Demonstrating Enrollment Feasibility

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

 1

Learning objectives

Define enrollment feasibility.

Describe the importance of enrollment feasibility in a sample size calculation.

2

Enrollment feasibility is the ability to accrue the planned sample size

Time constraints and funding constraints often limit enrollment potential.

3

Few trials attain recruitment goals

A 1984 survey of randomized controlled trials in the NIH's inventory found that just **34%** reached their planned recruitment.

Charlson et al, 1984

4

Culturally competent strategies may improve recruitment of minority and ethnic subgroups

A PubMed search reveals over 8,000 studies which discuss challenges and strategies for recruitment in clinical trials.

Different strategies are needed for different populations.

Otado et al., 2015

5

Investigators must consider characteristics of the study population that may affect recruitment

Health factors, socioeconomic factors, and demographic factors can be predictive of recruitment difficulty.

Patel et al., 2003

6

Factors reflecting poor health may foreshadow difficult recruitment

Examples:

- Recent or present illness
- Frequent use of medical care
- Smoking

Patel et al., 2003

7

Socioeconomic factors may predict recruitment challenges

Examples:

- Low educational status
- Low occupational status
- Low income

Patel et al., 2003

8

Demographic factors may also contribute to recruitment challenges

Examples:

- Greater age
- Male gender
- Urban residence

Patel et al., 2003

9

Grant proposals should explicitly discuss the practicality of enrollment goals

Investigators should address the following questions:

"Does the budget pose a limitation to sample size?"

"Is the target population sufficiently large?"

"Can recruitment be completed in the proposed time period?"

10

Design dimensions may constrain possible sample sizes

One can only recruit an integer number of people. Reality requires a physically realizable design.

Ask whether the adjusted sample size is divisible by the number of treatment arms.

Ask whether the adjusted sample size is divisible by the number of groups, if doing a subgroup analysis or block randomization.

11

We now demonstrate recruitment feasibility for the longitudinal study of pain recall

Vignette

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

12

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

13

Vignette, continued

On average, the dentist's office treated 30 patients per week. Researchers predicted that 40% of eligible patients would consent to participation in the study.

14

As demonstrated in lecture 15, adjust the required sample size for anticipated loss to follow up

$$\frac{44}{1-0.25} = 58.6$$

$$\approx 60$$

15

Calculate the number of patients that can realistically be recruited per week

30 Patients eligible per week

× 0.40 Consent rate

12 Patients enrolled per week

16

Using estimated enrollment per week, forecast a realistic timeline for recruitment

$$\frac{60 \text{ patients total}}{12 \text{ patients per week}} = 5 \text{ weeks}$$

Required sample size	Duration of enrollment	Available sample size
60	5 weeks	60 ✓

17

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

The clinic treats 30 patients per week. Based on recruitment experiences in 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.

18

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. Expected dropout implies 44 participants will complete the study.

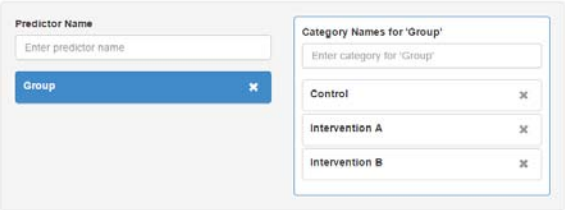
19

REVIEW OF LEARNING OBJECTIVES

20

Word problem

Investigators plan to compare alcohol consumption after either no treatment or one of two proposed interventions, A and B.



21

Word problem

Investigators have calculated a required sample size of 402 participants total to achieve 0.80 power.

22

Word problem

Participants will be assigned to intervention A, intervention B, or the control group using a 1:1:1 randomization scheme.

23

Word problem

Recruitment will take place at an outpatient health clinic. From previous experience, the investigators know that 30 people per week who fit the enrollment criteria appear at the clinic. Further, researchers know that approximately 70% of people invited to participate will enroll in the trial.

24

Word problem

Again from previous studies in the population of interest, researchers know that roughly 20% of participants are lost to follow up. The team needs to finish recruitment within eight months.

25

Summarize the facts

Power analysis suggests: 402 people (134 per group)

Number of randomization arms: 3

Size of eligible population: 30 per week

Consent rate: 70%

Expected loss to follow up: 20%

26

How many people total should the investigators recruit?

Step 1: Adjust for 20% loss to follow up

$$\text{Adjusted} = \left(\frac{402}{1 - 0.20}\right) = 502.5 \text{ total}$$

which implies 504

27

How many people total should the investigators recruit?

Step 2: Check that sample size divides equally into three randomization arms

$$\frac{504}{3} = 168 \text{ per arm}$$

28

How many people total should the investigators recruit?

Step 3:

$$\frac{504}{3} = 168 \text{ per arm}$$

29

How many people total should the investigators recruit?

Step 4: Report total sample size

$$168 \text{ per arm} \times 3 = 504 \text{ people total}$$

30

How long will the recruitment take?

Step 1: Calculate feasible recruitment per week

30 Patients eligible per week

× 0.70 Consent rate

21 Patients enrolled per week

31

How long will the recruitment take?

Step 2: Given feasible recruitment per week, calculate recruitment time

504 ÷ 21 = 24 weeks

32

Is the recruitment feasible?

Yes. With an estimated recruitment time of 24 weeks, the investigators will accrue their required sample size before their deadline.

33


Questions?
34