RCT - CRITICAL APPRAISAL WORKSHEET

Study: RCT: Short Title…
Citation…

What question did the study ask? (PICO format)

Patients -In short, who included/excluded? -Who is the most typical patient in this RCT? -Any complicating factors that might impact? -Is population reasonably representative?	*If I want a lot of detail, I'll go to the article/supplement; rather that that, tell me in short who were these patients? Low vs high risk? Anything stand out? Age? Important exclusions or typical to be expected?*
Intervention -In short, what's the primary intervention -Describe any complicating factors, if present	*This might be super easy, unless there are some complicating factors to be cognisant of secondary to the difference in intervention vs control.*
Comparison -Placebo, or active control? -Fair comparison?	
Outcome(s) -What was the 1° outcome? -was it patient oriented or surrogate? -was it the outcome you would have chosen? -Any 2° or safety outcomes of high interest? -What about all cause mortality? SAE?	

Are the results of this trial valid? (What is the risk of bias?)

Was the assignment of patients to treatments randomised?	
Was the randomisation list concealed? ie allocation concealment	*Yes/No? How do you know? Why should you care?*
Were the participants / clinicians / analysts blinded? (Word clues: e.g. "open label")	*If "no", any idea as to how it might affect the treatment vs control groups, and resulting outcome data?*
Were all patients analysed in the groups to which they were randomised?	
Were the groups treated equally, apart from the intervention studied?	
Were the groups similar at the start of the trial? Any concerns?	
Any other concerns? -e.g. Funding? COI?	

What were the results?
Are the valid results of this randomised control trial important?

What was measured? -Think 1° outcome -Think any other outcome you are most interested in? -Think benefits vs harms -Think safety and overall net benefit/harm -serious adverse events -all-cause mortality -Of the above: …which provide the most robust data? …which are of most importance/interest?	
What does it mean?	
How large was the treatment effect? -Think 1° outcome, and/or any outcome of relatively high importance? -Absolute difference (e.g. ARR, NNT/NNH) -Relative difference (e.g. RR, OR, HR) -How would you categorize size of effect? -negligible-trivial, minimally important, small, moderate, large	
How precise was the estimate of the treatment effect? -Think confidence intervals (e.g. 95% CI) -often found in summary tables, but Forrest plots will also provide insight -less optimally, may consider p-value	
What were the potential harms? -Which specific ones stand out, if any? (based on either frequency, because they were common; or severity, even if rare) -How large was the harmful effect? -Absolute? Relative? -Overall composites: -serious adverse events? -all-cause mortality?	
How precise was the harm estimate? -Think confidence intervals (e.g. 95% CI) -less optimally, may consider p-value	
What is your summary take on the overall potential for benefit vs harm?	

To what extent can you apply the study results in caring for your patient(s)?

To what extent, or when, would these results apply to your patient(s)? -any caveats? -any subgroup results that increase or decrease your confidence in applying the results to any/all patients?	
Are any of your patients so different from those in the study that its results cannot apply?	
Is the treatment feasible in your setting? -what are the cost/resource implications: a) to clinic/clinician, b) to patient/caregiver, c) society	
Is the change/reduction of important clinical endpoints worth the increase of cost and/or risk of harm?	

Overall Summary/Synopsis

Additional notes/questions: