

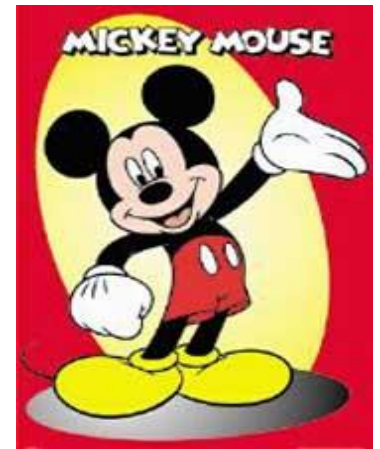
RANDOMISED CLINICAL TRIALS

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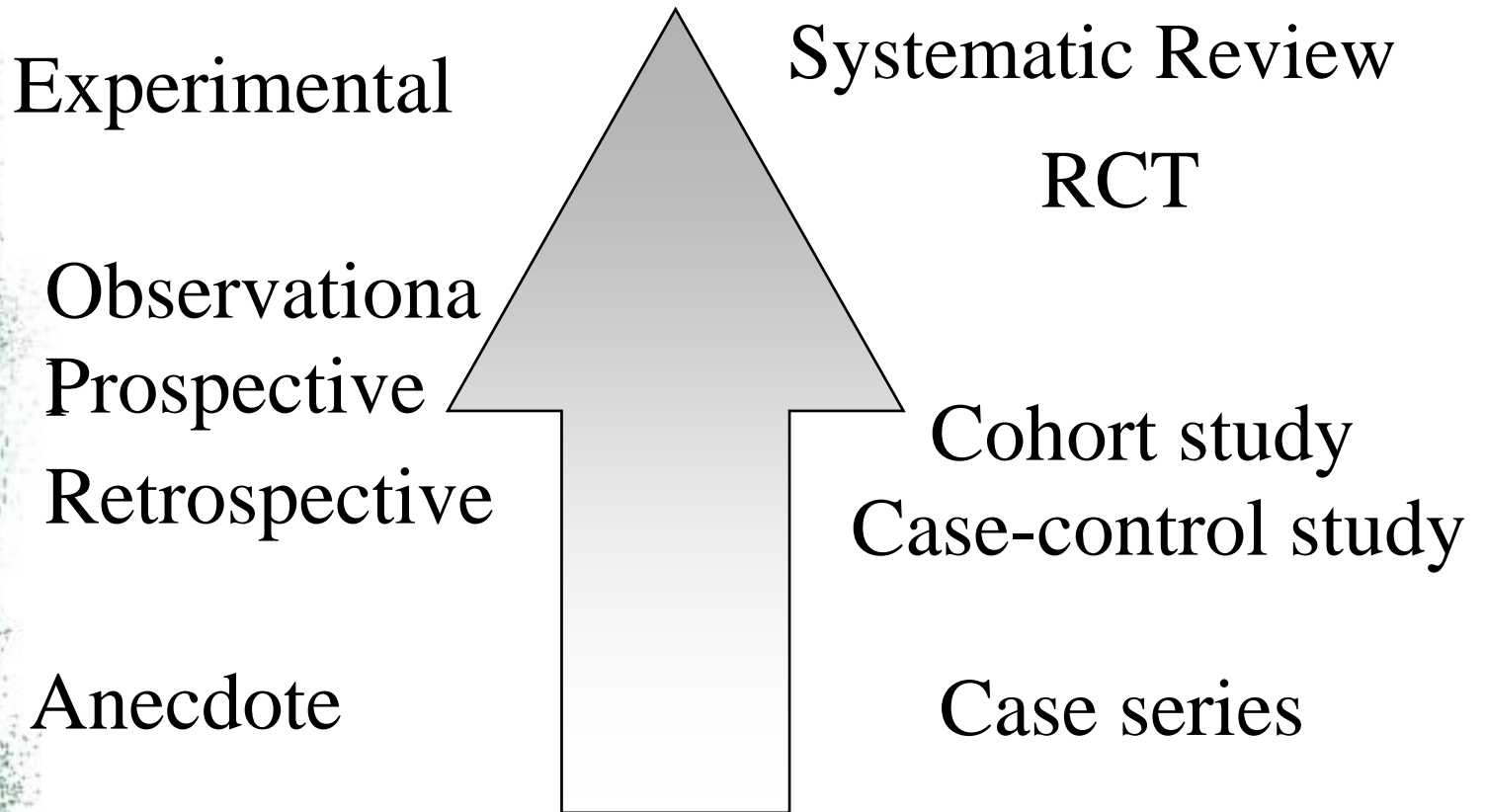
Randomised Controlled Trial (RCT)

RCT is a trial in which subjects are randomly assigned to two groups: one (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or controls) receiving an alternative treatment. The two groups are then followed up to see if any differences between the result. This helps in assessing the effectiveness of the intervention.

Source: Cochrane Collaboration Glossary



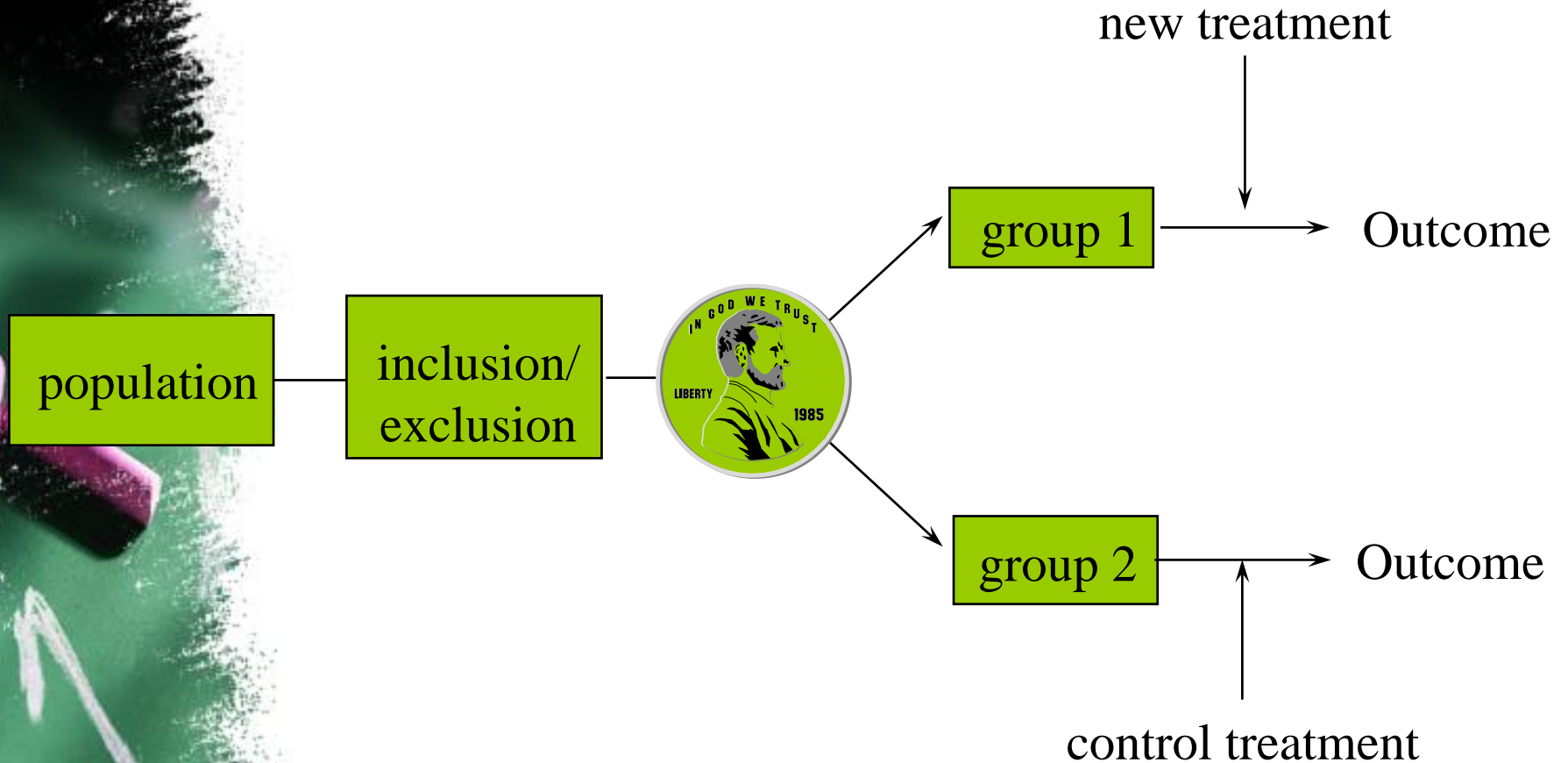
Strength of evidence



- *Study population (participant)*
treatment / control
- *Investigators*
- *Clinical intervention (medical surgical ,regimn ,hygiene)*
- *Outcome*



Randomised controlled trial



➤ *RANDOMIZATION*

definition

advantages

vit A in measles

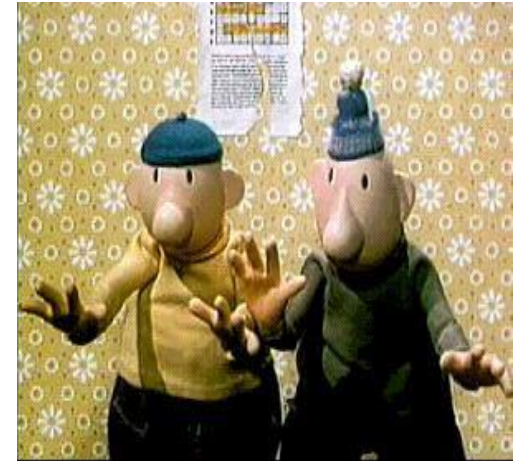
main goal

(laser in wound healing)

methods

➤ *Pseudo randomization*(quasi -R)

disadvantages

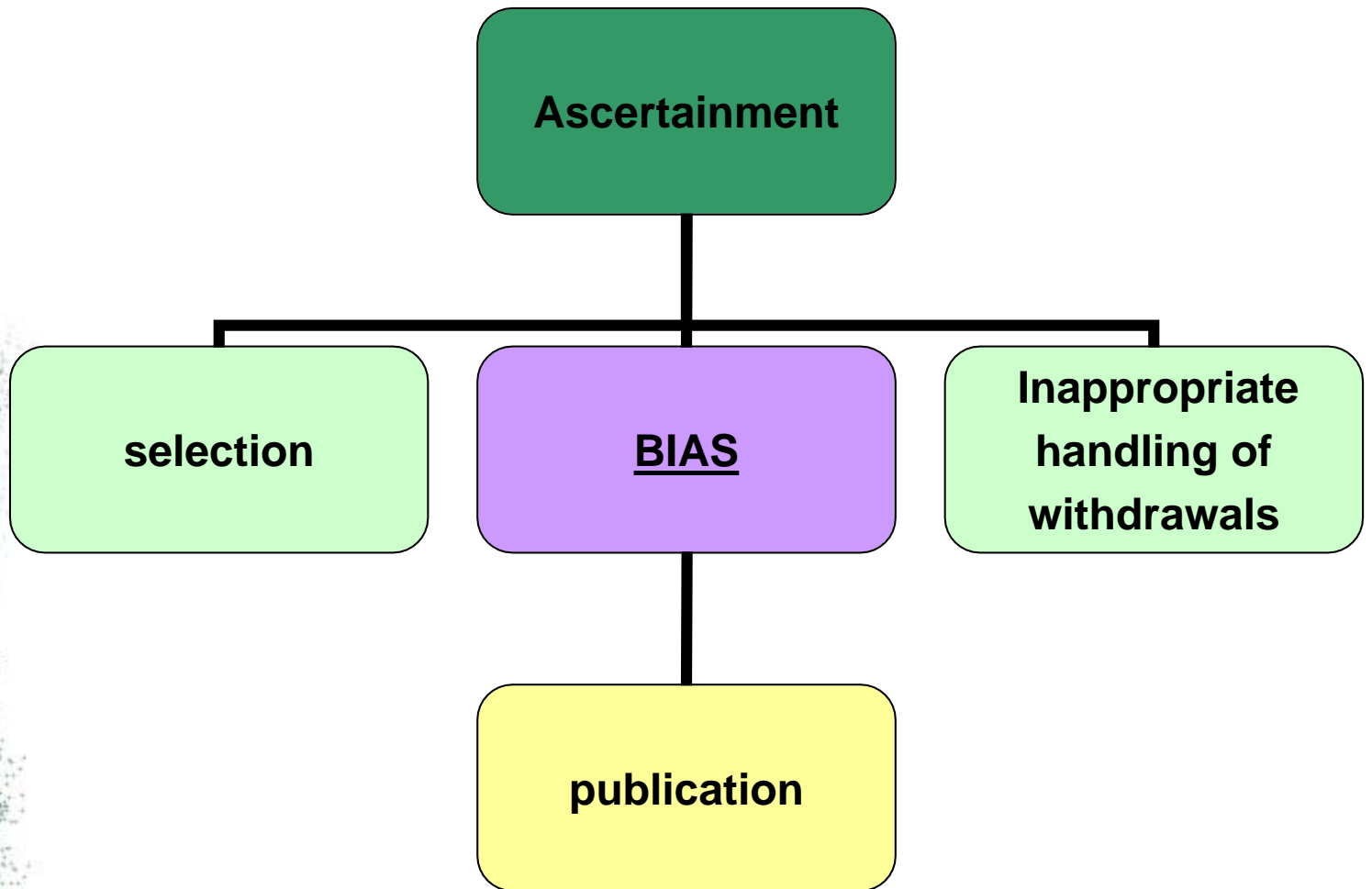


*All RCTs are controlled clinical
trial*

BUT

*Not all controlled trials are
RCTs*





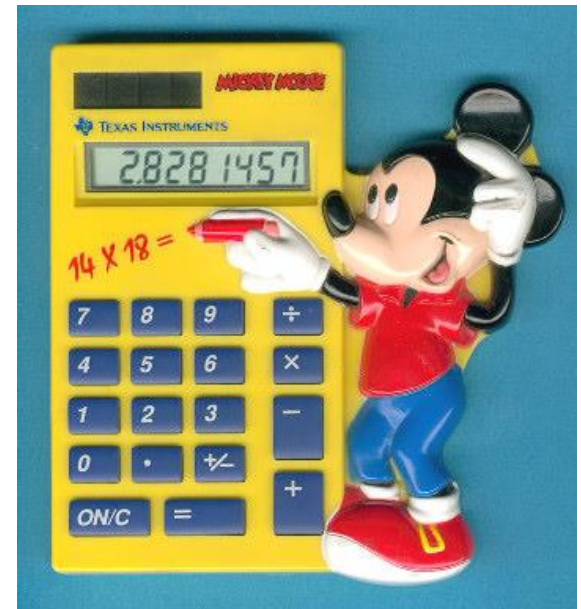
- SELECTION BIAS

Inclusion & exclusion

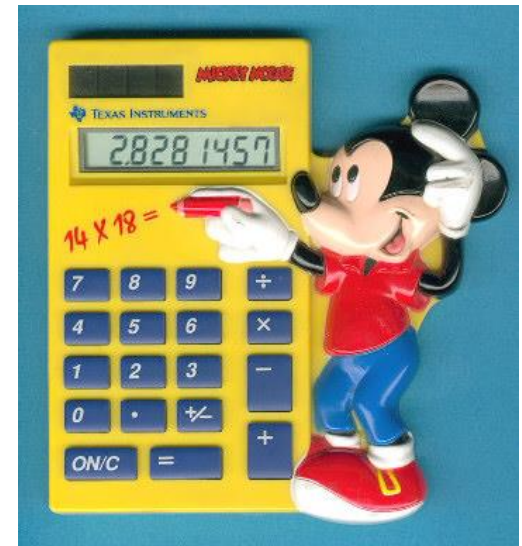
Intervention


New drug on MS and depression

concealment



- Ascertainment bias
- treatment of Blood pressure
- double blinding

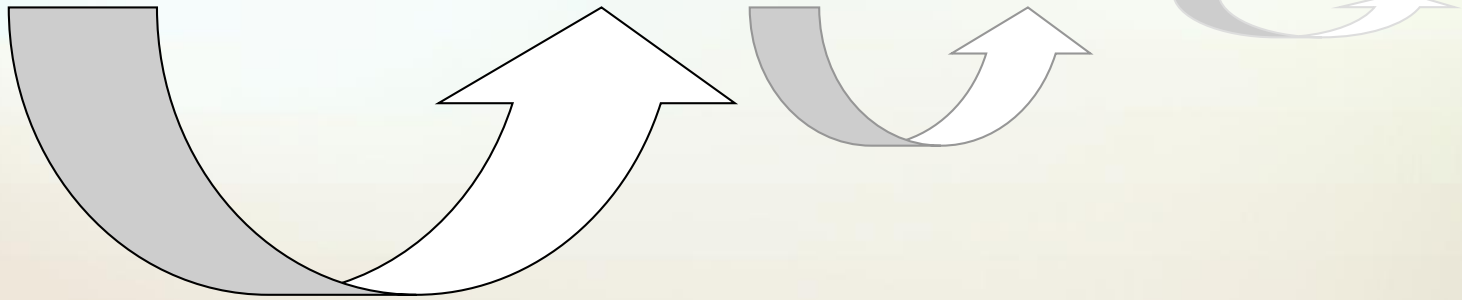


- 
- **Double blinding** prevents **ascertainment bias** and protects randomization after allocation and during study
 - **Allocation concealment** prevents **selection bias** and protects randomization during selection

**Trial
design**

**Study
execution**

**Reporting
Publication**



1. Was the study described as randomised?
2. Was the study described as double blind?
3. Was there a description of withdrawals and drop outs?

Give a score of 1 point for each "yes"
or 0 points for each "no"

Give 1 additional point
each

Deduct 1 point
each

If randomisation/
blinding appropriate

If randomisation/
blinding inappropriate

Scoring range: 0–5
Poor quality < 3

Figure 4.1 Validated quality scale. (From Jadad et al.¹)

RCT IS NOT suitable for:

- * ETIOLOGY AND CLINICAL COURSE

smoking and cancer

- * RARE & PROLONGED OUTCOME



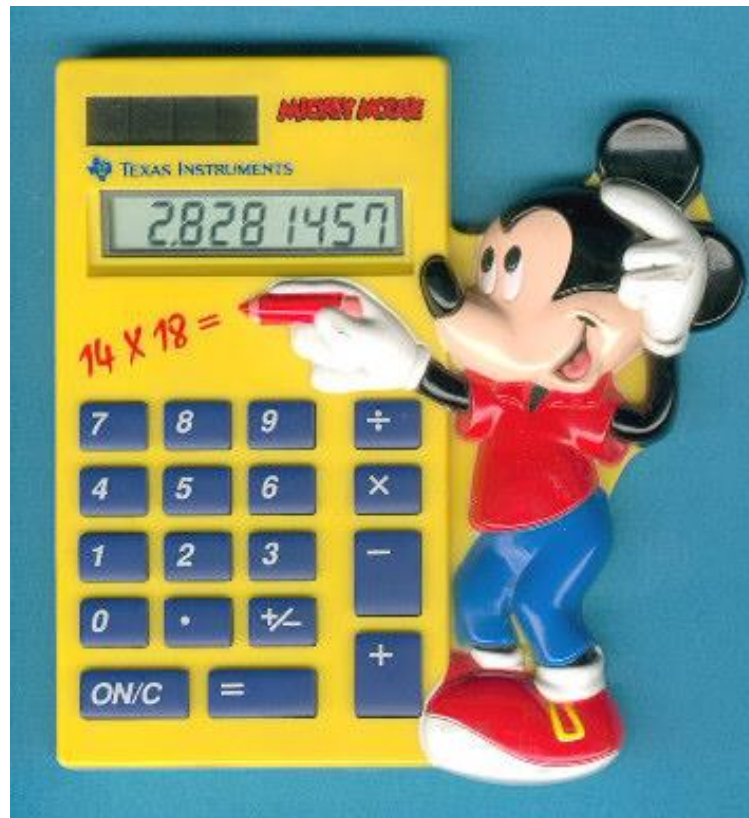
ethics

- Phase 1 *20-80*
- Phase 2 100-200
- Phase 3
- Phase 4



Example:

- Effect of laser therapy on mouse ulcer



RCTs - a checklist

- Good randomisation procedures
- patients blind to treatment
- clinicians blind to treatment
- all participants followed up
- all participants analysed in the groups to which they were randomised (intention to treat)

