CHIEF SCIENTIST OFFICE

CODE: HIPS/21/02

RESEARCH PROJECT BRIEFING

SupporTing Recruitment & retention Improvements for Diverse Ethnicities– the STRIDE Project

AIMS

Trial populations often lack ethnic diversity. This limits the relevance of the results to those not included, resulting in health inequalities. We aimed to:

1. Provide guidance to trial teams on how to choose the proportion of their trial participants who should come from different ethnic groups.
2. Identify ways to recruit and retain individuals from these ethnic groups.

KEY FINDINGS

- The INCLUDE Ethnicity Framework is a tool to help trialists to design ethnically diverse trials. We completed this framework for 23 trials across six disease areas and found repeated examples of failure to identify which ethnic groups are important to the trial, and poor consideration of language issues.
- Ten expert panels found that reaching a judgement as to which ethnic groups should have been involved in each trial was difficult. This was largely due to scarce data on disease prevalence by ethnicity.
- Panels recommended that trial populations should reflect the ethnic proportions of people that have the disease that the trial is targeting. If prevalence by ethnicity data are unavailable, ethnic involvement should be at census levels at recruiting sites.
- Currently there are very few effective recruitment and retention strategies that can be used to improve the diversity of trial populations.
- Qualitative interviews to discuss existing recruitment and retention interventions were conducted with 20 non-white British participants. Historical medical abuse and resulting mistrust were discussed in a trial context, as well as the importance of seeing participants as individuals, and demonstrating that they are valued throughout the trial process.

WHAT DID THE STUDY INVOLVE?

1) **Identifying trials and completing Frameworks.** Using the National Institute of Health and Care Research (NIHR) Journal Library and the World Health Organisation Trials Registry Platform, both from 2015 onwards, we identified 23 trials across six disease areas: cancer; cardiovascular; diabetes; maternal health; mental health; and smoking cessation. NIHR INCLUDE Ethnicity Frameworks were completed for all 23 trials.
2) **Panel discussions.** Ten panels of people with clinical expertise, trial and methodological expertise, lived experience of the clinical condition, experience of representing diverse ethnic communities in discussions about health, experience of funding trials, and health policy experience (38 people in total) discussed each trial to reach a judgement as to which ethnic groups should have been involved, and at what proportion.
3) **Mapping**. We took factors known to affect trial recruitment and retention, including those specific to ethnic minority groups, and looked for existing strategies to improve recruitment and retention that could address these factors. This creates a map of factors and what can be done to address them.
4) **Stakeholder consultation.** We conducted semi-structured interviews with 20 non-white participants living in the UK, to explore their views of trial participation and of recruitment and retention strategies highlighted by the the mapping process.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

1) Identifying trials and completing Frameworks

Completed INCLUDE Ethnicity Frameworks show that all 23 trials presented challenges for diverse ethnic involvement and some examples are shown in the table below. The completed Frameworks have been added to the INCLUDE Ethnicity Framework guidance available here.

Examples of challenges to diverse ethnic involvement in trials

- Not recognising that inclusion of some ethnic groups was essential for the trial’s findings to be applicable to everyone with the condition.
- Recruitment that assumes clinical services are used in the same way by all ethnic groups.
- Not recognising that many ethnic groups do not trust the health service, researchers and research, and that this mistrust is is built on many years of lived experience of not being listened to, poor service delivery and racism.
- Failure to consider both written and spoken language needs.
- Failure to recognise that recruitment strategies that give recruiters discretion over who to approach about the trial are likely to lead to unconscious or indeed conscious bias regarding the ethnicity of people recruited to a trial.
- Failure to recognise the importance of culture on trial participation, as well as differing degrees and types of stigma regarding a disease, among some ethnic groups.

2) Panel discussions

Our ten panels often found it hard to judge which ethnic groups should have been included, generally because information on disease prevalence by ethnicity was unavailable. Where data exist, it was generally possible to reach decisions about proportions. The decisions were not easy though, underlining how important it is for whole trial teams, including public contributors, to be involved in making these design judgements.

Collectively, the panels made eight recommendations, which are available in full here. A key recommendation was that ethnic groups should be involved at disease level proportions if these data are available, or at local census data levels if not. Ethnicity should also be considered when selecting trial sites.

3) Mapping

The overwhelming conclusion from our mapping work is that there are very few evidence-based recruitment and retention interventions to support diversity in trials.

4) Stakeholder consultation

We interviewed 20 non-white British participants about trial recruitment and retention. Historical medical abuse and resulting mistrust were discussed in a trial context, as well as the importance of seeing participants as individuals, and demonstrating that they are valued throughout the trial process. History casts a long shadow: trial teams need to recognise that trust in research and researchers is low among some ethnic groups. Trialists need to earn trust and demonstrate how much participants are valued throughout the trial process.

Some selected quotes giving a flavour of what people said in our interviews are given in the table below.

Selected quotes from interview participants

- On seeing your own identity reflected in trial teams and building trust: *"If you're dealing with a specific community… you need to have their trust, and you can only have trust when they see their own people working in that field. … there are people who won't trust a white British, like they trust their only community person."* – Pakistani Man, aged 20-24.
- On mistrust of health professionals and researchers: *"I would have so many questions, and sometimes you're not sure if you actually get the truth, because they want you as a lab rat, so they'll lie and get you on the programme."* African Woman, aged 55-60.
- On being seen as an individual: *"If it feels like it's been targeted rather than a generic blanket letter out. If I'd received something like that, and I knew that it was because of* [referencing personal medical history] *then I think I… yeah, I would look into, at least respond to that to say, "Yeah, I would be interested." It's personal to me."* - Pakistani Man, aged 50-54.

WHAT IMPACT COULD THE FINDINGS HAVE?

Our findings demonstrate that the current approach to trial design means that all trials are likely to find diverse recruitment and retention challenging. Our results will feed into work led by Trial Forge on improving trial diversity, especially the need to develop targeted strategies to support greater ethnic diversity in trials, and the need for these strategies to be rigorously evaluated. The lack of data on disease prevalence by ethnicity is a substantial problem: we hope our results will highlight this and promote solutions to it in Scotland and elsewhere. Our recommendations for selection of recruitment and retention proportions by ethnicity will help trial teams to improve how inclusive, and therefore useful, their trials are.

HOW WILL THE OUTCOMES BE SHARED?

- We have released some of our findings already through Trial Forge: see here for panel recommendations and here for completed INCLUDE Ethnicity Frameworks.
- Information from STRIDE has been highlighted in discussions with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) on the idea of introducing diversity as part of trial approval processes.
- We will run webinars with our partners, including public contributors, and we will produce at least two scientific papers, one on the work with panels, the other on the qualitative work.
- Finally, we will share our results with people who contributed to our panels.

CONCLUSION

Failing to explicitly consider ethnicity when designing trials perpetuates inequality. STRIDE shows that the current approach to trial design is unlikely to increase the diversity of trial populations. Together with our panels, we have developed recommendations for inclusive recruitment and retention strategies. Trialists need better access to disease prevalence data by ethnicity and work to develop and evaluate interventions that support diverse trials is needed.

RESEARCH TEAM & CONTACT

Prof Shaun Treweek

Health Services Research Unit,
University of Aberdeen,
Health Sciences Building,
Foresterhill, Aberdeen AB25 2ZD

streweek@mac.com

+44 (0) 777 901 6955

Additional Information

Funding amount: £188,146

Project start date: 1st Jan 2022, Project end date: 31st August 2023