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Equivalence and Noninferiority Trials

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It is sometimes desirable to compare a less expensive treatment or intervention against a treatment or intervention that is already known to be effective. In these cases, it would be unethical to expose participants to an inactive placebo. Thus, these trial designs assess whether the treatment or intervention under study (the “new intervention”) is no worse than an existing alternative (the “active control”). In equivalence and noninferiority trials, authors must prespecify a margin of noninferiority (δ), within which the new intervention can be assumed to be no worse than the active control. There are a number of methods for arriving