

Calculating sample size

Please read through the following study examples below. Using this study information and a copy of Altman's nomogram provided, estimate the sample size required for two equally sized groups in order to identify a clinically significant difference in mean scores between the two groups.

Example Study 1: Comparing means in independent groups using the Independent t-test

Objective of study: to examine the effectiveness of aciclovir suspension (15 mg/kg) for treating 1-7 year old children with herpetic gingivostomatitis lasting less than 72 hours.

Study Design: Randomised, double-blind placebo controlled trial with 'treatment' administered five times a day for 7 days.

Main outcome for determining sample size: Duration of oral lesions.

Sample Size Question: How many children would be needed for this study in order to have a 90% power of detecting a 2.5 day difference in duration of oral lesions between the trial and control groups at the 5% level of significance?

The authors assume that the standard deviation of duration of oral lesions is approximately 5 days.

1. In the space below, state the formula that should be used to calculate sample size in Altman's nomogram for the above study.

2. Using the correct formula for Altman's Nomogram, calculate the standardised difference for the above study and then use Altman's nomogram to estimate the required sample size – show your workings below.

3. Write out your Power Statement below.

Example Study 2: Comparing two proportions in independent groups using Chi-Square test.

Objective of study: to compare the effectiveness of corticosteroid injections with physiotherapy for the treatment of painful stiff shoulder.

Study Design: Randomised controlled trial (RCT) in which patients are randomly allocated to 6 weeks of treatment, these comprising either a maximum of three injections or twelve 30 minute sessions of physiotherapy for each patient.

Main outcome measure for determining sample size: treatment is regarded as successful after 7 weeks if the patient rates themselves as having made a complete recovery or as having much improvement (on a six-point Likert scale).

Sample Size Question: How many patients are required in order to have an 80% power of detecting a clinically important difference in success rates of 25% between the 2 groups at the 5% level of significance?

The authors assume a success rate of 40% in the group having the least successful treatment.

1. In the space below, state the formula that should be used to calculate sample size in Altman's nomogram for the above study.
2. Using the correct formula for Altman's Nomogram, calculate the standardised difference for the above study and then use Altman's nomogram to estimate the required sample size – show your workings below.
3. Write out your Power Statement below.