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

OUTREACH (hypertension) https://www.isrctn.com/ISRCTN15911100

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.

General comments from the panel:

1. Black individuals were highlighted as being least likely to have treatment and don't engage the same extent with medication. Members of the panel had seen Black individuals who have hypertension that is extremely worrying but they themselves are unconcerned, they don't have symptoms as such and therefore do not see the need to treatment. Some of this could be linked to religious beliefs. Ignoring faith when trying to involve Black individuals would be a mistake, not only for this type of trial.

General comments from the panel:

2. It would be worth considering stratification by faith/belief as well as ethnicity.
3. Household structure may have a role with regard to the support people from some ethnic groups may have. Multigenerational households may provide more social support, something more likely to happen in South Asian cultures. This may mean that some ethnic groups are more likely to have a carer.
4. The influence of generations within a house will affect the decisions of other generations within the same house (four example the older generation may influence the younger). Those same younger individuals may take a different decision if they were living in their own house, away from the older generation (and vice versa).
5. Trial teams need to explicitly think about what other treatments a person may be taking. Some ethnic groups may supplement health service treatment with other forms of treatment, which may or may not be useful (or harmful). This points to an assessment of outcome by ethnicity and monitoring what additional treatments participants are taking.
6. The Panel wondered whether part of the trial design process should ask an open question of individuals along the lines of what would you do if your hypertension was not as it should be? What strategies would help you? How would these fit with your health belief systems? The answers may help to tailor both interventions design and delivery, and information provision.

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.