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Title **Recruitment to Randomized Trials: Strategies for Trial Enrolment and Participation Study. The STEPS Study**

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Aim

To identify factors associated with good and poor recruitment to multicenter trials.

Conclusions and results

While not producing sufficiently definitive results to make strong recommendations, this work suggests that future trials should consider the different needs at different phases in the life of trials and place greater emphasis on *conduct* (the process of actually doing trials). This implies learning lessons from successful trialists and trial managers, with better training for issues relating to trial conduct. The complexity of large trials means that unanticipated difficulties are highly likely at some time in every trial. The reference model developed in this project needs to be further considered in other similar and different trials to assess its robustness. These and other strategies aimed at increasing recruitment and making trials more successful need to be formally evaluated for their effectiveness in a range of trials. In the 114 trials found in our epidemiological review, less than one-third recruited their original target within the time originally specified, and around one-third had extensions. Factors observed more often in trials that recruited successfully were: having a dedicated trial manager, being a cancer or drug trial, and having interventions only available inside the trial. The most commonly reported strategies to improve recruitment were newsletters and mailshots, but it was not possible to assess whether they were causally linked to changes in recruitment. The analyses of the case studies suggested that successful trials were those addressing clinically important questions at a timely point. See Executive Summary link at www.hta.ac.uk/project/1564.asp.

Recommendations

The work here suggests that people undertaking trials ought to think about the different needs at different phases in the life of trials, and place greater emphasis on *conduct* (the process of actually doing trials). This implies learning lessons from successful trialists and trial managers, with better training for issues relating to trial conduct. The complexity of large trials means that unanticipated difficulties are highly likely at some time in every trial. Our research suggested that successful trials were those flexible and robust enough to adapt to unexpected issues. Arguably, the trialists should also expect agility from funders within a proactive approach to monitoring ongoing trials.

Methods

See Executive Summary link at www.hta.ac.uk/project/1564.asp.

Further research/reviews required

Three important areas for further research arise. First, an extension of our review of case studies to trials with different recruitment patterns (including 'failures') may help clarify whether the patterns seen in the 'exemplar' trials differ, or are similar. Second, our reference model was based around a single large trial with the unusual feature that patients were mainly unconscious. Before use as an audit tool for diagnosing and/or addressing management factors, the reference model needs to be considered in other similar and different trials to assess its robustness. Finally, these and other strategies aimed at increasing recruitment and making trials more successful need to be formally evaluated for their effectiveness in a range of trials.

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