The stepped wedge cluster randomised trial: rationale, design, analysis and reporting

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The stepped-wedge cluster randomised trial (SW-CRT) is a novel research study design that is increasingly being used in the evaluation of service delivery type interventions. The SW-CRT is a type of randomised trial in which clusters are randomised to a date at which they initiate the intervention under evaluation. The design involves random and sequential crossover of clusters from control to intervention, until all clusters are exposed.

It is a pragmatic study design which can reconcile the need for robust evaluations with political or logistical constraints. Whilst not exclusively for the evaluation of service delivery intervention it is particularly suited to evaluations that do not rely on individual patient recruitment. The SW-CRT design has the potential to be more powerful than the simple parallel cluster trial, in this talk however we show that contrary to popular opinion the efficiency depends on the intra cluster correlation (ICC) - i.e. the correlation between any two observations within the same cluster.

Unless the clusters are very large, any increase in the ICC will tend to have a detrimental increase on the precision of the SW study. However, whereas the power available in a conventional cluster trial plateaus with increasing cluster size, this is not the case in the SW-CRT.

In a SW-CRT more clusters are exposed to the intervention towards the end of the study than in its early stages. This implies that the effect of the treatment will be confounded with any underlying temporal trend. We show how sample size calculations and analysis must make allowance for both the clustered nature of the design and the confounding effect of time.

Finally whilst an extension to the Consort statement does not yet exist for the SW-CRT, we outline some recommended additional reporting items.