

A collaborative study between CTUs and other researchers to identify the activities needed to improve representation of under-served groups in trials and understand their implementation (ACCESS).

Abstract

Introduction

Clinical trials are rarely representative of the populations that might benefit from the treatment being tested, and trialists need to make changes to the way trials have been designed as they often exclude groups unnecessarily. There are frameworks to help researchers identify where their research might exclude groups of people, but there is no guidance on how to design trials to make them more accessible.

Methods

This research involved 4 work-packages to identify activities and trial design features that help recruit under-served groups and explored their implementation. A scoping review collected evidence of activities in UK and Ireland, and through roundtable meetings with a range of stakeholders, further activities were identified, providing us with a list of potential activities that aim to reduce unnecessary exclusion from trials. The activities identified in the first 2 work-packages, were then used to hypothetically redesign three trials with a number of stakeholders. We then undertook interviews with researchers and those with experience in trials to explore their views on the impact, practical and implementation issues. Findings from each work package were discussed with the collaborators and PPI contributors.

Results

Activities identified in the scoping review mainly looked at the impact of different recruitment pathways on recruitment of under-served groups, with some discussion around other design features. The roundtables identified many other activities being done to improve representation in trials. Based on the redesign of three trials we produced some key recommendations for trialists when designing trials. Barriers and facilitators of implementing these recommendations were identified through the interviews.

Conclusions

We are producing guidance for CTUs that provides recommendations for designing inclusive trials in two formats: 1) The full guidance will be on a website and provides the rationale for the recommendations, examples and discussion around implementation and links to relevant resources; 2) An infographic listing the key recommendations.

Introduction

Research shows that participants in clinical trials rarely reflect the populations that could benefit from the treatments being investigated and to explore this, the NIHR INCLUDE project (1) was commissioned to look at underrepresentation in clinical trials. It identified a range of under-served groups, which can vary across the types of studies, disease or condition being studied. To help researchers design more inclusive trials, there are three INCLUDE Frameworks (2–4) that make researchers think about which groups the trial results should apply to, and how the design of the trial and the intervention might make it more difficult for any group to take part. The frameworks

help researchers (alongside clinicians, patients and the public) consider the barriers for groups that are under-served and consider ways to remove these.

NIHR funding streams emphasise the need for consideration of inclusivity in NIHR trials, but CTUs likely lack the experience in this area. This project aims to identify how trials can be designed to make them more accessible to under-served groups.

Research question

What activities are being undertaken to improve representation of under-served groups in clinical research, and what are the facilitators and barriers of their implementation in trials?

Objectives

- Review the literature to develop a list of activities/design features that have been effective in improving the representation of under-served groups in trials.
- Undertake stakeholder meetings to explore the findings and gather further examples of activities that aim to increase representation.
- Redesign three previously funded and completed trials to include the activities needed to include relevant under-served groups.
- Undertake interviews with researchers with experience of recruiting under-served groups to explore facilitators and barriers to the implementation of activities or particular design features, and how barriers could be addressed.
- Hold a meeting with collaborators and PPI members to determine best-practice guidance
- Develop a study within a trial (SWAT) proposal of an intervention that may improve the recruitment of a particular under-served population

Methods and Results

Four work packages made up the ACCESS project - a full protocol can be found on the project website (<https://shorturl.at/nyES0>). Participants throughout ACCESS were invited through the collaborators' contacts and networks, emails to distribution lists for trialists, and we advertised through the NIHR's People in Research website.

Scoping review

The scoping review aimed to include papers that reported on activities to improve recruitment of under-served groups in clinical trials. We focused on the following under-served groups due to resource limitations:

- Socioeconomic disadvantaged backgrounds
- Ethnic minority backgrounds
- Those that lack the capacity to consent
- Older people

Seven papers were identified: A two arm RCT of a £100 incentive in the invitation letter across two trials recruiting elderly and socially deprived participants. Five 'lessons learnt' papers reporting on various methods to improve recruitment of the following underserved groups: elderly (N=3), ethnic minority group (N=1), and people living in areas of high socioeconomic deprivation (N=1). One mixed methods paper evaluating a Consent Support Tool (CST) for the recruitment of people with aphasia (who may lack the capacity to consent).

Three of the 'lessons learnt' papers compared different recruitment settings, as well as discussing other design elements that were not evaluated, such as employing bilingual staff, design and timing of the patient information, flexibility in appointments and highlighting affiliation with the university. One 'lessons learnt' paper reported on the use of workshops prior to screening and involvement, and the involvement of community researchers in delivering the intervention, and one 'lessons learnt' paper discussed the methods they used in the successful recruitment of an under-served population.

Evaluations of the activities showed:

- The mention of a £100 incentive payment in the invitation letter improved recruitment overall, but not of elderly or SE disadvantaged patients.
- Two papers reported written invitations from GPs were the most efficient recruitment method for older patients
- Telephone follow-up significantly increased recruitment in older patients
- Three studies reported success in using a community orientated approach (South Asian and elderly populations and deprived areas)
- The CST can support researchers to see if (1) a person with aphasia can provide informed consent, and (2) which format of participant information is appropriate.

'Roundtable' discussions

Following the scoping review, we undertook 5 online 'roundtables', (approximately 2 hours) each with 4 - 8 attendees including trialists, researchers and patient and public input (PPI). We identified additional activities being undertaken across the UK and Ireland to improve the recruitment of underserved groups to trials.

Across the 5 roundtables, the activities around the following categories were identified:

- Recruitment sites and setting (e.g., location, pathway)
- Stakeholder engagement (e.g., community engagement)
- Communication (e.g., simple language, interpretation)
- Patient Information and Consent (e.g., videos, co-production)
- Flexibility (e.g., methods and timing of delivery)
- Researchers (e.g., training, more time and resource)

The activities identified in the scoping review and roundtables are detailed in Appendix 1.

Redesign meetings

Three redesign meetings were held to discuss the practicalities of redesigning trials to include the identified activities, each had 8-12 attendees and included clinicians, researchers and PPI representatives.

Three trials were chosen to cover different types of intervention and conditions (drug trial in diabetes, therapy for depression, and a care home occupational therapy trial for stroke) which enabled focus on different under-served groups: Ethnic minority communities, Elderly, Socio-economically disadvantaged/ unemployed/low income and People who lack capacity to consent for themselves.

The study team chose an INCLUDE framework (2–4) to focus on for each trial and suggested redesign features that were then discussed at the meetings and added to by stakeholders. We noted any comments around implementation and considered the evidence of effectiveness from the scoping review.

Based on the feedback on the redesign elements across the three trials we produced some key recommendations for designing trials which are detailed in Appendix 2. These were updated following the interviews.

Interviews

To explore the implementation of inclusive trial designs, we conducted 15 interviews with CTU staff, clinical trialists and researchers with experience including under-served groups in research and held a collaborator meeting to discuss issues around implementing these activities.

We explored experience the interviewees have had in implementing activities aimed at improving representation of underserved groups, whether they were successful and the facilitators and barriers to their implementation.

The findings on implementation of the recommended activities will be detailed against the recommendations for CTUs in the full guidance. The key implementation issues identified in the interviews and the collaborator meeting (and throughout the ACCESS work-packages) were:

- Issues around intersectionality and recruiting different under-served groups
- Trying to recruit and retain under-served groups takes longer and requires more resource
- No clear processes or standards for translation/interpretation services
- Issues around collecting the data needed to monitor the trial population
- Reluctance of researchers to challenge Research Ethics Committees (RECs), or add time to the set-up period
- Meaningful community engagement is difficult for CTUs as it needs to be longstanding and bi-directional
- Concerns around sub-group analysis being overused and unscientific
- It is beneficial to have several methods for recruitment, delivery, and data collection as different methods will exclude different under-served groups

Patient and Public Involvement panel

The findings across all the work packages were combined and discussed in detail at a diverse PPI panel, two of the panel were also involved in the roundtable and/or redesign meetings. PPI members stated that the recommendations made sense, seemed obvious to them and they did not think there was anything missing. The panel thought that the recommendations around simple language were the most important and highlighted that diverse research staff is important for patients and building trust, but also in making research teams more open to change.

Guidance

Guidance is being produced in several formats, including a full guidance document detailing the recommendations, rationale and issues around implementation and shorter more accessible documents, see Appendix 2 for the recommendations that will be covered in the guidance. We highlight some key considerations for all trials and all stages: Using simple language and layering information; Translation and interpretation; Flexibility; Competent staff; Extra resources need to be built into the trial.

Study within a trial (SWAT)

SWATs aiming to improve the recruitment or retention of under-served groups are a priority for the SWAT network (https://www.trialforge.org/2021/06/swat_network/), inclusion is listed as a priority for recruitment research in the James Lind Alliance PRioRiT_y 1 project (5) and there are a number of existing SWATs in the SWAT repository (<https://shorturl.at/cortW>) that do not currently focus on under-served groups, but are assessing activities suggested in the guidance and could be adapted to focus on under-served groups. There are some existing SWATs looking at the use of videos (SWATs 15, 106, 142, 163 and 171) and translated videos (SWAT 156), that can be adapted for use in other trials.

Quintet Recruitment Intervention (QRI) methods (6) can be used during recruitment to test recruitment methods and make improvements to trial recruitment and this can be done with an inclusion lens.

Translation was considered an important topic for evaluation as CTUs are including costs for this at present, and there is no evidence for how much it is being used, or how successful it is. The first step to this could be to survey CTUs on their current use of translation and interpretation.

Conclusion

ACCESS has produced some key recommendations for trialists when designing a trial to help make it more accessible to under-served groups. Although there is little empirical evidence of the effectiveness of these activities, we have had input from over 40 experts (patients, clinicians, and researchers) in developing this guidance and have highlighted the implementation issues that need consideration. Future work is needed on reporting the ongoing work relating to improving representation in trials and evaluating the effectiveness of these activities.

Dissemination

The key recommendations for designing trials to make them more inclusive (Appendix 2) are presented in an infographic on the study website (<https://shorturl.at/nyES0>) and we are currently producing more detailed guidance as a website to aid researchers in using the recommendations and understanding the implementation issues. This will also be hosted on the study website and accessible via Trial Forge (<https://www.trialforge.org/>).

Acknowledgements

We thank all the patients, public, NHS staff, trialists and other academics who have contributed to this project for their valuable input.

This project is funded by the National Institute for Health Research (NIHR) CTU Support Funding scheme. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Contribution of authors

KB led the project and wrote the first draft of the report. All collaborators contributed to the design and oversight of the project and the final report. All collaborators have input to the guidance and will be authors on the main guidance document.

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Appendices

Appendix 1 - Activities identified in scoping review and roundtables

- Recruitment setting
 - Use different locations e.g., GPs, libraries, community venues
 - Sites in areas with diverse populations
 - Connect with charities with links to underserved groups
 - Target broader sites – not only ‘research ready’
- Stakeholder engagement
 - Research champions
 - Education about clinical trials
 - Build lasting, bi-directional relationships with communities
 - Identify key members of communities as advocates/ research staff
- Communication
 - Follow up phone calls
 - Social media and radio for recruitment
 - Diversity in research team
 - Interpretation – translation may not be sufficient
 - Tailor communication to audience
- Patient Information/Consent
 - Inclusive consent methods
 - Information layering
 - Video clips, animation, graphics
 - Co-production
 - Simplified terminology

- Involvement of family
- Flexibility
 - Flexibility for methods of follow-up
 - Timings to fit around work, other appts and childcare
 - Different incentives – consult with underserved group
 - Fair remuneration paid promptly via the best method
- Researchers
 - Culturally aware staff
 - Explain reasons for data collection
 - Diverse and open-minded RECs
 - Ringfence funding for EDI activity
 - Inclusion may mean slower recruitment

Appendix 2 - Key recommendations for designing trials

- Target population and recruitment
 - Always consider underserved groups
 - Low socioeconomic status linked to inequalities
 - Diverse PPI
 - Choose sites in diverse areas
 - Use more than one recruitment method as different methods exclude different people
 - Sub-studies should include representation from people from underserved groups
- Interventions
 - Videos to explain intervention
 - Staff from underserved group to deliver intervention
 - Cultural (or similar) awareness training for staff
 - Alternative modes of delivery
- Consent & communication
 - Simple language, layered information
 - Diverse recruiting staff
 - Provide cultural (or similar) awareness training to staff
 - Use interpreters
- Outcomes & analysis
 - Proxy completion where possible
 - Focus on key outcomes if burden is high
 - Monitoring demographics - issues around data protection
 - Specific questions to understand reasons for withdrawal by underserved group
 - Consider sub-group analysis even if not powered - need to collect the necessary data
 - Process evaluations should consider how they look at differences between underserved group
- Follow-up
 - Arrange travel or upfront payment
 - Allow different methods of data collection
 - Be flexible with times for clinic visits (out of hours)
- Dissemination
 - Short communications

- Translation
- Involve diverse PPI in dissemination plans

Conflict of interest declaration

Authors report no conflicts of interest for this work.