

DO YOU WANT YOUR DOCTOR TO BE AN EXPERT? – THE EXPERTISE-BASED TRIAL DESIGN

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In an expertise-based (EB) randomised trial, clinicians (e.g., surgeons) agree to carry out only one of the comparison interventions, with which they feel more competent or experienced. Patients in an EB trial are randomized to a clinician, which thereby defines the intervention they will receive. In contrast, in a conventional trial, patients are randomized to an intervention, and the same clinicians are then responsible for executing either intervention accordingly.

The EB design avoids so-called differential-expertise bias associated with clinicians having greater competence on one technique compared to the other, and interventions are now carried out by clinicians who have greater expertise on the procedures assigned to all their patients. This probably facilitates recruitment of clinicians and leads to fewer protocol deviations, and there may also be ethical advantages. A disadvantage, however, is that the EB design is potentially less efficient because of confounding of clinicians with treatment.

We have considered the relative efficiency of the EB and conventional trial designs, assuming that expected patient outcomes depend on the assigned intervention, and on the clinician's expertise with either or both of the comparison treatments. We illustrate the EB analysis using a large randomized trial of two alternative types of surgery for tibial fractures. Expertise of participating surgeons was measured according to experience with either or both interventions.

The EB design was originally proposed for surgical trials, but it is also potentially applicable whenever the likely success of an intervention depends on the skill of the clinician involved, or if it is not feasible for the same person to be involved in both arms of a study, such as in trials of clinical education programs.