
1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)?

2. Was the study described as double blind?

3. Was there a description of withdrawals and dropouts?

Scoring the items:

Either give a score of 1 point for each “yes” or 0 points for each “no”. There are no in-between marks.

Give 1 additional point if:

For question 1 the method to generate the sequence of randomisation was described **and** it was **appropriate** (table of random numbers, computer generated, coin tossing, etc).

and / or:

If for question 2 the method of double-blinding was described **and** it was **appropriate** (identical placebo, active placebo, dummy, etc).

Deduct 1 point if:

For question 1 the method to generate the sequence of randomisation was described **and** it was **inappropriate** (patients were allocated alternately, or according to date of birth, hospital number, etc).

and / or:

For question 2 the study was described as double-blind but the method of blinding was **inappropriate** (e.g., comparison of tablet vs. injection with no double dummy).

Guidelines for Assessment

1. Randomisation

A method to generate the sequence of randomisation will be regarded as appropriate if it allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers or alternation should not be regarded as appropriate.

2. Double-blinding

A study must be regarded as double-blind if the word double-blind is used. The method will be regarded as appropriate if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed, or if in the absence of such a statement, the use of active placebos, identical placebos or dummies is mentioned.

3. Withdrawals and drop outs

Participants who were included in the study but did not complete the observation period or who were not included in the analysis must be described. The number **and** the reasons for withdrawal must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, this item must be given no points.
