

Which ethnic groups should be in the trial and at what proportion?

Which ethnic groups should be in the trial?
V1 13/3/2023 Trial Forge

Trial: LONG LIMB

Type 2 diabetes and obesity

LONG LIMB (type 2 diabetes and obesity) <https://www.isrctn.com/ISRCTN15283219>;
<https://www.journalslibrary.nihr.ac.uk/eme/eme08030#/abstract>

The panel noted:

- Early stage trials should also consider the ethnic groups needed for the trial to be as informative as it can be.
- The trial should aim to include those most at risk of type 2 diabetes and obesity. The trial population should reflect the ethnic diversity of those who are most at risk of type 2 diabetes and obesity. This would certainly **include South Asian and Black individuals**.

The panel concluded:

- The panel did not reach a conclusion with regard to particular percentages for different ethnic groups.

Where a panel cannot reach a conclusion, STRIDE suggests adopting the following default inclusion position:

- The minimum target for **inclusion of the specified ethnic groups should be at the same proportion as is found among the population of people with the condition targeted by the trial**. The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should aim for national ethnic proportions by disease. A trial with more local reach could aim for proportions in its local area.

Where **disease data by ethnicity do not exist, or cannot be obtained**, STRIDE suggests adopting the following default inclusion position:

- The minimum target for **inclusion of the specified ethnic groups should be at the same proportion as is found in the most recent census data**. The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should use national census data. A trial with more local reach could aim for census proportions in its local area.



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General comments from the panel:

1. The extent to which being overweight is considered a problem varies by ethnic group. Trial teams working on obesity trials need to be aware of this difference, especially if groups that often do not consider being large to be a problem are those who are objectively at highest risk of poor health.
2. The same is true of surgery as a weight-reduction option: how acceptable it is may vary by ethnicity.
3. Obesity has a stigma among some ethnic groups and trial teams need to be aware of this when designing and running their trial.
4. Trials dealing with weight management need to be aware of wider social movement around weight and body size. For example a movement called 'health at every size' (HAES), is gaining support particularly with younger/more left-leaning people, including people from ethnic minority backgrounds.
5. Movements such as HAES mean that stigma is not only in one direction– there's also some stigma in trying to lose weight as it's seen to be conforming to patriarchal views. Young women in particular are now focusing on weight inclusivity and other measures of health (respectful care, eating for well-being, life-enhancing movement etc) and getting away from 'pathologising specific weights'. If weight loss is the goal for a trial then there will likely be some push back with groups looking into and following this and similar models.
6. The term 'person living with obesity' was considered better than calling someone obese. Language around weight and body size and shape is complex. A different group of panel members may have preferred different terms. The key message for trial teams is that they need to be sure that the language they use in the discussions with potential and actual trial participants is alive to these sensitivities.
7. Younger people of all ethnicities, especially those under 18, are often excluded from diabetes trials. Whether exclusion is appropriate should be carefully considered by the trial team.

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General comments from the panel:

8. The panel recognised that interventions targeting people under the age of 18 may need to be different to those targeting older people and a single trial of both would therefore be inappropriate. Nevertheless, there was a belief that exclusion was often more related to a perceived difficulty with consent or ethical procedures rather than whether the intervention could benefit younger people.
9. The trial team would need to carefully consider the language support that may be needed to ensure that members of the ethnic groups important to the trial can actually participate. This requires consideration of both written translation and interpretation.

NB. Completed by Shaun Treweek, University of Aberdeen, based on a discussion with an external panel brought together for this purpose as part of the STRIDE project (<https://www.abdn.ac.uk/hsru/what-we-do/research/projects/stride-supporting-recruitment-and-retention-improvements-for-diverse-ethnicities-283>). None of us was involved in this trial, we did not discuss the information below with the trial team.

Given the above, the information below may not be a proper reflection of what the trial team itself may have considered the ethnic groups needed by their trial. The information is therefore intended to be illustrative, not definitive.