

ORIGINAL RESEARCH

# Sometimes different, often the same: guidance on how recruitment and retention in trials need to be tailored to enhance participation of ethnic minority groups: a qualitative interview study in England

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Accepted 25 September 2025; Published online 30 September 2025

## Abstract

**Objectives:** Ethnic minority groups are consistently underrepresented in trials, limiting the generalizability and equity of research outcomes. This study explored the acceptability of existing recruitment and retention interventions for individuals from ethnic minority backgrounds.

**Study Design and Setting:** We conducted semi-structured interviews with 20 adults from ethnic minority groups identified as “non-White British” in England. We used maximum variation purposive sampling to ensure diversity in age, gender, ethnicity, urban/rural residence, and religious background. Data were analyzed thematically using an inductive and deductive approach.

**Results:** Twenty adults (aged 20–70; 60% female) took part in the interviews. Findings were categorized into two main areas: themes specific to ethnic minority groups and themes related to recruitment and retention interventions. Cultural and linguistic considerations were considered critical for effective recruitment and retention. Opinions were mixed on the involvement of family members in decision-making about trial participation. Building trust within ethnic minority groups was deemed essential for encouraging participation. Participants highlighted the need for transparent communication when collecting and using ethnicity data and expressed concerns about potential tokenism. All participants emphasized the importance of providing clear information to support informed decision-making. Most participants preferred receiving invitation letters from their general practitioners (GPs), viewing them as more trustworthy, while some favored emails, as they were more likely to read them. Participants preferred a layered information approach that was concise but prioritized content on risks, benefits, and trial relevance. Higher financial incentives were sometimes perceived as indicators of increased trial risk.

**Funding:** This work was funded by the Chief Scientist Office, Scottish Government Health Directorates, grant number HIPS/21/02. KK is supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration East Midlands (ARC EM) and the NIHR Leicester Biomedical Research Center (BRC). SD is supported by the National Institute for Health and Care Research (NIHR) Sheffield Biomedical Research Center. PB is supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration Greater Manchester (ARC GM). MDW is supported by the NIHR Newcastle Biomedical

Research Center, the NIHR Newcastle Clinical Research Facility and the Multiple Long-term Conditions cross-NIHR Collaboration (MLTC CNC).

**Disclaimer:** The content is solely the responsibility of the authors and does not necessarily reflect the views of the Chief Scientist Office or the National Institute for Health and Care Research.

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**Conclusion:** Recruitment and retention strategies must be tailored and co-designed to reflect the needs and preferences of ethnic minority groups. Clear, culturally sensitive, and transparent communication about trial aims, risks, and benefits is essential for building trust and enhancing informed decision-making for participation. Inclusive practices are vital for improving equitable representation in research. © 2025 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

**Keywords:** Ethnic diversity; Inclusion; Equity; Trials; Recruitment; Retention

### Plain Language Summary

We spoke with 20 adults from a range of ethnic backgrounds across England. Participants emphasized that clear, honest communication and respect for different cultures and languages are essential. Many preferred receiving information from their general practitioner (GP) due to existing relationship, as it felt more trustworthy than unsolicited text messages or emails from an unknown source. Some preferred emails over letters. People wanted simple, easy-to-read summaries about the study's purpose, the risks and benefits, and the reason for collecting information on their ethnicity. Some were concerned that offering higher financial payment made the research seem more riskier. Overall, we found that people conducting trials should take the time in building trust, communicating clearly, and considering cultural needs. This can help make research more inclusive and ensure fair representation of people from all backgrounds.

## 1. Introduction

Well-designed randomized trials are keys to improving global health. However, the benefits of these trials are not equally shared. Ethnic minority groups are often underserved and excluded, directly or indirectly, from trials. This exclusion limits the generalizability of findings and perpetuates health inequities. For example, a study of 407 UK National Institute for Health and Care Research (NIHR)-funded randomized trials between 2016 and 2021 found that ethnicity was recorded in only 67% and reported in 63% of the studies and only 9% transparently documented how it was both recorded and reported [1]. A previous Cochrane review explored the effectiveness of recruitment strategies of study participants [2] but did not report on the effectiveness of strategies for different participant groups. Much of the existing literature has focused on barriers and enablers/strategies to overcome these barriers; there is limited evidence on strategies to effectively recruit and retain ethnic minority groups. The Trial Forge 3 guidance, co-produced with input from UK trialists and ethnic minority community partners, offers four key recommendations to improve the inclusion and retention of ethnic minority groups to clinical trials: 1) eligibility criteria and recruitment pathway do not limit participation; 2) develop trial materials with inclusion in mind; 3) ensure staff are culturally competent, and 4) build trusting relationships with community organizations that work with ethnic minority groups [3]. There is a global movement among regulators to improve research inclusivity [4–6].

To address this knowledge gap, we present the Supporting Recruitment and retention Improvement for Diverse Ethnicities (STRIDE) project's [7] interview findings that

explored the acceptability of existing recruitment and retention interventions by people from ethnic minority backgrounds. This study is reported in line with the CONSolidated criteria for REporting Qualitative research (COREQ) [8].

The work is part of the Trial Forge initiative to improve trial efficiency (<https://www.trialforge.org/>).

## 2. Methods

### 2.1. Study design and setting

Data were gathered from UK adult ethnic minority participants. We defined ethnic minority group as “any ethnic group except those who identify as part of the majority population” [9], where the UK majority population is White British [10]. We used a maximum variation purposeful sampling framework (eg, age, gender, ethnicity, location, urban or rural, and faith) to capture diverse perspectives.

We used two recruitment approaches. Our primary recruitment route was to hire a market research company called Roots Research (<https://rootsresearch.co.uk>). They identified potential participants from their UK-wide panel of approximately 350,000 people at the time of recruitment (April–May 2023), with an ethnic profile broadly in line with the UK population (see <https://rootsresearch.co.uk/our-panel/demographics/>). We and Roots Research developed a project screening form, which Roots staff then used on our behalf to identify participants within their pool. Roots then forwarded the email address of people willing to be interviewed on to us, so we are unable to determine how many people declined to participate. In addition, we

**What's new?****Key findings**

- Participants from ethnic minority groups emphasized the importance of culturally sensitive, clear, and transparent communication to support informed decisions about participating in trials.
- Trust in the source of information, clarity on the use of ethnicity data, and preferences for communication formats were key factors influencing research participation and retention.

**What is the implication?**

- These findings highlight the need for trial teams to customize recruitment and retention strategies to the cultural, linguistic, and communication preferences of ethnic minority groups. By doing so, trust can be improved, participation can be increased, and more equitable representation in research can be encouraged.

**What is the implication and what should change now?**

- Trial teams should co-design recruitment and retention strategies with input from ethnic minority communities to ensure that they are culturally appropriate and responsive. This could include building capacity within communities to support data collection, training researchers on cultural sensitivity/humility training and ensuring flexible opportunities for participation.
- Additionally, standard practices should be updated to include personalized, trusted communication (eg, from GPs), layered information formats, and clear explanations about the use of personal and ethnicity data to build trust and support informed participation. In terms of collecting ethnicity data, this should be through participant self-identification. This information should be used to assess representation and inform who is included, and who is missing, from the trial and inform targeted outreach efforts.

group of participants and anticipated interviewing with approximately 20 to 25 people.

Our eligibility criteria were:

1. Aged 18 years or over
2. Able to read and speak English
3. Able to consent to an individual interview
4. Self-identified as a member of the ethnic minority group

The seven interventions were:

5. Using an open trial instead of a blinded trial
6. Telephone reminders for nonresponders of postal invitations
3. Tailoring the participant information leaflet
4. Using text messages to highlight the scarcity of trial places or provide quotes from existing participants
5. Email invitations compared to postal invitations
6. Changing the length and wording of the participant information leaflet
7. Offering financial incentives

We developed a comparable list of four retention interventions based on the Cochrane review of retention interventions [2]:

1. Self-sampling kits that may help to highlight the continued relevance of participation
2. Financial rewards
3. Giving participants a free pen during recruitment
4. Using diaries with usual follow-up

We did not introduce the complete set of recruitment and retention interventions into every interview; rather, they served as a list from which to select based on the direction of the discussion. Single, one-to-one interviews lasting up to 1 hour were conducted by an experienced qualitative researcher, HG (a White British woman) online via Zoom or Teams according to participant preference. Interviews were audio-recorded and transcribed verbatim.

**2.2. Data analysis**

Analysis was based on transcripts only. Transcripts were imported into NVivo, version 14.1 (QSR International), and analyzed thematically using both inductive and deductive approaches [13]. Two transcripts were independently coded (SD and ST) to identify initial patterns and themes. The remaining transcripts were independently coded by SD and BO. Comparisons were made, and differences resolved through consensus or with the involvement of a third researcher (ST), leading to the development of an initial codebook [14]. ST independently verified the coding, and further refinements were made. Once inductively coded, we organized the themes more deductively, partly based on the types of interventions we discussed. Transcripts were neither returned to participants for comment, nor were participants asked to provide feedback on the findings. Their

planned to use our networks to advertise the study if needed. Roots Research was a paid recruitment service. They had no role in data analysis, interpretation, or manuscript drafting.

Research has shown that with relatively consistent participant groups, data saturation can occur within the first 12 interviews [11,12]. As we were unsure about the variety of views we might encounter, we aimed to recruit a diverse

participation was on the basis of taking part in a single interview.

### 3. Results

All 20 interviewees were identified in April and May 2023, and all interviews were done in May 2023. All interviewees were identified by Roots Research (Table 1). Participants' ethnicity data were provided by Roots Research and are used when presenting our results below. Participants were also asked to self-describe their ethnicity during the interviews (Table 2).

We identified themes specific to ethnic minority groups and themes directly linked to the interventions. Our complete coding of quotes is provided in Supplementary File 2.

Themes specifically applicable to people from an ethnic minority group were:

1. Cultural and language factors
2. Family involvement
3. Importance of trust
4. Collecting ethnicity data

There were also four general intervention-level recruitment and retention themes:

5. Type of trial design
6. Mode of information delivery
3. Patient leaflets
4. Financial incentives.

Each of these is presented below, accompanied by illustrative quotes. Additional quotes are included in the [supplementary materials](#).

#### 3.1. Themes applying specifically to people from ethnic minority groups

##### 3.1.1. Cultural and language factors

The need to account for different cultures and languages in trial recruitment and retention approaches was raised, especially in relation to the time spent in the UK.

I think my dad would be a more on board because he's spent more of his life here [in the UK]. My mum is a bit old school (#20, Female, Pakistani).

Some thought that cultural practices, such as relying on homemade remedies to avoid seeking help, would hinder engaging certain ethnic groups with trials.

... it's always been home remedies, herbal remedies, try and stick to natural things to get you better in regards to health... you're then not including people that do take home remedies... it's a cultural thing or a cultural driven thing or not (#10, Male, Arab).

The potential benefits of research and participation are not always clear to some ethnic minority groups. Some

participants highlighted the need to engage with communities about the importance and potential benefits for themselves or the wider community.

...to get them [to] understand that actually if you do this, it's a good thing for future generations, but also for yourself, because the medicines are based on research for only certain demographic and how does that affect you, we don't know... if the community say we should do something, then we'll do it (#8, Female, Indian).

Some participants stated that word of mouth was important for raising awareness about trial participation. eg, people may be more interested if they can relate to the person who approaches them, and the characteristics of the researcher (eg, age, gender) can also be important.

##### 3.1.2. Family involvement

There were mixed responses regarding family or community involvement in the decision to participate. To some extent, this was influenced by either culture or education.

If I think it's beneficial to me, I don't care about the world, because it's me that's doing it, then I'd need to think about it and discuss it with my daughter and then I mean we'll sit and talk about it together (#14, Female, Caribbean).

One participant noted that their family is aware of their participation but is not supportive. They explained how they had to educate their family about how trials can benefit society.

My family know that I participate in the clinical trial, and they just ask me don't participate in clinical trial and I need to explain the reason I participate and how clinical trial can help in society [...] (#5, Male, Chinese).

##### 3.1.3. Importance of trust

Establishing trust with ethnic minority communities is crucial. This, to some extent, is also related to the diversity of the workforce.

...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, I guess (#7, Male, Pakistani).

Some participants reported that they could ask their general practitioner (GP) whether participating is advisable. However, poor care continuity means many are unable to tap into an existing trusted relationship with a health-care professional.

No because I don't really hear from the GP and because you don't have a designated person that

**Table 1.** Participant characteristics

Category	Details	Number of participants (n)
Gender	Female	12
	Male	8
Age	20–30	8
	31–40	4
	41–50	4
	51–60	3
	61–70	1
Marital status	Single	12
	Married	5
	Co-habiting	2
	Divorced	1
Religion	Buddhism	1
	Catholic	2
	Christianity	6
	Hinduism	2
	Islam	3
	Jainism	1
	Sikhism	1
	No religion	3
	Prefer not to say	1
Occupation	Health care/research	5
	Social services	1
	Administration/management	6
	Engineering	1
	Sales/property	2
	Student	1
	Unemployed/retired	4
Area	Suburban	5
	Urban	15
Region	East Midlands	1
	East of England	1
	Greater London	13
	North East and Cumbria	1
	South East	1
	South West	1
	West Midlands	2

you speak to every time, there's not that rapport built up or a level of trust (#20, Female, Pakistani).

### 3.1.4. Collecting ethnicity data

Participants strongly expressed the need for clarity on why ethnicity data are being collected and how they will be used. This was sometimes due to historical mistrust and discrimination, which led to reluctance and suspicion.

... ethnicity data there's pros and cons to it...sometimes you almost want to put that you don't want to declare your ethnicity because you don't know what they're going to do with that information...Is it going to be something that's going to be to your detriment? (#18, Female, African).

Additionally, concerns arose that collecting ethnicity data could be quite tokenistic.

If I'm the only Middle Eastern, whatever the case is, automatically, I'm going to feel some type of a pressure on having to be a certain way or to act accordingly to the people around me of what's expected. (#10, Male, Arab).

## 3.2. General intervention-level recruitment and retention themes

The previous four themes were specific to ethnic minority groups. Recruitment and retention intervention discussions led participants to mention other issues that seemed relevant to any participant, regardless of ethnicity. However, because participants brought them up, this suggested their relevance to people from ethnic minority groups.

### 3.2.1. Type of trial design

A few participants that mentioned trial design deemed it important to have complete information (eg, what participation entailed, risks and benefits, time commitment) to make an informed decision. However, the potential risks to personal health from trial participation were such that none would want to take part. This was especially true for blinded trials because they would not know what treatment they would receive.

... if I would be taking part in a trial, I would want to know what am I signing to. I wouldn't feel comfortable to be honest to be blinded if it's something that can affect my health (#1, Female, Mixed/Multiple ethnic backgrounds).

### 3.2.2. Mode of information delivery

Various options from our exemplar list, such as letters, telephone reminders, and email invitations, were discussed to determine if participants had preferences. Participants expressed a range of views, but none appeared specific to ethnic minority groups.

**3.2.2.1. Telephone reminders and text messages.** There is evidence suggesting that telephone reminders can improve recruitment (increase in recruitment of 6%, 95% confidence



**Table 2.** Roots Research ethnicity categories compared to examples of participants' self-reported ethnicity

Roots provided categories	Self-described	Number of participants
African	Don't even get me started on that ethnicity thing. If I'm going according to that I'm Black African. ie my ethnicity. But in terms of nationality, I've got dual nationality. I'm British and I'm Sierra Leonian. I would describe myself as... sometimes, depending on what the options are, I go for either Black African or Black British, sometimes they don't give you the option to choose what you really want to choose. I identify, personally identify, as Black African.	2
Arab	My background's Middle Eastern, from Yemen to be precise.	1
Caribbean	[...] they [parents] lived in Barbados by this time. [...] They came here in the sixties and then they left [...] I was born here. My parents are Jamaican. I was born in England, so technically I'm British. Even though I'm from there, but I was born here.	2
Chinese	For myself I would say I'm a Hongkongers. I would say Hongkongers just belongs to Hong Kong [...] But if you ask me for my feelings, if you ask me Hongkongers, I would be much happier if you called me Chinese. [...]	1
Indian	I am a British Indian. I was born and raised here, but my Dad is Kenyan, and my Mum is Indian.	6
Pakistani	I'm Pakistani.	3
Mixed White and Black African	My grandma [...] she raised them all in a village back home in Sierra Leone. [...]	1
Other Black/African/Caribbean	I'm from Nigeria but Nigeria, Africa.	1
Other Mixed/Multiple	Yes, if you look at me, I look pretty white but, yes, basically on my dad's side, he's part German and he was part Jewish, On my mother's side, I know there's quite a lot of Bulgarians, White and Black mixed. However, it's more like White Asian and yeah Black African, it's like this mix.	2
Other ethnic group	I'm first-generation immigrant. My family are Greek Cypriot immigrants who came to the UK in the fifties.	1

interval 3% to 9%) [2] However, recruiting via telephone calls was viewed unfavorably.

So many scam calls, scamming calls, and sometimes I don't even pick up anymore (#1, Female, Mixed/Multiple ethnic backgrounds).

That said, some participants were open to their GPs calling to introduce a trial.

...instead of getting a cold call, the GPs are calling people every day literally...I think they can propose that, there's research going on would you like to participate (#7, Male, Pakistani).

**3.2.2.2. Text reminders.** Short messaging service (SMS) reminders are more efficient and cheaper than telephone calls, but it remains unclear if they are better, similar, or worse than telephone reminders for recruiting participants (increase in recruitment around 3%, depending on the message [2]). Some participants were receptive to receiving a text message because it felt more personal than an email.

I think people pay more attention to a text that I suppose to you getting an email and you're assuming it's

just junk (#4, Female, Mixed White and Black African).

*Mentioning the scarcity of trial places in text messages probably increases recruitment.<sup>2</sup> Our participants had mixed views about mentioning scarcity, as some thought it was a scam (also see 3.2.1) and that it sounded "desperate".*

...I don't like that either. I don't know what number I am, what's the point. They only wanted five. This has probably gone out to a hundred people... It does, it seems scammy. It's almost like trying to buy you or draw you in. It's a bit desperate (#20, Female, Pakistani).

Others believed it would attract their attention. However, most felt that text messages containing quotes from existing participants were unlikely to impact participation.

I don't know. For me, it wouldn't, but the thing is I've got so desensitised to these things. I think I'm a bit less naïve than your average user (#9, Male, Any other Mixed/Multiple ethnic background).

**3.2.2.3. Letters and emails.** Participants had a strong preference for receiving trial information via letter or email because it provided more details, allowed them time to digest the information, and helped establish an understanding of expectations. Letters had to be personalized.

I mean if you are invited to research, you want to maybe feel special and not feel like they've sent this to a bunch of people (#1, Female, Any other Mixed/Multiple ethnic background).

A generic or nonspecific letter or email would be viewed as suspicious or concerning. Similarly, from a cultural perspective, there was a preference for receiving letters in a native language (see theme 3.1) as it would make people feel special, cared for, and more secure. There was a strong preference for letters from the GP since they felt more personal, although a few participants preferred emails because they were more likely to open and read them.

### 3.2.3. Patient leaflets

Participants preferred a layered approach to sharing trial materials with information provided in stages, with a clear attempt to present the most important information first. Participants wanted to know what the trial was about, its methods, why they were approached, what would be involved, what to expect, side effects, benefits, duration, and who was involved in developing it.

Usually, I will only have a glance through the description on the drugs, but I will read really carefully on the side effects. I like to see whether I can afford the risk (#5, Male, Chinese).

Presenting prioritized information about risks and side effects, and the trial significance and its results, in a short version of the study information was important.

*Summary could come first, and then the full thing could be at the end (#16, Female, African).*

There is a need to balance the amount of information shared.

If it's too long it, I don't read it, I get bored. So, I think it needs to be punchy and to the point...what are the key messages that you're trying to give to the individual. As long as it's there and the point of contact, that would work for me. If it's lengthy, I just switch off (#2, Female, Indian).

Participants also suggested bite-sized videos and PDFs via email in multiple languages (see theme 3.5), preferably delivered through GPs.

### 3.2.4. Financial incentives

While financial incentives were considered essential, participants generally felt that the higher the incentive, the greater the trial risks must be.

Well technically the main reason why I applied for it because they were offering me like eight grand... Oh, what's the catch? But what have I got to do though?... I think it gets more seedier as well, with more money (#3, Male, Caribbean).

However, being paid for completing and returning trial questionnaires was thought of as a straightforward and uncontroversial payment for the time spent doing so.

That's different. I feel like now you're just paying for my time to get it back. (#6, Female, Any other Black/African/Caribbean background).

## 4. Discussion

This study shows that in important ways, ethnic minority groups are not different from any other trial participants. They want information on what the trial is about, its methods, why they have been approached, who is approaching them, what is involved, what to expect, details about potential benefits and side effects, and why the trial results would be important to them and people with similar characteristics. Participants preferred layered information to balance detail with accessibility, presenting a brief participant information leaflet first, followed by the extended version. This highlights the need for researchers to prioritize clear communication about trial processes and what participation entails to help foster trust. All of this concurs with previous literature for general trial populations [15–17].

However, we observed some differences. Participants emphasized the need for recruitment strategies to be culturally sensitive, including a preference for using native languages, which underscores the necessity for explicitly inclusive approaches. The demand for multilingual materials and study staff from underserved groups has been widely recognised [18], including ethnicity matching between staff and participants [19].

Traditional approaches, such as letters, require customization, but participants prefer direct communication from health-care professionals. Health-care professionals, especially GPs, can leverage established relationships to improve recruitment for trials; however, increasingly poor care continuity and decreasing public satisfaction with general practice [20] mean a pre-existing trusted relationship cannot be assumed and that their leverage may be under threat.

There was uncertainty surrounding telephone outreach as many were wary of "cold calls". The wariness regarding unsolicited calls raises doubts about the applicability of evidence from 10 to 15 years ago [2] to current trials, particularly for ethnic minority participants. It emphasizes the limited shelf-life of evidence, as telephone communication is now likely viewed as spam.

The perception of financial incentives varied between recruitment and retention. Payment for completing a

questionnaire was uncontroversial: it simply acknowledged the time spent. However, for recruitment, the size of the payment was directly linked to perceived risk, which, to our best knowledge, is not discussed in the wider literature. A common concern is that financial incentives may reduce participants' risk perception [21–23]. However, for our participants, a large financial incentive had the opposite effect. Another issue is that incentives may disproportionately attract low-income individuals, creating an unfair system where the burden of research falls on them while everyone shares the benefits [24,25].

Participants also emphasized the need for culturally sensitive recruitment strategies. This included a preference for communication in native languages, underscoring the need for incorporating inclusive approaches to encourage greater engagement. Addressing cultural considerations supports recruitment and upholds the ethical and moral responsibility to include diverse populations in clinical research. The need for multilingual materials and recruiting study staff from underserved groups and training staff on cultural sensitivity/humility has been widely recognised [18], including matching staff team members and participants on ethnicity [19].

Participants expressed concerns about how ethnicity data are collected. The ethnicity categories commonly used in the UK, such as those from the Office for National Statistics, are arbitrary and selected for pragmatic reasons. Self-describing allows participants to provide detailed, contextual, and nuanced descriptions that predefined categories fail to capture [26,27]. There are clear distinctions between categorical ethnicity data and how some individuals would self-describe (Table 2).

#### 4.1. Limitations

Funding and time constraints meant we could not undertake further interviews or include individuals with limited or no English proficiency. We recognize that there may be a difference between ethnic minority individuals who are proficient English speakers and those who are not. Future research should include non-English speaking participants. We did not apply specific targets for the recruitment of different ethnic groups or consider intersectionality (eg, age, gender, and socioeconomic status). As a result, some groups (eg, South Asians) are more represented than others, which limits subgroup interpretation.

## 5. Conclusions

Potential ethnic minority trial participants require recruitment and retention approaches tailored to their information needs and preferences, particularly regarding cultural factors. However, many suggestions are not distinct from the needs of other groups. Our key message is that

approaches must be customized for those intended to be recruited and retained, which includes, but is not limited to, ethnic minority groups.

## Ethical approval

Ethical approval was obtained from the University of Aberdeen (SERB Reference: 665,617). All participants provided written consent and received £40.

## CRediT authorship contribution statement

**Shoba Dawson:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Bārbala Ostrovska:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Shaun Treweek:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Katie Gillies:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Miles Witham:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Declan Devane:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Kamlesh Khunti:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Peter Bower:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Adwoa Parker:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Irene Soulsby:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Heidi Green:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Data curation, Conceptualization.

## Declaration of competing interest

H.G. reports a relationship with Freelance that includes: consulting or advisory. S.T. reports a relationship with the National Institute for Health and Care Research (NIHR), the Oxford Health Biomedical Research Center, and the NIHR Cambridge Biomedical Research Center that includes: consulting or advisory. S.D. reports a relationship with Global Diversity, Equity and Inclusion in Clinical Trials Advisory Board for Boehringer and Ingelheim that includes: board membership and consulting or advisory. K. K. reports a relationship with Director for Center for Ethnic Health Research, University of Leicester; and he was Chair



of the ONS Ethnicity Coding Group and is Co-Chair of the UK Health Data Research Alliance Ethnicity Coding Working Group that includes: employment. There are no competing interests for any other author.

## Acknowledgments

We would like to thank all 20 members of the public who kindly took part in this study.

## Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2025.112005>.

## Data availability

Data will be made available on request.

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