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

WHELD (psychosis and dementia) https://www.isrctn.com/ISRCTN62237498; https://doi.org/10.3310/pgfar08060

The panel noted:

• The trial should set a minimum level for ethnic groups and then look to see where these people are living across the country (i.e. it should drive the selection of recruitment sites).

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

General comments from the panel:

1. The trial is based in care homes and the Panel was unsure as to how well the care home setting looked like the population at large with regard to ethnicity (opinion was divided). Regardless, the starting point for any trial team would be to consider whether the setting for their trial is the right setting with regard to the ethnicity of those who have the clinical problem targeted by the trial.

2. The Panel discussed a layering of questions that a trial team would need to ask. This would start with something like who are the people with dementia? Followed by and of these which people are in care homes? And of these what proportion are overmedicated? All questions would need to include consideration of ethnicity.

3. It is likely that the ethnic diversity of care homes will vary across the country and this should directly inform decisions about where to place recruitment sites.

4. The trial is about over-treatment but for ethnic minority individuals the Panel wondered whether the problem was more likely to be under-treatment.

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.