### THE UNIVERSITY of York

## — Department of — Health Sciences

## **YORK TRIALS UNIT**

## One Day Course in the design and conduct Of Randomised Controlled Trials

#### YORK TRIALS UNIT

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The Trials Unit is offering a cost-effective approach for training in RCT methodology. Experienced trialists from the Unit will deliver the course for a set fee with the host institution undertaking the course administration. For a recent course with about 50 students the cost per student was about £50.

#### **Course Aims**

This one day course will cover various issues related to trial design. The course aims to equip participants with the basic knowledge of the design and conduct of common randomized trial designs.

#### Format

The course will consist of a series of lectures followed by questions and discussion. It will consist of 8 sessions chosen from a suite of 13 options.

#### **Course Presenters**

These will be David Torgerson and other members of the Trials Unit

#### Cost

This will vary according to location but it will be approximately £1,200 plus expenses.

# Design and conduct of randomised controlled trials

- 1 Need for RCTs (history and description of problems with non-randomised experiments)
- 2 Design of pragmatic trials (why pragmatic trials are important for informing policy and how these are designed).
- 3 Sources of bias in RCTs (description of biases that can occur in RCTs and how, with careful planning, these can be minimised).
- 4 Randomisation methods (what are the best allocation methods to use, should restricted allocation or simple randomisation be used, describes minimisation)
- 5 Patient preference trial designs (looks at partially randomised patient preference, fully randomised patient preference, Wennberg, Rucker and Zelen's designs).
- 6 Design and conduct of cluster randomised trials (cluster trials are often more challenging than individual RCTs, they need to be planned with care).
- 7 Sample size and analytical considerations of cluster trials
- 8 Unequal allocation ratios (most trials use equal allocation ratios, unequal allocation ratios can achieve more statistical power in the context of fixed budgets and can contribute to the evaluation of learning curves).
- 9 Economic evaluation alongside trials.
- 10 Measuring outcomes within trials.
- 11 Recruitment to randomised trials (recruitment is difficult and complex, there are evidenced based strategies that can improve recruitment).
- 12 Enhancing follow-up (attrition is a major problem it is a source of bias and reduces power, there are methods to reduce attrition).
- 13 Basic data management of trial data.