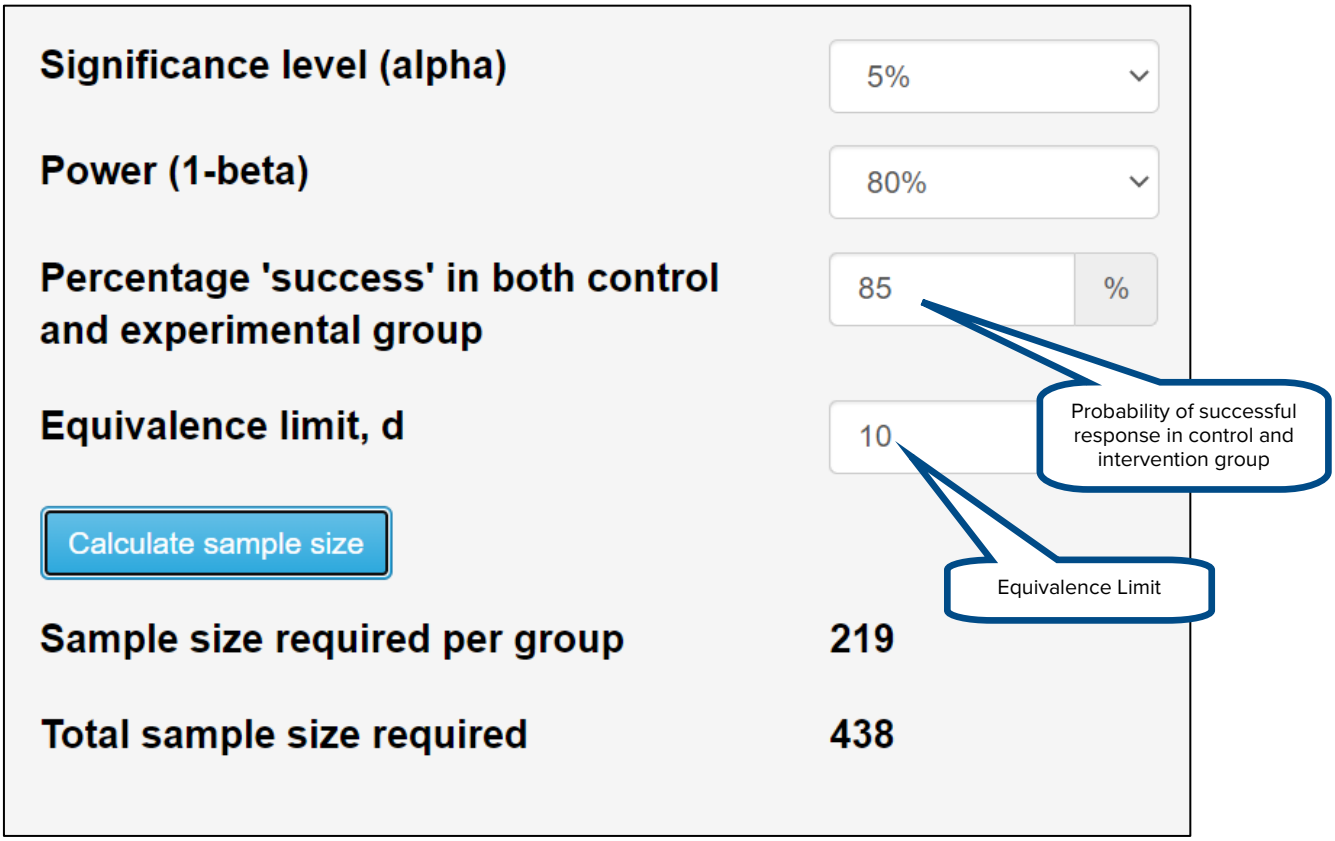
UCDAVIS HEALTH | Clinical and Translational Science Center

Equivalence Test: Binary 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 patients with renal failure. 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 response rate from the intervention after 1 year. The current standard-of-care has an 85% response rate, and the researcher is expecting a similar response rate for the new drug. The literature has shown that other similar drugs would be deemed equivalent to the standard-of-care if the new drug has a response rate no more than 10 percentage points difference than the response rate in the standard arm. The researcher needs to determine what sample size they will need for their experiment to have 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%
Success probability of the control group?	85%
What is the equivalence margin?	10%
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



A total sample size of at least 438 is necessary, meaning 219 participants in each group for a total of 438.

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