

Motivations behind randomisation method selection and the criteria that should be used to evaluate methods

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Background

Randomised Controlled Trials (RCTs) are considered the gold standard when evaluating interventions.

Many methods to allocate participants exist, but the literature shows differing opinions on the validity and performance of the different methods

Results

We conducted 4 focus groups including 25 participants from 18 institutions across the country.

The main themes of the discussion were: Current method selection, method opinions, method features and method measures.

Methods

We recruited researchers from three different backgrounds, Statisticians, IT/programmers and other clinical trials staff.

Focus groups were held on Teams. Recordings of the focus groups were transcribed and a thematic analysis was used to analyse the key themes of the groups.

Conclusions/Discussion

There is a wide variation in current practice in CTUs. Many participants believed that a method should be selected based on the design of the study, although currently this is not consistently happening in practice.

Current method selection

- Institutional standard
- Dependent on study design – Sample size / number of centres / number of variables balanced on

Method opinions

- A few favoured simple
- Most favoured either block stratified or minimised randomisation.

Method features

- Most important are balance vs predictability
- In most cases, which one is considered most important is dependent on study features

Measures of method features

- Balance can be easily monitored
- More work is needed to define and measure predictability

