

Quality criteria for RCTs and CCTs

| QUALITY CRITERIA   | DONE   | NOT CLEAR  | NOT DONE   |
|--|--|--|--|
| (a) Concealment of allocation  | Unit of allocation was institution, team or professional and any random process explicitly described, e.g. use of random number tables, OR unit of allocation was patient or episode of care and some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes used | Allocation procedure not described explicitly OR unit of allocation was patient or episode of care and reported use of 'list' or 'table', 'envelopes' or 'sealed envelopes' for allocation | Use of alternation, such as reference to case record numbers, dates of birth, day of the week or any other such approach OR unit of allocation was patient or episode of care and reported use of any allocation process that is entirely transparent before assignment, such as an open list of random numbers or assignments OR allocation was altered by investigators, professionals or patients |
| (b) Follow-up of professionals (protection against exclusion bias)               | Outcome measures for $\geq 80\%$ of professionals randomised (Do not assume 100% follow-up unless stated explicitly)   | Not specified  | Outcome measures for $< 80\%$ of professionals randomised  |
| (c) Follow-up of patients or episodes of care.                                   | Outcome measures for $\geq 80\%$ of patients randomised or patients who entered the trial (Do not assume 100% follow-up unless stated explicitly)  | Not specified  | Outcome measures for $< 80\%$ of patients randomised or patients who entered the trial   |
| (d) Blinded assessment of primary outcome(s) (protection against detection bias) | Stated explicitly that primary outcome variables were assessed blindly OR outcome variables are objective, e.g. length of hospital stay, drug levels assessed by a standardised test   | Not specified  | Outcomes not assessed blindly  |
| (e) Baseline measurement   | Performance or patient outcomes measured prior to the intervention, and no substantial differences present across study groups   | Baseline measures not reported, or unclear whether baseline measures are different across study groups   | Differences at baseline in main outcome measures likely to undermine the post-intervention differences, e.g. differences between groups before the intervention similar to those found post-intervention   |
| (f) Reliable primary outcome measure(s)  | Two or more raters with agreement $\geq 90\%$ or kappa $\geq 0.8$ OR outcome assessment is objective, e.g. length of hospital stay, drug levels assessed by a standardised test  | Reliability not reported for outcome measures obtained by chart extraction or collected by an Individual   | Two or more raters with agreement $< 90\%$ or kappa $< 0.8$ .  |
| (g) Protection against contamination   | Allocation by community, institution or practice and unlikely that control group received the Intervention   | Professionals allocated within a clinic or practice and possible that communication between experimental and control group professionals could have occurred                               | Likely that control group received the intervention, e.g. cross-over trials or if patients rather than professionals were randomised   |
| Risk of bias:  | Class I (Low risk) = all criteria checked as "Done"  | Class II (Moderate risk) = all criteria checked as "Done" or "Not clear"   | Class III (High risk) = one or more criteria checked as "Not done"   |

Legend: Except criterion (a) random process, the quality criteria apply for RCTs and CCTs. Source: Bero L, Grilli R, Grimshaw JM, Mowat G, Oxman A, Zwarenstein M: Cochrane Effective Practice and Organisation of Care Review Group (Cochrane Group Module). In: Bero L, Grilli R, Grimshaw JM, Mowat G, Oxman A, Zwarenstein M. Oxford: The Cochrane Library (Issue 3); 2001