Selecting a Valid Sample Size for Longitudinal and Multilevel Studies in Oral Behavioral Health

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Conflict of Interest

We have no conflicts of interest to declare.

Acknowledgments

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Learning Objectives

- Learn a conceptual framework for conducting a power analysis.
- Understand how to interact with our free, web-based power and sample size software.
- Write a sample size analysis.

The Sample Size Game

Object of the game:
Calculate sample size

- Speakers present information.
- Audience discusses the information in small groups using worksheets.
- Next speaker shows how the information can be used to calculate sample size.

Agenda

How Do we Choose Sample Size and Power for Complex Oral Health Designs? Dr. Henrietta Logan	10:50 – 11:00
Discussion: Hypothesis, Outcomes, and Predictors	11:00 – 11:10
Choosing a Hypothesis, Outcomes, and Predictors with Our Free, Web-based Software Dr. Aarti Munjal	11:10 – 11:20
Discussion: Mean, Variance, and Correlation	11:20 – 11:30

Agenda

Choosing Means, Variances, and Correlations with Our Free, Web-based Software Brandy M. Ringham	11:30 – 11:40
Discussion: Sample Size Calculation Summary	11:40 – 11:50
Wrapping it Up: Writing the Grant Deborah H. Glueck	11:50 – 12:00
Discussion: Question and Answer	12:00 – 12:15

How Do we Choose Sample Size and Power for Complex Oral Health Designs?

Dr. Henrietta Logan
University of Florida

Previous Study on Sensory Focus to Alleviate Pain

- Participants categorized into four coping styles
- Randomized to one of two intervention arms:

  sensory focus
  standard of care

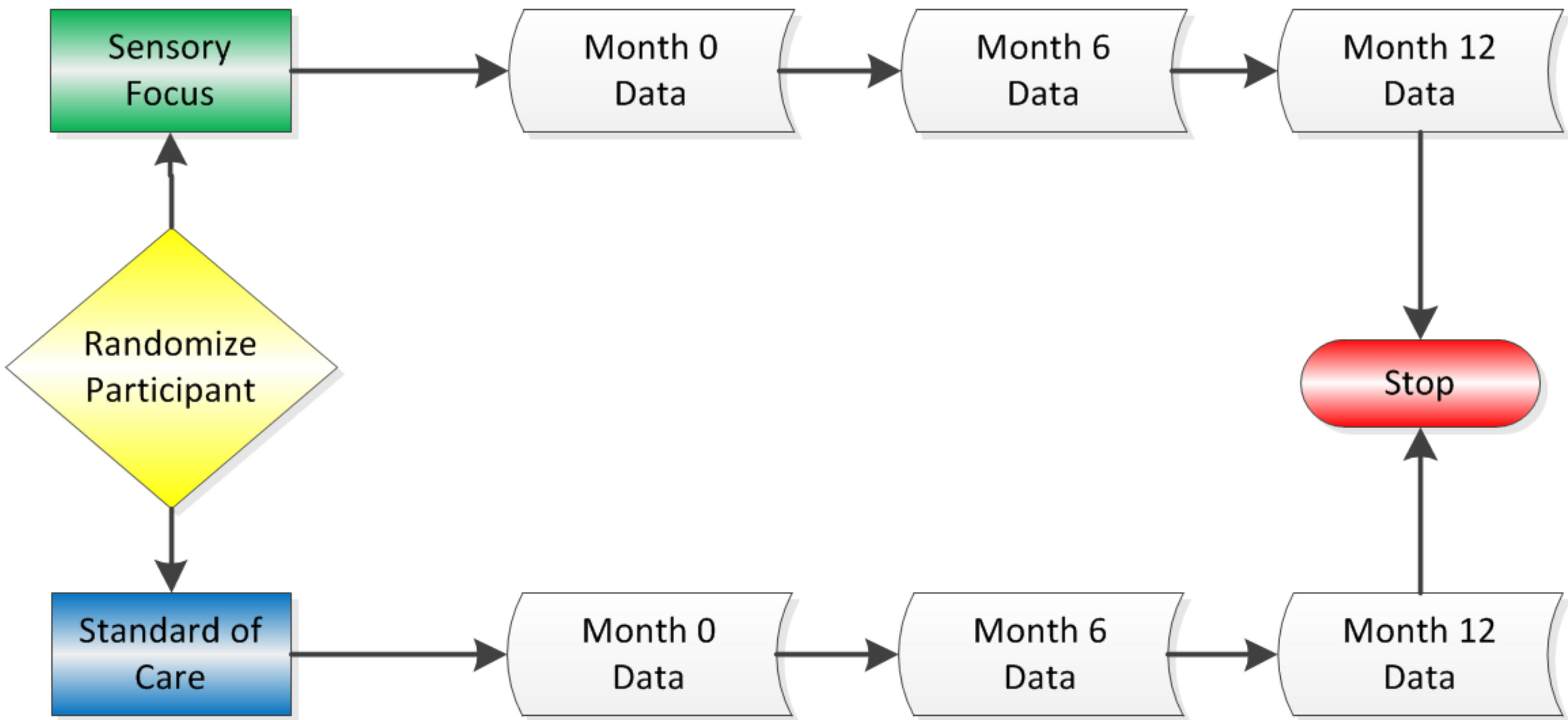
- Measured experienced pain after root canal

		Perceived Control	
		Low	High
Desired Control	High	1	2
	Low	3	4

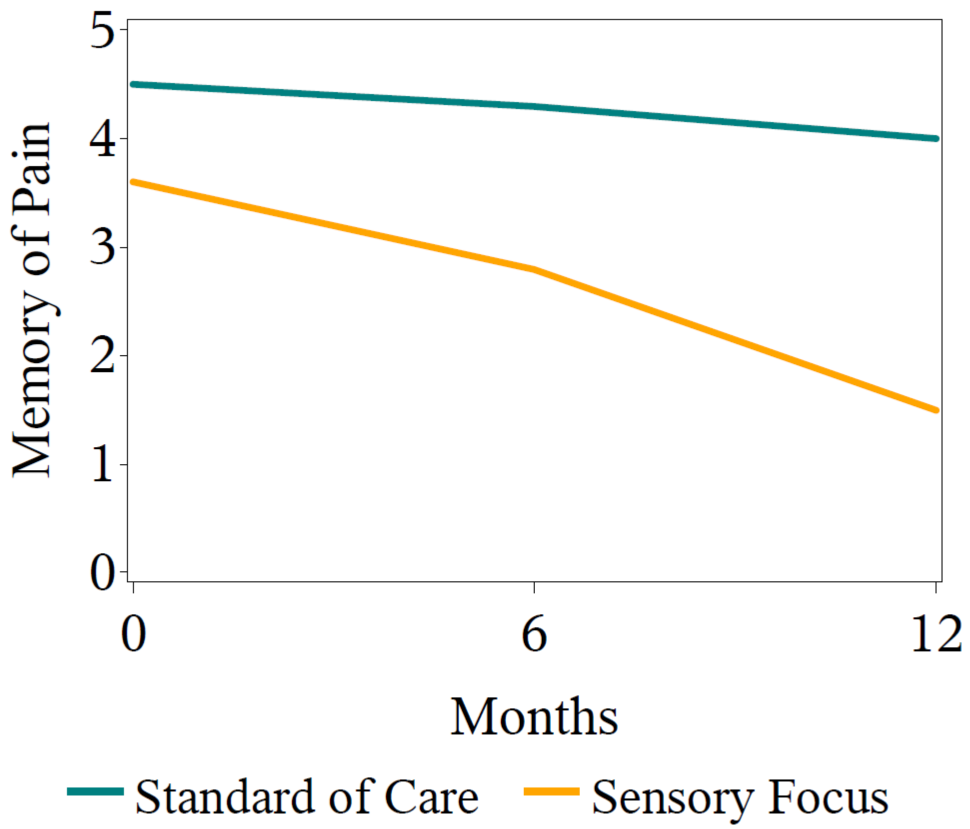
(Logan, Baron, Kohout, 1995)

Memory of Pain Trial

Study Design



Memory of Pain Trial
Research Question



Memory of Pain Trial
Study Population

- Recruit participants who have a high desire/low felt coping style
- 30 patients / week
- 40% consent rate for previous studies

Ethics of Sample Size Calculations

- If the sample size is too small, the study may be inconclusive study and waste resources
- If the sample size is too large, then the study may expose too many participants to possible harms due to research

How do we calculate an accurate sample size?

Consulting Session

- Type I error rate:
- Desired power:
- Loss to follow-up:

Consulting Session

- Type I error rate: 0.01
- Desired power:
- Loss to follow-up:

Consulting Session

- Type I error rate: 0.01
- Desired power: 0.90
- Loss to follow-up:

Consulting Session

- Type I error rate: 0.01
- Desired power: 0.90
- Loss to follow-up: 25%

Worksheet 1
Elements of Study Design

- Hypothesis: the question that the research study is designed to answer
- Outcome: a measureable trait used to answer the research question
- Predictors: factors that may affect the outcome of the study

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Choosing a Hypothesis, Outcomes, and Predictors with Our Free, Web-based Software

Dr. Aarti Munjal
University of Colorado Denver

Worksheet 1
Elements of Study Design

1. Solving for:

2. Desired power:

3. Type I error rate:

Worksheet 1
Elements of Study Design

1. Solving for: Sample size (B)

2. Desired power:

3. Type I error rate:

Worksheet 1
Elements of Study Design

1. Solving for: Sample size (B)

2. Desired power: 0.90 (B)

3. Type I error rate:

Worksheet 1
Elements of Study Design

1. Solving for: Sample size (B)

2. Desired power: 0.90 (B)

3. Type I error rate: 0.01 (D)

Worksheet 1
Elements of Study Design

4. Outcome:

5. Predictor:

6. Hypothesis:

Worksheet 1
Elements of Study Design

4. Outcome: memory of pain (C)

5. Predictor:

6. Hypothesis:

Worksheet 1
Elements of Study Design

4. Outcome: memory of pain (C)

5. Predictor: intervention group (D)

6. Hypothesis:

Worksheet 1
Elements of Study Design

4. Outcome: memory of pain (C)

5. Predictor: intervention group (D)

6. Hypothesis: time by intervention interaction (A)

GLIMMPSE

GLIMMPSE is a user-friendly online tool for calculating power and sample size for multilevel and longitudinal studies.

http://glimmpse.samplesizeshop.org/

Salient Software Features

- Free
- Requires no programming expertise
- Allows saving study designs for later use
- Also available on smartphones

Create a Study Design

Start Your Study Design

Welcome to GLIMMPSE. The GLIMMPSE software calculates power and sample size for study designs with normally distributed outcomes. Select one of the options below to begin your power or sample size calculation.

Guided Study Design

Build common study designs including ANOVA, ANCOVA, and regression with guidance from the study design wizard. This mode is designed for applied researchers including physicians, nurses, and other investigators.

Select

Matrix Study Design

Directly enter the matrices for the general linear model. This mode is designed for users with advanced statistical training.

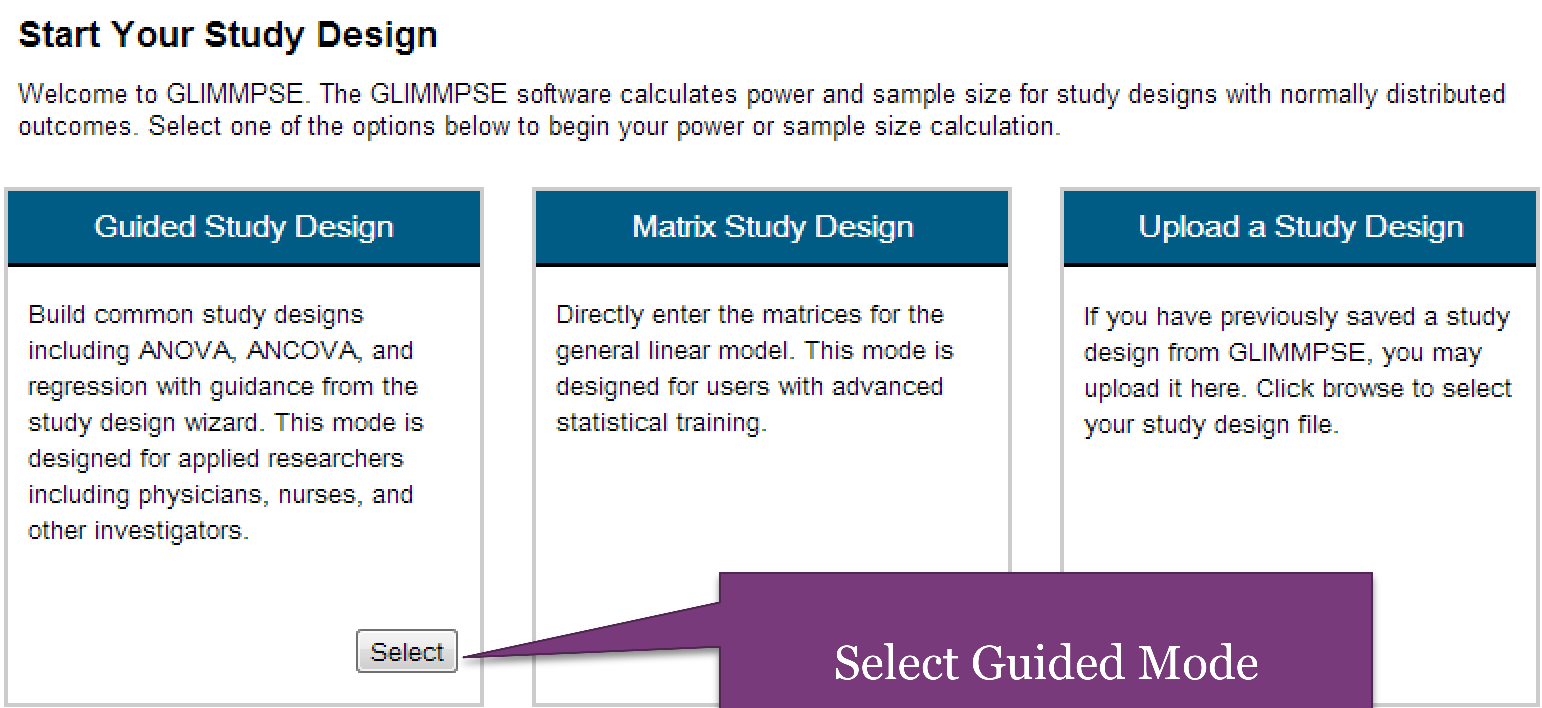
Select

Upload a Study Design

If you have previously saved a study design from GLIMMPSE, you may upload it here. Click browse to select your study design file.

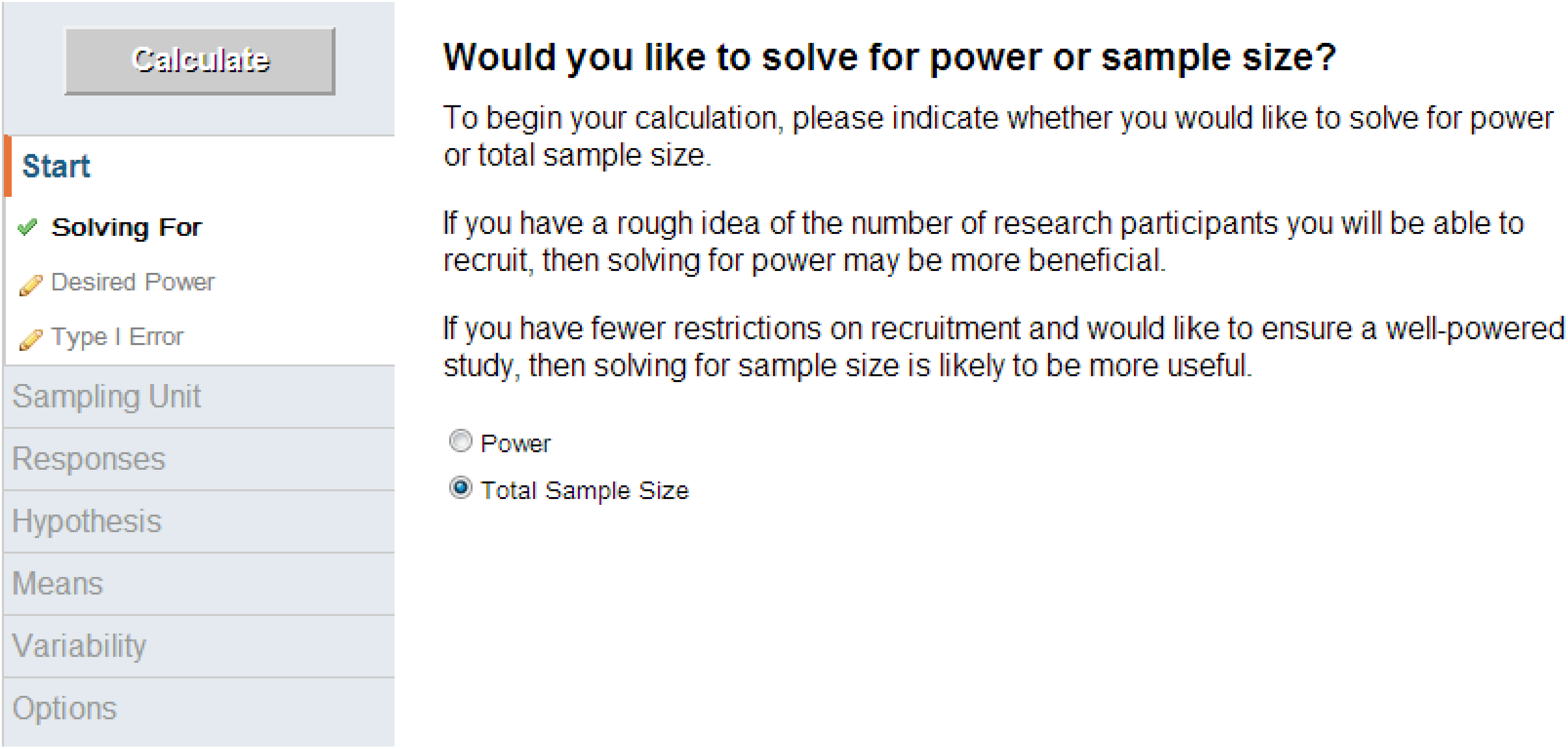
Choose File No f...sen

Create a Study Design

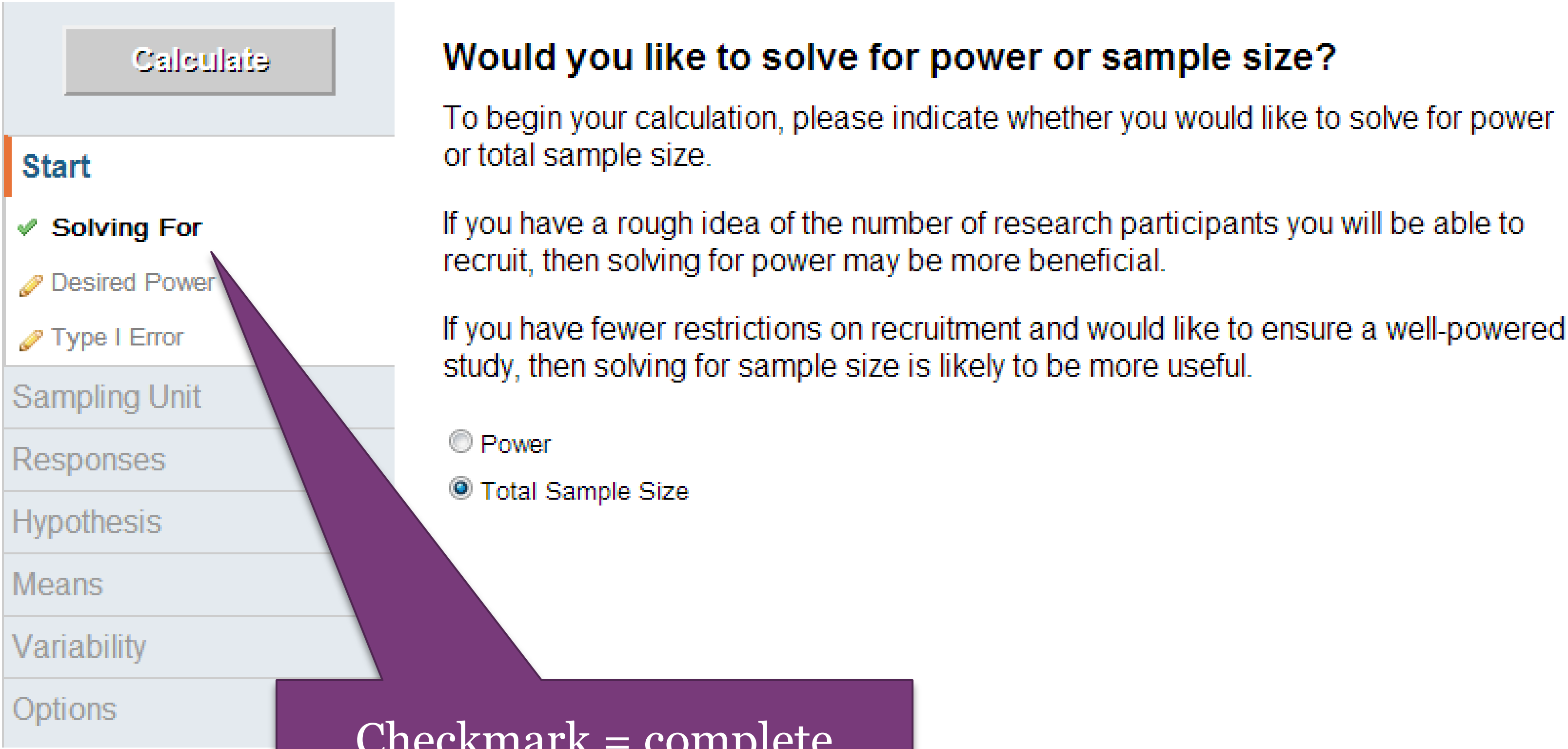


Select Guided Mode

GLIMMPSE Solving For

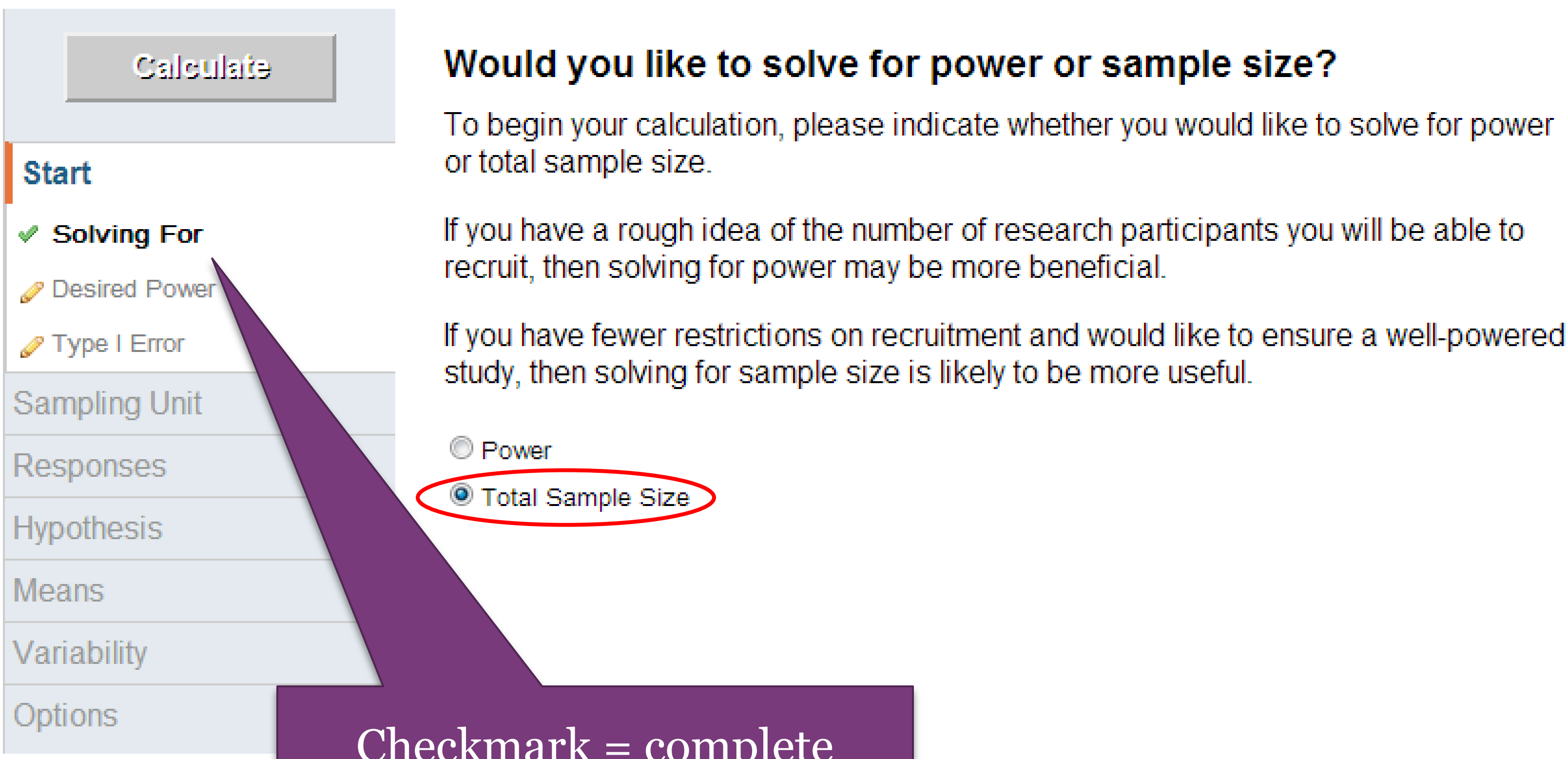


GLIMMPSE Solving For



Checkmark = complete
Pencil = incomplete

GLIMMPSE Solving For



Checkmark = complete
Pencil = incomplete

GLIMMPSE 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.

Power Values: Add Delete

0.9

GLIMMPSE Desired Power

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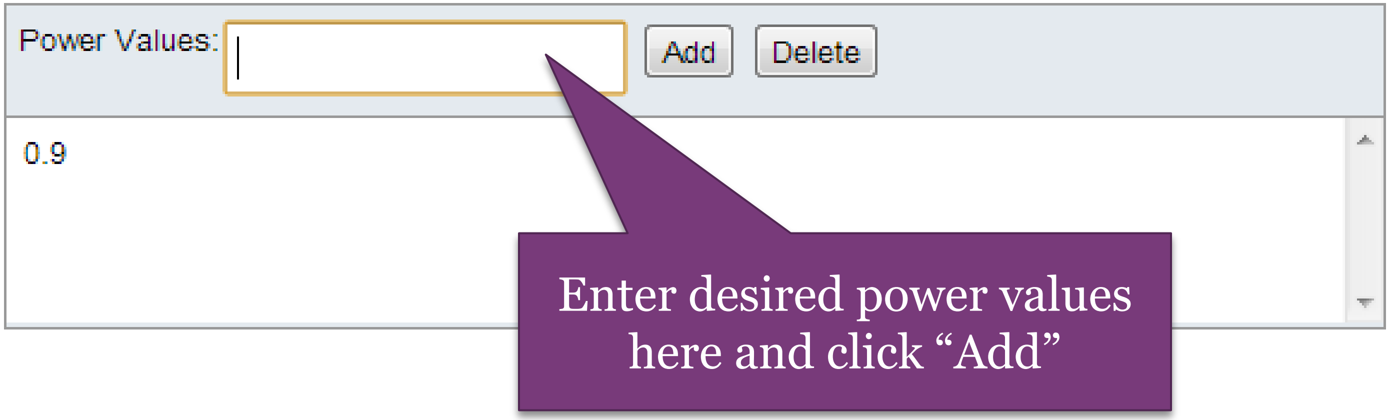

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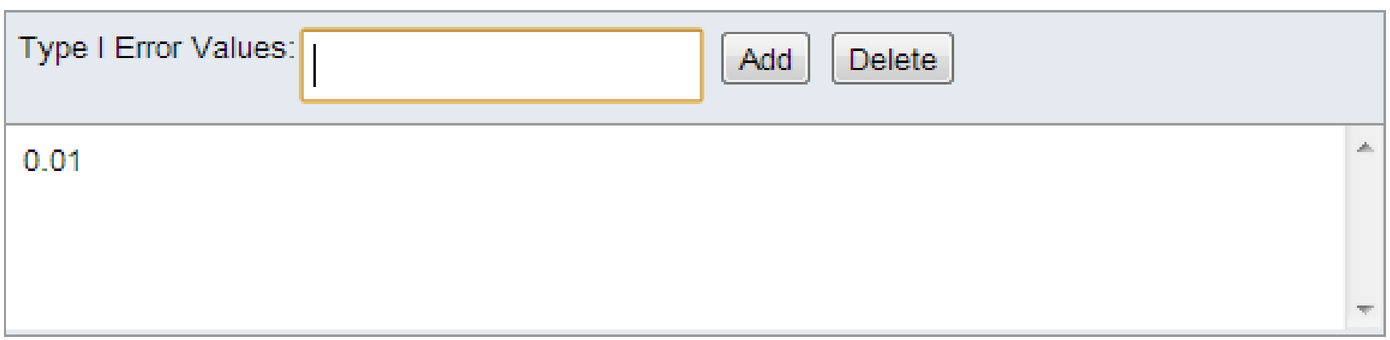
GLIMMPSE Type I Error Rate

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.



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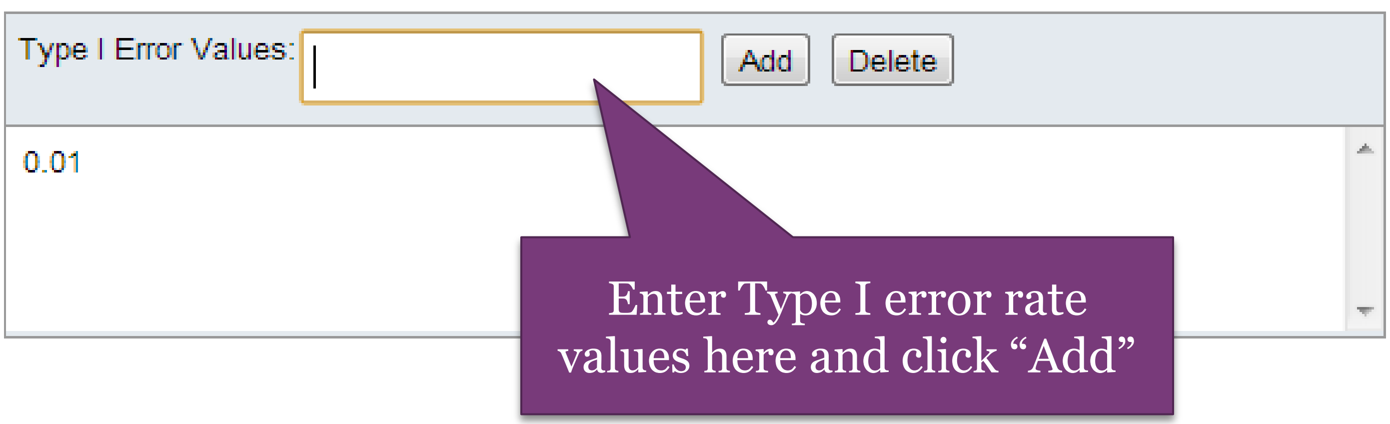

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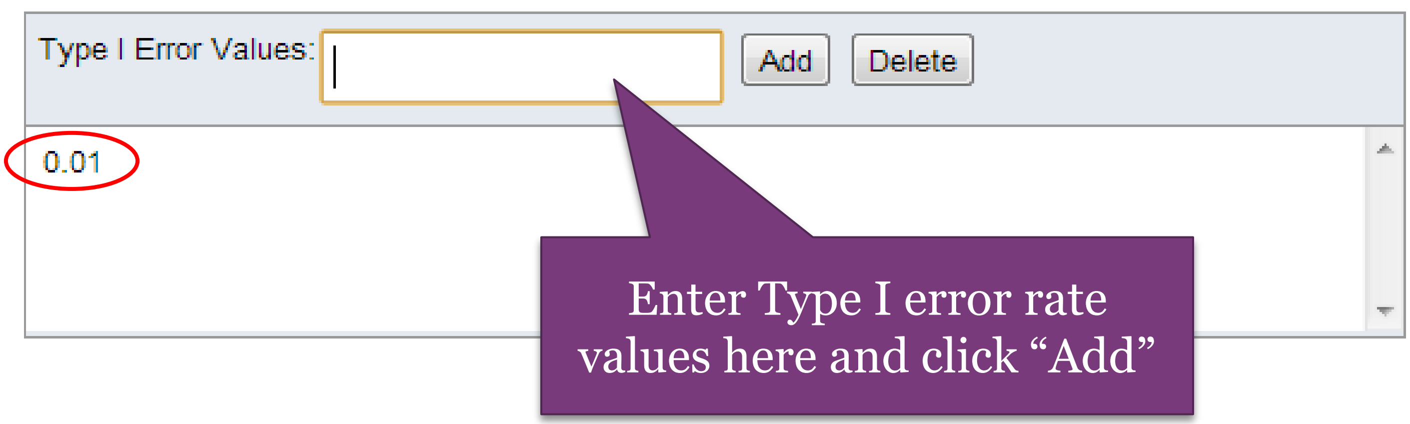
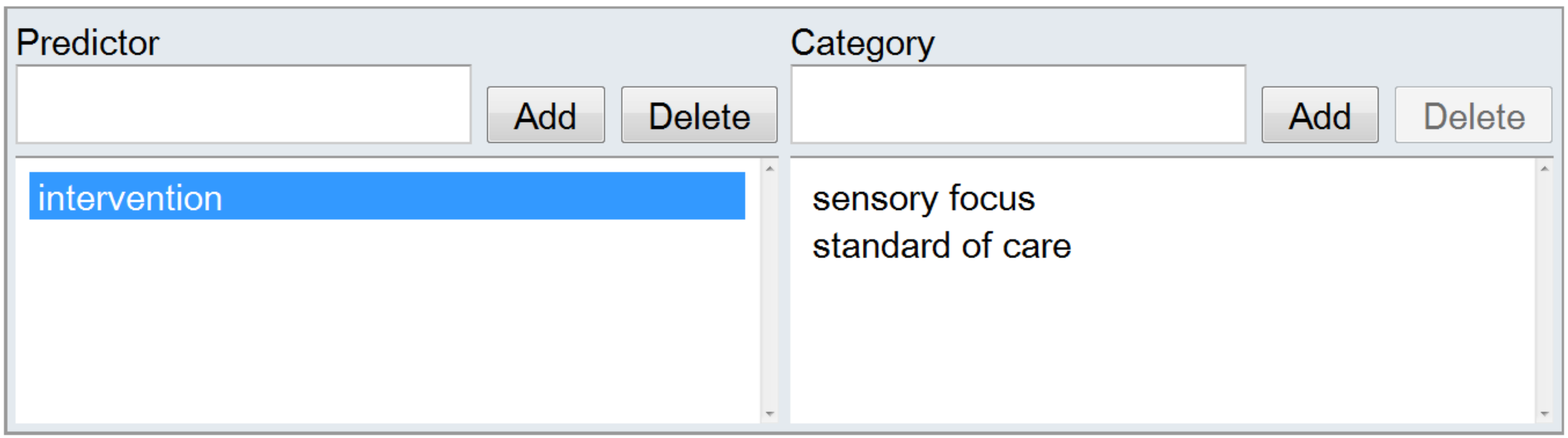


GLIMMPSE Predictors



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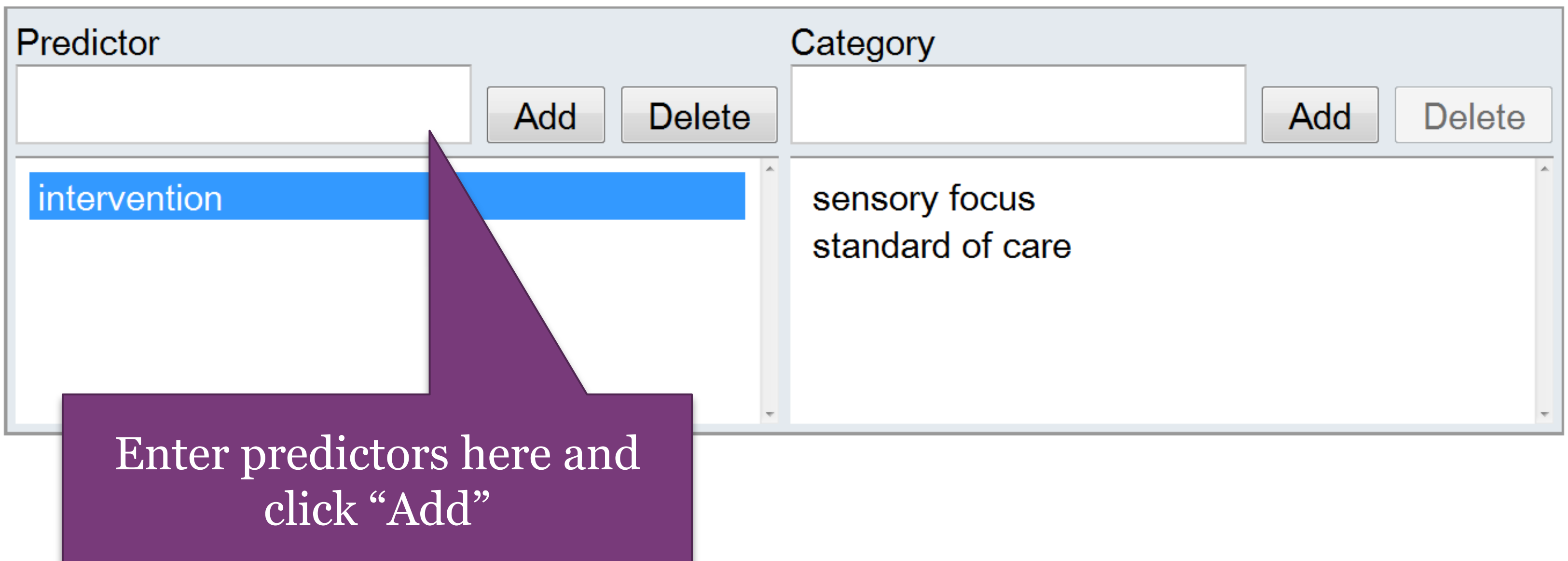
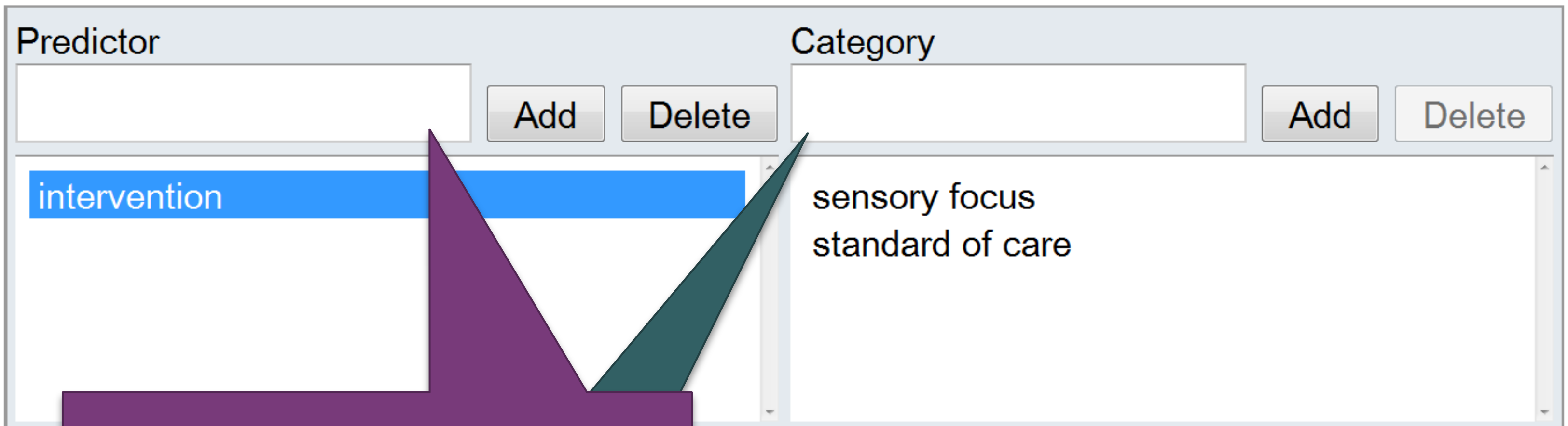


GLIMMPSE Predictors



Enter predictors here and click "Add"

Enter predictor categories here and click "Add"

GLIMMPSE Outcome

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

GLIMMPSE Outcome

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.

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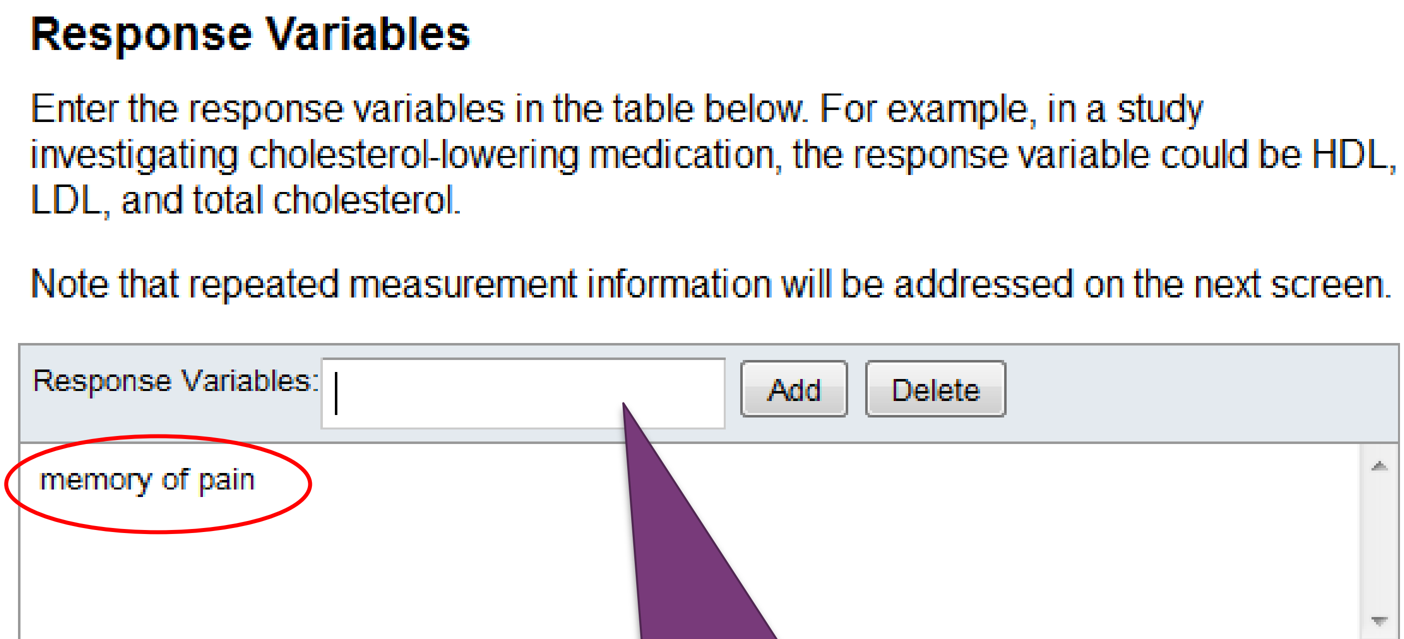
Enter outcomes here and click “Add”

GLIMMPSE Outcome



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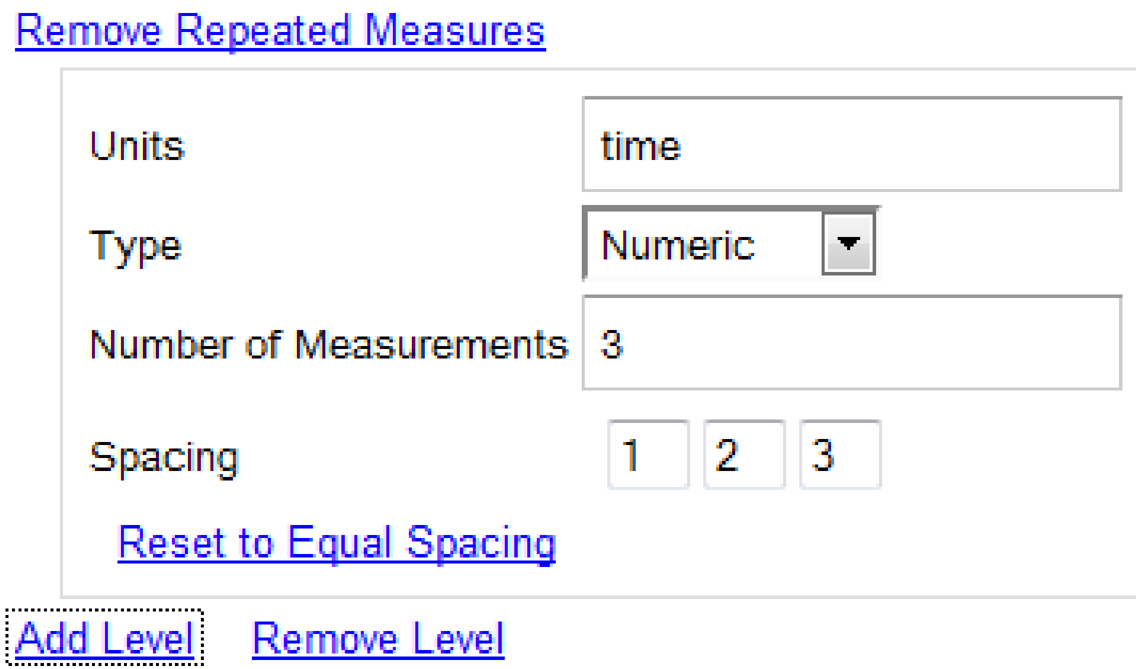
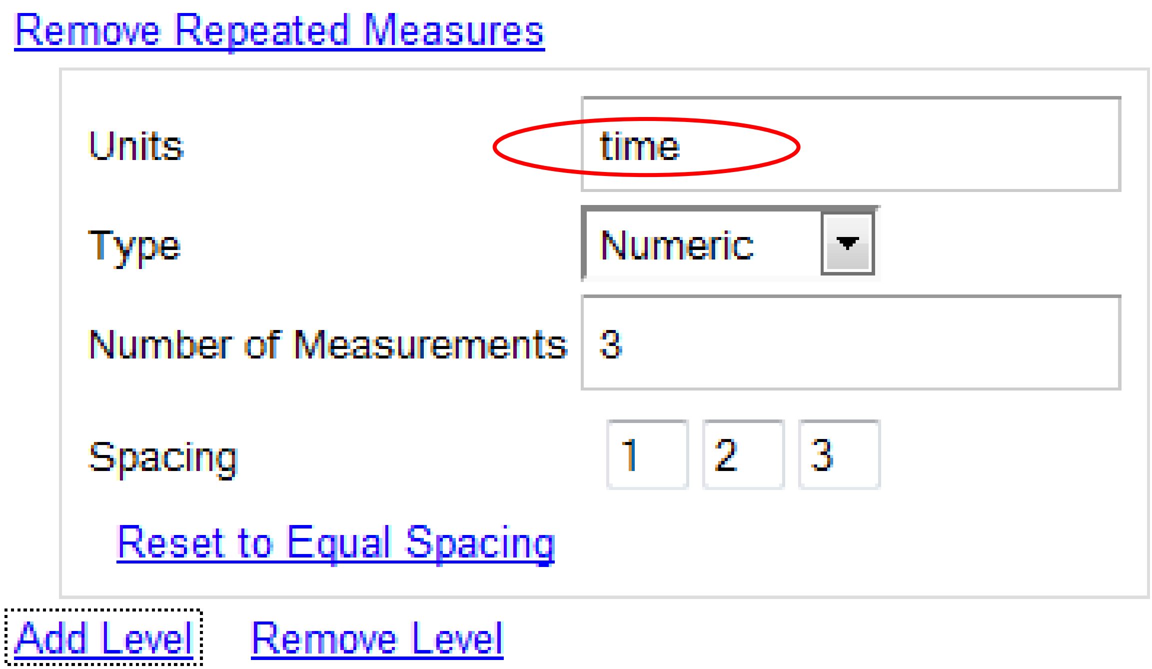
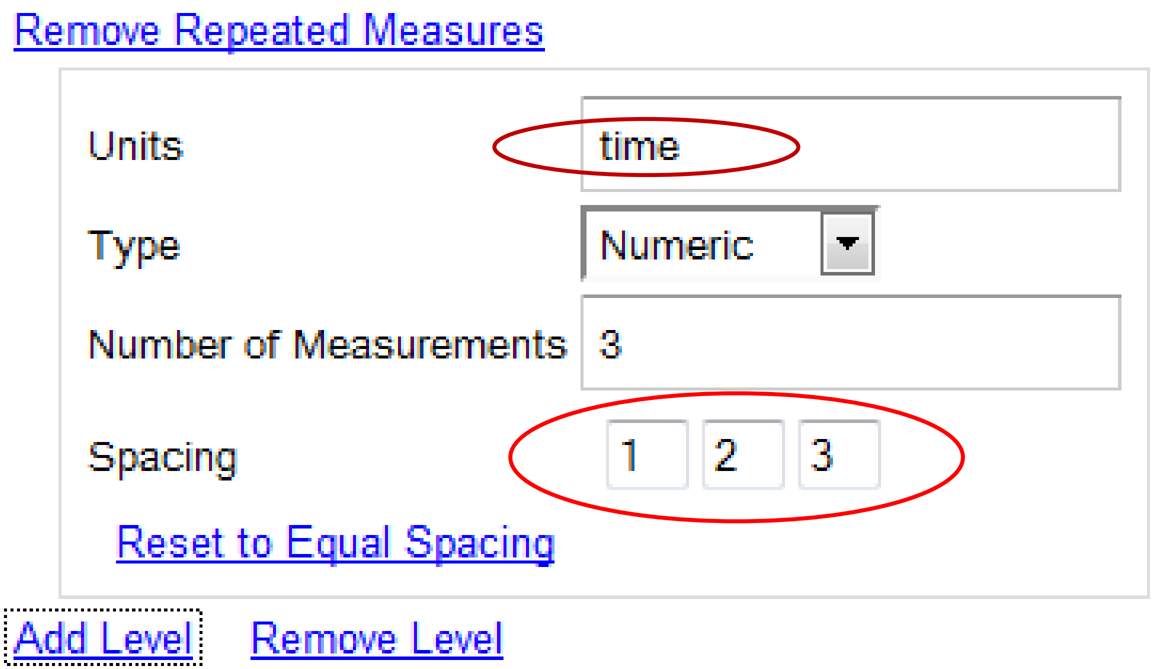
GLIMMPSE Repeated Measures



GLIMMPSE Repeated Measures

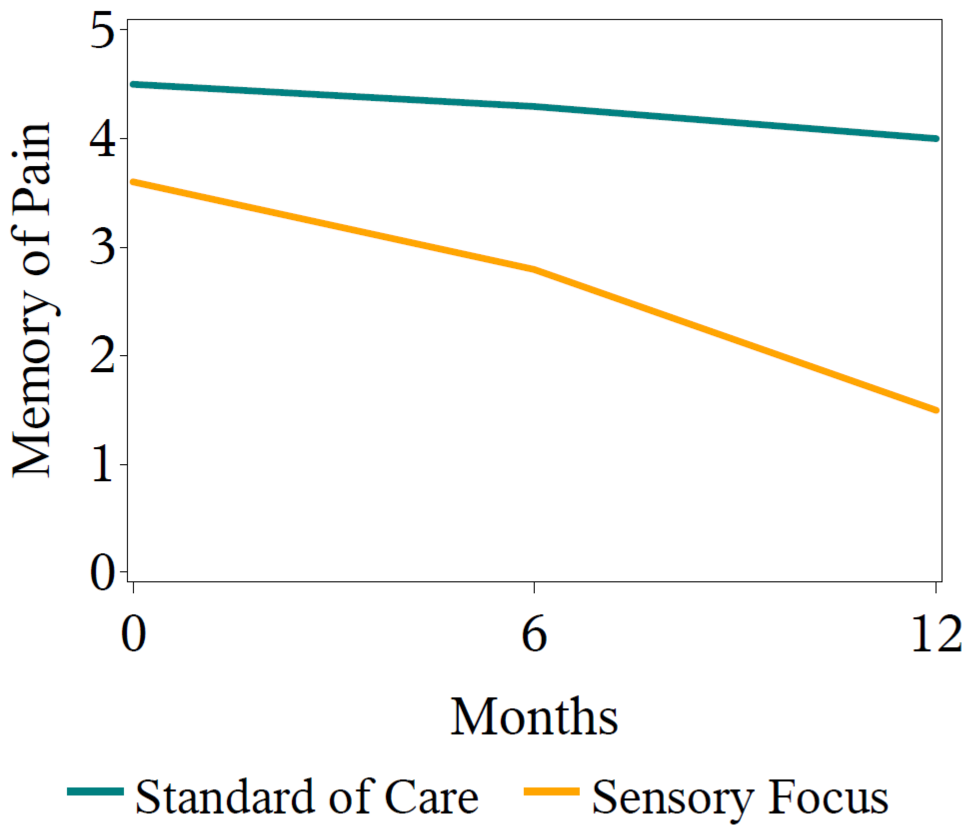


GLIMMPSE Repeated Measures



GLIMMPSE Hypothesis

time by intervention interaction



GLIMMPSE 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

intervention Edit trend : None

Within Participant Factors

time Edit trend : None

GLIMMPSE Hypothesis

Grand mean   Main Effect   Trend   Interaction

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GLIMMPSE 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

- [x] intervention Edit trend : None

Within Participant Factors

- [x] time Edit trend : None

Where Can I Find Means, Variances, and Correlations?

- Pilot study
- Similar published research
- Unpublished internal studies
- Clinical experience

Worksheet 2
Means, Variances, and Correlations

- Mean: a measure of the size of the intervention effect
- Variance: a measure of the variability of the outcome
- Correlation: a measure of the association between the repeated measures

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Choosing Means, Variances, and Correlations with Our Free, Web-based Software

Brandy Ringham
University of Colorado Denver

Worksheet 2
Means, Variances, and Correlations

Correlation Between Outcomes Over Time

Gedney, Logan, and Baron (2003) identified predictors of the amount of experienced pain recalled over time…One of the findings was that memory of pain intensity at 1 week and 18 months had a correlation of 0.4. …assume that the correlation between measures 18 months apart will be similar to the correlation between measures 12 months apart. Likewise, the correlation between measures 6 months apart will be only slightly greater than the correlation between measures 18 months apart.

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Means, Variances, and Correlations

Correlation Between Outcomes Over Time

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<u>Correlation Between Outcomes Over Time</u>

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Worksheet 2
Means, Variances, and Correlations

Correlation at 6 months apart

(A)

Correlation at 12 months apart

(B)

Worksheet 2
Means, Variances, and Correlations

Correlation at 6 months apart

(A)

Correlation at 12 months apart

(B) 0.4

Worksheet 2
Means, Variances, and Correlations

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Worksheet 2
Means, Variances, and Correlations

Correlation at 6 months apart

(A)

Correlation at 12 months apart

(B) 0.4

Worksheet 2
Means, Variances, and Correlations

Correlation at 6 months apart

(A) 0.5

Correlation at 12 months apart

(B) 0.4

Worksheet 2
Means, Variances, and Correlations

Standard Deviation of the Outcome

Logan, Baron, and Kohout (1995) examined whether sensory focus therapy during a root canal procedure could reduce a patient's experienced pain. The investigators assessed experienced pain on a 5 point scale both immediately and at one week following the procedure. The standard deviation of the measurements was 0.98.

Worksheet 2
Means, Variances, and Correlations

Standard Deviation of the Outcome

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Worksheet 2
Means, Variances, and Correlations

Standard deviation of memory of pain

(C)

Worksheet 2
Means, Variances, and Correlations

Standard deviation of memory of pain

(C) 0.98

Worksheet 2
Means, Variances, and Correlations

Intervention	Baseline	6 Months	12 Months
Sensory Focus (SF)	3.6	2.8	0.9
Standard of Care (SOC)	4.5	4.3	3.0
Intervention Difference (SF - SOC)	(D)	(E)	(F)
Net Difference Over Time (12 Months - Baseline)			(G)

Worksheet 2
Means, Variances, and Correlations

Intervention	Baseline	6 Months	12 Months
Sensory Focus (SF)	3.6	2.8	0.9
Standard of Care (SOC)	4.5	4.3	3.0
Intervention Difference (SF - SOC)	(D) -0.9	(E)	(F)
Net Difference Over Time (12 Months - Baseline)			(G)

Worksheet 2
Means, Variances, and Correlations

Intervention	Baseline	6 Months	12 Months
Sensory Focus (SF)	3.6	2.8	0.9
Standard of Care (SOC)	4.5	4.3	3.0
Intervention Difference (SF - SOC)	(D) -0.9	(E) -1.5	(F)
Net Difference Over Time (12 Months - Baseline)			(G)

Worksheet 2
Means, Variances, and Correlations

Intervention	Baseline	6 Months	12 Months
Sensory Focus (SF)	3.6	2.8	0.9
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Net Difference Over Time (12 Months - Baseline)			(G)

Worksheet 2
Means, Variances, and Correlations

Intervention	Baseline	6 Months	12 Months
Sensory Focus (SF)	3.6	2.8	0.9
Standard of Care (SOC)	4.5	4.3	3.0
Intervention Difference (SF - SOC)	(D) -0.9	(E) -1.5	(F) -2.1
Net Difference Over Time (12 Months - Baseline)			(G) -1.2

GLIMMPSE Means

Specifying a Mean Difference

treatment	memory of pain
sensory focus	-1.2
standard of care	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

GLIMMPSE Means
Specifying a Mean Difference

intervention	memory of pain
sensory focus	-1.2
standard of care	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

Choose a timepoint

GLIMMPSE Means

Specifying a Mean Difference

intervention	memory of pain
sensory focus	-1.2
standard of care	0

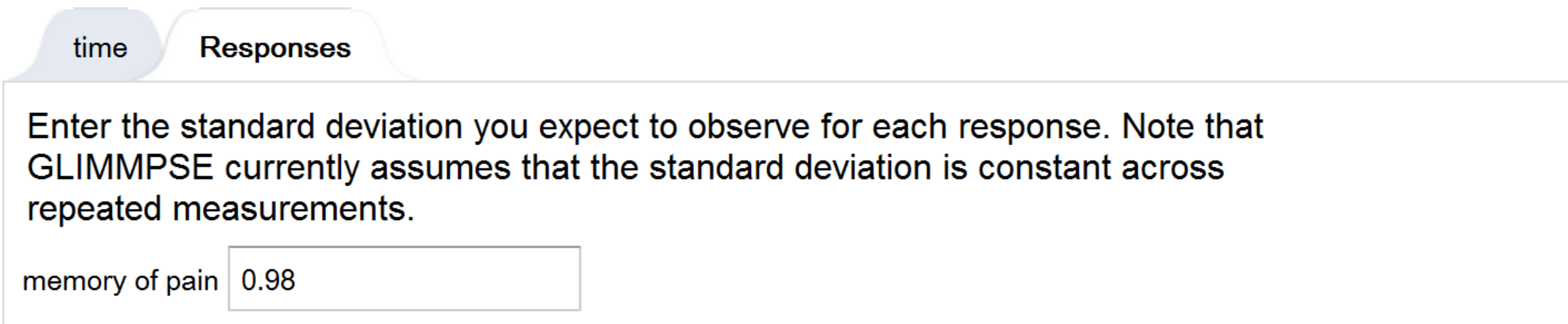
Select the time (location, etc.) from the list(s) bel This will allow you to edit the means at the selected time (location, etc.).

time 3

Choose a timepoint

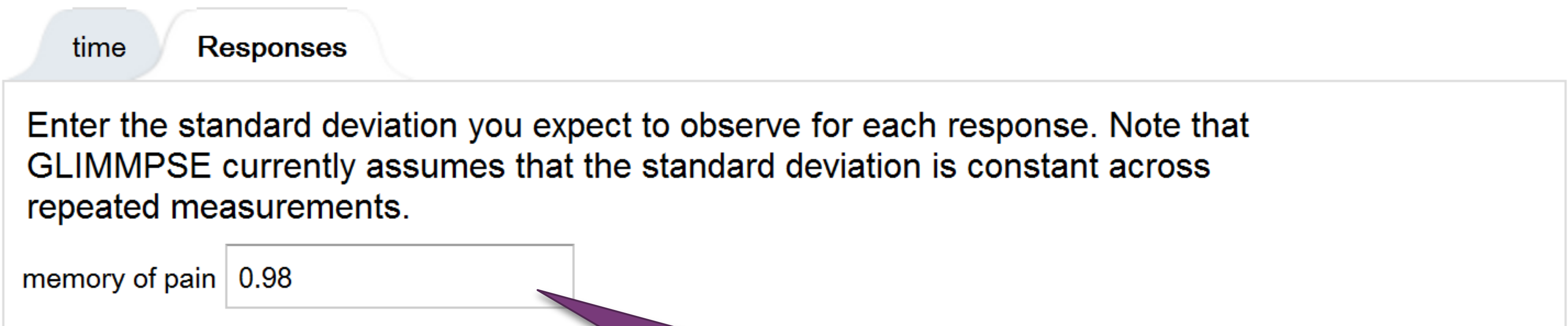
Enter the expected net mean difference

GLIMMPSE Variability
Entering Standard Deviation of the Outcome



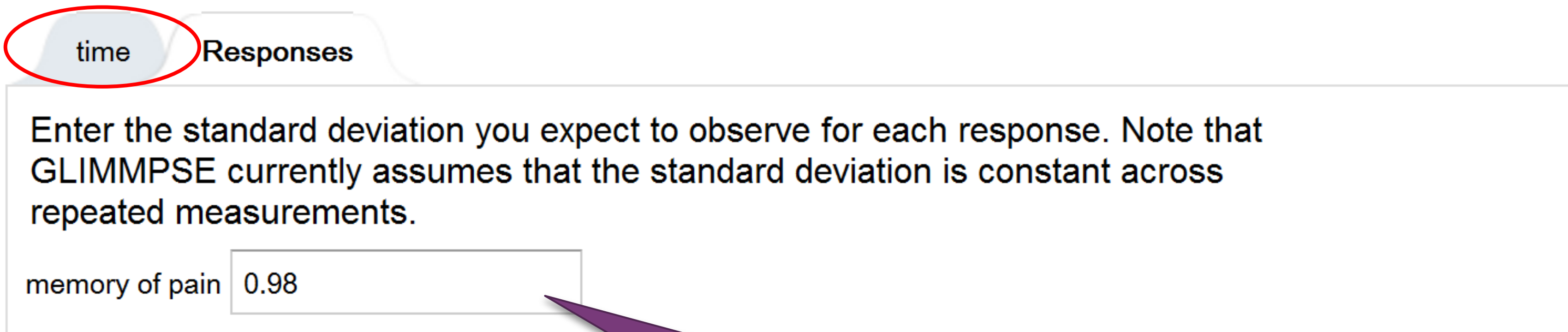
GLIMMPSE Variability

Entering Standard Deviation of the Outcome



Enter the standard deviation of the outcome variable

GLIMMPSE Variability
Specifying Correlations



Enter the standard deviation of the outcome variable

GLIMMPSE Variability

Specifying Correlations

time | Responses

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

	time,1	time,2	time,3
time,1	1	.5	.4
time,2	.5	1	.5
time,3	.4	.5	1

Structured correlation

Enter correlations between repeated measures

GLIMMPSE Hypothesis 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.

Click here to learn more about selecting an appropriate test.

- [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

GLIMMPSE Hypothesis 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.

Click here to learn more about selecting an appropriate test.

- Hotelling-Lawley Trace
- Pillai-Bartlett Trace
- Wilks Likelihood Ratio
- Univariate Approach to Repeated Measures with Box Correction
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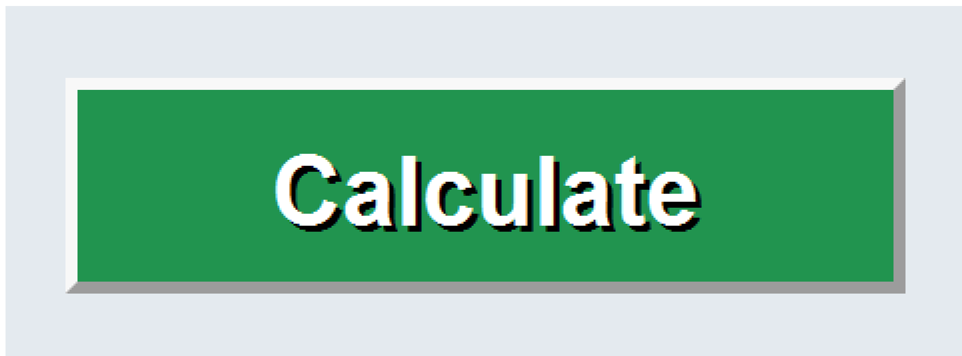
GLIMMPSE Calculate Button



GLIMMPSE Results

Power Results

Power	Total Sample Size	Target Power	Test	Type I Error Rate	Means Scale Factor	Variability Scale Fac
0.901	44	0.900	HLT	0.01	1	1
0.925	26	0.900	HLT	0.01	1	0.5
0.905	84	0.900	HLT	0.01	1	2

Save to CSV   View Matrices

GLIMMPSE Results

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Total sample size to achieve at least 90% power

GLIMMPSE Results

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Scale the standard deviation to ½ and 2 times to see how it affects sample size

Total sample size to achieve at least 90% power

GLIMMPSE Results

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Scale the standard deviation to ½ and 2 times to see how it affects sample size

Total sample size to achieve at least 90% power

Funding the Planned Study

Worksheet 3
Sample Size Calculation Summary

- Summarize the sample size calculation
- Include the following information:
    - Type I error rate
    - Desired power
    - Hypothesis
    - Hypothesis test used
    - Analysis method
    - Means, variances, correlation with justification
    - Calculated sample size

Agenda

Choosing Means, Variances, and Correlations with Our Free, Web-based Software Brandy M. Ringham	11:30 – 11:40
Discussion: Sample Size Calculation Summary	11:40 – 11:50
Wrapping it Up: Writing the Grant Deborah H. Glueck	11:50 – 12:00
Discussion: Question and Answer	12:00 – 12:15

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Wrapping it Up: Writing the Grant

Dr. Deborah Glueck
University of Colorado Denver

Outline
Writing the Grant

- Aligning power analysis with data analysis
- Justifying the power analysis
- Accounting for uncertainty
- Handling missing data
- Demonstrating enrollment feasibility
- Planning for multiple aims

Worksheet 3

Sample Size Calculation Summary

We plan a repeated measures ANOVA using the Hotelling-Lawley Trace to test for a time by intervention interaction.

Worksheet 3
Sample Size Calculation Summary

We plan a repeated measures ANOVA using the Hotelling-Lawley Trace to test for a time by intervention interaction.

Aligning Power Analysis with Data Analysis

- Type I error rate
  - $\alpha = 0.01$
- Hypothesis test
  - Wrong: power = intervention
    data analysis = time x intervention
  - Right: power = time x intervention
    data analysis = time x intervention

Worksheet 3

Sample Size Calculation Summary

Based on previous studies, we predict memory of pain measures will have a standard deviation of 0.98 and the correlation between baseline and 6 months will be 0.5. Based on clinical experience, we believe the correlation will decrease slowly over time, for a correlation of 0.4 between pain recall measures at baseline and 12 months.

Worksheet 3

Sample Size Calculation Summary

Based on previous studies, we predict memory of pain measures will have a standard deviation of 0.98 and the correlation between baseline and 6 months will be 0.5. Based on clinical experience, we believe the correlation will decrease slowly over time, for a correlation of 0.4 between pain recall measures at baseline and 12 months.

Justifying the Power Analysis

- Give all the values needed to recreate the power analysis
- Provide appropriate citation

Worksheet 3

Sample Size Calculation Summary

For a desired power of 0.90 and a Type I error rate of 0.01, we estimated that we would need 44 participants to detect a clinically meaningful mean difference of 1.2.

Worksheet 3

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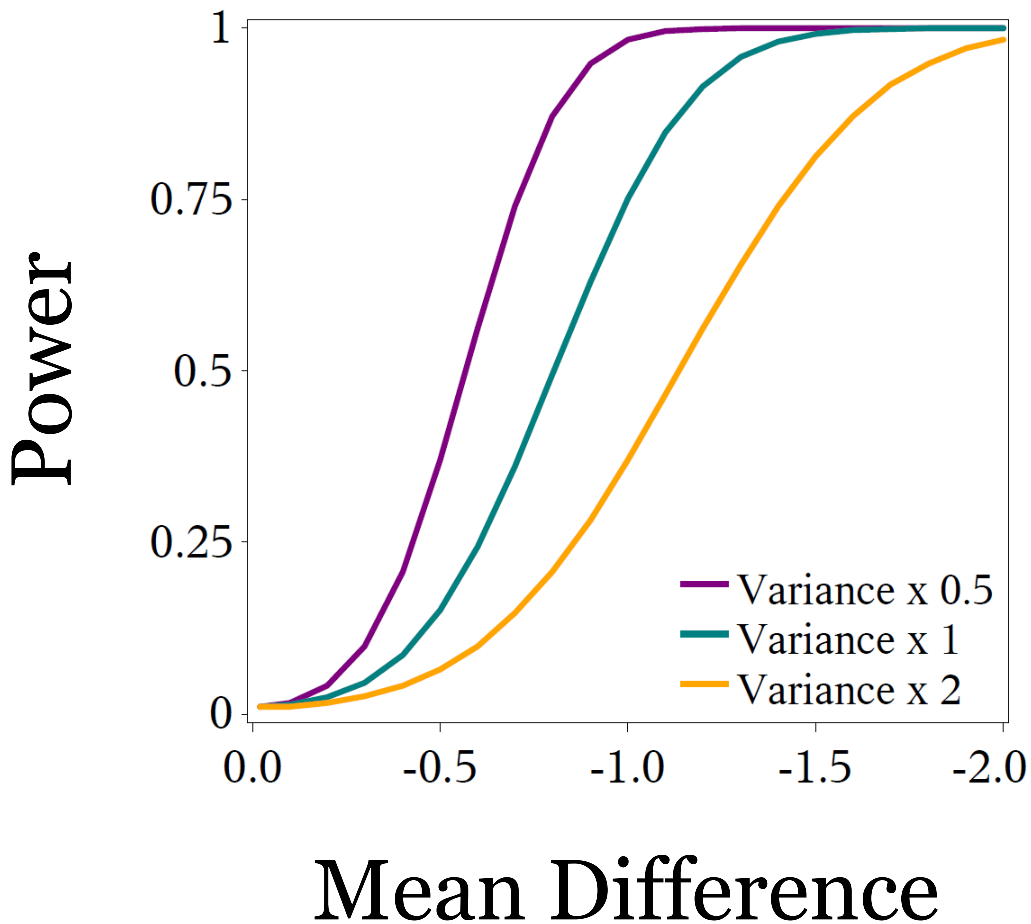
For a desired power of 0.90 and a Type I error rate of 0.01, we estimated that we would need 44 participants to detect a clinically meaningful mean difference of 1.2.

Accounting for Uncertainty



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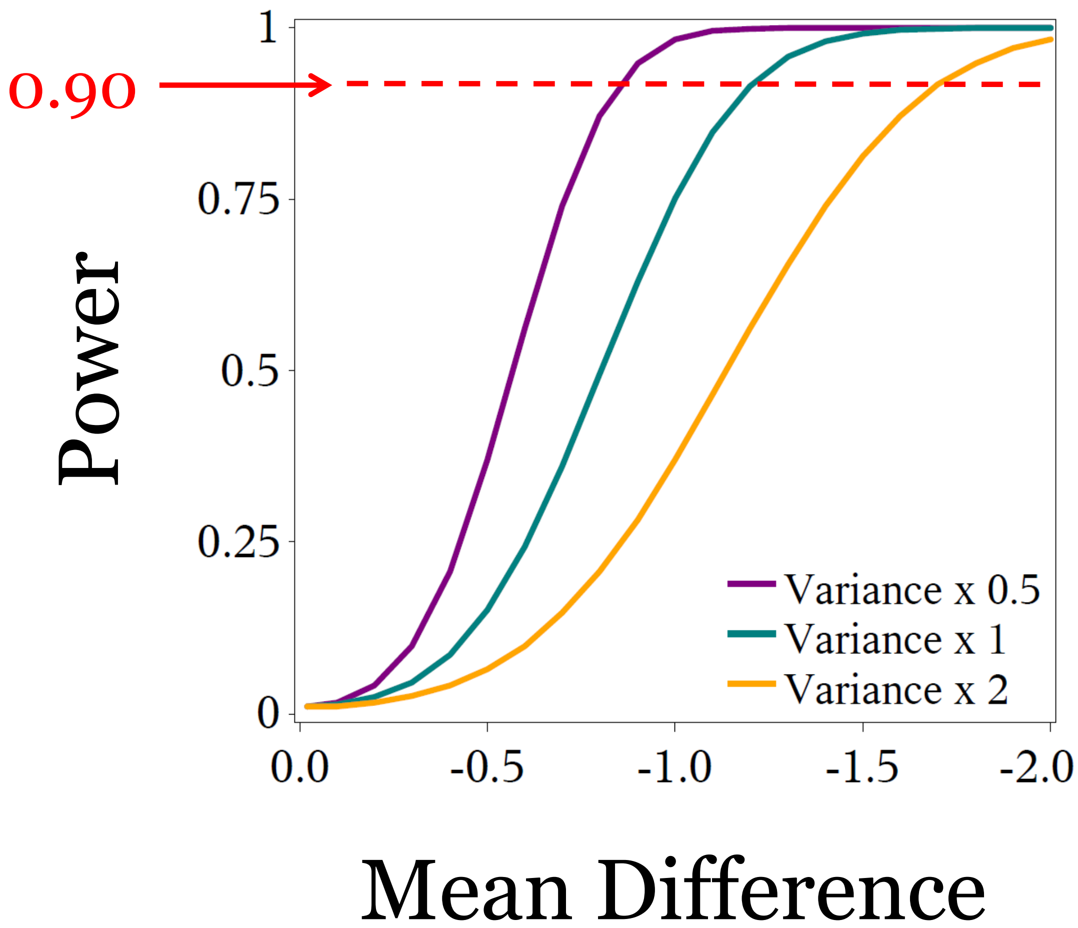

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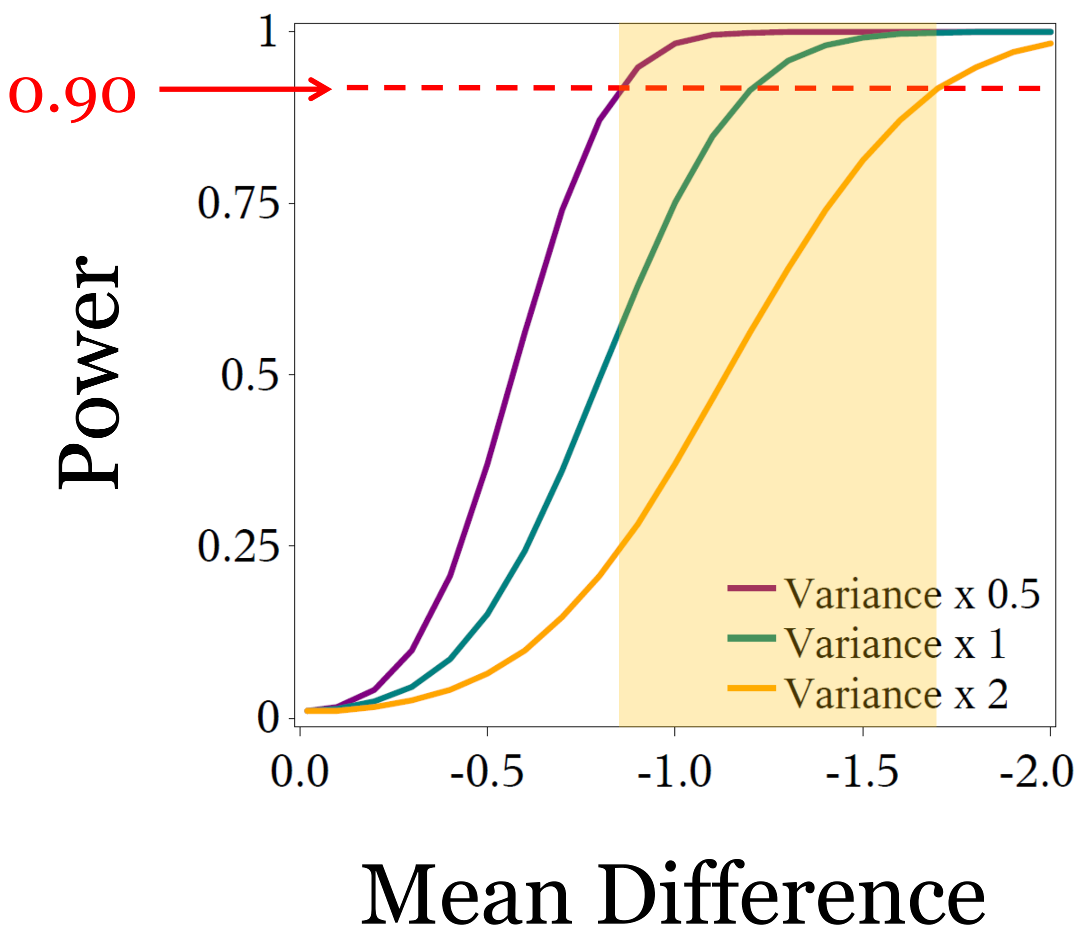

Worksheet 3

Sample Size Calculation Summary Draft

We plan a repeated measures ANOVA using the Hotelling-Lawley Trace to test for a time by intervention interaction. Based on previous studies, we predict measures of pain recall will have a standard deviation of 0.98. The correlation in pain recall between baseline and 6 months will be 0.5. Based on clinical experience, we predict that the correlation will decrease slowly over time. Thus, we anticipate a correlation of 0.4 between pain recall measures at baseline and 12 months. For a desired power of 0.90 and a Type I error rate of 0.01, we need to enroll 44 participants to detect a clinically meaningful mean difference of 1.2.

Handling Missing Data

- 25% loss to follow-up
- Account for missing data by increasing the sample size

$$44 / 0.75 = 59$$

Handling Missing Data

- 25% loss to follow-up
- Account for missing data by increasing the sample size

$$44 / 0.75 \approx 60$$

Worksheet 3

Sample Size Calculation Summary

Over 12 months, we expect 25% loss to follow up. To account for attrition, we will increase the sample size to 60 participants, or 30 participants per intervention arm.

Worksheet 3

Sample Size Calculation Summary

Over 12 months, we expect 25% loss to follow up. To account for attrition, we will increase the sample size to 60 participants, or 30 participants per intervention arm.

Demonstrating Enrollment Feasibility

- Is the target population sufficiently large?
- Can recruitment be completed in the proposed time period?

Planned Sample Size vs. Available Sample Size

- 30 patients per week with a high desire / low felt coping style
- 40% consent rate

Sample size needed	Sample size available
60	

Planned Sample Size vs. Available Sample Size

- 30 patients per week with a high desire / low felt coping style
- 40% consent rate

3 week enrollment period

Sample size needed
60

Sample size available
36

Planned Sample Size vs. Available Sample Size

- 30 patients per week with a high desire / low felt coping style
- 40% consent rate

5 week enrollment period

Sample size needed	Sample size available
60	60

Worksheet 3
Sample Size Calculation Summary

The clinic treats 30 patients per week with the high desire/low felt coping style. Based on recruitment experience for previous studies, we expect a 40% consent rate. At an effective enrollment of 12 participants per week, we will reach the enrollment goal of 60 participants in 5 weeks time.

Worksheet 3

Sample Size Calculation Summary

The clinic treats 30 patients per week with the high desire/low felt coping style. Based on recruitment experience for previous studies, we expect a 40% consent rate. At an effective enrollment of 12 participants per week, we will reach the enrollment goal of 60 participants in 5 weeks time.

Planning for Multiple Aims

- Aims typically represent different hypotheses
- Maximum of the sample sizes calculated for each aim

Questions?

Question & Answer

- How do I find GLIMMPSE?
- How can I put it on my smartphone?
- Can you review a point from the example power analysis?

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