



## PRAGMATIC RANDOMISED TRIAL DESIGNS FOR EVALUATING HEALTH POLICY AND PRACTICE CHANGE INTERVENTIONS

MACH and Monash Partners in conjunction with ViCBiostat are conducting 3 days of workshops to assist policy makers, clinician researchers, early career researchers and biostatisticians understand the options and merits of various pragmatic randomised designs to evaluate the impact of health policy and practice change interventions.

Particular attention will be paid to the stepped wedge design, which couples rigorous scientific evaluation of the effect of an intervention with policy or practice implementation at scale.

**Day 1 & 2:** Design, conduct, analysis and reporting of pragmatic stepped-wedge and related cluster randomised trial designs

*Target audience: clinical & health services researchers, trialists and biostatisticians*

**Day 3:** The stepped-wedge and related cluster randomised trial designs: tools for evidence-based policy and practice (overview)

*Target audience: clinicians and health policy makers as well as researchers*

We are delighted to announce two international guest presenters Prof Karla Hemming (UK) and A/Prof Monica Taljaard (Canada) along with our local experts in the field Prof Andrew Forbes, Dr Jessica Kasza and A/Prof Joanne McKenzie.



**Prof Karla Hemming PhD**

Institute of Applied Health Research  
Public Health, Epidemiology and  
Biostatistics  
University of Birmingham



**A/Prof Monica Taljaard**

Senior Scientist, Clinical Epidemiology Program  
Ottawa Hospital Research Institute  
Associate Professor, Epidemiology and  
Community Medicine, University of Ottawa

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FRI NOV 22  
& MON NOV 25  
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PRECINCT

Further details to come.  
Questions? Please contact:  
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## PRAGMATIC CLUSTER RANDOMISED TRIAL DESIGNS FOR EVALUATING HEALTH POLICY AND PRACTICE CHANGE INTERVENTIONS

21-25 November 2019

Cluster randomised trials are being increasingly used in clinical and public health research when individual randomisation is not possible, either for feasibility reasons, because the intervention is necessarily delivered at the cluster rather than individual level, or due to concerns about “contamination” across individuals. A range of possible cluster randomised trial designs exist, each with their own set of advantages and disadvantages for answering particular types of research questions. We present two workshops discussing these designs, with different emphases:

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### Workshop 1 (21-22 November 2019) 9am-5pm

#### Design, conduct, analysis and reporting of pragmatic stepped-wedge and related cluster randomised trial designs

This workshop will cover the fundamental components of cluster randomised trials and introduce key elements in their sample size planning, analysis and reporting, together with consideration of within-cluster correlation structures. Detailed discussion of the relative merits of the conventional parallel-arm cluster trial design, the stepped wedge design and the cluster crossover design will be provided and supplemented with case studies and the use of a web-based app to facilitate core understanding and sample size planning. Because the underlying principles are common to all of the designs, the presentation will be in the form of general principles followed by detailed discussions of each of the designs. All methods will be demonstrated via case studies and tutorial-style exercises.

The program over the two days will include:

- Introduction to cluster randomised designs and their different forms (parallel, stepped wedge, crossover)
- Sample size and power requirements and methods, including the use of a web-based RShiny app
- Comparative statistical efficiency of the different designs
- Methods of analysis for general cluster designs and specific considerations for the different designs
- Practical suggestions for mitigating bias
- Recent developments in design and methods
- Reporting guidelines for cluster randomised trial designs and specific elements for each form of design

#### Who should attend?

The workshop is designed for clinical & health services researchers, trialists and biostatisticians who have an interest in understanding, designing, conducting or analysing cluster randomised trials.

**Materials:** Participants will be provided with electronic copies of slides and hard copies of worksheets. Participants should have access to a laptop for use of the web-based sample size app, but no statistical software is required.

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## Workshop 2 (25 November 2019) 9am-5pm

### The stepped wedge and related cluster randomised trial designs: Tools for evidence-based policy and practice

This workshop will provide a broad and non-technical overview of the use of cluster randomised trial designs for assessing health policy and practice change interventions. Particular attention will be placed on the stepped wedge design which, when appropriately designed, is able to couple rigorous scientific evaluation of the effect of an intervention with policy or practice implementation at scale.

The workshop will include:

- An introduction to different types of cluster randomised trials useful for the evaluation of health policy interventions
- Discussion as to when different trial designs are appropriate, with focus on the stepped wedge design
- Non-technical overview of the main ingredients and requirements for designing, conducting and analysing cluster trials
- Review and discussion of published examples of policy and practice change trials
- A series of invited case studies describing policy or practice change interventions and their assessment. In addition to presentation of the proposed or existing interventional studies by the invited health/policy researchers, there will be expert and audience interaction concerning:
  - The suitability of cluster randomisation for the research question
  - Consideration of the various cluster randomised designs that could be used and aspects needed for their planning
  - Hints and tips about potential conduct of the trials
- A panel discussion about the merits of different types of cluster randomised trials for health policy and practice change

### Who should attend?

This workshop is presented in a non-technical manner and is appropriate for health policy makers, health service managers, clinicians and health researchers.

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***These workshops are offered by the Victorian Centre for Biostatistics (VICBiostat) with generous support from the Melbourne Academic Centre for Health (MACH) and co-sponsorship from Monash Partners and the Australian Clinical Trials Alliance (ACTA).***

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Registration: <https://www.trybooking.com/BFIDS>

### Venue:

University of Melbourne  
Lecture Theatre 2, Basement  
221 Bouverie St, Carlton, Melbourne 3053

### Contact Details:

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