

Table 5: Important factors to consider when performing sample size calculations

Terminology	Definition
Hypothesis Test	An example of a null hypothesis is: there is no difference (in the main outcome measure) between treatments A and B. The researcher wants to be able to reject the null hypothesis and to show that differences in the treatments' outcomes are not due to chance i.e. to conclude instead that there is a difference between the two treatments, as specified by the alternative hypothesis.
Significance Level (P Value)	Significance level is the probability cut-off (usually 0.05 or 5%) used, and is generally designated as two-tailed (i.e. an effect of sufficient magnitude will cause the null hypothesis to be rejected, regardless of the direction of this effect). It is chosen in advance of performing the test depending on how much safeguard is required against the possibility of erroneously rejecting the null hypothesis when it is true.
Power	Power is the probability of rejecting the null hypothesis when the alternative hypothesis is true. It measures the ability of a test to reject the null hypothesis when it should be rejected. At a given significance level, the power of the test is increased by having a larger sample size. 80% is usually considered to be the minimum level.
Effect size	The effect size quantifies the difference between two or more groups. It is a measure of the difference in the outcomes of the experimental and control groups i.e. a measure of the effectiveness of the treatment.
Minimal Importance Difference (MID)	The MID can be defined as the “smallest meaningful change score” or “the smallest (absolute) difference in score which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patient's management. Therefore differences in scores smaller than the MID are considered not important independent of their statistical significance”

	<p>http://www.jrheum.com/subscribers/07/03/463.html</p> <p>If the MID is underestimated, a study may be larger than necessary; if it overestimated, it is difficult to ascribe any clinical significance to any observed effect that is smaller than the chosen MID.</p>
Primary Outcome Measures	Sample size estimation should be based on the primary outcome measure but if there is more than one primary outcome then the largest sample size should be chosen.
Response Rate	After the sample size has been calculated, it will need to be increased depending on the expected response rate (i.e. the proportion of patients on whom full follow-up data can be expected). This can be estimated from previous publications or a pilot study. The sample size should be adjusted to cater for predicted loss to follow up (e.g. if required sample size is 65 per group but follow-up is estimated at 80%, 82 per group would need to be recruited).