A Scoping Review Protocol to Identify Strategies to Recruit Underserved Populations to Clinical Trials

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The scoping review protocol has been designed and led by BD (KTP associate) and supported by JK and KH (Manchester Metropolitan University) and HG (COUCH Health). Decisions in design adhere to recommendations outlined by the Joanna Briggs Institute (JBI) (Peters et al., 2022; Peters et al., 2015), and will be reported as specified by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis-Scoping Review (PRISMA-ScR) (Tricco et al., 2018). Details of the methodical steps followed are outlined below.

Registration

To confirm similar reviews had not been conducted, we completed an initial search on Cochrane Database of Systematic Reviews and PROSPERO. However, as these databases only include systematic or umbrella reviews, wider discussions within the research team who are embedded in the field helped provide understanding of reviews they were aware of. Additionally, we conducted searches within Google Scholar to identify any potential reviews that other methods missed. It was confirmed that no similar scoping reviews had been conducted, therefore we developed this protocol.

Information Sources

Databases searched included:

- CINAHL (EBSCO)
- MEDLINE (PubMed)
- SCOPUS
- Cochrane Central Register of Controlled Trials (CENTRAL)
- International Clinical Trials Registry Platform (ICTRP)

Search Strategy

In collaboration with Andrea Daly, an academic liaison librarian at Manchester Metropolitan University, we developed a search strategy categorised by Participants, Concept and Context incorporating MeSH terms (see

Table 1).

Table 1

Scoping Review Search Strategy

	Description	Search terms
Population	Underserved populations	(vulnerable OR marginali* OR minorit* OR underrepresented OR under-represented OR underserved OR under-served OR "medically underserved" OR "hard to reach" OR "hard-to-reach")
Concept	Recruitment Strategy	(recruit* OR enrol* OR "patient selection")
Context	Clinical trial	("clinical trial" OR RCT OR "randomized controlled trial" OR "randomized control trial" OR "randomised controlled trial" OR "randomised control trial")
	Location of interest	(portugal OR france OR spain OR germany OR italy or poland OR belgium OR "united kingdom" OR uk OR england OR britain OR scotland OR "northern ireland" OR wales) AND NOT ("united states" OR america OR usa OR u.s)

Note. This table provides an overview of the search strategies utilised.

Eligibility Criteria

The inclusion and exclusion criteria for article screening were formatted using Participant, Concept and Context guidelines outlined by Peters et al. (2015). These criteria are described in Table 2. However, in initial screening no criteria pertaining age were provided. Upon screening all full texts, a team decision to limit these criteria to anyone under the age of 18 was met due to an observed pattern in age,

Table 2

Scoping Review Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
Participant: Underserved Populations*	1) Any populations under the age of 18 are considered underserved (NIHR, 2020).	1) Any population over the age of 18.
Concept: Recruitment Strategies	1) Any discussed enrolment into a clinical trial. Articles will not be excluded at initial screening if method of recruitment is not discussed.	1) Recruitment strategy must be reported in practice, rather than a theorised suggestion. For example, a clinical trial recruited on social media rather than a clinical trial *should* recruit on social media.
Context: Clinical Trial**	1) Clinical trial conducted in the UK, and Europe (Portugal, France, Spain, Germany, Italy, Poland or Belgium). These countries were selected in line with ABPI (2023) global rankings for number of industry clinical trials initiated in 2021 by country. 2) Any study published after 1993 in line with Federal law for inclusion of women in clinical research (Institute of Medicine (US) Committee on Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies, 1994). 3) Clinical trial with any health outcome.	1) Rest of the World. 2) Any clinical trial that is observational or not linked to a randomised-controlled trial (RCT).

Note. This table describes the protocol inclusion and exclusion criteria aligned to the Participant, Concept and Context guidelines outlined by Peters et al. (2015).

*Underserved populations (community) are defined by the NIHR (n.d.) as:

"A group that is less well represented in research than would be desirable from population prevalence and healthcare burden"

**Clinical trials are defined by the FDA (2023) as:

"Research studies in which people volunteer to help find answers to specific health questions"

Additionally, articles were eligible at screening if full text was available in English language, and included a trial protocol, quantitative study, qualitative study, review (including scoping and systematic), or secondary data analysis under the precedence that recruitment was discussed. Articles not eligible at screening included conference abstracts, letters to editors, article responses or theses.

Selection of Sources of Evidence

Database search yields were exported to EndNote (2013) for removal of duplicates and imported into Rayyan (Ouzzani et al., 2016) for screening. KTP associate, BD, independently screened each article abstract against inclusion and exclusion criteria for eligibility. To prevent bias in selection, 20% of articles were selected at random using a corresponding random number generator (Haahr, 2024) for independent screening by reviewers (Leanne Harvey (LH), Emma Johnstone (EJ), and Chloe Stephenson (CS)). Decision-based discrepancies were then discussed between the team to reach a consensus. Although a full team discussion was needed to finalise an inclusion, or exclusion decision when a consensus was not met, this was not required.

Full texts were sought for each article that satisfied inclusion criteria at initial screening. Where these were not available, interlibrary loans (ILL) were requested, if this was unsuccessful authors were contacted directly for a copy. If authors did not supply a copy within 1-week from initial contact, the article was excluded. Upon obtaining full-text articles, BD independently screened the methodology section and the outlined aims and objectives of each article to assess eligibility. The same second reviewer and discrepancy process discussed for article abstracts was implemented.

Upon amending participant criteria, articles initially included at full text were rescreened; article including populations over the age of 18 were subsequently excluded by BD with supporting decisions from JK and KH. All included articles were then used for data charting.

Data Charting Process

Bradbury-Jones et al.'s (2022) PAGER framework will be utilised to chart data from each article. Doing so will allow identification of Patterns, Advances, Gaps, Evidence for Practice and Research recommendations. Charting will be completed by BD, with JK and KH facilitating with double coding.

Synthesis of Results

Findings will be synthesised as a descriptive narrative and will be reported in line with PRISMA-ScR (Tricco et al., 2018). A narrative summary will be provided by tabulating patterns of key findings into distinct themes, before identifying advances in the literature by positioning these into the wider research context of clinical trial recruitment. Gaps in findings will be discussed, synthesising which strategies need to be improved, and providing evidence in practice for how stakeholders can prioritise these. Finally, a call to action providing research recommendations in developing inclusive recruitment strategies for underserved populations may be discussed, however this is dependent on the identified study outcomes.

Study status

As of 7th November 2024 the scoping review remains ongoing, however the status of each methodological stage is described below:

1) Title, background and review questions - COMPLETE
2) Inclusion criteria (including participants, concept, context) - COMPLETE

3) Type of evidence sources - COMPLETE
4) Search strategy - COMPLETE
5) Evidence screening and selection – COMPLETE
6) Data charting process – STARTED
7) Data analysis – NOT STARTED
8) Presentation of results – NOT STARTED

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Parent publications

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Conflict of interest

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