

# The stepped wedge trial cluster randomised trial (SW-CRT)

A potentially robust research design for evaluations of policy interventions

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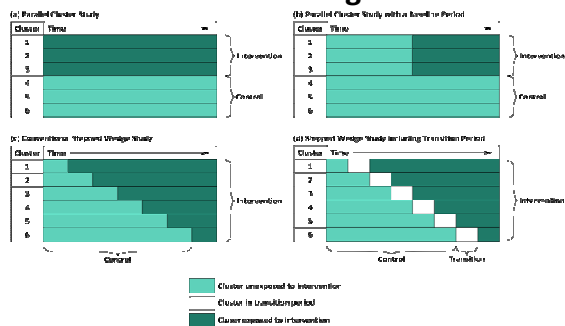
## What is a SW-CRT?

- Modification of cross-over design:
  - All clusters start in control
  - Clusters (or groups of clusters) cross to intervention at randomly assigned times until all have received intervention
  - Outcome typically observed at each time point

STEPS (Cluster or Group of Clusters)	Time					
	1	2	3	4	5	6
1	Exposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention
2	Exposed to intervention	Exposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention
3	Exposed to intervention	Exposed to intervention	Exposed to intervention	Unexposed to intervention	Unexposed to intervention	Unexposed to intervention
4	Exposed to intervention	Exposed to intervention	Exposed to intervention	Exposed to intervention	Unexposed to intervention	Unexposed to intervention
5	Exposed to intervention	Exposed to intervention	Exposed to intervention	Exposed to intervention	Exposed to intervention	Unexposed to intervention

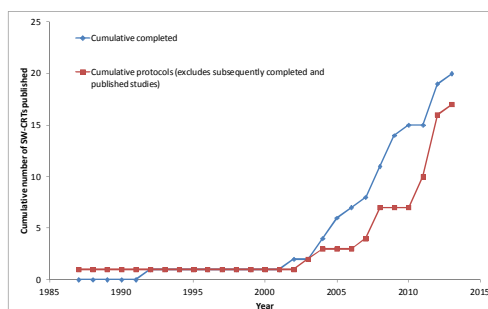
Exposed to intervention      Unexposed to intervention

## How the SW-CRT relates to other cluster designs



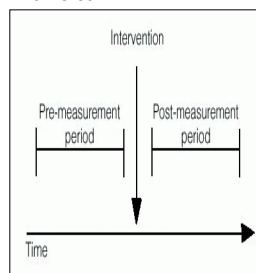
Hemming K, Lilford R, Gilling AJ. Stepped-wedge cluster randomised controlled trials: a generic framework including parallel and multiple-level designs. Stat Med. 2015 Jan 30;34(2):181-96.

## Systematic review of SW-CRTs

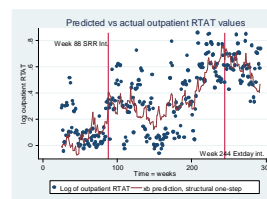


## The SW-CRT provides a better level of evidence than alternatives

At worst...



At best....



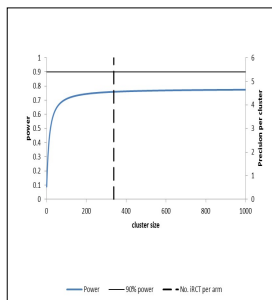
## The SW-CRT can be an appealing study design from a logistical perspective

- Provides a phased implementation;
- Can be very helpful when it is not possible to roll-out the intervention to all clusters simultaneously;
- (But, can achieve this using a parallel CRT)

## The SW-CRT can have social appeal

- All clusters ultimately receive the intervention;
  - (But not all participants)
- This can help acquire willingness to participate from more clusters.

## The SW-CRT can be a more powerful design



- The SW-CRT will provide more power when:
  - The number of clusters is small;
  - The ICC is large;
  - The cluster size is large.

## Reasons to be cautious about using the SW-CRT

- What if the intervention is inferior to the control condition (will be rolled-out to all clusters):
  - Is the intervention likely to pose any **harm**?
  - Can the intervention be **removed**?
- All regulatory / site approvals need to be in place before the trial can start.
- Complexity of analysis:
  - Risk of bias if time effects not allowed for in an appropriate way.

## Recommendations

- SW-CRT a pragmatic study design which reconciles the need for robust evaluations with political or logistical constraints.
- The design likely provides a much higher level of evidence than a before and after study, or an interrupted time series analysis.
- But, it does have disadvantages and the parallel design should be used where feasible.

## Why use the SW-CRT in the PITHIA Trial?

- Because there are only 22 kidney units:
  - It was unlikely that the desired power could be achieved with a parallel CRT.
- Social acceptability desirable:
  - If some clusters refuse to participate in a design which they would not receive the intervention would mean the trial would not be feasible.

## Interested in hearing more...

The screenshot shows the website for the Pragmatic Clinical Trials Unit at Queen Mary University of London. The page title is "Current Developments in Cluster Randomised Trials and Stepped Wedge Design". The page content includes a description of the meeting, which will consist of short talks, poster presentations, and discussions about new perspectives for the design, the analysis, and the reporting of cluster and stepped wedge designs. It also mentions a short workshop led by Kafa Hemming and Monica Tufjarud on the CONSORT extension for stepped wedge trials. The location is Queen Mary University of London, and the dates are November 30<sup>th</sup> 2017. The registration and cost is £30 including lunch. A link to register for the event is provided, and contact information for Emma Croyal is given for further information.

Queen Mary University of London

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### Current Developments in Cluster Randomised Trials and Stepped Wedge Design

This meeting will consist of a series of short talks, poster presentations and discussions about new perspectives for the design, the analysis, and the reporting of cluster and stepped wedge designs. As part of the meeting there will be a short workshop led by Kafa Hemming and Monica Tufjarud on the CONSORT extension for stepped wedge trials which is currently being developed.

**LOCATION:** Queen Mary University of London

**DATES:** November 30<sup>th</sup> 2017

**REGISTRATION AND COST:** £30 including lunch

Please register for this event [here](#).

For further information, please contact [Emma Croyal](#).

## Coming soon....

- The CONSORT extension for the SW-CRT
- To be published in 2018