

# 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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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.

# Poll Question #1

Which of the following best describes your role at the VA?

- A. Clinician
- B. Data scientist / Statistician
- C. Student / Intern / Fellow
- D. Other researcher
- E. Support staff

# 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.

# Agenda

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

**Dr. Henrietta Logan**

**10 minutes**

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

**Dr. Aarti Munjal**

**10 minutes**

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

**Dr. Sarah M. Kreidler**

**10 minutes**

# Agenda

**Wrapping it Up: Writing the Grant**

**Dr. Deborah H. Glueck**

**10 minutes**

**Discussion: Question and Answer**

**10 minutes**

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

Dr. Henrietta Logan  
University of Florida

# Ethics of Sample Size Calculations

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

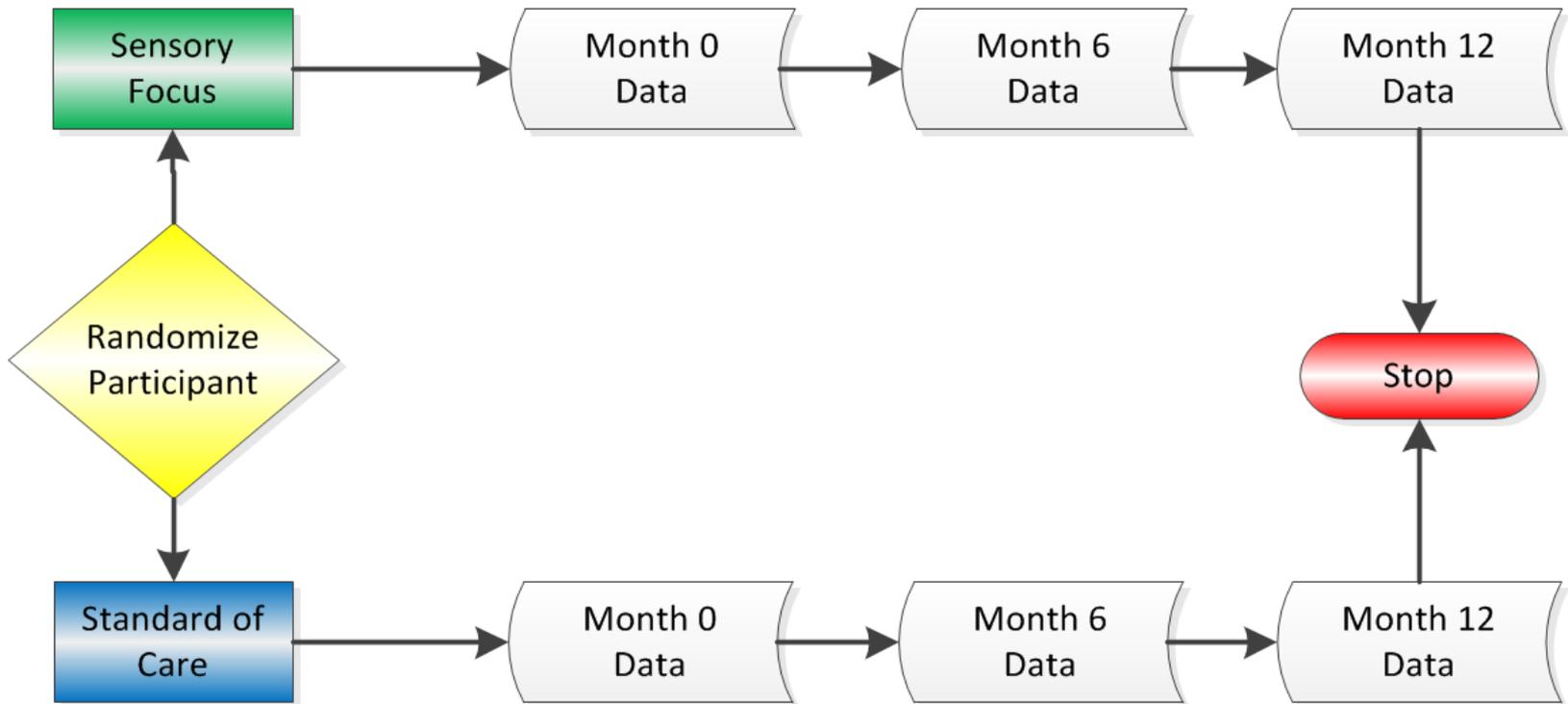
# Previous Study on Sensory Focus to Alleviate Pain

- Participants categorized into four coping styles
- Randomized to one of two treatment arms:
  - sensory focus
  - standard of care
- Measured experienced pain after root canal

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

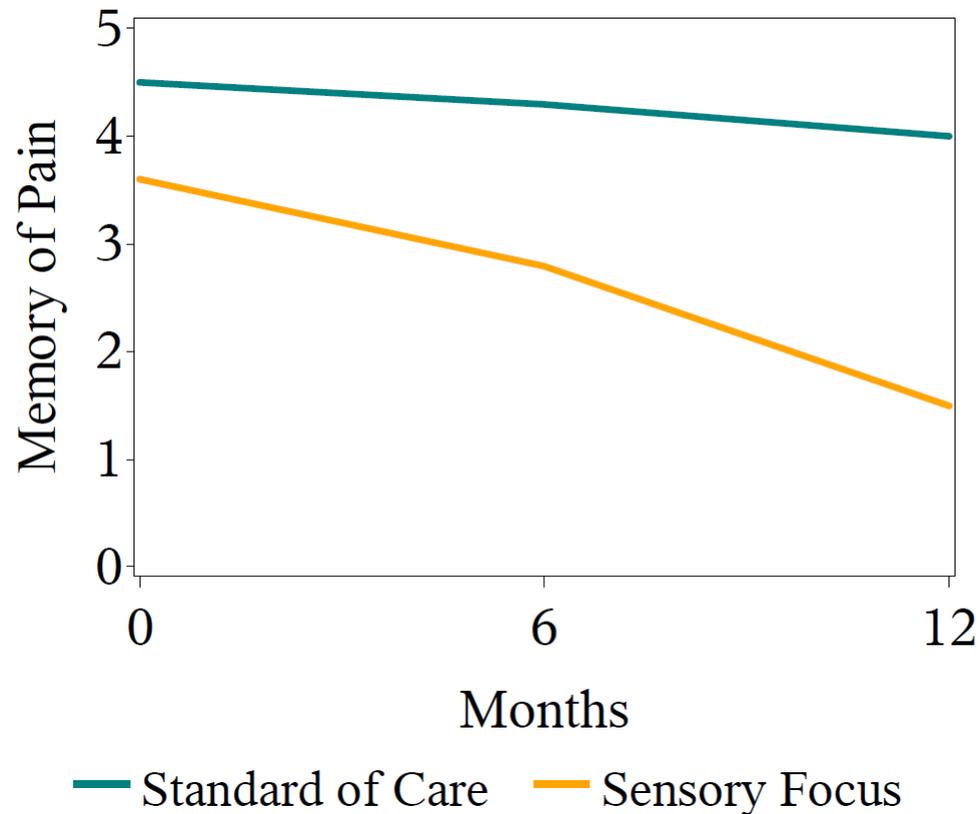
(Logan, Baron, Kohout, 1995)

# 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

**How do we calculate  
an accurate sample size?**

# Inputs for Power Analysis

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

# Inputs for Power Analysis

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

# Inputs for Power Analysis

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

# Inputs for Power Analysis

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

# Agenda

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

Dr. Henrietta Logan

10 minutes

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

Dr. Aarti Munjal

10 minutes

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

Sarah M. Kreidler

10 minutes

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

Dr. Aarti Munjal  
University of Colorado Denver

# 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
- Coming soon on iPad

# 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

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Select Guided Mode

# GLIMMPSE Solving For

---

**Start**

✓ **Solving For**

 Desired Power

 Type I Error

---

Sampling Unit

---

Responses

---

Hypothesis

---

Means

---

Variability

---

Options

## 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

# GLIMMPSE Solving For

Calculate

**Start**

✓ Solving For

✎ Desired Power

✎ Type I Error

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- Power
- Total Sample Size

Checkmark = complete  
Pencil = incomplete

# GLIMMPSE Solving For

Calculate

**Start**

✓ Solving For

✎ Desired Power

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- Power
- Total Sample Size

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:	<input type="text"/>	<input type="button" value="Add"/>	<input type="button" value="Delete"/>
0.9			

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Power Values:

0.9

Enter desired power values here and click "Add"

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Power Values:

0.9

Enter desired power values here and click "Add"

# 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  $\alpha$ . 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:

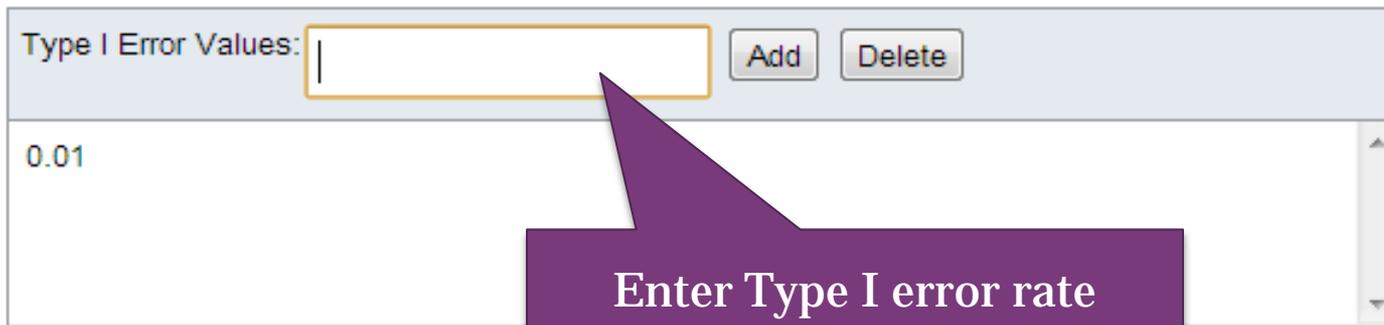
0.01

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Type I Error Values:

0.01

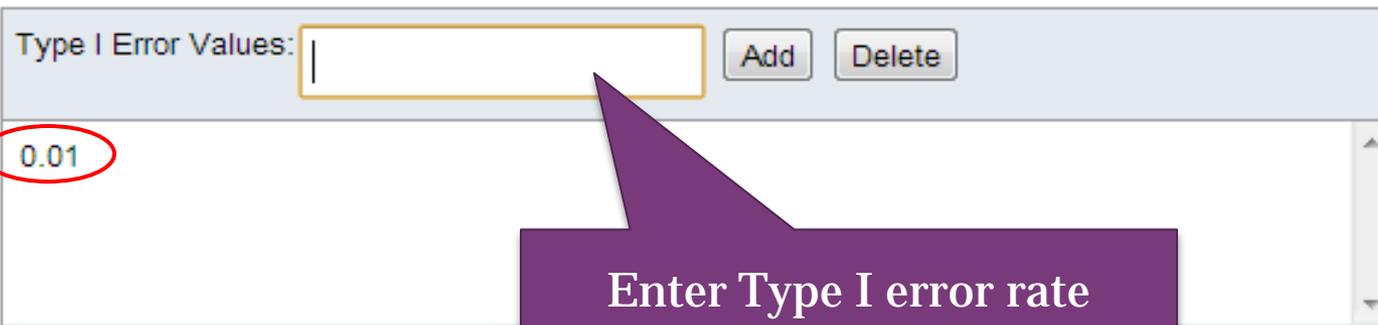
Enter Type I error rate values here and click "Add"

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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.



The screenshot shows a software interface for entering Type I error rates. At the top, there is a label "Type I Error Values:" followed by a text input field. To the right of the input field are two buttons: "Add" and "Delete". Below the input field is a list box containing the value "0.01". A red circle highlights the "0.01" value in the list box. A purple callout box with a white border points to the input field and contains the text "Enter Type I error rate values here and click 'Add'".

Enter Type I error rate values here and click "Add"

# GLIMMPSE Predictors

Predictor	Category
<input type="text"/>	<input type="text"/>
<input type="button" value="Add"/>	<input type="button" value="Add"/>
<input type="button" value="Delete"/>	<input type="button" value="Delete"/>
<ul style="list-style-type: none"><li>treatment</li></ul>	<ul style="list-style-type: none"><li>sensory focus</li><li>standard of care</li></ul>

# GLIMMPSE Predictors

Predictor	Category
<input type="text"/>	<input type="text"/>
<input type="button" value="Add"/> <input type="button" value="Delete"/>	<input type="button" value="Add"/> <input type="button" value="Delete"/>
<ul style="list-style-type: none"><li>treatment</li></ul>	<ul style="list-style-type: none"><li>sensory focus</li><li>standard of care</li></ul>

Enter predictors here and  
click "Add"

# GLIMMPSE Predictors

The screenshot shows a web interface for managing predictors. It is divided into two main sections: 'Predictor' and 'Category'. Each section has an input field at the top, followed by 'Add' and 'Delete' buttons. Below the input fields are lists of items. In the 'Predictor' list, the item 'treatment' is highlighted in blue. In the 'Category' list, the items 'sensory focus' and 'standard of care' are listed.

Predictor	Category
treatment	sensory focus
	standard of care

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:	<input type="text"/>	<input type="button" value="Add"/>	<input type="button" value="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.

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

Response Variables:	Add	Delete
memory of pain		

Enter outcomes 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:

memory of pain
----------------

Enter outcomes here and  
click "Add"

# GLIMMMPSE Repeated Measures

## [Remove Repeated Measures](#)

Units	<input type="text" value="time"/>
Type	<input type="text" value="Numeric"/> ▼
Number of Measurements	<input type="text" value="3"/>
Spacing	<input type="button" value="1"/> <input type="button" value="2"/> <input type="button" value="3"/>
<a href="#">Reset to Equal Spacing</a>	

[Add Level](#)

[Remove Level](#)

# GLIMMPSE Repeated Measures

## [Remove Repeated Measures](#)

Units	<input type="text" value="time"/>
Type	<input type="text" value="Numeric"/> ▼
Number of Measurements	<input type="text" value="3"/>
Spacing	<input type="button" value="1"/> <input type="button" value="2"/> <input type="button" value="3"/>
<a href="#">Reset to Equal Spacing</a>	

[Add Level](#)

[Remove Level](#)

# GLIMMPSE Repeated Measures

## [Remove Repeated Measures](#)

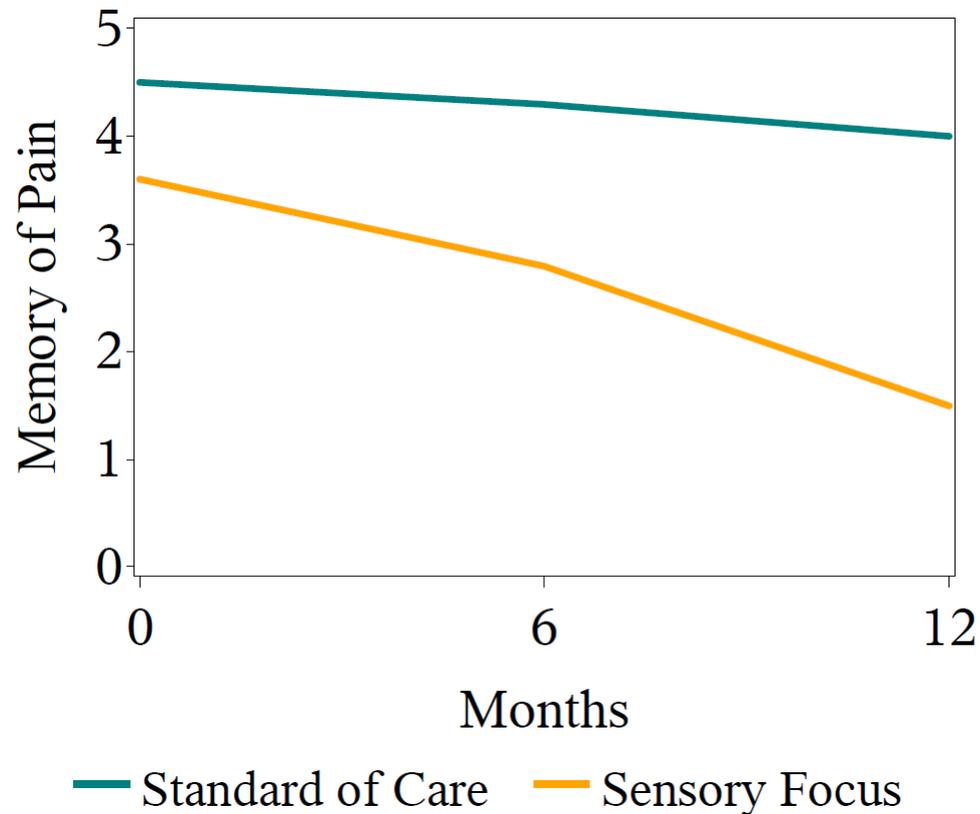
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<a href="#">Reset to Equal Spacing</a>	

[Add Level](#)

[Remove Level](#)

# Hypothesis

time by treatment 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**

treatment [Edit trend](#) : None

**Within Participant Factors**

time [Edit trend](#) : None

# GLIMMPSE Hypothesis

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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.

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**Between Participant Factors**

treatment [Edit trend](#) : None

**Within Participant Factors**

time [Edit trend](#) : None

**Next step:**

**Choosing Means, Variances, and  
Correlations**

# Agenda

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

**Dr. Henrietta Logan**

**10 minutes**

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

**Dr. Aarti Munjal**

**10 minutes**

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

**Sarah M. Kreidler**

**10 minutes**

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

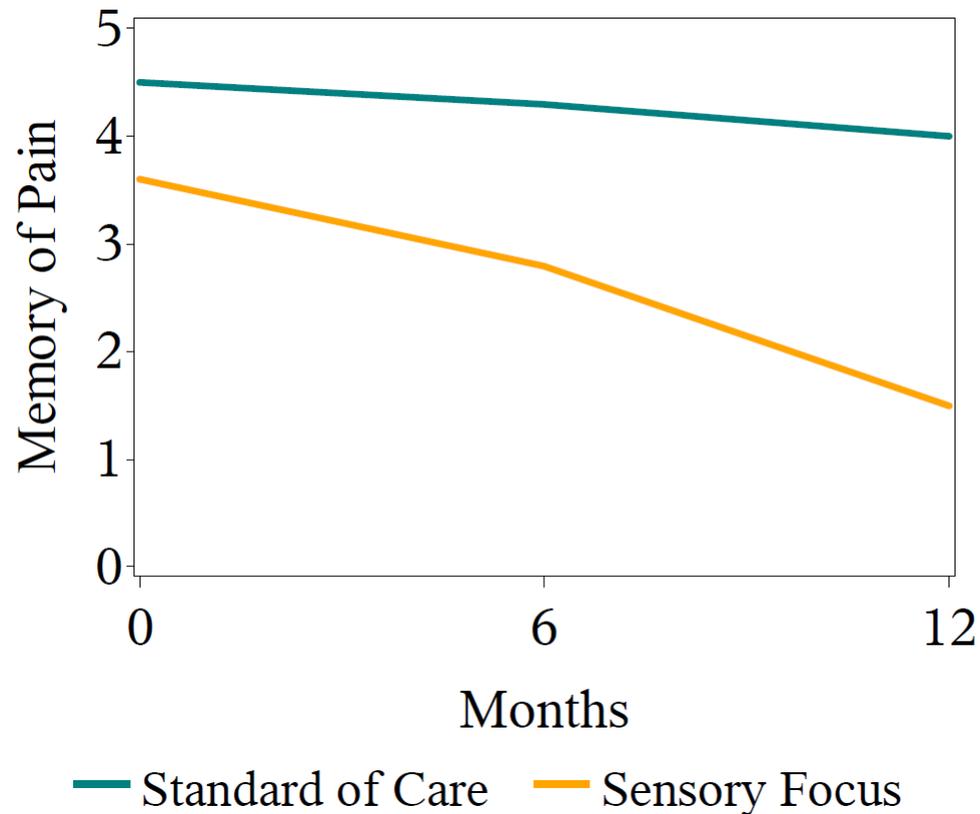
Sarah M. Kreidler  
University of Colorado Denver

# Where Can I Find Means, Variances, and Correlations?

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

# Hypothesis

time by treatment interaction



# Means

---

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)



Net Difference Over Time  
(12 Months - Baseline)



# Means

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)	-0.9		
Net Difference Over Time (12 Months - Baseline)			

# Means

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)	-0.9	-1.5	
Net Difference Over Time (12 Months - Baseline)			

# Means

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)	-0.9	-1.5	-2.1
Net Difference Over Time (12 Months - Baseline)			

# Means

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)	-0.9	-1.5	-2.1
Net Difference Over Time (12 Months - Baseline)			-1.2

# Variances and Correlations

- Consider the sources of variability and correlation in the study design
  - Repeated measures within a given participant will be correlated
  - Outcome measurements will vary between participants

# 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.

# 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.

# GLIMMPSE Means

## Specifying a Mean Difference

treatment	memory of pain
sensory focus	<input type="text" value="-1.2"/>
standard of care	<input type="text" value="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

# GLIMMPSE Means

## Specifying a Mean Difference

treatment	memory of pain
sensory focus	<input type="text" value="-1.2"/>
standard of care	<input type="text" value="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



Choose a timepoint

# GLIMMPSE Means

## Specifying a Mean Difference

treatment	memory of pain
sensory focus	<input type="text" value="-1.2"/>
standard of care	<input type="text" value="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

Choose a timepoint

Enter the expected net mean difference

# GLIMMPSE Variability

## Entering Standard Deviation of the Outcome

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

# GLIMMPSE Variability

## Specifying Correlations

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

Enter the standard deviation  
of the outcome variable

# GLIMMMPSE 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.

- 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

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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

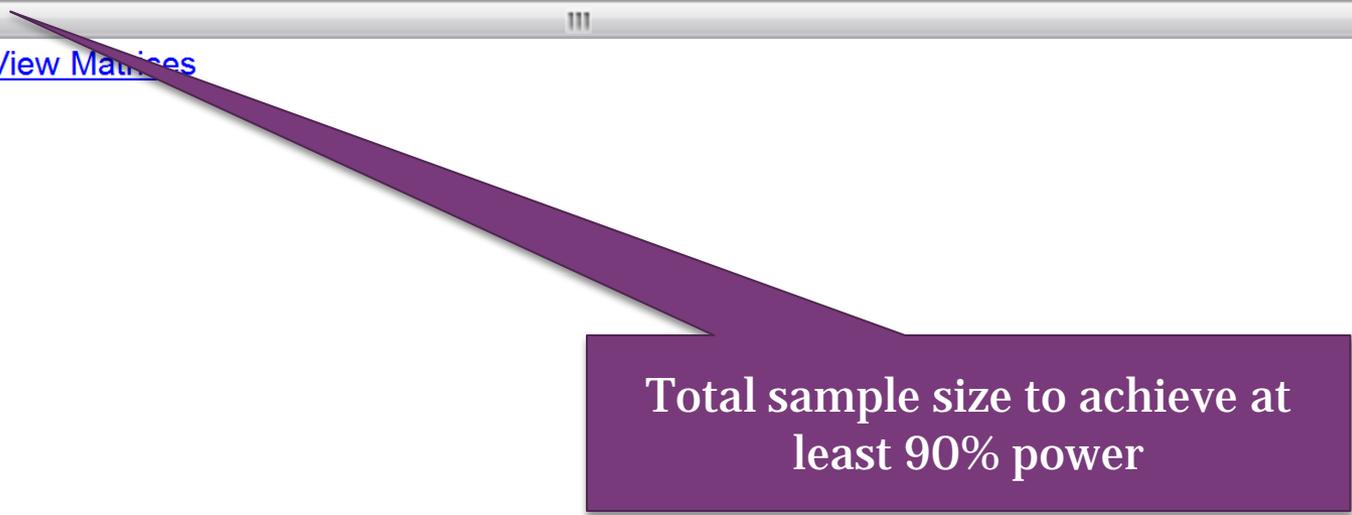
[Save to CSV](#) [View Matrices](#)

# GLIMMPSE Results

## Power Results

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Total sample size to achieve at least 90% power

# GLIMMPSE Results

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[Save to CSV](#) [View Matrices](#)

Scale the standard deviation to  $\frac{1}{2}$  and 2 times to see how it affects sample size

Total sample size to achieve at least 90% power

# GLIMMPSE Results

## Power Results

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[Save to CSV](#)

[View Matrices](#)

Scale the standard deviation to  $\frac{1}{2}$  and 2 times to see how it affects sample size

Total sample size to achieve at least 90% power

# Funding the Planned Study



# Agenda

**Wrapping it Up: Writing the Grant**

**Deborah H. Glueck**

**10 minutes**

**Discussion: Question and Answer**

**10 minutes**

# 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**

# Sample Size Calculation Summary

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

# Sample Size Calculation Summary

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

# Aligning Power Analysis with Data Analysis

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

# 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.

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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

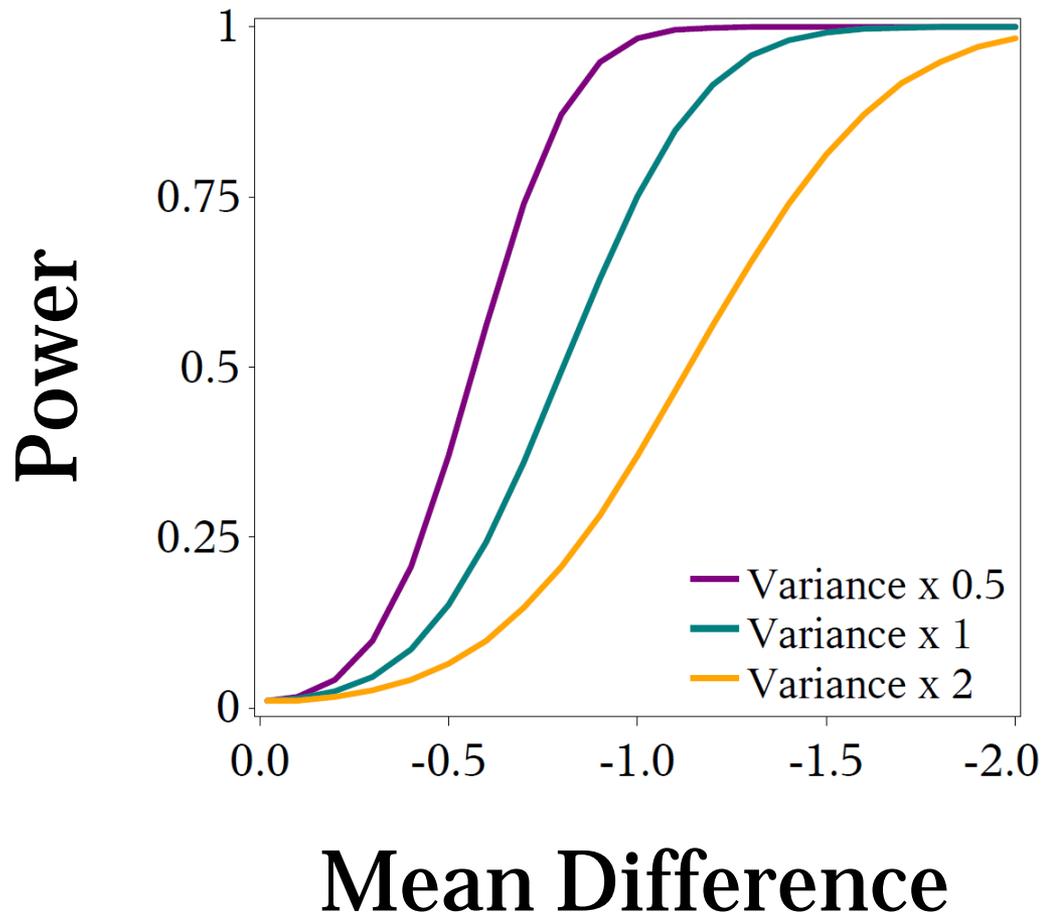
# Sample Size Calculation Summary

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 mean difference of 1.2.

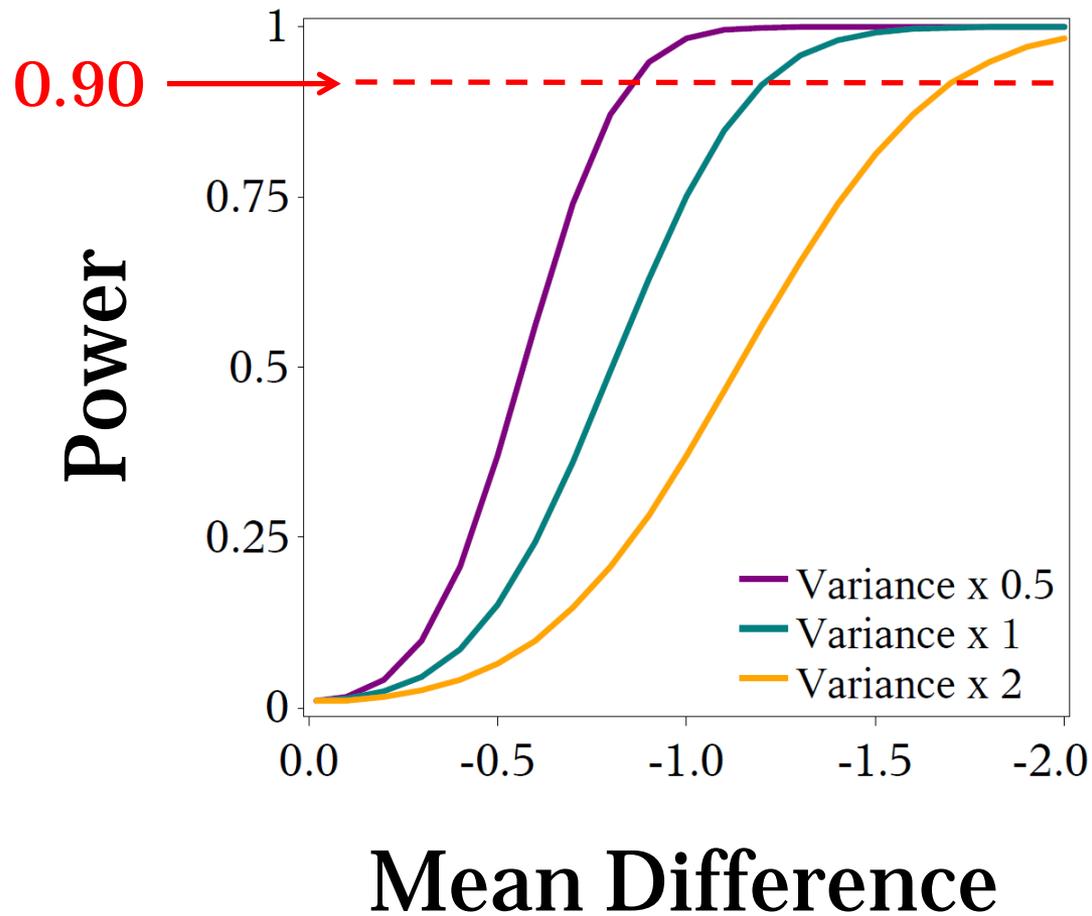
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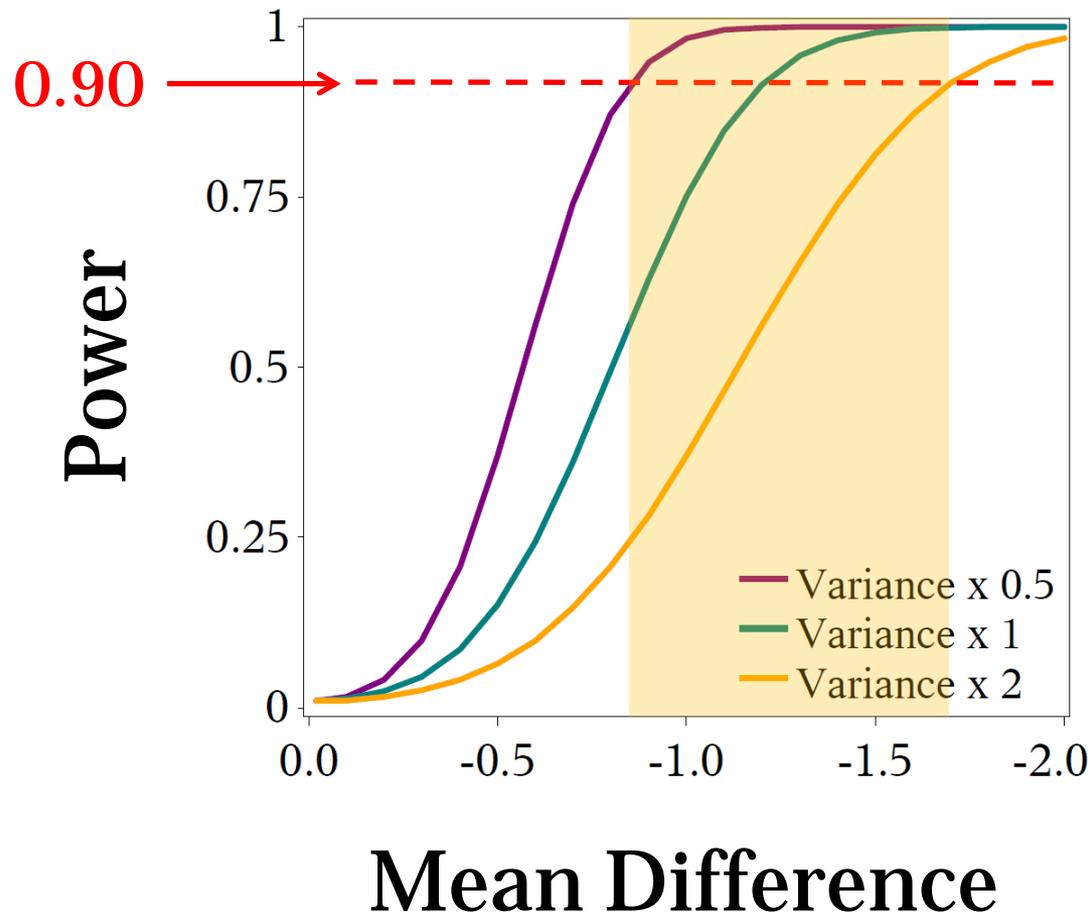
# Accounting for Uncertainty



# Accounting for Uncertainty



# Accounting for Uncertainty



# Sample Size Calculation Summary

## Draft

We plan a repeated measures ANOVA using the Hotelling-Lawley Trace to test for a time by treatment 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 mean difference of 1.2.

# Handling Missing Data

- 25% loss to follow-up
- Inflate calculated sample size by 25%

$$44 \times 1.25 = 55$$

# Handling Missing Data

- 25% loss to follow-up
- Inflate calculated sample size by 25%

$$44 \times 1.25 \approx 56$$

# Sample Size Calculation Summary

Over 12 months, we expect 25% loss to follow up. We will inflate the sample size by 25% to account for the attrition, for a total enrollment goal of 56 participants, or 28 participants per treatment arm.

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# 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  
56

Sample size available

# 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  
56

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  
56

Sample size available  
60

# 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 56 participants in 5 weeks time.

# 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 56 participants in 5 weeks time.

# Planning for Multiple Aims

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

# Poll Question #2

What topics would you like to see in the future?

- A. Power and sample size for missing data
- B. Power and sample size for mixed models
- C. Power and sample size for binary or Poisson outcomes
- D. Choosing cluster sizes for multilevel studies

# Questions?

For more information visit

<http://www.SampleSizeShop.org>

Or contact Dr. Deb Glueck at

[deborah.glueck@ucdenver.edu](mailto:deborah.glueck@ucdenver.edu)



# References

- Adams, G., Gulliford, M. C., Ukoumunne, O. C., Eldridge, S., Chinn, S., & Campbell, M. J. (2004). Patterns of intra-cluster correlation from primary care research to inform study design and analysis. *Journal of clinical epidemiology*, *57*(8), 785-794.
- Catellier, D. J., & Muller, K. E. (2000). Tests for gaussian repeated measures with missing data in small samples. *Statistics in Medicine*, *19*(8), 1101-1114.
- Demidenko, E. (2004). *Mixed Models: Theory and Applications* (1st ed.). Wiley-Interscience.
- Glueck, D. H., & Muller, K. E. (2003). Adjusting power for a baseline covariate in linear models. *Statistics in Medicine*, *22*, 2535-2551.

# References

- Gedney , J.J., Logan, H.L., Baron, R.S. (2003). Predictors of short-term and long-term memory of sensory and affective dimensions of pain. *Journal of Pain*, 4(2), 47–55.
- Gedney, J.J., Logan H.L. (2004). Memory for stress-associated acute pain. *Journal of Pain*, 5(2), 83–91.
- Gurka, M. J., Edwards, L. J., & Muller, K. E. (2011). Avoiding bias in mixed model inference for fixed effects. *Statistics in Medicine*, 30(22), 2696-2707. doi:10.1002/sim.4293
- Kerry, S. M., & Bland, J. M. (1998). The intraclass correlation coefficient in cluster randomisation. *BMJ (Clinical research ed.)*, 316(7142), 1455.

# References

- Kreidler, S.M., Muller, K.E., Grunwald, G.K., Ringham, B.M., Coker-Dukowitz, Z.T., Sakhadeo, U.R., Barón, A.E., Glueck, D.H. (accepted). GLIMMPSE: Online Power Computation for Linear Models With and Without a Baseline Covariate. *Journal of Statistical Software*.
- Laird, N. M., & Ware, J. H. (1982). Random-effects models for longitudinal data. *Biometrics*, *38*(4), 963-974.
- Law, A., Logan, H., & Baron, R. S. (1994). Desire for control, felt control, and stress inoculation training during dental treatment. *Journal of Personality and Social Psychology*, *67*(5), 926-936.
- Logan, H.L., Baron, R.S., Keeley, K., Law, A., Stein, S. (1991). Desired control and felt control as mediators of stress in a dental setting. *Health Psychology*, *10*(5), 352–359.

# References

- Logan, H.L., Baron, R.S., Kohout, F. (1995). Sensory focus as therapeutic treatments for acute pain. *Psychosomatic Medicine*, 57(5), 475–484.
- Muller, K. E, & Barton, C. N. (1989). Approximate Power for Repeated-Measures ANOVA Lacking Sphericity. *Journal of the American Statistical Association*, 84(406), 549-555.
- Muller, K. E, Edwards, L. J., Simpson, S. L., & Taylor, D. J. (2007). Statistical Tests with Accurate Size and Power for Balanced Linear Mixed Models. *Statistics in Medicine*, 26(19), 3639-3660.
- Muller, K. E, Lavange, L. M., Ramey, S. L., & Ramey, C. T. (1992). Power Calculations for General Linear Multivariate Models Including Repeated Measures Applications. *Journal of the American Statistical Association*, 87(420), 1209-1226.

# References

- Muller, K. E., & Peterson, B. L. (1984). Practical Methods for Computing Power in Testing the Multivariate General Linear Hypothesis. *Computational Statistics and Data Analysis*, 2, 143-158.
- Muller, K.E., & Stewart, P. W. (2006). *Linear Model Theory: Univariate, Multivariate, and Mixed Models*. Hoboken, NJ: Wiley.
- Taylor, D. J., & Muller, K. E. (1995). Computing Confidence Bounds for Power and Sample Size of the General Linear Univariate Model. *The American Statistician*, 49(1), 43-47. doi:10.2307/2684810