



Conducting Focus Groups

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Therapeutic Misconception for RCTs

- Incorrect belief that individualized treatment needs will be taken into account in assignment to conditions
- Conflation of medical research with medical treatment
- Research on TM conducted with MC populations for RCTs cancer and other medical diseases



Alternative Explanations for TM

- Consent comprehension
- Over or under estimation of medical benefits from research
- Therapeutic optimism



Specific Aims

- *Do traditional explanations for TM adequately characterize drug users understanding of RCTs for addiction?*



100 Participants: 11 Focus Groups

Demographics

- 68% Male
- 76% Heterosexual
- 22 - 70 years, M = 43
- 39% HIV+
- 61% unemployed
- 46% lived at a shelter, community housing, boarding home or with a family member
- 79% \leq high school education
- 75% previous research experience

Ethnicity

- African American (33%)
- Hispanic (37%; majority Puerto Rican)
- non-Hispanic White (22%)
- Other Latino or mixed Hispanic Caribbean/West Indian (8%)

Commonly used drugs

- powder cocaine (45%)
- heroin (44%)
- crack (32%)
- marijuana (29%)
- illicit methadone (18%)
- speedball (heroin + cocaine) (13%)



GFE Focus Group Procedures

- Ensure that participants are familiar with the research methods and context for which their opinions are sought
- Avoid procedures that discourage non-contemplative responses
- Encourage an “opinions in progress” deliberation of the ethical issues (Fisher & Wallace, 2000)
- Video Vignettes + Focus Groups



- Community Advisory Board helped develop scripts
- Introduction
- Video
- Focus Group Questions
- Coding



Do SDU Understand Treatment Uncertainty?

- **Comprehension:** *“There aren’t any guarantees. You don’t know if it’s gonna work or not. It’s just a chance you’re taking.”*
- **Therapeutic Optimism:** *“I would take the chance, too. If I wanted to really get off of this mess, this other drug, I would take it.”*
- **Experimental Mistrust:** *“It’s like she’s [the investigator] more interested in if their study gonna work. That’s what we need you for. We need you to be a guinea pig, to take this stuff and see if it works for you.”*



Perception of Risk

- Experimental Mistrust and History of Health Care Neglect
 - *“Don’t you think that every time you go in the doctor’s office they are experimenting on you?”*
 - *“AZT aspect I didn’t know, I mean, all I kept seeing was my friends dying, and they were guinea pigs in a certain sense too.”*



Risk: TM + Mistrust

- **“She should have been better prepared”**
 - *Doctors know everything and always have an answer for the questions, the investigator must really know, or should know, whether the treatment will be effective.*
- **“This woman is not saying everything to me”**
 - *“Because someone comes looking for help and if what they hear is that she [investigator] was neither sure about the information she was giving him nor the reason was for saying it, that person will not believe her.”*



Therapeutic Mis-estimation

- *“Any medication that's up for research, that ain't gonna work and it may just kill you.”*
- *“At least with my cocaine I know what the effects are. Why would I take a chance at hurting myself? Three times she [the investigator from the video] said there could be long term effects. Why would you do that when I can just do my coke and I don't have to worry about the long term effects.”*



Random Assignment to Placebo: Experimental Realism

- *“She is professional enough to explain to him that over and over... This is a trial. You may not end up with the medicine.”*
- *“But if you sign up for it and you know it can be a placebo or not, and if you’re willing to take that and accept that then it’s all good.”*



Random Assignment : Experimental Mistrust

“She reeled him in”

- Who's to say that everybody ain't getting it? They give everybody the placebo for the first eight weeks just to see if they'll come back.
- ...come on, what you gonna give me, a sugar pill? And I won't know if I'm taking the real medicine? But most likely she'll be giving him the real med, to see his reaction within eight weeks.



Risks of Placebo: Experimental Realism

- *“When people find out they’ve taken the placebo, it makes them regret, after -- ‘Oh my God, I’ve been taking the placebo, and it worked’. Well, no it didn’t.*
- *“Because you will not know if he quit because he had will power or because of the placebo. You will never know if the medicine actually works or not.”*



TM + Placebo + Addiction Beliefs

“Mental Will”

- They are doing an experiment to find out about what kind of attitude people have in the program; if it works psychologically with the placebo or if it works with the real medicine.
- What I see is that this is a way of knowing if the person had a psychological will, a mental response or if he had a true reaction.



Implications for Goodness of Fit Ethics

- A “reasoned” RCT participation decision is linked to histories of health disparities & research exploitation.
- Experimental Realism (understanding) is not the same as believing in the honesty of the information provided (Experimental Mistrust).
- Therapeutic misconception & mis-estimation are linked to experimental distrust & addiction beliefs.



Conclusions TM Through the Community Lens

- Participants are experts on their own lived realities and interpretations of research risks and benefits.
- Investigators and participants have mutual investment in valid and ethical drug addiction research.
- They may have different perspectives on the value, validity, risks and potential benefits of research.
- The responsible conduct of research must be informed by these different perspectives.



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Questions/further discussion

