exclusions of people with cognitive impairment are seen in areas such as geriatrics, rehabilitation interventions after hip fracture, learning disabilities, perioperative medicine, trauma and neurological research [9]. In one systematic review of hip fracture, trials excluded potential participants based on cognitive impairment, despite the fact that one in three patients with hip fracture typically has cognitive impairment [10]. We also know, in the UK, participant ethnicity in clinicals is under recorded and underreported [11] and sometimes eligibility criteria in a trial, through a combination of factors, makes it much less likely that ethnic minority individuals will be able and willing to participate in a trial [12].

Research on how to support the inclusion of some underserved groups has been conducted and reported by the National Institute for Health and Care Research (NIHR) INCLUDE project in the UK([13]). Frameworks to guide trial teams have been published for minoritized ethnic groups [6], adults who lack capacity to consent [14] (one part of the disability community) and those who are socioeconomically disadvantaged [15]. Interventions to increase representation of underserved groups have also been identified [16], guidance for trial teams on how to decide the proportions and diversity of ethnic groups in their trials [17], guidance on how to ask questions on sex and gender (sex and gender equity in research-guidelines) [18] and some more disease specific studies, eg, determining clinical perspectives and strategies for improving enrollment of minoritized communities in prostate cancer clinical trials [19]. Recent guidance has also been developed by the Multiregional Clinical Trials Center of the Brigham and Women's Hospital and Harvard University [20]. This accessibility by design toolkit is a comprehensive resource intended to be used by sponsors, institutions, investigators, ethics committees/institutional review boards, participants, and patient advocacy groups to support greater inclusion of people with disabilities in clinical research. This is welcomed by the research community as 16% of the global population worldwide, more than 1 billion people, have a significant disability, experience health inequity and will engage with the health service more frequently than those without disabilities [21,22].

One of the recognized challenges in this research area is an agreed model or definition of disability and this makes reporting of disability in trials even more challenging [23]. For example, disability can be described in terms of a medical model, ie, people are disabled by their impairments or differences or a social model, ie, disability is caused by the way society is organized [24]. Demographic questions can take different approaches to disability based upon the models of disability; asking individuals if they self-define as disabled, asking about impairments or following the social model asking about any barriers the individual experiences [25].

Definitions in legislation also vary from country to country and even within countries, eg, UK. For example, under the UK Employment Equality Act 2010 [26] you are disabled if you have a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities. 'Substantial' is more than minor or trivial, eg, it takes much longer than it usually would to complete a daily task like getting dressed and 'long-term' means 12 months or more, eg, a breathing condition that develops as a result of a lung infection. People with progressive conditions, eg, multiple sclerosis, HIV, are also classed as disabled. However, the UK Employment Equality Act 2010 does not apply in Northern Ireland. The employment equity act of the Government of Canada (1995) ([27]) defines a disability as, ''persons with disabilities means persons who have long-term or recurring physical, mental, sensory, psychiatric or learning impairment and who (a) consider themselves to be disadvantaged in employment by reason of that impairment or (b) believe that an employer or potential employer is likely to consider them to be disadvantaged in employment by reason of that impairment and includes persons whose functional

limitations owing to their impairment have been accommodated in their current job or workplace''. The examples for a 'disability' given are: ''acquired brain injury, attention deficit hyperactivity disorder, autism spectrum disorder, chronic health disability (e.g., Crohn's disease, hemophilia, epilepsy, asthma, diabetes, HIV/AIDS, cancer, pain, etc.), coordination or dexterity disability (eg, arthritis, cerebral palsy, cystic fibrosis, multiple sclerosis), deaf, deafened, hard of hearing, learning disability, mental health disability (eg, schizophrenia, chronic depression, anxiety disorder, bipolar disorder, etc.), mobility disability (eg, amputations; paraplegia; reliance on a walker, scooter or mobility aid due to disability), speech impairment (eg, aphasia, stuttering, cluttering, etc.), vision loss or impairment, legally blind (not correctable by glasses or contact lenses)''. For the purposes of our study, we have followed the Canadian definition.

Recent research cites the lack of comprehensive data on participation of people with disabilities in trials [2]. The purpose of our study is to establish if trial teams collect information on people with disabilities for diversity monitoring purposes to understand the representativeness of their trial population, the measures they use to collect this information about disability and how they report disability data.

2. Methods

We conducted an observational retrospective study of trial reports published in the NIHR library of UK trials and international trials in which there was a UK site.

2.1. Source of the data

We generated a list of all NIHR trial reports published between 2016 and 2021, inclusive. Full details of the methods are available in Wallace et al [11]. In brief, we selected all randomized controlled trials (RCTs) and excluded reports of all other trial types. We considered trial protocols as a potential source of information also, but we established that the trial reports were in fact more detailed than the trial protocols for the information we were seeking.

2.2. Data extraction and coding

We accessed the full trial reports from each trial. This included the main report, the scientific summary, and the lay summary. In addition to establishing if trial teams collected information on people with disabilities for diversity monitoring purposes, we wanted to know what measures they use to collect this information and how they report disability data. Thus, after the initial question was answered, we took a three-stage screening approach. Stage 1: Trials were included for further extraction if they mentioned the terms 'disability', 'impairment', 'impair', anywhere in the trial report. SC did the first screen. Stage 2: We reviewed the included trial reports from stage one with the following criteria in mind: trials had to collect disability information in some form to be described as having collected information on disability and to proceed to further extraction. Stage 3: AR, FS and EL examined each trial report from stage 2 over three online meetings. We assessed each report to see if it collected disability information. We agreed the template for the data extraction (Supplementary File 1). Finally, we extracted data on: whether disability information was collected and reported; how and when was it collected; who collected it; the measurements used; the specific categories of the measurements used; and the purpose of collecting disability. We were also interested in collecting information on whether disability was presented alongside participant characteristics, if it could be found in the discussion, if at any point they combined disability with anything else to provide an intersectional understanding of disability, and if it was mentioned in the lay or scientific summary.

SC and FS piloted the further data extraction for five trials. Extractions were compared and discrepancies discussed between SC, FS, AR, and EL. A further sample of five trials were piloted by SC. FS independently verified these and no discrepancies were found. SC conducted the remaining additional data extractions.

2.3. Data analysis

Descriptive statistics were used. Categorical and binary data were summarized as frequencies and proportions.

3. Results

Reports of 407 RCTs were found in the NIHR library, published between 2016 and 2021, inclusive. Of these, none recorded disability for diversity monitoring purposes.

One hundred and forty-three trial reports included the term disability or impairment (Stage 1). Thirty-four were excluded as no disability information was recorded, eg, the word disability may have appeared in the background in reference to the condition being investigated – blindness, but no disability data were collected as part of the trial. One hundred and nine trial reports collected either disability or impairment for reasons other than diversity monitoring (Stage 2) in their trial reports (27%). For this study's purpose, we use the term disability to include both disability and impairment. Disability could be collected multiple times within a trial, eg, as both an outcome or for a serious adverse event. Seventy-five (69%) collected disability as an outcome measure, 43 (39%) for serious adverse events, 24 (22%) to assess eligibility and 7 (6%) as part of determining working status.

The characteristics of the 109 trials that collected disability data for their trial, for reasons other than diversity monitoring, are presented in Table 1. The majority

Table 1. Trial characteristics

Characteristic	No. of trials ($n = 109$)	%
Location		
UK only	99	90.8
UK and other (multicentre, multinational, trials)	10	9.2
Population		
Children (<18)		
Adults 18-64	8	7.3
Adults ≥65	5	4.6
All adults	5	4.6
All ages	82	75.2
Others/not specified	9	8.3
Design/randomization		
2-arm individually randomized	73	67.0
3-arm individually randomized	14	12.8
Cluster randomized	11	10.1
Other	11	10.1
Intervention		
Drug (medicinal)	20	18.3
Nondrug (nonmedicinal)	86	78.9
Mixed	3	2.8
Phase		
Feasibility/pilot	40	36.7
1	0	0
2	14	12.8
3	17	15.6
4	4	3.7
Not specified	34	31.2
Comparator		
Active	28	25.7
Placebo	11	10.1
Treatment as usual	65	59.6
Mixed	5	4.6
Commercial/noncommercial		
Commercial	1	0.9
Noncommercial	108	99.1

were 2-arm (67%), nondrug (79%) RCTs in the UK (91%), conducted with adults (85%). All but one were academic trials.

3.1. Source of the disability data

Of the 109 trials that collected and reported on disability, the most common methods used to collect disability information were self-report questionnaires (71%) followed by clinical assessment (21%), and interviews (8%). Table 2 provides further details. In terms of who recorded disability status, 61 (56%) were self-reported and a further six were self-reported in combination with a researcher or clinician. Thirty-one (28%) were recorded by a clinician.

Table 2. Source of disability data

Measurement	$N = 109$[a]	%
Questionnaire (e.g., GAF, Global Assessment of Functioning, LIFE-RIFT The Longitudinal Interval Follow-up Evaluation – Range of Impaired Functioning Tool)	77	70.6
Clinical assessment	23	21.2
Interview	9	8.3
Existing records (e.g., disability living allowance records, National Pupil Database, receipt of disability benefit, postal codes)	3	2.8

[a] Numbers exceed the total as more than one source was sometimes recorded in an individual trial report.

3.2. Measures used to collect disability

Trials that collected disability by self-report or clinical assessment used a wide range of measures. Most of these covered specific aspects of disability related to the condition of interest (ie, cognitive function, physical function, specific symptoms etc.). The most used measure was the Mini Mental State Examination, a measure of cognitive function, which was used in 15% of trials collecting disability. Table 3 shows the most frequently used disability measures. The full list of measures is detailed in Supplementary File 1.

4. Discussion

The findings of this study shed light on the current landscape of disability data collection and reporting practices within RCTs. Strikingly, none of the 407 RCT reports presented disability information to assess the diversity or inclusivity of the trial population, indicating a notable gap in understanding the representation of individuals with disabilities in clinical research.

There is a global recognition of the need for inclusivity, and it is a protected characteristic under the UK 2010 Equality Act [28], and in Ireland under the Equal Status Act, 2000([29]). It is estimated that 1.3 billion people worldwide live with a disability [21], a number which is increasing due to demographic changes and rising chronic health conditions. Despite this, research has shown that data about disability at population level is poor [22,30], and in research people with disabilities are underrepresented in studies [2,31]. Our study on clinical trials is no different.

A recent review, of inclusion and exclusion criteria in a Cochrane systematic review of interventions for enhancing medication adherence found that in the 182 included studies, 1% excluded persons for hearing impairment, 3% for motor impairment, 7% for visual impairment, and

Table 3. Disability measures

Measurement $n = 109$	Purpose	$N = 109$[a]	%
The Mini Mental State Examination (MMSE)	11 questions used to check for cognitive impairment.	16	14.7
Modified Rankin Scale	Measures the degree of disability in patients who have had a stroke.	8	7.3
Oswestry Disability Index	Patient-completed questionnaire which gives a percentage score of level of function (disability) in activities of daily living in those rehabilitating from low back pain	5	4.6
Barthel Index (BI)	Measures the extent to which somebody can function independently and has mobility in their activities of daily living	5	4.6
Disability Rating Index	Measures physical disability of patients within a clinical setting	5	4.6
Glasgow Outcome Scale	Measures global disability and recovery after traumatic brain injury	4	3.7
Expanded Disability Status Scale	Used to decide who can take part in clinical trials of many MS drugs	4	3.7
The Montreal Cognitive Assessment	Screening instrument for dementia to differentiate mild cognitive impairment (MCI) or dementia from normal	4	3.7
Roland-Morris Disability Questionnaire	Measures self-rated physical disability caused by low back pain.	3	2.8
Bristol Activities of Daily Living Scale	Short assessment used to measure functional ability	3	2.8
Parent Report of Children's Abilities-Revised	A parent completed questionnaire that can be used to assess children's cognitive and language development at 24 months of age.	2	1.8
Work and Social Adjustment Scale	Global measure of functional impairment that is used in adult health	2	1.8
The Western Ontario and McMaster Universities Arthritis Index	Assesses the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints.	2	1.8
Global Assessment of Functioning (GAF)	Used to measure how serious a mental illness may be	1	0.9
Other (please see Supplementary File 1)	Measures children's and adolescents' subjective health and well-being, measures patients' independence in activities of daily living.	54	49.5

[a] Numbers exceed the total as more than one measure was sometimes recorded in an individual trial report.

32% for cognitive impairment [31]. In addition, the investigators in some of these studies had the ability to exclude people based on their judgment, thus the real figures are likely conservative estimates of exclusions based on disability. This research shows that people with disabilities are likely excluded; however, the extent of the problem cannot be known without collecting disability data from participants for the purposes of diversity monitoring to account for their representation. Well-known barriers affecting people with disabilities such as the availability of alternative formats of trial information, or transportation and access to research facilities [32] likely further exacerbate the explicit exclusion criteria used in many studies, leading to poor inclusion of this underserved group. Adjusting trial design decisions to a more pragmatic design to include real world data would mitigate this [33].

The characteristics of the 109 trials that collected disability data for purposes other than diversity monitoring provide valuable insights into current practices. Notably, the majority of these trials were two-arm, nondrug RCTs conducted in the UK with adult participants, predominantly academic in nature. The high prevalence of academic trials within this subset suggests a potential area for targeted intervention and collaboration between academic institutions and other stakeholders to address the underrepresentation of individuals with disabilities in clinical research.

Lack of data can mean lack of visibility. According to the World Health Organization, not collecting data on disability means disability becomes invisible and under prioritised in the health sector. They recommend 10 strategic actions for disability inclusion, one of which is to engage persons with disabilities in research [21]. The trial community has an opportunity to make a unique contribution to facilitate engagement with persons with disabilities [21]. In the UK, for example, the NIHR Involve framework for inclusion of patients and the public in research has been published since 2015. Furthermore, the INCLUDE project has published guidance and frameworks for including other underserved groups; the INCLUDE Ethnicity Framework [6], the INCLUDE Socioeconomic Disadvantage Framework [15] and the INCLUDE Impaired Capacity to Consent framework [14]. Most recently, the development of STEP-UP, guidance to help researchers design inclusive clinical trials https://step-up-clinical-trials.co.uk/ identifies six targeted areas for consideration, with suggestions for implementation, to improve accessibility to clinical trials for groups underserved by research [34].

One of the challenges faced by trial teams is that there is no one definition of disability. Disability can be thought of as an identity and collected in demographic data or, it can be seen as a nondemographic characteristic [35] or a health status [1] and classified alongside other health data and

only collected when relevant to a trial. We presented such examples in our introduction. However, one definition that may be workable is that of the WHO which defines disability in the International Classification of Functioning, Disability and Health (ICF) as an umbrella term for impairments and limitations that have a significant and long-term negative effect on the ability to participate in activities [36]. Despite critiques of the ICF, including those that call for greater recognition of the socioeconomic determinants of disability, it does provide an internationally recognized approach to describing disability [37]. These observations into the complexity of disability recording are not to discourage trialists by implying that there is too much intricacy in disability collection/recording. Many protected characteristics have complexity, but this cannot be a reason to perpetuate health inequalities through a lack of inclusivity in clinical trials [38]. The NIHR now ask disability questions to align its diversity monitoring for grant applications in line with the Equality Act[1]. When submitting for funding, an applicant is asked; ''Do you consider yourself to be disabled? Do you have any physical or mental health conditions or illnesses lasting or expecting to last for 12 months of more? With ''Y/N/prefer not to say'' options for answers [39]. Yet this same data is rarely collected from trial participants. While the NIHR Involve project is still active, is it time now to consider mandatory collection of data on underserved groups, including people with disabilities, to ensure equity for all? Or if not mandatory, evidence that the relevant considerations have been given during trial planning to ensure a diverse and representative population for the particular clinical area under research?

Another consideration is, who should provide this disability data and what type of disability data can be provided by different sources? In our paper, we present evidence of self-reported disability and clinician reported disability in the trial reports. Clinicians can report impairment and/or conditions listed in legislation regarding disability (eg, those listed in employment equity act of the Government of Canada (1995) (26). However, a clinician cannot report if an individual considers themselves to be disabled or give details of the barriers an individual experiences. The choice of source for disability data will inform the type of data supplied and will be grounded in the model of disability a trial team are working with [23]. We can also draw on past examples of our research where participants were excluded unjustifiably based on clinician opinion [7] and where we provide practical guidance to support better practice on how to recruit and retain individuals from ethnic minority groups to trials (Trial Forge Guidance 3) [12]. We suggest here that having worked with patient and public partners in Trial Forge Guidance 3, the same guiding principles/recommendations apply when thinking about disability status in your trial population: (1) Ensure your eligibility criteria and recruitment pathway do not limit participation in ways you do not intend. (2) Ensure your trial materials are developed with inclusion in mind. (3) Ensure trial staff is culturally competent. (4) Build trusting partnerships with community organizations that work with [disability] groups. Refer also to the Accessibility by Design Toolkit for comprehensive guidance on including people with disabilities in clinical research [20].

We know that people with disabilities are considered one of the major underserved groups in medical research [1]. A recent scoping review highlighted some of the systemic factors that affect the inclusion of this underserved population in trials [32]. Barriers included time and resource constraints on researchers making it difficult to pursue demanding inclusive practices, and a lack of support and guidance from research bodies on inclusive practices. Facilitators included greater involvement and advocacy for inclusive practice by ethics review boards, and additional resource provision by research bodies to researchers. These are not difficult fixes if researchers, funders, sponsors, ethics committees and journal editors work together.

4.1. Strengths and limitations

We systematically searched the NIHR library for 6 years, ensuring our inclusion of all pertinent studies. However, this is just one trial repository in the UK and our findings may not reflect all recently reported trials in the UK, or internationally. However, given that our sample included international trials, albeit 9%, and along with the literature we reviewed for this study, we do not believe our findings would be any different. Still, we cannot be definitive about this. There were some weaknesses. The study focuses primarily on the characteristics and practices of trials within the NIHR library, overlooking potential differences in disability data collection practices across different research contexts and regions. A broader analysis encompassing diverse datasets and sources could provide a more comprehensive understanding of disability representation in clinical research. We did not consult patients and the public in this research because it was a retrospective study of recording and reporting practices, and thus the findings may not reflect the views of persons with disabilities or disability activists. Further qualitative work with people who have disabilities would be beneficial to answer remaining questions centered on who should report the disability information. Our study can only include information that is provided in the trial reports. It's possible that some trials collected disability information and did not report it, but we have no means of checking that.

[1] The RMS website states ''We have updated the diversity monitoring questions on all of our NIHR research/award management systems. The updated questions ask you to provide information relating to all 9 protected characteristics from the Equality Act 2010, as well as your socio-economic background. A 'prefer not to say option is available for each question.

1. Implications for practice
2. We recommend:

- Collecting self-reported disability data from all trial participants for the purposes of diversity monitoring. This should be planned during the design phase of the trial. Use the Accessibility by Design Toolkit to facilitate this [20].
- The best way to collect this information should be investigated systematically with people who identify as having a disability.
- Investigators should consider the particulars of the clinical area under study and aim for proportional recruitment and representation of people with disabilities in trials.
- When writing trial protocols, teams should include recruitment and retention strategies to increase the representation of those with disabilities and ensure the trial is accessible to all. The STEP UP Guidance can support this process https://step-up-clinical-trials.co.uk/.
- Using the WHO ICF definition of disability (as an umbrella term for impairments and limitations that have a significant and long-term negative effect on the ability to participate in activities) [36] until a specific definition and framework for including persons with disabilities is available for trials.
- Funding bodies support the development of a framework that focuses on people with disabilities, such as those we have in the INCLUDE project for ethnicity, impaired capacity to consent etc.

5. Conclusion

RCTs do not collect information about disability for diversity monitoring to ensure the representativeness of the trial population. People with disabilities remain excluded from clinical trials, despite an increased awareness of the need to include those from underserved groups. People with disabilities have a right to be offered the opportunity to take part in clinical trials. They also need to be confident that trials of new drugs, vaccines and therapies have been tested on their contemporaries, otherwise we risk their nonparticipation in vaccination schemes, or willingness to try new drugs or therapies because they are not confident, they will work for them. Trial teams are responsible for recruiting a diverse range of participants, but funders, regulators, ethics committees, sponsors and policymakers have an equal responsibility to ensure trials they fund, regulate, give guidance and ethical approval to, and sponsor, are not exclusionary, particularly for those people who already experience significant health inequity.

CRediT authorship contribution statement

Shauna Cunningham: Writing − original draft, Investigation, Formal analysis, Data curation. **Amy M. Russell:** Writing − review & editing, Writing − original draft, Validation, Supervision, Methodology, Formal analysis, Conceptualization. **Emma Lidington:** Writing − review & editing, Writing − original draft, Supervision, Methodology, Conceptualization. **Frances Shiely:** Writing − review & editing, Writing − original draft, Supervision, Project administration, Methodology, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

F.S. is a member of the editorial board of JCE. There are no competing interests for any other author.

Acknowledgments

The authors thank the Inclusivity group of the Trials Methodology Research Partnership for bringing the team together and the Health Research Board, Trial Methodology Research Network (HRB TMRN) for funding this research.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2025.111715.

Data availability

Data will be made available on request.

References

[1] Witham MD, Anderson E, Carroll C, Dark PM, Down K, Hall AS, et al. Developing a roadmap to improve trial delivery for under-served groups: results from a UK multi-stakeholder process. Trials 2020;21:1−9.
[2] Camanni G, Ciccone O, Lepri A, Tinarelli C, Bedetti C, Cicuttin S, et al. 'Being disabled'as an exclusion criterion for clinical trials: a scoping review. BMJ Glob Health 2023;8(11):e013473.
[3] Rios D, Magasi S, Novak C, Harniss M. Conducting accessible research: including people with disabilities in public health, epidemiological, and outcomes studies. Am JPublic Health 2016;106:2137−44.
[4] Sugimoto CR, Ahn Y-Y, Smith E, Macaluso B, Larivière V. Factors affecting sex-related reporting in medical research: a cross-disciplinary bibliometric analysis. Lancet 2019;393(10171):550−9.
[5] Khunti K, Bellary S, Karamat M, Patel K, Patel V, Jones A, et al. Representation of people of South Asian origin in cardiovascular outcome trials of glucose-lowering therapies in type 2 diabetes. Diabet Med 2017;34:64−8.
[6] Treweek S, Banister K, Bower P, Cotton S, Devane D, Gardner HR, et al. Developing the INCLUDE Ethnicity Framework—a tool to help

trialists design trials that better reflect the communities they serve. Trials 2021;22(1):1−12.
[7] Moloney C, Shiely F. Underserved groups remain underserved as eligibility criteria routinely exclude them from breast cancer trials. J Clin Epidemiol 2022;147:132−41.
[8] Thompson K, Peters S, Woodward M, Carcel C, Norton R. Reporting sex and gender in medical research. Lancet 2019;393(10185):2038.
[9] Shepherd V. Advances and challenges in conducting ethical trials involving populations lacking capacity to consent: a decade in review. Contemp Clin Trials 2020;95:106054.
[10] Sheehan K, Fitzgerald L, Hatherley S, Potter C, Ayis S, Martin F, et al. Inequity in rehabilitation interventions after hip fracture: a systematic review. Age Ageing 2019;48:489−97.
[11] Wallace N, O'Keeffe S, Gardner H, Shiely F. Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability. J Clin Epidemiol 2023;162:81−9.
[12] Dawson S, Banister K, Biggs K, Cotton S, Devane D, Gardner H, et al. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice. Trials 2022;23(1):672.
[13] NIHR. Improving inclusion of under-served groups in clinical research: guidance from the NIHR-INCLUDE project UK2020. Available at: www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435. Accessed August 5, 2024.
[14] Shepherd V, Joyce K, Lewis A, Flynn S, Clout M, Nocivelli B, et al. Improving the inclusion of an under-served group in trials: development and implementation of the INCLUDE Impaired Capacity to Consent Framework. Trials 2024;25(1):83.
[15] Gardner HBK, Sherratt FC. The NIHR INCLUDE socioeconomic disadvantage framework. 2022. Available at: https://www.trialforge.org/trial-forge-centre/socioeconomic-disadvantage-framework. Accessed August 5, 2024.
[16] Biggs K, Dix C, Shiely F, Treweek S, Shepherd V, Lane A, et al. Effective interventions to increase representation of under-served groups in randomised trials in UK and Ireland: a scoping literature review. NIHR Open Res 2024;4(12):12.
[17] Treweek S, Gillies K, Witham MD, Devane D, Khunti K, Bower P, et al. How should trial teams make decisions about the proportions and diversity of the ethnic groups in their trial? Trials 2024;25(1):768.
[18] Van Epps H, Astudillo O, Martin YDP, Marsh J. The sex and gender equity in research (SAGER) guidelines: implementation and checklist development. Eur Sci Ed 2022;48:e86910.
[19] Brady L, Lee JR, Evan YY, Lin D, Gore JL, Nelson PS, et al. Determining clinical perspectives and strategies for improving enrollment of minoritized communities in prostate cancer clinical trials. Am J Clin Exp Urol 2023;11(5):385.
[20] Center M. Accessibility by design (AbD) in clinical research toolkit (v1.3). 2023. Available at: https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/. Accessed August 5, 2024.
[21] World Health Organization. Global report on health equity for persons with disabilities. Geneva, Switzerland: WHO; 2022.
[22] UNICEF. Seen, counted, included: using data to shed light on the well-being of children with disabilities. 2022. Available at: https://data.unicef.org/resources/children-with-disabilities-report-2021/. Accessed August 5, 2024.
[23] Barnartt SN, Altman BM. How to get what you want to know and know what you've gotten in research: measuring disability past, present, and future. In: Brown RL, Maroto M, Pettinicchio D, editors. The Oxford Handbook of the Sociology of Disability online ed. Oxford, UK: Oxford University Press; 2021.
[24] Palmer M, Harley D. Models and measurement in disability: an international review. Health Pol Plann 2012;27(5):357−64.
[25] Wellcome Trust EDIS. Diversity and inclusion survey (DAISY) question guidance - working draft (V2). 2022. Available at: https://edisgroup.org/wp-content/uploads/2022/05/DAISY-guidance-current-upated-May-2022-V2.pdf. Accessed August 5, 2024.
[26] UK Government. Employment equality act 2010 c.15 2010. Available at: https://www.legislation.gov.uk/ukpga/2010/15/contents. Accessed August 5, 2024.
[27] Government of Canada. In: Employment Equity Act (S.C. 1995, c. 44). https://laws-lois.justice.gc.ca/PDF/E-5.401.pdf. Accessed August 5, 2024.
[28] Hepple B. The new single equality act in Britain. Equal Rights Rev 2010;5(1):11−24.
[29] Irish Human Rights and Equality Commission. The equal status acts 2000-2018 2020. Available at: https://www.ihrec.ie/app/uploads/2022/08/IHREC-Equal-Status-Rights-Leaflet-WEB.pdf. Accessed August 5, 2024.
[30] World Health Organization. Strengthening the collection of data on disability 2023. Available at: https://www.who.int/health-topics/disability/collection-of-data-on-disability#tab=tab_1. Accessed December 4, 2023.
[31] Schwartz JK, Unni E. Inclusion of people with disabilities in research to improve medication adherence: a systematic review. Patient Prefer Adherence 2021;15:1671−7.
[32] Shariq S, Cardoso Pinto AM, Budhathoki SS, Miller M, Cro S. Barriers and facilitators to the recruitment of disabled people to clinical trials: a scoping review. Trials 2023;24(1):171.
[33] Willis A, Shiely F, Treweek S, Taljaard M, Loudon K, Howie A, et al. Comments, suggestions, and criticisms of the Pragmatic Explanatory Continuum Indicator Summary-2 design tool: a citation analysis. J Clin Epidemiol 2024;176:111534.
[34] Biggs K, Hullock K, Dix C, Lane JA, Green H, Treweek S, et al. Development of the STEP UP guidance to help researchers design inclusive clinical trials. BMC Med Res Methodol 2024;24:227.
[35] US Food and Drug Administration. Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry. Silver Spring, MD: USFDA; 2020.
[36] World Health Organisation. International classification of functioning, disability and health (ICF). 2024. Available at: https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health. Accessed August 5, 2024.
[37] Mitra S, Shakespeare T. Remodeling the ICF. Remodeling the ICF disability and. Health J 2019;12:337−9.
[38] Morris A. Disability groups win fight to be included in health equity research. Washington Post Newspaper. 2023. Available at: https://www.washingtonpost.com/wellness/2023/09/26/disability-groups-win-fight-be-included-health-equity-research/. Accessed August 8, 2024.
[39] National Institute for Health and Care Research. Diversity data - FAQs 2024. Available at: https://www.nihr.ac.uk/about-us/our-key-priorities/equality-diversity-and-inclusion/diversity-data-report.htm. Accessed August 5, 2024.