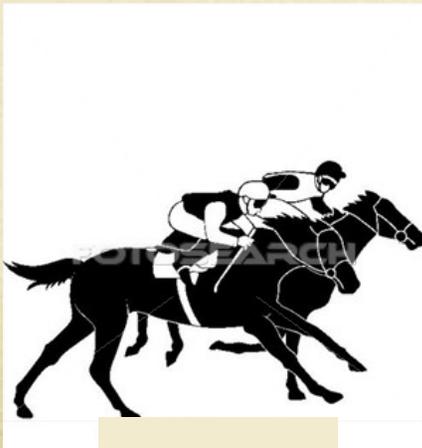


# *Beyond Primary Outcomes in Effectiveness Research:*

*A Platform–Study Update and Some Reflections  
on Directions for the CTN*

Varda Shoham & Michael J. Rohrbaugh  
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CTN 10<sup>th</sup> Anniversary  
*Albuquerque NM, April 2010*



## Part 1. A Platform Study Update

### *Elusive Effects of Brief Strategic Family Therapy (BSFT) for Adolescent Drug Abuse:*

*Results from the CTN-014 Mediator-Moderator Platform Study  
(R01-DA017539; NIDA's Behavioral & Integrative Treatment Branch)*

Varda Shoham & Michael J. Rohrbaugh  
*University of Arizona*

CTN Steering Committee Meeting  
*Bethesda, October 2009*



Part 2.  
Reflections on Directions for the CTN

*...in the spirit of JSAT's (2010) special issue  
commemorating CTN's 10<sup>th</sup> anniversary...*

## *Acknowledgements*

- CA–AZ node PIs and staff: Jim Sorensen, Joe Guydish, et al.
- U. Miami (Florida node) co–investigators and collaborators: Jose Szapocznik, Michael Robbins, Daniel Feaster, Viviana Horigian
- NIDA: CCTN and the Behavioral & Integrative Treatment Branch
- University of Arizona and University of Miami research staff
- Protocol PIs, therapists, and research assistants at participating sites and CTPs:
  - La Frontera (Tucson, CA–AZ node)
  - Crossroads (Cincinnati, Ohio Valley node)
  - The Village (Miami, Florida node)
  - Gateway (Jacksonville, Florida node)
  - Bayamon (Puerto Rico, Florida node)
  - Daymark (Salisbury, North Carolina node)
  - Arapaho House (Denver, Rocky Mountain node)
  - Tarzana (Los Angeles, Pacific node).

# 1. Platform study update

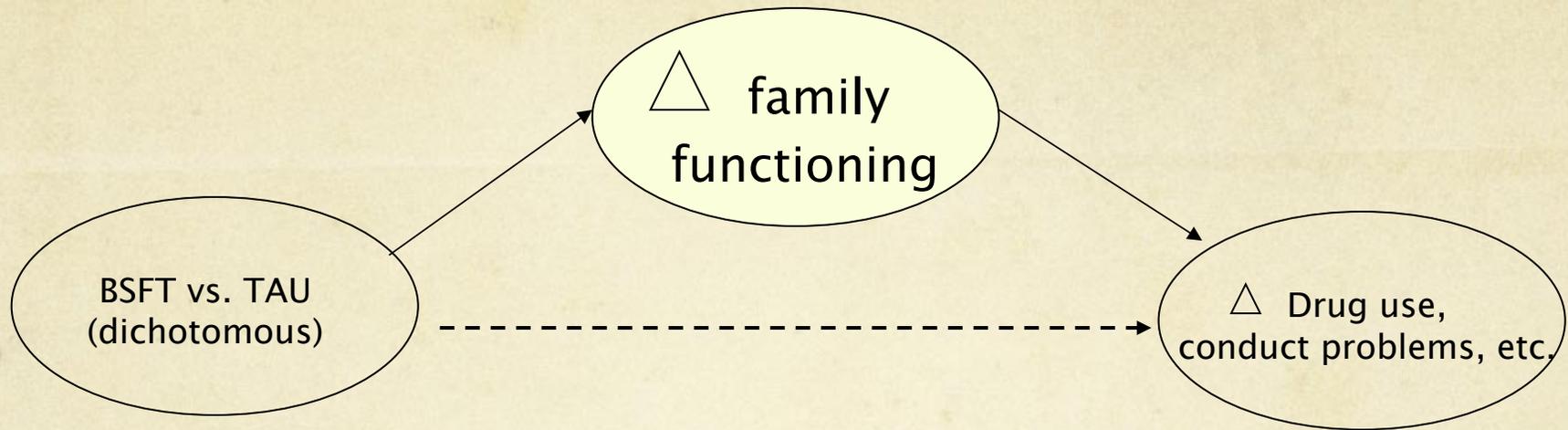
## *Background*

- Previous research on BSFT and other promising treatments for adolescent drug abuse has focused mainly on outcomes, with little attention to *how* a treatment works (mediator questions) or *for whom* it may be especially beneficial (moderator questions).
- Using the CTN-0014 protocol as a platform, we aimed to test hypotheses about mediators and moderators (M&Ms) of BSFT, a relatively pure form of family therapy based on structural family systems theory.

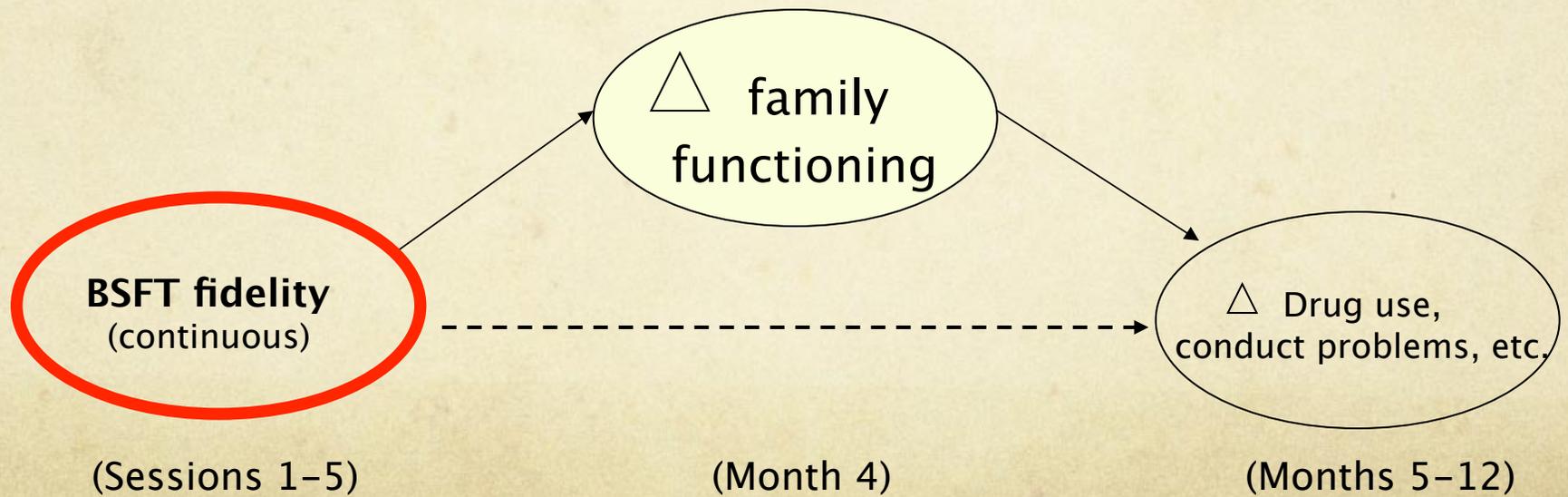
## *Original hypotheses*

- Change on structural dimensions of family functioning during therapy should *mediate* effects of treatment (and BSFT fidelity) on subsequent drug use outcomes.
- Family functioning at baseline should *moderate* these treatment effects, with BSFT proving most useful when family functioning is poor.
- More specifically, assuming a main effect of treatment, we aimed to test for...

Between-treatment mediation



Within-treatment mediation



*Additional aim...*

Identify therapist characteristics and training processes (e.g., acquisition of 'systemic' conceptual skills) that predict effective implementation of BSFT in community treatment programs.

## *Participants*

- 480 adolescents substance users and their families, randomly assigned to receive BSFT ( $n=245$ ) or TAU ( $n=235$ ) at 8 CTPs
  - 79% male
  - 44% Hispanic, 31% White, 23% African American, 2% other
  - 25% from intact family (2 bio parents in household)
  - 78% arrested previously, 44% more than once
  - 59% positive urine at baseline
  
- 70 community therapists randomized to BSFT or TAU
  - Mean age = 40 (range 21–59)
  - 75% female
  - 53% White, 23% Afr Am, 19% Hispanic, 5% other
  - 22% bachelors or specialist degree, 68% masters, 10% doctorate
  - Median years clinical experience = 13 (range 1–30)
  - Of 30 therapists assigned to BSFT, 23 completed training and 20 participated in the trial

## *Outcome measures*

### *A. Primary (substance use) outcomes, assessed monthly but aggregated in 4-month intervals for analysis:*

1. % drug use days, based on TLFB self-report\*
2. Any positive urine, given at least one valid test
3. Type or level of use, based on TLFB *or* urine test\*\*  
(0=no use, 1=alcohol or tobacco use only, 2=marijuana use, and 3= 'hard' use)
4. Substance use composite (combines 1, 2 and 3)\*\*

### *B. Secondary outcomes, assessed at 4-month intervals:*

1. Reported family functioning (composite of parent, adolescent FES and PPQ)
2. Externalizing behavior (composite of adolescent YSR, DISC, NYS, DAP)
3. Any adolescent adverse event involving youth problem behavior\*\*  
(arrest, runaway, school problem, etc)

\* A priori primary outcome

\*\* Outcome added for platform study

## *Additional platform study measures*

- Observational ratings of family functioning (FIATs) at baseline and 4 months later
  - Specific structural family systems dimensions (e.g., enmeshment, role reversal)
  - Global family functioning (GARF)
- Observational ratings of BSFT treatment fidelity
  - Session- and case-level fidelity ratings by independent panel
  - Qualitative analysis of core dynamics and fidelity failures
- Assessment of BSFT therapists' conceptual skills before, during, and after 3+ months of training
  - Case Formulation Exercises (Ramon, Katie & Charles)
  - Views of Adolescent Drug Abuse Q-sort (conceptual affinity with BSFT model)

*More on BSFT fidelity (the 'independent' variable)*

- For each eligible TFS case, an Arizona panel reviewed at least 2 session videos and all case notes for sessions before the 4-month assessment.
- Eligible TFS cases had sufficient data to test mediation hypotheses.
- In addition to session-level fidelity, the TFS panel made case-level consensus ratings (on 1-5 scales) of formulation quality, intervention quality, off-model behavior, and over-all fidelity to the BSFT model.
- The panel also did a qualitative analysis of fidelity failures across the TFS cases.

## *Results of the parent study*

- No significant main effects of treatment (BSFT v. TAU) on substance use outcomes in primary analyses
- Possible moderation of treatment effects by race/ethnicity, with better abstinence outcomes for minority (Hispanic and African American) participants.
- Main effects of treatment on engagement ( $\geq 2$  sessions) and retention ( $\geq 8$  sessions)
- Main effect of treatment on reported family functioning at 12 months

*What did the platform study add?*

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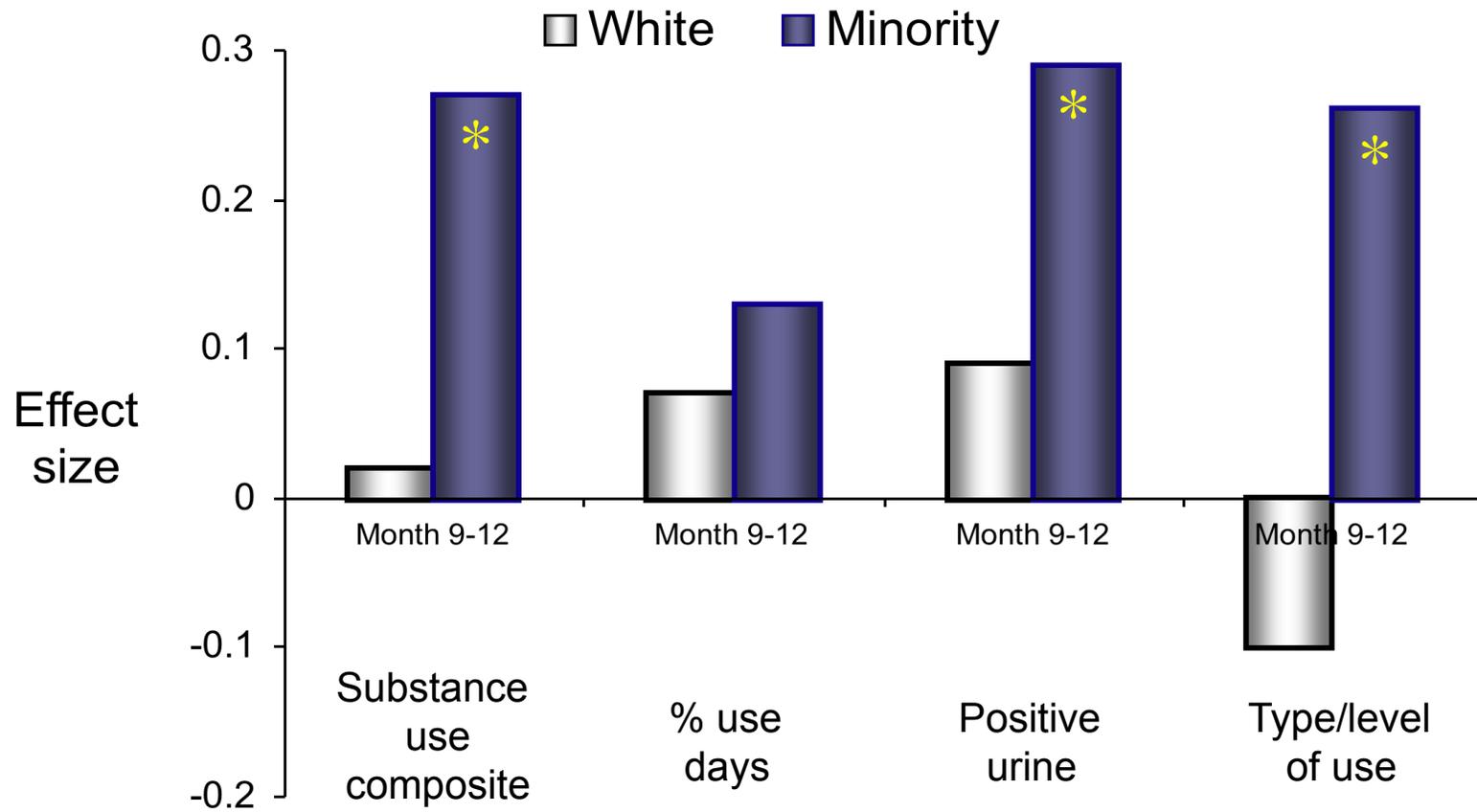
*Some good news!?*



*Within-treatment associations between BSFT fidelity and outcome:*

Case-level fidelity correlated positively and significantly with most outcomes at most follow-up intervals, with minority participants accounting for most of these associations.

*Effect Sizes for Associations Between BSFT Fidelity and Reduced Substance Use by Ethnicity (months 9-12)*



\*  $p < .05$

## *Treatment fidelity and family change*

- Associations between BSFT fidelity and observed family change also varied by ethnicity, with significant correlations appearing on specific culturally-relevant dimensions for minority families but not whites.

*e.g., High-fidelity BSFT reduced observed enmeshment for Hispanics, but reduced disengagement, role reversal, and identified-patienthood for African Americans.*

*Some not so good news:*

*Some not so good news:*

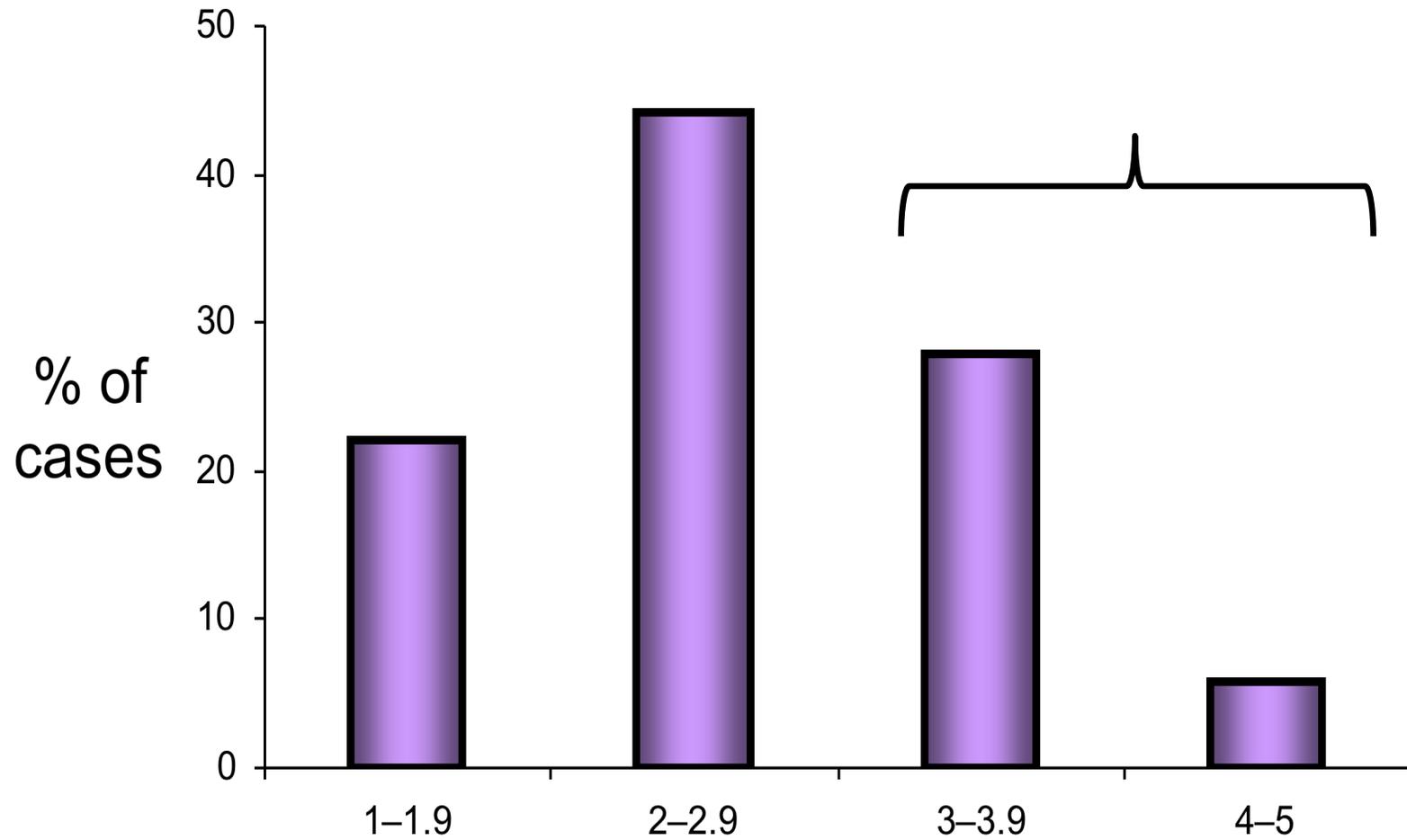
We didn't see much good BSFT



## *Treatment fidelity results:*

- The modal quality of BSFT was less than ideal: Only a third of the TFS cases received what the expert panel considered “adequate” BSFT (fidelity  $\geq 3$  on a 1–5 scale).
- Therapist (n = 20) was a strong and significant source of variation in BSFT fidelity.
- Fidelity appeared *responsive* to adolescent (but not family) characteristics, with multiple prior arrests, high substance abuse, and high externalizing scores at baseline predicting poorer BSFT and more off-model therapist behavior.

*Case-Level Ratings of BSFT Fidelity*  
(n = 104)



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## *Fidelity results (updated)*

- Hispanic families received better BSFT (higher fidelity scores) than White and African American families.
- Hispanic families received *poorer* BSFT from Hispanic therapists than from White therapists.
- A strong therapeutic alliance in session 1, especially with the adolescent IP, was associated with *poorer* BSFT later in therapy (Friedlander et al.).
- Adolescents entrenched in parent–demand/ adolescent–withdraw interaction before therapy began had poorer substance–use outcomes when they also withdrew from a demanding BSFT therapist (Rynes et al., 2010).

## *Patterns of BSFT Fidelity Failure*

	<b>% of cases</b>
1. Failure to engage key family members	72
2. Failure to think in threes	67
3. Failure of restructuring, given adequate structural objectives	57
4. Failure of joining (e.g., split alliance)	46
5. Therapist centrality prevents eliciting and working with core dynamics	36
6. Didactic, instructive intervention	36
7. Off-model (non-systemic) formulation or intervention	36
8. Over focus on IP	34

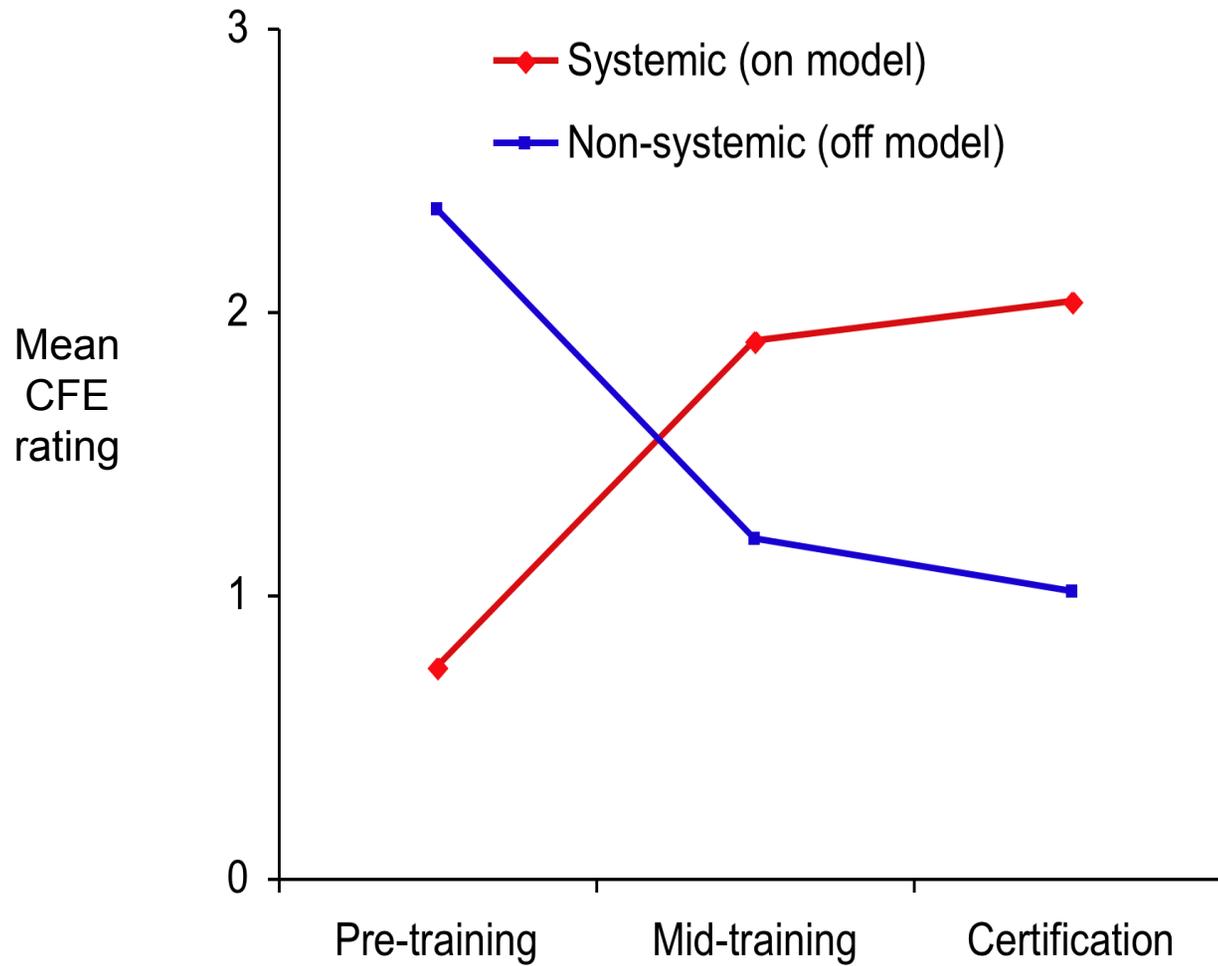
Some interesting (?) news regarding therapist development...



## *Therapist development results:*

- BSFT therapists acquired measureable systemic conceptual skills during training, as reflected in their responses to Case Formulation Exercises
- Conceptual skill acquisition during training correlated with a parallel increase in behavioral adherence and with prior (pre-training) conceptual affinity with the BSFT model (VADA Q-sort).
- Acquisition of systemic case-formulation skills during training predicted a therapist's case outcomes during the trial *and* his or her behavioral fidelity to the BSFT model.
- *Proscribed* case formulation (especially *non*-systemic thinking about the problem) was the strongest predictor of BSFT fidelity and case outcomes.
- Other predictors of fidelity and/or outcome were a therapist's age (-), degree (-), recovery status (+), and training dose (+).

*Systemic and non-systemic case formulation skill  
before, during, an after BSFT training\**



\*Certified therapists only

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## *Whither treatment fidelity?*

- Fidelity is at the heart of good psychosocial intervention trials, good treatment effectiveness research, and replicable dissemination.
- Establishing and maintaining high fidelity was very difficult in the BSFT trial.
- How to understand this? Should we look toward the traits or skills of BSFT therapists or toward the immediate social/organizational context in which implementation occurs?
- Probably both...

*Meanwhile...*

Data analyses in collaboration with the Miami team continue, and we look forward to preparing reports on observational analyses of treatment fidelity, family functioning, and other aspects of this complex clinical trial.

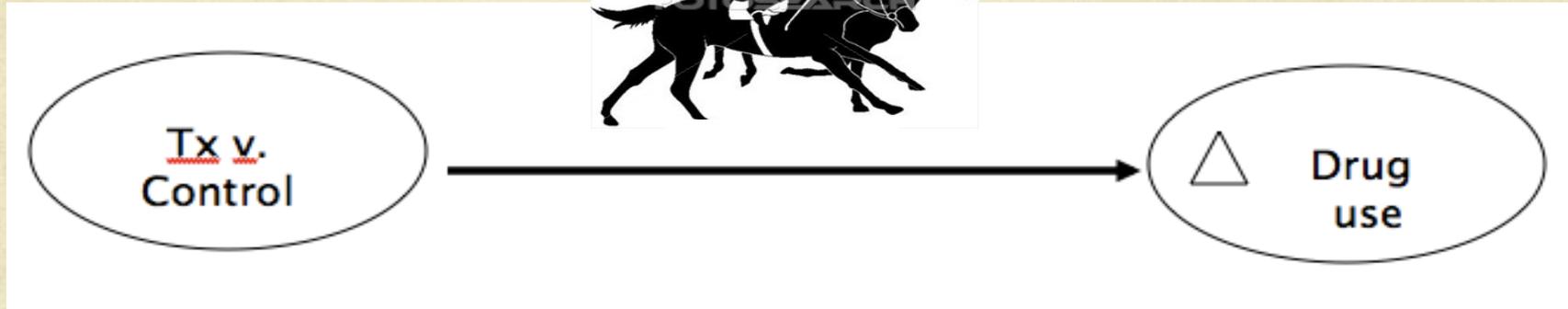
Part 2.  
Reflections on Directions for the CTN

*...in the spirit of JSAT's (2010) special issue  
commemorating CTN's 10<sup>th</sup> anniversary...*

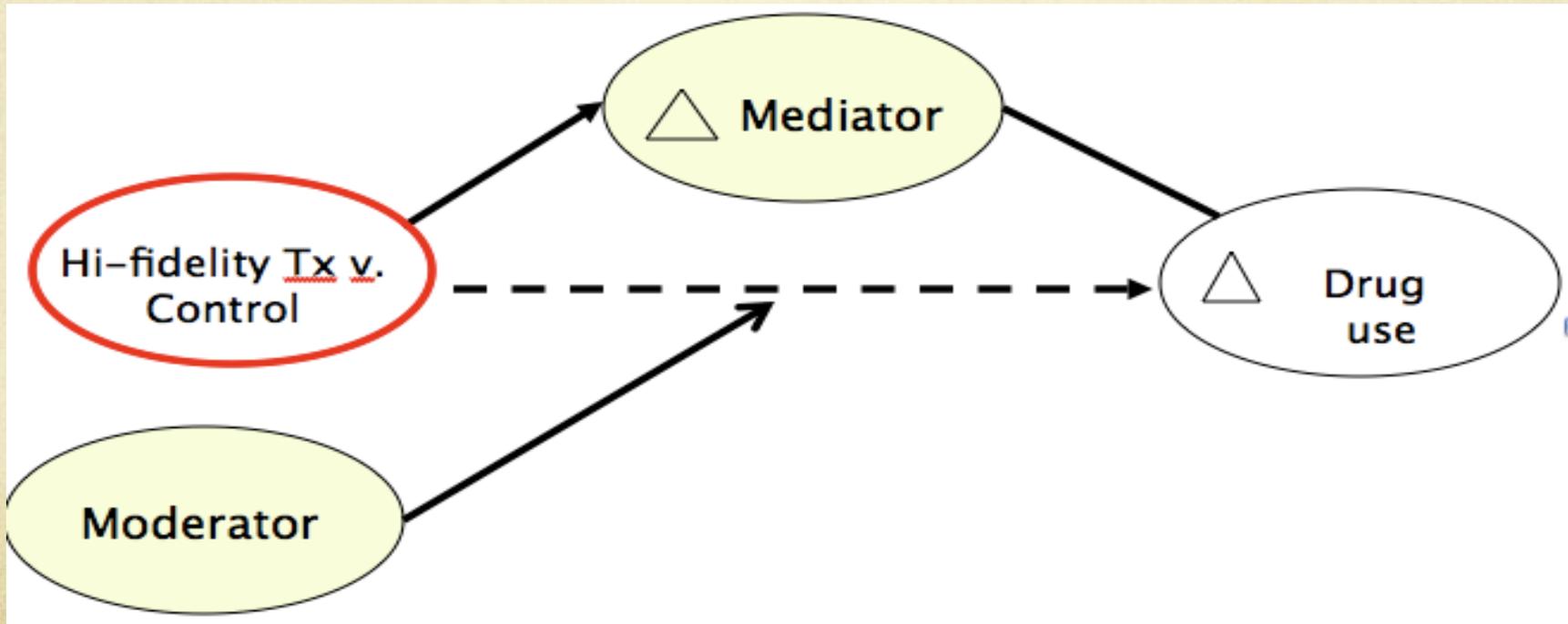
## *Recommendations for the CTN*

1. Elevate the study of mechanisms.
2. Focus on moderators at both case and organization levels.
3. Study therapist development to maximize fidelity of independent variables.
4. Have “...centrally organized but independently conducted trials” across sites  
(McLellan, 2010).

Replace:



With:



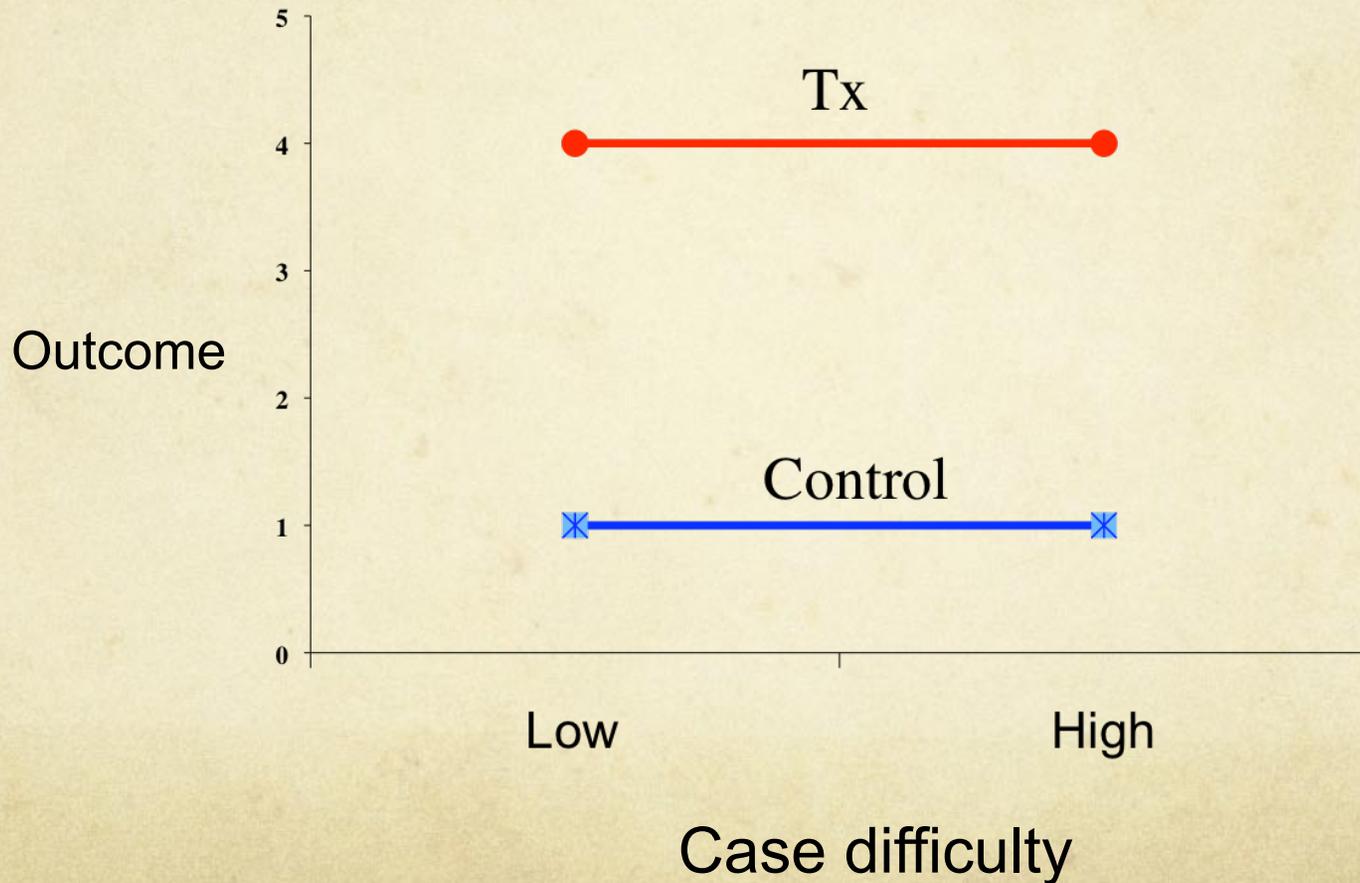
## 1. *Elevate the study of mechanisms*

- We know little about *how* treatments works.
- Identifying mechanisms can help to economize treatments by enhancing their effective elements and discarding redundant ones.
- We can then transport treatments that are conceptually-coherent, experimentally-supported, cost-effective, and scientifically plausible.

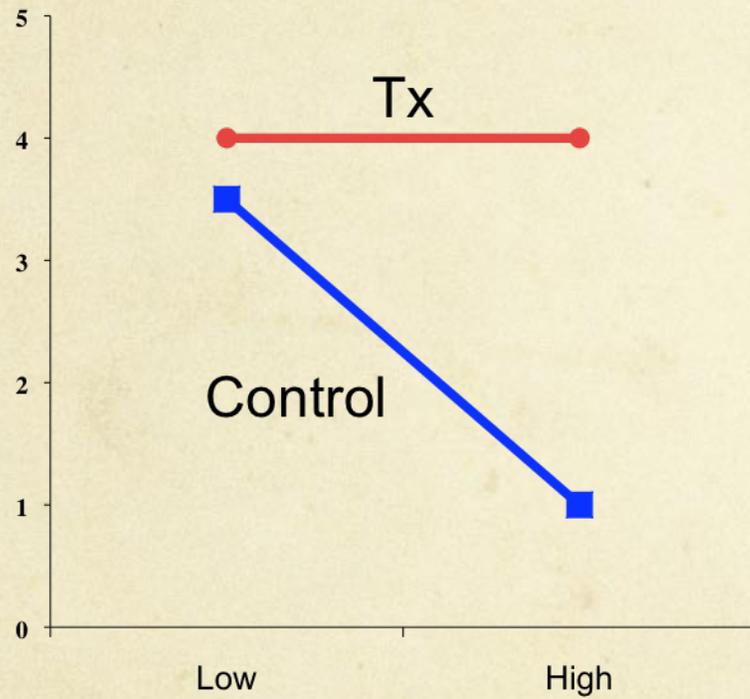
## 2. *Examine moderators at both case and organization levels*

- At the case level, average outcome equivalence can mask treatment effects for sub-groups.
- Markers of case difficulty (e.g., problem severity) may be important moderators of treatment effects.
- At the organizational level, site differences may reflect useful moderators as well. (*More on this later...*)

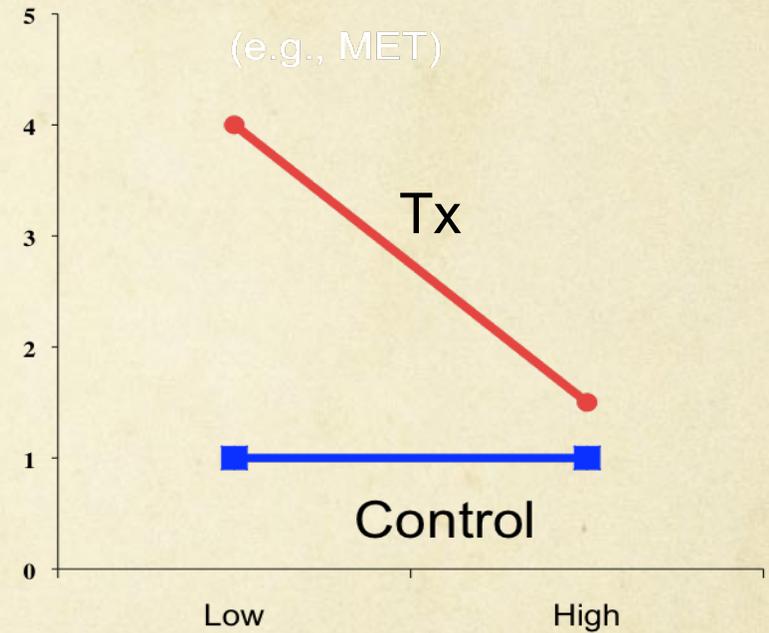
*Scenario 1:  
Treatment works (with equivalent effect size)  
regardless of case difficulty*



*Scenario 2:  
Treatment necessary  
for difficult cases*



*Scenario 3:  
Treatment sufficient  
for easy cases*



Case difficulty

## *Fundamental questions:*

- When is a more intensive or expensive treatment necessary?
- When is a briefer, less intensive treatment sufficient?
- How does the effect size of a particular treatment vary with case difficulty?

## 2. *Examine moderators at both case and organization levels*

- At the case level, average outcome equivalence can mask treatment effects for sub-groups.
- Markers of case difficulty (e.g., problem severity) may be important moderators of treatment effects.
- At the organizational level, site differences may reflect useful moderators as well. (*More on this later...*)

### *3. Study therapist development to maximize fidelity of the independent variable*

- Psychosocial treatments are not like pills.
- Treatment fidelity is at the heart of good psychosocial intervention trials and replicable dissemination.
- Establishing and maintaining high fidelity has been the Achilles heel of many large-scale trials.
- Fidelity requires direct observation and continuous feedback; didactic training is not enough (Carroll, Martino, & Rounsaville, 2010; Miller et al., 2004).

*Research on therapist development can parallel good intervention research*

<i>Intervention Research</i>	<i>Therapist development research</i>
Client characteristics related to outcome	Therapist characteristics related to effectiveness
Mechanisms of clinical change	Processes of therapist skill acquisition (conceptual and behavioral)
Durability of clinical outcomes	Sustainability of therapist adherence and competence

4. Have “...centrally organized but independently conducted trials” across 4-6 sites (McLellan, 2010)

*How?*

- Central leadership specifies a few (but not too many) delimiting elements of a promising protocol (e.g., type of drug problem, length of therapy, measures) and a total budget.
- Nodes propose designs suitably powered for a single-site study, then collect and analyze the data.

## *Why?*

- Will produce more results, more rapidly
- Provides a better template for behavioral trials than the multisite, centrally managed, common-protocol approach of medication trials
- Permits systematic examination of naturally-occurring site effects that can't and shouldn't be controlled away
- Gives CTN studies more weight in meta-analytic reviews
- Increases opportunities for young investigators

*Having “...centrally organized but independently conducted trials” will also...*

- encourage the best study possible at each site, capitalizing on local resources and expertise.
- permits investigation of mechanisms and moderators (and even therapist development) as secondary aims.
- give ‘agency’ to agencies, hence facilitate adoption (“We built it, let’s keep it”).
- encourage hypothesis generation about organizational/contextual factors related to successful implementation and adoption (e.g., site factors as moderators in meta-analytic reviews).