

## 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

- Individualized treatment decisions
- Physician selects treatment for patient benefit
- Other treatments provided if thought likely to be helpful
- Dosage adjusted for maximum benefit

#### Clinical Trials

- Randomized assignment to intervention
- Physician blinded to the treatment being provided
- Restrictions on other treatments
- 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.



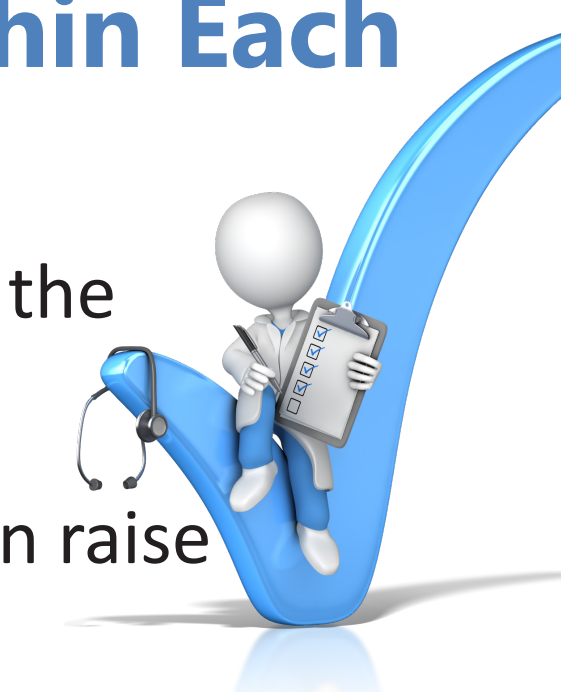
### Clinical Trials Differ from Usual Medical Treatment

- 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?				
Condition		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.