

What Does Randomisation Mean?

Clinical trial design

Clinical trials are used in medical research to investigate the safety and effectiveness of some form of intervention for an illness, whether in the form of a drug, a device, or a procedure. Usually subjects are assigned at random to two or more different treatment groups. This can be to compare two or more different treatments, or sometimes a treatment versus no treatment. Generally a trial aims to answer a question, such as whether a treatment is helpful, and it does so by comparing an 'end point' such as symptom control or survival in people allocated to the different treatment groups.

Bias

There are numerous factors that can affect whether the question addressed by a trial is accurately and honestly answered. These factors are said to 'bias' the results. Bias can be introduced at many levels such as by including different patients in the two groups, by treating patients and recording results differently, or by being selective in interpreting results. At each level there are factors we can know about (for example the age, gender and severity of disease in our subjects) and factors that can not be known (such as differences in how our bodies handle medications and unknown co-existing illness). By randomly allocating patients to the different treatment groups, all of these factors (known and unknown) are evenly distributed between the groups, helping to minimise bias at the treatment allocation stage.

How do we randomise?

Randomisation can be as straight forward as rolling a dice or flipping a coin but these methods may result in uneven numbers in the groups and have no record of them until they are documented. Opening a numbered envelope with the treatment allocated to that patient written inside is popular but near the end of the trial may allow people to guess which group is most likely to come up next, potentially introducing bias. One of the most common methods is to use a computer program to allocate patients to group at random.

Why is randomisation important in clinical trials?

Clinical trials are critical for advancing medicine and improving treatment for patients. The science of clinical trials has evolved to ensure they are properly conducted and have useful results. There is scope for researchers to influence their results by the way they conduct their trial, whether inadvertently or on purpose. Trials are often very expensive and there may be the potential for pressure on researchers from their hospital / institution, funding bodies, or companies involved. Essentially randomisation means that the medical team does not choose which treatment group the subject is allocated to, eliminating bias at this stage. This is one of many steps in the design of clinical trials to ensure they accurately and honestly answer the questions asked.

Author: Dr Ross Hunter, Cardiology Research Fellow
Dr Richard Schilling, EP
Endorsed by: Dr Matthew Fay, GP
Dr Andrew Grace, EP
Mrs Jayne Mudd, Arrhythmia Nurse Specialist
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