Patient Selection and Distribution Between Arms

Were the right patients included in the trial?

Patient selection may be important to enable a study to detect a difference in the primary endpoint between study arms.

For example, a randomised clinical trial of an antidepressant for fatigue in patients with advanced cancer required patients to score 4 or more out of 10 for fatigue before entering the trial. This is important, because the problem needed to be there in order to potentially be improved by the intervention. Look at the study inclusion and exclusion criteria.

Were all patients treated identically other than for the intervention in both arms?

Ideally, other supportive care measures and contact with study staff should be the same in all arms of an intervention study, to minimise the risk of introducing bias through factors other than the intervention.

Patient groups are balanced for important prognostic factors

The distribution of important prognostic factors between patients in study arms is shown in a table of patient characteristics, often 'Table 1'. Prognostic factors may be unevenly distributed by chance alone. Assess whether imbalance may explain the direction of study results.