

METHODOLOGY

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Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action

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Abstract

Background: Without inclusion of diverse research participants, it is challenging to understand how study findings will translate into the real world. Despite this, a lack of inclusion of those from under-served groups in research is a prevailing problem due to multi-faceted barriers acting at multiple levels. Therefore, we rapidly reviewed international published literature, in relation to clinical trials, on barriers relating to inclusion, and evidence of approaches that are effective in overcoming these.

Methods: A rapid literature review was conducted searching PubMed for peer-reviewed articles that discussed barriers to inclusion or strategies to improve inclusion in clinical trial research published between 2010 and 2021. Grey literature articles were excluded.

Results: Seventy-two eligible articles were included. The main barriers identified were language and communication, lack of trust, access to trials, eligibility criteria, attitudes and beliefs, lack of knowledge around clinical trials, and logistical and practical issues. In relation to evidence-based strategies and enablers, two key themes arose: [1] a multi-faceted approach is essential [2]; no single strategy was universally effective either within or between trials. The key evidence-based strategies identified were cultural competency training, community partnerships, personalised approach, multilingual materials and staff, communication-specific strategies, increasing understanding and trust, and tackling logistical barriers.

Conclusions: Many of the barriers relating to inclusion are the same as those that impact trial design and healthcare delivery generally. However, the presentation of these barriers among different under-served groups may be unique to each population's particular circumstances, background, and needs. Based on the literature, we make 15 recommendations that, if implemented, may help improve inclusion within clinical trials and clinical research more generally. The three main recommendations include improving cultural competency and sensitivity of all clinical trial staff through training and ongoing personal development, the need to establish a diverse community advisory panel for ongoing input into the research process, and increasing recruitment of staff from under-served groups. Implementation of these recommendations may help improve representation of under-served groups in clinical trials which would improve the external validity of associated findings.

Keywords: Equality, Diversity, Inclusion, Ethnicity, Clinical research, Clinical trial, Review

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Background

The importance of inclusion in health and social care research has gained increasing recognition, as further highlighted in the COVID-19 pandemic [1]. Without participants from a broad range of backgrounds (age, gender, ethnicity, comorbidities), it is not possible to understand how study findings will translate into real-world application, and this is particularly true for clinical trials.

The term under-served group refers to segments of the population who are represented in health research at lower levels than would be expected from population estimates [2]. Groups considered under-served [2] in clinical research are heterogeneous and are often crudely considered in terms of basic characteristics, such as ethnicity, disability, or age. But what constitutes under-served is complex and context-specific—and may be disease or study-specific [2]. General examples of under-served groups are often defined by demographic, social, or economic factors; health factors; and/or disease-specific characteristics [2]. Working-age populations, for example, are often under-served in research, despite not typically being considered as under-served in other settings. Despite the ethical and scientific implications of a lack of inclusion in research, it remains a widespread issue [3–6], as demonstrated in recent COVID-19-specific trials [7].

For example, ethnic minority involvement in health and social care research mostly occurs during the research design phase and least in data analysis and interpretation [8]. The majority of evidence on ethnic minority inclusion in clinical research is from the USA, with relatively little other research globally [9]. Furthermore, defining the true scale of the issue is made difficult by a lack of reporting relating to protected characteristics. For example, a systematic review found that of 1518 COVID-19-related studies registered on [ClinicalTrials.gov](https://www.clinicaltrials.gov), only six reported collecting data on ethnicity [10]. There are numerous inter-related reasons for the lack of diversity among clinical research participants, not least, that recognition and acceptance of the issue is relatively new compared with long-standing practices of research. Barriers to successful inclusion (i.e. increased representation of under-served groups in clinical trial populations) can broadly be considered to coalesce into issues relating to communication between researchers and participants, how trials are designed and delivered, differing agendas of research teams and participant groups, and a lack of trust in the research process [11, 12].

Given the COVID-19 pandemic has demonstrated the necessity of improving inclusion in clinical research and the UK government's call for increased diversity in clinical research, there is a pressing need for understanding and education around barriers to inclusion in clinical

research and improvement strategies. In particular, the current and ongoing COVID-19 trials require up-to-date and actionable information on how to improve inclusion in their cohorts. Therefore, there is a distinct necessity for a rapid review of the literature on barriers and enablers of inclusion in clinical research.

Consequently, the primary purpose of this paper was to review international published literature and produce a high-level summary of existing evidence and studies that consider the specific barriers in relation to inclusion in clinical trials and evidence of approaches that are effective in overcoming these. A second aim was to make recommendations for how clinical researchers can support trials to be diverse and inclusive.

Methods

Design

A rapid review is a method of knowledge synthesis that accelerates the process of conducting a systematic review, by simplifying or omitting various stages of the process (e.g. search terms and inclusion criteria, data extraction, and bias assessment). This streamlining of the traditional systematic review methodology permits the production of evidence synthesis in a timely/resource-efficient manner for use by stakeholders. A rapid review was conducted over a 3-week period, from 13/03/2021 to 30/03/2021.

Search strategy

A search of published literature was conducted in PubMed using the search terms detailed in Additional File 1. The search was limited to papers published in English language from 1 January 2010 onwards to ensure that the findings represented the contemporary research landscape. Reference lists of included articles were hand-searched for additional relevant literature.

Eligibility criteria, study selection, and quality assessment

The inclusion criteria included peer-reviewed articles that discussed barriers to inclusion or strategies to improve inclusion in clinical trial research published between January 2010 and March 2021. Grey literature articles were excluded.

Title and abstract screening of articles identified from electronic searches against the inclusion criteria was performed by a single reviewer (DHB). Full-text articles were also screened for inclusion by a single reviewer (DHB). Quality assessment of included articles was not undertaken to facilitate the rapid review of evidence.

Data synthesis

The following data were extracted: first author, year, country, study type/design, number of trials, and number of participants (some studies reported both because they

reported on their approaches over multiple trials), under-served groups considered, conditions considered (e.g. sleep, asthma, cancer, breastfeeding), and findings/information relating to enabling strategies or barriers. Findings from included articles were synthesised using tables and a narrative summary by a single reviewer (DHB), following a narrative, descriptive synthesis approach. Findings were summarised into two key themes relating to barriers to inclusion, and strategies used to overcome these, with a number of sub-themes within each overarching theme.

Results

Screening results

A total of 1861 results were returned from the search and screened for inclusion. Overall, 72 articles were included within this review (see Fig. 1 for screening data). The majority of the included articles (74%) were from the USA and a third focused on cancer trials (33%). In

relation to the type of under-served groups included, half of all articles (50%) focused on inclusion issues relating to ethnic minority populations. The remainder focused on general under-served groups, children and young people, adolescents, women, and others (e.g. deaf, transgender). Sixty-one (85%—see Additional File 1 for more details) of the included articles reported on strategies to improve inclusion (of which $n = 13$ also included information on barriers). Eleven articles reported on barriers to inclusion alone. The 72 papers are included within the “Results” section, Additional File 1, or a combination of these.

Barriers to inclusion

A consistent theme across the literature is that many of the barriers relating to inclusion are the same as those that impact trial design and delivery [13]. The nuance is around how these barriers present among different,

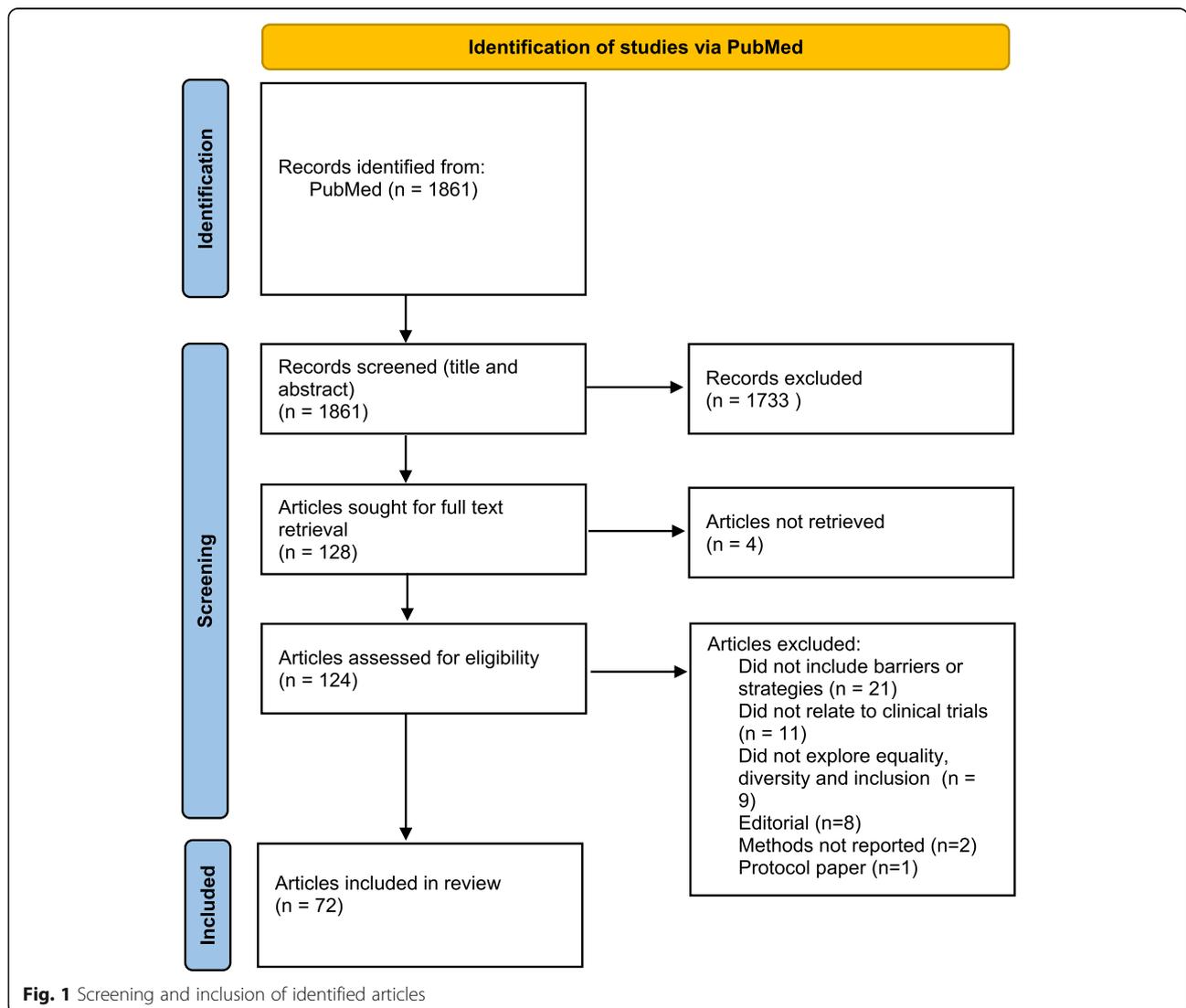


Fig. 1 Screening and inclusion of identified articles

under-served groups, which is often unique to each population's particular circumstances, background, beliefs, and needs. Barriers are summarised below.

Language and communication

This well-known barrier to inclusion, particularly among recent migrant ethnic groups, remains an ongoing issue. In trials conducted in the USA and Europe, being unable to speak and/or read English is a common barrier faced by individuals [14]. Closely related to this is the ability to speak and/or read English to a certain level, without fully comprehending the meaning of everything that is said or written [15]. There is also the further issue of how this decision is made, i.e. who decides whether someone speaks good enough English to take part and what criteria are used. Importantly, language barriers can also be viewed as a failure to show respect to potential participants if the information has not been made available in a culturally relevant and accessible language format [16].

Finally, language/literacy barriers do not only apply to migrant ethnic groups, as other under-served populations also experience language/literacy barriers due to a range of issues such as disability or the impact of lack of education/access to education on literacy. For example, deaf individuals may need support with sign language [17, 18].

Poor communication was another common barrier that was predominantly identified in studies with groups [19, 20]. This may relate to literacy generally and also to health literacy more specifically [15]. Similarly, studies in children need age-appropriate communication [21].

Lack of trust

For potential participants, having a lack of trust in research, doctors, investigators, drugs, and the medical industry was a recurring theme across the literature [14–16, 19, 20, 22–24]. This may arise from previous bad experiences and previous severe adverse events in reported studies [25] and was often compounded by related beliefs or fears [23]. For example, older adults may fear that experimentation could damage their health [26] or that participation would not benefit younger generations [27].

Access to trials

A lack of access to relevant clinical trials manifested in a number of different ways. First, a lack of information about trials for which potential participants are eligible and available is a barrier [22, 23, 28]. This may particularly be the case for people without a usual place for care, who are also often not eligible for relevant trials [29]. Similarly, the inability to access the healthcare or research centre was a barrier [20, 28, 30]. Not being invited to eligible trials was another access-related barrier

[31]. Finally, other practical factors preventing access to trials more generally remain important in under-served groups, such as recruitment competition for other studies and lack of recruitment staff [32].

Eligibility criteria

Some studies highlighted that inclusion/exclusion criteria often disproportionately exclude people in under-served groups, including older adults, pregnant women, obese individuals, people with existing/multiple chronic conditions (multi-morbidity), and people with severe mental illness [27, 28, 32]. This exclusion may be explicit; for example, lack of capacity to consent is a common exclusion criterion that means individuals without this capacity are denied the opportunity to participate in research [33]. It also means there is consequently a limited evidence base regarding health interventions in this population [33]. On the other hand, eligibility criteria may indirectly exclude some populations to a greater extent than others; for example, exclusion criterion may be more prevalent in some ethnic minority groups than in White Europeans, such as chronic diseases [34].

Attitudes and beliefs

This barrier can present in many different ways and is often context and populationspecific. Examples that arise in the literature include no personal or family history of the condition under study [29]; stigma surrounding the condition under study [13, 16, 24]; beliefs among older adults that they were too old to participate in trials [26]; concerns around immigration status for some ethnic minority populations [23]; concerns about side effects or taking an experimental medicine [27, 35]; stress, fatalism, and a conservative attitude to risk-taking among Asian women [25]; religious beliefs [30]; “Guinea pig” perceptions [36]; not feeling comfortable, welcome, or respected [36]; privacy concerns [23]; and negative attitudes to clinical trials [30]. In addition, not only the individual's own beliefs and attitudes, but also those of their friends and families can prevent under-served groups from taking part in trials, as lack of social approval was found to be an important barrier [27, 28, 36, 37].

Lack of knowledge around clinical trials

There were a large number of studies that identified a lack of understanding about clinical trials as a barrier in a range of populations, particularly among ethnic minorities [14, 19, 22, 30]. Examples of where this lack of knowledge/information was apparent included the trial process such as during recruitment or the collection of data [22, 23].

Logistical and practical issues

Logistical and practical barriers were particularly prevalent among under-served groups studied [15], including lack of transport [16, 20, 28, 30, 32], time [16, 22, 24, 28], additional visits/tests [25], indirect costs associated with participating [23], childcare [20, 30], work responsibilities [20], and issues related to the condition under study, e.g. pregnancy or drug abstinence [24, 25, 28].

Other barriers

Aside from these key barriers that were commonly referred to across the literature, single papers also highlighted the following barriers which may be relevant to clinical trials, including lack of follow-up during the recruitment process [32], lack of investigator/study team outreach to communities [28], challenging patient social and structural factors (e.g. homelessness) [24], difficulty locating eligible patients in clinic (HIV-related study) [24], and unavailability of research staff out-of-hours [35].

Evidence-based strategies and enablers

The main evidence-based strategies and enablers to improving inclusion identified through the literature search are fully detailed in Additional File 1. The remainder of this section summarises the key evidence-based strategies identified within the literature.

Cultural competency training

There was a range of evidence suggesting that inclusion in trials was improved when staff had received specific training on that topic [13, 15, 19, 38–46]. This may include teaching study staff about cultural humility, existing health inequities, and the background and context as to how these have arisen [44], including previous research abuses (e.g. deception and mistreatment in research, such as the Tuskegee syphilis study). Acknowledgement of these was found to be important, particularly for African Americans [47]. It was also noted that applying knowledge of culturally important practices was also beneficial [16, 42, 48].

Community partnerships

A recurring theme was that strategies that closed the gap between the study team and the community were very effective [17, 19, 20, 38, 42, 46, 49–53], particularly community-based participatory research (CBPR) approaches [54, 55]. Some specific strategies around this included the use of a community advisory board [38, 46]; patient advocates/navigators, including to recruit participants [38, 49, 56]; ongoing partnerships with community members, leaders, groups, and organisations [19, 20, 38, 41, 42, 49, 50, 52, 56, 57]; direct outreach to community participants followed by electronic health record data for clinical information and follow-up [58]; oversight by a

community panel [20]; and consultation with community members regarding study resources [49].

Personalised approach

Emphasis has been placed on strategies that lead to a more personal approach within clinical trials. These strategies may help people feel that they are seen both as an individual, as well as part of the groups with which they identify. Examples include building good rapport and relationships with participants [48, 51, 59, 60], individual communication styles [60], a human (i.e. not automated) phone call in the participant's preferred language [61], birthday and holiday cards [57], thank you letters [53, 57], acknowledgement certificates [53], and relationship-centred recruitment and retention [43].

Multilingual materials and staff

A number of studies directly overcame language barriers for non-English speakers by providing bilingual staff [20, 42, 47, 52, 57, 59, 62], materials in non-English languages [20, 42, 49, 57, 62, 63], and/or an interpreter [42, 63]. Similarly, in a study conducted with deaf individuals, a variety of contact methods (video call and email) and materials in both sign language video and written English were found to help [17]. Many studies explicitly aimed to recruit study staff from under-served groups so that research teams are representative of the people being recruited, especially if from the local community [13, 17, 39, 47–50, 52], and some even matched study team members and participants on ethnicity [54].

Communication-specific strategies

Aside from language, a number of other strategies specifically related to communication have been implemented, including community providers or physicians sending letters of support to potential participants prior to study contact [42, 49, 62], mass mailing [64, 65], third party contact obtained at enrollment [59], out-of-hours contact [52, 59], keeping phone calls short [59], reminder calls or postcards [57, 59], regular study updates [57], maintaining up-to-date information [59], using social media for recruitment and retention (particularly Facebook) [56, 66], appropriate readability/simplified English materials [20, 44, 47], patient-centred/preferred communication methods [20], use of multimedia [15, 30], and appointment cancellations followed up vigorously [67].

Increasing understanding and trust

In order to tackle barriers related to a lack of understanding or trust in clinical trials, several studies provided educational sessions for communities [23, 39, 47, 49, 50, 65, 68], with one successfully employing teach/teach-back methodology [20]. Others aimed to build

trust through communications [50] or by sharing patient safety information [47]. Using social proof was also a key strategy for improving trust either through participant testimonials [56, 63] or friends and family referrals [30, 64, 69].

Tackling logistical barriers

Multiple logistical barriers to recruitment and retention exist in clinical trials, and they remain a pertinent issue in under-served groups. Strategies that attempt to overcome these include flexible timings and locations of study visits [16, 20, 70], including home-based assessments [48]; providing childcare [42]; transport [24, 42]; and reducing costs associated with trial participation [42].

Additional strategies

Aside from these key strategies that were commonly referred to across the literature, some articles also highlighted the following enabling practices which may be relevant to clinical trials, including leadership from organisations and management around inclusion [38, 40, 42]; partnering with local healthcare centres/practices and clinical staff [20, 35, 43, 44, 49, 67, 71]; non-discriminatory inclusion/exclusion criteria [35, 48, 53, 64, 72]; recruitment targets for diverse groups [48, 52, 53, 64, 72]; electronic database to track participants throughout the study [44]; two-step method of collecting sex at birth and gender identity on data collection forms [46]; alleviating burdensome data collection [73]; study-branded items with study information, e.g. fridge magnets [53, 59]; and family involvement [42, 48].

Discussion

Summary of main findings

This rapid review aimed to synthesise the international published literature on studies that consider the specific barriers in relation to inclusion in clinical trials, and evidence of approaches that have been effective in overcoming these. It is notable that the majority of publications around equality, diversity, and inclusion (EDI) relate to ethnicity, whereas there is less contemporary literature around other protected characteristics. Furthermore, the majority of the literature is from the USA and focuses on cancer trials. The main barriers identified in the literature included language and communication, lack of trust, access to trials, eligibility criteria, attitudes and beliefs, lack of knowledge around clinical trials, and logistical and practical issues. The primary strategies to improve inclusion in clinical trials identified in the literature relate to staff cultural competency training, building community partnerships, taking a personalised approach, utilising multilingual materials and staff, communication-specific strategies, increasing understanding and trust, and tackling logistical barriers.

Recommendations for policy and practice

There were two important points that arose from reviewing this literature. First, a multi-faceted approach is essential. The vast majority of studies found that multiple strategies were required to improve inclusion [13, 16, 17, 19, 20, 22, 24, 30, 35, 38–40, 42–45, 47–53, 56, 57, 59, 60, 62–64, 67, 72, 73]. Furthermore, most successful strategies had elements that operated at different levels, such as within the study team and within the community of interest.

Second, no single strategy was universally effective either within or between trials. For example, many studies found that providing incentives of some form was an enabler [16, 52, 57, 59, 67], whereas this was directly tested in one study that found no benefit of incentives [74]. Similarly, other studies found that strategies that worked well at one site did not necessarily work well at another site [52]. Effective strategies are also likely to be population-specific and may be contradictory. It is therefore important to consider the target population when choosing an approach. For example, a study of South Asians found that it was important to refer to gender throughout communications and have separate versions for men and women [42], whereas transgender individuals may have different preferences [46].

From reviewing the literature, we have made a series of 15 recommendations (Table 1) that may help improve inclusion within clinical trials and clinical research. The recommendations focus on 6 areas/strategies: [1] research staff covering the need for improving cultural competency and sensitivity of all clinical trial staff through training and ongoing learning, and the need to increase recruitment of staff from under-served groups [2]; communication including personalisation of communications, providing alternative languages, having video calling as an option, using social testimony, offering community outreach, and extending office hours [3]; establishing a diverse community advisory panel [4]; developing public education about clinical trials [5]; feasibility and or identification including examining demographics of excluded populations, encouraging the use of sites with high enrollment of under-served groups, exploring linkages with non-healthcare data sources, and creating a local registry of interested under-served groups; and [6] collecting participant data on both sex at birth and gender identity. Although much of the literature identified in this rapid review is drawn from the USA, our recommendations are general principles that are broadly applicable to similar clinical and healthcare contexts. Implementation of these recommendations may help improve representation of under-served groups in clinical trials which would lead to greater external validity of associated findings. Without external validity of research-informed treatments and services, delivering equitable high-quality care within healthcare systems is impaired.

Table 1 Recommendations for improving inclusion in clinical trials and clinical research

| Type/area of strategy | Recommendation | Justification | Additional points to consider |
|-----------------------|--|--|---|
| Research staff | All research staff should receive cultural competency training | There was evidence that culturally sensitive study staff improved the recruitment and retention of diverse populations | Training should be given to staff at all levels so that cultural competency is present across research organisations. To foster an open environment where learning is continuous, it is also recommended that staff are encouraged to reflect on mistakes and lesson learnt [51]. Role-play may also be helpful as part of the training [44]. |
| Communication | Increase recruitment of staff from under-served groups | To better ensure that teams represent the communities that trials serve | This is also an important part of ensuring a culture that has inclusion at the forefront of its values. |
| Communication | Personalise communications as far as possible | There was strong evidence that people preferred to be seen as individuals | This could include, for example, having a consistent point of contact rather than having contact with lots of different individuals and sending personalised mailings such as birthday cards and thank you letters. |
| Communication | Have video calling as a contact option | Some under-served groups require or prefer a visual option for communications, e.g. deaf individuals | This may also benefit other groups that rely on visual cues for communication. |
| Communication | Alternative language options available for all communications | There was strong evidence that availability of non-English communications greatly assisted under-served groups | This relates to both written and verbal communications, and so bilingual staff or translators may be required. Also, consider non-foreign language options for other under-served groups, e.g. sign language and braille. |
| Communication | Consider offering community outreach | Outreach to community leaders, groups, and providers was highly effective in several studies | Research teams could consider offering outreach (e.g. community events/meetings) to increase the participation of under-served groups. |
| Communication | Include social proof where possible in communications | Social proof and validation were important enablers | Social proof could include, for example, testimonials. This may also help with building trust. |
| Communication | Offer extended office hours | A lack of out-of-office availability was a consistent barrier | This could potentially cover evenings or weekends and could be delivered via telephone, email, or instant messenger chat. Under-served groups will be best placed to advise on how this could support them best. |
| Community | Establish a diverse community advisory panel for ongoing input into the research process | Closing the gap between researchers and under-served groups was consistently highlighted as an effective strategy | It is vital that the voices of under-served groups are heard. Building relationships with these groups and consulting regularly with them will help to ensure that existing inequities are not perpetuated. |
| Education | Include education about clinical trials for the public on study websites | A lack of knowledge about and trust in trials was a recurring barrier | This could focus particularly on the importance of inclusion in clinical trials and |

Table 1 Recommendations for improving inclusion in clinical trials and clinical research (Continued)

| Type/area of strategy | Recommendation | Justification | Additional points to consider |
|-----------------------------------|---|---|---|
| Feasibility and or identification | Examine demographic summary of excluded populations | Eligibility criteria may directly or indirectly exclude under-served groups | how the research organisation is working towards that. Where possible (i.e. with access to local data), researchers should compare demographic summaries of the initial target population compared with that of eligible participants so that the generalisability of results can be determined. |
| | Encourage the use of sites with high enrollment of under-served groups | For research to be generalisable, it is key that the research goes where the need is and not only where investigators already are | This may require an initial understanding of which under-served groups are particularly relevant to the condition of interest. |
| | Explore whether linkages with non-healthcare data sources could increase trial access for people without access to healthcare | Inability to access healthcare and/or not being part of the traditional system were barriers to accessing trials | This could include, for example, working with refugee, prison, or homeless data providers. |
| | Consider creating a local registry of individuals from under-served groups who are interested in participating in trials | A diverse registry of people interested in participating in trials was an effective strategy | This could initially be piloted for one particular under-served group before being rolled out more widely. |
| Outcomes | Collect data on both sex at birth and gender identity | This was identified as an effective strategy among transgender individuals | This could also potentially benefit other under-served gender groups as well. |

Strengths and limitations

A key strength of this rapid review is the identification of a large evidence base on barriers and enablers to inclusion, which can be used to inform practice in clinical research. There are, however, limitations of the rapid review approach. By searching a single electronic database and only including peer-reviewed publications, potentially relevant publications may have been omitted, therefore, introducing some bias. Examples of studies that would be systematically excluded from the search are grey literature, as well as studies that include barriers or enablers as secondary aspects that are not clearly searchable within the title or abstract. However, it is unlikely that the barriers or enablers in such studies would be systematically different from those identified in this search, and so the results are presumed to be unbiased. In addition, the use of a single reviewer to ensure consistency and reduce the time required for this review may have also introduced bias. A further limitation is the lack of a quality assessment of included studies. By not appraising the methodological quality of studies, the quality of the evidence on which our findings are based is not known.

Conclusion

This review identified a range of barriers relating to inclusion, and the available literature suggests these issues may manifest differently depending on the population. A number of strategies to overcome these barriers to inclusion were identified, but the implementation of multiple approaches and at differing levels may be required. Based on the available evidence, we made a series of recommendations that, if implemented, may help improve inclusion within clinical trials and clinical research.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-021-05849-7>.

Additional file 1. EDI Rapid Review Paper Author Responses

Authors' contributions

The review concept was conceived by KK and DHB, with critical input from AW, WE, CG, CL, TY, FZ, and MJD. The review was conducted by DHB. The manuscript was drafted by AR and DHB. All other authors contributed to critical revisions of the manuscript.

Funding

KK, AR, AW, and WE are supported by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands (ARC EM). KK and MD are supported by NIHR Leicester Biomedical Research Centre (BRC). The views expressed are those of the authors and not necessarily those of the NIHR, NHS, or the Department of Health and Social Care. This review was originally commissioned and funded by NHS DigiTrials.

Availability of data and materials

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

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Competing interests

KK is a director of The Centre for Ethnic Health Research at the University of Leicester, is a trustee of the charity South Asian Health Foundation and co-chair of its diabetes working group, and is chair of the SAGE ethnicity subgroup.

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Received: 29 July 2021 Accepted: 20 November 2021

Published online: 04 December 2021

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