How much participant data is missing from trials?

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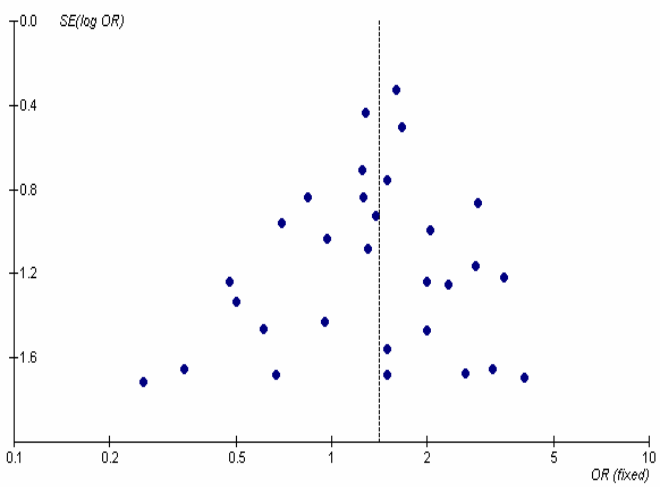
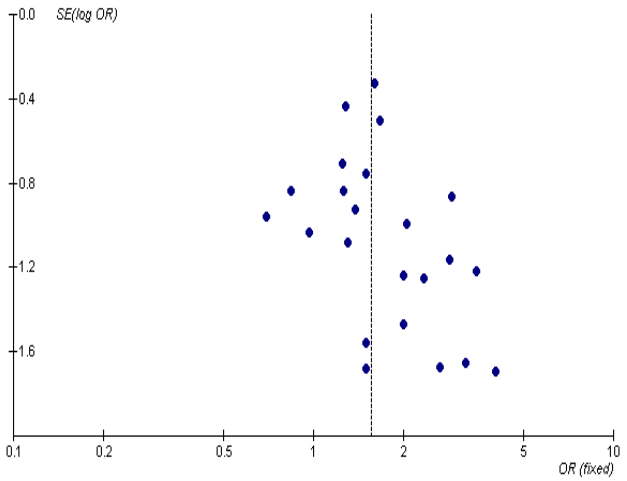
Sources of missing outcome data

Publication Bias: whole study is not published

Outcome Reporting Bias (selective non-reporting bias): Outcome of interest have been measured and analysed but not reported





Odds Ratio 1.41 (1.04,1.91)

Odds Ratio 1.55 (1.13,2.14)

Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias — An Updated Review

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"Empirical research on randomised controlled trials shows strong evidence of an association between significant results and publication: **studies that report positive or significant results (P<0.05) are more likely to be published**, and outcomes that are **statistically significant have higher odds of being fully reported** than those that are not significant (range of odds ratios: 2.2 to 4.7)".

Aims and Objectives

Aim: To estimate the proportion of missing participant data due to lack of publication of the study and the proportion due to missing outcome data within a published study.

Objective:

- Compute the proportion of fully reported outcome data
- Compute the proportion of partially reported data
- Compute the proportion of missing data from published studies (selective reporting)
- Compute the proportion of missing data from unpublished studies (publication bias)
- Compute the proportion of missing data from all studies (published and unpublished)

Data sources: Protocols of clinical research projects submitted to the research ethics committee of the University of Freiburg (Germany) and associated full published articles

Results

- **Study cohort:** 308 studies; 167 (54%) published
  - Increased risk of commercially funded studies being published
    [Relative risk 1.20, 95% CI (0.86, 1.67)]

- **Outcomes**: 3407 (from 308 studies)
  - Commercially funded studies less likely to publish all outcomes
    [Relative risk 0.64, 95% CI (0.30, 1.38)]

- **Total participant data:** 2,618,116 (*sample size x outcomes)

*For published studies the sample size was taken from the study publication (actual sample size achieved); for unpublished studies this was taken as the planned sample size from the study protocol.

Results

Proportions of reporting/missingness	
Proportion of fully published data	47%
Proportion of partially reported data	34%
Proportion of missing data from published studies (within-study selective outcome reporting)	4%
Proportion of missing data from unpublished studies (publication bias)	15%
Proportion of missing data from all studies	19%
Sensitivity analyses	
Proportion of missing data from all studies (partially reported = unpublished)	53%

Conclusions

- Missing participant data from both published and unpublished studies is frequent

- Clinical trial registration helps
    - Identify that clinical trials exist
    - Monitor trials to help prevent and detect selective study publication and selective reporting of outcome data