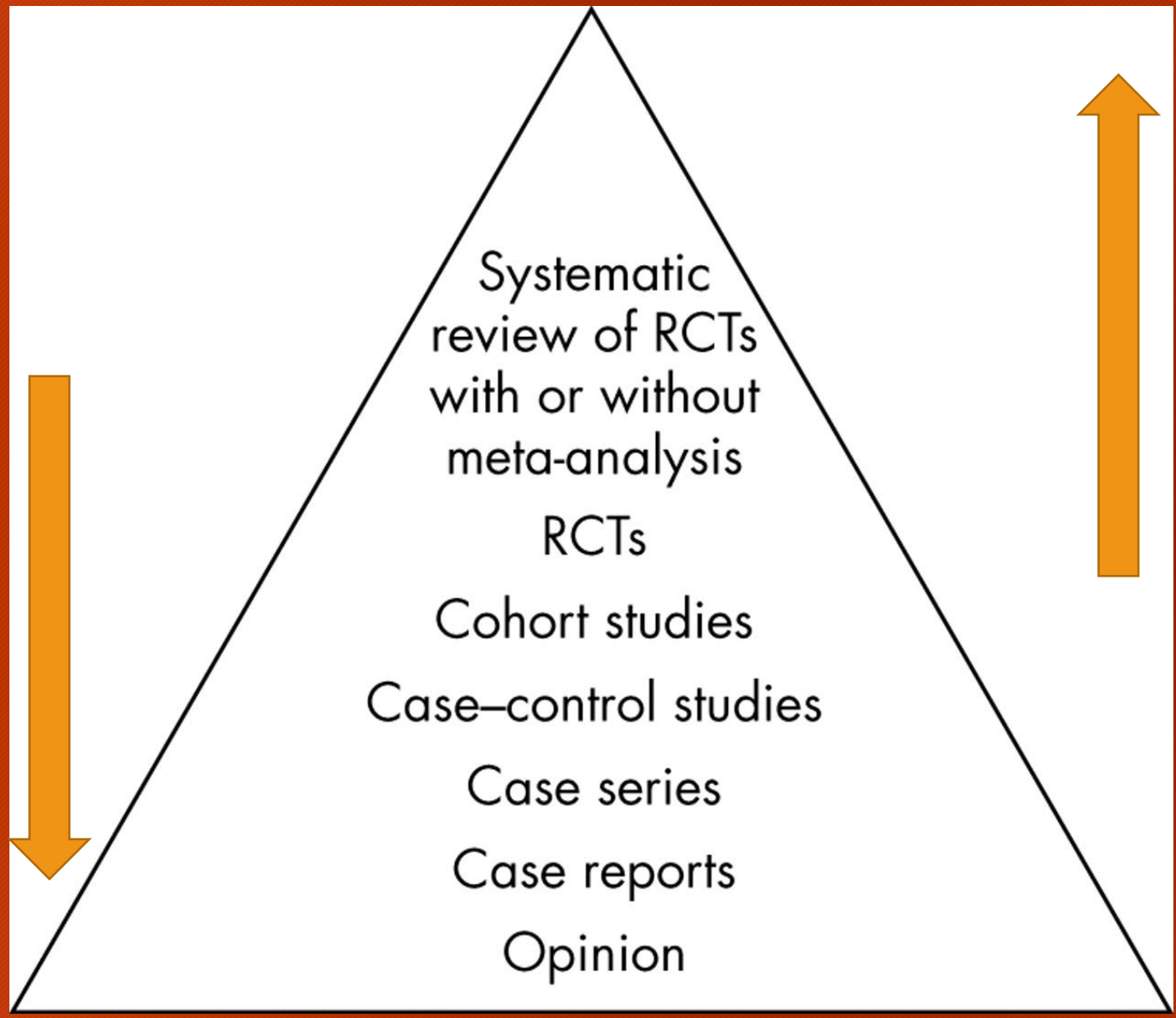
Randomised Controlled Trial

RCT

Hierarchy of evidence

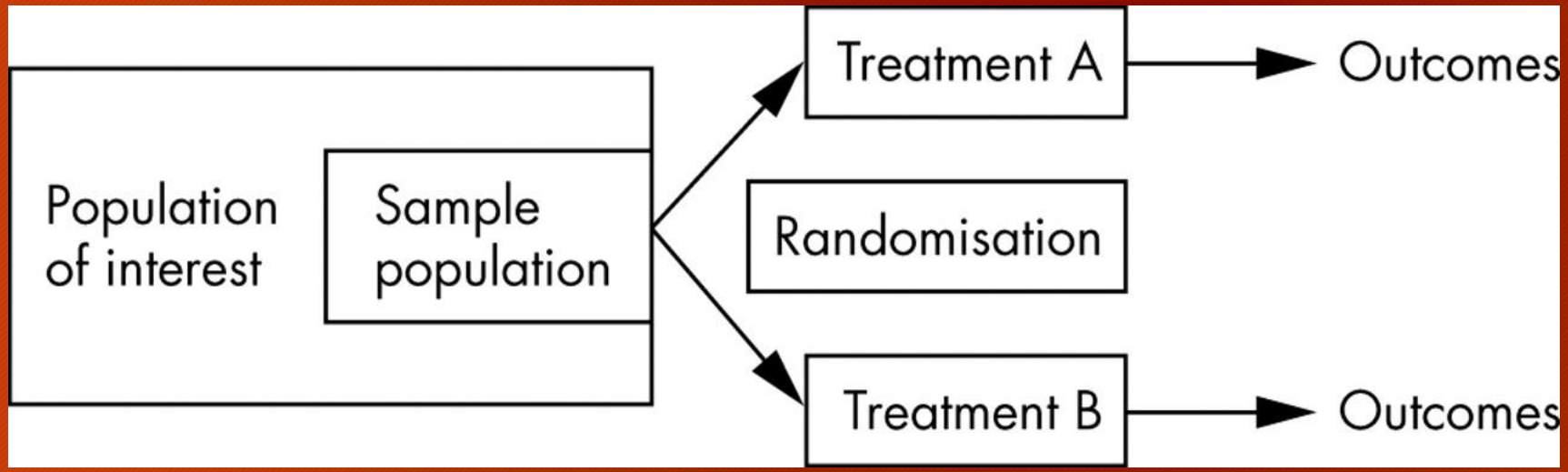
It is well recognised that some research designs are more powerful than others in their ability to answer research questions on the effectiveness of interventions.

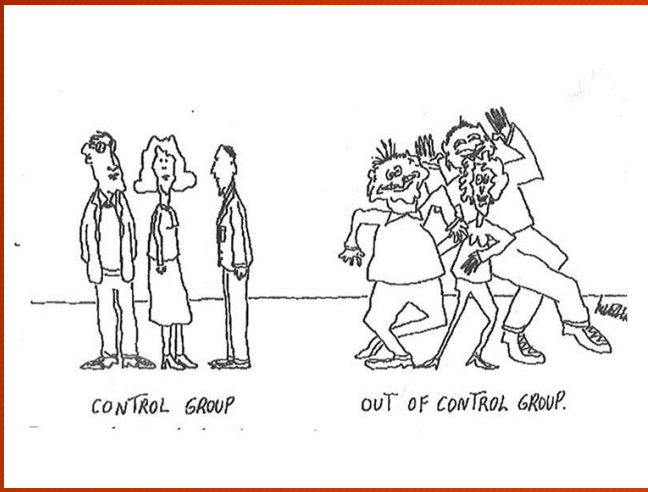
Increasing risk of bias inherent in study designs



Increasingly rigorous methodologies

Structure of an RCT





- The RCT is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimise the risk of confounding factors influencing the results.

- Random allocation makes it more likely that there will be balancing of baseline systematic differences between intervention groups with regard to factors—such as age, sex, disease activity, and duration of disease—that may affect the outcome.

Questions to consider

- Did the study ask a clearly focused question?
- Was the study an RCT and was it appropriately so?
- Was randomization adequately done and described? Participants appropriately allocated to intervention and control groups?
- Were participants, staff, and study personnel blind to participants' study groups? / Blinding of outcome assessment: Were outcome assessments made by independent assessors?
- Were all the participants who entered the trial accounted for at its conclusion?
- Were participants in all groups followed up and data collected in the same way?
- Did the study have enough participants to minimise the play of chance? *Power and sample size calculation, Statistical and Clinical significance*
- How are the results presented and what are the main results? Selective outcome reporting?
- How precise are the results?
- Incomplete outcome data: Was outcome data missing, due to attrition (drop-out) during the study or exclusions from the analysis?
- Were all important outcomes considered and can the results be applied to your local population?
- Publication bias: Negative results are 50% less likely to be published. Positive is news. Involvement of industry, conflict of interest?
- Are there any other threats to validity that are not reflected in the risks above?

(Higgins and Green 2011; Lane, 2016)

Example from new meta-analysis - Karkou et al (2019)

Figure 4: Risk of bias across all included studies.

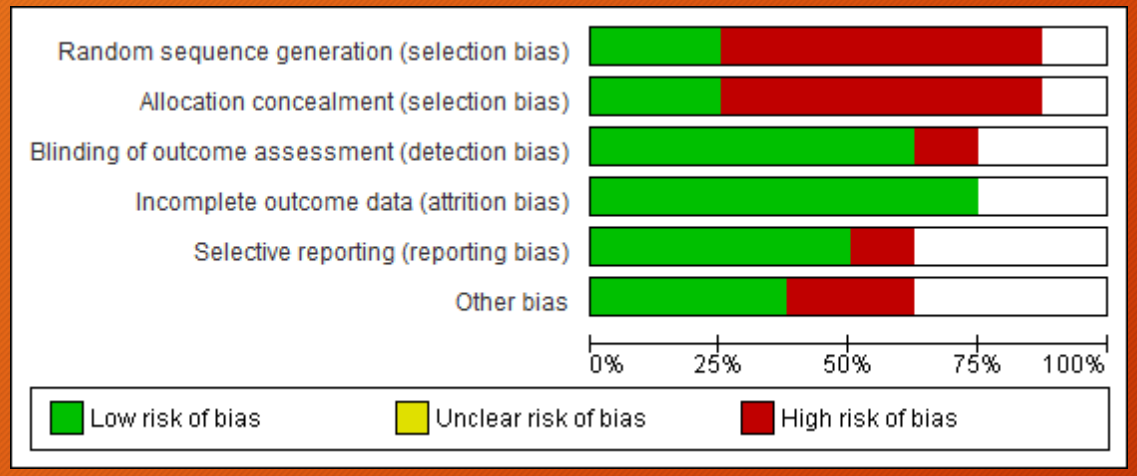
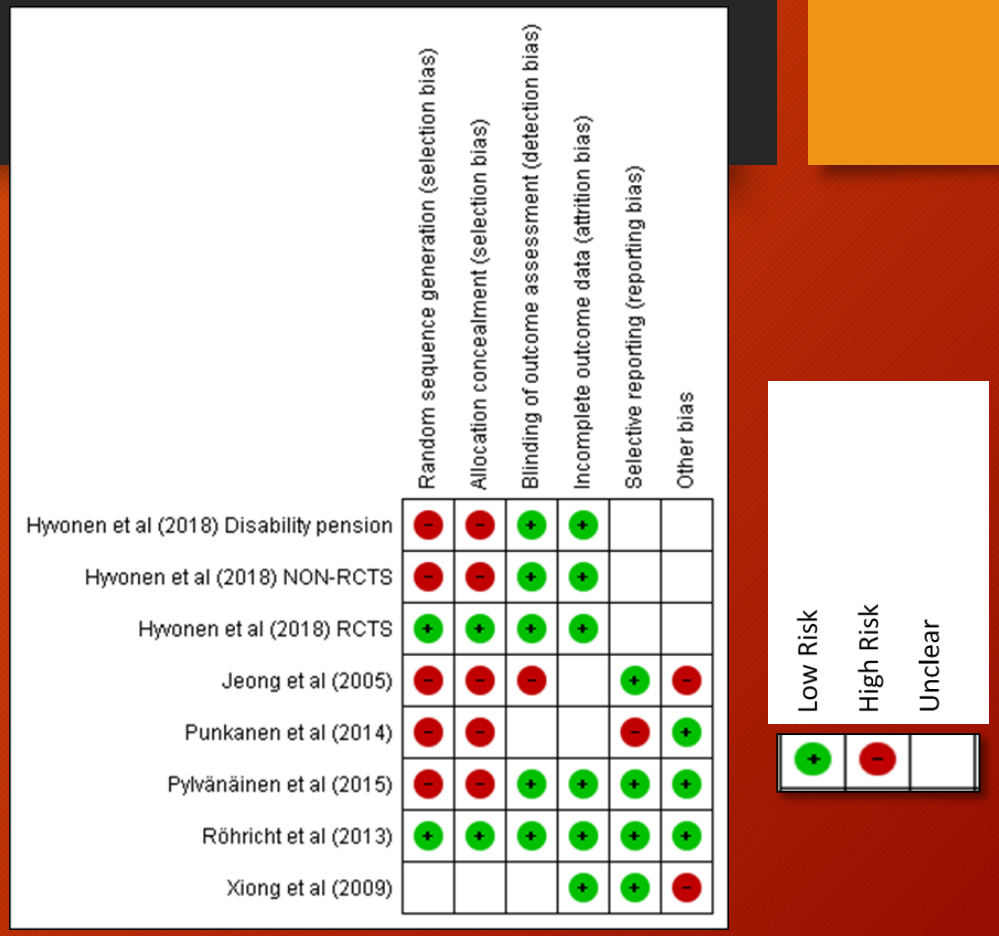
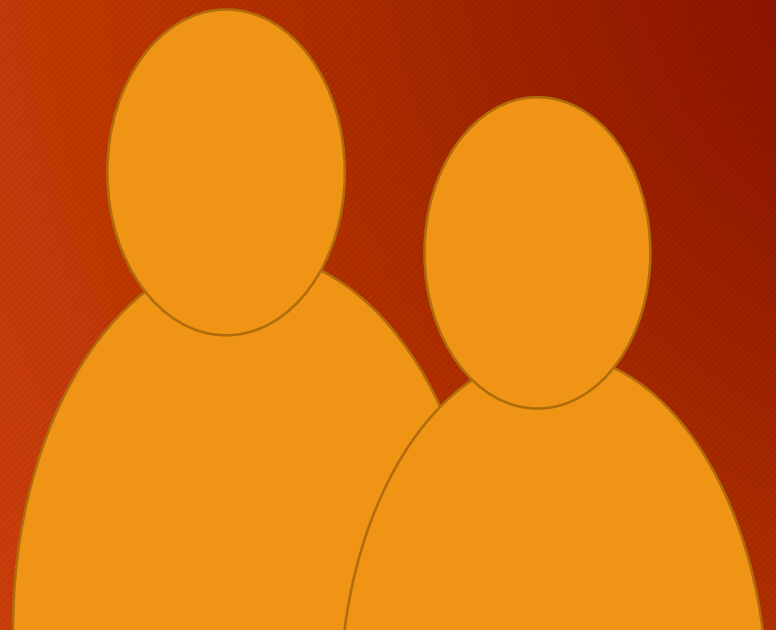


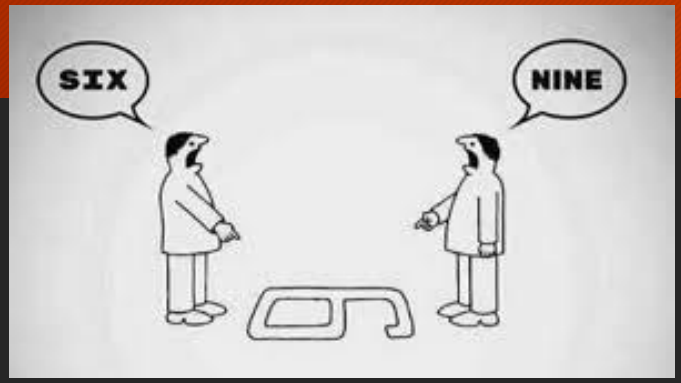
Figure 5: Risk of bias for each included study



Judgements about clinical significance should take into consideration how the benefits and any adverse events of an intervention are valued by the patient.



CONCLUSIONS



An RCT is the most rigorous scientific method for evaluating the effectiveness of health care interventions.

RCTs are resource intensive and normally need large teams and diverse expertise but they are vital for establishing effectiveness.

However, bias could arise when there are flaws in the design and management of a trial.

It is important for people reading medical reports to develop the skills for critically appraising RCTs, including the ability to assess the validity of trial methodology, the magnitude and precision of the treatment effect, and the applicability of results.