Sample Size Calculations and Analysis Plan

A calculation of sample size to be used is required. This may be omitted only if the study is a pilot designed to gain information with which to make further progress e.g. design the main trial. An appropriate sample size, neither too big nor to small, is needed to ensure that the study will be ethical, by providing scientific value and not wasting anyone's time by being involved with it.

The sample size calculation needs to be explicit, so that transparency is assured. It is not sufficient just to give the sample-size resulting from a power calculation, even if this has been done by an eminent statistician. The calculation needs to show, as well as the significance level (and power), other input parameters, e.g. mean difference to be detected, and assumed standard deviation. (The actual parameters required will of course depend on the nature of the study). Also detail of the way the calculation was done needs to be shown. Just the relevant formula will do. (If the calculation was done by a computer program, sufficient information needs to be given, so that it is clear what has occurred, in detail, to someone who does not have access to that particular program.)

In other words sufficient detail is required so that the calculation can be reproduced by someone else. (It is not unknown for simple mistakes to have occurred in performing the calculation.) Also the values of the parameters used need, of course, to be realistic. This is something that other subject specialists can check.

It is important that the calculation ties in with the objectives of the study. It is therefore necessary that the analysis plan provided shows that this is so.

Some Points on Randomisation

It is important that randomisation is done well. Statistical procedures assume random samples.

The randomisation process should be specified clearly in advance and it should be made clear that the allocation of subjects to treatment groups can not be altered by anyone.

It is often useful to randomise in 'blocks' in order maintain equal group sizes. Randomisation computer programs and randomisation services exist.