Randomization

Randomization in trials is the act of assigning treatment units (usually persons) to treatment via a random process.

As noted in the essay on *random*, the expectation is that randomization will produce treatment groups having comparable entry and baseline characteristics. If one wants a "guarantee" of comparability, one has to resort to stratification or matching.

Although the expectation is usually satisfied, there is no "guarantee" of comparability. Large differences in the treatment groups can occur by chance in the same way that one can have a fortuitous or disastrous run at the blackjack table. Hence, an aberrantly small p-value for a given baseline variable does not, by itself, provide evidence of a "randomization breakdown".

The primary purpose of randomization is to avoid treatment-related selection bias. The notion of bias free assignment is at the heart of any comparative trial and chance via randomization represents the best available tool for achieving bias-free assignment.

randomization *n* - 1. An act of assigning or ordering that is the result of a **random process** such as that represented by a sequence of numbers in a table of **random numbers** or a sequence of numbers produced by a **random number generator**, eg, the **assignment** of a **patient** to **treatment** using a **random process**. 2. The process of deriving an order or sequence of items, specimens, records, or the like using a **random process**. rt: **haphazardization**, **quasirandomization** ***Usage note***: Do not use as a characterization except in settings where there is an explicit or implied mathematical basis for supporting the usage, as discussed in usage notes for **random** *adj*. Use other terms implying less rigor than implied by **randomization**, such as **haphazardization**, **quasirandomization**, or **chance**, when that basis is not present or evident.

Other related terms

randomization breakdown *n* - A **breakdown** (defn 2) in **randomization** (defn 1) because of failure to follow the **treatment assignment schedule** as determined by a given **random process**, eg, as a result of using assignments in an order other than the one indicated. ***Usage note***: A randomization process should not be characterized as having broken down without evidence of departures from the assignment schedule. It is a mistake to equate a small **p-value**, as obtained from a **randomness test**, as proof of a breakdown. Large departures (hence, small p-values) can occur by chance alone with random processes. See also **randomness test**.

simple random sample *n* - 1. A **random sample** that arises from a sampling scheme such that every **element** or **unit** in the **population** of interest has the same **probability** of selection. 2. A random sample arising from **unrestricted randomization**. rt: **stratified random sample**

simple randomization *n* - **complete randomization**

complete randomization *n* - **Randomization** not constrained by restrictions, such as those imposed by **blocking**. syn: simple randomization, unrestricted randomization

restricted randomization *n* - **Randomization** involving restrictions, such as in **blocked randomization**; not **complete randomization**. ant: **complete randomization**, unrestricted randomization

stratified randomization *n* - A **treatment assignment process** using **stratified random treatment assignment**. ***Usage note***: See **stratified-blocked randomization**.