SWAT 9: Pre-randomisation matching of sites in a cluster randomised trial

Objective of this SWAT
To determine if variables used for matching or stratification before randomisation in a cluster randomised trial remain similar through the duration of the trial.

Study area: Randomisation.
Sample type: Sites in a cluster randomised trial.
Estimated funding level needed: Medium (depending on the resources needed to do repeated measurement during the trial of the factors that were used to match the sites pre-randomisation).

Background
One challenge in cluster randomised trials is that baseline imbalances between what might be a small number of clusters in the trial can lead to differences between the outcomes that would have happened regardless of the allocated intervention. In some studies, efforts might be made to minimise the impact of this by matching sites before randomisation, in the hope that any differences that emerge in the outcomes in the sites is due to the intervention being assessed. For example, in a matched-pair design, similar sites might be paired in a 2-group trial, with one being randomised to receive the intervention and the other allocated the alternative. This matching might be done on pre-existing characteristics of the sites such as likely case-mix, size or volume of activity, or demographics. This SWAT will examine whether the matching holds true throughout the trial, or whether it breaks down leading to problems with the interpretation of the analyses.

Comparison
Matching between “similar” sites before randomisation versus matching after randomisation (possibly at multiple time points in the trial) for sites that were similar before randomisation.

Index Type: Method of Randomisation

Method for allocating to intervention or comparator
Before and after study.

Outcome measures
Primary outcomes: Similarity of the matched sites on the balancing variables before and after randomisation.
Secondary outcomes: Whether the pre-randomisation matching of sites would have been different if post-randomisation data had been used instead of pre-randomisation data.

Analysis plans
The matching between sites based on their pre- and post-randomisation characteristics would be compared. The statistical analysis used for this would depend on the method used for matching. If possible, and relevant in the context of the trial, analyses would be done for three after-randomisation periods at least: (1) while the trial is recruiting; (2) while the intervention is being delivered (if this continues for a long enough period after recruitment); and (3) when the final outcomes are measured (if this is long enough after the end of the recruitment and intervention periods). Potential changes in the matching would be determined by re-matching the sites at each time point for which the characteristics are measured (ideally blind to matching at any other time points, including pre-randomisation), and reporting on the number and extent of any changes to the matching.

Possible problems in implementing this SWAT
If the trial interventions have an effect on the characteristics used for matching this will introduce confounding to the pre- and post-randomisation comparison, which might bias these comparisons. Ideally, the characteristics used in the matching should not be variables that might be affected by the interventions being studied in the trial.

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