Confidence Interval

* 1. Coder

- ◯ Jen
- ◯ Rachel

* 2. Article

* 3. Journal

* 4. Design

- ◯ Parallel
- ◯ Crossover
- ◯ Other (please specify)

* 5. Sponsor

- ☐ Industry
- ☐ Government
- ☐ Professional association / foundation
- ☐ Academic Institution / department funds
- ☐ None (explicitly stated)
- ☐ Not reported
- ☐ Other (please specify)

* 6. Condition

- ◯ Cancer
- ◯ Neurological (e.g., Movement disorders, Cognitive issues)
- ◯ Pain (excluding orthopedic associated pain such as OA)
- ◯ Respiratory
- ◯ Cardiovascular
- ◯ Infectious diseases (e.g., viral and bacterial infections)
- ◯ Obesity
- ◯ Pregnancy outcomes
- ◯ Smoking cessation
- ◯ Gastro/intestinal disorders other than cancer (i.e., GERD, IBS)
- ◯ Diabetes
- ◯ Orthopedic
- ◯ Other (please specify)

7. Is the study for prevention or treatment?

- ◯ Prevention
- ◯ Treatment

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* 8. Did the authors identify a primary outcome measure?

- ◯ Yes
- ◯ No
- ◯ uncertain

notes

* 9. Did the authors identify a primary analysis or analyses (including primary outcome measure, time of comparison, groups to be compared, and statistical test used?)

- ◯ Yes
- ◯ No
- ◯ uncertain

notes

* 10. Did they identify multiple primary analyses

- ◯ Yes
- ◯ No
- ◯ N/A, no primary analysis identified
- ◯ uncertain

notes

* 11. Do authors report the confidence interval for the estimate of the treatment effect (e.g., difference between group means, difference between group proportions or percentages, treatment group odds ratio)?

- ◯ Yes
- ◯ No

* 12. Did you have to look in the Supplementary materials to find the confidence interval for question 9?

- ◯ Yes
- ◯ No
- ◯ N/A, the answer to question 9 was no

* 13. If the answer to question 9 was yes, what confidence coefficient is reported? Please fill in box below.

* 14. Does the significance level (alpha) used to declare a treatment effect significant match the confidence interval coefficient that was reported (e.g., alpha = 0.05, CI = 95%; alpha = 0.1, CI = 90%; alpha = 0.025, CI = 97.5%)

- ◯ Yes
- ◯ No
- ◯ N/A, no confidence interval was reported
- ◯ No significance level (alpha) reported for individual significance tests (this will occur if they state that the family-wise alpha was set to a certain point, but don't say what the individual alpha levels were)

NOTE: For **question 12** , if they do not specifically state something like "a p-value (or alpha) below 0.05 was considered significant", but are obviously interpreting the trial with this cut-off in mind, please assume that the alpha was set to 0.05 for the above question.

* 15. Did the authors report a confidence interval for each treatment group (including a confidence interval for the final outcome value, the change from baseline, or the percentage change from baseline, etc.)

- ◯ Yes
- ◯ No

* 16. Was the study ended early for a reason<u>other than</u> a planned interim analysis with specific stopping rules?

- ◯ Yes
- ◯ No

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* 17. Was the result of any analysis performed with a primary outcome measure not significant? (if they do not state a significance level (i.e., alpha) used to determine significance, please assume 0.05 was significant)

- ◯ Yes
- ◯ No
- ◯ N/A, no primary outcome measure identified

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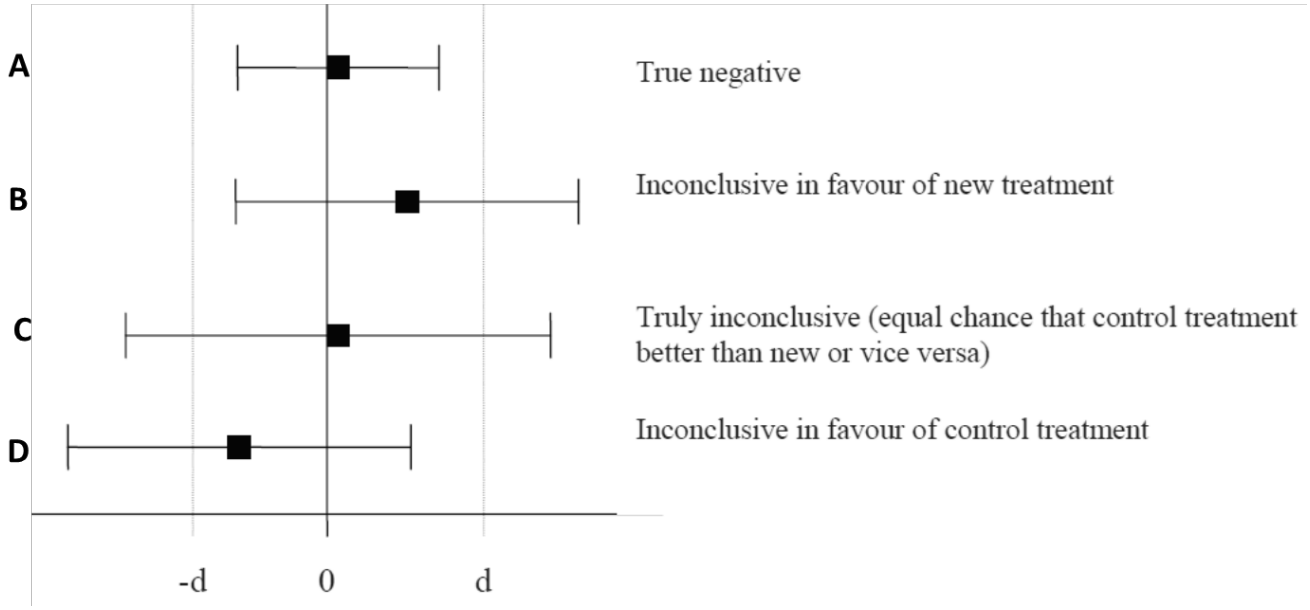
Please only answer the next set of questions if ANY analysis used to compare treatments using a primary outcome measure did NOT demonstrate a statistically significant treatment effect (if they do not state a significance level (i.e., alpha) used to determine significance, please assume 0.05 was significant). If there is a primary analysis identified, please answer the following questions using that analysis If there is more than one analysis of a primary outcome measure and none are identified as primary or there are multiple primary analyses, please answer the following questions pertaining to the first NOT SIGNIFICANT analysis for the primary outcome measure presented in the Results section that compares the treatment groups .

d represents the CMTE or the difference on which the trial was powered; control = placebo in coding manual



* 18. If the article (1) defines a clinically meaningful treatment effect (CMTE) or (2) reports the magnitude of the treatment effect that was used to justify the sample size, please indicate which of the following is true about the confidence interval for the treatment effect.

See figure above with corresponding illustrations to help clarify definitions for A-D.

Please note that CMTE is used in the below options to indicate either the author-specified CMTE or difference the study was powered on

- ◯ A. The confidence interval does NOT include the CMTE or the magnitude of the treatment effect that was used to justify the sample size (i.e., we can conclude that a clinically meaningful treatment effect can be ruled out with whatever confidence was specified (e.g., 95%))
- ◯ B. The confidence interval includes the CMTE or the magnitude of the treatment effect that was used to justify the sample size in favor of the investigational treatment, but not in favor of placebo. Thus, a clinically meaningful treatment effect in favor of placebo can be ruled out with whatever confidence was specified (e.g., 95%). It cannot be ruled out, however, that the treatment is efficacious compared to placebo.
- ◯ C. The confidence interval includes the CMTE or the magnitude of the treatment effect that was used to justify the sample size in favor of both the investigational treatment and the placebo. Thus, a clinically meaningful treatment effect cannot be ruled out in either direction (i.e., in favor of treatment or in favor of placebo)
- ◯ D. The confidence interval includes the CMTE or the magnitude of the treatment effect that was used to justify the sample size in favor of the placebo, but not in favor of the investigational treatment. Thus, a clinically meaningful treatment effect in favor of treatment can be ruled out with whatever confidence was specified (e.g., 95%), but it cannot be ruled out, however, that the treatment is worse than placebo.
- ◯ Authors provide multiple estimations of the CMTE and/ or magnitude of the treatment effect that was used to justify the sample size **AND** depending on which one is considered, the answer to this question changes. Please explain in the box provided below .
- ◯ N/A, neither the CMTE nor the treatment effect that was used to justify the sample size were reported.
- ◯ N/A, no confidence interval was reported for the treatment effect
- ◯ Uncertain, please explain in the notes box

notes

* 19. If the article reports a clinically meaningful treatment effect (CMTE) or reports the treatment effect that was used to justify the sample size, do the authors explain what the confidence intervals suggest regarding whether the trial is negative or inconclusive?

- ◯ Yes
- ◯ No
- ◯ N/A, authors do not report an CMTE or treatment effect used to justify the sample size
- ◯ N/A, no confidence interval for the treatment effect was reported
- ◯ Uncertain, please make a note

notes

* 20. If the answer to question 17 is yes, is the authors' explanation appropriate regarding whether the trial could conclusively determine that the treatment was not efficacious (e.g., You would answer yes if you concluded that the results could conclusively determine the treatment was not efficacious and so did the authors.)

NOTE: the authors may only comment on whether the trial could conclusively determine that the investigational treatment was not efficacious, and not whether the trial could rule out that the investigational treatment was worse than placebo. In this case the authors' conclusions may match yours even if they do not report as much detail as is outlined in the answers in question 12.

- ◯ Yes, the authors' conclusions match mine
- ◯ No, the authors' conclusions do not match mine
- ◯ Author discussed multiple interpretations based on different assumptions for the CMTE or magnitude of the treatment effect that was used to justify the sample size. Please explain in the box provided below.
- ◯ Uncertain
- ◯ N/A, the answer to question 17 was no or N/A

Please explain in the box below how your interpretation differs from the authors' or why you are uncertain

21. Did they report a post hoc power calculation?

- ◯ Yes (please explain below)
- ◯ No

notes