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

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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

Clusters

Randomised level 1

Treatment A

Randomised level 2

Control A

Treatment B

Control B

Treatment B

Control B
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

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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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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