

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: PRODIGY

Young people with emerging
severe mental illness

PRODIGY (young people with emerging severe mental illness)

<https://www.isrctn.com/ISRCTN47998710>; <https://doi.org/10.3310/hta25700>

The panel noted:

- Broad inclusion of ethnic groups across the trial population because all ethnic groups are susceptible to mental illness.
- The poor availability of data to inform decisions about who should be in the trial was noted. There was doubt as to whether a single intervention that was acceptable to all ethnic groups was possible.

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 framing of this trial suggested a particular view of what was a useful way of spending time and that this is likely a majority white view and potentially middle-class too. For example the outcome of the trial is linked to what the team calls structured activity, which includes economic activity (i.e. working), school and social activities such as going to the cinema. It is far from clear that all ethnic groups share the same views of what those structured activities should be especially the non-work activities.
2. Socio-economic status is important for this trial and is intertwined with ethnicity in that some ethnic groups are more likely to be socio-economically disadvantaged than others.
3. Irrespective of what people might want to do (i.e. if helped by the intervention) their ability to do the sorts of activities, particularly social ones suggested by the trial team, may be limited by lack of money. This makes it less likely that some ethnic groups (and more socio-economically disadvantaged people within all ethnic groups) will be less able to take part.
4. It would have been better for the program itself to provide the activities free of charge. Depending on where activities take place, there is a risk that a person's mental illness may be made more visible in the local community. The stigma of mental illness (common across all ethnic groups) and the risk of being identified as a person with mental illness may be enough to prevent participation.
5. Intersectionality is important.
6. The main trial outcome was considered a potential problem. There may be a clinical recovery and social recovery that form part of the outcome, and there is judgement required as to what constitutes recovery. The outcome chosen is a value laden judgement.

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.