Classification of Eligible Trial Reports

Trial reports included in the „Database of clinical trials in haematological malignancies“ are classified according to the Cochrane Collaboration eligibility criteria that were agreed upon in 1992. They were published in 1994, in Section 5 of the Cochrane Handbook (1) and are now included as Appendix 5b.1 of the Cochrane Reviewers Handbook.

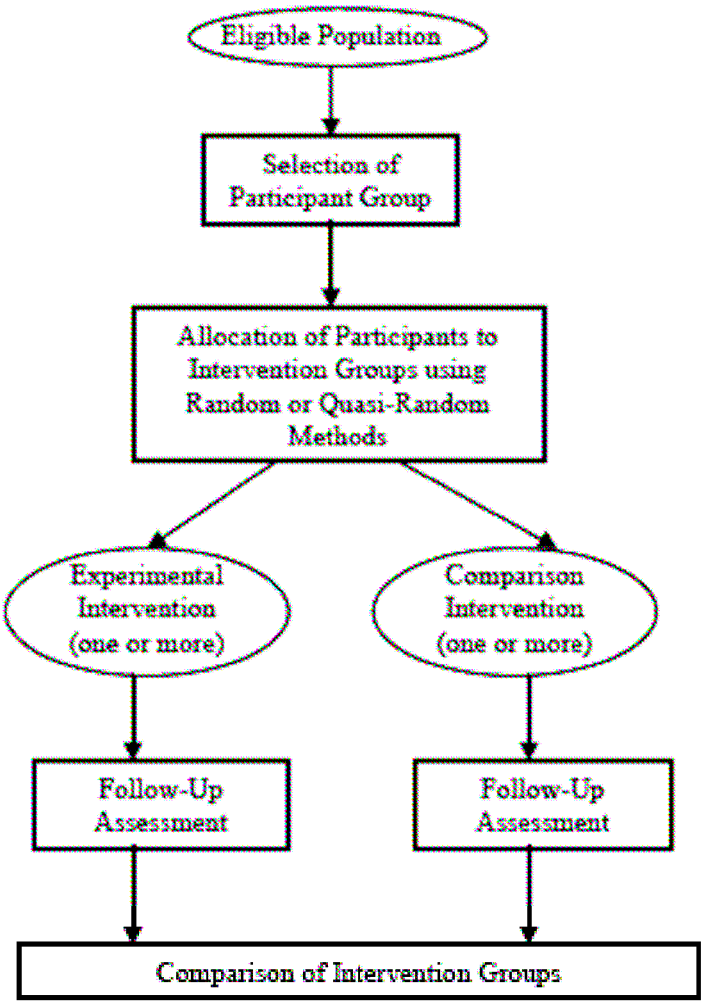
A trial is eligible if it is judged - on the basis of the best available information – that the patients included in the trial were definitely or possibly assigned prospectively to one of two (or more) alternatives of treatment/medication with random allocation or a quasi-random method of allocation.

Trial reports are classified according to the degree of certainty that random allocation was used to form the comparison group: if it is random allocation then the trial is classified as “RCT” (randomized controlled trial). All other eligible trial reports are classified as “CCT” (controlled clinical trial).

The Cochcrane Collaboration supports the US National Library of Medicine (NML) to identify and classify RCT and CCT for MEDLINE. Newly identified RCT and CCT are used to update CENTRAL, the “Cochrane Collaboration’s CENTRAL Register of Controlled Trials”.
Moreover Cochrane contributors (e.g. volunteers, journal editors) identify trials using both electronic and handsearching methods.
These trials are used for the preparation of systematic reviews. “Cochrane reviews are based on the best available information about healthcare interventions. They explore the evidence for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc) in specific circumstances.” (2)

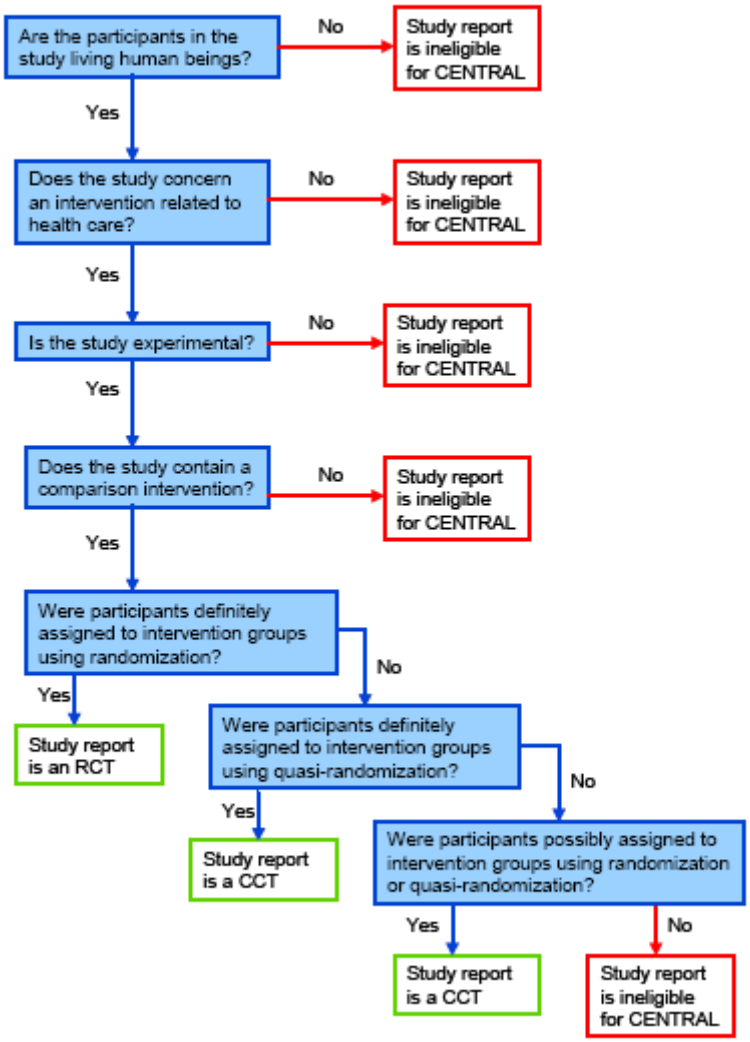
The figure shows the typical steps in the conduct of an RCT or CCT (2):

Figure 1
Steps in conducting a randomized or quasi-randomized clinical trial



The figure shows the sequence of decisions to be made in identifying and classifying a trial for CENTRAL (2):

Figure 2
Decision tree for identification and classification of RCTs and CCTs



Criteria for RCT and CCT (2):

1. An RCT or CCT must compare interventions in living human beings.
2. An RCT or CCT must be related to health status, health care or health research.
3. An RCT or CCT must be experimental.
4. A RCT or CCT must contain two or more interventions.
5. A RCT must have participants definitely assigned to interventions by randomization.
6. A CCT must have participants assigned to interventions by either a) quasi-randomization or b) possible randomization or quasi-randomization.
7. A CCT may have participants definitely assigned to interventions by quasi-randomization.
8. If the method of assignment to treatment was definitely not random and not quasi-random, the study is not an RCT or CCT and is not eligible for CENTRAL.

Literature

1.Chalmers I, Dickersin K, Chalmers TC. Getting to grip with Archie Cochrane's agenda. BMJ 1992; 305:7868.
2. Training Hand Search Guide New Handsearch Guide version for pdf Training Manual for Handsearchers