Non-Inferiority: Numeric Outcome

Objective: Determine whether one group is inferior to another, within a certain margin.

A researcher wants to see if a new drug is non-inferior to the current standard-of-care for participants with peripheral artery disease (PAD). The researcher plans a double-blind study with participants being equally randomized into one of two arms. One gets the current standard-of-care while the other receives the newly developed drug. The outcome of interest is the number of steps a participant can take in a ten-minute time span. From the literature the standard deviation for the number of steps taken is 25. The researcher wants to determine the sample size they will need to determine if the new drug is non-inferior to the standard of care. The new drug will be considered non-inferior if the mean number of steps is not more than 12 steps lower than standard of care with 80% power and a significance level of 5%.

Required Information	Inputs
What is the desired power for the test?	80%
At what significance level do you want to test your hypothesis?	5%
What is the standard deviation of the response variable?	25
What is the non-inferiority margin?	12
Is your hypothesis one-sided or two-sided?	One-sided
What will the ratio of samples be in the intervention group to the control group?	1:1

Significance level (alpha) 5%

Power (1-beta) 80%

Standard deviation of outcome 25

Standard deviation of response from literature

Non-inferiority limit, d 12

Non-inferiority margin

Calculate sample size

Sample size required per group 54

Total sample size required 108

A total sample size of at least 108 is necessary, meaning 54 participants in each group for a total of 108.

Example using the Sealed Envelope Statistical Power (Sample Size) Calculator:
Sealed Envelope Ltd. 2012. Power calculator for continuous outcome non-inferiority trial. [Online] Available from: https://www.sealedenvelope.com/power/continuous-noninferior/ [Accessed Mon Jun 08 2020].