

# N-OF-1 RESEARCH (SINGLE-CASE EXPERIMENTAL DESIGNS)

While there are certainly a plethora of scholarly articles and definitions regarding an N-of-1, also known as the Single-Case Experimental Designs, in a nutshell, I prefer the simplicity of the (pertinent part) definition given by Wikipedia. In essence, a single-case experimental design is the study of one patient (or subject) and that one individual comprises the entire case study. David H. Barlow and Michel Hersen stated quite succinctly introducing their book, *Single Case Experimental Designs*, when they said: “The individual is of paramount importance in the clinical science of human...change.” (p.1).

Wikipedia’s definition states (in pertinent part): An N-of-1 trial is a clinical trial in which a single patient is the entire trial, a single case study. A trial in which random allocation can be used to determine the order in which an experimental and a control intervention are given to a patient is an N-of-1 randomized controlled trial. The order of experimental and control interventions can also be fixed by the researcher.

This type of study has enabled practitioners to achieve experimental progress without the overwhelming work of designing a group comparison study. It can be very effective in confirming causality.

It is both my professional and personal belief that science advances quickest with an N-of-1. My belief comes from an understanding that there are possibly many potential medical cures that will never make it to market because the authorization process for testing multiple-subject/multiple-patient clinical trials and control groups is so rigid and arduous that some scientists never get past the dauntingly scrutinizing Institutional Review Board (IRB) process to receive IRB approval so as to test their discovery. On the one hand, IRB’s exist to ensure patient/subject safety; on the other hand IRB’s impose extremely rigid parameters on tests to be performed on human patients/subjects.

Again, to keep everything understandable, I will use the simplest scientific description of Single-Case Experiments, which are commonly structured using an A-B-A-B design, where A represents the baseline and B represents the intervention. With the A-B-A-B design, “[T]he

special feature that distinguishes the methodology is the provision of some means of rigorously evaluating the effects of interventions with the individual case.” Further, “[I]t is a mistake to discount them [single-case designs]....” (Kazdin, Alan E., 1982, *Single-Case Research Designs; Methods for Clinical and Applied Settings*, pp. 3-4; [text added for clarity].)

To conclude, here are a few of the more notable single-case experimental designs (or N-of-1), which have advanced medical science at light-speed:

Steve Ludwin and Tim Friede, (snake anti-venom): <https://www.theguardian.com/environment/2018/feb/11/poison-pass-the-man-who-became-immune-to-snake-venom-steve-ludwin> and <https://www.outsideonline.com/2395803/snakebite-antivenom-tim-friede>;

Alexander Fleming (penicillin) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4520913/>; and

Jonas Salk (Polio vaccine) <https://www.biography.com/scientist/jonas-salk>.