Surgeons' and methodologists' perceptions of utilising an expertise-based randomised controlled trial design: A qualitative study

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Abstract

Background: Randomised controlled trials (RCTs) are widely recognised to be the most rigorous way to test new and emerging clinical interventions. When the interventions under study are two different surgical procedures, however, surgeons require to be trained and sufficiently proficient in the different surgical approaches to take part in such a trial. It is often the case that even where surgeons can perform both trial surgical procedures, they have a preference and/or have more expertise in one of the procedures. The expertise-based trial design, where participating surgeons only provide the procedure in which they have greatest expertise, has been proposed to overcome this problem. When expertise-based designs should be best used remains unclear; such approaches may be more suited to addressing specific questions. The aim of this qualitative study was to improve understanding about the range of views surgeons and methodologists have regarding the use of the expertise based RCT design. Methods: Twelve individual interviews with surgeons and methodologists with experience of surgical trials were conducted. Interviews were semi-structured and conducted face-to-face or by telephone. Interviews were audio-recorded, transcribed and analysed systematically using an interpretive approach. Results: Both surgeons and methodologists saw potential advantages in the expertise-based design particularly in terms of surgeons participation and in trials where the procedures being evaluated were significantly different. The main disadvantages identified were methodological (e.g. the potential for surgeons carrying out one arm being systematically different) and operational (e.g. the need to “transfer” patients between surgeons with potential consequences for the surgeon/patient relationship). Conclusion: This study suggests that the expertise-based trial design has significant potential to increase surgeon participation in trials in some settings. Particularly suitable conditions include those where the surgical procedures under evaluation are substantially different, where they are routinely delivered by different health professional/surgeons with clear proficiencies in each; and contexts in which a multiple surgeon model is operating and trust between the patient and surgeons can be suitably protected. Several logistical and methodological concerns remain to be addressed, however, before the design is likely to be more widely adopted.