

"What randomisation is meant to do and how most commentators get it wrong"

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ABSTRACT: Many critics of randomisation have assumed that it is supposed to guarantee balance of prognostic factors, proceeded to show that this is impossible and then concluded that the theory is flawed. However, the shocking truth about randomisation is exactly the opposite of what they suppose. If we knew that all prognostic factors in a randomised clinical trial were balanced, the standard analysis of such trials would be wrong. The analysis that Fisher proposed for randomised experiments makes an allowance for factors being unbalanced. I shall show how this fundamental misunderstanding of how the randomisation and analysis combination deals with error is the origin of a serious error in interpreting trials. I shall illustrate the points with a game of chance and an actual trial. I conclude by recommending that would-be commentators should not presume to analyse the logic of trials until they have analysed some results.