

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: REMEDY Sexual dysfunction in people with psychosis

REMEDY (sexual dysfunction in people with psychosis) <https://www.isrctn.com/ISRCTN15969819> ;
<https://www.journalslibrary.nihr.ac.uk/hta/hta24440/#/abstract>

The panel noted:

- The trial should set a minimum level for ethnic groups based on who takes these drugs and the likelihood of sexual dysfunction 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.



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General comments from the panel:

1. The trial would need to ask a set of layered questions about who are the people who have sexual dysfunction after taking these drugs and what is their ethnicity? Gender is likely to be important too.
2. Trial teams need to be cautious about assuming that sensitivity around the trial topic maps onto ethnicity in the way they think unless they have spoken to people from those ethnic groups as part of trial design and their assumptions confirmed.
3. Trials teams may need to consider whether separate trials that involve different interventions tailored to particular ethnic groups might be necessary. This may be a general consideration where the trial is tackling something very sensitive and cultural values may play a strong role. These challenges need to be tackled though, otherwise little will change.
4. Language is a particularly important consideration for a trial dealing with a sensitive topic, it needs to be exactly right. Funders need to be willing to pay for language support, including interpretation where needed.
5. The Panel talked around how the proportion of individuals from particular ethnic groups might be increased and noted work from health economists that can be summarised as which participant will add most value to the study?
6. If the study has already a large number of individuals from one ethnic group then adding one more is of less value to the study's ability to generate information than to add an individual from a different ethnic group. This might be a consideration that all trials, not just this one, could consider.

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/huru/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.