Research Made Easy

We previously explored how the double-blind randomised controlled trial (RCT) design was developed to reduce the extent to which patients’ beliefs and researchers’ behaviour affect research findings. This article will help you to understand a further source of bias: differences between groups at baseline.

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EXAMPLE

Imagine an RCT in which subjects were allocated either to eat lots of chocolate plus their normal meals (the intervention) or just their normal meals (the control). If you love chocolate and the abstract of the paper stated that subjects who frequently ate chocolate lost significantly more weight than the control group, you might be tempted to accept this finding at face value!

HOW MIGHT THE STUDY BE BIASED?

To assess if the abstract findings are truthful and correct you need to read the full article. In this example, you might have found from the table of baseline subject characteristics that the intervention group did more exercise than the control group. As this would affect weight loss, it is reasonable to conclude that the findings were biased by the differences between groups at baseline rather than frequent chocolate intake being an effective weight loss programme!

HOW MIGHT THIS TYPE OF BIAS HAVE BEEN AVOIDED?

- By ensuring that randomisation is properly conducted. This will increase the likelihood of baseline subject characteristics being evenly divided between the intervention and control groups.
- By identifying subject characteristics that might affect the findings and ensuring that these are equally divided between the intervention and control groups. Subjects could have been categorised by exercise level and then randomised so that an equal number of exercisers and non-exercisers were in the intervention and control groups. This is called ‘stratification’ and is particularly useful in small RCTs.
- Lastly, the data can be statistically analysed to adjust for baseline differences between groups. This should be clearly stated in the analysis of results section.

ACTION

The Papworth method improves respiratory symptoms, dysfunctional breathing and adverse mood compared with usual care of asthma. Further controlled trials are needed.