Randomized Controlled Trials

Margaret A. Winker and Stephen J. Lurie

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The randomized controlled trial (RCT) generally leads to the strongest inferences about the effect of medical treatments. Randomized controlled trials assess efficacy of the treatment intervention in controlled, standardized, and highly monitored settings, and usually among highly selected samples of patients. Thus, their results might not reflect the effects of the treatment in real-world settings, or in other groups of individuals who were not enrolled in the trial. Information from RCTs may thus be supplemented by results of observational studies (see , Observational Studies) as well as other types of studies.The methods of RCTs must be described in detail to

Crossover Trials

Margaret A. Winker and Stephen J. Lurie

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In a crossover trial, participants receive more than 1 of the treatments under investigation, usually in a randomly determined sequence, and with a prespecified amount of time (a) between sequential treatments. The participants and the investigators are generally to the treatment assignment (double-blinded). This experimental design is often used for evaluating drug treatments. Each participant serves as his or her own control, thereby eliminating variability when comparing treatment effects and reducing the sample size needed to detect a effect. Most considerations of parallel-design randomized trials apply. Rather than indicating which participants were assigned to which condition, the CONSORT flow

Parallel-Design Double-blind Trials

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In this study design, participants are assigned to only 1 treatment group of the study. These trials are generally designed to assess whether 1 or more treatments are superior to the others. Participants and those administering the intervention should all be unaware of which intervention individual participants are receiving ("double-blinding"). Ideally, those rating the outcomes should also be blinded to treatment assignment ("triple-blinding"). Blinded parallel-design trials are often the optimal design to compare 2 or more types of drug or other therapy, since known and unknown potentially confounding factors should be randomly distributed between intervention and control groups. The CONSORT

Equivalence and Noninferiority Trials

Margaret A. Winker and Stephen J. Lurie

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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 (#), within which the new intervention can be assumed to be no worse than the active control. There are a number of methods for arriving at