

Bias in randomised controlled trials

Main type of bias	Explanation	Effect
Selection bias	Systematic differences in the way in which people are accepted or rejected for inclusion in the trial or differences in the way in which interventions are allocated to participants once they have been accepted into the trial; allocation concealment prevents it	Exaggeration of effects of intervention
Ascertainment bias	Knowledge of which intervention each participant is receiving, introduced by the investigator administering the interventions, the assessor responsible for measuring outcomes and/or data analysis, and/or the participants receiving the intervention	Exaggeration of effects of intervention
Performance bias/Response bias, e.g. Hawthorne effect, placebo effect	Insufficient adherence to the study protocol by the investigator or the participant as a result of systematic differences in the way study groups are treated	Investigator: exaggeration of effects of intervention
Attrition bias	Unequal loss of participants during the trial – ‘drop-outs’ and exclusions – including withdrawal of informed consent, adverse events, poor treatment efficacy, participants not following the trial protocol (not complying with the regimen or seeking additional treatment), participants move away, and some participants may die	Reduces the power of the trial. Affects the balance of covariates in study groups
Bias due to missing data	Data missing from the trial is handled inappropriately during analysis. Reasons for missing data include participants drop out of the trial before it ends, participants do not follow the trial protocol, and/or outcomes are not measured appropriately or not measured on one or more of the designated time-points during the trial	Exaggeration of benefit and under-estimation of harm