Randomized controlled trial

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Flowchart of four phases (enrollment, intervention allocation, follow-up, and data analysis) of a parallel randomized trial of two groups, modified from the CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement¹¹ A randomized controlled trial (or randomized control trial;^[2] RCT) is a type of scientific (often medical) experiment which aims to reduce bias when testing a new treatment. The people participating in the trial are randomly allocated to either the group receiving the treatment under investigation or to a group receiving standard treatment (or placebo treatment) as the control. Randomization minimises selection bias and the different comparison groups allow the researchers to determine any effects of the treatment when compared with the no treatment (control) group, while other variables are kept constant. The RCT is often considered the <u>gold standard</u> for a <u>clinical trial</u>. RCTs are often used to test the efficacy or effectiveness of various types of medical intervention and may provide information about adverse effects, such as drug reactions. <u>Random assignment</u> of intervention is done after subjects have been assessed for eligibility and recruited, but before the intervention to be studied begins.

Random allocation in real trials is complex, but <u>conceptually</u> the process is like <u>tossing a coin</u>. After randomization, the two (or more) groups of subjects are followed in exactly the same way and the only differences between them is the care they receive. For example, in terms of procedures, tests, outpatient visits, and follow-up calls, should be those intrinsic to the treatments being compared. The most important advantage of proper randomization is that it minimizes allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments.^[3]

The terms "RCT" and **randomized trial** are sometimes used synonymously, but the methodologically sound practice is to reserve the "RCT" name only for trials that contain <u>control</u> groups, in which groups receiving the experimental treatment are compared with control groups receiving no treatment (a <u>placebocontrolled study</u>) or a previously tested treatment (a <u>positive-control study</u>). The term "randomized trials" omits mention of controls and can describe studies that compare multiple treatment groups with each other (in the absence of a control group).^[4] Similarly, although the "RCT" name is sometimes expanded as "**randomized clinical trial**" or "**randomized comparative trial**", the methodologically sound practice, to avoid ambiguity in the <u>scientific literature</u>, is to retain "control" in the definition of "RCT" and thus reserve that name only for trials that contain controls. Not all randomized <u>clinical trials</u> are randomized *controlled* trials (and some of them could never be, in cases where controls would be impractical or unethical to institute). The term **randomized controlled clinical trials** is a methodologically sound alternate expansion for "RCT" in RCTs that concern <u>clinical research</u>;^{[5][6][7]} however, RCTs are also employed in other research areas, including many of the <u>social sciences</u>.