Quasi-randomisation in emergency setting trials: a recipe for selection bias, or an efficient approach?

Mark Corbett (Research Fellow)
Thirimon Moe-Byrne (Research Fellow)
Sam Oddie (Consultant Neonatologist)
Bill McGuire (Professor of Paediatrics & Child Health)

THE UNIVERSITY of York
Centre for Reviews and Dissemination

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Objectives

- Compare the prevalence of important baseline imbalances between groups (which may have been a consequence of selection bias) in quasi- and truly-randomised emergency or urgent care trials

- Is there any evidence to suggest that any possible benefits of using true randomisation might be offset in other areas of trial recruitment, such as slower recruitment rates, or the recruitment of less representative populations?

Why use quasi-randomisation?

- Potential to avoid any delay in treatment
- Recruit more patients - delays from proper randomisation may result in some eligible patients not being recruited in time (implications for sample size, and external validity)

Why might selection bias be less common in emergency or urgent care trials than in other trials?

- Very limited (pre-intervention) time to judge prognosis
- Investigators cannot delay allocation of treatment (delaying allocation is one of the two key mechanisms of introducing selection bias)

Methods

- Emergency setting reviews in the Cochrane Library
- At least one trial using true randomisation (RCT) and one trial using quasi-randomisation (qRCT)
- Possible selection bias: assessed baseline imbalances in pre-specified prognostic indicators (with pre-specified magnitudes of difference)
- Trial accrual and recruitment data were also recorded

Results

- 7 reviews, 27 trials: 16 RCTs, 11 qRCTs
- Baseline imbalance in 4 RCTs (25%) and 2 qRCTs (18%)
- 3 of the 4 RCTs had adequate methods of allocation concealment (though all were small: ≤ 50 patients per arm)

- Limited trial recruitment data reported: in 2 reviews qRCTs associated with faster accrual (x2 and x3) than the equivalent RCTs. In 2 reviews there was little or no indication of differences in accrual rates

Conclusions

- Review did not find any evidence that quasi-randomisation results in selection bias more often than true randomisation in emergency settings

- High risk of bias judgements for quasi-randomised studies should therefore not be assumed in systematic reviews of emergency setting interventions

- Results suggest that chance imbalances affecting trial results may also be an important issue to be aware of (use of minimisation or stratification methods may prove to be difficult or impossible)

- Early view, open-access article now published in Research Synthesis Methods: *Randomization methods in emergency setting trials: a descriptive review.* DOI: 10.1002/jrsm.1163