

ORAL PRESENTATION

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The need for a cultural shift from two-arm to multi-arm RCTs

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Proposal

We need a faster and more efficient way of improving patient outcomes in all disease areas. There is a need for a cultural shift in randomised phase III superiority trials. We propose there be fewer two-arm trials and more trials that incorporate multiple research arms.

Setting

Well-designed, well-conducted randomised controlled trials (RCTs) are the most reliable way to collect comparative evidence on efficacy and effectiveness, and drive changes in policy and healthcare. A literature search has shown that ~80% of all trials have only 2 arms. A key problem is their low success rate, defined as a convincing finding that the research treatment is better than the current standard-of-care. New treatments commonly do not work as well as hoped, yet we persist with traditional phase III RCTs, that are both expensive and often take many years. A direct conclusion from the high failure rate is that the information on which phase III trials are designed must be flawed. In planning any 2-arm phase III trial, fundamental uncertainties often remain; for example, whether we have reliably selected the most appropriate dose and/or duration of treatment or, for the academic community, whether other treatments have equal (or greater) priority for being assessed?

Conclusion

An academic RCT should not be seen as a way of assessing a specific treatment, but considered as a central tool to improving outcomes for patients with a particular condition as quickly as possible. Therefore, we argue that many more trials should have more than one research arm.

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