Finding Power and Sample Size for the Most Common Hypotheses in Mixed Models

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Sponsorship

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The progress described in this talk was supported by the National Institute of Dental and Craniofacial Research under award NIDCR 1 R01 DE020832-01A1, Multilevel and Longitudinal Study Sample Size Tools for Behavioral Scientists (12/09/10-11/30/14), led by Keith Muller and Deborah Glueck. The content is solely the responsibility of the authors, and does not necessarily represent the official views of the National Institute of Dental and Craniofacial Research nor the National Institutes of Health.

Saga of Sample Size Selection

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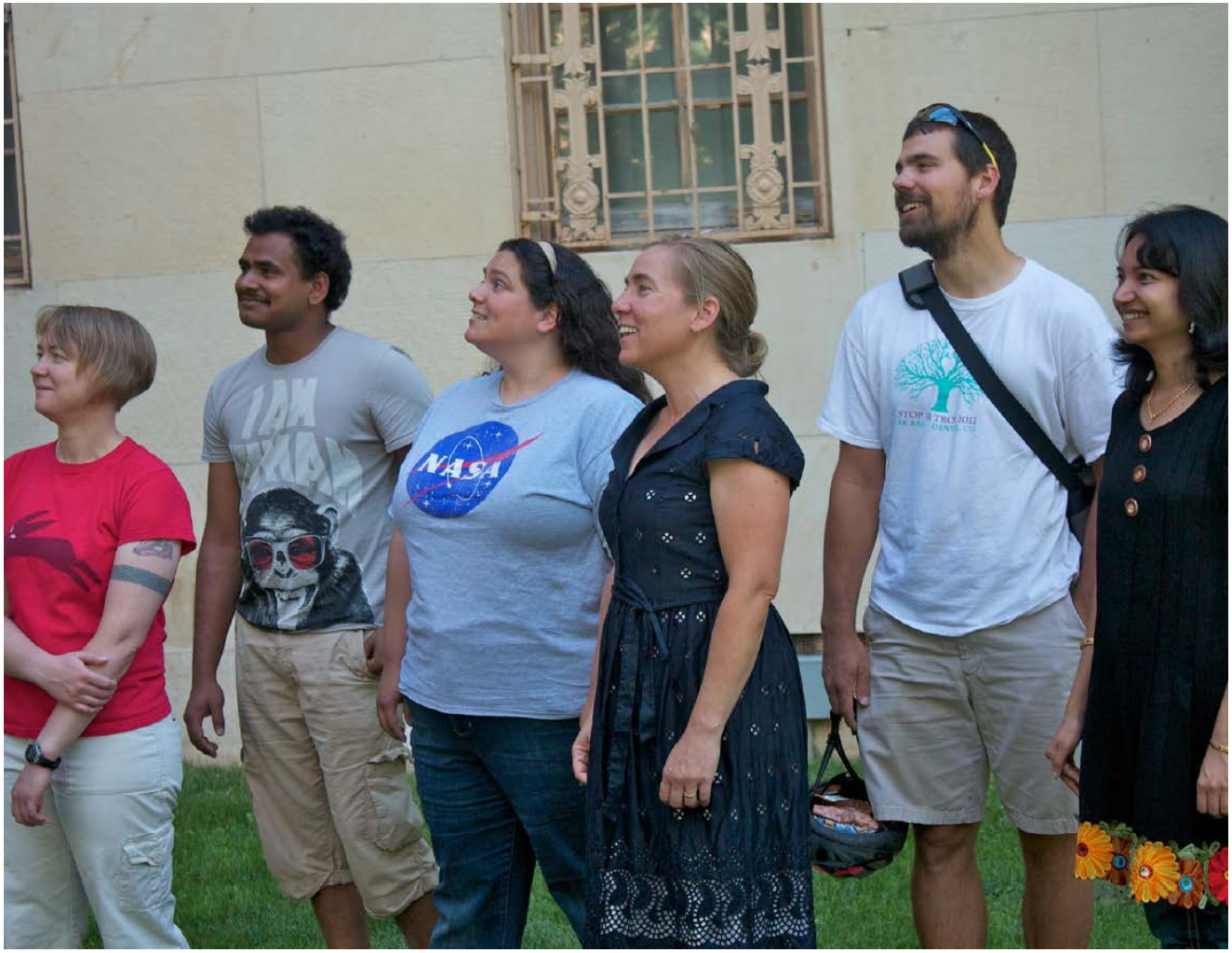
- Behavioral scientists have always needed to select sample size for repeated measures, or multivariate data, and now multilevel structure.
- We think the ideas and software we present today make the job easier than ever before.

- The first version of free power software was written 30 years ago.
- Previous versions matrix based, user hostile. Now point and click (GUI).

Software Development Team UCD



Agenda for Skill Building Session

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- 10:05-10:45 AM
  Power and Sample Size for the Most Common Hypotheses in Mixed Models – A. Barón
- 10:45-10:50 Questions
- 10:55-11:35 AM
  Mixed Model Power Analysis By Example: Using Free Web-Based Power Software – S. Kreidler
- 11:35-11:40 Questions
- 11:40-11:50 Discussion

Power and Sample Size for the Most Common Hypotheses in Mixed Models

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Outline

- Mixed Model (MM): Clustered and Repeated Measures Data
  - Common Hypothesis Tests in the Linear MM (LMM)
  - The LMM as a General Linear Multivariate Model
- Going with the Flow (Diagram)
  - Two Real World Examples
  - Towards a Simple and Valid Power or Sample Size Analysis
- Missing Data
- Summary and Segue to Software Solution: GLIMMPSE

Outline

- **Mixed Model (MM): Clustered and Repeated Measures Data**
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LMM Commonly Used for Clustered and Repeated Measures Data

- Linear MM: Laird and Ware, 1982; Demidenko, 2004; Muller and Stewart, 2007
- Studies with Clustering
  - Designed: Cluster randomized studies
  - Observational: Clustered observations
- Studies with Repeated Measures (RM)
  - Designed: Randomized clinical trials
  - Observational: Cohort studies, natural history
- Combination
  - Cluster randomized longitudinal studies

Data Structures

Clustering

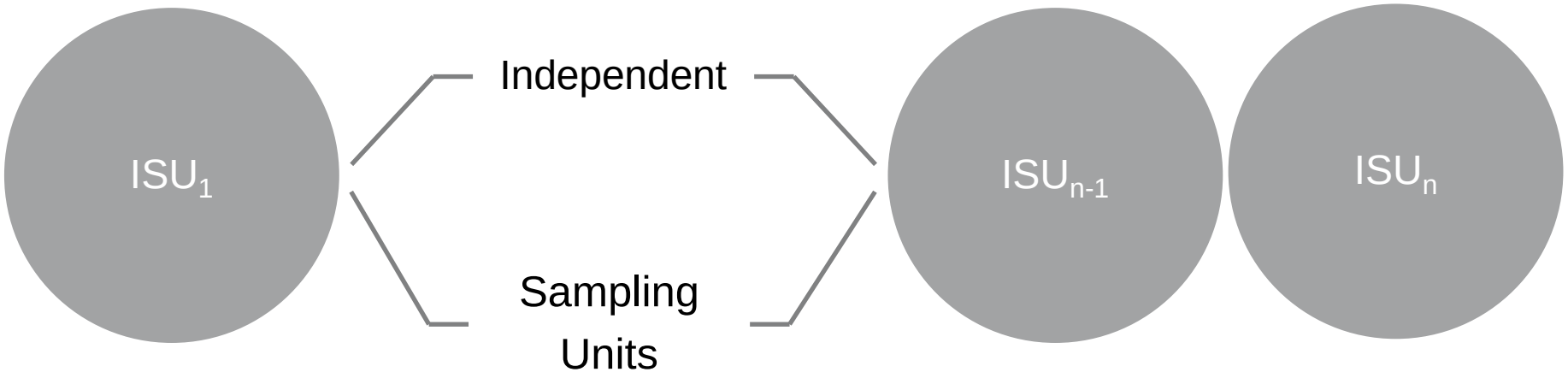
⇔ Restricted Multi-level

Repeated Measures

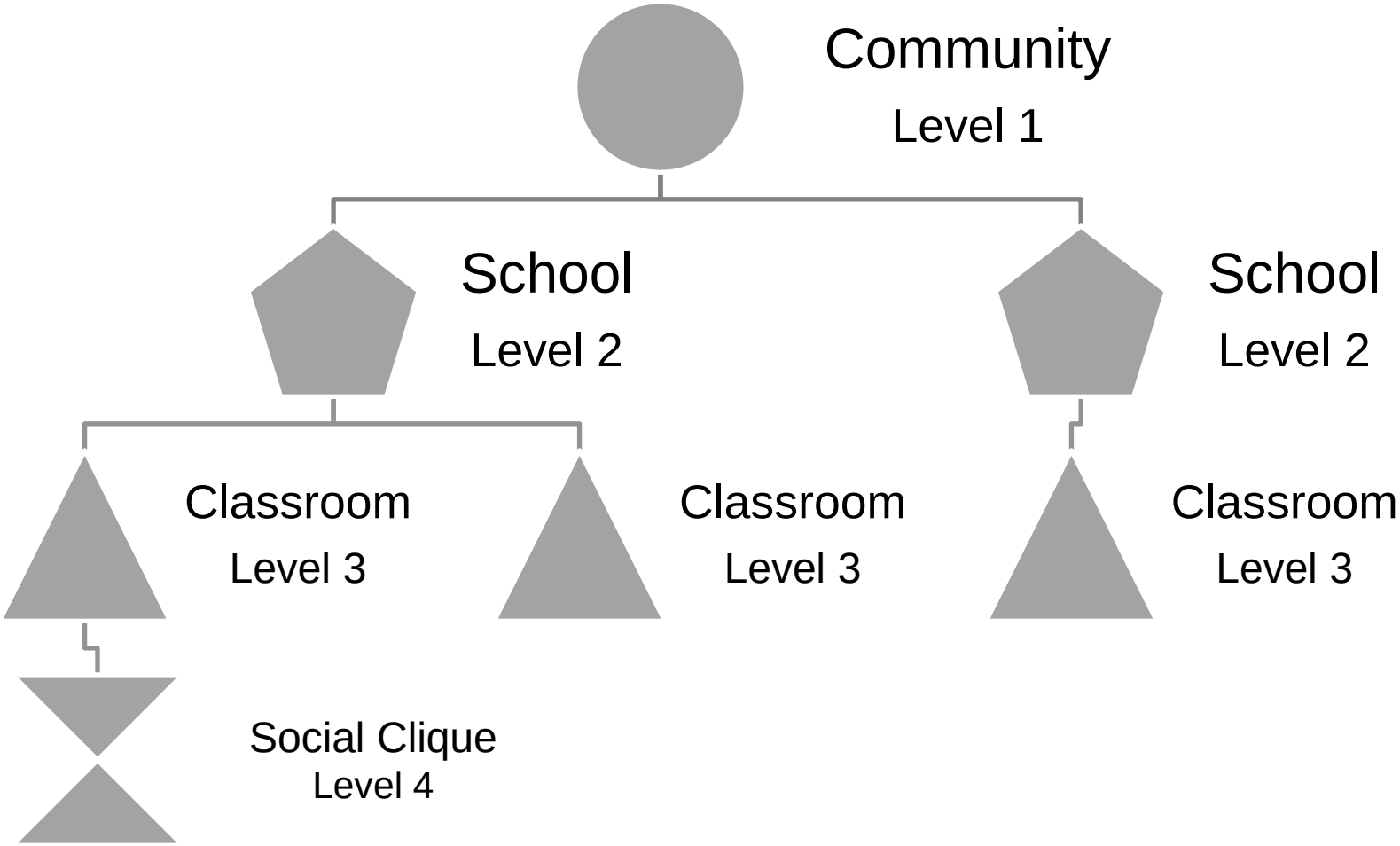
⇔ Restricted Longitudinal

Clustering – Level 1

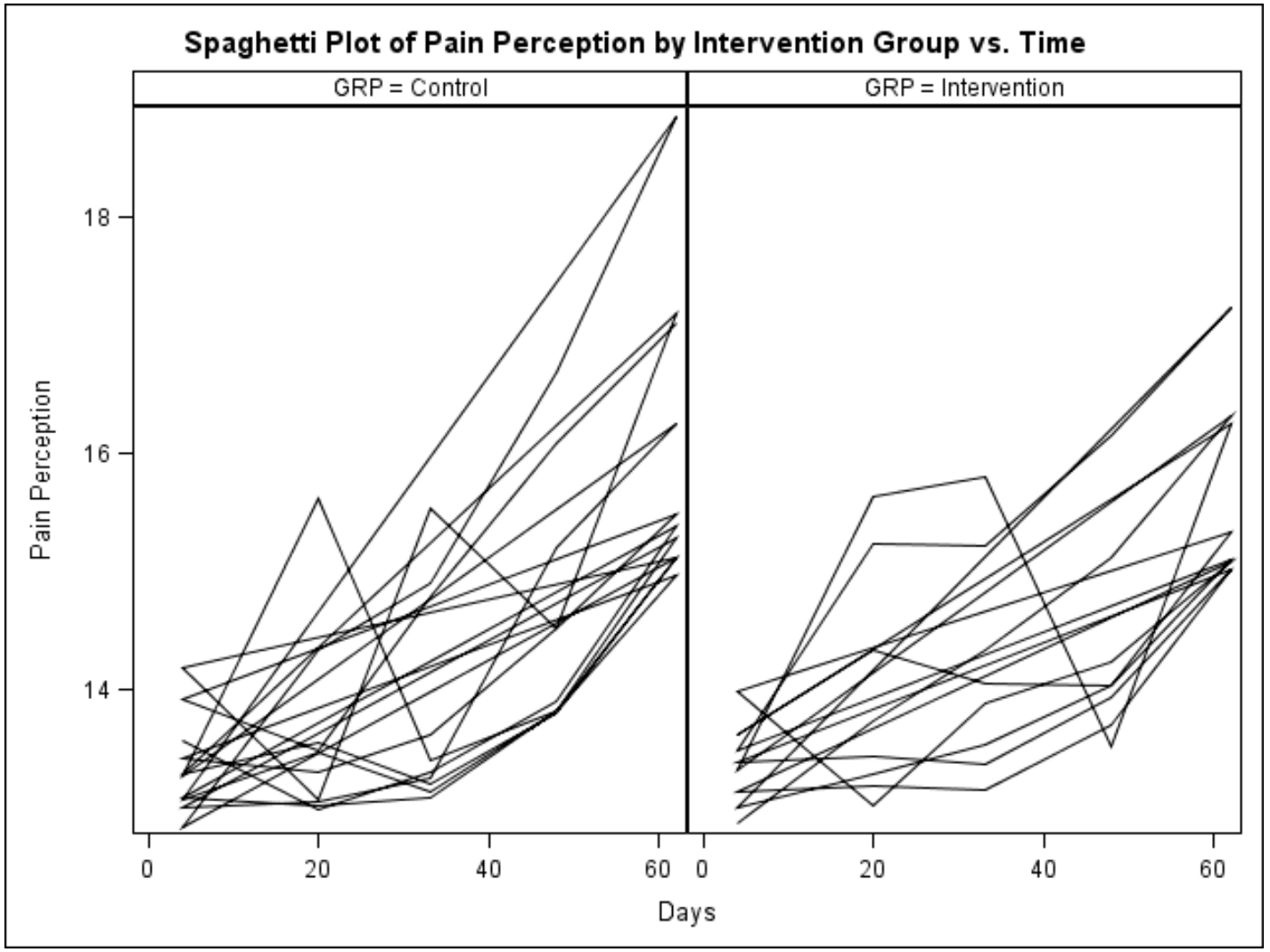
Clusters: Communities as Independent Sampling Units (ISU)



Clustering: Additional Levels



Repeated Measures



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Power for the Most Common Hypothesis Tests for the Linear Mixed Model

✓ A) Power for testing fixed effects (means)

x B) Power for testing random effects (covariance)

x C) Power for testing fixed and random effects

General and accurate power and sample size methodology is not available.

There are, however, good methods for most of class A.

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Power and Sample Size for Fixed Effects in the Linear Mixed Model

Key idea: Some LMM can be recast as a General Linear Multivariate Model

- Which ones?
  - No missing data and no mistimed data
  - Unstructured covariance model across responses (a robust, safe, conservative assumption)
  - Typical clinical trial or longitudinal study in which main inference is about time by treatment interaction
- Why do we care?
  - Muller, et al. (1992) show how to do power for time by treatment using GLMM framework!

Four Specific Requirements for a LMM to be Recast as a GLMM – 1.

To be reversible to a General Linear Multivariate Model, a LMM must:

1. Have a Balanced Design within ISU; no repeated covariates; saturated with regard to between-within effects
   - ***No missing or mistimed data***
   - ***Unequal group sizes ok***
   - ***Treatment assignment does not change over time***
   - ***Factorial design including Interaction between Treatment (between) and Time (within)***

Four Specific Requirements for a LMM to be Recast as a GLMM – 2.

To be reversible to a General Linear Multivariate Model, a LMM must:

2. Have an Unstructured Covariance Model
   - ***All variances and covariances unspecified, i.e. they do not follow a pattern or rule***

Four Specific Requirements for a LMM to be Recast as a GLMM – 3.

To be reversible to a General Linear Multivariate Model, a LMM must:

3. Use Wald test for inference about Fixed Effects
   - ***Most common test used for LMM analysis by standard packages***

Four Specific Requirements for a LMM to be Recast as a GLMM – 4.

To be reversible to a General Linear Multivariate Model, a LMM must:

4. Use Kenward-Rogers df approach
   - ***DF approximation method with modified covariance matrix***
   - ***Under reversibility, covariance matrix is unstructured and test is equivalent to Hotelling-Lawley Trace test***
   - ***Muller et al. (2007) showed it's the best test***

Power and Sample Size for GLMM

- Muller, LaVange, Ramey and Ramey (1992)
- Multivariate approach to repeated measures and MANOVA: Hotelling-Lawley Trace
- Kenward-Rogers Wald Test equivalent when LMM is reversible

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First of Two Examples

- **Stress Inoculation Training (SIT) Trial**: Sample size for proposed repeated measures study comparing sensory focus intervention vs. placebo with regard to long-term memory of dental pain (Law et al., 1994)

- **Project Northland Chicago (PNC) Trial**: Power for proposed longitudinal cohort study using data from previous community-randomized controlled trial to test intervention to prevent alcohol use in adolescents (Komro et al., 2007)

The SIT Trial: Repeated Measures

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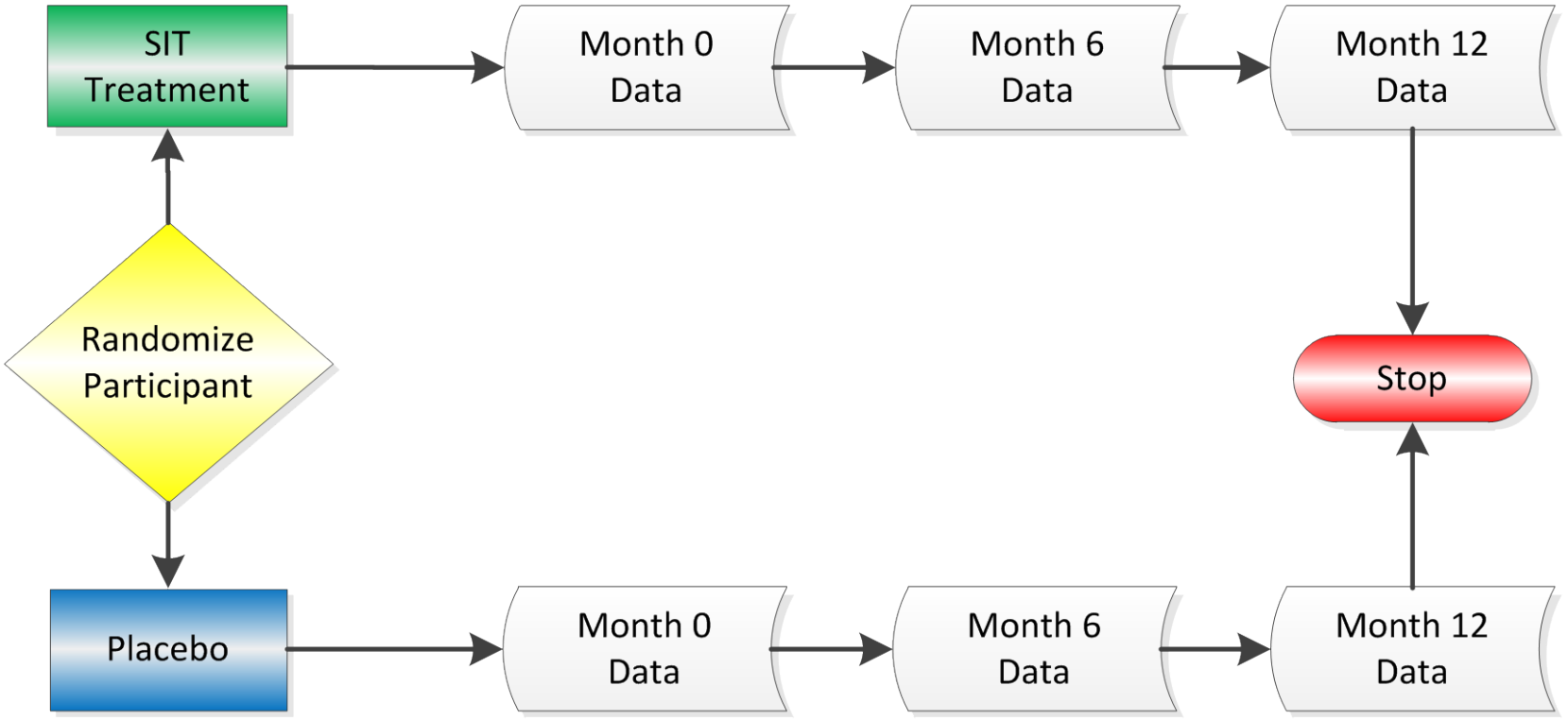

Second of Two Examples

- **Stress Inoculation Training (SIT) Trial**: Sample size for proposed repeated measures study comparing sensory focus intervention vs. placebo with regard to long-term memory of dental pain (Logan et al., 1995)

- **Project Northland Chicago (PNC) Trial**: Power for proposed longitudinal cohort study using data from previous community-randomized controlled trial to test intervention for adolescents (ages 11-14) designed to prevent alcohol use (Komro et al., 2007)

The PNC Trial: Cluster Randomized Design

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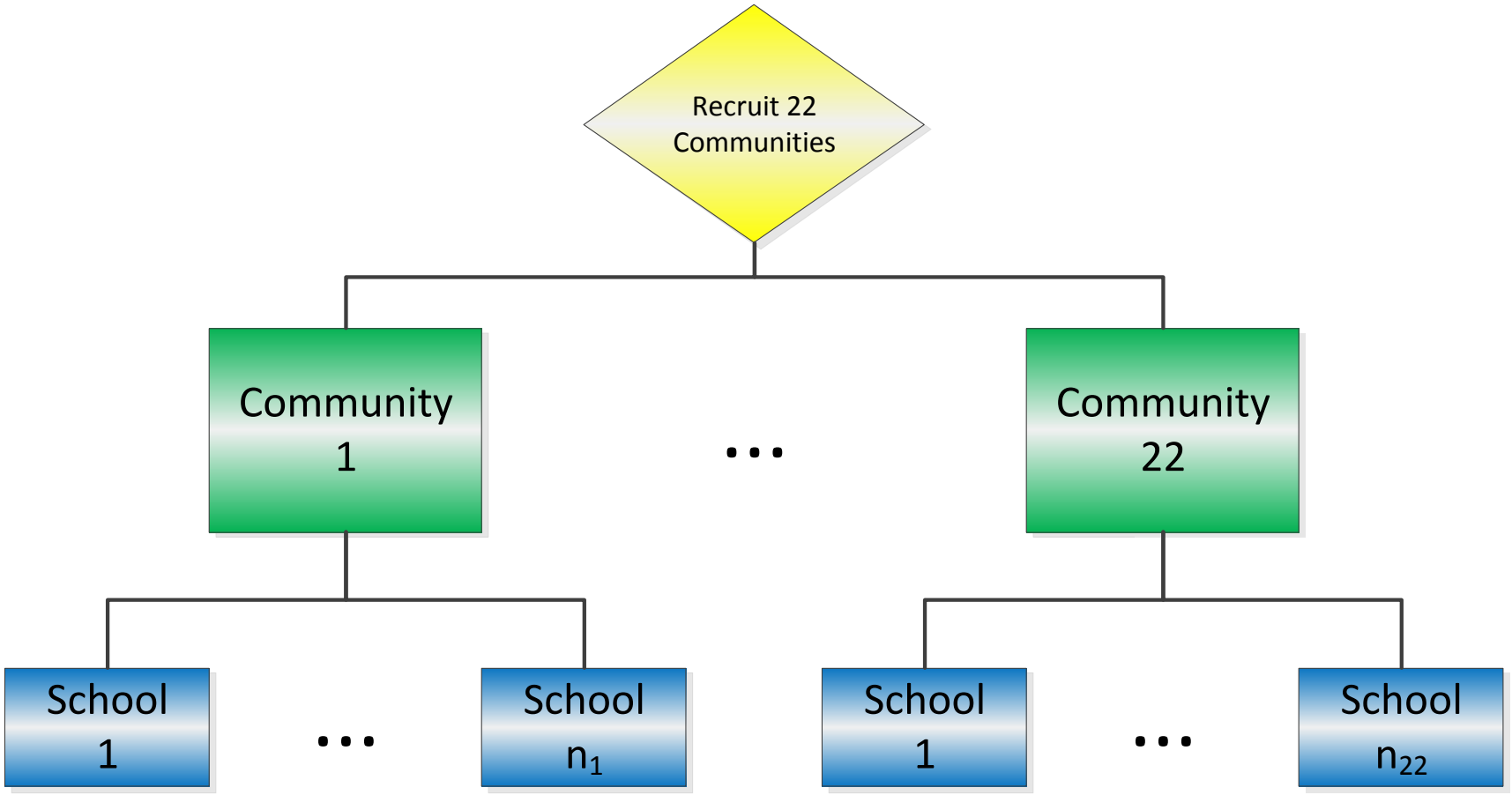
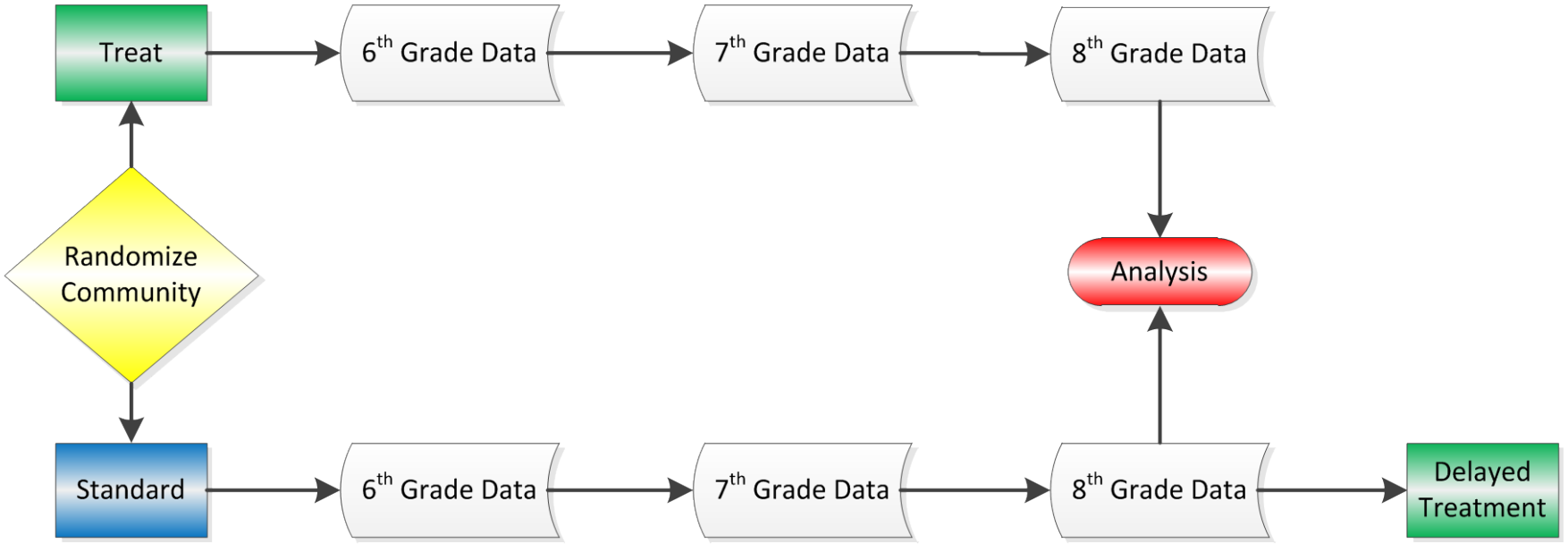


The PNC Trial: Clustering + RM



Towards a Simple and Valid Power or Sample Size Analysis – Six Steps (1-3)

Step 1

- **What is the study design goal?**

Step 2

- **What is the sampling scheme?**

Step 3

- **What responses are measured?**

Towards a Simple and Valid Power or Sample Size Analysis – Six Steps (4-6)

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Step 4

- **What is the primary hypothesis of interest?**

Step 5

- **What are the means?**

Step 6

- **What is the variance structure?**

Step 1. What is the Study Design Goal?

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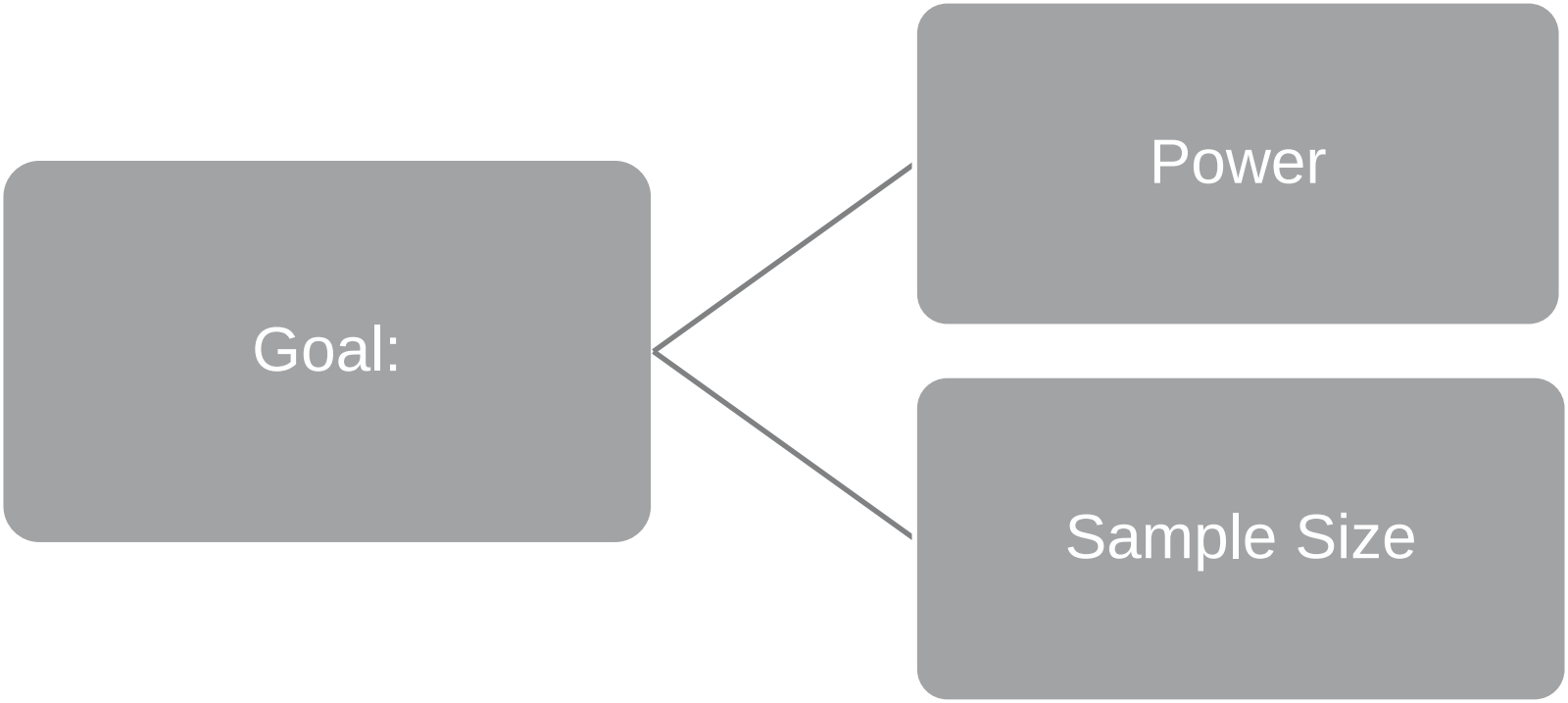


Goal for the SIT Trial

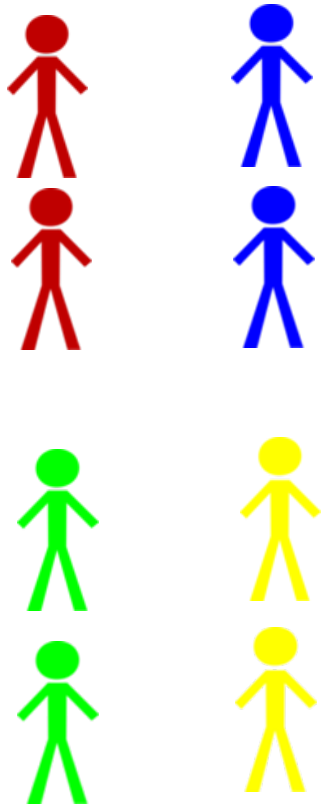
- Determine Sample Size
- Power of 0.9 and α (Type I Error Rate)= 0.01
- Primary Hypothesis: Time trend by Treatment Interaction
- Expect the Treated group mean to be 1.2 points lower in Memory of Pain (5-point scale) compared to the Placebo at the last time measurement (12 months)

Step 2a. Specify Study Design Groups

One-sample

Two-sample

Multi-sample



Two Samples for the SIT Trial

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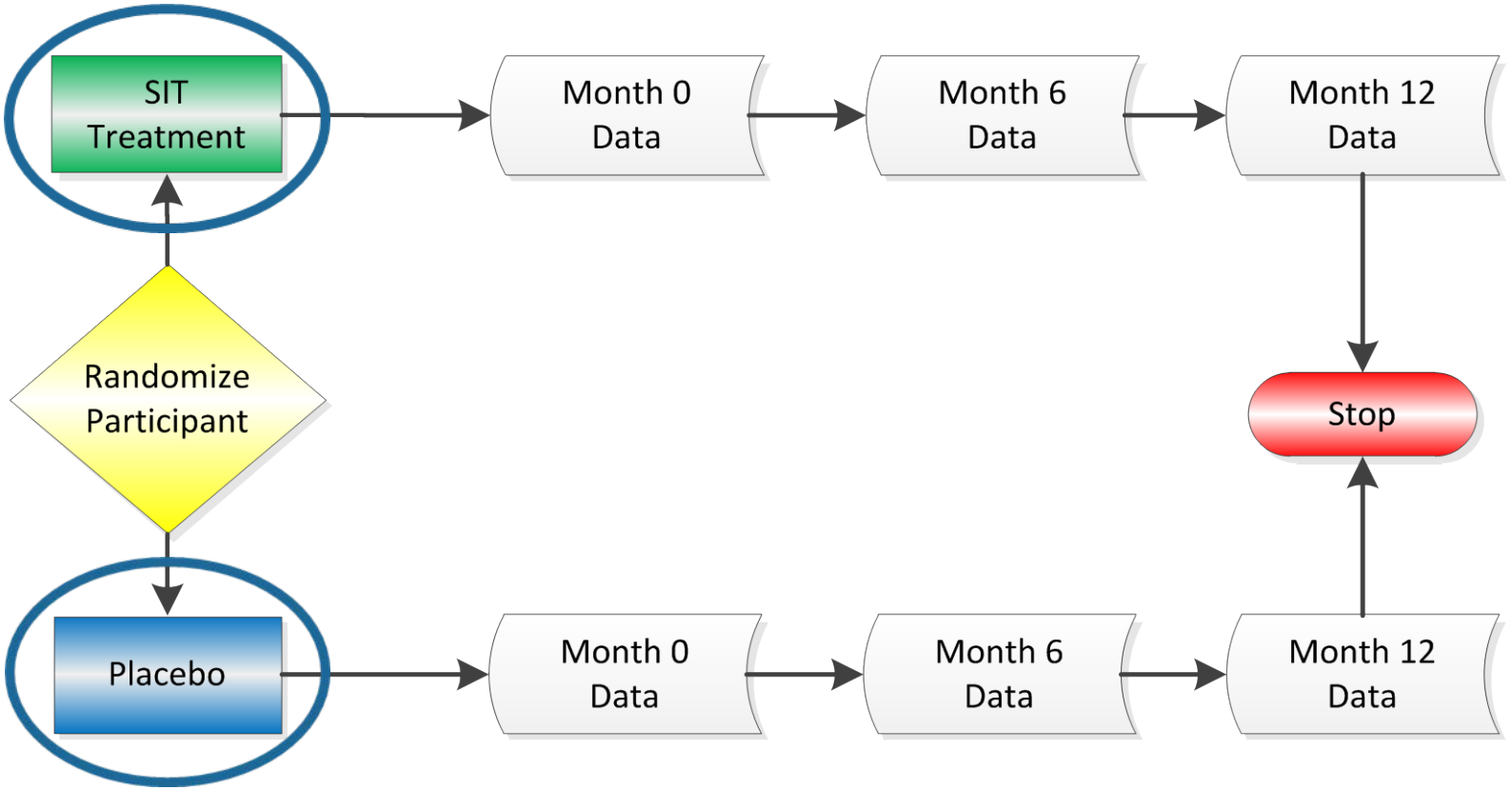
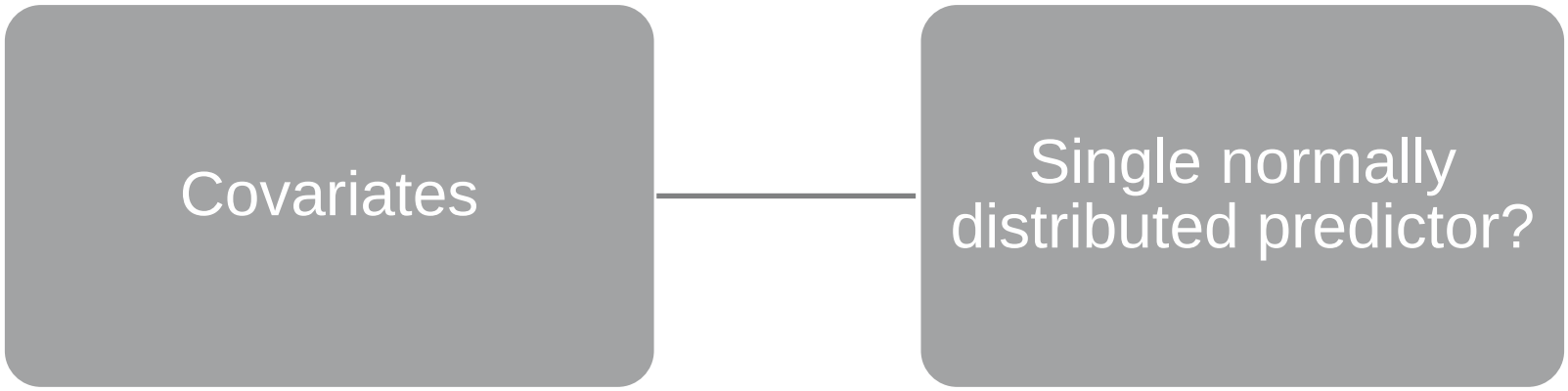
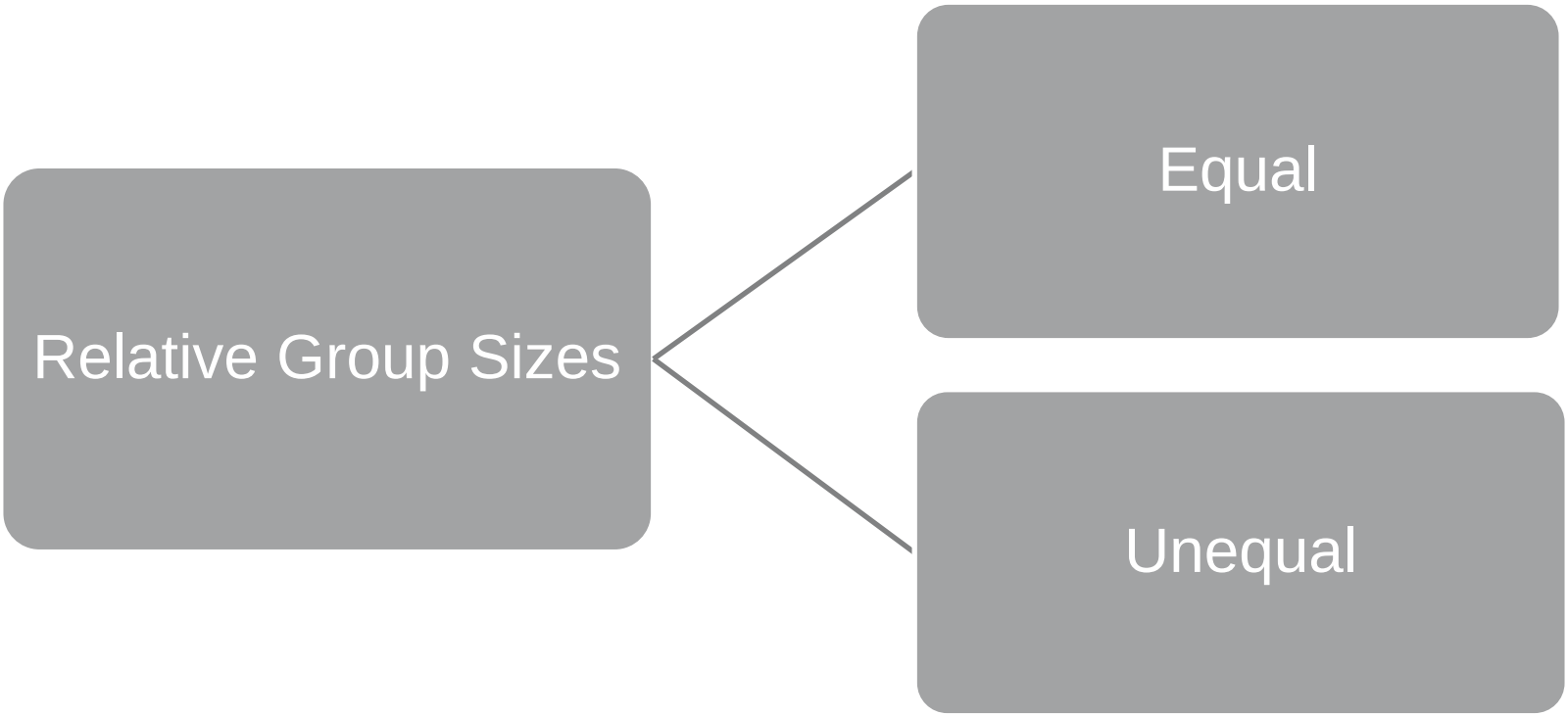


Step 2b. Specify Study Design Covariates

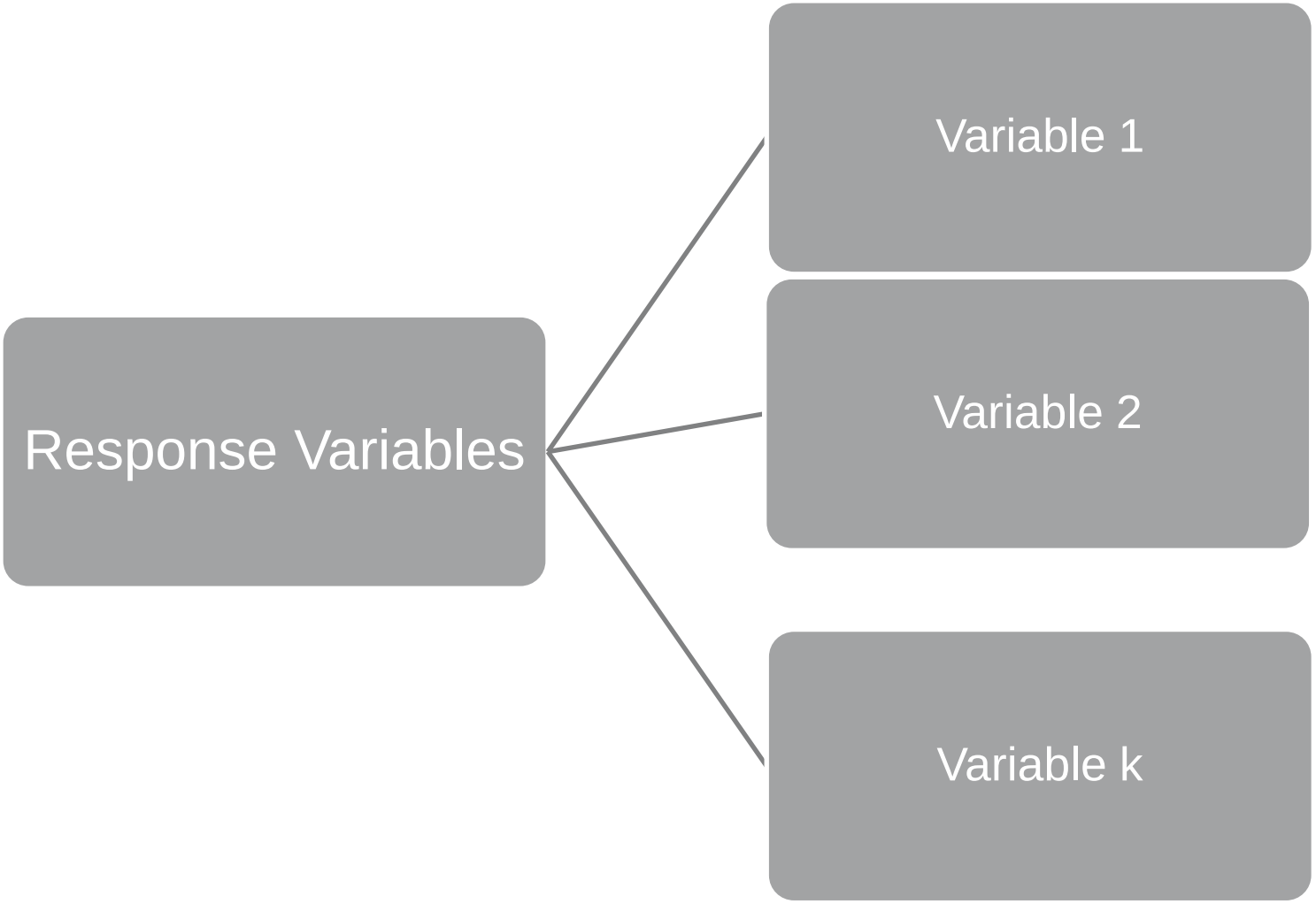


Step 2c. Specify Cluster Sampling Scheme

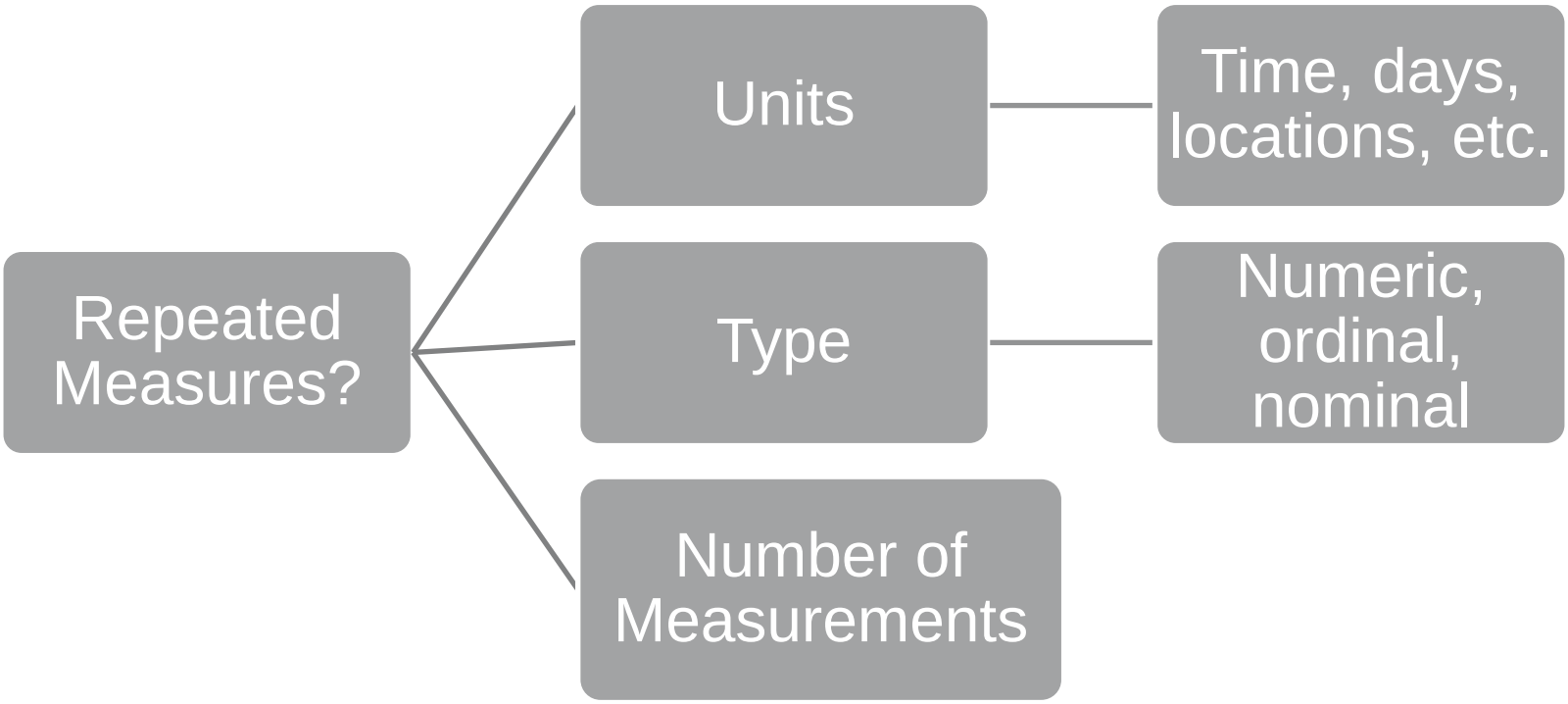
Step 2d. Specify Relative Group Sizes



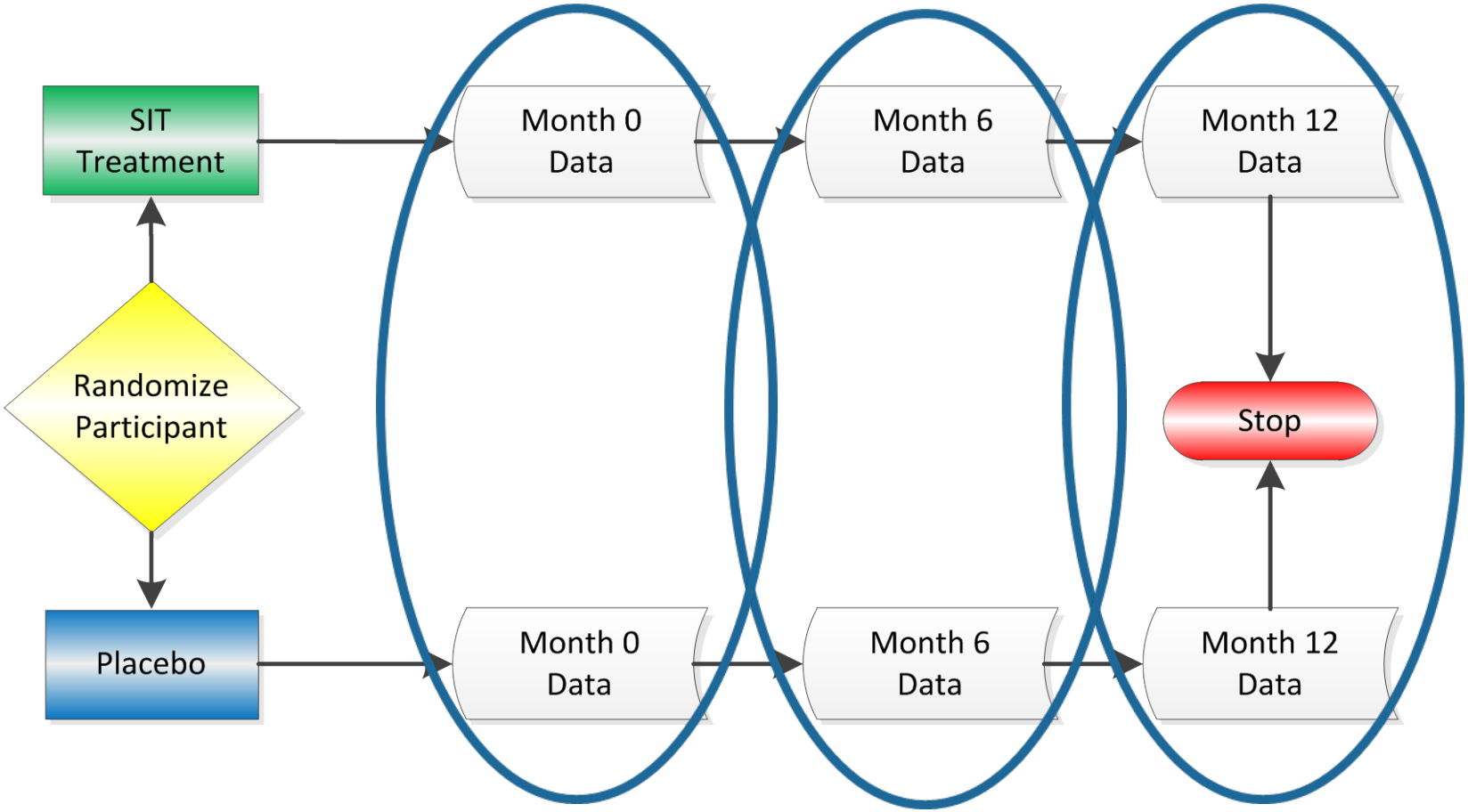
Step 3a. Specify Response Variables



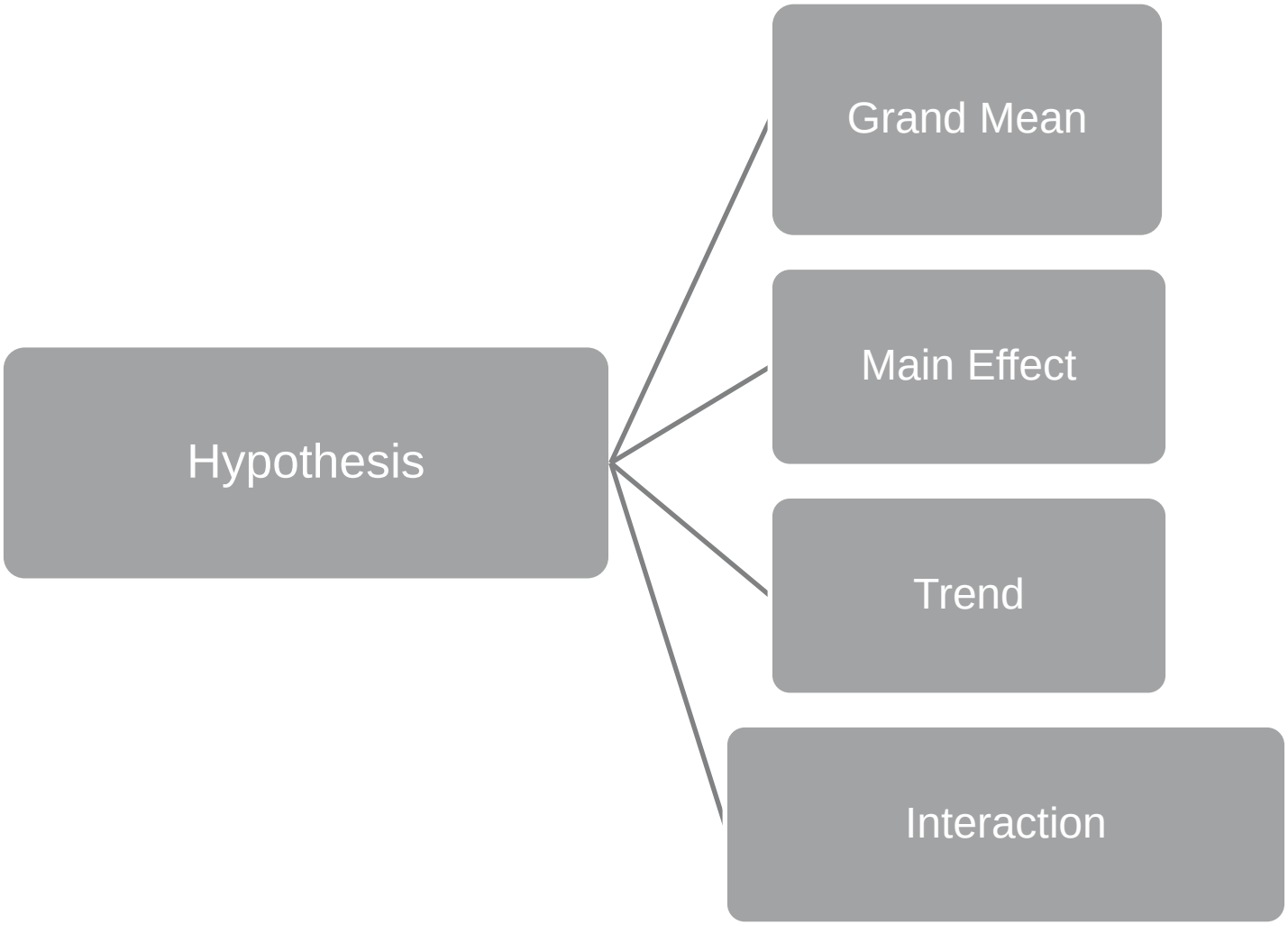
Step 3b. Specify Repeated Measures



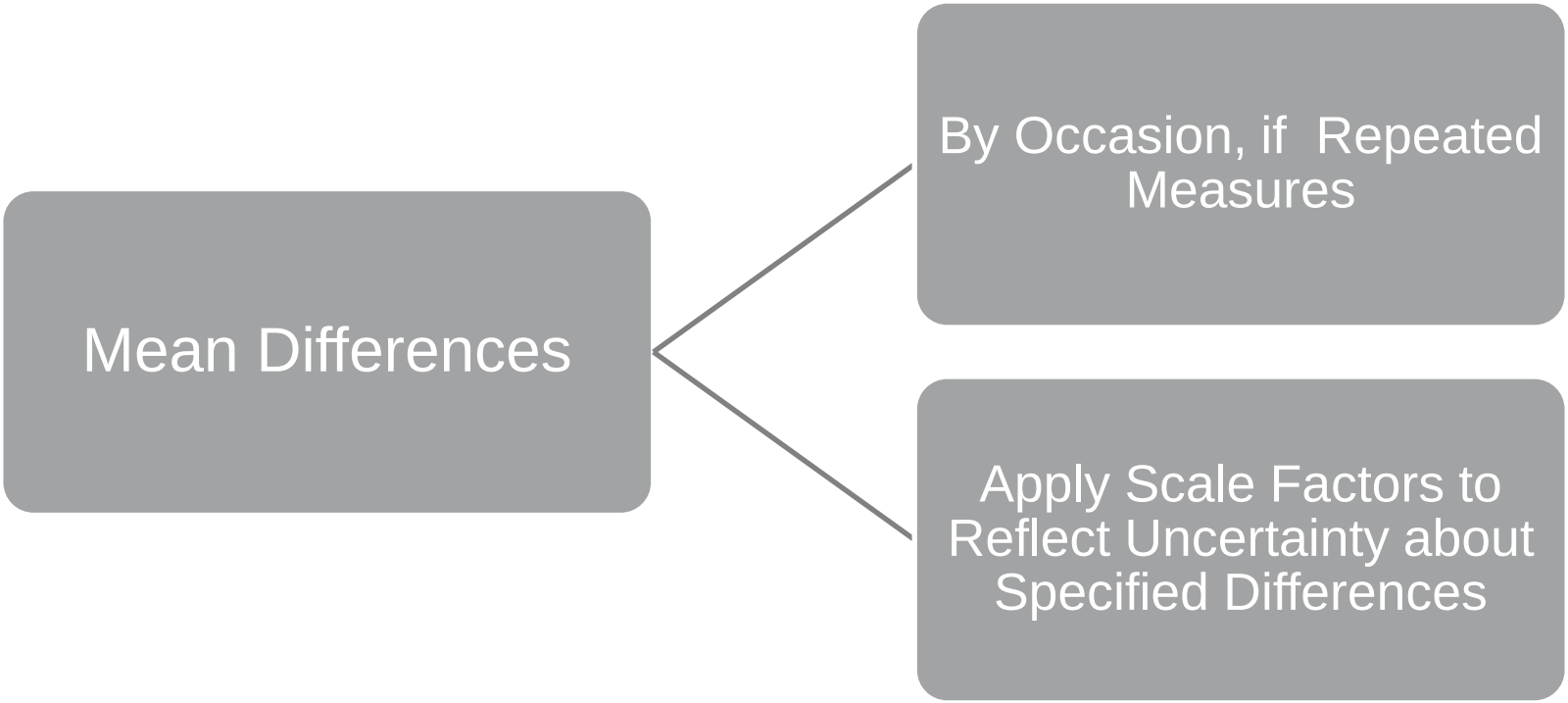
Repeated Measures for the SIT Trial



Step 4. Specify Primary Hypothesis of Interest



Step 5. Specify Mean Differences Between Groups



Mean Differences for the SIT Trial

SIT Treatment group mean is 1.2 points lower on Memory of Pain compared to the Placebo group mean at the last time measurement (12 months).

Consider effect sizes of .5x up to 2x the stated effect to allow for uncertainty of the input information.

Step 6. Variance Structure: Multi-level Model Sources of Correlation

Clustering

Repeated Measures

Multiple Response Variables

Common Covariance Pattern for Clustering

Compound Symmetry

$$\sigma^2 \begin{bmatrix} 1 & \rho & \rho \\ \rho & 1 & \rho \\ \rho & \rho & 1 \end{bmatrix} = 0.25 \begin{bmatrix} 1 & 0.3 & 0.3 \\ 0.3 & 1 & 0.3 \\ 0.3 & 0.3 & 1 \end{bmatrix}$$

Commonly Used Covariance Patterns Appropriate for Repeated Measures

- Unstructured
- AR(1)
- Linear Exponent AR(1) (LEAR)

Covariance Patterns for Repeated Measures – Unstructured

Unstructured

$$\sigma^2 \begin{bmatrix} 1 & \rho_1 & \rho_2 \\ \rho_1 & 1 & \rho_3 \\ \rho_2 & \rho_3 & 1 \end{bmatrix} = 0.25 \begin{bmatrix} 1 & 0.3 & 0.2 \\ 0.3 & 1 & 0.5 \\ 0.2 & 0.5 & 1 \end{bmatrix}$$

Covariance Patterns for Repeated Measures – AR(1)

First order autoregressive

$$\sigma^2 \begin{bmatrix} 1 & \rho & \rho^2 \\ \rho & 1 & \rho \\ \rho^2 & \rho & 1 \end{bmatrix} = 0.25 \begin{bmatrix} 1 & 0.3 & 0.09 \\ 0.3 & 1 & 0.3 \\ 0.09 & 0.3 & 1 \end{bmatrix}$$

Covariance Patterns for Repeated Measures – LEAR

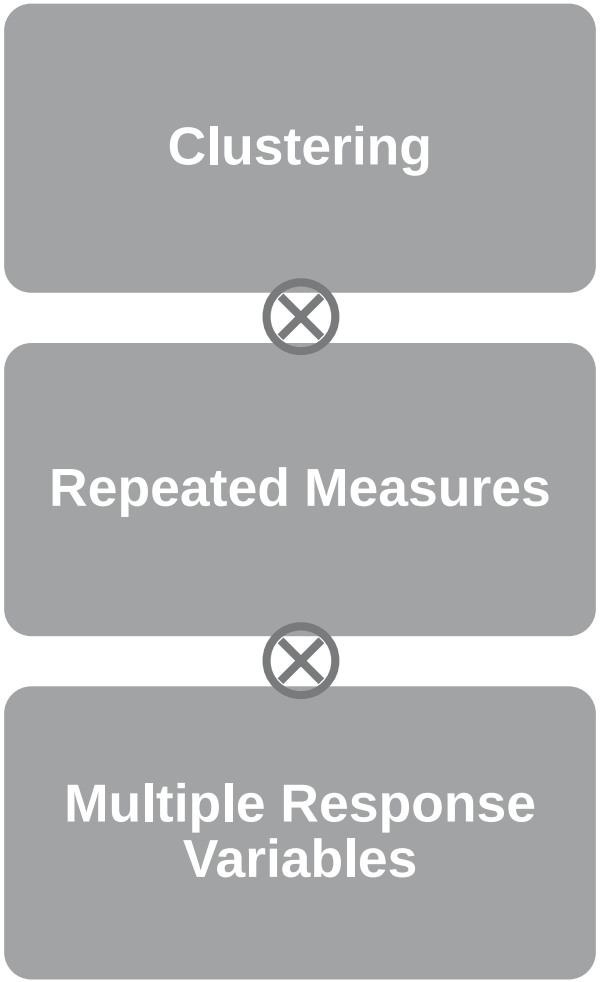
Linear Exponent AR(1) ($\delta = 0.5$)

$$\sigma^2 \begin{bmatrix} 1 & \rho & \rho^{1+\delta} \\ \rho & 1 & \rho \\ \rho^{1+\delta} & \rho & 1 \end{bmatrix} = 0.25 \begin{bmatrix} 1 & 0.3 & 0.16 \\ 0.3 & 1 & 0.3 \\ 0.16 & 0.3 & 1 \end{bmatrix}$$

Commonly Used Covariance Patterns for Multiple Response Variables

- Unstructured observed
- Structure from Structural Equations Model
- Theoretical framework

Building Overall Covariance Structure



Building Overall Covariance Structure

Variance Clusters | Repeated Measures | Multiple Responses

$$\sigma^2 \begin{bmatrix} 1 & \rho & \rho \\ \rho & 1 & \rho \\ \rho & \rho & 1 \end{bmatrix} \otimes \begin{bmatrix} 1 & \rho_1 & \rho_2 \\ \rho_1 & 1 & \rho_3 \\ \rho_2 & \rho_3 & 1 \end{bmatrix} \otimes \begin{bmatrix} 1 & \rho_4 \\ \rho_4 & 1 \end{bmatrix}$$

Clusters of Size 3 | 3 Repeated Measures | 2 Response Variables

Overall Covariance Model for SIT Trial

- Variance of Memory of Pain = 0.96
- Correlation of responses 6 months apart = 0.5
- Correlation decays slowly over time, between 0 and 12 months correlation = 0.4

Overall Covariance Model for SIT Trial

$$\sigma^2 \begin{bmatrix} 1 & \rho_1 & \rho_2 \\ \rho_1 & 1 & \rho_3 \\ \rho_2 & \rho_3 & 1 \end{bmatrix} = 0.96 \begin{bmatrix} 1 & 0.5 & 0.4 \\ 0.5 & 1 & 0.5 \\ 0.4 & 0.5 & 1 \end{bmatrix}$$

Example 2 - Power

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Alcohol Use Prevention Study

Alcohol Use Prevention Study Example for Power

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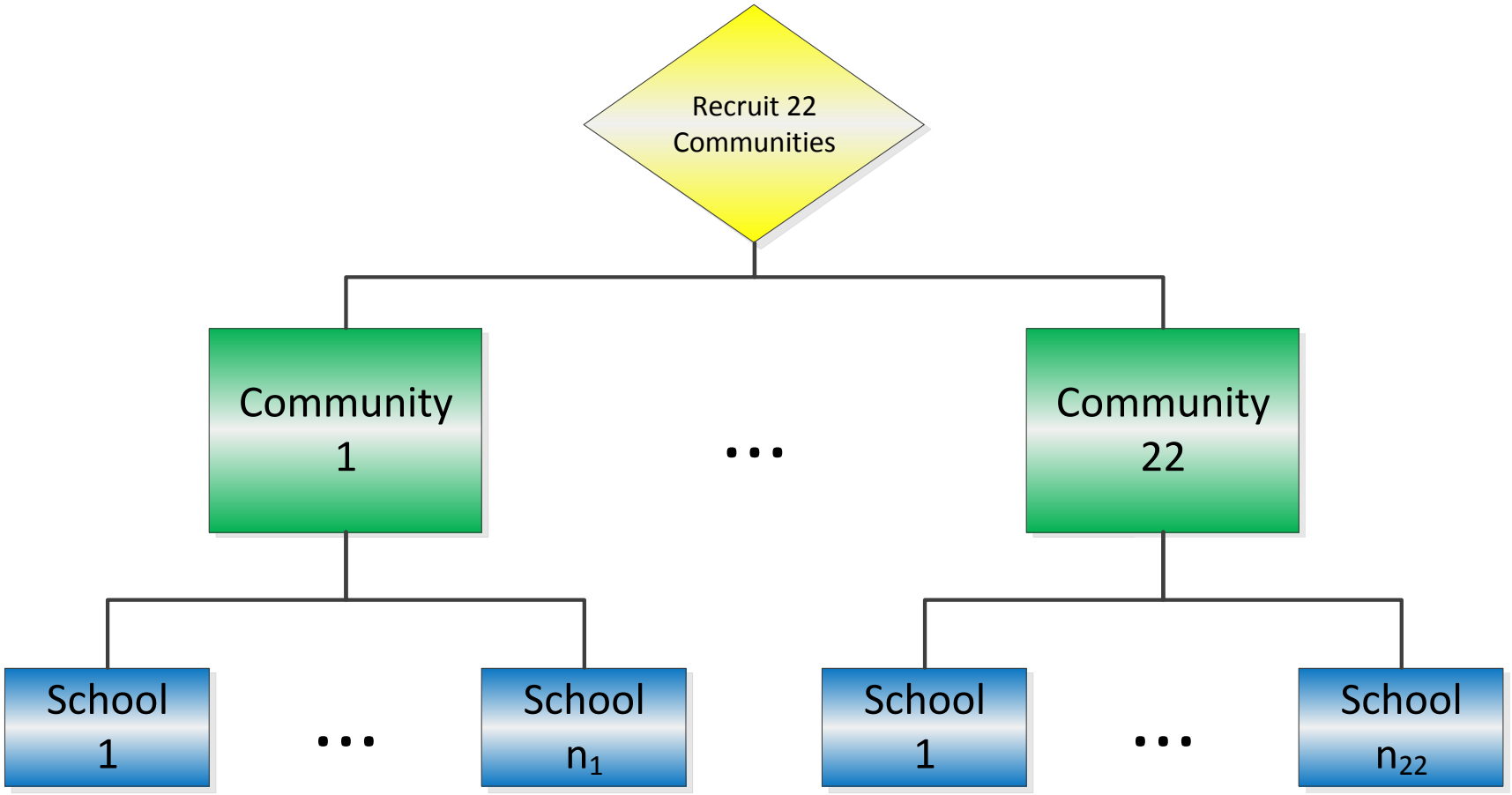

Alcohol Use Prevention Study Example for Power

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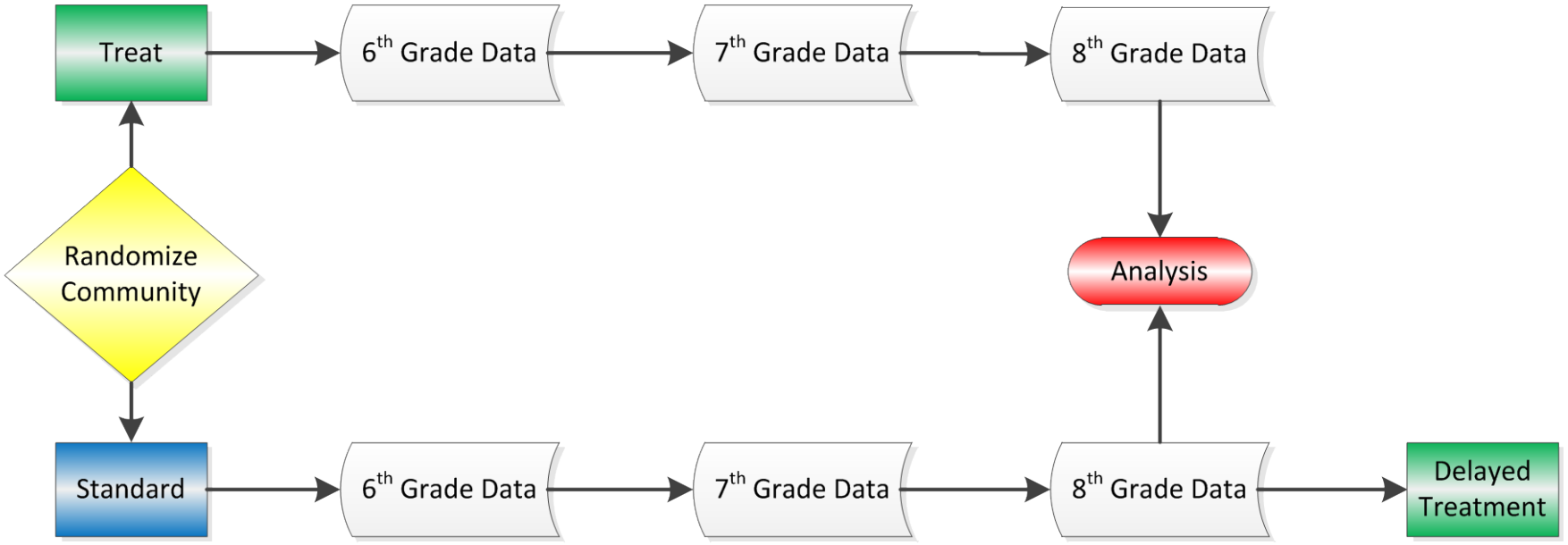

PNC Trial: Study Design Checklist

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1. What is the study design goal?
   a. Solving for power or sample size
      Power
   c. Type I error rate
      0.05

PNC Trial: Study Design Checklist

2. What is the sampling scheme?
   a. How many groups?
      2 treatment groups
   b. What are the covariates?
      None
   c. Is clustering present?
      Yes; one level
   d. Are group sizes equal or unequal?
      Yes, with 10 communities per group

PNC Trial: Study Design Checklist

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3. What responses are measured?
   a. What are the response variables?
      Alcohol use behavior scale
   b. Are repeated measures present?
      Yes, at 6th, 7th and 8th grades

4. What is the primary hypothesis of interest?
   Time Trend by Treatment Interaction

PNC Trial: Study Design Checklist

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5. What are the means?

Mean difference is 0.25 reduction in self reported alcohol use in treatment group vs. control

PNC Trial: Study Design Checklist

6. What is the variance structure?
   a. What are the sources of correlation in the study design?
      - **Clustering (one level), with clusters of size 10 (# children/cluster)**
      - **Repeated Measures, 3 occasions, 1 year apart**

PNC Trial: Study Design Checklist

6. What is the variance structure?
   b. What is the pattern of variability for each source of correlation?
   - **Variance: 0.09**
   - **Intraclass correlation for community: 0.01 (ρ_c)**
   - **Correlation for responses 1 year apart: 0.3 (ρ_r)**
   - **Correlation decays slowly over time with decay rate of 0.3 (δ)**

Overall Covariance Structure for PNC Trial

$$\sigma^2 \begin{bmatrix} 1 & \cdots & \rho_c \\ \vdots & \ddots & \vdots \\ \rho_c & \cdots & 1 \end{bmatrix} \otimes \begin{bmatrix} 1 & \rho_r & \rho_r^{1+\delta} \\ \rho_r & 1 & \rho_r \\ \rho_r^{1+\delta} & \rho_r & 1 \end{bmatrix}$$

$$= 0.09 \begin{bmatrix} 1 & \cdots & 0.01 \\ \vdots & \ddots & \vdots \\ 0.01 & \cdots & 1 \end{bmatrix} \otimes \begin{bmatrix} 1 & 0.3 & 0.21 \\ 0.3 & 1 & 0.3 \\ 0.21 & 0.3 & 1 \end{bmatrix}$$

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- **Missing Data**
- Summary and Segue to Software Solution: GLIMMPSE

Missing Data Adjustments

- Some useful crude approximations (Catellier and Muller, 2000):
  - Complete data power is an upper bound
  - Power for N = (100% - % missing) x # ISUs appears conservative, requires assuming data are Missing at Random
- Work is in progress to identify better approximations

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- **Summary and Segue to Software Solution: GLIMMPSE**

Summary

- Under widely applicable restrictions a LMM can be expressed as a General Linear Multivariate Model for which accurate power and sample size analysis is available.
- Answers to a series of simple questions can completely specify the inputs to a power analysis.
- Convenient adjustments appear to suffice for simple missing data patterns.
- **Bonus**: FREE software is now available to implement the methods - GLIMMPSE - next!

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Mixed Model Power Analysis By Example: Using Free Web-Based Power Software

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Grant Support

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The progress described was supported by the National Cancer Institute of the National Institutes of Health under award number NCI 3K07CA088811-06S, and by the National Institute of Dental and Craniofacial Research under award NIDCR 1 R01 DE020832-01A1. The content is solely the responsibility of the authors, and does not necessarily represent the official views of the National Cancer Institute, the National Institute of Dental and Craniofacial Research nor the National Institutes of Health.

Agenda

- Motivate the need for GLIMMPSE
- Introduce the GLIMMPSE software
- Present GLIMMPSE validation results
- Example 1: The Stress Inoculation Training (SIT) trial
- Example 2: The Project Northland Chicago (PNC) trial

Agenda

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Motivate GLIMMPSE

- Power and sample size calculation is critical for ethical study design.
- Known results are underutilized.
- Our goal: provide a user-friendly tool for calculating power and sample size.

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What is GLIMMPSE?

- GLIMMPSE is an online tool for calculating power and sample size for the general linear multivariate model (GLMM) and for a broad class of general linear mixed models (LMM)

- http://glimmpse.samplesizeshop.com/

- http://glimmpsebeta.samplesizeshop.com/

GLIMMPSE Development Team

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- Sarah Kreidler, Tech Lead
- Vijay Chander Akula, Software Engineer
- Uttara Sakhadeo, Software Engineer

- Manual Preparation:
  - Zacchary Coker-Dukowitz
  - Brandy Ringham
  - Yi Guo

Why a Web-based Interface?

- Free
- Requires no programming expertise
- Built with industry standard Java technology

GLIMMPSE Features

- Web-based
- Free and open-source
- Designed with an intuitive wizard input style
- Able to produce power curves
- Able to export power results
- Able to save study designs for later use

Supported Study Designs

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- Cross-sectional studies
- Longitudinal designs
- Multilevel designs
- Designs with a baseline covariate

Two Interaction Modes

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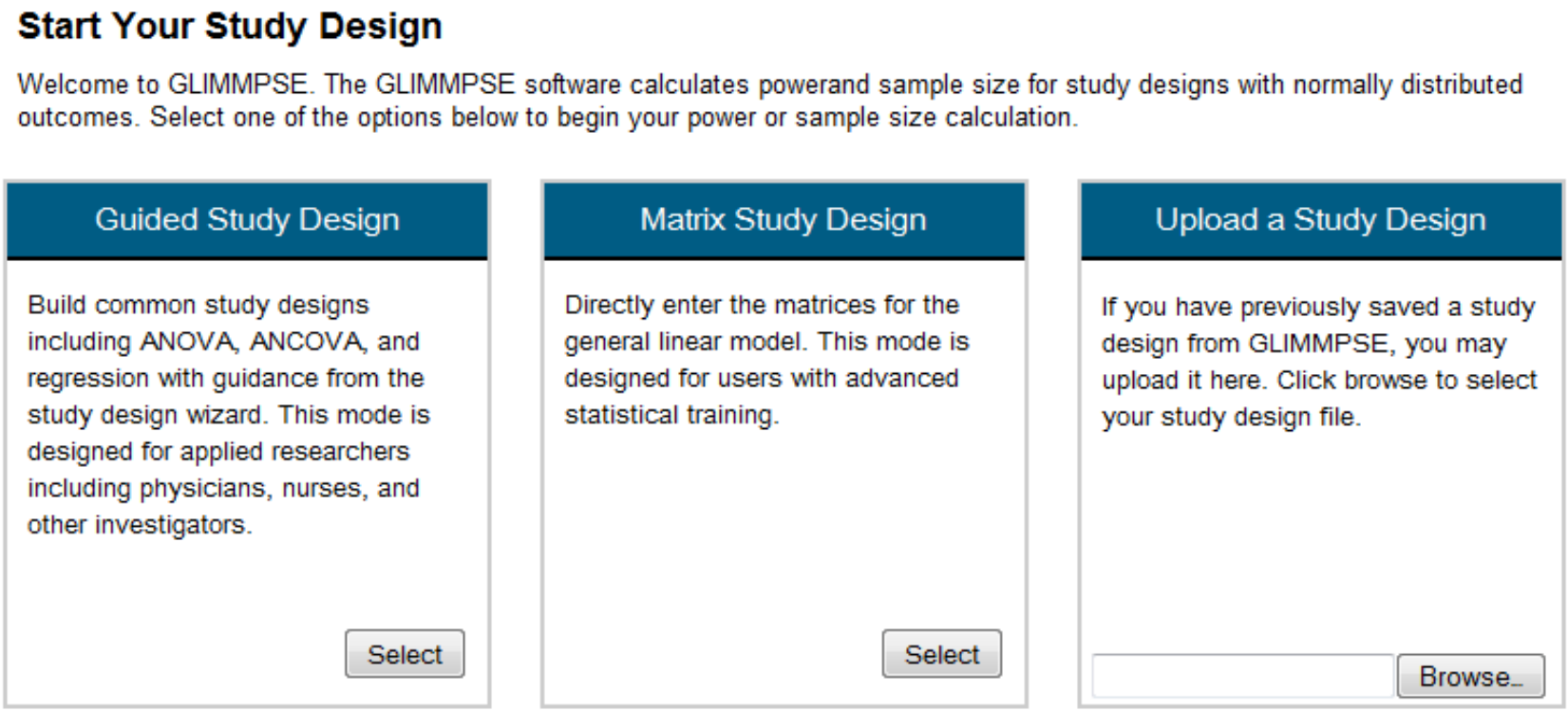

Related Publications

- GLMM with fixed predictors
  - Muller and Peterson, 1984
  - Muller and Barton, 1989
  - Muller *et al.*, 1992
  - Muller *et al.*, 2007

- GLMM with fixed predictors and a Gaussian covariate
  - Glueck and Muller, 2003

GLIMMPSE Limitations

- Binary or count data
- Very high dimensional, low sample size designs
- Certain classes of mixed models
- Adjustments for missing data
- Sample size based on confidence interval width

Agenda

- Motivate the need for GLIMMPSE
- Introduce the GLIMMPSE software
- **Present GLIMMPSE validation results**
- Example 1: The Stress Inoculation Training (SIT) trial
- Example 2: The Project Northland Chicago (PNC) trial

Validation

- Validated against published results and simulation

- Full validation results are available online

http://samplesizeshop.com/documentation/glimmpse-validation-results/

Validation Results

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- 6 decimal accuracy against published results
- 2 decimal accuracy against simulation
- Worst case error in 1st decimal for complex multivariate designs

Agenda

- Motivate the need for GLIMMPSE
- Introduce the GLIMMPSE software
- Present GLIMMPSE validation results
- **Example 1: The Stress Inoculation Training (SIT) trial**
- Example 2: The Project Northland Chicago (PNC) trial

The Stress Inoculation Training (SIT) Trial

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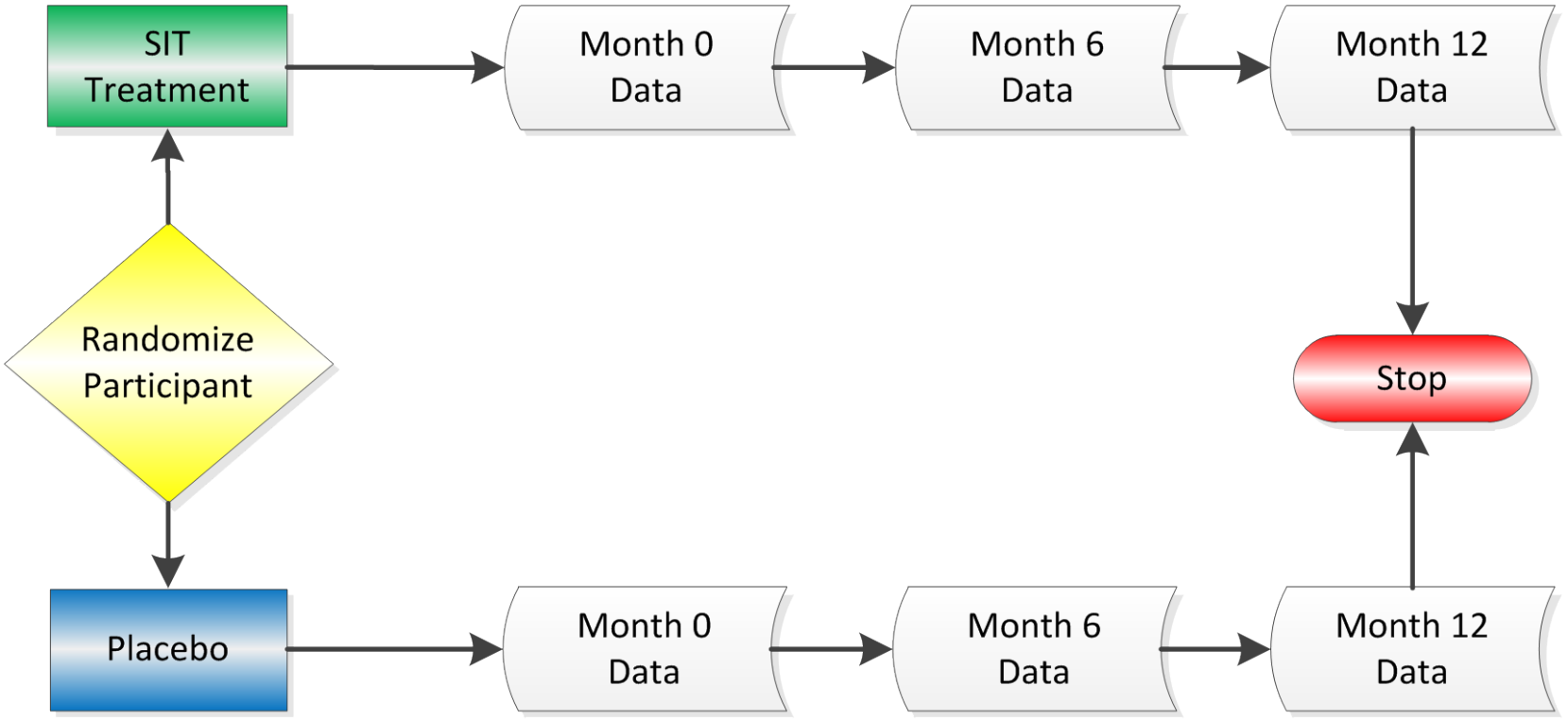


The SIT Trial: Checklist

1. What is the study design goal?

   a. Solving for sample size

   b. Desired power 0.9

   c. Type I error rate 0.01

The SIT Trial: Checklist

2. What is the sampling scheme?

   a. 2 treatment groups, 4 coping styles

   b. No covariates

   c. No clustering

   d. Equal group sizes

The SIT Trial: Checklist

3. What responses are measured?

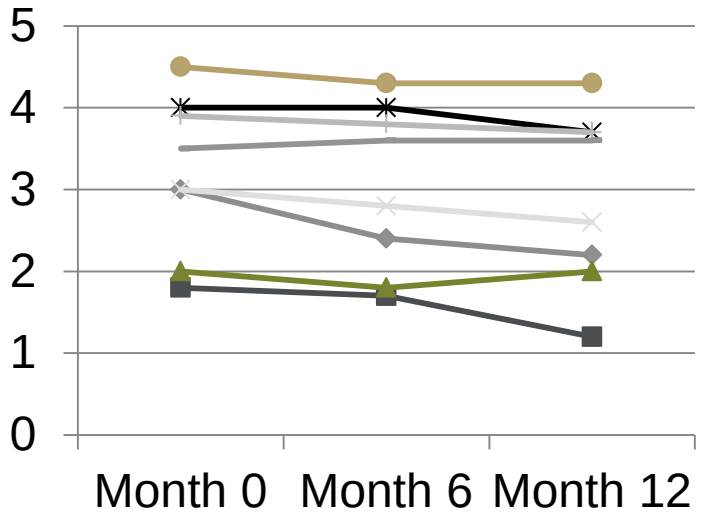
   a. Response variable: memory of pain

   b. Repeated measures at 0, 6, and 12 months

The SIT Trial: Checklist

4. What is the primary hypothesis of interest?

Time trend by treatment interaction



The SIT Trial: Checklist

5. What are the means?

Treated, “high need for and low feelings of control” group with mean 1.2 points lower than corresponding untreated group at month 12.

The SIT Trial: Checklist

6. What is the variance structure?

   a. Correlation due to repeated measures
      - *Variance in memory of pain: 0.96 points*
      - *Correlation 6 months apart: 0.5*

   b. Expect correlation to decay slowly over time
      - *Correlation 12 months apart: 0.4*

Sample Size with GLIMMPSE

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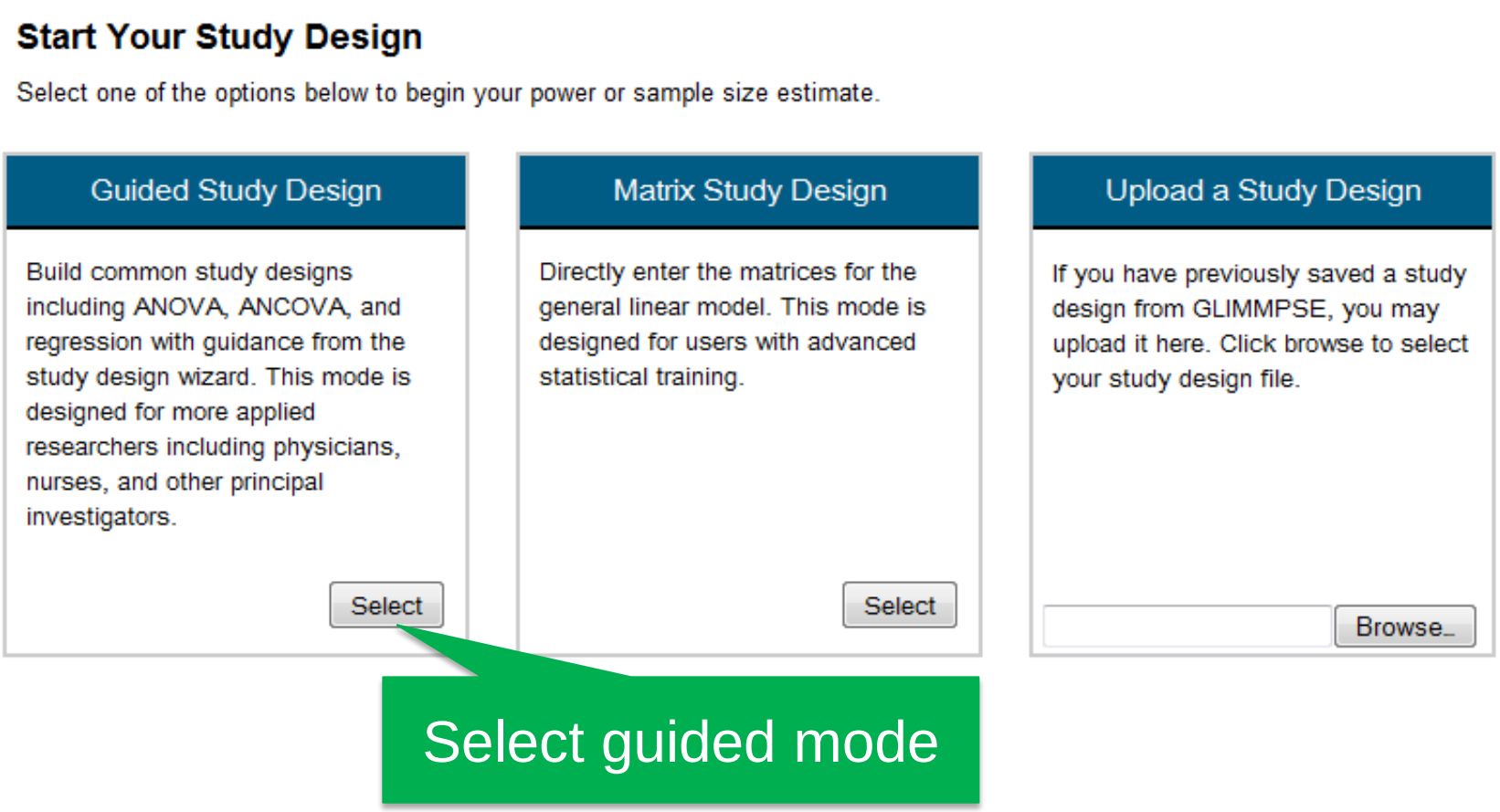

Sample Size with GLIMMPSE

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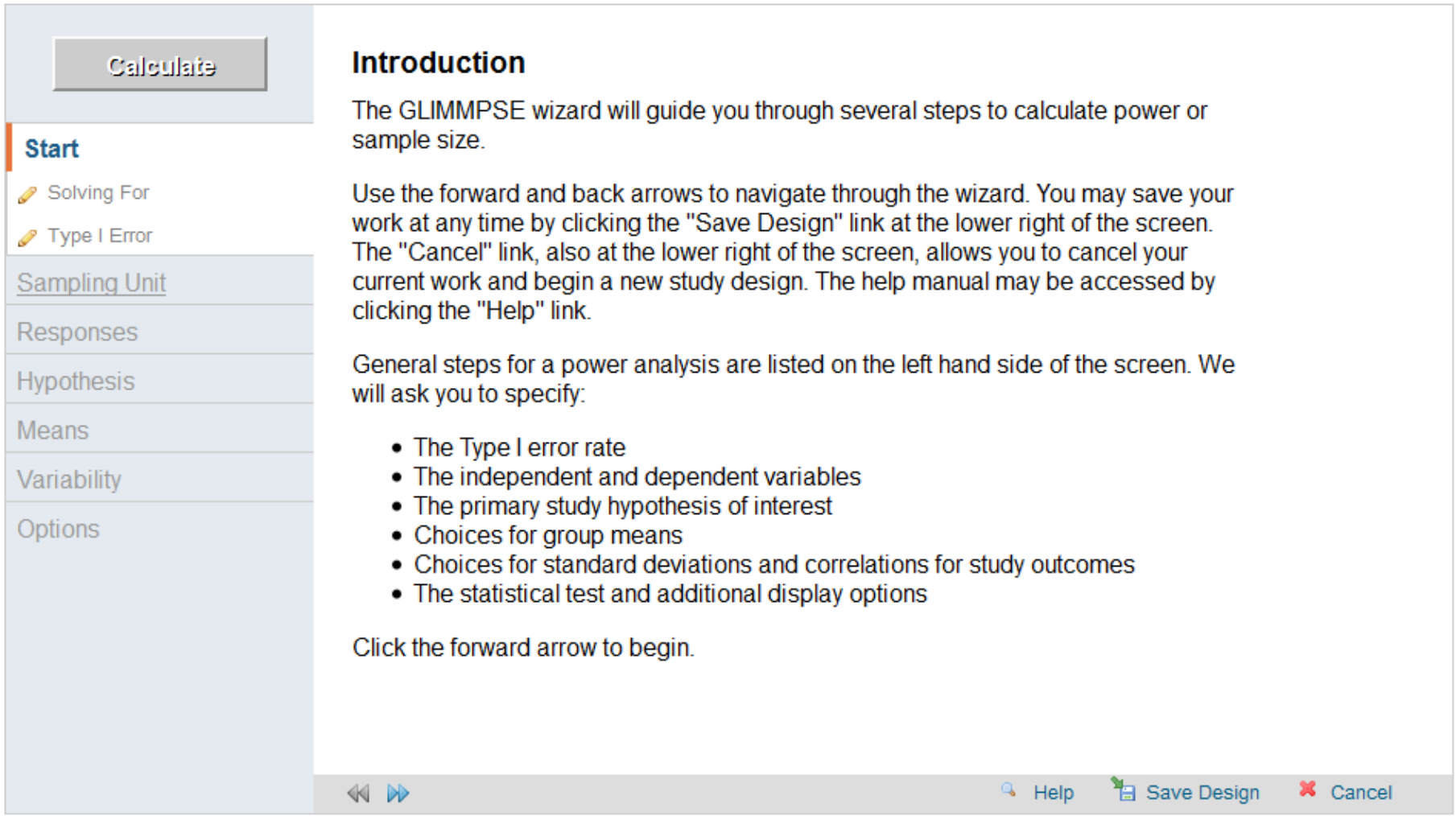

Sample Size with GLIMMPSE

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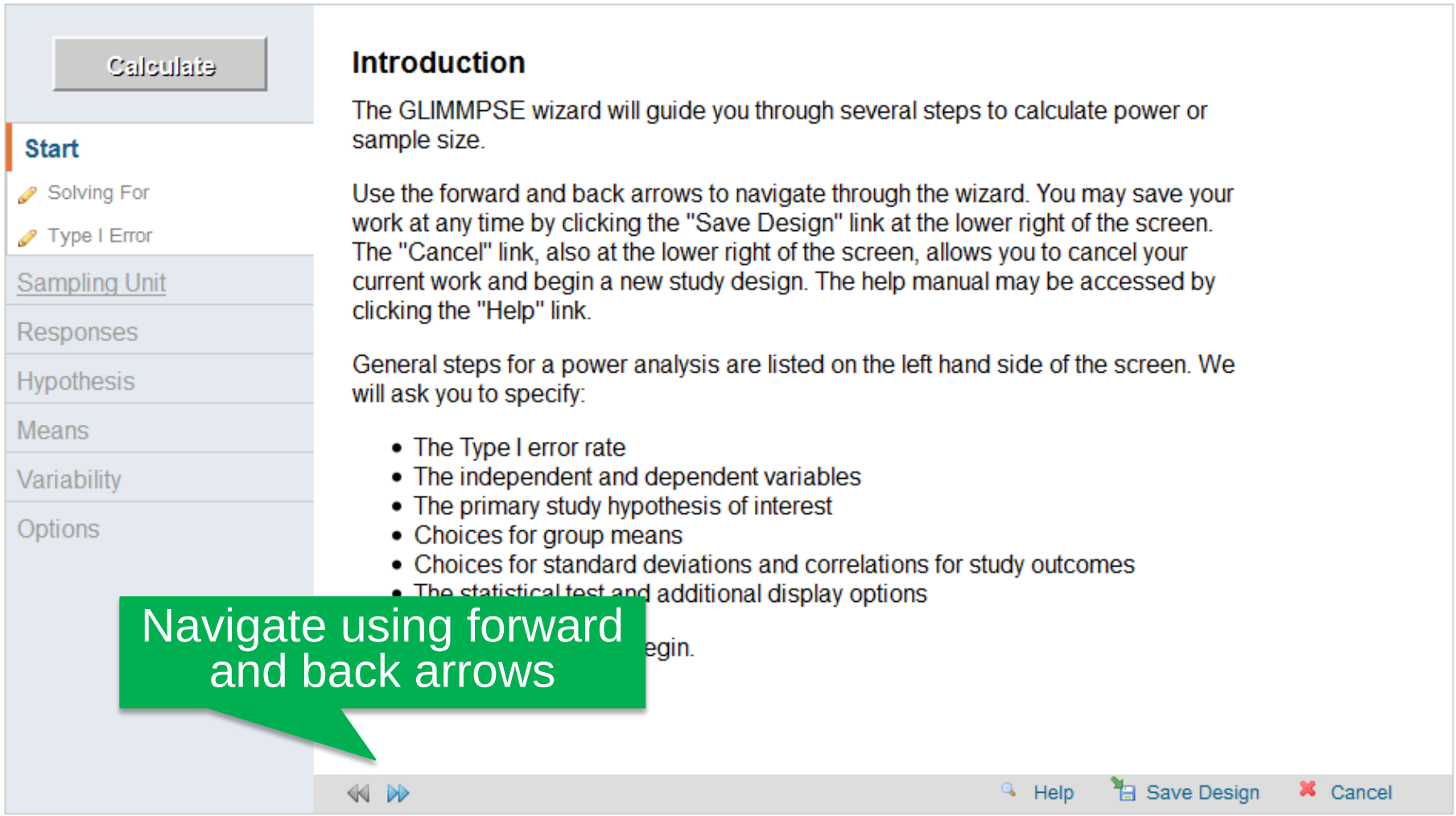

Navigate using forward and back arrows

Sample Size with GLIMMPSE

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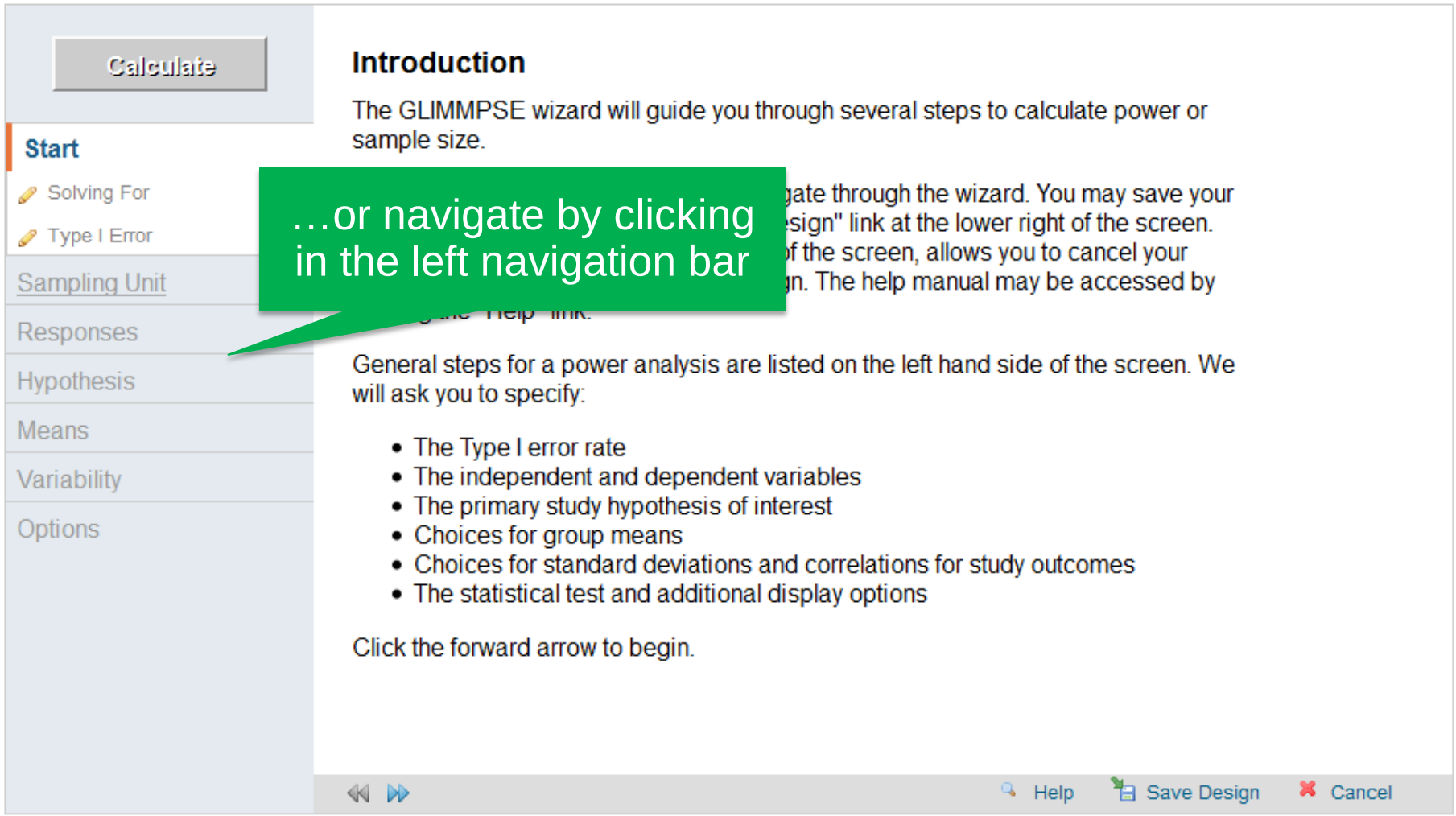

Sample Size with GLIMMPSE

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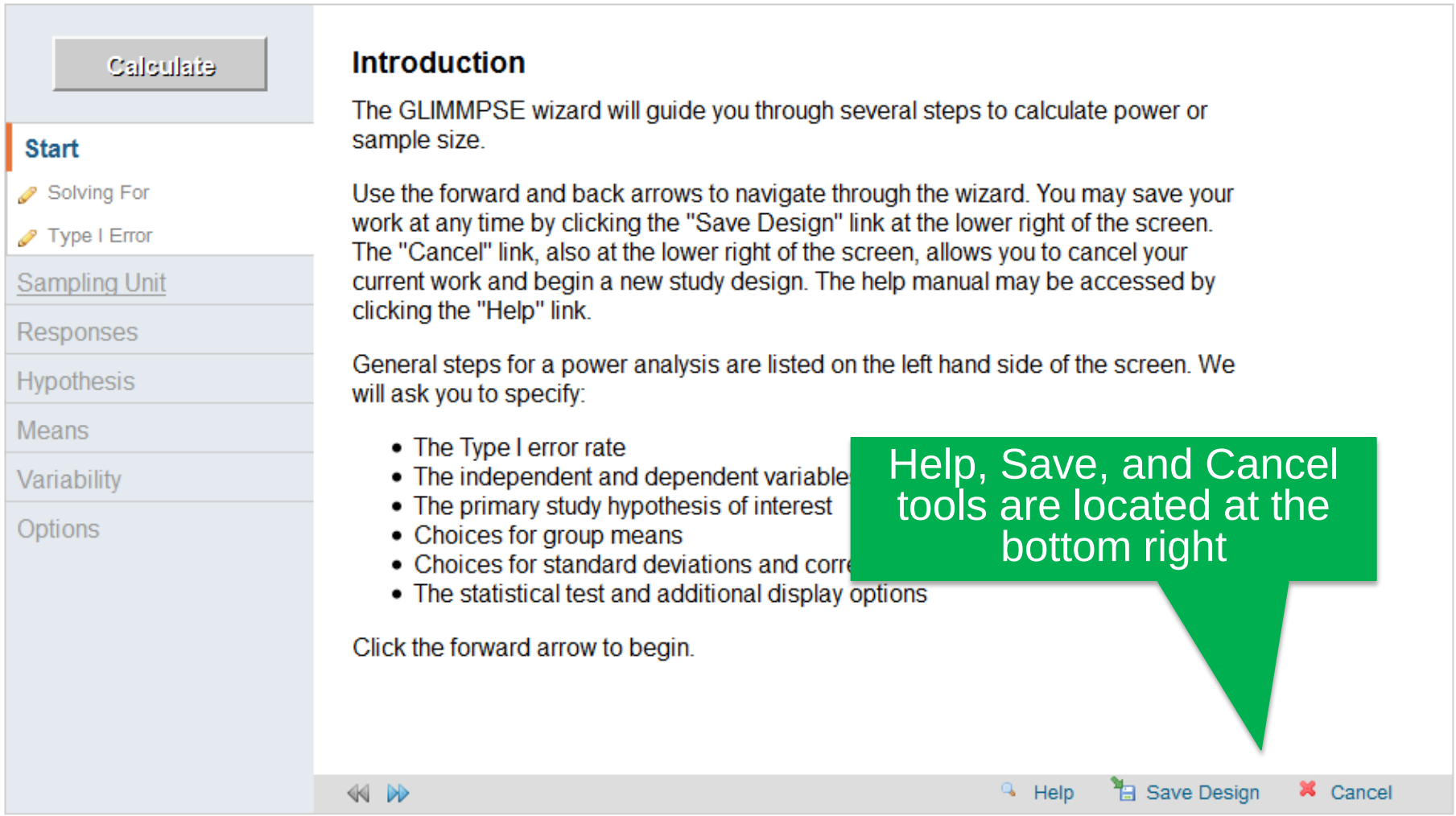

Solving for Sample Size

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Would you like to solve for power or sample size?

To begin your calculation, please indicate whether you would like to solve for power or total sample size.

If you have a rough idea of the number of research participants you will be able to recruit, then solving for power may be more beneficial.

If you have fewer restrictions on recruitment and would like to ensure a well-powered study, then solving for sample size is likely to be more useful.

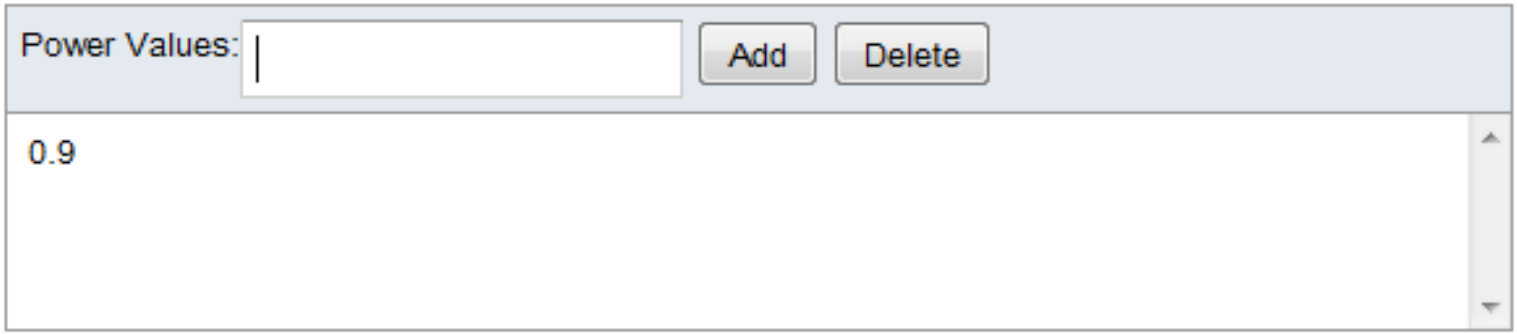
- ○ Power
- ◉ Total Sample Size

Entering the Desired Power

Power Values

Enter the desired power values in the list box below. Power values are numbers between 0 and 1. Higher values correspond to a greater likelihood of rejecting the null hypothesis. Common values are 0.8 or 0.9, although 0.9 or higher is usually preferred.

Type each value into the list box and click "Add". To remove an item, highlight the value and click the "Delete" button.

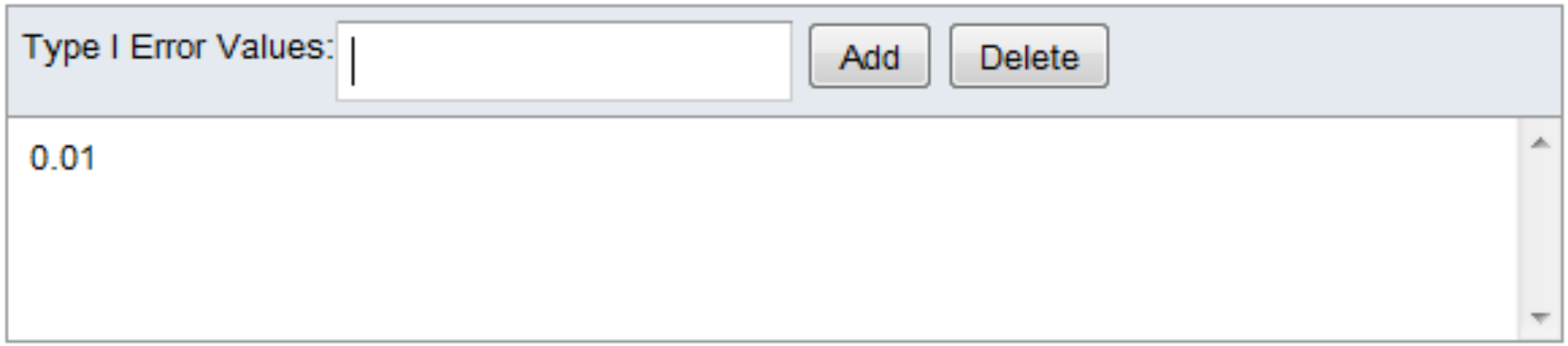


Entering the Type I Error Rate

Type I Error

A Type I error occurs when a scientist declares a difference when none is actually present. The Type I error rate is the probability of a Type I error occurring, and is often referred to as α. Type I error rates range from 0 to 1. The most commonly used values are 0.01, 0.05, and 0.1.

Enter each Type I error value into the text box and click "Add". You may enter up to 5 values. To remove a value, select the value in the list box and click the "Delete" button.



Defining Study Groups

Study Groups

Describe the predictors which assign independent sampling units into groups, such as gender or treatment. If the study includes only one group, select the "One group" button. If the study includes multiple groups, select the " Multiple groups" button.

- ○ One group
- ◉ Multiple groups

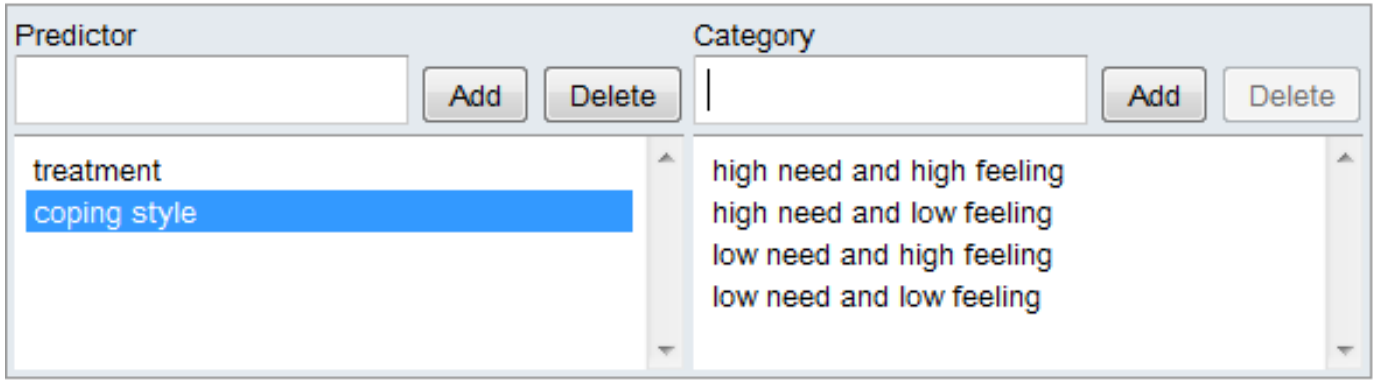
Defining Study Groups

In the table below, specify the fixed predictors. The choice of study design determines the values of fixed predictors (such as drug dose or gender). A common example of a fixed predictor is treatment group, for which the independent sampling unit is randomized to a placebo or an active drug group.

To enter fixed predictors:

1. Enter the name of each predictor in the left text box and click "Add". For example, one might enter "treatment" as a predictor.
2. Select the predictor from the left text box to display the current list of values associated with the predictor. To add a new value, enter the value in the "Category" text box and click "Add". For example, one could select "treatment", then add the values "drug" and "placebo."

Each predictor should have at least two values.



Defining Relative Group Sizes

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Relative Group Sizes

Specify whether the study subgroups are of equal or unequal size.

For equal group sizes, select a "1" in the drop-down list next to each study subgroup. This is the default study design.

For unequal group sizes, specify the ratio of the group sizes. For example, consider a design with an active drug group and a placebo group. If twice as many study participants receive the placebo, a value of "2" would be selected for the placebo group, and a value of "1" would be selected for the active drug group.

Relative Group Size	treatment	coping style
1	SIT	high need and high feeling
1	SIT	high need and low feeling
1	SIT	low need and high feeling
1	SIT	low need and low feeling
1	placebo	high need and high feeling
1	placebo	high need and low feeling
1	placebo	low need and high feeling
1	placebo	low need and low feeling

Defining Relative Group Sizes

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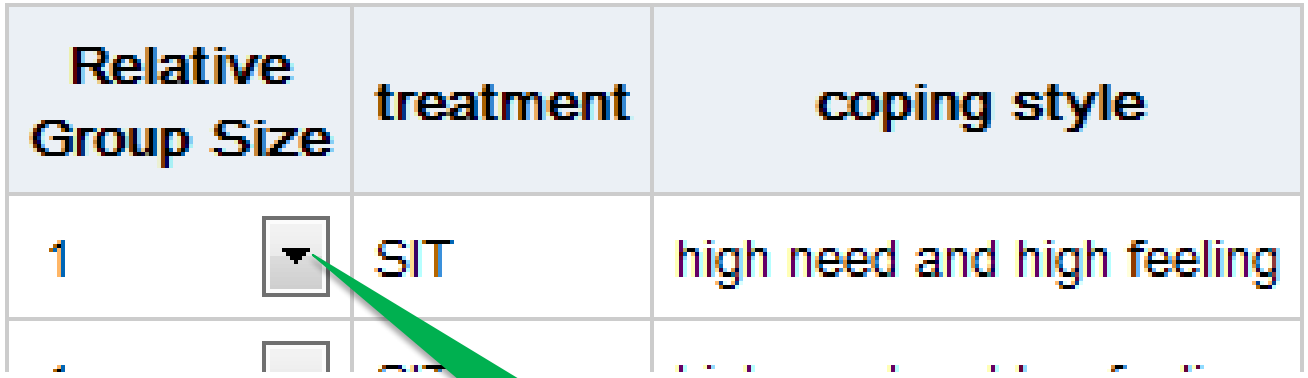


Modify the relative size using the dropdown lists

Entering Response Variables

Response Variables

Enter the response variables in the table below. For example, in a study investigating cholesterol-lowering medication, the response variable could be HDL, LDL, and total cholesterol.

Note that repeated measurement information will be addressed on the next screen.

Response Variables: | Add | Delete

memory of pain

Entering Repeated Measures

Repeated Measures

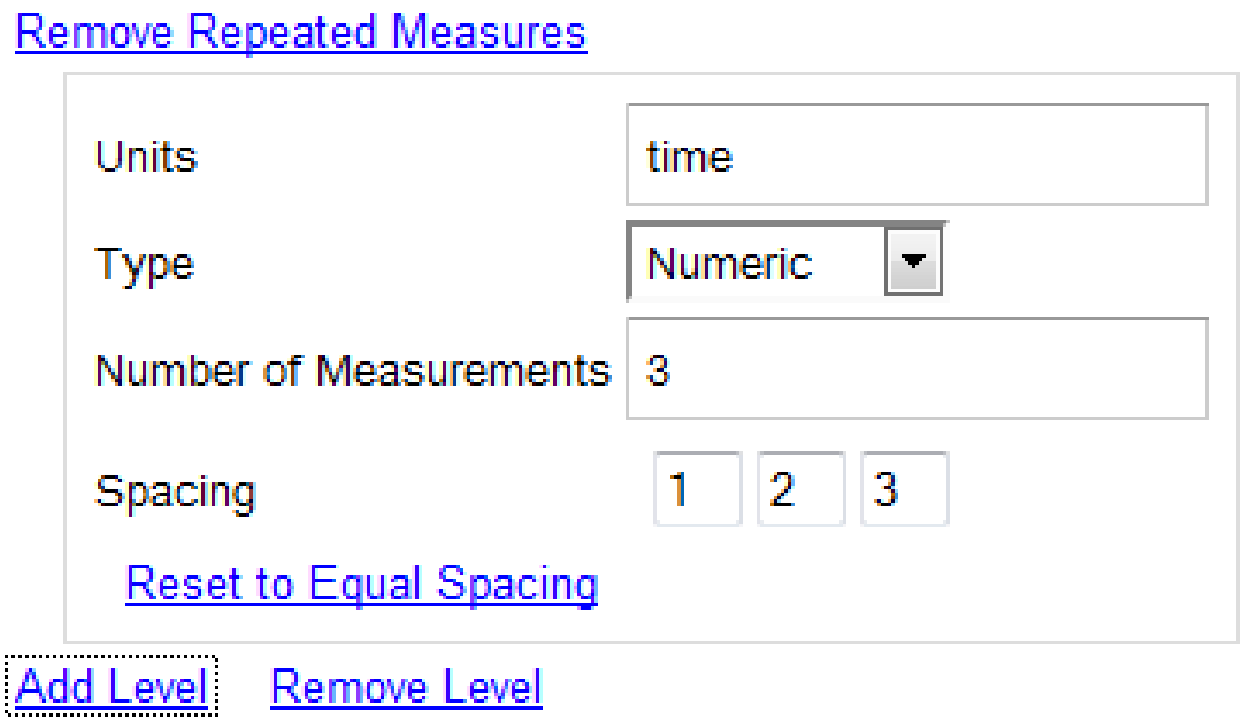
Repeated measures are present when a response variable is measured on each research participant on two or more occasions or under two or more conditions.

If the study includes repeated measurements, click "Add repeated measures" and follow the prompts. The text entered in the "Units" text box indicates the dimension over which measures were taken (ex. time, days, locations, etc.). The choice of "Type" indicates whether the repeated measures are numeric (ex. time), ordinal (ex. 1st, 2nd, 3rd), or categorical (ex. arm, leg, hand).

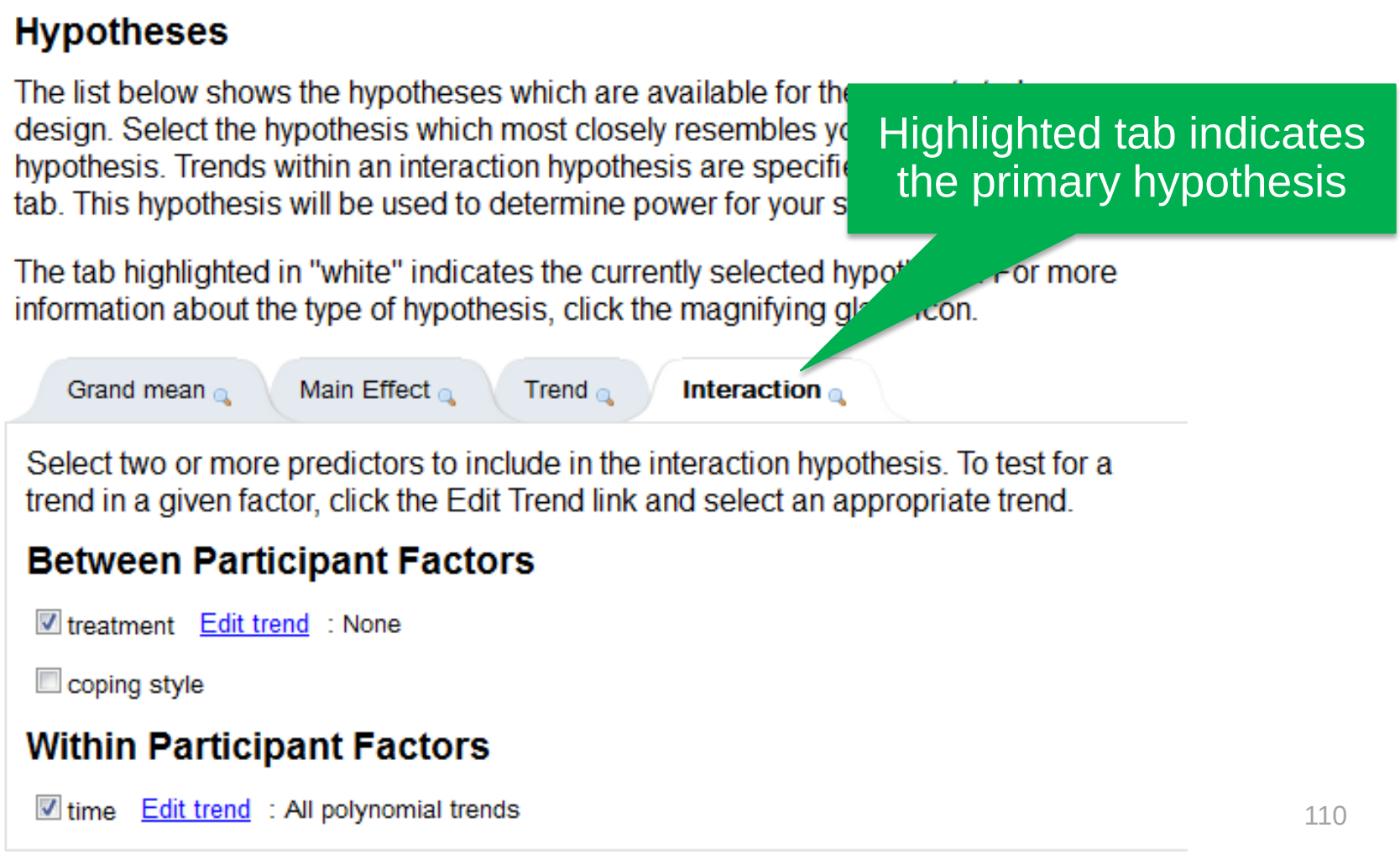
You may specify up to 3 levels of repeated measures.

Add Repeated Measures

Entering Repeated Measures

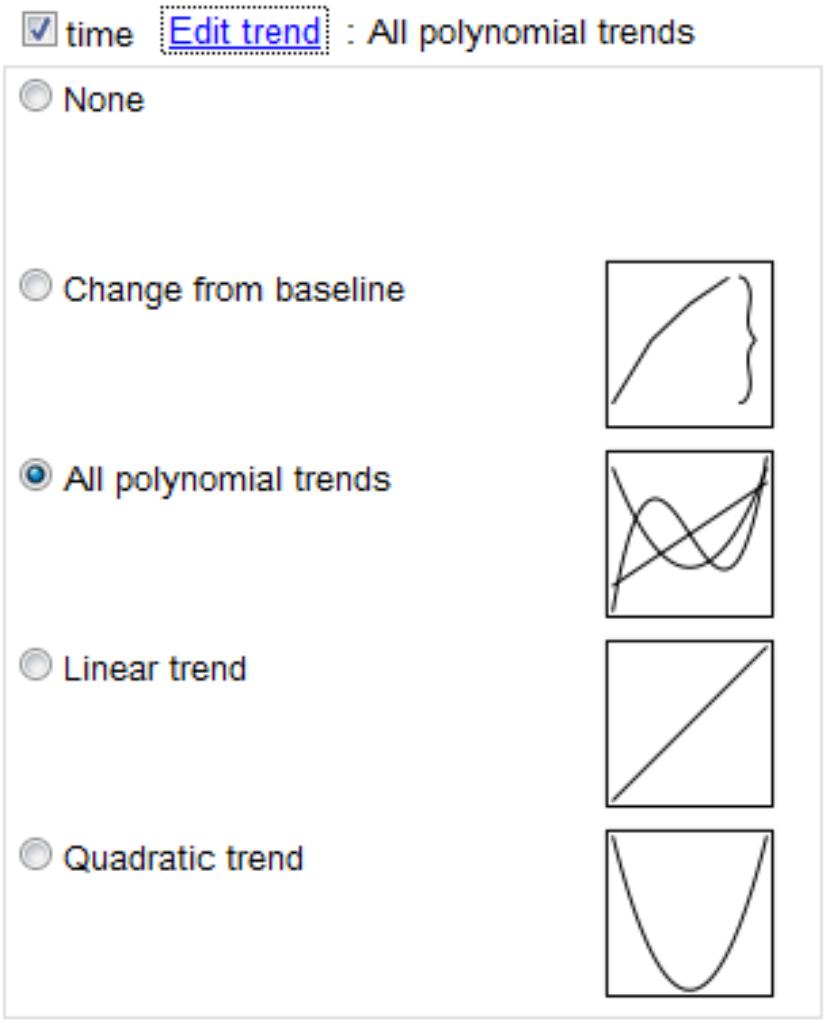


Selecting a Hypothesis



Highlighted tab indicates the primary hypothesis

Selecting a Trend



Entering Means

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Means

The table below shows the mean values for each outcome within each study subgroup. The study subgroups are listed along the left hand side of the table, and the outcomes are listed across the top.

Enter the mean values you expect to observe for each outcome within each study subgroup. The table should contain at least one value that is non-zero. Also, at least two subgroups should have means which differ by a scientifically meaningful amount.

treatment	coping style	memory of pain
SIT	high need and high feeling	0
SIT	high need and low feeling	-1.2
SIT	low need and high feeling	0
SIT	low need and low feeling	0
placebo	high need and high feeling	0
placebo	high need and low feeling	0
placebo	low need and high feeling	0
placebo	low need and low feeling	0

Select the time (location, etc.) from the list(s) below. This will allow you to edit the means at the selected time (location, etc.).

time 3

Entering Means

Select the time (location, etc.) from the list(s) below.

etc.).

Enter means at different times

Entering Means

treatment	coping style	memory of pain
SIT	high need and high feeling	0
SIT	high need and low feeling	-1.2
SIT	low need and high feelin	0
SIT	low need and lo ng	0

Clinically meaningful difference

Checking a Range of Means

Flexible Means

Power and sample size results will change depending on the mean values specified on the previous screen. It is not possible to know exact values for the means until the experiment is observed. To account for the uncertainty, it is common to calculate power for the mean values as specified, the mean values divided by 2, and the mean values multiplied by 2.

☐ Yes, include power calculations for the mean values as entered, the mean values divided by 2, and the mean values multiplied by 2.

Entering Variability

Variability and Correlation within an Individual Research Participant

For a given research participant, responses vary across response variables and across repeated measurements . The amount of variability can dramatically impact power and sample size. Click on each of the tabs below to describe the varibility you expect to observe for the response variables and each within-particpant factor.

time | Responses

Tabs represent each "source" of correlation

Structured Correlation: The Linear Exponenti
(LEAR, Simpson et al., 2010)

The LEAR model describes correlation which monotonely decreases with distance between repeated measurements. The model has two correlation parameters, the base correlation and the decay rate. The base correlation describes the correlation between measurements taken 1 unit apart. The decay rate describes the rate of decrease in the base correlation as the distance or time between repeated measurements increases. Our experience with biological and behavioral data lead us to suggest using decay values between 0.05 and 0.5.

Base Correlation

Decay Rate

	time,1	time,2	time,3
time,1	1	0	0
time,2	0	1	0
time,3	0	0	1

Unstructured correlation

Entering Variability

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Variability and Correlation within an Individual Research Participant

For a given research participant, responses vary across response variables and across repeated measurements . The amount of variability can dramatically impact power and sample size. Click on each of the tabs below to describe the varibility you expect to observe for the response variables and each within-particpant factor.

time | Responses

Structured Correlation: The Linear Exponential Auto-Regressive Model (LEAR, Simpson et al., 2010)

The LEAR model describes correlation which monotonely decreases with distance between repeated measurements. The model has two correlation parameters, the base correlation and the decay rate. The base correlation describes the correlation between measurements taken 1 unit apart. The decay rate describes the rate of decrease in the base correlation as the distance or time between repeated measurements increases. Our experience with biological and behavioral data lead us to suggest using decay values between 0.05 and 0.5.

Base Correlation

Decay Rate

	time,1	time,2	time,3
time,1	1	0	0
time,2	0	1	0
time,3	0	0	1

Unstructured correlation

Use unstructured correlation view

Entering Variability

time | Responses

Enter the correlations you expect to observe among the repeated measurements.

	time,1	time,2	time,3
time,1	1	0.5	0.4
time,2	0.5	1	0.5
time,3	0.4	0.5	1

Structured correlation

Entering Variability

time **Responses**

Enter the standard deviation you expect to observe for each response. Note that GLIMMPSE currently assumes that the standard deviation is constant across repeated measurements.

memory of pain 0.98

Checking a Range of Variability

Flexible Variability

On the previous screens, you entered standard deviations and correlations. GLIMMPSE has used these values to calculate a covariance matrix which describes the overall variability.

Changes in variability can dramatically affect power and sample size results. It is not possible to know the variability until the experiment is observed. To account for this uncertainty, it is common to calculate power or sample size for alternative values for variability.

By clicking the box below, GLIMMPSE will calculate power using the calculated covariance matrix, the covariance matrix divided by 2, and the covariance matrix multiplied by 2.

☑ Yes, include power for the covariance matrix, the covariance matrix divided by 2, and the covariance matrix multiplied by 2.

Selecting a Test

Statistical Tests

Select the statistical tests to include in your calculations. For study designs with a single outcome, power is the same regardless of the test selected.

Note that only the Hotelling-Lawley Trace and the Univariate Approach to Repeated Measures are supported for designs which include a baseline covariate.

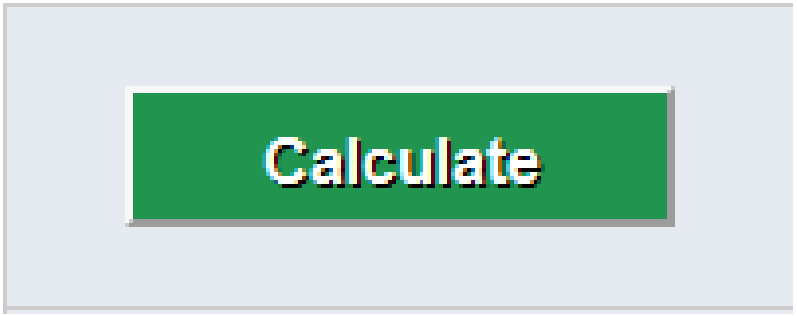
- [x] Hotelling-Lawley Trace
- [ ] Pillai-Bartlett Trace
- [ ] Wilks Likelihood Ratio
- [ ] Univariate Approach to Repeated Measures with Box Correction
- [ ] Univariate Approach to Repeated Measures with Geisser-Greenhouse Correction
- [ ] Univariate Approach to Repeated Measures with Huynh-Feldt Correction
- [ ] Univariate Approach to Repeated Measures, uncorrected

Additional Options

- Confidence intervals for power
- Power curves

Obtaining Results

- When a complete study design has been entered, the calculate button will highlight
- Click the calculate button to obtain your results



Results

Power Results

Test	Actual Power	Total Sample Size	Beta Scale	Sigma Scale	Alpha	Nominal Power	Power Method
HLT	0.9017	600	1.0000	1.0000	0.0100	0.9000	CONDITIONAL
HLT	0.9124	312	1.0000	0.5000	0.0100	0.9000	CONDITIONAL
HLT	0.9035	1200	1.0000	2.0000	0.0100	0.9000	CONDITIONAL

Save to CSV

▶ View Matrices

Minimum total sample size to achieve 0.90 power

Summary for Manuscript

Participants were categorized by coping style, and randomized to receive either the SIT intervention or placebo. Sample size was calculated assuming a Type I error rate of 0.01, and a standard deviation of 0.98 for pain scores. Correlation between repeated pain scores was assumed to be 0.5 for measurements 6 months apart, and 0.4 for measurements 12 months apart. To achieve 0.90 power for detecting a time by treatment interaction of 1.2 points using the Hotelling-Lawley trace test, a total sample size of 600 participants was required.

Agenda

- Motivate the need for GLIMMPSE
- Introduce the GLIMMPSE software
- Present GLIMMPSE validation results
- Example 1: The Stress Inoculation Training (SIT) trial
- **Example 2: The Project Northland Chicago (PNC) trial**

The PNC Trial: Cluster Randomized Design

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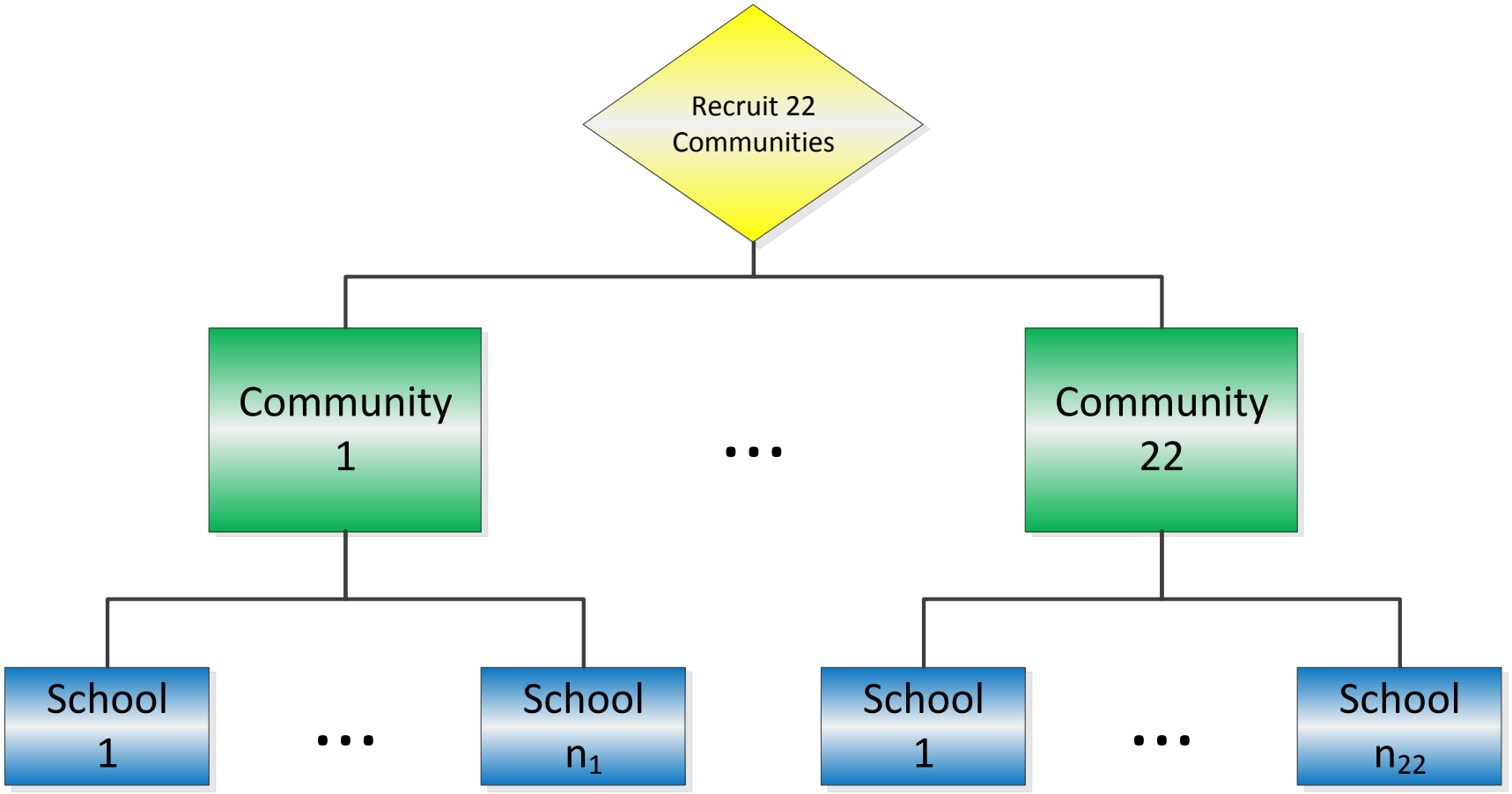

The PNC Trial: Longitudinal Features

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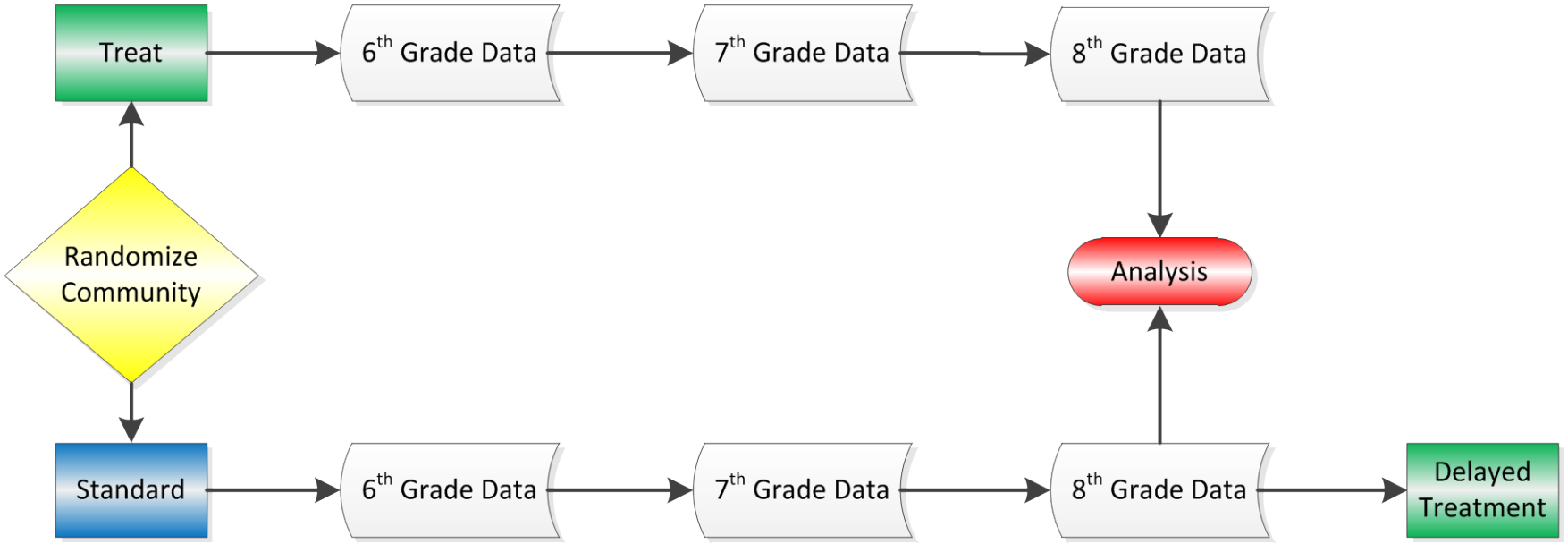

The PNC Trial: Checklist

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1. What is the study design goal?

   a. Solving for power

   c. Type I error rate is 0.05

The PNC Trial: Checklist

2. What is the sampling scheme?

   a. 2 treatment groups

   b. No covariates

   c. Clustering by community

   d. Equal treatment group sizes

   e. 3, 4,…,10 communities

The PNC Trial: Checklist

3. What responses are measured?

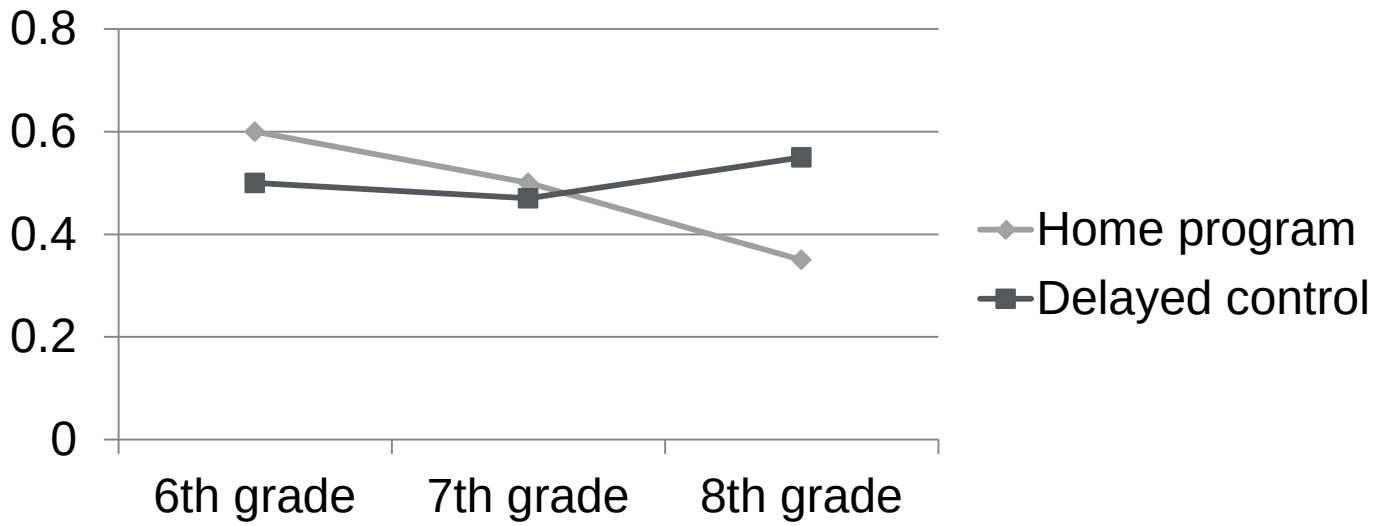
   a. Response variable: alcohol behavior scale

   b. 3 repeated measures in 6th, 7th, and 8th grade

The PNC Trial: Checklist

4. What is the primary hypothesis of interest?

Time trend by treatment interaction



The PNC Trial: Checklist

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5. What are the means?

Clinically meaningful difference is 0.25 reduction in alcohol use in treatment group in 8th grade.

The PNC Trial: Checklist

6. What is the variance structure?

   a. Correlation due to clustering and repeated measures
      - *Cluster size: 10*
      - *Standard deviation of alcohol behavior scale: 0.3*

   b. Patterns of variability
      - *Clustering*
        - Compound symmetry
        - ICC: 0.01
      - *Repeated Measures:*
        - Correlation 1 year apart: 0.3
        - Decay rate: 0.3

Power with GLIMMPSE

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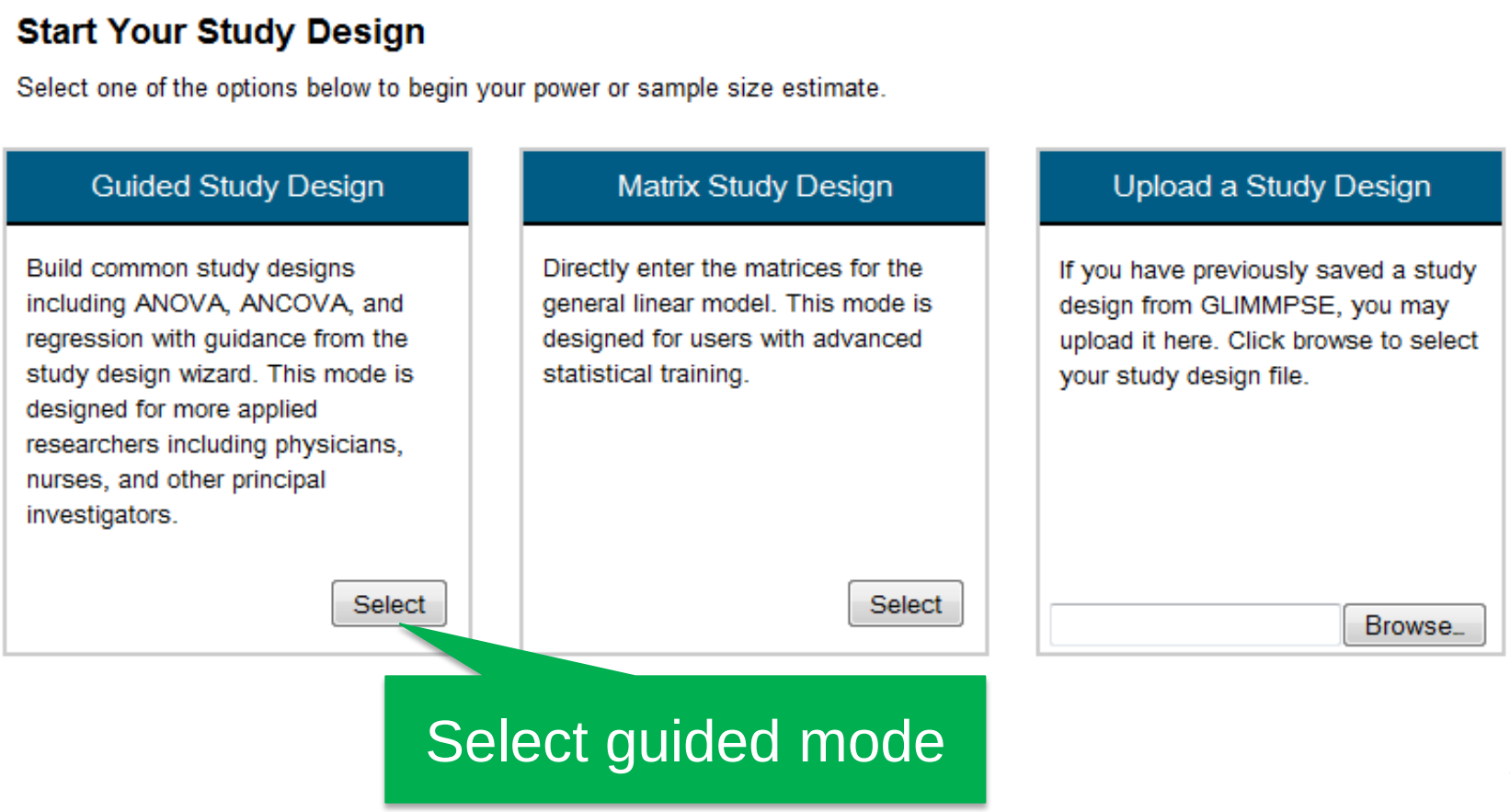

Solving for Power

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Would you like to solve for power or sample size?

To begin your calculation, please indicate whether you would like to solve for power or total sample size.

If you have a rough idea of the number of research participants you will be able to recruit, then solving for power may be more beneficial.

If you have fewer restrictions on recruitment and would like to ensure a well-powered study, then solving for sample size is likely to be more useful.

- (•) Power
- ( ) Total Sample Size

Entering the Type I Error Rate

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Type I Error

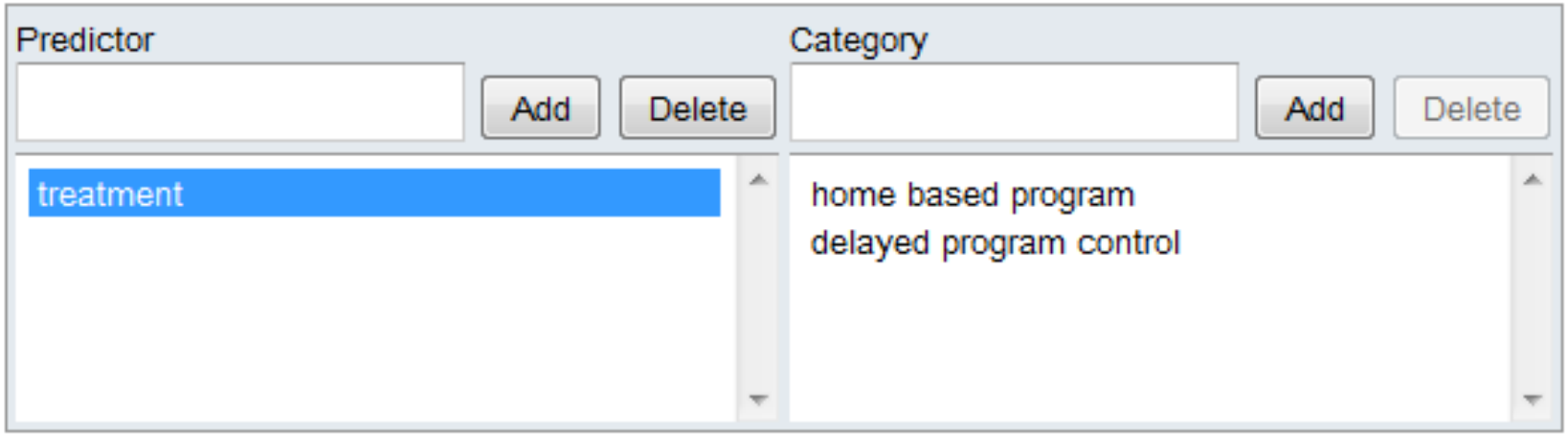
A Type I error occurs when a scientist declares a difference when none is actually present. The Type I error rate is the probability of a Type I error occurring, and is often referred to as α. Type I error rates range from 0 to 1. The most commonly used values are 0.01, 0.05, and 0.1.

Enter each Type I error value into the text box and click "Add". You may enter up to 5 values. To remove a value, select the value in the list box and click the "Delete" button.

Type I Error Values: [ ] Add Delete

0.05

Defining Study Groups



Defining Clustering

Clustering

In a clustered design, the independent sampling unit is a cluster, such as a community, school, or classroom. Observations within a cluster are correlated. The labels for observations within a cluster must be exchangeable. For example, child "id" within classroom can be reassigned arbitrarily. In contrast, observations across time cannot be reassigned and should not be considered clustered observations. Clustering, or repeated measures, or a combination, creates a multilevel design. The common correlation between any pair of cluster members is termed the intraclass correlation or intracluster correlation.

To include clustering in the study, click "Add clustering" and follow the prompts. Use the "Remove clustering" button to remove clustering information.

Add clustering

Defining Clustering

Remove clustering

Cluster label	community
Number of observations or sub-clusters within each cluster of this type	10
Intra-cluster correlation	0.01

Add subgroup Remove subgroup

Defining Relative Group Sizes

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Relative Group Size	treatment
1	home based program
1	delayed program control

Entering Sample Size

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Size of the Smallest Group

Enter the number of independent sampling units (participants, clusters) in the smallest group in the study. If your group sizes are equal, the value is the same for all groups. You may enter multiple values for the smallest group size in order to consider a range of total sample sizes.

Enter one or more sample sizes in the text box below and click "Add". To remove a sample size from the list, highlight it and click the "Delete" button.

Entering Response Variables

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Response Variables

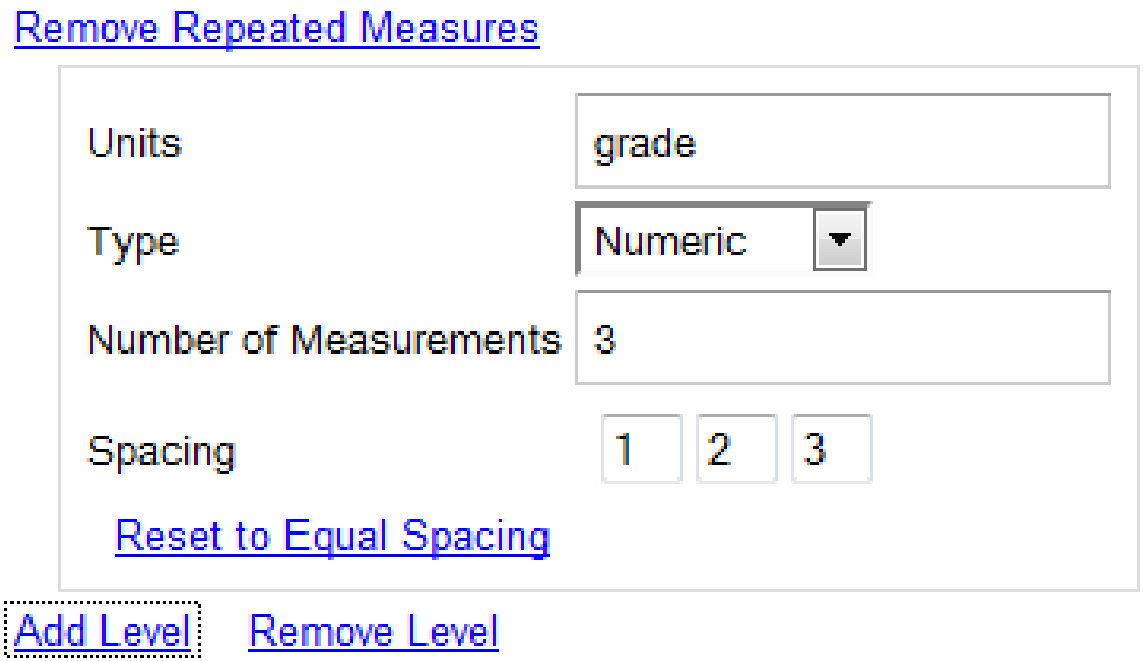
Enter the response variables in the table below. For example, in a study investigating cholesterol-lowering medication, the response variable could be HDL, LDL, and total cholesterol.

Note that repeated measurement information will be addressed on the next screen.

Response Variables: [ ] Add Delete

alcohol behavior scale

Entering Repeated Measures



Selecting a Hypothesis

Grand mean | Main Effect | Trend | **Interaction**

Select two or more predictors to include in the interaction hypothesis. To test for a trend in a given factor, click the Edit Trend link and select an appropriate trend.

Between Participant Factors

☑ treatment Edit trend : None

Within Participant Factors

☑ grade Edit trend : All polynomial trends

Entering Mean Differences

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treatment	alcohol behavior scale
home based program	-0.25
delayed program control	0

Select the time (location, etc.) from the list(s) below. This will etc.).

grade 3

Checking a Range of Means

Flexible Means

Power and sample size results will change depending on the mean values specified on the previous screen. It is not possible to know exact values for the means until the experiment is observed. To account for the uncertainty, it is common to calculate power for the mean values as specified, the mean values divided by 2, and the mean values multiplied by 2.

☐ Yes, include power calculations for the mean values as entered, the mean values divided by 2, and the mean values multiplied by 2.

Entering Variability

grade | Responses

Structured Correlation: The Linear Exponential Auto-Regressive Model (LEAR, Simpson et al., 2010)

The LEAR model describes correlation which monotonely decreases with distance between repeated measurements. The model has two correlation parameters, the base correlation and the decay rate. The base correlation describes the correlation between measurements taken 1 unit apart. The decay rate describes the rate of decrease in the base correlation as the distance or time between repeated measurements increases. Our experience with biological and behavioral data lead us to suggest using decay values between 0.05 and 0.5.

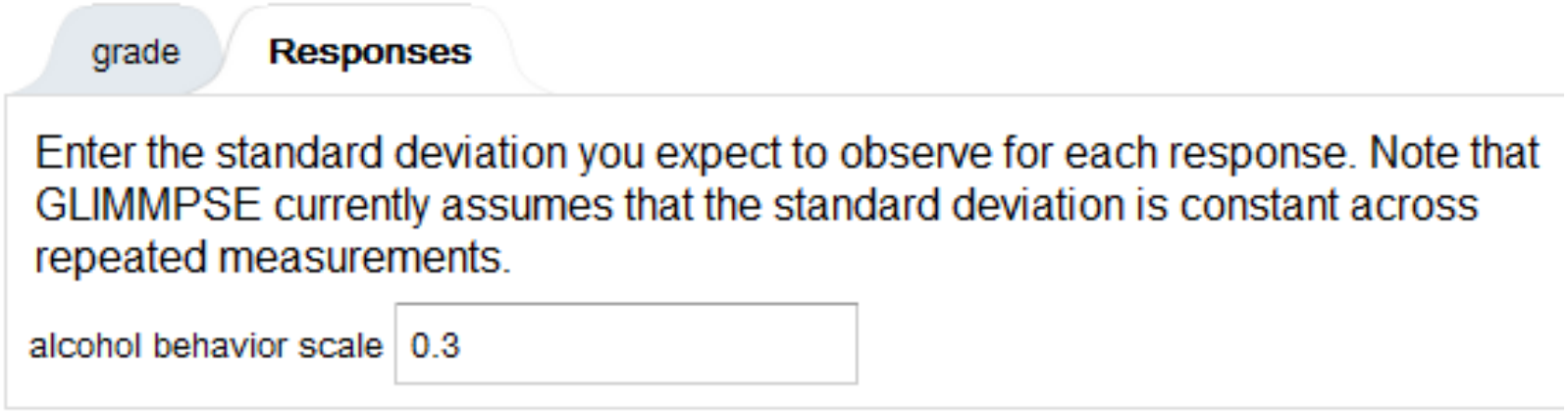
Base Correlation 0.3

Decay Rate 0.3

	grade,1	grade,2	grade,3
grade,1	1.0	0.3	0.209053
grade,2	0.3	1.0	0.3
grade,3	0.209053	0.3	1.0

Unstructured correlation

Entering Variability



Checking a Range of Variability

Flexible Variability

On the previous screens, you entered standard deviations and correlations. GLIMMPSE has used these values to calculate a covariance matrix which describes the overall variability.

Changes in variability can dramatically affect power and sample size results. It is not possible to know the variability until the experiment is observed. To account for this uncertainty, it is common to calculate power or sample size for alternative values for variability.

By clicking the box below, GLIMMPSE will calculate power using the calculated covariance matrix, the covariance matrix divided by 2, and the covariance matrix multiplied by 2.

☐ Yes, include power for the covariance matrix, the covariance matrix divided by 2, and the covariance matrix multiplied by 2.

Selecting a Test

Statistical Tests

Select the statistical tests to include in your calculations. For study designs with a single outcome, power is the same regardless of the test selected.

Note that only the Hotelling-Lawley Trace and the Univariate Approach to Repeated Measures are supported for designs which include a baseline covariate.

- [x] Hotelling-Lawley Trace
- [ ] Pillai-Bartlett Trace
- [ ] Wilks Likelihood Ratio
- [ ] Univariate Approach to Repeated Measures with Box Correction
- [ ] Univariate Approach to Repeated Measures with Geisser-Greenhouse Correction
- [ ] Univariate Approach to Repeated Measures with Huynh-Feldt Correction
- [ ] Univariate Approach to Repeated Measures, uncorrected

Adding a Power Curve

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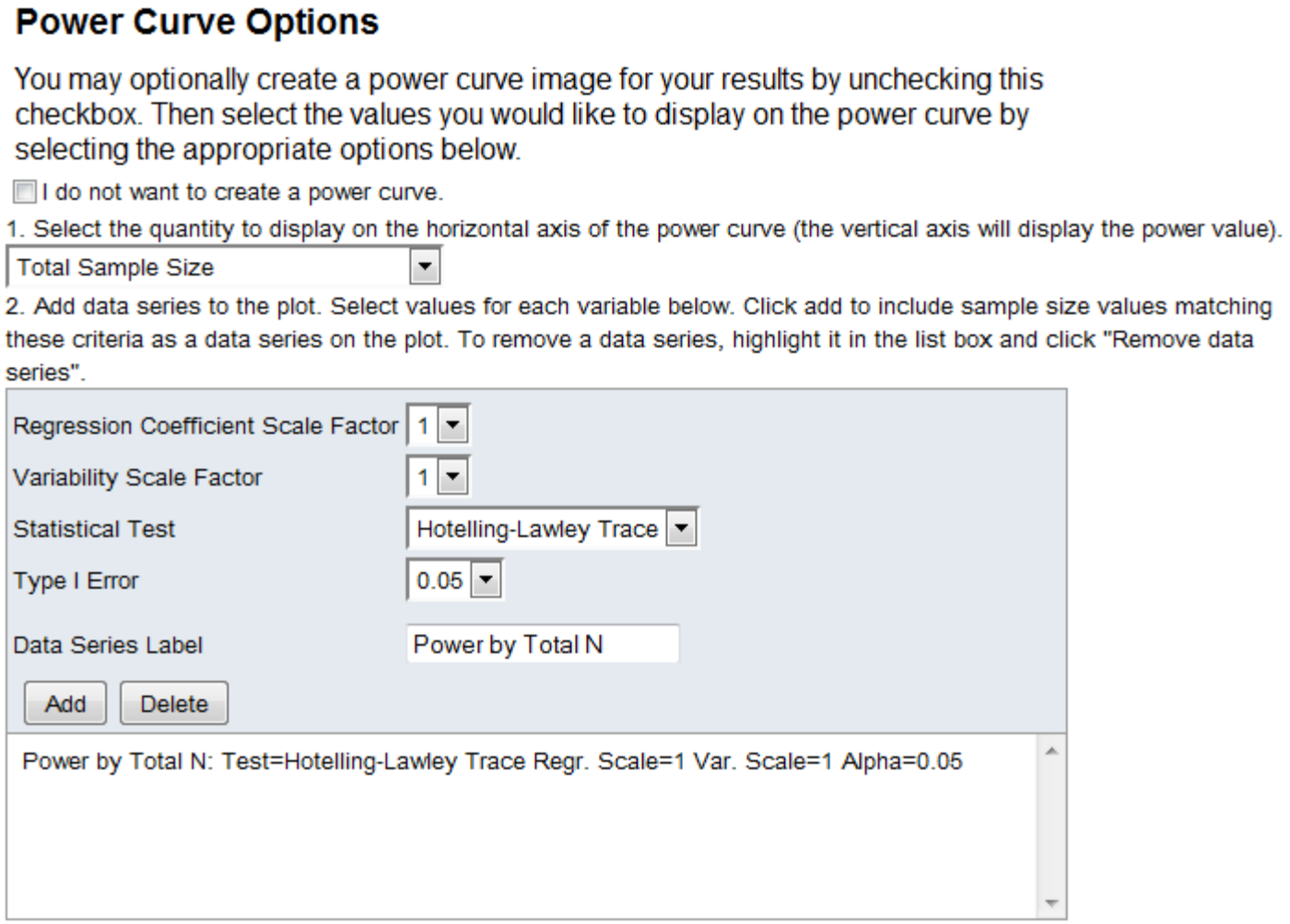
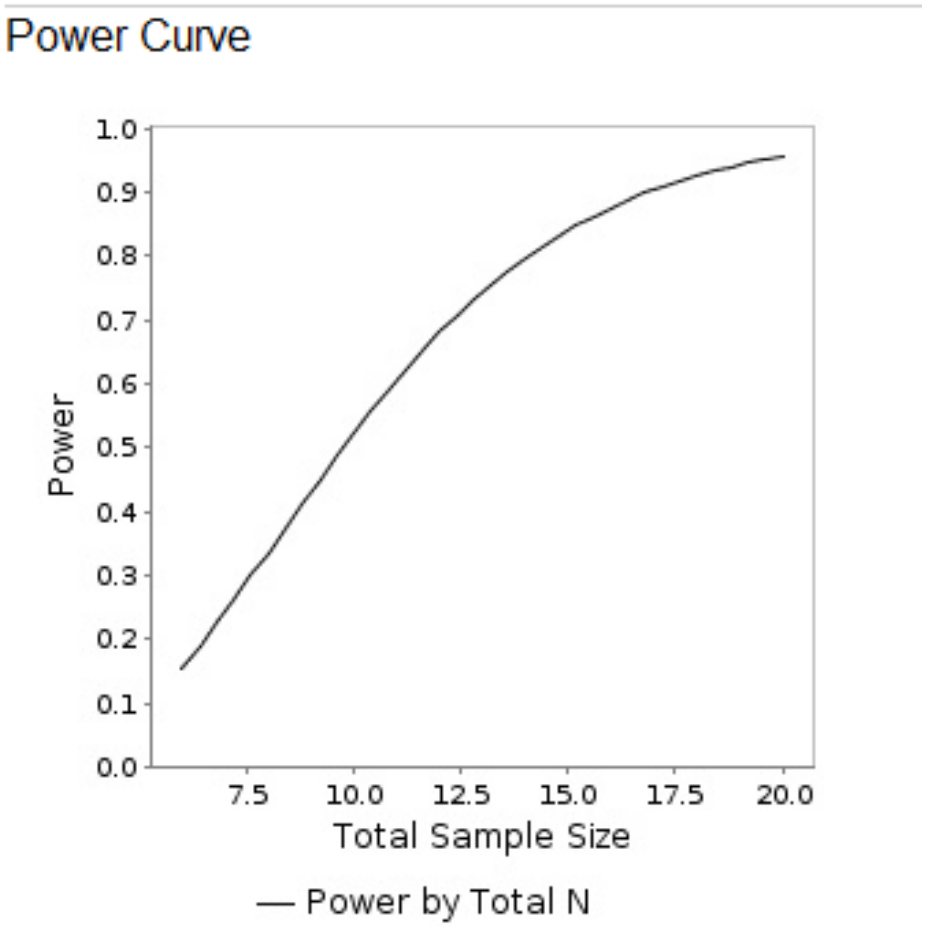


Results

Power Results

Test	Actual Power	Total Sample Size	Beta Scale	Sigma Scale	Alpha	Nominal Power	Power Method
HLT	0.1538	6	1.0000	1.0000	0.0500	0.1538	CONDITIONAL
HLT	0.3359	8	1.0000	1.0000	0.0500	0.3359	CONDITIONAL
HLT	0.5237	10	1.0000	1.0000	0.0500	0.5237	CONDITIONAL
HLT	0.6800	12	1.0000	1.0000	0.0500	0.6800	CONDITIONAL
HLT	0.7955	14	1.0000	1.0000	0.0500	0.7955	CONDITIONAL
HLT	0.8746	16	1.0000	1.0000	0.0500	0.8746	CONDITIONAL
HLT	0.9256	18	1.0000	1.0000	0.0500	0.9256	CONDITIONAL
HLT	0.9572	20	1.0000	1.0000	0.0500	0.9572	CONDITIONAL

Results


Power Curve
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Power
7.5
10.0
12.5
15.0
17.5
20.0
Total Sample Size
— Power by Total N

Summary for Manuscript

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Ten communities were randomized to receive either the home based intervention or delayed intervention. Ten students were recruited from each community. The intracluster correlation within community was assumed to be 0.01. Correlation between repeated alcohol behavior scores within a student was assumed to be 0.3 for measures taken one year apart, with gradual decay over time. Power was calculated for a time by treatment interaction using the Hotelling-Lawley trace test. For a Type I error rate of 0.05, and an assumed standard deviation of 0.3 for alcohol behavior scores, the study had 0.98 power to detect a difference of 0.25 in a time by treatment interaction.

Summary

• Power and sample size calculations are a critical part of study design

• Answers to basic questions about the study design can lead investigators to an appropriate sample size calculation

• GLIMMPSE is a free, web-based tool to aid in calculating power or sample size for a variety of multilevel and longitudinal designs

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