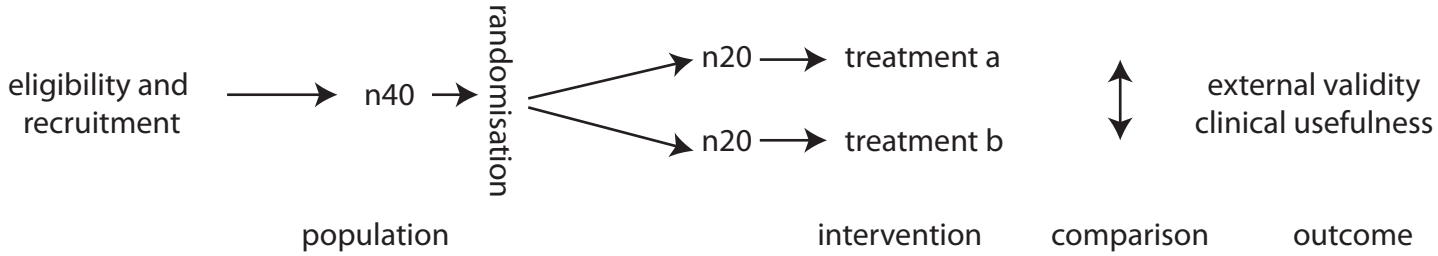
FEB 2008
QUESTION 20

What are the strengths and weakness of an RCT study design

Randomised controlled trial is where after assesment of eligibility and recruitment, study subjects are randomly allocated into different treatment groups, and the difference in outcome variables are then compared.



Classification

- design - parralell (same as above - most common), crossover, cluster
- outcome - efficacy (narrow - aim to explain), effectiveness (broader - aim to test clinical utility)
- hypothesis - superiority (most studies aim to show one treatment is superior), inferiority, equivalence
- randomisation characteristics - double blind (most superior, subjects and investigators are blinded)

Advantages

Considered the gold standard

Higher internal validity compared to other designs

Prospective therefore outcome not predetermined

Unbiased distribution of confounders

Statistical analysis
- meaningful
- enables probablility assessment

Blinding is more likely
- less selection bias

More likely than other designs to be reproducible

Disadvantages

Limitations of external validity
- may only be relevant to specific population
- reduced by multicentre/international study

More expensive

Time consuming

Efficacy studies have limited applicability
- eligibility rules may exclude many

Ethical limitations / consent
- withholding treatment / harm / paeds

May not be feasible to randomise

Effects may occur far into the future
- environmental radiation exposure lead time

Not practical to study very rare effects
- idiosyncratic drug effects

Subject to publication bias
- positive studies more likely to be reported

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