Predictability and Subversion in Randomised Controlled trials

Cydney L Bruce[1], Antony Ndungu[1], Reuben Ogollah[1], Christopher Partlett[1], Alan Montgomery[1]

1. Nottingham Clinical Trials Unit, University of Nottingham

Background

Subversion occurs when researchers deliberately or unconsciously alter recruitment based on knowledge of upcoming allocations.

A trial that has been subverted has a greater risk of selection bias which could invalidate the trial results.

Allocation concealment is used to guard against this, however a sequence that is too predictable may still be at risk.

From focus groups, (P-525, researchers felt that subversion was a more historical problem, however there is limited evidence to support this.

Aims

This project aims to explore the behaviour of recruiters to randomised controlled trials and to ascertain the extent to which trialists should be concerned by the predictability of a randomisation sequence.

It will also attempt to identify prediction strategies employed by recruiters to guess the next allocation of a randomised sequence.

Methods

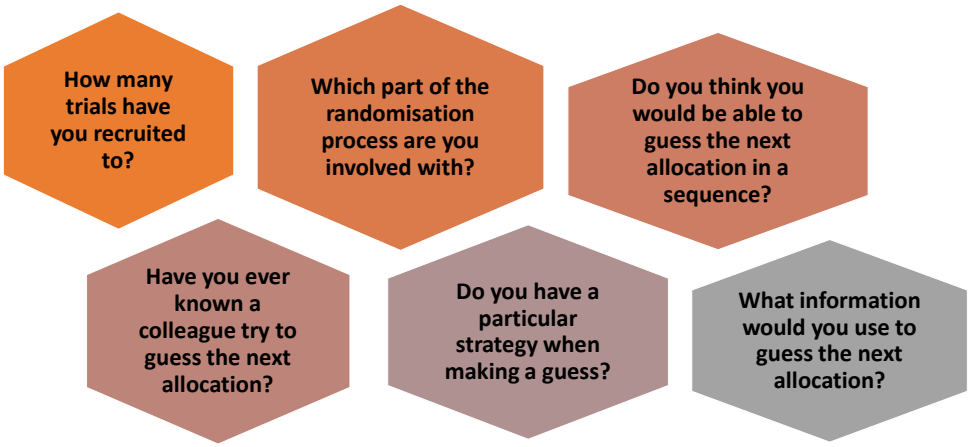
The survey was designed in Microsoft teams and distributed through hospital R&D departments to any staff involved in recruitment to trials.

We calculated that 196 responses would be required to estimate the proportion of participants who attempt to guess the next allocation with a margin of error of 7.

At the time of analysis, we had 72 survey responses.

The survey

Questions in the survey included:

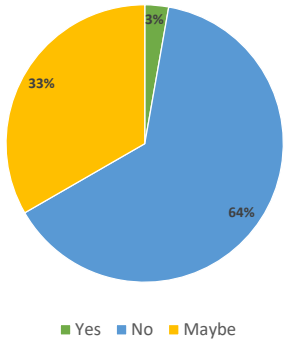


Preliminary Results

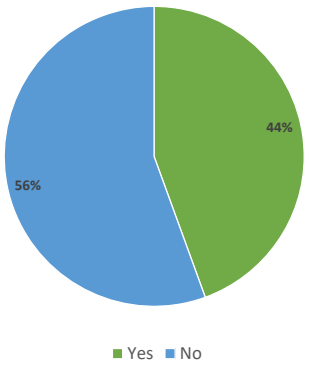
Of our 72 responses, 24 (33%) responded that they may be able to predict the next allocation dependent on information provided. The most common response when asked what information would be used to make this prediction was the “previous allocation”, mentioned by 28 participants. 4 participants additionally stated they would consider “participant characteristics”.

Finally, when asked if they ever tried to guess the next allocation, 32 (44%) responded yes.

Do you think you would be able to predict the next allocation in a randomisation sequence?



Have you ever tried to guess the next allocation when recruiting?



Note: Results are on 72 of the full sample size of 196.

Discussion

From current data whilst very few researchers report that they thought they would be able to predict the next allocation, 35% did respond “maybe dependent on available information”, suggesting that among our sample there is a belief that it is possible to guess allocations based on previous allocations and participant characteristics.

This, combined with the fact almost half of our sample had previously tried to guess an allocation, underlines the importance of researchers designing randomised controlled trials to consider whether the randomisation method they select creates a predictable sequence.

For more information on the research at Nottingham Clinical Trials Unit:

Keep up to date with this research:

@CydneyLBruce

University of Nottingham
UK | CHINA | MALAYSIA

Trials Methodology TMRP Research Partnership