

Writing the Sample Size Section for your Proposal

Course developed by
Deborah H. Glueck and Keith E. Muller

Slides developed by Jessica R. Shaw, Keith E. Muller,
Albert D. Ritzhaupt and Deborah H. Glueck

© Copyright by the Regents of the University of Colorado 1

Learning objectives

Demonstrate how to structure the sample size section of a proposal.

2

We first review the six components required in the sample size section of a proposal

1. Align power analysis with data analysis
2. Justify the power analysis
3. Account for uncertainty
4. Plan for missing data
5. Demonstrate enrollment feasibility
6. Plan for multiple aims

3

For proposal-writing practice, we refer back to our longitudinal pain trial example

Vignette

Researchers conducted a study to determine if patients who are instructed to use a sensory focus have a different pattern of long-term memory of pain than patients who did not.

Adapted from Logan et al., 1995

4

Vignette, continued

Patients were selected and randomly assigned to either intervention or no intervention. Those in the **intervention group** listened to automated audio instructions to pay close attention only to the physical sensations in their mouth.

Adapted from Logan et al., 1995

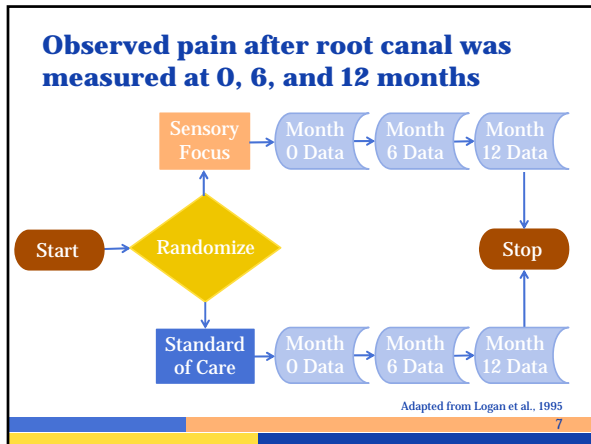
5

Vignette, continued

Patients in the **no intervention group** listened to automated audio instruction on a neutral topic to control for media and attention effects.

Adapted from Logan et al., 1995

6



Researchers analyzed three distinct hypotheses

1 **Between-independent sampling unit null hypothesis:**

Mean pain experienced by patients in the sensory focus treatment group does not significantly differ from that experienced by patients in the standard of care group.

Adapted from Logan et al., 1995

8

Researchers analyzed three distinct hypotheses

2 **Within-independent sampling unit null hypothesis:**

Mean pain experienced does not vary significantly over time.

Adapted from Logan et al., 1995

9

Researchers analyzed three distinct hypotheses

3 Between by within-independent sampling unit null hypothesis:

The **pattern** of pain perception over time is different for the sensory-focus group than for the control group.



Adapted from Logan et al., 1995
10

Six components are required in the sample size section of a proposal.

1. ALIGN POWER ANALYSIS WITH DATA ANALYSIS

11

First, indicate the type of data analysis you will employ and compute power for.

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

12

2. JUSTIFY THE POWER ANALYSIS

13

Begin by outlining your power inputs

Give all the values needed to recreate the power analysis.

Provide an appropriate citation detail for the method and software.

14

Describe the sources and reasons for choosing your parameter choices

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.

15

Next document your power goals and inputs

Based on the parameter choices, 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. Sample size analysis was conducted using GLIMPSE, housed at SampleSizeShop.org (Kreidler et al., 2013).

16

**3. ACCOUNT FOR UNCERTAINTY AND
4. ACCOUNT FOR MISSING DATA**

17

Adjust your sample size for anticipated missing data and revise your grant proposal section

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 60 participants, or 30 participants per treatment arm.

18

5. DEMONSTRATE ENROLLMENT FEASIBILITY

19

Include an outline of your enrollment timeline in your power and sample size section

The clinic treats 30 patients per week. 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.

20

6. PLAN FOR MULTIPLE AIMS

21

Plan for multiple aims

Recall that **aims** typically represent different hypotheses.

With no ethical or cost constraints, select the **maximum** of the sample sizes calculated for each aim as the overall required sample size for the study.

22

Your final sample size section of your grant proposal should resemble the following paragraphs

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**.

23

Your final sample size section of your grant proposal should resemble the following paragraphs

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**.

24

Your final sample size section of your grant proposal should resemble the following paragraphs

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 60 participants, or 30 participants per treatment arm.

25

Your final sample size section of your grant proposal should resemble the following paragraphs

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.

26

REVIEW OF LEARNING OBJECTIVES

27

We discussed six components that should be in the sample size section of a grant proposal. Name as many as you can.

1. Align power analysis with data analysis
2. Justify the power analysis
3. Account for uncertainty
4. Plan for missing data
5. Demonstrate enrollment feasibility
6. Plan for multiple aims

28



29
