0289 CLUSTER RANDOMISED TRIALS IN INJURY RESEARCH: A HOW-TO GUIDE

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10.1136/ip.2010.029215.289

Introduction Are you thinking about conducting a cluster randomised trial (CRT) but feel unsure about what design issues you must consider? Do you read published CRTs and wonder if they were properly conducted? If so, this workshop is for you.

Background CRTs involve the random allocation of existing groups of individuals to intervention and control groups. They are particularly suited to group-level interventions commonly used for injury prevention, such as mass media campaigns or clinic- or school-based education. However, CRTs are more complex to design, implement and analyse than are individually randomised trials. Investigators must understand these complexities to successfully design and conduct CRTs.

Objectives After this 90-min interactive workshop, participants will be able to:

1. Justify use of a CRT design.
2. Decide who should consent to participation, when additional input from cluster members is required, and how to address refusals and withdrawals.
3. Address risks for selection, attention, dilution and information bias unique to CRTs.
4. Identify an appropriate intracluster correlation coefficient and apply it to sample size estimation.
5. Recognise the need to take clustering into account in data analysis.

Approach Workshop coordinators will provide brief overviews of key methodological concepts. Participants will work in small groups, facilitated by workshop coordinators, to apply these concepts to trials proposed by participants and facilitators, or already published. An easy-to-use spreadsheet for estimating required sample size will be provided. Several laptops will be available; each participant is encouraged to bring a laptop and an idea for a CRT.