

The NERDCAT Revision Project – A Resource for Clinicians and Students

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OBJECTIVE: To improve an existing resource that clinicians and students use to appraise medical studies

Before

Two PDF checklists with interspersed information

Informative but content dense (22 pages)

Traditional table of contents

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FUNDAMENTALS

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ADVANCED

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Assumes background knowledge

Were there important clinical differences between study participants and my patient (i.e. SCRAPP characteristics)?

Walls of text

Lack of or unclear double-blinding is associated with a ~13% exaggeration of the relative benefits of an intervention for dichotomous outcomes, and a 68% exaggeration of the relative benefits of an intervention for continuous outcomes, which typically leads to over-estimation (typically in favor) of the effect of the intervention.

- Adequate blinding of participants & personnel is essential to avoid bias. Inadequate blinding of participants & personnel is associated with a 13% exaggeration of the relative benefits of an intervention for dichotomous outcomes, and a 68% exaggeration of the relative benefits of an intervention for continuous outcomes.
- Statistical heterogeneity is assessed using either Cochran's Q test, or I² statistic (preferred). Cochran's Q is a yes/no test that shows statistical evidence of heterogeneity if p < 0.10 (analogous to the test for heterogeneity in meta-analysis).
- Rules of thumb (e.g. >20%) are misleading; loss-to-follow-up is significant when it is similar to or greater than the occurrence of the outcome of interest.
- If there is differential loss to follow-up, do your own rudimentary "worst-case scenario" analysis: would the results remain similar if all participants lost-to-follow-up in one treatment group had suffered the bad outcome whilst all those lost-to-follow-up in the other group had had a good outcome?
- ITT analysis (see below) cannot correct the bias introduced by differences in loss-to-follow-up between groups.
- E.g. In a trial assessing quetiapine vs placebo for adjunctive treatment of depression, discontinuation due to adverse events in the placebo, quetiapine 150 mg, and quetiapine 300 mg groups were 1%, 11%, and 18%, respectively.
- Note: One group receiving the treatment had a higher rate of discontinuation due to adverse events than the other group.
- Some situations initially thought to be "not important" may be important when evaluated with visual evaluation of differences in individual-trial point estimates & confidence intervals.
- E.g. In ROCKET-AF, INR was measured at baseline and at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100.

Structure

Content

Navigation

Jargon

Visual Learning

After

Two fillable Google Doc checklists supported by an accompanying Pressbook textbook (www.nerdcat.org)

Expanded for novice and advance users (138 pages)

Clickable table of contents, sections, and subsections

II. Randomized Controlled Trials

2. Risk of bias: Are the results internally valid?

Checklist Questions

Allocation Bias: Were patients appropriately randomized with allocation concealment?

- Checklist Questions +
- Allocation Bias: Were patients appropriately randomized with allocation concealment? +
- Blinding: Were participants, treating clinicians, outcome assessors, or investigators aware of treatment assignment during the trial? +
- Crossover bias: Did participants from the comparator group receive the intervention from the intervention group (or vice versa)? +
- Missing data and loss to follow-up (LTFU): Was follow-up complete (i.e. were all patients accounted for at the end of the trial)? +

Click-to-learn

ference between groups. However, **composite outcomes** require careful interpretation of the individual components. An outcome which consists of multiple component endpoints. For example, a cardiovascular composite may include stroke, myocardial infarction, and death.

Easy to Understand Visual Aids

