

What study designs can be considered for inclusion 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, but not always appropriate to include a broader range of study designs in EPOC reviews.

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

- Randomised trials
- Non-randomised trials
- Controlled before-after studies
- Interrupted time series studies and repeated measures studies

There may be good reasons for not including all of these study designs. For example, controlled before-after and interrupted time series studies may add little to what is known when sufficient evidence is available from randomised trials. However, there may sometimes be compelling reasons for including study designs other than those listed above; for example, cohort studies, regression discontinuity designs, or higher order interaction 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 should consider their specific review question in deciding which study designs to include and provide a compelling justification or rationale for this decision in the review proposal form and protocol. Where review authors propose including study designs other than randomised trials, they also need to show: that there is likely to be added value by including these other study designs; that the review team has the technical expertise to deal with any additional types of studies; and that such studies exist in relation to their review question (examples of such studies should be cited in the review proposal form and protocol). Review authors should be aware that increasing the range of study designs included in a review is likely to add considerable time to the review and that they need to have sufficient resources available to manage this additional work. The final decision on whether to include additional study designs rests with the EPOC editors.

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

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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 [Suggested risk of bias criteria for EPOC reviews](#))

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](#), 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 studies

Interrupted time series 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.

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 and exclusions

Suggested terms	Notes	Definition	Exclusions
	Avoid using abbreviations		
Randomised trial	Instead of randomised controlled trial* , which is redundant.	An experimental study in which people are allocated to different interventions using methods that are random.	Studies with only one intervention or control site For cluster randomised trials, non-randomised cluster trials, and controlled before-after studies, we

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Non-randomised trial	Instead of controlled clinical trial . EPOC reviews do not include clinical trials (and randomised trials are also controlled trials). 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.	recommend only including studies with at least two intervention sites and two control sites. 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	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.	For controlled before –after studies Studies in which data collection is not contemporaneous in study and control sites during the pre- and post-intervention periods of the study and / or does not use identical methods of measurement
Interrupted time series study	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
Repeated measures study		An interrupted time series study where measurements are made in the same individuals at each time point.	

* Although “randomized controlled trial” is commonly used, it is ambiguous what the adjective “controlled” adds, other than confusion for people who do not already understand the meaning of “randomized controlled trial”; and a commonly used abbreviation (RCT), which is convenient for authors and people who like jargon, but not for readers (like most abbreviations).

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Most English speakers are likely to know the word “trial” and understand that in this context it means “the act of trying, testing, or putting to the proof”. “Randomise”, on the other hand, is a word that few English speakers are likely to understand. However, it is the defining feature of this research design and has a clear meaning in this context: “to select in a random manner in a trial, to reduce bias”.

One could argue that including the noun “control” would help to clarify what is randomised in a randomised trial, but this is more likely to confuse people who do not already understand what a randomised trial is, than it is to help them understand that randomized means that participants in the trial were assigned to comparison groups using a chance process.

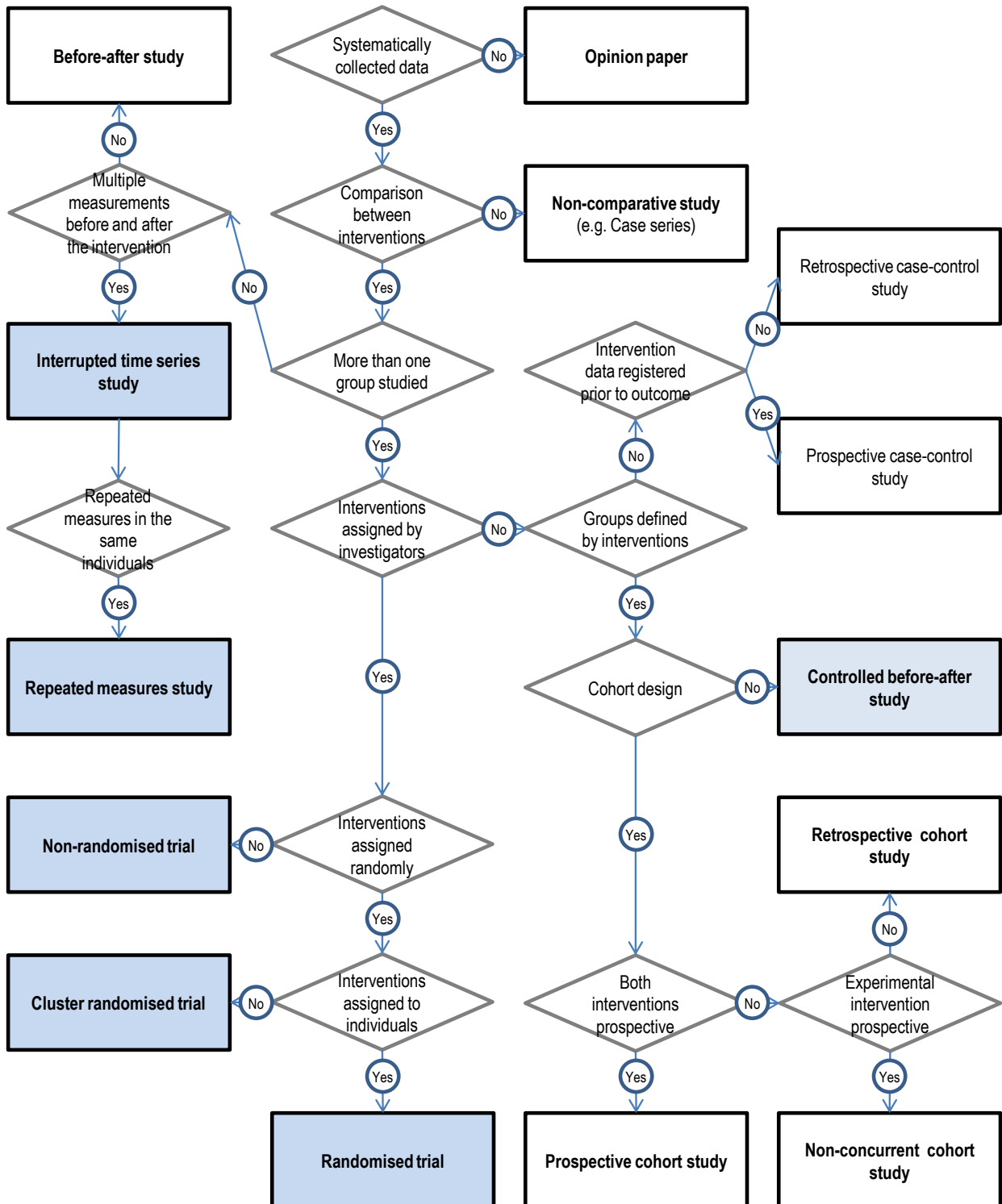
Adding a second adjective, “controlled”, which is more commonly used, is probably even more confusing. English speakers are likely to know the word “control”, but it has several different meanings, and few are likely to understand what “controlled” means in this context. In fact, it is unclear whether it means that there are comparison groups or it means that the trial is controlled by the investigators. Both uses of the word “controlled” are superfluous at best.

For other study designs, we recommend using the terms in the algorithm below.

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Study designs for evaluating the effects of healthcare interventions

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



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