

What study designs should be included in an EPOC review and what should they be called?

Randomised trials are often not available to address questions about the effects of health system interventions and implementation strategies. Consequently it is often appropriate to include a broader range of study designs in EPOC reviews.

Review authors should consider their specific review question in deciding which study designs to include and provide some justification or rationale for the decision.

Consideration should generally be given to four types of study designs:

- Randomised controlled trials (RCTs)
- Non-randomised controlled trials (NRCTs)
- Controlled before-after CBA (studies)
- Interrupted time series (ITS) and repeated measures studies

There may be a good reason for not including all of these study designs. For example CBA and ITS studies may add little to what is known when sufficient evidence is available from randomised trials. On the other hand, there are seldom good reasons for including other study designs. Inclusion of uncontrolled before-after studies or cross sectional studies is strongly discouraged. It is difficult, if not impossible to attribute causation from such studies. Review authors wanting to include study designs other than the four listed above should provide a compelling reason for doing so.

Randomised trials

Randomisation ensures that participants in each comparison group should differ only in their exposure to the intervention. All other factors that might affect the outcomes of interest should be distributed equally, provided there is a large enough sample size – whether they are known and measured or not.

Randomisation of individual recipients of care is not appropriate if the intervention is targeted at health care providers or groups of people. Under these circumstances providers or clusters (groups) of people should be randomised. Trials where groups of people are allocated (or where individual health professionals are randomised and outcomes are measured in patients) are called cluster-randomised trials. In these trials the assumption of independence is violated; because people within any one cluster are more likely to respond in a similar manner (e.g. treatment of patients by a single physician is likely to be more consistent than treatment by several physicians). This lack of independence means larger sample sizes are required to adjust for the clustering effect and analysis should be undertaken at the cluster level or using special analytic techniques. In addition, when relatively few clusters are randomised other factors that might affect the outcomes of interest may not be distributed equally. This should be taken into consideration when assessing the risk of bias. Consequently, we suggest including criteria to assess whether baseline outcome measurements were similar and whether baseline characteristics were similar. (See EPOC risk of bias criteria.)

Non-randomised trials

These are trials where the investigators allocated participants to the different groups that are being compared using a method that is not random. These studies have a greater risk of bias than randomised trials (See Cochrane Handbook for Systematic Reviews of Interventions, www.cochrane-handbook.org, Section 8.9.1.)

Controlled before-after studies

In controlled before-after studies decisions about allocation to the different comparison groups are not made by the investigators. Outcomes of interest are measured in both intervention and control groups before the intervention is introduced and again after the intervention has been introduced. These studies have a high risk of bias because there may be unidentified differences between the intervention and control groups that may affect changes in the outcome measure.

Interrupted time series designs (ITS)

ITS studies can provide a method of measuring the effect of an intervention when randomisation or identification of a control group are impractical. Multiple data points are collected before and after the intervention and the intervention effect is measured against the pre-intervention trend. There is no way to assess the impact of any concurrent events on the outcomes of interest.

Other study designs

Because other study designs generally provide little, if any, reliable evidence of the effects of interventions we discourage including them in EPOC reviews. Review authors wanting to include other study designs should provide clear and compelling reasons for doing so.

Terminology and exclusions

We suggest using consistent terminology for different types of studies in EPOC reviews to avoid confusion and to help to ensure clear definitions and understanding. We also suggest excluding controlled studies with only one intervention or control site and ITS studies that do not have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. These suggestions are summarised in the table below.

Suggested terminology, abbreviations and exclusions

| Suggested terms | Notes | Definition | Exclusions |
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| Randomised controlled trial (RCT) OR randomised trial | | An experimental study in which people are allocated to different interventions using methods that are random. | Studies with only one intervention or control site We recommend only including cluster randomised trials, non-randomised cluster trials, and CBA studies with at least two intervention sites and two control sites. |
| Non-randomised controlled trial (NRCT) OR non-randomised trial | Instead of controlled clinical trial . EPOC reviews do not include clinical trials (and RCTs are also CCTs). Also instead of ' quasi-randomised controlled trials ', which is used to mean different things by different authors. | An experimental study in which people are allocated to different interventions using methods that are not random. | In studies with only one intervention or control site the intervention (or comparison) is completely confounded by study site making it difficult to attribute any observed differences to the intervention rather than to other site-specific variables. |
| Controlled before-after study (CBA) | Instead of controlled before and after . | A study in which observations are made before and after the implementation of an intervention, both in a group that receives the intervention and in a control group that does not. | |
| Interrupted-time-series study (ITS) | Use study instead of design or analysis . | A study that uses observations at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time. | Studies that do not have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention |

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| Repeated measures study (RMS) | Not in the EPOC checklist | An ITS study where measurements are made in the same individuals at each time point. | |
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For other study designs, we recommend using the terms in the algorithm below.

Study designs for evaluating the effects of healthcare interventions

(Shaded boxes are study designs that should be considered for inclusion in EPOC reviews.)

