Journal of Clinical Epidemiology 170 (2024) 111366

Journal of Clinical Epidemiology

METHODOLOGICAL CONSIDERATIONS RELATED TO EQUITY, DIVERSITY, AND INCLUSION IN CLINICAL EPIDEMIOLOGY

"We are not invited": Australian focus group results on how to improve ethnic diversity in trials

Bianca Brijnath[a,b,c,*], Rachel Muoio[b], Peter Feldman[b], Davina Ghersi[d,e], An-Wen Chan[f], Vivian Welch[g], Shaun Treweek[h], Heidi Green[h,i], Aaron M. Orkin[j,k,l], Ebenezer Owusu-Addo[b,m]

[a]*Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia*
[b]*Social Gerontology, National Ageing Research Institute, Melbourne, Australia*
[c]*School of Social Sciences, University of Western Australia, Perth, Australia*
[d]*School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia*
[e]*NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia*
[f]*Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Canada*
[g]*School of Epidemiology and Public Health, University of Ottawa, Ottawa, Canada*
[h]*Health Services Research Unit, School of Medicine, Medical Sciences and Nutrition, University of Aberdeen, Aberdeen, Scotland*
[i]*Research and Insights Team, COUCH Health, Manchester, UK*
[j]*Department of Family and Community Medicine, University of Toronto, Toronto, Canada*
[k]*Dalla Lana School of Public Health, University of Toronto, Toronto, Canada*
[l]*Li Ka Shing Knowledge Institute of Unity Health, Toronto, Canada*
[m]*Bureau of Integrated Rural Development, Kwame Nkrumah University of Science & Technology, Kumasi, Ghana*

Accepted 9 April 2024; Published online 16 April 2024

Abstract

Objectives: Lack of ethnic diversity in trials may contribute to health disparities and to inequity in health outcomes. The primary objective was to investigate the experiences and perspectives of ethnically diverse populations about how to improve ethnic diversity in trials.

Study Design and Setting: Qualitative data were collected via 16 focus groups with participants from 21 ethnically diverse communities in Australia. Data collection took place between August and September 2022 in community-based settings in six capital cities: Sydney, Melbourne, Perth, Adelaide, Brisbane, and Darwin, and one rural town: Bordertown (South Australia).

Results: One hundred and fifty-eight purposively sampled adults (aged 18−85, 49% women) participated in groups speaking Tamil, Greek, Punjabi, Italian, Mandarin, Cantonese, Karin, Vietnamese, Nepalese, and Arabic; or English-language groups (comprising Fijian, Filipino, African, and two multicultural groups). Only 10 participants had previously taken part in medical research including three in trials. There was support for medical research, including trials; however, most participants had never been invited to participate. To increase ethnic diversity in trial populations, participants recommended recruitment via partnering with communities, translating trial materials and making them culturally accessible using audiovisual ways, promoting retention by minimizing participant burden, establishing trust and rapport between participants and researchers, and sharing individual results. Participants were reluctant to join studies on taboo topics in their communities (eg, sexual health) or in which physical specimens (eg, blood) were needed. Participants said these barriers could be mitigated by communicating about the topic in more culturally cognizant and safe ways, explaining how data would be securely stored, and reinforcing the benefit of medical research to humanity.

Conclusion: Participants recognized the principal benefits of trials and other medical research, were prepared to take part, and offered suggestions on recruitment, consent, data collection mechanisms, and retention to enable this to occur. Researchers should consider these community insights when designing and conducting trials; and government, regulators, funders, and publishers should allow for greater innovation and flexibility in their processes to enable ethnic diversity in trials to improve.

Keywords: Ethnic diversity; Trials; Inclusion; Focus groups; Recruitment; Cross-cultural

Funding: This project was supported by funding from the Australian National Health and Medical Research Council (CN3847784). The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

* Corresponding author. Division of Social Gerontology, National Ageing Research Institute Ltd., 34-54 Poplar Road, Parkville Victoria 3052, Australia.

E-mail address: b.brijnath@nari.edu.au (B. Brijnath).

https://doi.org/10.1016/j.jclinepi.2024.111366

Plain language summary

Between August and September 2022, members of the research team based in Australia held discussions with 158 members of the Australian public who volunteered to speak to us about their expectations and past experiences of medical research. Volunteers were from communities that speak languages other than English, including Tamil, Greek, Punjabi, Italian, Mandarin, Cantonese, Karin, Vietnamese, Nepalese, and Arabic, as well as English language speakers from Fijian, Filipino, and African communities in Australia. These are important conversations to have and share with other researchers because people from culturally, ethnically, and linguistically diverse communities have often not been effectively included in trials. The information we learned from volunteers, such as how best to recruit people from their communities into research studies, could be used to create more inclusive trials in the future, which may lead to improved health outcomes for people from ethnically diverse backgrounds.

1. Introduction

When participants in randomized controlled trials (hereafter trials) are not representative of the ethnic diversities of patients in the clinical setting, then diverse communities may not benefit from the latest scientific advances; differences in the metabolism, clinical effectiveness, and adverse effects of new drugs are often unclear; and innovative ways to ensure treatment accessibility and acceptability across diverse populations remain unexplored [1−4]. For example, angiotensin-converting enzyme (ACE) inhibitors are less effective in African-Americans for the treatment of hypertension [5]; some drug treatments for hepatitis C have variable impact across ethnic groups [6]; and despite increased dementia risk among Black, Asian, Hispanic, and Native American patients, 91.5% of the donanemab drug trial participants were White [7].

In Australia, where this study was conducted, 30% of the population are ethnically diverse but this diversity is not reflected in current trial populations: for example, 10 of the 15 dementia trials published between 2016 and 2018 reported no ethnicity-related data at all [8] and ethnic diversity is not consistently collected in public resources such as trial registries [9]. Low English proficiency (Australia's official language), lack of translated multilingual materials, and limited resources to support such translations are commonly cited barriers to trial participation [10,11]. However, there are increasingly calls [12,13] to go beyond just trial participant's linguistic proficiency and consider how sites (eg, clinician time) and sponsors (eg, trial protocols) facilitate the inclusion of ethnically diverse groups [12].

The US National Academies of Sciences, Engineering, and Medicine [14] estimates trillions of dollars will be lost by 2050 due to reduced life expectancy among populations that are not sufficiently represented in trials. By contrast, it was estimated that if 1% of health disparities were alleviated in diabetes and heart disease by improved ethnic diversity among trial participants, over the same time period there would be economic gains of >US$ 40 billion and US$ 60 billion in these two diseases alone [14].

There is now growing expectation from governments (eg, the Biden administration [15]), funders (eg, National Institutes of Health [16], National Institute for Health and Care Research [17], the Medical Research Future Fund [18]), and journals (eg, Journal of the American Medical Association [1]) that ethnic diversity is improved in trials and quality representative data are generated. The current trial landscape is undergoing major change with the US Food and Drug Administration (FDA) soon mandating late-stage trials must have a plan for recruiting a diverse range of participants to secure FDA approval [19,20]. Funders such as the Australian Medical Research Future Fund define ethnically diverse groups as a priority population for targeted research funding to create equitable health outcomes [18].

These shifts necessitate a stronger focus on how to improve ethnic diversity in trials. Too often, ethnically diverse populations are described as "hard to reach," [21] despite a literature [2,22−26] on how to improve participation. Drawing on the perspectives of ethnically diverse populations themselves, we explored what steps they recommend to improve diversity in trials.

2. Methods

2.1. Overview of project RECONSIDER

This work is part of the Reporting extension of Consolidated Standards of Reporting Trials and Standard Protocol Items: Recommendations for Interventional Trials for Inclusion, Diversity, Ethnicity and Race (RECONSIDER) Study [27], which will provide methodological and reporting guidance to researchers on how to improve ethnic diversity in trials. Established methods [28] for developing RECONSIDER were followed, with the novel addition of qualitative research.

The study is reported in line with the consolidated criteria for reporting qualitative research (COREQ) [29].

What is new?

Key findings

- 16 focus groups from 21 different ethnic communities indicated strong support for taking part in medical research, including trials.
- To encourage participation, they want more inclusive and engaging recruitment, consenting, and retention approaches, as well as more transparency on data collection, storage, and disposal, especially for taboo subjects and/or where there has been a history of discrimination.

What this adds to what is known?

- Government, regulators, funders, and publishers are pushing for greater study diversity in medical research, especially in trials, to improve applicability.
- To date, there has been a paucity of research investigating the perspectives and preferences of ethnically diverse peoples themselves about how ethnic diversity can be improved in trials.

What is the implication and what should change now?

- Researchers should consider these community insights when designing and conducting trials.
- Government, regulators, funders, and publishers should consider these insights and allow for greater innovation and flexibility in their processes to enable ethnic diversity in trials to improve.

2.2. Ethics

Ethical approval was obtained from the University of Western Australia and governance from the National Ageing Research Institute. All participants provided written informed consent and received an AUD$20 gift voucher for their participation. Data collection and analyses were grounded in a postpositivist realist framework [30], which theorizes that objective reality may be different from one's knowledge of it and therefore it is important to elicit participants' ways of knowing and seeing to establish the credibility of one's assumptions [30].

2.3. Study design and setting

Data were gathered in six Australian capital cities (Sydney, Melbourne, Perth, Adelaide, Brisbane, and Darwin) and one rural town (Bordertown, South Australia). A maximum variation purposive sampling framework was designed to capture participation from a spectrum of ethnically diverse groups ranging from well-established economic migrant communities (>30 years) through to emerging newcomer communities (<10 years) of predominantly humanitarian migrants. Ethnicity—an evolving and contested definition—refers here to a shared identity based on characteristics such as a common culture, history, and language and ethnic diversity as groups of people from different ethnic backgrounds [31]. Participants from 21 communities were identified by engaging 10 ethno-specific health and care organizations, four of whom we had previously partnered with. These project partners advertised the study through their normal communication channels (eg, phone, email, word-of-mouth) and by posting translated fliers provided by the research team. The sample was consistent with the number of focus groups needed to typify the sampling framework. Inclusion criteria were self-identifying as a person of one of the target ethnicity groups (see Table 1), aged 18+, able to consent, and able to attend an in-person focus group. Recruitment continued until data saturation was reached, that is, when the study investigators and interviewers (B.B., P.F.) judged no significant new themes were emerging in the group discussions and preliminary analyses of these transcripts. Data collection occurred from August 21, 2022, to September 26, 2022, in community centers.

2.4. Data collection and measurements

Qualitative data collection occurred via focus groups with participants aged >18 years (groups ranged from 3 to 17 participants). Guided by a realist framework [32], participants were asked how they felt about participation in trials and medical research; what steps they recommended to improve recruitment and retention processes; and the types of questions that could be asked pertaining to culture and ethnicity, how relevant such questions were in a medical research context, and their level of comfort in discussing their cultural background and ethnicity with medical research staff (see Supplement 1). Focus groups were in-person, facilitated by experienced qualitative researchers: B.B. (woman) and P.F. (man), with professional interpreting of all questions and responses to and from English for 11 focus groups conducted in languages other than English. These languages were Tamil, Greek, Punjabi, Italian, Mandarin, Cantonese, Karin, Hazaragi, Vietnamese, Nepalese, and Arabic. Two multicultural groups and three separate groups for Fijian, Filipino, and African participants, respectively, were conducted in English. Participants were known to each other prior to the discussion but not to the researchers or interpreters. Focus groups were 90 minutes duration each, audio recorded with notes taken during the discussion, and recordings were professionally transcribed.

2.5. Data analysis

Transcripts were imported into NVivo, version 12.6.0.959 (QSR International) and analyzed thematically

Table 1. Characteristics of 16 focus groups (n = 158 participants)

No.	Group size, *N*	Location	Ethnicity	Language	Age range	Sex	Migrant circumstance	Established (>30 years) or emerging (<10 years) communities
1	10	Darwin, NT	Multicultural (Indian, Filipino)	English	65+	7W, 3M	Economic migrants	Emerging
2	15	Darwin, NT	Multicultural (Indian, Pakistani, Nepalese, Filipino)	English	18–85	6W, 9M	Economic migrants	Emerging
3	8	Melbourne, VIC	Tamil	Tamil	65+	2W, 6M	Economic migrants	Emerging
4	17	Melbourne, VIC	Greek	Greek	65+	7W, 10M	Economic migrants	Established
5	9	Melbourne, VIC	Sikh	Punjabi	26–65, 1 over 65	3W, 6M	Economic migrants	Emerging
6	5	Perth, WA	Italian	Italian	80+	3W, 2M	Economic migrants	Established
7	11	Perth, WA	Chinese	Mandarin	55–75	9W, 2M	Economic migrants	Established
8	10	Perth, WA	Chinese	Cantonese	55–75	7W, 3M	Economic migrants	Established
9	17	Brisbane, QLD	Burmese	Karin	55–80	5W, 12M	Humanitarian migrants	Emerging
10	9	Bordertown, SA	Afghan Hazara	Hazaragi	30–55	0W, 9M	Humanitarian migrants	Emerging
11	4	Bordertown, SA	Fijian	English	30–55	2W, 2M	Economic migrants	Emerging
12	3	Bordertown, SA	Filipino	English	30–55	2W, 1M	Economic migrants	Emerging
13	11	Adelaide, SA	Vietnamese	Vietnamese	30–80	6W, 5M	Humanitarian migrants	Established
14	9	Adelaide, SA	Bhutanese	Nepalese	30–80	3W, 6M	Humanitarian migrants	Emerging
15	4	Adelaide, SA	African (Congolese, Burundi, Zimbabwean)	English	18–55	1W, 3M	Economic and Humanitarian migrants	Emerging
16	16	Bankstown, NSW	Syrian, Iraqi, Iranian	Arabic	30–65	14W, 2M	Humanitarian migrants	Emerging

using inductive and deductive approaches [33]. Experienced qualitative researchers R.M. and P.F. independently coded 16 transcripts inductively to glean initial patterns and themes [34]. Comparisons were made, differences resolved by consensus, and an initial codebook developed [34]. B.B. independently verified the coding schemata and subsequent transcripts were coded using the codebook with further refinements made [33,34]. Once coding was completed, themes and patterns were organized iteratively in several rounds, mapped to the interview schedule, discussed with the study investigators, and the RECONSIDER Extension Group [30,33]. Data were analyzed from September 2022 to August 2023.

3. Results

There were 158 participants (Table 1) representing 21 diverse communities (77 women [49%]). Seven main themes were identified (see Supplement 2). These were (1) perceptions and past participation in trials, (2) using inclusive recruitment strategies, (3) translating trial materials, and (4) promoting retention via building rapport and feedback on the study results. Participants were reluctant to (5) join study topics that were considered taboo in their communities, (6) where physical specimens were needed, and (7) where sensitive questions were asked about their culture and ethnicity. Quotes illustrative of these results and representative from all focus groups are included below.

3.1. Perceptions and past participation in trials

Three (1.9%) of the 158 participants had previously taken part in a trial, with one of these discontinuing because of the paperwork. A further seven (4.4%) had participated in medical research of any type (eg, surveys), and one had attempted to join a trial but did not succeed. The remainder of participants did not report any involvement or invitation to participate in any kind of medical research until this study.

Despite their limited participation, medical research was perceived by participants to deliver opportunities to learn about disease and treatment, to socialize with others, and to advance clinical practice for the benefit of humanity:

Why we participate here, because it's not only for our body or the Afghan body, it's a good − this research maybe something find for all the human, for everyone…we understand the value: the medical treatment, the health, and if more like this research, we are ready to participate *(Afghan Hazara focus group, in Hazaragi).*

3.2. Using inclusive recruitment strategies

Partnering with communities and facilitating access were crucial to recruitment across all groups. Community leaders, physicians, other healthcare professionals, and government agencies were deemed trustworthy sources for information and advertising in places such as language schools, migrant organizations, schools, universities, and religious institutions legitimized research and encouraged participation.

The key thing is that you identify the community leaders, and through them you will be able to access all the different types of group organizations or community groups—and, that is probably the best way *(Vietnamese focus group, in Vietnamese).*

Recruiting through online advertising was viewed unfavorably, especially by older people: ''Every email that comes to me, I think more than 100 emails asking for this, asking for that, scam, scam, scam'' *(Older multicultural focus group, Indian and Filipino, in English).* Participation that required travel far from home and/or to locations inaccessible by public transport, even when transportation costs were reimbursed, was also viewed negatively: ''If you're far away, I won't like to go…If it's not easily accessible, the place, I would say no'' *(Tamil focus group, in Tamil).* Overall, financial incentives were less important for participation, but only Chinese and Filipino groups expressly stated that money was not a motivating factor to participate in research.

3.3. Translation of trial materials

Translation was viewed as particularly important for trials so that participants could easily convey their symptoms and any other issues they might encounter throughout the study. Lack of linguistic translation was seen to diminish the quality of consent and data quality as questions and instructions only offered in English were not fully understood. The availability of translated materials and translation services also had symbolic value, indicating to participants that they were welcome and that their participation was appreciated.

If some study is looking forward to some diverse kind of audience, then it should be advertised in multiple languages…If some study is targeting a multicultural community, then why should it be in English? It should be in multiple languages *(Sikh focus group, in Punjabi).*

Large amounts of written material deterred participation, even when in a preferred language. Participants who had taken part in medical research felt that the study information was not always written clearly and simply, irrespective of what language it was available in. Use of graphics and videos to communicate information about the study and offering verbal consent were recommended to make the process more user-friendly, reduce the monotony of ''too much'' text, and stop participants feeling overwhelmed.

Also, make it more interesting. Like, instead of having 50 words of all these long questions, just do some graphics and sort of stuff just to keep people entertained, so they have fun at the same time…just see something different *(Multicultural focus group—Indian, Pakistani, Nepalese, and Filipino, in English).*

3.4. Promoting retention

Enabling participation outside usual business hours, providing clear explanations for the reasons for (burdensome) repeat measures, spacing follow-up times to no more than once per month, and providing information about the study's progress and preliminary findings were identified as ways to retain participants. Participants also wanted to establish a positive rapport with the research team, be treated courteously, and have their questions answered kindly and patiently: ''The person who is conducting the study must be very pleasant and very tolerant, and must be able to answer the questions, rather than expect us to listen to everything'' *(Tamil focus group, in Tamil).*

3.5. Overcoming taboo topics

Topics of interest were COVID-19, diabetes, high blood pressure, heart disease, dementia, Parkinson's disease, and Alzheimer's disease. Mental health, sexual health, family violence, and sexual violence deterred participation due to the negative stigma associated with them in many communities. The latter topics were seen to bring families and communities into disrepute and emotionally trigger participants who emigrated from conflict zones or had significant prior exposure to violence.

To overcome these barriers, participants suggested researchers emphasize the confidentiality of the study, recruit through trusted sources in communities, and collect data

individually rather than in group settings. If group-based interventions and/or data collection were essential, then it was suggested that clustering participants by sex and age could mitigate some discomfort:

It also depends on the grouping…Big boys, small boys, I mean old men and that, it makes them feel that they fear you know how to speak and all those things. So even if you do research, you don't group all of them together…-when the kids are there, or youth are there, they feel no—this is not the right time for them to hear this. We don't want them to know *(African focus group—Congolese, Burundi, and Zimbabwean, in English).*

African participants also highlighted the importance of involving researchers from their own cultural and ethnic group to improve participant's sense of comfort and trust as such interlocutors could navigate sensitive topics in culturally safe and appropriate ways.

If you ask them direct questions, sometimes it's difficult for them to answer…they still refer to parts of the body in a different way, because in our culture it's just as you said, a taboo for you to go straight and mention it…in our culture, when you say it, it doesn't show respect. So, depends on how you present the questions, and how you ask them *(African focus group—Congolese, Burundi, and Zimbabwean, in English).*

3.6. Providing physical specimens

Requirements to provide blood, stool, and other physical samples were seen as invasive and negatively affected participation. However, the use of discrete sampling methods such as self-testing kits could partially ameliorate this hesitancy:

They give you the sample where you can test yourself, right, and you send it back…they do not intrude to you in any other ways, so they do it in a nice and sophisticated manner *(Greek focus group, in Greek).*

Explaining the necessity of taking samples and how the samples would be confidentially used, safely stored, and disposed of enhanced the study's transparency and addressed community concerns.

If you want to do a health check or any blood tests, take our blood, we need to know the purpose of the research and which organization did organize this and then who's the person in charge — where is the blood going to? *(Chinese focus group, in Mandarin).*

3.7. Asking sensitive questions about culture and ethnicity

Opinion was divided about what questions should be asked about culture and ethnicity. Asking about country of birth, languages spoken, proficiency in the dominant language spoken in the country of residence, and religious practices were acceptable to those who connected culture and ethnicity to dietary and lifestyle factors, susceptibility to disease, and beliefs and attitudes about medicines and treatments.

Health and our culture are interrelated, illness and the culture interrelated. For instance, for Chinese, we eat tripe and maybe we eat too much and that this may cause health issues, so health and culture are interrelated *(Chinese focus group, in Cantonese).*

The opposing group queried the relevance of such questions, construing them as discriminatory or tokenistic efforts:

American, Canada, and Nepal—when you pour into one glass it won't separate, it's all one. So, today we became as one here, so…don't ask every individual what sort of background, where it is, and what sort of conditions, I think it is not really, you know, relevant *(Bhutanese focus group, in Nepalese).*

Participants said discrimination based on ethnicity was still prevalent in Australia, including in healthcare settings. Consequently, for some, it felt dangerous to discuss cultural background and ethnicity: ''Australians don't like Arabs'' *(Arabic focus group, in Arabic)* and ''Refugees are discriminated against'' *(Bhutanese focus group, in Nepalese).*

Even among participants who were comfortable discussing their cultural and ethnic background, questions relating to educational attainment, visa status, political affiliations, and clan, tribe, or caste identity were generally considered unacceptable and lacking relevance in the context of medical research. To convince participants to answer such questions, clear justifications for their inclusion and good rapport with researchers were seen as essential.

4. Discussion

This study shows that ethnically diverse communities are prepared to take part in trials and other kinds of medical research but want more inclusive and engaging recruitment, consenting, and retention approaches, as well as more transparency on data collection, storage, and disposal, especially for taboo subjects and/or where there has been a history of discrimination.

However, many ethnically diverse communities are seldom invited to participate despite literature on strategies and approaches to improve the representativeness of trial participants [2,22–26]. This finding was also noted by Garza et al. [35] in the United States and Low et al. in Australia [8]. This is a missed opportunity and a methodological deficiency, as the benefits of medical research are clearly recognized by these populations and there is preparedness to take part. The onus is therefore on researchers to think more expansively and creatively about where and how to recruit such populations [26]. Preferred gatekeepers and settings mentioned by participants accord with previous findings [24,36–40] but pre-recruitment, at the design stage, researchers must engage with end users and critically reflect on the inclusivity of their eligibility criteria and recruitment pathways [26].

Ethics and consent processes must move beyond the current written form [41,42]. Jargon- and text-heavy materials, available primarily in English, deter participation and introduce ethical problems when impenetrable participant information and consent forms serve to manage institutional risk at the expense of participants' genuine informed consent [43,44]. To better match trial populations to real-world end users, more dynamic and engaging consent processes are needed, especially given the rapid proliferation of digital trials [41,42]. Alongside, the ethics committee themselves must facilitate greater innovation and flexibility in their processes to allow this to occur.

Retention is a persistent challenge in trials but remains a neglected aspect of research design [25]. Many of the techniques outlined by the focus group participants align with other participant-centric approaches [24,37,45]. Fundamentally, these techniques underscore that good rapport with the research team gives participants opportunities to learn, socialize, and feel listened to—intangible outcomes that are more valued by participants than just financial reimbursements [35].

Finally, stigma around certain research topics [46,47], trepidation to provide physical samples [23,48], and reluctance to disclose cultural and ethnic information for fear of being discriminated [31,49] are well-known barriers to participation in medical research. These anxieties are rooted in cultural norms and in past and current discriminatory environments, including healthcare systems, which many ethnically diverse populations navigate daily. Though no single study can overcome the legacies of marginalization and disenfranchisement, progressive research practices can play a role in redressing these historical injustices [23,46]. As other studies have highlighted, the focus group participants also emphasized research transparency around data collection, storage, and disposal; clear justifications for why intrusive questions may be asked or invasive data collection methods applied; and a sensitive approach to mitigating potential discomfort as ways to overcome these barriers [23,46].

4.1. Limitations

While a sampling framework was applied to guide recruitment, quotas were not adopted to achieve balanced recruitment by age, sex, and other intersecting factors. Therefore, some groups were less represented in this research than others (eg, younger people), and we do not know who declined to participate. Similarly, findings were not analyzed by sex, although there may be specific factors related to sex [22] that influence research participation in ethnically diverse communities. In addition, the use of interpreters did render some discussions staccato and not free-flowing but facilitation by researchers experienced in working with different linguistic groups partially ameliorated this limitation. Linguistic variances also made it difficult for us to return transcripts to participants for checking and to provide feedback on the findings. Finally, focus groups were only conducted in Australia, which is a limitation given the global reach of the RECONSIDER Guidelines [27], and so our study's implications should be tempered with respect to other regions.

5. Conclusions

Government, regulators, funders, and publishers are pushing for greater study diversity in medical research, especially in trials, to improve applicability. Our participants also recognized the benefits of medical research and were prepared to take part, offering suggestions on recruitment, consent, data collection mechanisms, and retention to enable this to occur.

Disclaimer

The content is solely the responsibility of the authors and RECONSIDER Extension Group and does not necessarily represent the official views of the Australian National Health and Medical Research Council.

Data sharing statement

See Supplement 1 and 2.

Previous presentation/posting

Preliminary analyses were presented at the Australian National Multicultural Health and Wellbeing Conference, November 21-22, 2023 and at the ACTA International Clinical Trials Symposium, November 27-28, 2023.

CRediT authorship contribution statement

Bianca Brijnath: Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Rachel Muoio:** Writing – original draft, Project administration, Formal analysis, Data curation. **Peter Feldman:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Davina Ghersi:** Writing – review & editing, Investigation, Conceptualization. **An-Wen Chan:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Vivian Welch:** Writing – review & editing, Validation, Methodology, Investigation, Conceptualization. **Shaun Treweek:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Heidi Green:** Writing – review & editing, Validation, Investigation, Conceptualization. **Aaron M. Orkin:** Writing – review & editing,

Methodology, Investigation, Conceptualization. **Ebenezer Owusu-Addo:** Writing − review & editing, Investigation, Conceptualization.

Data availability

Data will be made available on request.

Declaration of competing interest

B.B. has received funds from the Australian National Health and Medical Research Council for projects related to dementia, ethnicity, and aging. H.G. works for COUCH Health, which undertakes research commissioned by the pharmaceutical, academic, and charity sectors. No COUCH Health clients participated in the collection, analysis, or interpretation of the data for the RECONSIDER Project. There are no competing interests for any other author.

Acknowledgments

We thank The RECONSIDER Extension Group for their advice and feedback on this manuscript. The group members are:

- Hayat Ahmed, MSc, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT Centre), Cambridge, US;
- Nita Bhandari, PhD, Centre for Health Research and Development, Society for Applied Studies, New Delhi, India;
- Barbara E. Bierer, MD, MRCT Centre, Harvard Medical School, Cambridge, US;
- Owen Chinembiri, MA, Macmillan Cancer Support, London, UK;
- Kenzie A. Cameron, PhD, MPH, Departments of Medicine, Medical Education, Medical Social Sciences and Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, US;
- Daniel Coase, MA, Federation of Ethnic Communities Councils of Australia, Canberra, Australia;
- Maria Cuervas, MPH, Public contributor, Santiago, Chile;
- Shoba Dawson, PhD, Sheffield Centre for Health and Related Research, University of Sheffield, Sheffield, UK;
- Robert M. Golub, MD, Department of Medicine and Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, US;
- Farrokh Habibzadeh, MD, Global Virus Network, Shiraz, Iran;
- Merilyn Heuschkel, MPH, Strategic Research Initiatives, NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia;
- Lindsey Jasicki, Clinical Trials Program Manager, Cancer Institute New South Wales, Sydney, Australia;
- Lillian Leigh, LLM, Public contributor, Sydney, Australia;
- Tianjing Li, PhD, University of Colorado, Aurora, US;
- Lawrence Mbuagbaw, PhD, Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Canada;
- Raylynn Benn, BSc, Migrant and Refugee Health Partnership, The Social Policy Group, Canberra, Australia;
- John Norrie, MSc, Edinburgh Clinical Trials Unit, The University of Edinburgh, Edinburgh, Scotland;
- Mayra Ouriques, MIPH, Cancer Institute New South Wales, Sydney, Australia;
- George Papadopolous, MBBS (Hons), Public contributor, Melbourne, Australia;
- Dawn Richards, PhD, Patient and Public Engagement, Clinical Trials Ontario, Toronto, Canada;
- Nandi Siegfried, DPhil, South African Medical Research Council, Cape Town, South Africa;
- Nicola Straiton, PhD, Nursing Research Institute, St Vincent's Health Network Sydney and Australian Catholic University, Sydney, Australia;
- Jvan Yazdani, PhD, Public contributor, Aberdeen, Scotland;
- John Zalcberg, PhD, Department of Medical Oncology, Alfred Health, Cancer Research Program, School of Public Health and Preventive Medicine, Faculty of Medicine, Monash University, Non-executive Board Director, Australian Clinical Trials Alliance.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2024.111366.

References

[1] Bibbins-Domingo K, Helman A, Dzau VJ. The Imperative for Diversity and Inclusion in Clinical Trials and Health Research Participation. JAMA 2022;327(23):2283−4.

[2] Witham MD, Anderson E, Carroll C, Dark PM, Down K, Hall AS, et al. Developing a roadmap to improve trial delivery for underserved groups: results from a UK multi-stakeholder process. Trials 2020;21(1):694.

[3] Magavern EF, Gurdasani D, Ng FL, Lee SSJ. Health equality, race and pharmacogenomics. Br J Clin Pharmacol 2022;88(1):27−33.

[4] Abubakar I, Aldridge RW, Devakumar D, Orcutt M, Burns R, Barreto ML, et al. The UCL−Lancet Commission on Migration and Health: the health of a world on the move. Lancet 2018; 392(10164):2606−54.

[5] Peck RN, Smart LR, Beier R, Liwa AC, Grosskurth H, Fitzgerald DW, et al. Difference in blood pressure response to ACE-Inhibitor monotherapy between black and white adults with

arterial hypertension: a meta-analysis of 13 clinical trials. BMC Nephrol 2013;14:201.
[6] Muir AJ, Hu KQ, Gordon S, Koury K, Boparai N, Noviello S, et al. Hepatitis C treatment among racial and ethnic groups in the IDEAL trial. J Viral Hepat 2011;18(4):e134−43.
[7] Manly JJ, Deters KD. Donanemab for Alzheimer Disease—Who Benefits and Who Is Harmed? JAMA 2023;330(6):510−1.
[8] Low LF, Barcenilla-Wong AL, Brijnath B. Including ethnic and cultural diversity in dementia research. Med J Aust 2019;211(8):345−346.e1.
[9] Seidler AL, Willson ML, Aberoumand M, Williams JG, Hunter KE, Barba A, et al. The changing landscape of clinical trials in Australia. Med J Aust 2023;219(5):192−6.
[10] Smith A, Agar M, Delaney G, Descallar J, Dobell-Brown K, Grand M, et al. Lower trial participation by culturally and linguistically diverse (CALD) cancer patients is largely due to language barriers. Asia Pac J Clin Oncol 2018;14(1):52−60.
[11] Stanaway F, Cumming RG, Blyth F. Exclusions from clinical trials in Australia based on proficiency in English. Med J Aust 2017;207(1):36.
[12] Pal A, Smith B, Allan C, Karikios D, Boyle F. Improving Access to Cancer Clinical Trials for Patients From Culturally and Linguistically Diverse Backgrounds in Australia: A Survey of Clinical and Research Professionals. JCO Oncol Pract 2023;19(11):1039−47.
[13] Harrison R, Walton M, Chitkara U, Manias E, Chauhan A, Latanik M, et al. Beyond translation: Engaging with culturally and linguistically diverse consumers. Health Expect 2020;23(1):159−68.
[14] National Academies of Sciences E, Medicine. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press; 2022.
[15] Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It. Washington DC: The White House; 2022: [press release].
[16] National Institutes of Health (NIH). Inclusion of Women and Minorities as Participants in Research Involving Human Subjects. In: NIH Policy and Compliance. Bethseda, MD: NIH; 2022.
[17] National Institute for Health and Care Research. Improving inclusion of under-served groups in clinical research: Guidance from the NIHR-INCLUDE project. London: NIHR; 2020.
[18] The Australian Medical Research Future Fund. Australian Medical Research and Innovation Strategy 2021-2026. Canberra: Department of Health and Aged Care, Australian Government; 2021.
[19] US Food and Drug Administration (FDA). Diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials; draft guidance for industry. Rockville, MD: FDA; 2022.
[20] Kozlov M. FDA to require diversity plan for clinical trials. Nature News. https://doi.org/10.1038/d41586-023-00469-4. Accessed February 16, 2023.
[21] Bonevski B, Randell M, Paul C, Chapman K, Twyman L, Bryant J, et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. BMC Med Res Methodol 2014;14(1):42.
[22] Bierer BE, White SA, Meloney L, Ahmed H, Strauss D, Clark L. Achieving diversity, inclusion, and equity in clinical research. Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)[Google Scholar]; 2020.
[23] Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, et al. Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. Curr Probl Cardiol 2019;44(5):148−72.
[24] Masood Y, Bower P, Waheed MW, Brown G, Waheed W. Synthesis of researcher reported strategies to recruit adults of ethnic minorities to clinical trials in the United Kingdom: A systematic review. Contemp Clin Trials 2019;78:1−10.
[25] Poongothai S, Anjana RM, Aarthy R, Unnikrishnan R, Narayan KMV, Ali MK, et al. Strategies for participant retention in long term clinical trials: A participant -centric approaches. Perspect Clin Res 2023;14(1):3−9.
[26] Dawson S, Banister K, Biggs K, Cotton S, Devane D, Gardner H, et al. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice. Trials 2022;23(1):672.
[27] RECONSIDER − Reporting extension of CONSORT and SPIRIT for Inclusion, Diversity, Ethnicity and Race. 2022. Available at: https://www.equator-network.org/library/reporting-guidelines-under-development/reporting-guidelines-under-development-for-clinical-trials/#RECONSIDER. Accessed August 16, 2023.
[28] Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med 2010;7(2):e1000217.
[29] Guba EG, Lincoln YS. Competing paradigms in qualitative research. Handbook Qual Res 1994;2(163-194):105.
[30] Angen MJ. Evaluating interpretive inquiry: reviewing the validity debate and opening the dialogue. Qual Health Res 2000;10(3):378−95.
[31] Flanagin A, Frey T, Christiansen SL, AMA Manual of Style Committee. Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals. JAMA 2021;326(7):621−7.
[32] Psillos S. Choosing the realist framework. Synthese 2011;180(2):301−16.
[33] Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology 2006;3(2):77−101.
[34] Saldaña J. The coding manual for qualitative researchers. London: SAGE Publications; 2021.
[35] Garza MA, Quinn SC, Li Y, Assini-Meytin L, Casper ET, Fryer CS, et al. The influence of race and ethnicity on becoming a human subject: Factors associated with participation in research. Contemp Clin Trials Commun 2017;7:57−63.
[36] Nicholson LM, Schwirian PM, Groner JA. Recruitment and retention strategies in clinical studies with low-income and minority populations: progress from 2004−2014. Contemp Clin Trials 2015;45:34−40.
[37] Carroll JK, Yancey AK, Spring B, Figueroa-Moseley C, Mohr DC, Mustian KM, et al. What are successful recruitment and retention strategies for underserved populations? Examining physical activity interventions in primary care and community settings. Transl Behav Med 2011;1(2):234−51.
[38] Ibrahim S, Sidani S. Strategies to recruit minority persons: a systematic review. J Immigr Minor Health 2014;16(5):882−8.
[39] Heller C, Balls-Berry JE, Nery JD, Erwin PJ, Littleton D, Kim M, et al. Strategies addressing barriers to clinical trial enrollment of underrepresented populations: a systematic review. Contemp Clin Trials 2014;39(2):169−82.
[40] Haughton CF, Silfee VJ, Wang ML, Lopez-Cepero AC, Estabrook DP, Frisard C, et al. Racial/ethnic representation in lifestyle weight loss intervention studies in the United States: a systematic review. Prev Med Rep 2018;9:131−7.
[41] Chen C, Lee P-I, Pain KJ, Delgado D, Cole CL, Campion TR Jr. Replacing paper informed consent with electronic informed consent for research in academic medical centers: a scoping review. AMIA Jt Summits Transl Sci Proc 2020;2020:80−8.
[42] Teare HJA, Prictor M, Kaye J. Reflections on dynamic consent in biomedical research: the story so far. Eur J Hum Genet 2021;29(4):649−56.
[43] Simonds VW, Garroutte EM, Buchwald D. Health Literacy and Informed Consent Materials: Designed for Documentation, Not Comprehension of Health Research. J Health Commun 2017;22(8):682−91.
[44] Embedding Health Literacy in Clinical Trials to Improve Recruitment and Retention. In: French MG, Wojtowicz A, editors. Health Literacy in Clinical Research: Practice and Impact: Proceedings of

a Workshop. Washington DC: National Academies of Sciences, Engineering, and Medicine; 2020.

[45] Glover M, Kira A, Johnston V, Walker N, Thomas D, Chang AB, et al. A systematic review of barriers and facilitators to participation in randomized controlled trials by Indigenous people from New Zealand, Australia, Canada and the United States. Glob Health Promot 2015;22(1):21−31.

[46] Botfield JR, Newman CE, Zwi AB. Drawing them in: Professional perspectives on the complexities of engaging 'culturally diverse'young people with sexual and reproductive health promotion and care in Sydney, Australia. Cult Health Sex 2017;19(4):438−52.

[47] Dean J, Wollin J, Stewart D, Debattista J, Mitchell M. Hidden yet visible: methodological challenges researching sexual health in Sudanese refugee communities. Cult Health Sex 2012;14(8): 911−24.

[48] Ferguson E, Dawe-Lane E, Khan Z, Reynolds C, Davison K, Edge D, et al. Trust and distrust: Identifying recruitment targets for ethnic minority blood donors. Transfus Med 2022;32(4):276−87.

[49] Borrell LN, Elhawary JR, Fuentes-Afflick E, Witonsky J, Bhakta N, Wu AHB, et al. Race and genetic ancestry in medicine—a time for reckoning with racism. N Engl J Med 2021;384:474−80.