A Simulated Clinical Trial to Reduce Therapeutic Misconception

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What is Therapeutic Misconception (TM)?

Therapeutic Misconception (TM) is recognized as a major limitation on valid consent to clinical trials. Therapeutic Misconception occurs when a research subject fails to grasp the distinction between clinical research and ordinary treatment and attributes therapeutic intent to research procedures

Contrasting Treatment and Clinical Trials

Treatment	Clinical Trials
• Individualized treatment decisions	• Randomized assignment to intervention
• Physician selects treatment for patient benefit	• Physician blinded to the treatment being provided
• Other treatments provided if thought likely to be helpful	• Restrictions on other treatments
• Dosage adjusted for maximum benefit	• Limited adjustments of dosage prescribed by protocol

TM and Differing Cognitive Frames

- People understand each other in socially structured cognitive frames
  - Conflicting frames can lead to misunderstandings
- Researchers see trials primarily in a SCIENTIFIC frame
  - Based on an abstract concept of how efficacy can be demonstrated
  - Regard participants as patients to be treated as similarly as possible
- Participants see the study from the point of view of the individual (i.e., themselves and their needs)
  - High expectations of benefits
  - Either overlook what they hear about design features or internalize into their personal frame

Goals

1. To see if educating participants about the researcher's framework would reduce TM and improve informed consent
2. To implement the TM tool in a hypothetical clinical trial without reducing enrollment rates

Methods

- Two groups of subjects in MOCK clinical trials
  - Control group views a narrated power point presentation similar to a regular informed consent discussion and consent form
  - Experimental group views same presentation but preceded by a short presentation about the purpose, nature, and design of clinical trials
- All subjects view a mock trial consent form that is consistent with their medical condition including the following conditions:
  - Cardiac stent
  - Breast cancer
  - Head and neck cancer
  - Depression
  - Diabetes
  - Hypertension
- After the presentation each individual completes a survey which includes background information, a TM scale, and decision whether they would participate in such a trial
- Recruitment is primarily based at UMass Clinics

Experimental Condition Sample Slides

What are Clinical Trials?

- Clinical trials are scientific tests of new, possibly helpful treatments.
- They are meant to answer the question – does a new experimental treatment work better than the treatment that is already available?
- Clinical trials are not primarily meant to benefit the people who participate.

Clinical Trials Differ from Usual Medical Treatment

- In order for researchers to get good information from clinical trials, there are some differences, compared to the way treatment is ordinarily delivered.
- Without these differences in clinical trials, we would know a lot less about which treatments work and which do not.

Using a Protocol Keeps the Treatments within Each Group Similar

- To make the treatments within each group as similar as possible, the treatments are controlled by a set of rules called a "protocol."
- The rules tell the doctors what the dose should be; when they can raise or lower it; and also how long the treatment should go on.

Why Can't Doctors Choose the Treatment?

- If doctors got to choose, trial participants in the control and experimental groups could differ in important ways.
- For example, the doctors might pick the sickest patients or the oldest ones to be in one of the treatment groups.
- That would make it harder to tell which treatment really worked better.

How do these three differences affect people in clinical trials?

- ✓ Random assignment, protocols, and blinding mean that doctors can't individualize treatment.
- ✓ Random assignment means doctors can't prescribe the treatment they think is better.
- ✓ Protocols limit doctors' decisions to change dosages or medications.
- ✓ With blinding, it may make it take longer for doctors to recognize side-effects.
- ✓ But to protect participants, if they aren't doing well, they can always be returned to usual treatment.

Demographic Data

	Cardiology	Oncology-HN & BC	Psychiatry-MDD	Diabetes	Hypertension	Total:
Participated	23	20	23	17	4	87
Experimental	11	11	10	7	2	41
Control	12	9	13	10	2	46
Refused	30	4	4	2	0	38
Ineligible	50	5	65	12	5	137

Do/did you work in the following:		
	Frequency	Percent
Health care	27	31
Higher education	3	3.4
Research	1	1.1
Other	54	62.1
Total	85	97.7

Preliminary Analyses

If you had to make a decision today, would you agree to participate in this Study?

		Decision		Total
		No	Yes	
Condition	Experimental	17 (43.6%)	22 (56.4%)	39 (100%)
	Control	20 (43.5%)	26 (56.5%)	46 (100%)
Total		37 (43.5%)	48 (56.5%)	85 (100%)

There were no significant differences between decision and condition. Phi = .001, p = .992

Does this predict TM?

Condition		N	Mean	Std. Deviation	Std. Error Mean
Sum of TM Items	Experimental	41	36.2439	13.34687	2.08443
	Control	46	31.2826	12.37500	1.82459

An independent t-test was conducted to compare TM total scores and experimental and control conditions. Using a one-tailed t-test, the means are going in the predictive direction (p = .038).

SPARC faculty and staff have been conducting a simulated clinical trial on a new method for reducing TM involving two groups. The control group gets a narrated slide show that mimics an ordinary consent process. The experimental group gets the same slide show but it is preceded by a detailed explanation of the design of clinical trials. Preliminary results show a significant reduction in TM.

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