Trials within Cohorts (TwiCs)

Trials within Cohorts (TwiCs) is an innovative approach to research that combines the strengths of observational research (cohorts) and experimental research (the randomised trial).

The traditional approach to randomised trial design requires the creation of a bespoke infrastructure to identify, recruit and retain participants and obtain outcomes. At the trial end, all is disbanded. Instead of creating bespoke infrastructures for each trial, the TwiCs embeds multiple trials within a single cohort infrastructure.

The most commonly cited TwiCs approach is the ‘cohort multiple’ RCT (cmRCT) design [Relton et al, 2010]. In the cmRCT design participants enrol in an observational cohort with regular outcome measurement. This provides a framework for the implementation of multiple RCTs. For each RCT embedded in the cohort, a random selection of RCT-eligible patients is contacted and offered the intervention. Outcomes of patients randomly allocated to the intervention group are compared to outcomes of RCT-eligible patients not randomly allocated to the intervention, who receive only usual care.

TwiCs designed studies that compare interventions to usual care often take a ‘patient-centred’ approach and try to replicate informed consent as it would be applied in clinical care. This means that patients are only told about interventions if (and when) they have access to them (Relton et al, 2010).

There is growing use of the approach (Relton et al, 2015; Relton et al, 2017). An extension to CONSORT Reporting guidelines for Trials Using Cohorts and Routinely Collected Data are currently being developed (Kwakkenbos et al, 2018).

We hold short Introduction to TwiCs courses [link], meetings on TwiCs topics [link to TwiCs efficiency and analysis day] and have a TwiCs research group [link]. For more information contact c.relton@qmul.ac.uk or b.nickoll@qmul.ac.uk

Specific topics of our work include:

- Informed Consent
- Efficiency and Analysis
- Reporting Guidelines
- Ethics
- Recruitment

References

