Implementation research design: an introduction to the split-plot randomised controlled trial

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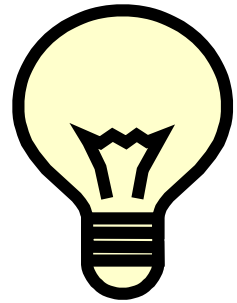
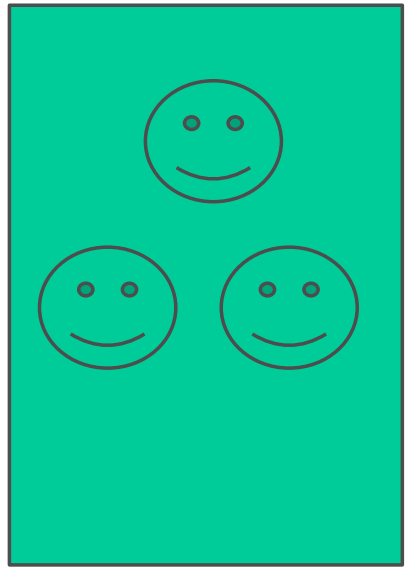
HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.

Multi-level research questions need complex RCT designs



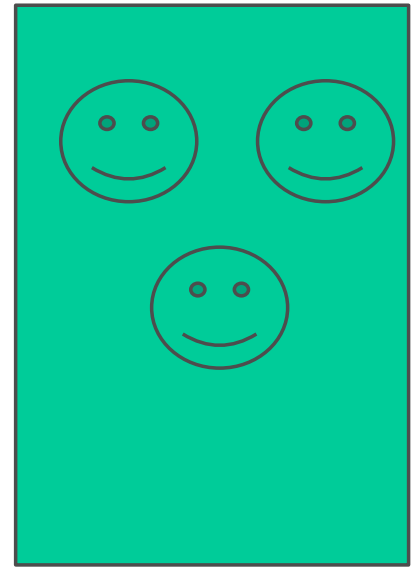
Scholes 2006. A randomized trial of strategies to increase chlamydia screening in young women.

Cluster randomised trial



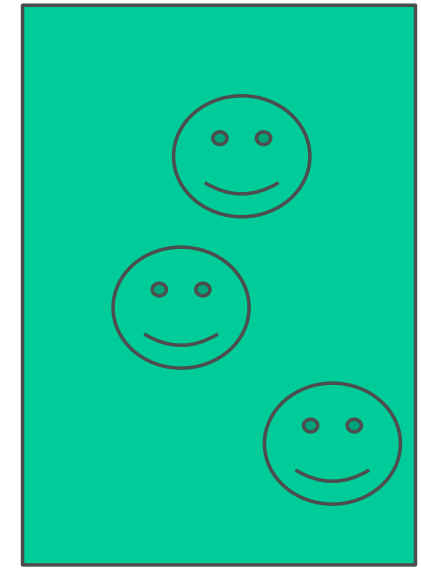
Primary care practice 1

Implementation package



Primary care practice 2

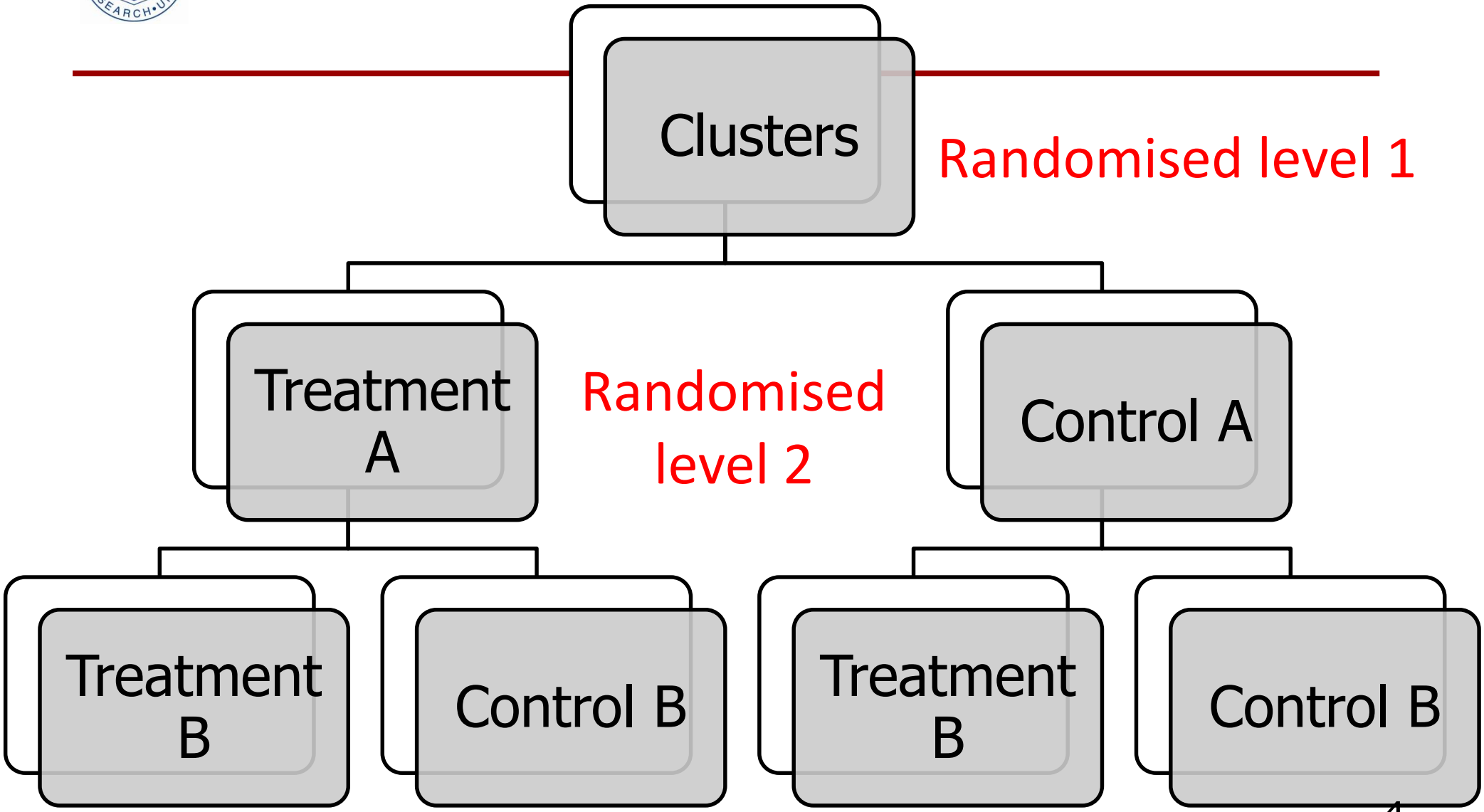
Implementation package



Primary care practice 3

Implementation package

Possible solution



When A+B are present

1. No interaction
2. Positive / synergistic interaction
   - Implementation package + chart = better results than
     - Only implementation package or only chart
3. Negative / Antagonistic interaction
   - Implementation package + chart = worse results than
     - Only implementation package or only chart

Factorial design

- **Using a factorial design is more efficient but assumes no interaction**
- **Usually in a factorial design, the study is underpowered to detect an interaction**
- **Is the assumption of no interaction realistic in complex interventions and multi-level structures?**

Our work

1. Review of the literature
    1. How are split-plot RCTs designed, analysed and reported in the healthcare literature?
2. Sample sizes for the split-plot
    1. How should researchers calculate a sample size for a split-plot RCT and report it?

Our work

ELSEVIER

CrossMark

Journal of Clinical Epidemiology 96 (2018) 120–125

Journal of Clinical Epidemiology

REVIEW

The split-plot design was useful for evaluating complex, multilevel interventions, but there is need for improvement in its design and report

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Accepted 30 October 2017; Published online 4 November 2017

Abstract

Objectives: To describe the sample size calculation, analysis and reporting of split-plot (S-P) randomized controlled trials in health care (trials that use two units of randomization: one at a cluster-level and one at a level lower than the cluster).

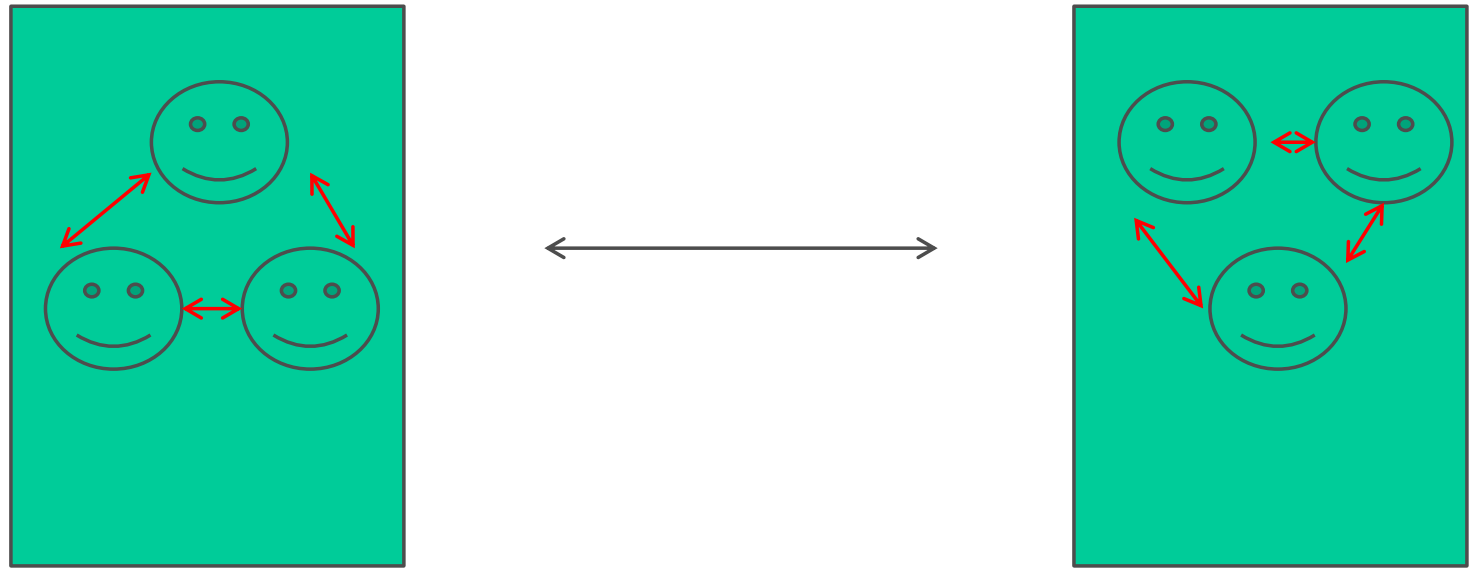
Review results

- 18 studies included
- Half of the studies report interest in the combined effects of the interventions
- Poorly reported design and flow of participant's diagram
- No closed formulae for sample size with researchers taking different approaches

Split-plot sample size: approach

- **Part I:**
  - **Cluster randomised trial: how many clusters do we need to recruit and what is their size?**
- **Part II:**
  - **Participant randomised trial: with that number of participants, what power do we have to detect a given target difference between groups?**
- **Part III:**
  - **Interaction**

Intracluster correlation



Practice 1

Practice 2

Split-plot sample size: approach

- **Part I:**
  - Cluster randomised trial: how many clusters do we need to recruit and what is their size?
- **Part II:**
  - **Participant randomised trial: with that number of participants, what power do we have to detect a given target difference between groups?**
- **Part III:**
  - **Interaction**

Sample size project: aims

- **Inform the design of future split-plot designs by calculating their power under a variety of scenarios in a statistical simulation**
- **Provide Stata tutorial to help other researchers calculate sample sizes for this design**

Sample size project: methods

- Monte Carlo simulations (Stata 13)
- Estimate power to detect a certain effect size (small, medium or large) in each level of the split-plot design given a certain number of clusters
- Cluster size, intracluster correlation and interaction varied
- Type I error 5%

Sample size project: main results

1. When no interaction is present: straight forward sample size calculation for each level of the design
2. Most cases: C-RCT will drive the sample size but the decision depends on a number of variables (intracluster correlation, target differences, cluster size)

Sample size project: main results

3. **Split-plot design might have sufficient power to detect interactions between interventions**
   - **Depending on the intracluster correlation, cluster size and number of clusters recruited as well as the interaction effect size**

Conclusion

- Review of split-plot designs in healthcare:
  - Useful designs in implementation science
  - Scarcely used
- We provided guidance on the report of split-plot designs, including their CONSORT style diagrams

Conclusion

- **Particularly useful to detect an interaction between interventions**
- **There is need to improve the reporting of sample sizes in these trials**

Thank you for your attention!

If you have any further question please contact:

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