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TRIALS

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An empirical evaluation of the impact of missing data on treatment effect

Royes Joseph*, Julius Sim, Reuben Ogollah, Martyn Lewis

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Objectives

Missing data represent a potential source of bias in randomized clinical trials (RCTs). A simple approach that makes use of the responses subsequently obtained via reminder is proposed to assess the validity of the inferences from a missing at random (MAR)-based primary analysis of incomplete RCTs.

Methods

We explored mechanism behind the reminder responses in two pragmatic RCTs - the TATE and STarT Back trials - by utilizing the fact that data that are recovered through reminders would otherwise have been missing. The present approach considered two data scenarios: (i) with the actual dataset and (ii) with a modified dataset, where outcome responses obtained after a certain number of reminders were treated as missing. The impact of the reminder responses was assessed by comparing the estimates from MAR-based analyses between the two data scenarios.

Results

In the TATE trial, the reminder approach showed that an MAR-based analysis was likely to yield biased estimates of treatment effect. Therefore, further sensitivity analyses were required under a range of plausible missing not at random (MNAR) assumptions. However, in the STarT Back trial, this approach showed that an MAR-based analysis was likely to yield an unbiased estimate of treatment effect.

Conclusion

The proposed reminder approach can be used to assess the robustness of the MAR assumption by checking expected consistency in MAR-based estimates. If the results deviate, then MAR-based estimates are likely to be biased, and analyses incorporating a range of plausible MNAR assumptions are advisable at least as sensitivity tests for the evaluation of treatment effect.

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Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, UK