9.2 Quality assessment of studies of the effects of interventions

The Randomised Controlled Trial (RCT)

is the gold standard for assessing the effects of interventions. The RCT has a control group who do not get the intervention of interest. The changes in health (or other) outcomes for the control group serve as a signal of what would have happened in the intervention group if they had not received the intervention. Hence it is the comparison between outcomes for the intervention group and the control group after the intervention that provides us with information about the true effects of the intervention.

It is therefore of great interest to us to determine whether outcomes for intervention and control groups could have been affected by factors other than the intervention. There are a number of key factors that are thought to have the potential to systematically bias outcomes.

Selection bias
Participants in intervention and control groups should be drawn from the same population.

Allocation bias
Participants should be randomly allocated to intervention and control groups.

Concealment
The person who allocated participants to intervention or control groups should do so without information that could affect allocation. This would occur if participants were enrolled in the study before they were allocated to groups and if there was no opportunity for the allocation officer to predict or manipulate the assignment of group allocation.

Participant blinding
Ideally participants should be unaware of whether they are in an intervention or control group. While this is relatively easy to achieve if the intervention is a drug or a well designed sham treatment, it is virtually impossible when the intervention is ‘delivered’ by the participant as would occur for example if the intervention was an exercise program.

Therapist/Interventionist blinding
Ideally those delivering the intervention should be unaware of whether they are delivering intervention or control conditions. While this is relatively easy to achieve if the intervention is a drug or a well designed sham treatment, it is virtually impossible when...
the intervention is ‘delivered’ by the therapist, again, as would occur for example if the intervention was an exercise program

Outcome assessor blinding

The person assessing outcomes should be unaware of a participant’s group assignment. This may be complicated if the intervention resulted in visible indicators (for example, surgical scars), but in most cases can be included in the RCT design.

Attrition bias

This would occur if participants drop out of either the intervention group or the control group. If data are those who remain in the study is all that is available for analysis, it is not possible to know the true ‘average’ effect of the intervention and control conditions. Some arbitrary rules have been tabled by the scientific community that specify how many participants can drop out before the potential bias threatens the validity of the outcomes.

Methods of analysis and verifying data

Data analysis can include all the data that is available for analysis including ‘worst case’ estimates for drop outs, or it can be based only on data for those who remain in the study (per protocol analysis). When participants change groups during a study (for example if they demand and are given the intervention even though they were allocated to the control group), data can be analysed using intention to treat analysis (ITT) which assigns all data for analysis to the group dictated by the original allocation. ITT analysis is expected in high quality RCTs. In addition, data should be reported that enables cross checking results through replication of analysis.

Examples of high quality critical appraisal instruments for RCTS

Most RCT appraisal checklists address these key sources of bias. An example of such a checklist is the PEDro scale. This provides reviewers with an 11 item checklist (10 of which are ‘scored’) and a decision rule for each item that guides decisions about whether or not the quality criterion is met.

Another example is the Cochrane Collaboration Risk of Bias assessment instrument. The decision rules are less unambiguous than those that support the PEDro scale, so reviewers might have to consider how to define the methods used in making decisions on some of the items.

Many other checklists exist. Whichever is chosen for critical appraisal of reports included in the review, it should conform to the standards expected of high quality critical appraisal instruments.