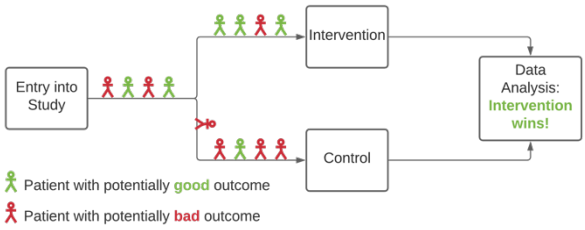
# Notes

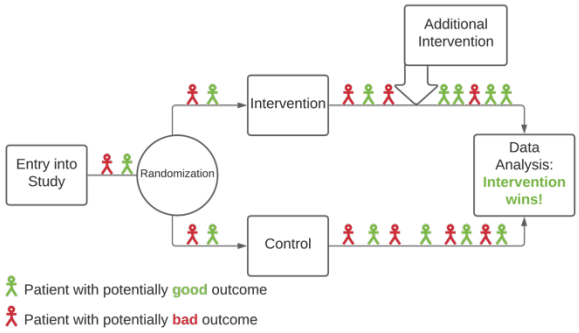
## Assessing Systematic Error (Bias) of Clinical Trials

## Internal Validity

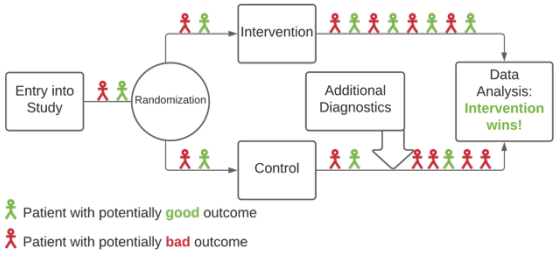
**Selection Bias**: biased allocation to comparison groups; can be controlled by random allocation of patients and concealment to allocation sequence.



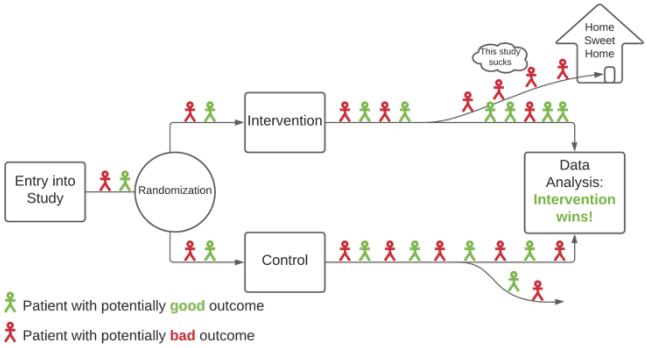

**Performance Bias**: unbalanced co-interventions; can be controlled by blinding of participants and care providers / investigators to group allocation.




**Detection Bias**: knowledge about patient assignment leads to unbalanced assessment of outcomes; can also be controlled by blinding of participants and care providers / investigators to group allocation.




**Attrition Bias**: non-random loss to follow-up can lead to systematic error of results (breaks randomization!); can be somewhat mitigated through “intention-to-treat” analysis.



# External Validity

**Patients**: Do patients selected for the trial match those you intend to treat in terms of age, sex, severity of disease and risk factors, as well as comorbidities?

**Treatments**: Does your patient population match the study population in terms of dosage and concomitant treatments?

**Setting**: Differences in patient populations depending on level of care (university hospital vs. general practitioner) and specialization.

**Modalities of outcomes**: Are the outcomes measured of direct interest for your patient population (surrogate vs. “hard” outcomes)? Is the duration of follow-up adequate to answer the research question?