MERIT
Minority ExpeRiences In Trials

Minority ExpeRiences In Trials (The MERIT Project): Understanding why ethnic minority groups are under-represented in trials through a rapid qualitative evidence synthesis, and mapping evidence to find solutions

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Abstract

Despite growing diversity in the UK's population, non-White British people are less likely to be represented in clinical trial populations. Poor diversity is a public health issue; if trial participants do not reflect the patients/population the trial is designed to serve, there is no guarantee that the results will apply to under-served/under-represented populations. There is also a moral imperative to ensure that everyone has equal opportunity to participate in trials. This research aims to explore factors that impact on recruitment of ethnic minority people to trials, and to better understand how those factors differ from the recruitment of predominantly White people. Our objectives are to: 1) Rapidly review trial recruitment evidence specific to the views and experiences of ethnic minority groups in a qualitative evidence synthesis, 2) Compare the factors that impact on trial recruitment found in objective 1 to the existing Cochrane Recruitment Qualitative Evidence Synthesis to explore similarities and differences between mainly white participants and people from ethnic minority backgrounds, and 3) Analyse findings from objective 2 to suggest if/how existing interventions/strategies originally designed to increase recruitment might or might not work to increase recruitment of specific ethnic groups – and if they do not work, make suggestions/recommendations on designing new interventions/strategies for trialists.

Background

Description of the topic

COVID-19 has highlighted stark inequalities between ethnic groups; Black people are most likely to be diagnosed with COVID-19, deaths are highest in Black and Asian communities, and Bangladeshi people are around twice as likely to die from COVID-19 than White British people (Public Health England, 2020). Six months after the first UK COVID-19 vaccine trials opened for recruitment, over 270,000 people had participated, 93% were from White majority groups (National Institute for Health Research, 2020). In comparison, 86% of the UK population identify as White (Office for National Statistics, 2020). The disparities in participation seen in COVID-19 trials are not unusual (Smart *et al.,* 2017; Stewart *et al.*, 2018). For example, a 2016 systematic review found that 5.5% of participants in cardiovascular trials for Type 2 diabetes were South Asian (Khunti *et al*., 2016), despite this group accounting for 11.2% of the UK's Type 2 diabetes population (Khunti *et al*., 2016).

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Trial populations with poor diversity are a public health issue. Failing to include participants representative of the population impacted by the trials results ultimately leads to healthcare practices being built on discriminatory evidence that has ignored the needs and experiences of ethnic minority populations (Ferdinand *et al.,* 2014).

The MERIT Project will collate and synthesise the available published evidence on the experiences reported by people from ethnic minority backgrounds about invitation to, and/or participation in, trials. This will provide trialists with the first global overview of factors that impact recruitment of people from ethnic minorities in clinical trials. The results will be a first step in directly informing decisions about strategies to help minimise the disparities that exist for these under-served groups compared to others.

Why is it important to do this review?

In 2017 NIHR recognised representation as a substantial problem and launched the INCLUDE project (Innovations in Clinical Trial Design and Delivery for the Under-served) (Witham *et al*., 2020), which aims to improve representation of under-served groups in trials. The INCLUDE Ethnicity Framework has been developed to help trialists design better trials by making them consider which ethnic groups to include in their trial and to identify barriers and come up with solutions to improve inclusion of people from ethnic groups (Trial Forge, 2020). When using the tool, teams identify and interpret qualitative data about ethnic minority views and experiences specific to their planned intervention, disease, and trial design. The Framework launched in 2020 and is highlighted in the NIHR Standard Guidance for Applicants (National Institute for Health Research, 2019), Chief Scientist Office in Scotland guidance (Chief Scientist Office, 2015) and Wellcome Trust Clinical Trial Policy (Wellcome Trust, 2020).

The Cochrane qualitative evidence synthesis of factors that impact on trial recruitment concluded that further research with under-served populations was required (Houghton *et al.*, 2020). Searching the ORRCA recruitment database (Online Resource for Research in Clinical triAls (ORRCA), 2020); a database specifically for methodological research on recruitment and retention in trials) for the word 'minority' in the title, provides 83 results (15/07/21). None of the 83 references were among the 30 studies contained in the Cochrane review, which itself did not include or analyse qualitative research with an ethnicity lens.

A separate project focussing specifically on ethnic minority groups is needed and MERIT is that project. MERIT will ensure that trialists, including those using the INCLUDE Ethnicity Framework, are able to understand the potential barriers to recruitment for ethnic minority groups and tailor their recruitment strategies accordingly. This work also addresses question #7 from the James Lind Alliance recruitment PRioRiTy project (Healy *et al*., 2018): "What are the best approaches to ensure inclusion and participation of under-represented

or vulnerable groups in randomised trials?" and meets the TMRP aim to facilitate work to improve inclusivity and representativeness of trials.

The overall aim of the MERIT Project is to identify factors that influence recruitment of ethnic minority participants to trials, and to better understand if and how those factors differ from predominantly White populations.
This will be addressed through the following linked objectives.

Objectives

1) Review the qualitative literature to identify factors that influence recruitment of people from ethnic minority groups to trials.
2) Map the factors found in objective 1 onto the existing recruitment literature, to explore if/how factors differ between mainly White participants and people from ethnic minority groups.
3) Analyse findings from objective 2 to suggest if/how existing recruitment interventions might or might not work – and if they do not work, what we should be doing to design new ones.

Methods

This protocol has been designed following the Interim Guidance on Cochrane Rapid Reviews (Garritty *et al*., 2020), Healthcare Improvement Scotland's Guide to Conducting Rapid Qualitative Evidence Synthesis for Health Technology Assessment (Healthcare Improvement Scotland, 2019), and the Cochrane Effective Practice and Organisation of Care group's qualitative evidence synthesis template (*Glenton et al*., 2020) and guidance (Cochrane Effective Practice and Organisation of Care (EPOC), 2017).

Search strategy

We will search the ORRCA database (Online Resource for Research in Clinical triAls (ORRCA), 2020) for recruitment research focussing on ethnic minority participants that has used qualitative methods, using the 'Research Methods' categorisation searches for qualitative interviews, focus groups, and surveys. We will use the 'recruitment' arm of the database, which uses a recruitment-specific search strategy adapted for use in Medline (OVID), CINAHL (EBSCO), PsycINFO (EBSCO), Scopus, Web of Science Core Collection (SCI-expanded, SSCI, CPCI-S, CPCI-SSH, ESCI), and the Cochrane library (CENTRAL). Population of the ORRCA database began in 2015 with a comprehensive search without data limitations, additional searches are re-run annually to keep the database up to date. A team of volunteers review the returned records for inclusion, and eligible articles are then categorised according to all relevant domains in the recruitment framework.
Due to COVID-19, the database update for 2020 was delayed. The ORRCA team are currently in the process of finishing the update of 2018-2019 publications due to delays

caused by COVID restricting reviewer availability. These records along with the 2020 search results (which have not been reviewed for inclusion or domain categorisation) are accessible to us through co-author AK, who works on ORRCA. AK will search the 2020 search records using a strategy comparable to the search strategy that we will use for ORRCA (shown in Supplemental file 1). To gather records from 2021, we will use the recruitment-specific search strategy applied for ORRCA (Supplemental file 2), with the addition of keywords designed to tailor the search to literature exploring the experiences of ethnic minority groups in relation to trial participation. We will not apply date limits to any of our searches.

We will also use a purposive sampling approach to include known key recent grey literature reports such as those from COUCH Health (Couch Health, 2021), Demand Diversity (Demand Diversity, 2021), the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, 2021), and the Centre for Ethnic Health Research (Centre for Ethnic Health Research, 2021). We will extend our search with both forward and backward citation chaining of these reports.

Eligibility criteria

Types of studies

We will include studies that use qualitative methods (e.g., open-ended survey questions (O'Cathain and Thomas, 2004), focus group discussions, interviews). We will also include studies using mixed methods, where there is an identifiable component that uses qualitative analysis methods, and the data can be identified as separate from the quantitative component.
We will limit included studies to those written in English due to the language capabilities of the project team, and the short time-scale available to us.

Topic of interest

The review will focus on the views and experiences of ethnic minority groups that contribute to factors that impact on their recruitment to randomised trials. We will not include studies of experiences of trial recruiters as this is beyond the scope of MERIT and likely requires a focused research project of its own. There will be no limits on trial phase or design.

Study selection

Two reviewers (HG and one other) will screen titles and abstracts for at least 20% of search results, these will then go through moderation and consensus, and all remaining abstracts screened by one reviewer (HG). A third reviewer will screen excluded abstracts to validate the process. Should we identify a very large number of eligible studies, we will use purposive sampling to ensure inclusion of studies with rich data (Cochrane Effective Practice and Organisation of Care (EPOC), 2017). Using purposive sampling for qualitative

evidence syntheses is a relatively new methodological strategy, but a necessary one to ensure the quality of the synthesis particularly in a project as short as MERIT (Ames *et al.,* 2019). Analysis of qualitative data requires detailed engagement with text, and the more data a researcher must synthesise, the less depth and richness they are likely to be able to extract from it (Morse, 2010; Sandelowski, 1995); an overwhelming number of primary studies with a high volume of data therefore has the potential to threaten the quality of the synthesis (Suri, 2011). Various approaches to purposive syntheses have been described, though it is not yet clear which of these are best suited to specific types of synthesis, synthesis processes and/or research questions. Should the volume of eligible studies make effective synthesis unmanageable in our short timeframe, we will use a criterion approach (Ames *et al.,* 2019), prioritising studies that are as relevant as possible to the review, represent a diverse range of participants and trials, and have rich data.

Sampling criteria

Our sampling criteria are as follows:

1. Studies where the study objectives closely matched our synthesis objectives.
2. Studies where the participants involved represent a diverse mix of ethnicities.
3. Studies that include perspectives on recruitment to a range of different trial environments, including setting, clinical area, and intervention type.
4. Studies scoring 4 or more on a 5-point scale for data richness (see Table 1 below) (Ames *et al.,* 2019; Ames *et al.,* 2017).

Score	Measure	Example
1	Very few qualitative data presented. Those findings that are presented are descriptive.	For example, a mixed methods study using open ended survey questions or a more detailed qualitative study where only part of the data relates to the synthesis objective.
2	Some qualitative data presented.	For example, a limited number of qualitative findings from a mixed methods or qualitative study.
3	A reasonable amount of qualitative data.	For example, a typical qualitative research article in a journal with a smaller word limit and often using simple thematic analysis.
4	A good amount and depth of qualitative data.	For example, a qualitative research article in a journal with a larger word count that includes more context and setting descriptions and a more in-depth presentation of the findings.
5	A large amount and depth of qualitative data.	For example, from a detailed ethnography or a published qualitative article.

Table 1: Data richness scale used by Ames *et al.* to purposive sample qualitative studies for inclusion into a Cochrane qualitative evidence synthesis of parents' and informal caregivers'

views and experiences of communication about routine childhood vaccination (Ames *et al.,* 2017).

Data extraction

One reviewer (HG) will extract data using a piloted form, and a second reviewer will check extracted data for accuracy and completeness. This process will be followed for three studies; any required revisions to the form will be made, and then used by one reviewer (HG) for full data extraction from all included studies. A random 20% of results will be checked by a second reviewer.

The data extraction form will be developed to support the 'best fit' framework approach that will be used to analyse and synthesise the evidence. Previous qualitative syntheses have suggested that this facilitates a smooth transition from extraction to analysis (Biesty *et al.,* 2020). Google Forms will be used throughout the extraction stage.

Data items extracted

We will extract the following study characteristics: authors, year of publication, aims and purpose, research methods (including methods used for data collection and analysis), characteristics about the participant group including ethnicity, and outcomes (reported views and experiences, barriers and facilitators to recruitment in trials and related themes).

Assessment of methodological limitations

We will assess the methodological limitations of included studies using an adapted version of the Critical Skills Appraisal Programme (CASP) tool (Critical Appraisal Skills Programme, 2018). Each study will be appraised by one reviewer (HG) and then discussed with the team. Final assessment will be based on consensus. We will not exclude any studies based on quality, and any methodological limitations will be presented in the GRADE-CERQual assessment as described in the 'Assessment of confidence in synthesised findings' section.

Data analysis and synthesis

We will use a 'best-fit' framework approach (Booth *et al.,* 2015; Carroll *et al.,* 2013) to achieve objective 1. This is a pragmatic method based on the framework approach used to analyse primary qualitative data (Pope *et al.,* 2000), which "offers a highly structured approach to organising and analysing data (e.g., indexing using numerical codes, rearranging data into charts etc.)" (Barnett-Page and Thomas, 2009). A 'best-fit' approach to framework synthesis has been successfully used for previous rapid syntheses (Shaw *et al.,* 2020; Stuart Bright *et al.,* 2018; Weisbeck *et al.,* 2021), as it uses an augmentative and deductive approach (building on this existing model or framework), rather than grounded or inductive (starting with a blank page), presenting a practical and methodical way to guide analysis for projects with a short timescale.

We have identified a pre-existing framework that will be used to analyse included studies under the domains of system level, individual level, and interpersonal level factors (Hamel *et al.,* 2016). The framework identified is a multilevel model that depicts potential barriers to recruitment experienced by ethnic minority patients. This differs slightly from the topic at the centre of MERIT; views and experiences of ethnic minority groups that contribute to factors that impact on recruitment in randomised trials, but as the name of the analysis method suggests, this is a 'best-fit' approach, and provides a relevant pre-existing framework with which to map and code the data from included studies. The framework will enable us to highlight and interrogate data to explore high level questions around the reasons why ethnic minorities are currently underrepresented in clinical trials: 1) People from ethnic minority backgrounds are less likely to be invited to take part in trials, and 2) People from ethnic minority backgrounds are more likely to decline a trial invitation.

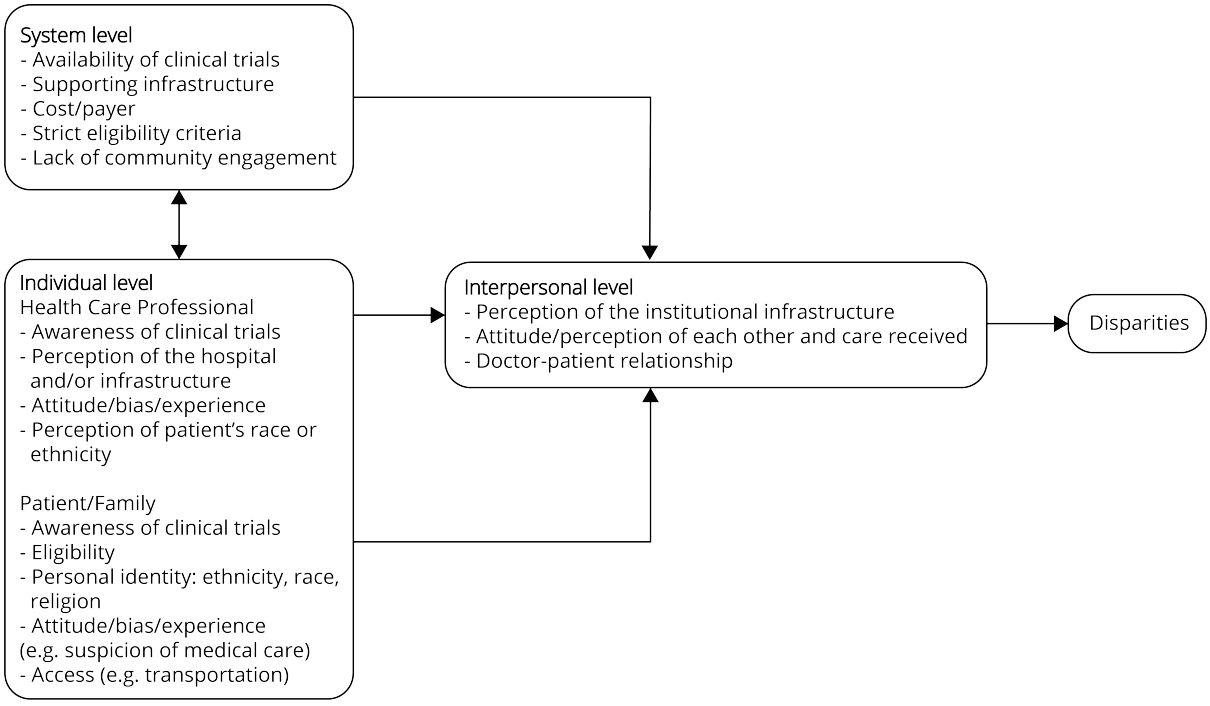

Figure 1: A multilevel model of factors contributing to disparities in clinical trials, taken from Hamel *et al.* 2016.

We will use NVivo software (QSR International Pty Ltd, 2020) to code both verbatim quotations from study participants and findings reported by authors that are clearly evidenced by study data into themes with the above framework in mind. Coding will focus only on the 'Results' section of included studies to allow us to contextualise and interpret data without the addition of the original study authors' perspectives. Themes and subthemes will encompass codes that cover both differences and similarities on a specific topic or experience, and subthemes used to further focus comparisons. One reviewer (HG)

will carry out this process for three of the included studies, and coding will be discussed with a second reviewer and edited as necessary to ensure that interpretation of data and themes are consistent throughout. Once coding has been agreed for these three studies, one reviewer (HG) will code all included studies into the agreed themes. Where relevant data are identified that do not fit the pre-identified framework, we will create additional themes as needed (Miles and Huberman, 1994), building on the existing framework to expand, reduce and add new themes as necessary, generating an updated model that is tailored to the specific aims of our review. A core group of reviewers (HG and two others) will familiarise themselves with the data extracted from all included studies to conduct analysis and synthesis simultaneously. We will work together to populate the various domains of the pre-existing framework, communicating frequently to discuss our interpretation of the data and ensure consistency throughout.

Assessment of confidence in synthesised findings

One reviewer (HG) will use the Confidence in the Evidence from Review of Qualitative Research (GRADE-CERQual) approach to assess confidence in each of the review findings (Lewin *et al.,* 2018), the rest of the group will moderate. Final assessment will be based on consensus across the team.

Mapping evidence to find solutions

This mapping process will allow us to compare the views and experiences of predominantly White participants with participants from ethnic minority groups. Understanding if and how the findings link with interventions identified in existing systematic reviews, will enable us to: 1) suggest if interventions may be appropriate for ethnic minority recruitment, 2) identify interventions that may further exacerbate issues of recruitment in trials among ethnic minority groups, and 3) suggest recommendations to consider when designing new interventions.

We will compare the factors reported to influence recruitment to trials in the Cochrane recruitment qualitative evidence synthesis (Houghton *et al.,* 2020), the interventions in the Cochrane randomised recruitment intervention review (Treweek *et al., 2018)*, and the interventions reported in the non-randomised recruitment intervention review (Gardner *et al.,* 2020), to the factors found in our synthesis (objective 1). To do this, we will use the analysis framework used for the MERIT project as a starting point (figure 1), and then re-categorise the factors reported in the other reviews to fit that framework.

Figure 2 below shows an example of the structure of this process. We have highlighted the MERIT analysis framework (as it currently stands, as described in the 'Data analysis and synthesis' section we will expand, reduce, and add new themes as necessary) to show an individual level factor of 'awareness of clinical trials' from the health care professional perspective. MERIT's findings could include something along the lines of '*health care professionals working in inner city hospitals where ethnic minority populations are highest, have*

limited knowledge of clinical trials going on in their geographic area, this leads to fewer patients from ethnic minority backgrounds being invited to take part in trials'; the issue here centres on ethnic minorities not being given an opportunity to be recruited into a trial. We will focus on this finding and contextualise it in two ways; 1) comparison with related findings in the factors qualitative evidence synthesis (the dark pink box in figure 2), and 2) alignment with related findings in the randomised and non-randomised intervention reviews (the two lighter pink boxes in figure 2). Comparison with factors from the qualitative evidence synthesis will enable us to assess if and how the experiences of people from ethnic minority backgrounds differ from experiences of the white majority, and this knowledge will then enable us to provide context to the recruitment strategies that are found when aligning the MERIT finding with the two intervention reviews. If the White majority's experience is substantially different from the ethnic minority experience that we are focusing on in MERIT, then we will need to think carefully about whether a strategy developed with the White majority in mind is appropriate to recommend. In this case we would likely suggest recommendations to consider when designing new interventions.

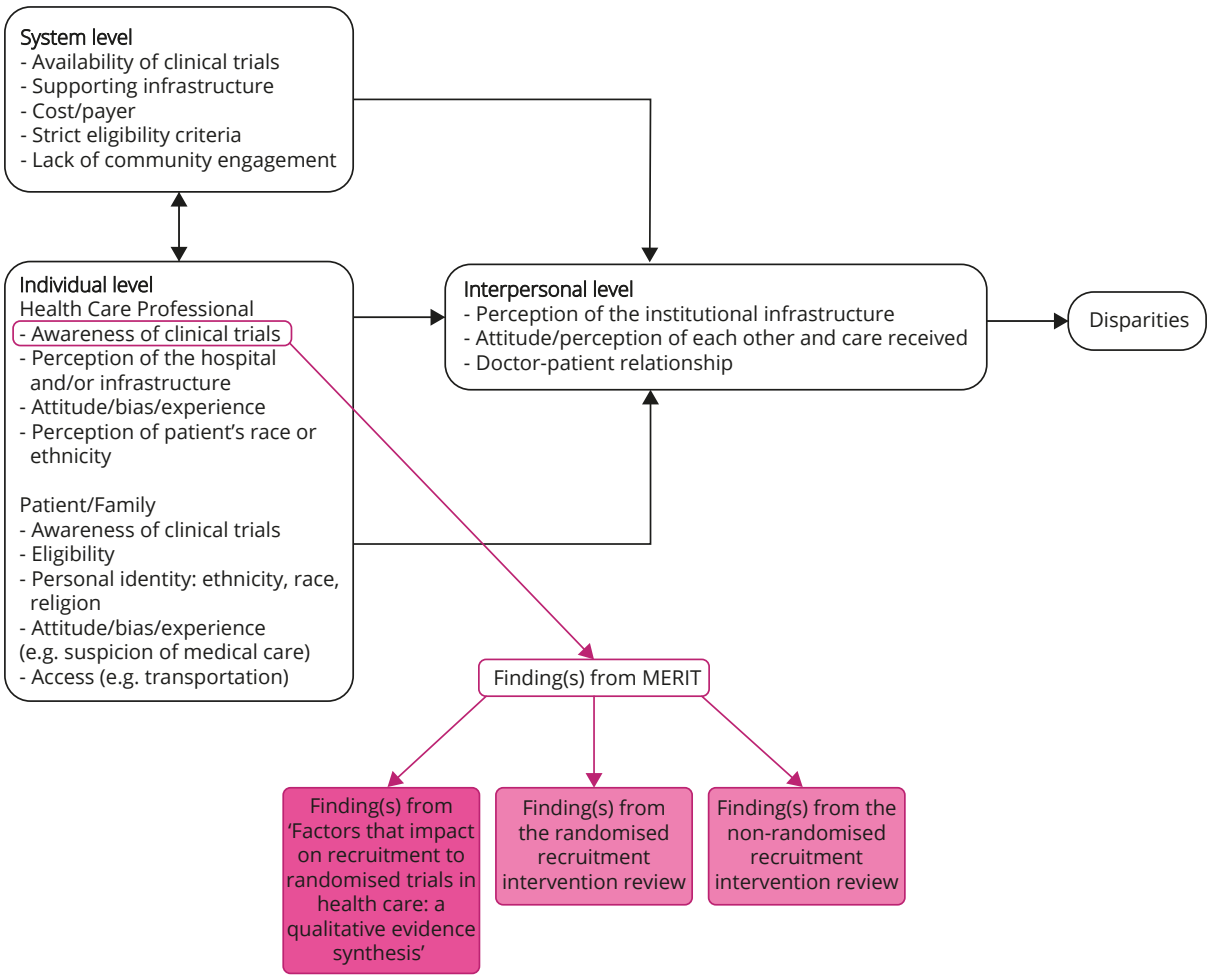

Figure 2: The process we will use to map factors from the MERIT project on to findings from relevant interventional and qualitative reviews.

HG will lead this process, supported by at least one other researcher within the team. We will then present the mapping process and findings at a group meeting for review and discussion by and with the wider project team.

Patient and public involvement

Four members of our project team are public contributors (FA, AC, IH, VS). These individuals are core to the project, will engage with the project just as the rest of the team do, and were also co-applicants on the grant funding application.

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Timetable

Project activity	J	J	A	S	O	N
Objective 1 Searching for evidence	■					
Objective 1. Study selection		■				
Objective 1. Data extraction		■				
Objective 1. Assessment of methodological limitations		■	■			
Objective 1. Analysis and synthesis			■	■		
Objective 1. Assessing confidence in findings				■		
Objective 2. Mapping findings from objective 1					■	
Objective 3. Analysis of the findings from objective 2					■	■
Submission of final TMRP report						■

Ethical approval

This rapid qualitative evidence synthesis will use published evidence; therefore, no ethical approval is required.

Funding

This work is funded by the Medical Research Council-National Institute for Health Research Trials Methodology Research Partnership (TMRP), reference number TMRP/WG/2.

Competing interests

None declared.

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Minority ExpeRiences In Trials

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Witham, M. D., Anderson, E., Carroll, C., Dark, P. M., Down, K., Hall, A. S., Knee, J., Maier, R. H., Mountain, G. A., Nestor, G., Oliva, L., Prowse, S. R., Tortice, A., Wason, J., Rochester, L., on behalf of the INCLUDE Writing Group, 2020. Developing a roadmap to improve trial delivery for under-served groups: results from a UK multi-stakeholder process. Trials, 21, 694.

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Supplemental file 1: Search strategy used to gather records from ORRCA

Title search	Abstract search	Research methods search	Domain search
Ethnic	N/A	Qualitative interviews	N/A
Ethnic	N/A	Focus groups	N/A
Ethnic	N/A	Survey	N/A
N/A	Ethnic	Qualitative interviews	N/A
N/A	Ethnic	Focus groups	N/A
N/A	Ethnic	Survey	N/A
Minority	N/A	Qualitative interviews	N/A
Minority	N/A	Focus groups	N/A
Minority	N/A	Survey	N/A
N/A	Minority	Qualitative interviews	N/A
N/A	Minority	Focus groups	N/A
N/A	Minority	Survey	N/A
N/A	N/A	Qualitative interviews	C9 Trial conduct: Cultural considerations and minority groups
N/A	N/A	Focus groups	C9 Trial conduct: Cultural considerations and minority groups
N/A	N/A	Survey	C9 Trial conduct: Cultural considerations and minority groups
N/A	N/A	Qualitative interviews	D5 Recruitment information needs: Cultural considerations and minority groups
N/A	N/A	Focus groups	D5 Recruitment information needs: Cultural considerations and minority groups
N/A	N/A	Survey	D5 Recruitment information needs: Cultural considerations and minority groups

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Supplemental file 2: Search strategies used by ORRCA

CMR (Cochrane Library Online) – archived in July 2012
#1 "accrual and sample size":kw or "attitudes to trials":kw or "informed consent":kw
#2 (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ti or (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ab
#3 (#1 OR #2)

Cochrane Database of Systematic Reviews (Cochrane Library Online)
#1 "accrual and sample size":kw or "attitudes to trials":kw or "informed consent":kw
#2 (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ti or (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ab
#3 (#1 OR #2)

MEDLINE via Ovid
1. Patient Selection/
2. ((participat* or recruit$* or enrol*) adj4 trial?).tw
3. ((Participant* or subject* or patient* or volunteer*) adj4 trial*)
4. ((Participant* or subject* or patient* or volunteer*) adj4 selection)
5. ((Participant* or subject* or patient* or volunteer*) adj4 recruit*)
6. 1 or 2 or 3 or 4 or 5
7. Informed Consent/
8. informed consent.tw
9. consent adj5 recruit*
10. 7 or 8 or 9
11. exp Clinical Trial as Topic/
12. Research Subjects/
13. (trial? or study or studies or research).tw.
14. 11 or 12 or 13
15. 6 or (10 and 14)
16. Research Support, NIH, Extramural.pt.
17. Research Support, NIH, Intramural.pt.
18. Research Support, Non US Gov't.pt.
19. Research Support, US Gov't, Non PHS.pt.
20. Research Support, US Gov't, PHS.pt.
21. recruit* adj4 random*
22. recruitment.ab./freq=2
23. participation.ab./freq=2
24. research.tw.
25. or/16-24
26. randomized controlled trial.pt
27. controlled clinical trial.pt.

28. random$.ab.
29. 26 or 27 or 28
30. humans.sh.
31. 29 and 30
32. comment.pt.
33. editorial.pt.
34. 31 not (32 or 33)
35. 15 and 25 and 34

SCOPUS (including EMBASE)

1. TITLE(participat*) OR TITLE(recruit*) OR TITLE(enrol*) OR TITLE(enter*) OR TITLE(entry) OR TITLE(accru*)
2. TITLE(trial?) OR TITLE(study)
3. 1 and 2
4. TITLE-ABS (select W/3 participants) or TITLE-ABS (select W/3 patients) or TITLE-ABS (select W/3 controls) or TITLE-ABS (select W/3 subjects) or TITLE-ABS (select W/3 volunteers)
5. ABS (recruit*)
6. ABS (participat*)
7. TITLE-ABS(research)
8. 5 or 6 or 7
9. 4 and 8
10. TITLE-ABS (informed consent) or TITLE-ABS (consent) or TITLE-ABS (consent process*) or TITLE-ABS (consent procedure?)
11. TITLE-ABS (patient W/2 information)
12. TITLE-ABS (patient W/2 leaflet)
13. TITLE-ABS (patient W/2 booklet)
14. TITLE-ABS (patient W/2 video)
15. TITLE-ABS (patient W/2 website)
16. 11OR 12 OR 13 OR 14 OR 15
17. TITLE-ABS (participant W/2 information)
18. TITLE-ABS (participant W/2 leaflet)
19. TITLE-ABS (participant W/2 booklet)
20. TITLE-ABS (participant W/2 video)
21. TITLE-ABS (participant W/2 website)
22. 17 OR 18 OR 19 OR 20 OR 21
23. TITLE-ABS (subject W/2 information)
24. TITLE-ABS (subject W/2 leaflet)
25. TITLE-ABS (subject W/2 booklet)
26. TITLE-ABS (subject W/2 video)
27. TITLE-ABS (subject W/2 website)
28. 23 OR 24 OR 25 OR 26 OR 27
29. 16 OR 22 OR 28

30. INDEXTERMS (feasibility AND study) or INDEXTERMS (pilot AND project)
31. INDEXTERMS (Clinical AND Trial)
32. TITLE-ABS (trial?) OR TITLE-ABS (study) OR TITLE-ABS (studies) OR TITLE-ABS (research)
33. 10 and (29 OR 30 OR 31 OR 32)
34. 3 OR 9 OR 33
35. INDEXTERMS (randomised AND controlled AND trial)
36. TITLE-ABS (random*)
37. INDEXTERMS (major AND clinical AND study)
38. 35 OR 36 OR 37
39. INDEXTERMS (nonhuman)
40. DOCTYPE (ed)
41. 39 OR 40
42. 38 AND NOT 41
43. 34 AND 42
44. DOCTYPE (le)
45. 43 AND NOT 44

Science Citation Index Expanded and Social Sciences Citation Index, ISI
TS=(recruitment same “clinical trial”) or TS=(recruitment same “clinical trials”) or TS=(recruitment same “controlled trial”) or TS=(recruitment same “controlled trials”)

ERIC
(recruit* or participat*) and ((clinical trial*) or (controlled trial) or randomi*)