

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

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V1 13/3/2023 Trial Forge

Trial: TOPSAT2

Haemorrhage

TOPSAT2 (haemorrhage) <https://www.isrctn.com/ISRCTN15960635>; <https://doi.org/10.3310/eme08080>

The panel concluded:

- The minimum target for diverse ethnic involvement should be that the trial **involves different ethnic groups at the proportions found in the most recent census data for the geographical areas where recruitment is being done.**
- Decisions around the ethnic groups to include **need epidemiological data** and that these data should be as local to a recruitment site as they can be. Context is important.
- The Panel introduced the idea of including **stratification by ethnicity** into the randomisation system to ensure that equal numbers of particular ethnic groups were allocated to intervention and comparison groups. This is especially important because the number of individuals from some groups is likely to be small.

General comments from the panel:

1. The data available to inform decisions is often not sufficiently detailed enough to give this sort of information. Issues around the data collection and coding of the data are important if research and health systems are to be improved with regard to the care given to ethnic minority individuals.
2. Data for the type of stroke is important because, for example, haemorrhagic stroke is more common in Black people and Chinese people. This sort of information should directly inform who is in the trial.

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.