

Citation:

Are the results of the study valid?

1. Was the assignment of patients to treatments randomized?	
2. Was the randomization list concealed?	
3. Was follow-up of patients sufficiently long and complete?	
4. Were all patients analyzed in the groups to which they were randomized?	
5. Were patients, clinicians, and study personnel kept "blind" to treatment?	
6. Were the groups treated equally, apart from the experimental treatment?	
7. Were the groups similar at the start of the trial apart from the experimental therapy?	

Are the results of this study important?

1. What is the magnitude of the treatment effect?	
2. How precise is the estimate of the treatment effect?	

Are the results applicable to your patient?

1. Is our patient so different from those in the study that its results cannot apply?	
2. Is the treatment feasible in your setting?	
3. What are the patient's potential benefits and harms from the study?	
4. What are the patient's values and expectations for both the outcome you are trying to prevent and the treatment you are offering?	

Formulas for Therapy Trials (only useful if outcome parameter is dichotomous)

	Outcome		Totals
	Present	Absent	
Experimental Group	A	B	A+B
Control Group	C	D	C+D
Totals	A+C	B+D	A+B+C+D

Experimental event rate (EER)

→ probability of outcome occurring in the experimental group
→ $A / A+B$

Control event rate (CER):

→ probability of outcome occurring in the control group
→ $C / C+D$

Relative risk (RR):

→ ratio of risk of outcome occurring in experimental group to the risk of outcome occurring in the control group
→ EER / CER

Relative risk reduction (RRR):

→ percent reduction in risk of outcome compared to the control group
→ $[(CER - EER) / CER] \times 100 \%$
→ $1 - RR$

Absolute risk reduction (ARR):

→ difference in risk of outcome between the control group and the experimental group
→ $CER - EER$

Number needed to treat (NNT):

→ number of patients that must be treated over a specified time period to prevent one adverse outcome
→ $1 / ARR$.