

STOR 155.10 Lecture 01

Introduction

Aniruddhan (Ani) Ganesaraman

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Motivating example: Randomized Control Trials (RCTs)

- **Objective:** Evaluate the effectiveness of cognitive-behavior therapy for chronic fatigue syndrome.
- **Participant pool:** 142 patients who were recruited from referrals by primary care physicians and consultants to a hospital clinic specializing in chronic fatigue syndrome.
- **Actual participants:** Only 60 of the 142 referred patients entered the study. Some were excluded because they didn't meet the diagnostic criteria, some had other health issues, and some refused to be a part of the study.

Study design

- Patients randomly assigned to treatment and control groups, 30 patients in each group:
 - **Treatment group:** Cognitive behavior therapy – collaborative, educative, and with a behavioral emphasis. Patients were shown on how activity could be increased steadily and safely without exacerbating symptoms.
 - **Control group:** Relaxation – No advice was given about how activity could be increased. Instead progressive muscle relaxation, visualization, and rapid relaxation skills were taught.
- 7 patients dropped out of the study later: 3 from the treatment and 4 from the control group.

Results

The table below shows the distribution of patients with good outcomes at 6-month follow-up. Note that 7 patients dropped out of the study: 3 from the treatment and 4 from the control group.

		<i>Good outcome</i>		Total
		Yes	No	
<i>Group</i>	Treatment	19	8	27
	Control	5	21	26
	Total	24	29	53

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- Proportion with good outcomes in control group:

$$5/26 \approx 0.19 \rightarrow 19\%$$

Understanding the results

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- Suppose you flip a coin 100 times. While the chance a coin lands heads in any given coin flip is 50%, we probably won't observe exactly 50 heads. This type of fluctuation is part of almost any type of data generating process.
- The observed difference between the two groups ($70 - 19 = 51\%$) may be real, or may be due to natural variation.
- Since the difference is quite large, it is more believable that the difference is real.
- We need statistical tools to determine if the difference is so large that we should reject the notion that it was due to chance.

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Are the results of this study **generalizable** to all patients with chronic fatigue syndrome?

- These patients had specific characteristics and volunteered to be a part of this study.
- Therefore, maybe not representative of all patients with chronic fatigue syndrome.
- While we cannot immediately generalize the results to all patients, this first study is encouraging.
- The method works for patients with some narrow set of characteristics, and that gives hope that it will work, at least to some degree, with other patients.