Web-based Sample Size Calculator for Stepped-Wedge Designs

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Background

❑ **Stepped-wedge (SW) designs** are pragmatic trial designs that are becoming increasingly popular due to logistical constraints that require interventions to be implemented at the cluster (e.g., site, clinic) level

❑ SW designs are a type of cluster randomized trial (CRT) in which all clusters experience both the control and intervention conditions. Clusters start in the control condition and sequentially switch over to the intervention at one of a fixed number of steps, with the order in which they switch being randomized.

❑ **Power/sample size calculations** are used to assess the feasibility of a proposed design for detecting a clinically meaningful effect of an intervention. Tools that perform these calculations are essential in the planning of an effective study and for assessing various design options.

Example Calculation

We demonstrate the use of the online calculator for an example power calculation for a fixed study design and desired effect size.

The study design is a complete stepped-wedge with 12 clusters, 10 subjects per cluster-period, and 6 steps.

What is the power for detecting a standardized effect size of 0.3-0.5 using this design (alpha=0.05) assuming an ICC of 0.01?

Outcome
- Continuous (standardized effect size)

Parameter
- Solving for **Power**

Hypothesis Test
- Two-sided

Power and Alpha
- Alpha = 0.05

Design
- K=12 clusters, k=10 subjects per cluster-period
- 6 steps, clusters rolled out 2 at a time

Effect size
- Effect size = "0.3 to 0.5 by 0.1"

Variability
- Residual standard deviation = 1 (standardized)
- ICC = 0.01

Online Application

❑ **Objective:** To develop a **free, web-based applet** to perform power and sample size calculations for stepped-wedge designs

❑ The application is developed and hosted online using **R Shiny**

❑ Using a guided sidebar, users specify the parameters of their trial design. Required **inputs** include the type of outcome, what they are interested in solving for (e.g., power, sample size), study design (number of clusters, subjects per cluster-period), effect size, and variability (residual standard deviation, intraclass correlation coefficient (ICC))

❑ **Outputs** include a customizable visualization of the study design, and a summary table and statement describing the design, assumptions, and power/sample size values.

https://CUaccords.shinyapps.io/powercalc

Future Extensions

❑ We propose to increase the utility of the application to accommodate **SW design variants** (e.g., washout periods, incomplete, banded SW, hybrid SW-CRT)

❑ We aim to provide an Optimization tab to help identify an "optimal SW" given a range of design and parameter inputs

❑ We will update the app based on **feedback** to make it more user-friendly and incorporate requests for additional features.

❑ Use the link below or scan the QR code to try our app!

References
1. Hussey, M. A., & Hughes, J. P. (2007). Design and analysis of stepped wedge cluster randomized trials. Contemporary clinical trials, 28(2), 182-191.
2. Hemming, K., Haines, T. P., Chilton, P. J., Girling, A. J., & Lilford, R. J. (2015). The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. BMJ, 350, h391

1 The **Navigation Bar** provides access to various pages

- **Home:** Read about SW designs and the mathematical formulas used to perform the power calculations
- **Power Calculator:** Compute power, sample size, or effect size for a specified SW design
- **About the Design:** Find resources for helping you choose the appropriate design, analyze the collected data, and for further reading
- **Feedback:** Fill out a form to let us know what you think of the application, what we can improve, and if you want to receive information about updates

2 **Drop-down information tabs** can be clicked on to provide additional information about the requested parameter inputs

3 **User inputs** vary based on the outcome type and parameter to solve for (e.g., sample size, power)

4 Produces a customizable **visualization of study design** that allows users to change the color scheme, the axis labels, and export and save the image for use in a paper or grant application

5 Sortable and searchable **table of results** from the requested sample size/power calculations

6 **Summary statement** printed for a user-selected row in the results table, describing the study design, and providing sample text for the power calculation for use in a grant application or manuscript