Rapid Critical Appraisal of an RCT

Step 1: What question did the study ask?

Population/problem: .....
Intervention: .....
Comparison: .....
Outcome(s): .....

Step 2: How well was the study done? (internal validity)

Recruitment **– were the subjects representative?**	
What is best?	**Where do I find the information?**
What group of patients are investigated (setting, inclusion/exclusion criteria)? Ideally, the subjects should be consecutive (or sometimes random), but the proportion of eligible patients who consent and are included should be known.	The **Methods** section should tell you how patients were selected for the study.
Does the study follow best recruitment criteria? Yes ❑ No ❑ Unclear ❑ Comment:	

Allocation **– was the allocation randomised and concealed…?**	
What is best?	**Where do I find the information?**
Centralised computer randomisation is ideal and often used in multicentre trials. Smaller trials may use an independent person (e.g. the hospital pharmacist) to 'police' the randomisation.	The **Methods** should tell you how patients were allocated to groups and whether or not randomisation was concealed. The authors should describe how the process was 'policed' or if there is some mention of masking (e.g. placebos with the same appearance or a sham therapy).
Does the study follow best allocation criteria? Yes ❑ No ❑ Unclear ❑ Comment:	

… Were the groups comparable at the start of the trial?	
What is best?	**Where do I find the information?**
If the randomisation process worked (that is, achieved comparable groups) the groups should be similar. The more similar the groups, the better it is.	The **Results** should have a table of 'Baseline characteristics' comparing the randomised groups on a number of variables that could affect the outcome (age, risk factors, etc). If not, there may be a description of group similarity in the first paragraphs of the **Results** section.
Does the paper report comparable groups? Yes ❑ No ❑ Unclear ❑ Comment:	

Maintenance **– did the groups have equal co-interventions…?**	
What is best?	**Where do I find the information?**
Apart from the intervention the patients in the different groups should be treated exactly the same (e.g. with respect to additional treatments or tests, measurements).	Look in the **Methods** for the precise protocol followed for each group (such as follow-up schedule, permitted additional treatments) and in the **Results** for any further information.
Does the study treat both groups in the same way other than the intervention? Yes ❑ No ❑ Unclear ❑ Comment:	

…and was there adequate follow-up?	
What is best?	**Where do I find the information?**
Losses to follow-up should be minimal – preferably less than 20%. Patients should also be analysed in the groups to which they were randomised – '*intention-to-treat* analysis'.	The **Results** section should say how many patients were randomised and how many patients were actually included in the analysis. Sometimes a flowchart is given (but if not, try to draw one yourself).
Does the paper report adequate follow up? Yes ❑ No ❑ Unclear ❑ Comment:	

Measurement **– were the subjects and assessors kept 'blind' as to which treatment was being received and/or were the measures objective?**	
What is best?	**Where do I find the information?**
For *objective* outcomes (e.g. death) blinding is less critical, but for *subjective* outcomes (e.g. symptoms or function) then blinding the outcome assessor is critical.	The **Methods** section should describe how the outcome was assessed and whether the assessor(s) were aware of the patients' treatment.
Were the subject and assessor blind to the treatment? Yes ❑ No ❑ Unclear ❑ Comment:	

Step 3: What do the results mean?

What measure was used and how large was the treatment effect? **Could the effect have been due to chance?**
Consider concepts such as (risk, risk difference, number needed to treat, relative risk, confidence intervals).

Step 4: Are these results applicable to our patients? (external validity)

- **Is our patient so different from those in the study that the results can't apply?**
- **Is the treatment feasible in our setting?**
- **What are our patient's potential benefits and harms from the therapy?**
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