**Sample size calculation**

**Sample size calculation formula:**

**n= 2x (Z1-α/2 + Z1-β)2 x design effect**

**(standardized difference)2**

Where :

* ***Z1-α/2***= Z score for 95% confidence level = 1.96
* ***Z1-β*** = Z score for the power of study . If the power for the study is **85%** then Z1-β =1.0364
* ***Standardized difference:*** is the standardized difference between the outcomes of the two groups. being studied. This can be estimated from the following formula:

**Standardized difference= (p1 - p2)**

**√ˉp(1-ˉp) ------------🡪 ˉp= (p1 + p2)**

**2**

**Where:**

**p1= The proportion of outcome in the case (or experimental group)**

**P2 = the proportion of outcome in the control groups**

**ˉp= the mean proportion of the two groups, i.e. average proportion of the two groups.**

* ***Design effect:***

This is associated with the stage of sampling. Multistage sampling requires a larger than usual sample size. The design effect can be obtained from literature with the same study design.

**Sample size considering the proportion of patients lost to follow up:**

Because this is a clinical trial, we need to put into consideration the proportion of patients lost to follow up. Therefore, the more accurate sample size calculation will be as follows:

n considering lost to follow up = n .

1-proportion of lost to follow up

*The proportion of lost to follow up, or refusal rate, can be obtained from the literature of similar studies.*

**Difference between type 1 error and type 2 error:**

**Type 1 error: (α)**

The error of rejecting the null hypothesis when it is true.

**Type 2 error: (β)**

The error of failing to reject the null hypothesis.

**Type 3 error:**

Rejecting the null hypothesis when it should actually be rejected, but for the wrong reasons.

**Associations between types of error and other statistical variables:**

**Level of significance:**

It is the probability of having type 1 error. *(P value)*

**Power of study:**

The probability that the test will reject the null hypothesis when the null hypothesis is actually false and should be rejected. (1-type 2 error)

*It is equal to 1- β.*