CRITICAL APPRAISAL CHECKLIST FOR AN ARTICLE ON TREATMENT OR PREVENTION.

Study Design: Randomised Controlled Trial

Adapted from:

Critical Appraisal Skills Programme (CASP), Public Health Resource Unit, Institute of Health Science, Oxford.

Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? *JAMA* 1993; 270: 2598-2601.

Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients? *JAMA* 1993; 271: 59-63.

DOES THIS STUDY ADDRESS A CLEAR QUESTION?

1. Were the following clearly stated: • Patients • Intervention • Comparison Intervention • Outcome(s)	**Yes**	**Can't tell**	**No**

ARE THE RESULTS OF THIS SINGLE TRIAL VALID?

A. The main questions to answer:

2. Was the assignment of patients to treatments randomised? **3. Was the randomisation list concealed? Can you tell?**	**Yes**	**Can't tell**	**No**
4. Were all subjects who entered the trial accounted for at it's conclusion? **5. Were they analysed in the groups to which they were randomised, i.e. intention-to-treat analysis**			

B. Some finer points to address:

6. Were subjects and clinicians 'blind' to which treatment was being received, i.e. could they tell?	**Yes**	**Can't tell**	**No**
7. Aside from the experimental treatment, were the groups treated equally?			
8. Were the groups similar at the start of the trial?			

WHAT WERE THE RESULTS?

	Outcome event		Total
	Yes	No	
Experimental group	a	b	a + b
Control group	c	d	c + d

Experimental event rate = risk of outcome event in experimental group = EER = a/(a+b)

Control event rate = risk of outcome event in control group = CER = c/(c+d)

Relative risk (RR) = $\frac{\text{EER}}{\text{CER}}$ Odds ratio (OR) = $\frac{\text{ad}}{\text{bc}}$

Relative risk reduction (RRR) = (CER - EER)/CER or 1 - RR

Absolute risk reduction (ARR) = CER - EER

Number needed to treat (NNT) = 1/ARR = 1/(CER - EER)

9. How large was the treatment effect? Consider • How were the results expressed (RRR, NNT, etc).	
10. How precise were the results? Were the results presented with confidence intervals?	

CAN I APPLY THESE VALID, IMPORTANT RESULTS TO MY PATIENT?

	Yes	Can't tell	No
11. Do these results apply to my patient? • Is my patient so different from those in the trial that the results don't apply? • How great would the benefit of therapy be for my particular patient?			
12. Are my patient's values and preferences satisfied by the intervention offered? • Do I have a clear assessment of my patient's values and preferences? • Are they met by this regimen and its potential consequences?			

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Randomised controlled trial (RCT)	Clinical trial where at least two treatment groups are compared. One must be a control group, e.g. receiving standard care or a placebo treatment. Allocation to a group must be random and unbiased.
Randomisation	Process of allocating individuals to the alternative treatments in a clinical trial, avoiding bias. Should produce groups which are similar, except for the treatment of interest.
Blinding	The process of ensuring that participants or researchers (single-blind) or participants and researchers (double-blind) are unaware of which treatment group participants have been randomised to, reducing the possibility of bias in the results.
Intention-to-treat analysis (ITT)	All patients allocated to one arm of a RCT are analysed in that arm, whether or not they completed the prescribed treatment/regimen.
Experimental event rate (EER)	Risk (or chance) of outcome event in experimental group.
Control event rate (CER)	Risk (or chance) of outcome event in control group.
Relative risk (RR)	A measure of the chance of the event occurring in the experimental group relative to it occurring in the control group.
Relative risk reduction (RRR)	The difference in the proportion of events between the control and experimental groups, relative to the proportion of events in the control group. Can also be calculated as 1-RR.
Absolute risk reduction (ARR)	The absolute difference between the risk of the event in the control and experimental groups.
Number needed to treat (NNT)	The number of patients who needed to be treated to prevent the occurrence of one adverse event (e.g. complication, death) or promote the occurrence of one beneficial event (e.g. cessation of smoking).
Confidence interval	For whatever effect being measures (e.g. RR, RRR, ARR, NTT) the confidence interval is the range of values within which the “true” value in the population is found. Generally expressed as a 95% confidence interval, i.e. you can be 95% confident that the population value lies within those limits.