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Clinical trials with nonblinded outcome assessors have high observer bias

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A new study of randomized clinical trials found significant observer bias toward a more beneficial treatment effect in nonblinded trials when the researcher knew the treatment being given to the participant. The study is published in *CMAJ* (*Canadian Medical Association Journal*).

"Nonblinded assessors of subjective measurement scales outcomes in randomized clinical trials tended to generate substantially biased effect sizes," writes Dr. Asbjørn Hróbjartsson, The Nordic Cochrane Centre, Rigshospitalet Department, Copenhagen, Denmark, with coauthors.

Danish and French researchers conducted a systematic review of 24 randomized clinical trials with both blinded and nonblinded assessment of the treatment effects. This design enabled a direct and reliable comparison between blind and nonblind results. Sixteen trials (with 2854 patients) had subjective outcomes and were included in the final meta-analysis. Neurology, cosmetic surgery, cardiology, psychiatry, otolaryngology, dermatology, gynecology and infectious diseases were all represented.

"In some trials, conscientious nonblinded assessors may overcompensate for an expected bias in favour of the experimental intervention and paradoxically induce a bias favouring the control, whereas other trials will have fairly neutral assessors with no important bias. Thus, the degree of observer bias in trials with clearly predisposed outcome assessors is likely to be considerably higher than the mean we see here," write the authors. They suggest using blinded assessors in trials to

remove this bias.

"Failure to blind outcome assessors in such trials results in a high risk of substantial bias," conclude the authors.

More information: Research paper: www.cmaj.ca/lookup/doi/10.1503/cmaj.120744

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