Design and Sample-Size Issues for Cluster-Randomized Trials:
Can We Do Better Than Hand-Waving???

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DISCLAIMER

- I don't claim to be an expert in the design, analysis, and power and sample-size calculation for cluster-randomized trials (CRTs).

- What you are about to see is more akin to a travelogue of my process in learning the basic concepts of CRTs, important design considerations, sample-size calculation and finding available resources for CRTs.

- *I will point you at the experts …*
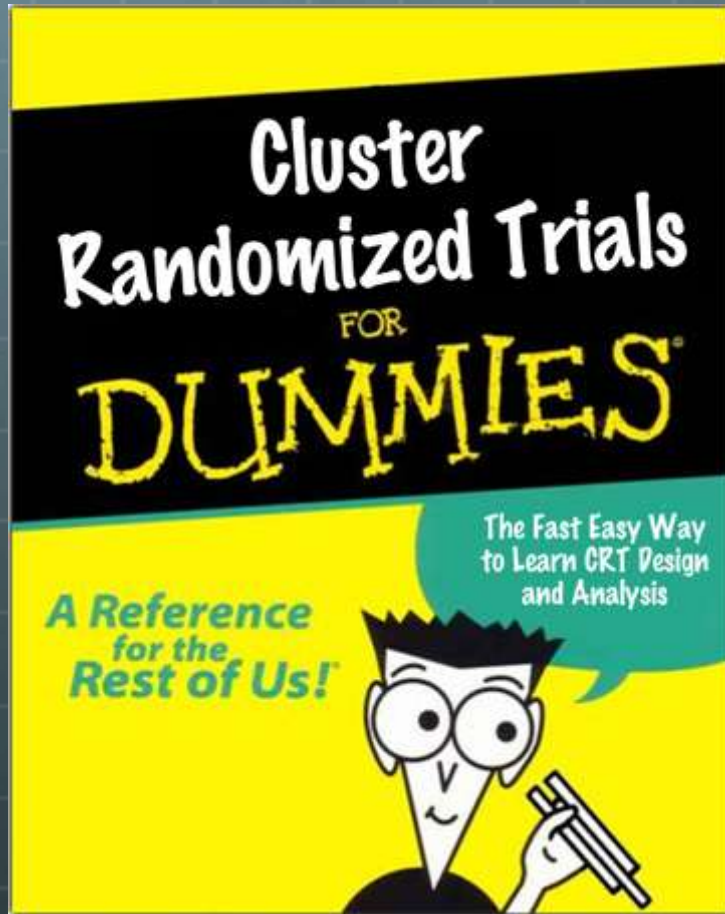
Learning Objectives

I want you to walk out of here with knowledge of:

- a basic understanding of cluster randomized trials,

- what are the big issues in designing and analyzing CRTs, and

- where do you go to learn more and get the software tools you need to do sample size planning for CRTs.
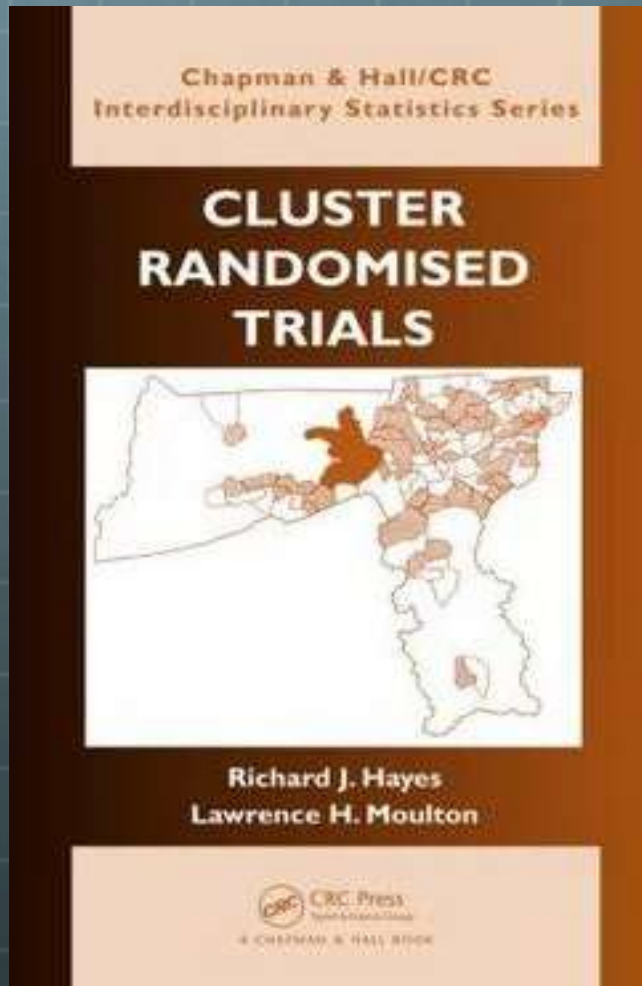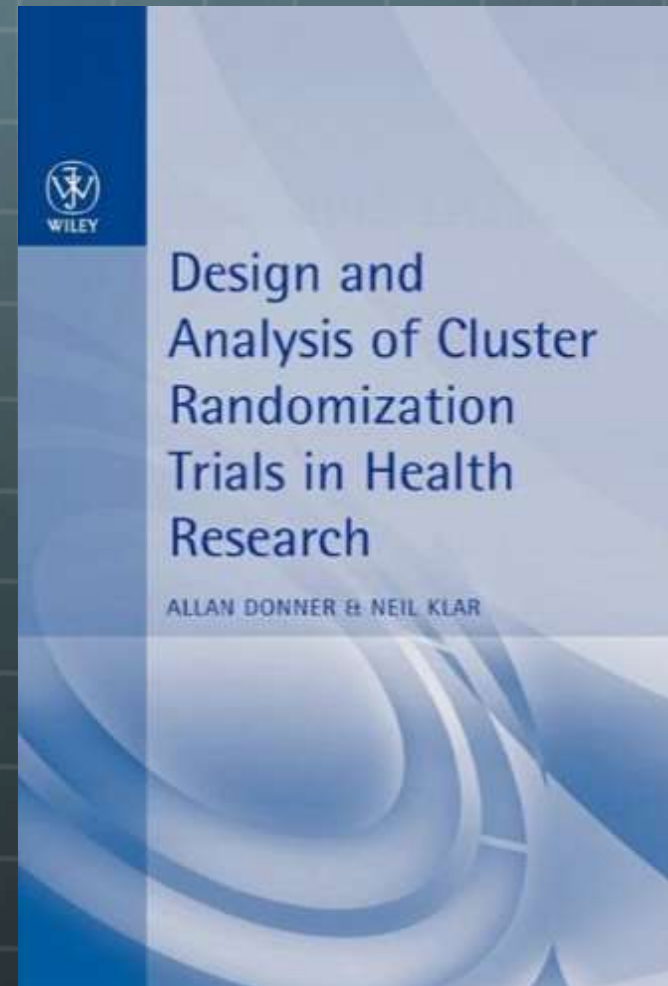
East Africa

What I was really looking for was ...

Richard Hayes &
Lawrence Moulton
Pub. CRC Press
2009

Allan Donner &
Neil Klar
Pub. Wiley
2000

What Are Cluster Randomization Trials?

Cluster randomization trials are experiments in which clusters of individuals rather than independent individuals are randomly allocated to intervention groups.

Reasons for Adopting a Cluster Randomization

➡ **Need to minimize or remove contamination**

> Example: In a trial for the prevention of coronary heart disease, factories were chosen as units of randomization to minimize the likelihood of subjects in different intervention groups sharing information concerning preventive advice on coronary risk factors.

➡ **Basic feasibility considerations**

> Example: Evaluate a programme to enhance the effectiveness of hypertension screening and management in general practice. It was recognized that such a programme would not function effectively if some patients in a practice but no others were entered into it. Unit of randomization: physician practice.

➡ **Only natural choice**

> Example: Intervention programmes that use mass education.