

# 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**. This has obvious efficiencies.

What is now known as the TwiCs approach was first described in the BMJ in 2010 as the '[cohort multiple' RCT \(cmRCT\) design. Relton & Nickol et al](#). 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 those randomly allocated to the intervention group are compared to outcomes of RCT-eligible patients not randomly allocated to the intervention, who receive usual care.

TwiCs style studies that compare interventions to usual care often take a '**patient-centred' approach** to informed consent - replicating 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. This approach has been refined by [Young-Afat et al, \(2016\)](#)

There is [growing use of the approach](#), and an extension to CONSORT Reporting guidelines for Trials Using Cohorts and Routinely Collected Data are currently being developed ([Kwakkenbos et al, 2018](#)).

Members of our TwiCs methodology group regularly hold talks as well as one day [Introduction to TwiCs courses](#) at the Pragmatic Clinical Trials Unit at Queen Mary University of London, UK.

Our most recent international meetings were [Symposium on the Efficiency and Analysis of TwiCs, \(2019\)](#) and [Symposium on the Ethics of TwiCs, \(2017\)](#)

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## Specific topics of our work include:

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