Demonstrating Enrollment Feasibility

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Learning objectives

Define enrollment feasibility.

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

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Enrollment feasibility is the ability to accrue the planned sample size

Time constraints and funding constraints often limit enrollment potential.

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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

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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

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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

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Factors reflecting poor health may foreshadow difficult recruitment

Examples:

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

Patel et al., 2003

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Socioeconomic factors may predict recruitment challenges

Examples:

- Low educational status
- Low occupational status
- Low income

Patel et al., 2003

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Demographic factors may also contribute to recruitment challenges

Examples:

- Greater age
- Male gender
- Urban residence

Patel et al., 2003

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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?"

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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.

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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.

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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.

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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.

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

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

$$\approx 60$$

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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

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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 ✓

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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.

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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.

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Review Summary

- We look at enrollment feasibility so we understand our ability to recruit the planned sample size
- Researchers need to consider the characteristics of the study population, time constraints, and funding constraints
- You can calculate how many participants can be recruited each week, then use that value to calculate how many weeks it would take to recruit your total sample size

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