

Equivalence Test: Numeric Outcome

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

A researcher wants to see if a new drug is equivalent to the current standard-of-care for participants with Type 2 Diabetes Mellitus. The researcher plans a double-blind study with participants being equally randomized into one of two arms. One arm gets the current standard-of-care while the other arm receives the newly developed drug. The outcome of interest is the participants hemoglobin A1C (HbA1c) percent after 2 weeks. From the literature the standard deviation for HbA1c percent is 2%. The researcher wants to determine the sample size they will need to determine if the new drug is equivalent to the standard of care. The new drug will be considered equivalent if the HbA1c percent is not more than 1% different 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?	2
What is the equivalence margin?	1
Is your hypothesis one-sided or two-sided?	Two-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 2

Equivalence limit, d 1

Standard deviation of response from literature

Equivalence Limit

Sample size required per group **69**

Total sample size required **138**

A total sample size of at least 138 is necessary, meaning 69 participants in each group for a total of 138.

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-equivalence/> [Accessed Mon Dec 14 2020].