

# Critically appraising a trial

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- RCT is logistically complex, simple experiment
- What is the experiment?
  - Aims, intervention, superiority, non-inferiority
- Is it a good one? Can I trust the result? (Internal validity)
  - Sample size, clear protocol/intervention, blinding, randomisation method
- Can its finding be extended to my practice? (External validity)
  - Population, intervention

# Why and what...

- Last paragraph of intro – aims
  - First paragraph of methods – study type
  - First paragraph of ‘outcomes’ – primary outcome
  - First paragraph of ‘statistical analysis’ – power calculation
- 
- The backbone of the study

# Key bits of methods...

- Design – superiority, non-inferiority
- Randomisation – individual, clusters
- Regulatory approvals, registration, published protocol and SAP
- How was randomisation performed – computer-generated, permuted blocks, allocation concealment
- Population
- Intervention
- Blinding

# Outcomes and stats

- Don't need to be an expert in stats but also don't be overwhelmed
- Outcomes – primary is key, secondary are interesting, check what is *a priori* and what is *post hoc*
- Sample size should be crystal clear
- Is there a clear explanation of analysing each outcome (even if you don't know what the test is)
- Is there a statistician on the author list
- If it's a cluster randomised trial, there should be some reference to stats specific to that type of trial (intra cluster correlation)

# Results...

- Start of results will describe the recruitment and patients
  - And recruitment issues. Was it stopped early?
- Look over consort diagram
  
- Check whether there was separation in trial arms by the intervention – e.g. Vit C levels or BP levels
  
- Figures and tables I find most helpful
- Look at point estimate and confidence intervals
- (then p values)

# Discussion...

- Are the authors conclusions reasonable given your assessment of study?
- Is it definitive?
- If internal validity weak – its low value
- If external validity weak – its interesting but don't know if it will work in my hands
- Realise that usually a large volume of research is need to get close to the truth.

# Final comments re EBM...

- Beware of unintended consequences
  - ‘There are no side effects’, ‘there is no risk’
- Last ditch treatments because the patient is dying COULD hasten their death! Why do we assume its benefit or nothing?
- Lower quality studies show larger treatment effects
  - Observational study -> poor RCT -> good RCT
  - Big effect -> small effect -> no effect

# Other resources

- <http://www.consort-statement.org/> for RCTs
- <http://www.prisma-statement.org/> for MA and systematic reviews
- <https://www.strobe-statement.org/> for observational studies
- <https://www.equator-network.org/reporting-guidelines/stard/> for diagnostic studies