

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: WILL

Early-term delivery

WILL (early-term delivery) <https://www.isrctn.com/ISRCTN77258279>;
<https://fundingawards.nihr.ac.uk/award/16/167/123>

The panel noted:

- The panel noted the increased levels of hypertension (and uncontrolled hypertension) in non-Hispanic Black women, suggesting these women as an important group for the trial. It was also noted that there are other groups with increased hypertension perhaps not linked to ethnicity, but e.g. socio-economic status. The ethnic background of many of these individuals may well be white. Age was also mentioned. In other words intersectionality was mentioned.
- The panel also noted the difficulty regarding using diagnostic information. Historically white women have been more diagnosed as having endometriosis than other ethnic groups. This means the background rate data are likely to under-represent endometriosis among other ethnic groups. There was general agreement that this is a clear problem for trialists attempting to design a trial that represents the ethnic groups most affected.
- The Panel thought over-sampling of some ethnic groups would be likely to be helpful.
- In summary, the trial should target ethnicities at high risk, in particular Black women.

The panel concluded:

- The Panel struggled to reach a firm conclusion around the ethnic groups involved and at what proportion but tended towards the trial **involving different ethnic groups at the proportions found in the most recent census data for the geographical areas where recruitment is being done.**



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General comments from the panel:

1. The panel discussed how people from some ethnic groups access care later, which leads to a greater chance of problems. This was particularly true for ethnic minority groups. How to interact with women in a culturally competent way, and overcoming system and structural problems (and language potentially) are challenges that trial teams need to consider explicitly during design and conduct.
2. Engagement with the health care system, including maternity care, depends on how the service engages with you. In other words 'How seen 'and how validated (i.e. that your perspective is listened to and considered important) you feel after interactions. If the feeling you are left with is that you are neither seen nor validated, you are less likely to continue engaging.
3. The panel discussed how people from some ethnic groups access care later, which leads to a greater chance of problems. This was particularly true for ethnic minority groups. How to interact with women in a culturally competent way, and overcoming system and structural problems (and language potentially) are challenges that trial teams need to consider explicitly during design and conduct.
4. The panel though over-sampling would be sensible to increase the amount of data available on historically under-served ethnic groups and which would increase the certainty of what could be said from the data collected for those groups.
5. Moreover, this should be linked to eligibility criteria and perhaps an extra table in trial reports highlighting numbers of individuals from particular ethnic groups linked to eligibility (and need).
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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>). One member of the panel was involved in the WILL trial, which means this discussion is likely to be a good reflection of what the trial team itself may have considered the ethnic groups needed by their trial.