

Inclusion and diversity in the PRINCIPLE trial

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on behalf of the PRINCIPLE Trial Collaborative Group

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Word count: 265

Main text

We welcome Prof Gill and colleagues' call for diverse participation in clinical trials like PRINCIPLE.¹

We initiated many inclusive recruitment strategies including appointment of a leading and national pharmacist expert working with ethnic minority communities; targeted socio-economically deprived areas, ethnic minority communities, and people with learning difficulties; developed UK-wide relationships with community and religious organisations (including places of worship); collaborated with universities, and national and regional healthcare institutions; and gathered nationwide support from ethnic minority leaders, health professionals and their organisations (Table 1).

We consistently promoted the trial in many languages, via local and national media channels, internet and social media platforms. Our pharmacy and general practice networks helped establish PRINCIPLE footprints in approximately 7,500 community pharmacies UK-wide, with over 1000 general practice co-investigators helping recruitment from a range of settings.

This contributed to the inclusion of 55 (4.0%) South Asian and 7 (0.5%) Black participants in our azithromycin analysis,² is comparable to 3.7% Asian ethnicity, and 1.6% Black ethnicity among people aged over 50 years (PRINCIPLE's target age group) in England and Wales.³ Proportions of participants' in Index of Multiple Deprivation (IMD) quintiles were: IMD1 (most deprived) 352/1375, 25.6%, IMD2 267/1375, 19.4%, IMD3 270/1375, 19.6%, IMD4 241/1375, 17.5%, IMD5 (least deprived) 245/1375, 17.8%). Overall, this demonstrates good recruitment from socio-economically deprived and ethnic minority communities.

PRINCIPLE's innovative approach now supports recruitment of ethnic minority participants to other national trials. We recognise that our initial outreach strategy requires further and targeted investment, initiatives, collaboration and institutional support to enable sustainable engagement of ethnic minorities in primary care research, ultimately for inclusive, equitable health for all.

References

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