

# *Balancing Clinical Flexibility while Preserving Efficacy in Delivering EBPs for PTSD*

Tara E. Galovski, PhD

Tara E. Galovski, PhD  
Director, Women's Health Sciences Division  
National Center for PTSD  
VA Boston Healthcare System



National Center for  
**PTSD**  
POSTTRAUMATIC STRESS DISORDER

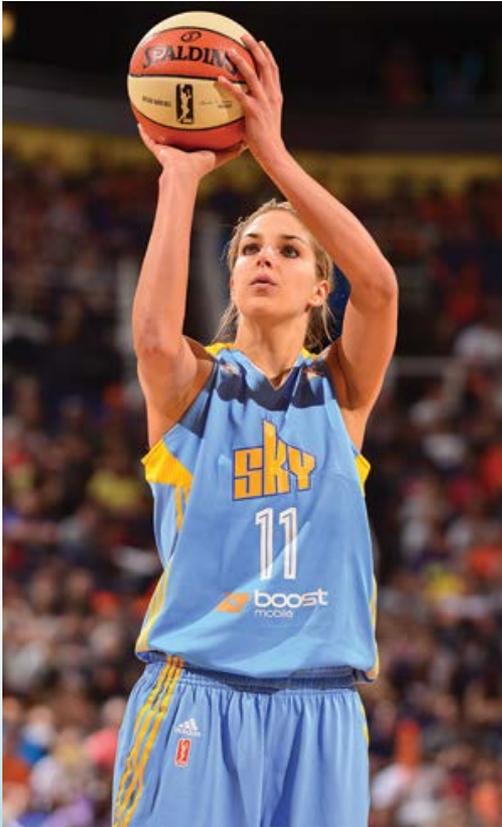
# Acknowledgements

- CPT team
  - Deb Kaysen, PhD
  - Reg Nixon, PhD
- Shannon Kehle-Forbes, PhD
- All the PTSD patients who contributed so much to these clinical trials
- Funding sources: NIH, SAMHSA, STL Mental Health Fund

# Goals of this Webinar

- Provide historical overview of the natural tension between efficacy and effectiveness in the development of treatment protocols
- Touch on ways this tension translates into delivery of EBPs in clinical care
- Provide examples of recent studies that have tested modifications to protocols
- Describe parameters around manual flexibility in current practice

# A Certain Amount of Precision is Critical for Success



# Field of Psychology: Less Precise

Vast number of theoretical orientations and schools of thought

Goldfried, 1980: over 100 different approaches to psychotherapy

Causes difficulties in arriving at consensus & presents a challenge in moving forward as a science.

Difficulty categorizing schools of thought:  
Meta-analytic study by Smith and Glass (1977)

Result: Dodo bird verdict

# From a practical standpoint: Who cares?

- The historical divisions between the schools of thought results in a lack of integration of the field of psychology.<sup>1</sup>
- The lack of integration has had direct implications for the perceived effectiveness of psychological interventions.<sup>1,2,3</sup>
- 1990s: Substantial effort to close the scientist-practitioner gap due to a host of economic and political forces<sup>4,5,6</sup>
- The pressure to “empirically validate” psychological interventions grew substantially<sup>5,6,7</sup>
- The schisms between schools of psychology grew more apparent

<sup>1</sup>Messer and Winokur, 1980; <sup>2</sup>Messer, 1986; <sup>3</sup>Lazarus, 1977;

<sup>4</sup>Goldfried & Wolfe, 1996; <sup>5</sup>Hayes & Follette, 1996; <sup>6</sup>Goldfried & Wolfe, 1998;

<sup>7</sup>Butler et al., 2006

# The Debate:

## How Evidence-based are EBPs?

- Some therapies lend themselves to empirical investigation (RCTs) more so than others.
- **Argument**: Therapy conducted in an RCT is not consistent with therapy conducted in real world practice.
  - Most treatment protocols are diagnosis specific
  - Most do not take into account fundamental error in basic measurement/ assessment
  - Outcomes cannot possibly reflect meaningful change in the vastness of the human experience.
- **Concern**: Generalizability of the results are limited at best and the claim of “evidence-based” is premature. (reviewed in Butler et al., 2006)

# Increasing generalizability ...

Efficacy	Move toward Effectiveness
Random assignment	Construct effectiveness question/condition and compare to a more tightly controlled condition
Control for nonspecific factors	e.g. Patients choose therapist
Operationalized target outcomes	Treatment success defined more broadly
Fixed number of sessions	Therapy length determined by patient progress
Homogenous sample	Increase heterogeneity (comorbidity, patient populations, etc.)
Strict adherence to manualized treatment	Modifiable depending on variation in client's life circumstances and response to intervention

# Evidence-based Practices in PTSD

Accumulation of empirical support for manual-based therapies over the last 3 decades



Evidence-based practices and clinical practice guidelines designed to promote and ensure optimal care.



**BUT**, rates of nonresponse to treatments for PTSD and attrition from trauma-focused therapy remain high



Clearly there is room for improvement.



**Where does flexibility fit in the administration of standardized protocols?**

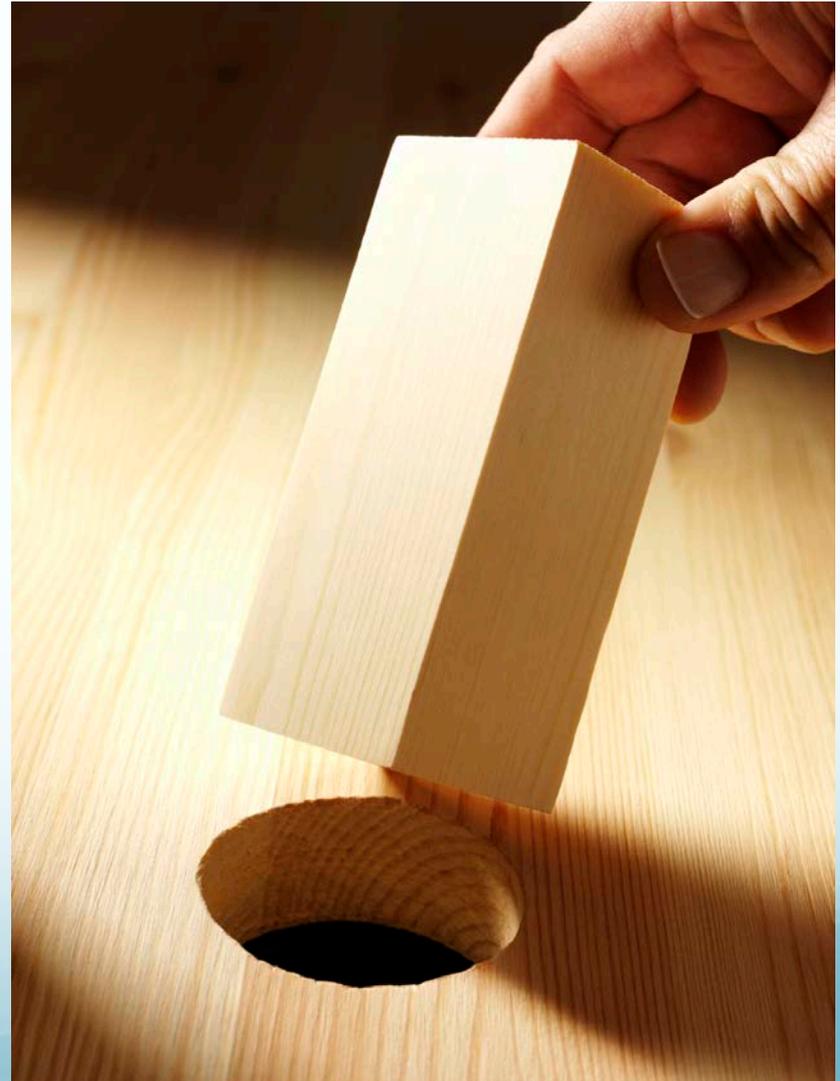
# Consider the clinically complex Veteran population...

- 87% of VHA-engaged Veterans with PTSD have at least 1 comorbid psychiatric disorder<sup>1</sup>
- Over 50% report suicidal ideation<sup>1</sup>
- The nature of war-related traumas, such as traumatic losses and moral injury, may contribute to clinical complexity<sup>2,3</sup>
- Veterans have high rates of homelessness, unemployment<sup>4</sup>
- Veterans also have compromised physical health conditions, often related to service.<sup>5</sup>
- These types of clinical complexities present challenges to the clinician trying to administer protocol-driven treatment for PTSD.
- Complexities may also contribute to lower effect sizes as compared to those observed in civilian clinical trials.<sup>6</sup>

<sup>1</sup> Magruder et al., 2005; <sup>2</sup> Litz et al., 2009; <sup>3</sup> Stein et al., 2012; <sup>4</sup> Fargo et al., 2012; <sup>5</sup> Agha et al., 2000; <sup>6</sup> Alvarez, et al., 2011

# Square peg in a round hole

- As clinicians, we are sometimes left feeling torn between adhering to the manual and treating a clinically complex patient.
- Sometimes the fit doesn't seem quite right.



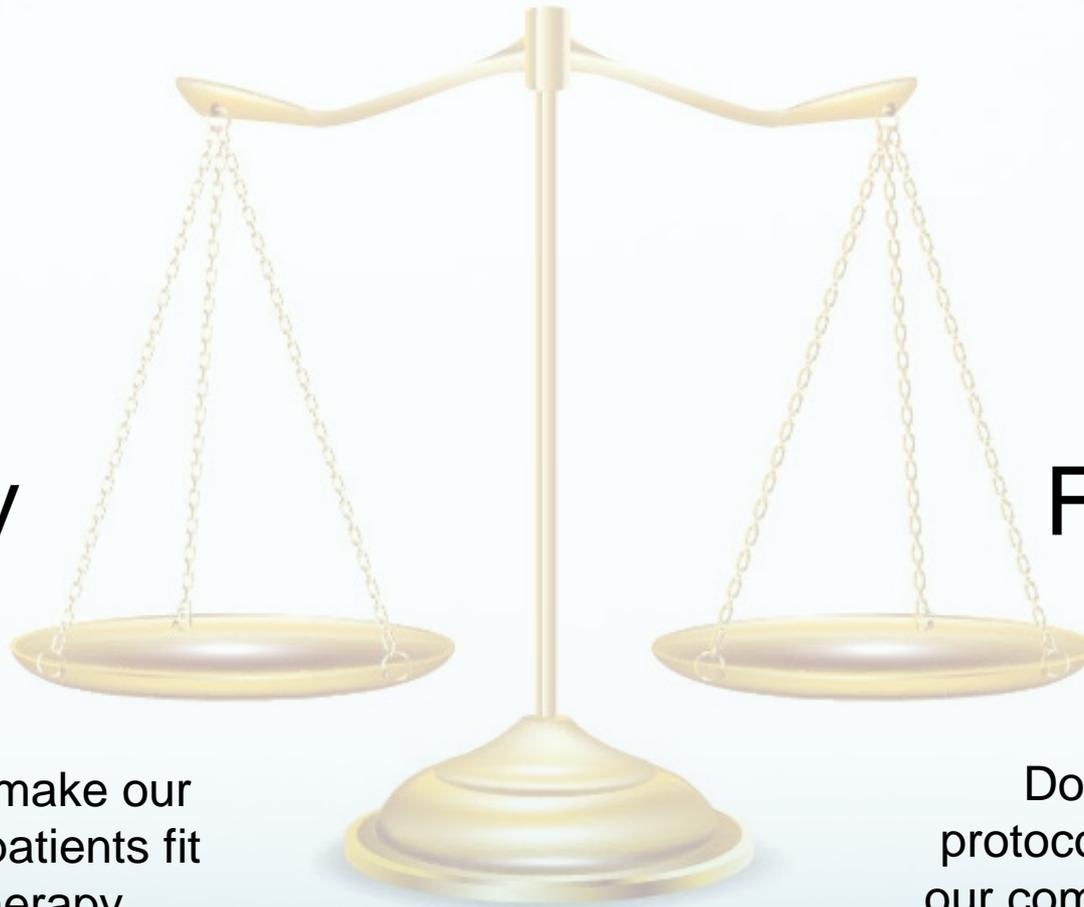
# Delivery of EBPs for PTSD in VA

- Qualitative data gathered from VA clinicians suggests that overly rigid adherence to treatment protocols can lead to premature drop-out.<sup>1</sup>
- Data from one VHA clinic suggested that approximately 50% of therapists are modifying treatment protocols in some way to address clinical complexities.<sup>2</sup>
- However, the patients who received a modified treatment had significantly worse outcomes than standardized therapy.<sup>2</sup>
- The perception of lack of flexibility in the face of clinical complexity results in providers choosing to use EBPs for PTSD with fewer patients.<sup>1</sup>

# How can I make this work?

**Fidelity**

Do we try to make our complicated patients fit into our therapy protocols?

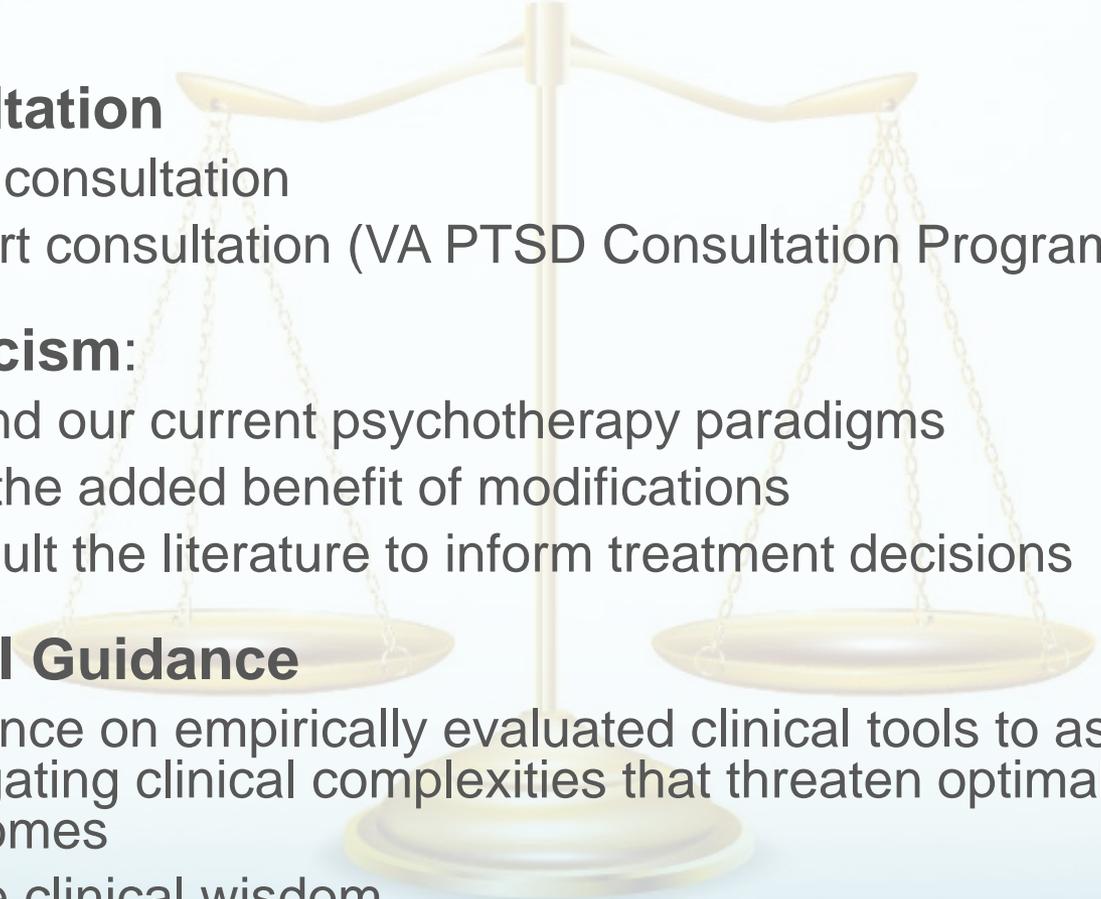


**Flexibility**

Do we make our protocols work better for our complicated patients?

**-OR-**

# Balancing Flexibility with Fidelity



- **Consultation**
  - Peer consultation
  - Expert consultation (VA PTSD Consultation Program)
- **Empiricism:**
  - Extend our current psychotherapy paradigms
  - Test the added benefit of modifications
  - Consult the literature to inform treatment decisions
- **Clinical Guidance**
  - Reliance on empirically evaluated clinical tools to assist in navigating clinical complexities that threaten optimal therapy outcomes
  - Value clinical wisdom

# Consider Cognitive Processing Therapy...

- Named as a first line treatment across clinical practice guidelines<sup>1,2,3,4</sup>
- Primarily a cognitive treatment designed to treat PTSD<sup>5</sup>
- One of the therapies for PTSD with the most empirical support to date<sup>6,7</sup>
- Originally developed at the Center for Trauma Recovery, University of Missouri- St. Louis and tested with female, civilian rape victims
- Began as a 12 session protocol delivered weekly or twice a week
- Can administer in either group or individual format

<sup>1</sup> ISTSS, 2008; <sup>2</sup> NHRMC, 2013; <sup>3</sup> APA, 2017; <sup>4</sup> VA/DoD, 2017;

<sup>5</sup> Resick et al., 2017; <sup>6</sup> Watts et al., 2013; <sup>7</sup> Haagan et al., 2015

# The Development of CPT

Clinical Complexity	Modification of original protocol
Patient crises, ongoing trauma, major psychosocial stressors	Add emergency sessions, use modified worksheets, rely on other creative ways to move therapy into patient's lives
Fixed number of sessions and/or timing and location of sessions	Let patient progress determine the length of therapy. CPT in one week – massed trial CPT via telemental health
Complex trauma history or a non-combat trauma	Efficacy of CPT has been demonstrated in multiple trauma populations (interpersonal violence, MVA, MST, Veteran, active duty, adolescents, CSA)
Cross cultural applications	Translated into 11 different languages Tested internationally: Australia, Germany, Israel, Kurdistan, Congo, etc.
Your study participant doesn't look like my patient! (comorbidity, ambivalence, cognitive functioning, suicidality or self-harm, TBI)	Adjunctive therapies: MCET, sleep-directed hypnosis, BA, MI, TMS Tested the effectiveness of CPT in a host of comorbid conditions: e.g. SMI, TBI, depression, panic, etc.

# PRETREATMENT STUCK POINTS

- My client is not ready for trauma-focused therapy
- My clients are more difficult than those in research studies
- My client is too fragile
- Clients will get worse if we talk about their traumas in any detail
- If I use a manual, the “art” of therapy is lost and it will damage rapport with the client
- CPT won't work with comorbidities (depression, dissociation, substance abuse, personality disorders )

# Patient complexities increase the challenges inherent in clinical care

Two examples of CPT studies with different types of challenges



# The St. Louis Study

- Can we effectively implement CPT in:
  - An urban, outpatient, community mental health clinic?
  - With individuals suffering from SMI? And other comorbidities – active substance dependence?
  - And experiencing a host of additional major psychosocial stressors and complicating factors including homelessness, poverty, illiteracy?
  - And recently diverted from jail?

# SMI and PTSD combined

When compared to SMI alone....



(Resnick, Bond, & Mueser, 2003<sup>7</sup>; Mueser, Essock, Haines, Wolfe, & Xie, 2004; Switzer et al., 1999<sup>8</sup>; Brekke, Prindle, Woo Bae, & Long, 2001<sup>9</sup>; Walsh et al., 2003<sup>10</sup>; Brekke et al., 2001<sup>11</sup>; Chapple et al., 2004<sup>12</sup>; Hiday et al., 1999<sup>13</sup>; Sells, Rowe, Fisk, & Davidson, 2003<sup>14</sup>; Chapple et al., 2004<sup>15</sup>; Dean et al., 2007<sup>16</sup>; Stumbo, Yarborough, Paulson, & Green, 2015<sup>17</sup>; Carballo et al., 2008<sup>18</sup>)

# Challenges to Trauma-focused Therapy in Community Mental Health

- State regulations determine diagnostic eligibility for qualifying as SMI and for reimbursed care<sup>19</sup>
  - PTSD is often not considered an SMI<sup>20</sup>
- Clinicians may be reluctant to provide trauma-focused treatment
  - May exacerbate the patient's psychotic or depressive symptoms<sup>21</sup>
  - Lack of data supporting EBPs for PTSD in SMI populations and in community mental health settings<sup>22,24</sup>
  - Lack of training in evidence-based practices for PTSD<sup>23-24</sup>

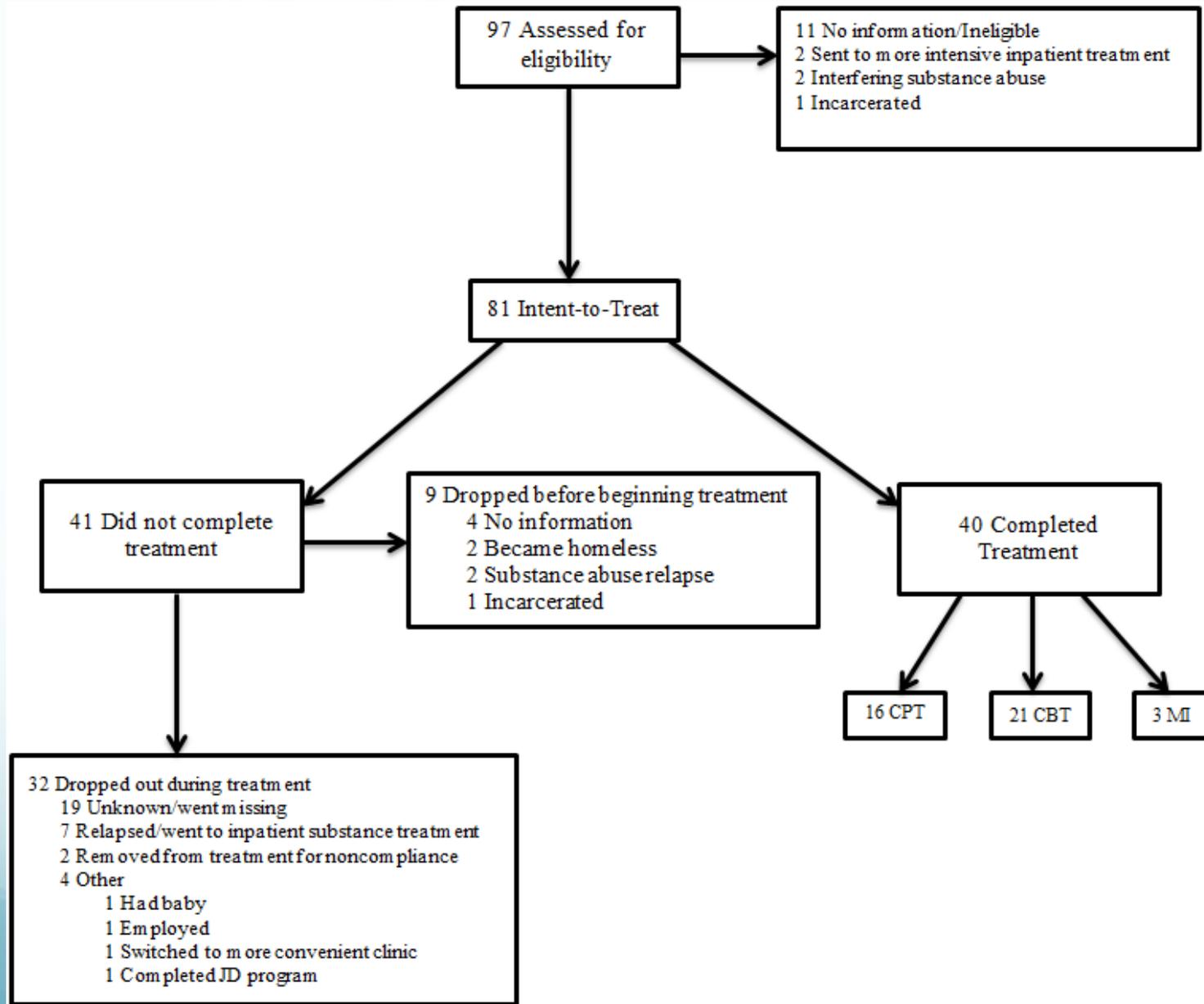
(Peck & Scheffler, 2002<sup>19</sup>;SAMSHA, 2016<sup>20</sup>;van Minnen, Harned, Zoellner, & Mills, 2012<sup>21</sup>;Ronconi, Shiner, & Watts, 2014<sup>22</sup>;Cusack et al., 2004<sup>23</sup>;Imel, Laska, Jakupcak, & Simpson, 2013<sup>24</sup>)

# St. Louis Project

(Feingold, Fox-Galalis, Galovski, 2017)

- Funded by SAMHSA, then St. Louis Mental Health Fund
  - Partnership of DHHS, Community Alternatives, Barnes Jewish Hospital, Parole, Public Safety, and Corrections, St. Louis Drug Courts, 22<sup>nd</sup> Judicial Circuit Adult Felony Court, Municipal Mental Health Court, Center for Trauma Recovery – UMSL
- Chart review of 97 patients referred from St. Louis City Jail Diversion Program from 2011-2014.
- At least one Criterion A event and clinically significant levels of PTSD and/or depressive symptoms.
- PCL-S & BDI-II
- **Treatment Options:** Depending on clinical presentation and patient preference, patient matched with intervention.
  - 35 patients -> CPT; 1 progressed to CPT from MI
  - 26 patients -> CBT; 2 patients transferred from MI
  - 8 patients -> MI and did not switch over to CPT or CBT

# Completion and Attrition



# Psychiatric Diagnoses

- The majority of participants (70%) were diagnosed with two or more Axis I disorders.

## Most Common:

- Major depressive disorder (65%)
- PTSD (62%)
- substance abuse disorders (30%)
- psychotic disorders (schizophrenia or schizoaffective disorder) (27%)
- Bipolar disorder (7%)

# Participant Characteristics

Demographics	Percentage
Sex	<ul style="list-style-type: none"><li>• Male (<b>52%</b>)</li><li>• Female (<b>48%</b>)</li><li>• Transgender (<b>1%</b>)</li></ul>
Age	<ul style="list-style-type: none"><li>• 18-65 years (<b>M = 39.26, SD = 10.98</b>)</li></ul>
Race	<ul style="list-style-type: none"><li>• Black/African-American (<b>74%</b>)</li><li>• White/Caucasian (<b>24%</b>)</li><li>• Other (<b>1%</b>)</li></ul>

Living Situations	Percentage
Cohabitated with a S/O or family member	<b>33%</b>
Independently	<b>21%</b>
Homeless	<b>21%</b>
Therapeutic housing settings	<b>17%</b>
Hotel or with a friend	<b>9%</b>

# Criminal Offenses

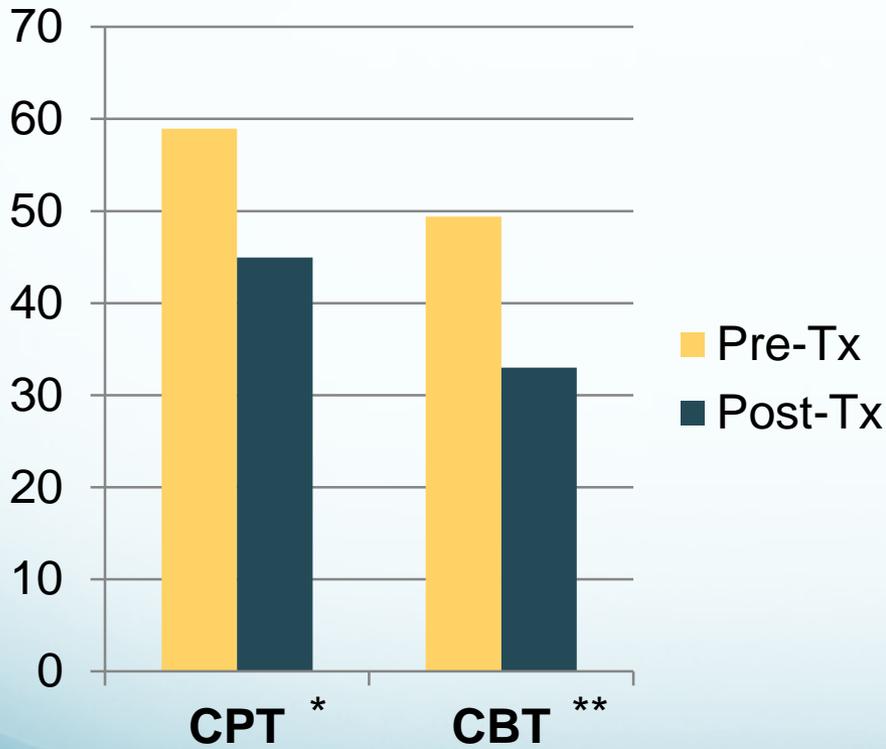
Drug possession (16%)	Resisting arrest (3%)
Assault (16%)	Destruction of property (3%)
Petty theft (15%)	Driving under the influence (3%)
Traffic violations (11%)	Child abuse or neglect (3%)
Disturbing the peace, panhandling, or public intoxication (11%)	Violating a restraining order (1%)
Robbery (9%)	Riding in a stolen vehicle (1%)
Fraud (9%)	Leaving the scene of an accident (1%)
Trespassing (8%)	Unlawful possession of a firearm (1%)
Prostitution (5%)	Arson (1%)
Felony drug charges (3%)	

# Completers vs. Non-Completers

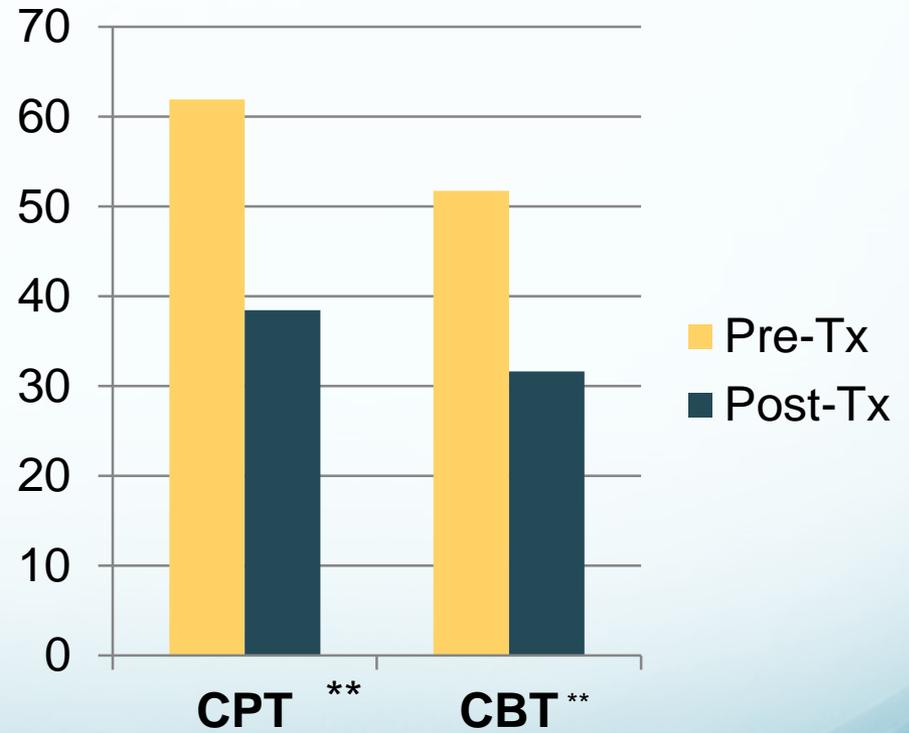
- **Our biggest challenge:** Getting people to treatment!
- 89% of ITT patients engaged in at least 1 session
  - CPT: completed an average of 10 sessions
  - CBT: completed an average of 12 sessions
  - MI: completed an average of 6 sessions
- Race, gender, trauma type, homelessness, prevalence of mental disorders or criminal offenses committed did not differ across groups.
- Groups did not differ on baseline PTSD or depression severity

# Change in PTSD

## ITT



## Completer

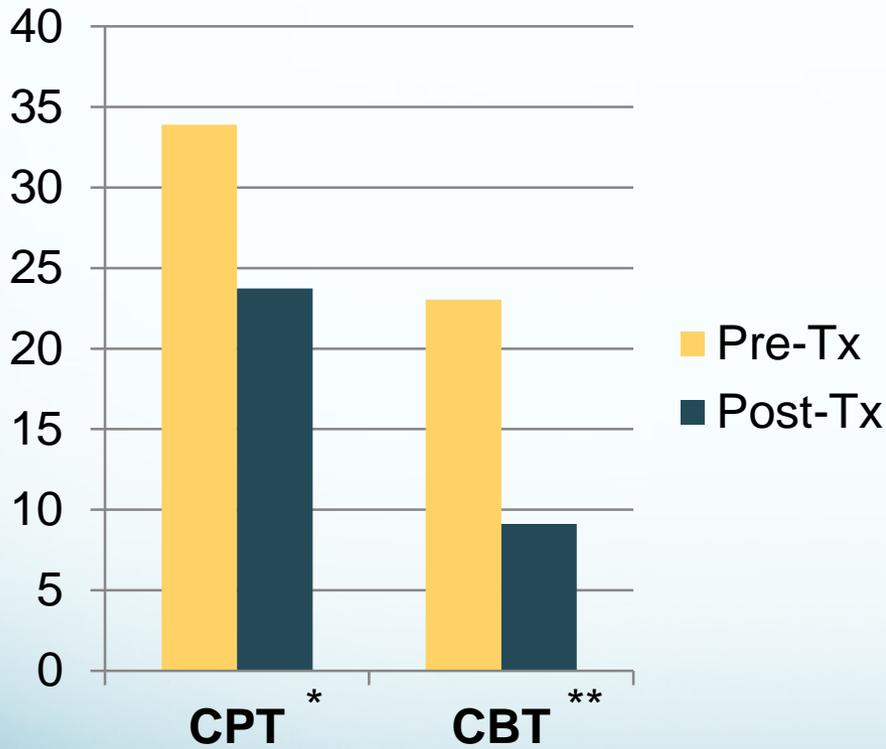


\*  $p < 0.05$

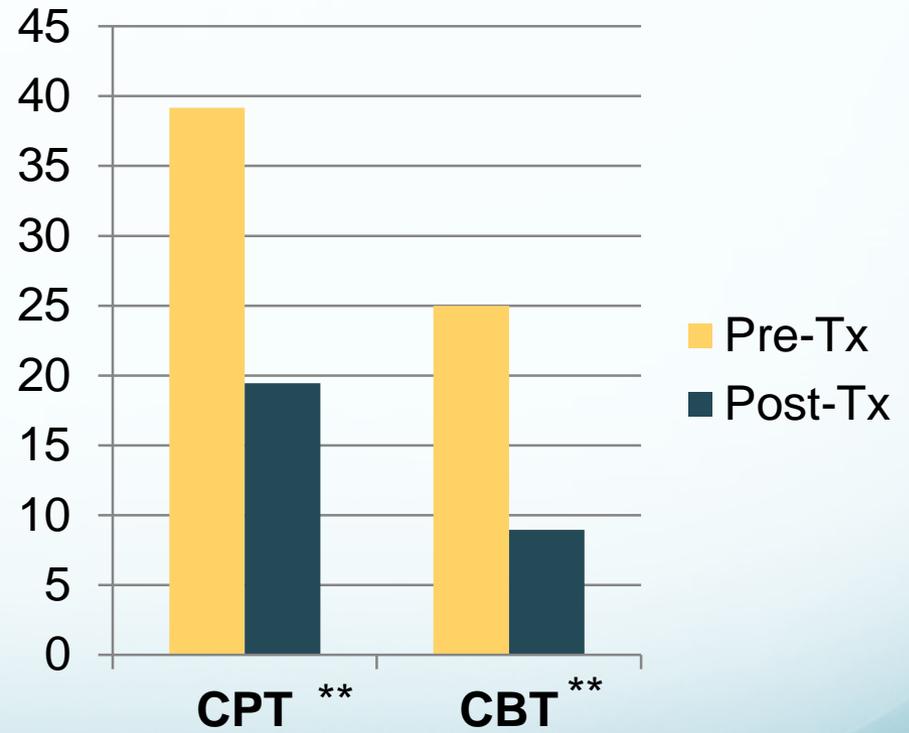
\*\*  $p < 0.01$

# Change in Depression

## ITT



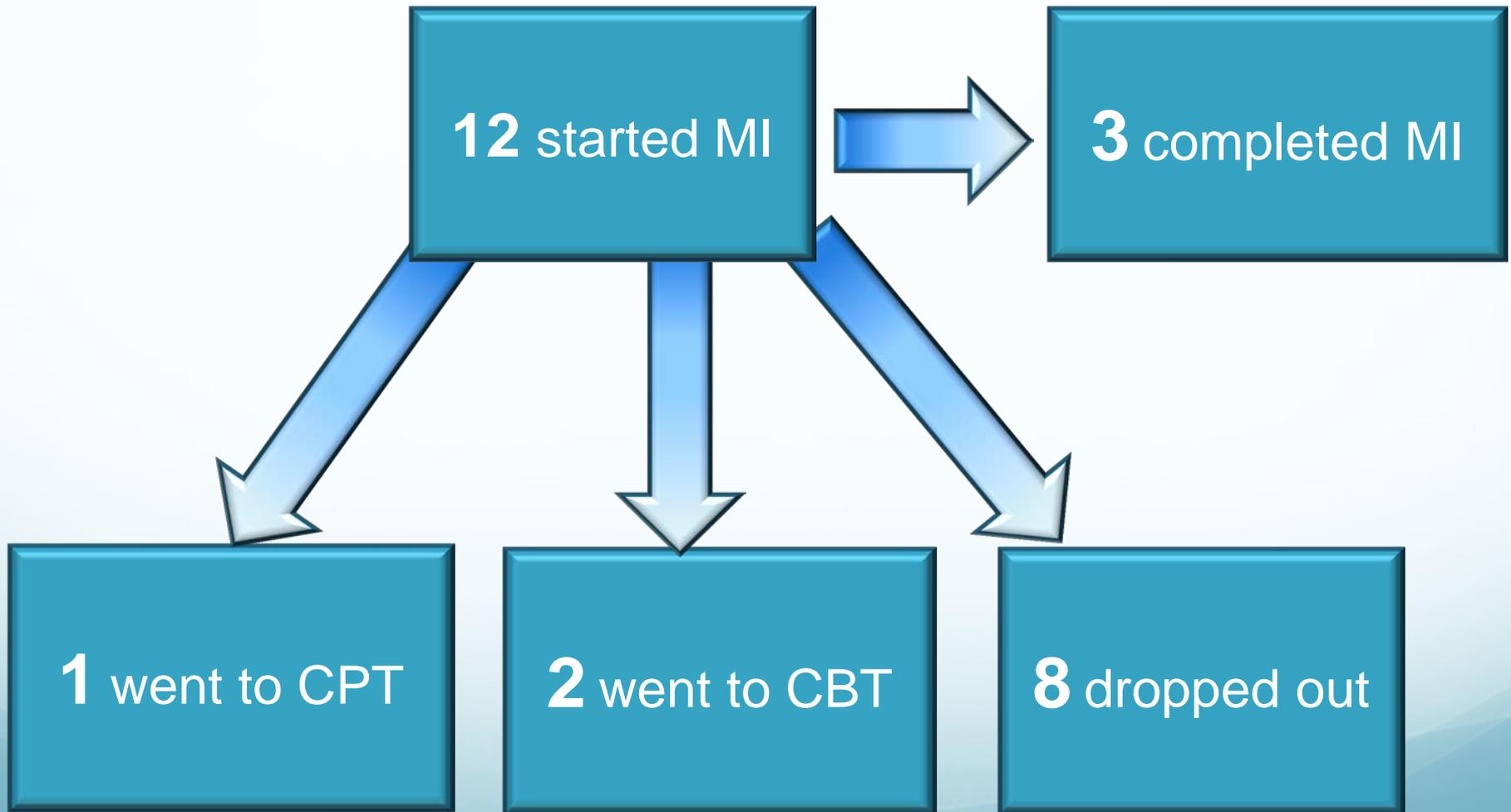
## Completer



\*  $p < 0.05$

\*\*  $p < 0.01$

# Flow of MI Participants

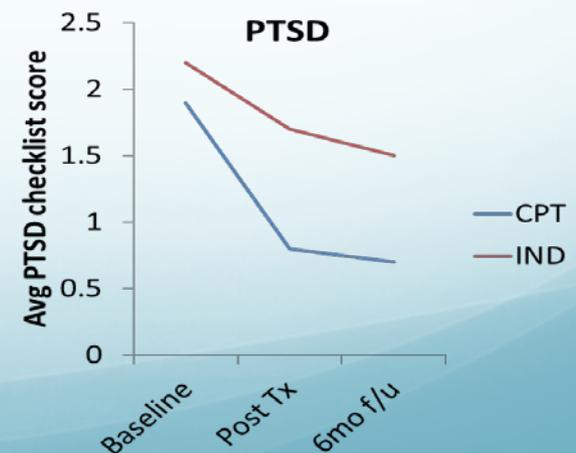
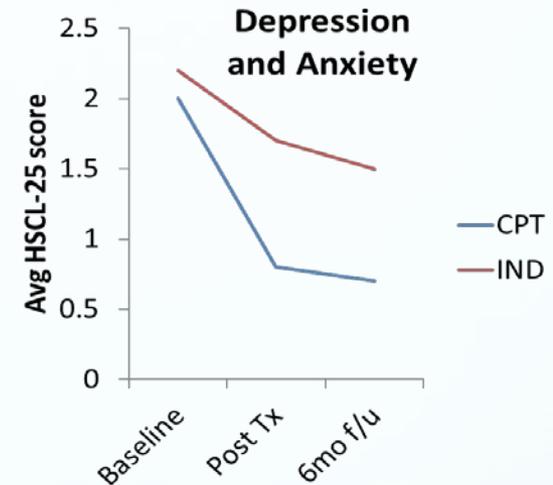


# In summary: We relied on creativity and flexibility

- Alternatives to trauma-focused therapy (addition of MI, CBT)
- Managing emergence of non-trauma related symptoms (psychosis, mania, evidence of alcohol or substance use)
- Lots of emergencies – SI/HI, CPS issues, additional traumas, basic needs like housing, laundry, meals, illnesses
- Practice work and attendance
- Adherence to the protocol (repeating sessions, extending the length, reconvening after long absences)

# Controlled Trial of Psychotherapy for Congolese Survivors of Sexual Violence (Bass et al., 2013)

- RCT of group CPT in the Democratic Republic of Congo
  - CPT: 7 villages (n= 157)
  - Individual Support: 8 villages (n= 248).
- Therapists had high school education or less.
- Participants were illiterate, so worksheets were simplified and participants memorized the forms and concepts.
- War was going on around them.
- Assessed pretreatment, post treatment and 6 months follow-up.



# Modifications were made to the CPT to accommodate the lack of resources at sites and the high degrees of illiteracy

- More emphasis on therapy buy-in
- Limit homework
  - Daily memorizable steps
  - Condensed, succinct forms
- Modifications for illiteracy
  - Balancing amount someone can remember with adequate practice
  - Use of naturally occurring cues
  - Using pictorial cues



A. Situation	B. Thought (stuck point)	D. Challenging Thoughts	E. Problematic patterns	F. Alternative Thought
Describe the event, thought or belief leading to the unpleasant emotion(s).	Write thought(s) related to Column A. Rate belief in each thought below from 0-100% (How much do you believe this thought?)	Use <b>Challenging Questions</b> to examine your automatic thoughts from Column B. Is the thought balanced and factual or extreme?	Use the <b>Problematic Thinking Patterns</b> sheet to decide if this is one of your problematic patterns of thinking.	What else can I say instead of Column B? How else can I interpret the event instead of Column B? Rate belief in alternative thought(s) from 0-100%
	C. Emotion(s) Specify sad, angry, etc., and rate how strongly you feel each emotion from 0-100%	Evidence?  Habit or Fact?  Interpretations not accurate?  All or none?  Extreme or exaggerated?  Out of context?  Source unreliable?  Low versus high probability?  Based on feelings or facts?  Irrelevant factors?	Jumping to conclusions  Exaggerating or minimizing  Disregarding important aspects  Oversimplifying  Overgeneralizing  Mind reading  Emotional reasoning	G. Re-rate how much you now believe the thought in Column B from 0-100%  H. Emotion(s) Now what do you feel? 0-100%

## Changing Beliefs and Feelings Form

1. Stuck point



2. Feelings



3. Questions



A habit or a fact?

Extreme words or phrases?

The whole of the situation just 1 part?

Confusing a possibility with a certainty?

Feelings rather than facts?



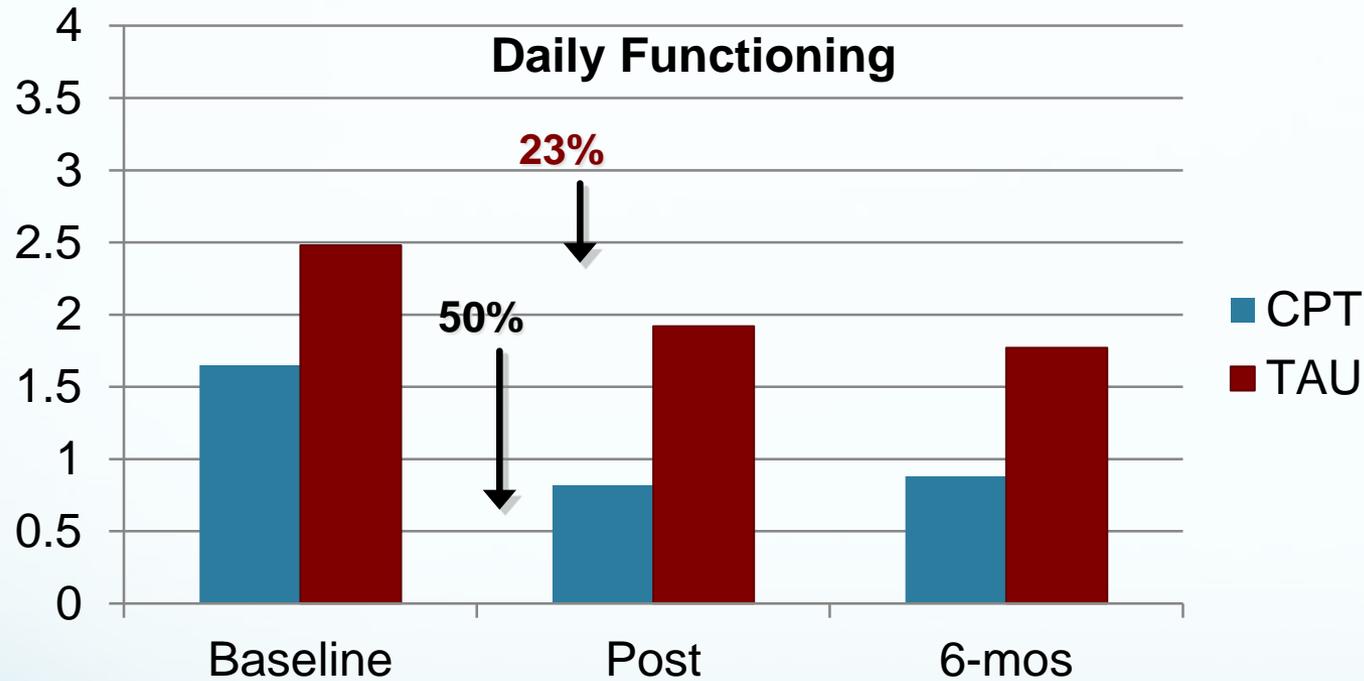
4. New thought



5. Change in Feelings



# Women who received CPT also reported significant and sustained functional improvements



	CPT Mean (SD)	TAU Mean (SD)	Effect Size
Average Functioning score			
Baseline	1.65 (0.69)	2.48 (0.82)	(<0.001)
Post intervention	0.82 (0.67)	1.92 (0.89)	1.29 (<0.001)
6-month follow up	0.88 (0.70)	1.77 (0.87)	1.06 (<0.001)

# Translating the research into clinical practice

**DISTRESS**



**WELLNESS**

- Increased flexibility of evidence-based therapy
- Demonstrated Efficacy in New Trauma Populations
- Tested Cross-Cultural Applications

- Demonstrated effectiveness in challenging populations
- Augmented our protocol to address clinical challenges
- **What can we do in the course of clinical care?**

At what point do the modifications to the protocol render the final product something that no longer resembles CPT?

Perhaps the biggest culprit in tipping the scale is therapist drift



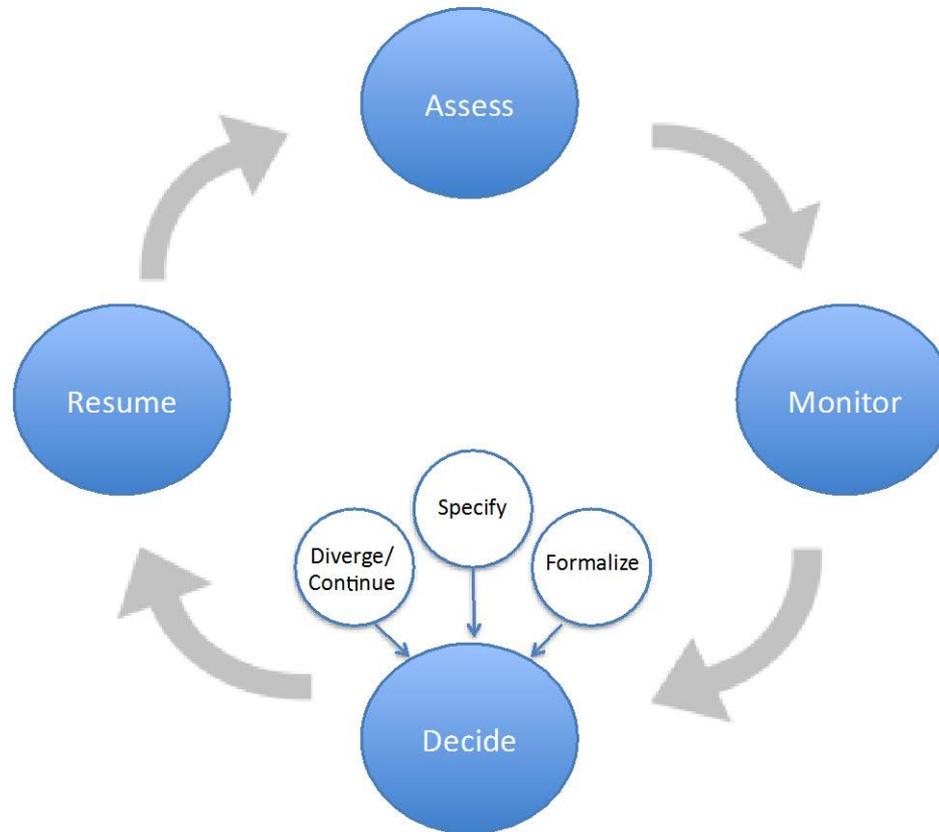
# Balancing Flexibility with Fidelity During Clinical Care

- It is critical to note that modifications to the CPT protocol previously discussed were 1. tested and 2. published in peer-reviewed journals
- Investigators were careful to maintain fidelity to the core protocol and serve as consultants on each others' trials.
- As a result: Clinicians have more **clinical choices** within the manual
  - Worksheets
  - **Flexibility** in the application of the intervention (length of protocol, duration of therapy, emergency sessions)
  - More guidance in the inclusion of adjunctive therapies.

# Common Points of “Drift”

- **Adding elements of other treatment approaches**
  - Tendency to drift to what is familiar
  - Risks:
    - Water down CPT effectiveness
    - Reinforce avoidance
    - Confuse patients about focus/rationale
- **Repeated sessions**
  - Add sessions at the end of the protocol if additional sessions are needed.
  - Adding sessions mid-treatment slows acquisition of new skills and can reinforce avoidance
- **Crisis/Emergency sessions become routine**
- **Long extensions of CPT**
- **Managing practice assignment non-compliance**

# What can we do as clinicians?



# Step 1. **Assess** (prior to treatment)

## Strengths

### Resources

- 1.
- 2.
- 3.

**PTSD**

Path of Recovery

Well-Being

## Challenges

### Avoidance

- 1.
- 2.

### Engagement

- 1.
- 2.

### Emotional Regulation

- 1.
- 2.

### Concurrent Mental & Physical Health Difficulties

- 1.
- 2.

### Current Major Stressors

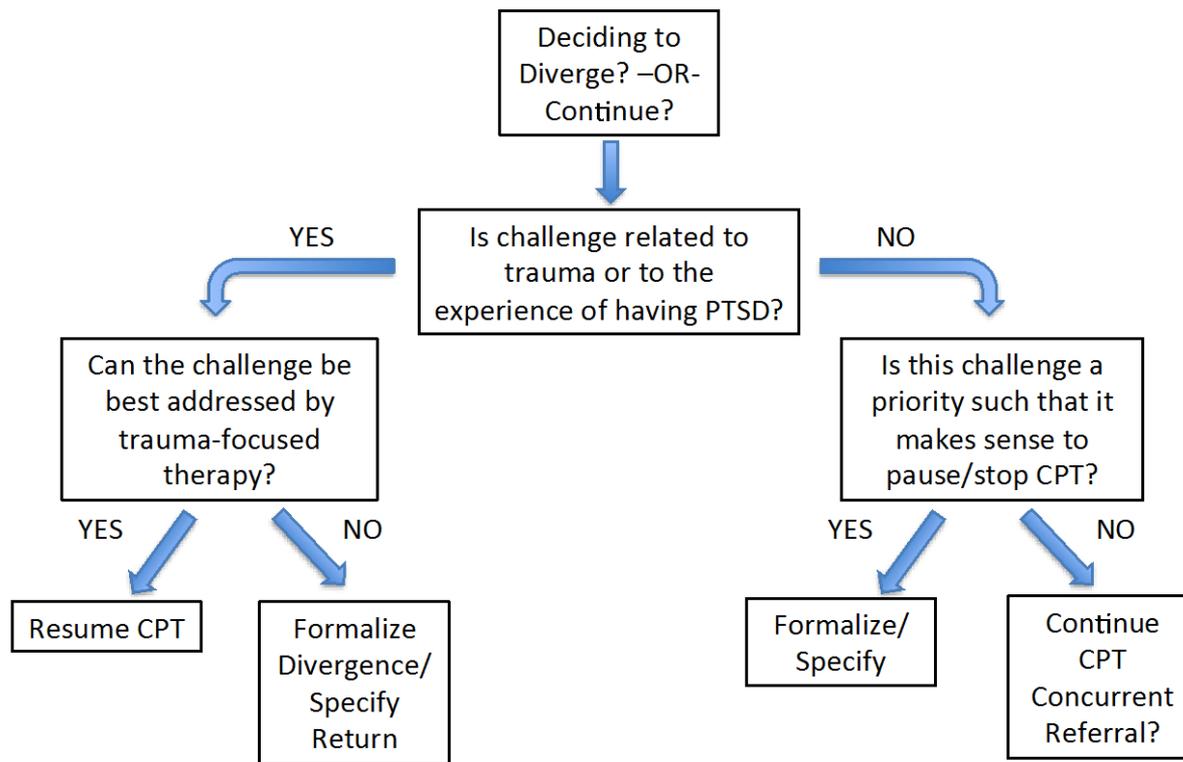
- 1.
- 2.

# Step 2: Monitor Treatment Challenges

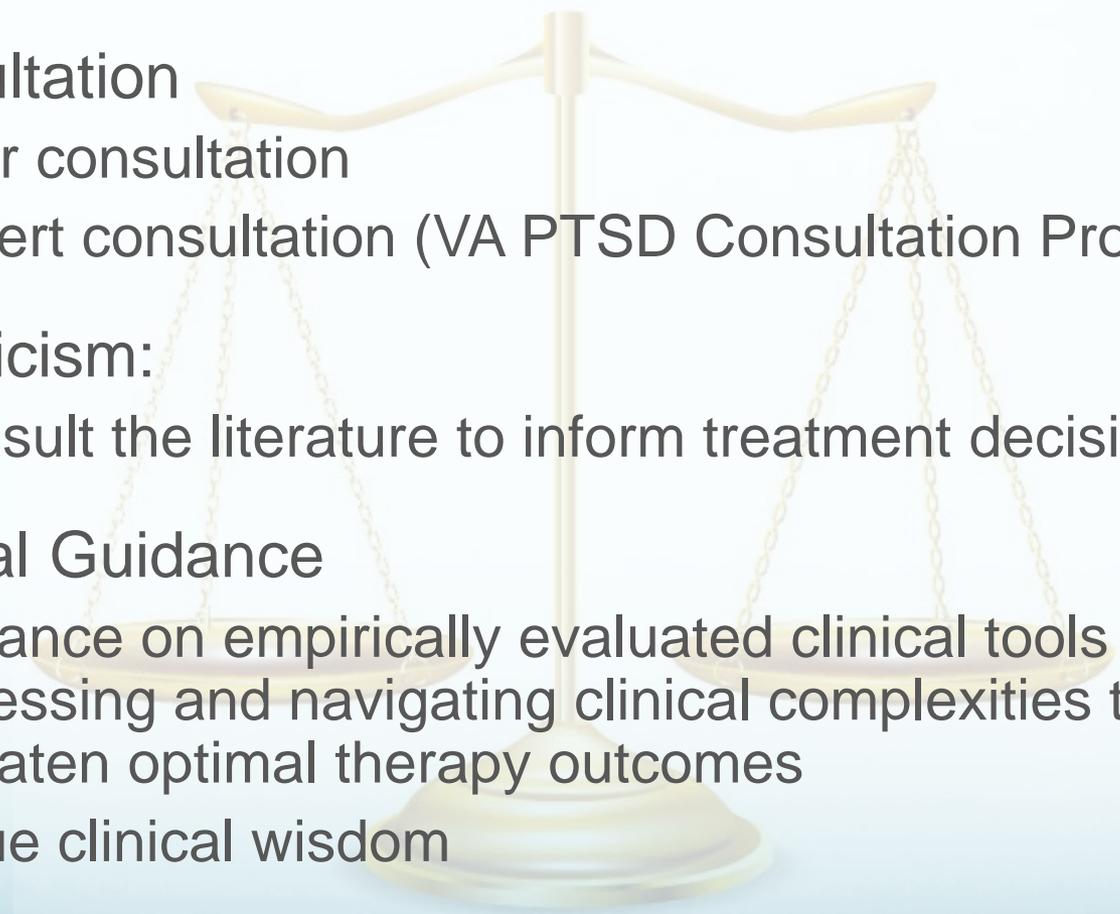
- **Tools:**
  - Daily symptom monitoring diary
  - Standardized measures
  - Verbal check-ins
- **Questions:**
  - What is the baseline frequency/intensity?
  - What does a clinically significant increase look like for your patient?
  - Any increases in previously defined parameters become a red flag

# Step 3: Informing the Intervention

When Faced With a Challenge to Optimal Therapy Outcomes...  
Decision-Making Process



# In summary...Balancing Flexibility with Fidelity

- 
- Consultation
    - Peer consultation
    - Expert consultation (VA PTSD Consultation Program)
  - Empiricism:
    - Consult the literature to inform treatment decisions
  - Clinical Guidance
    - Reliance on empirically evaluated clinical tools to assist in assessing and navigating clinical complexities that threaten optimal therapy outcomes
    - Value clinical wisdom



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Please enter your  
questions in the Q&A box  
and be sure to include your  
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*The lines are muted to avoid background noise.*



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*Listen to the  
lecture.*



*Return to  
TRAIN for  
evaluation.*



*Follow the  
directions to  
print  
certificate.*

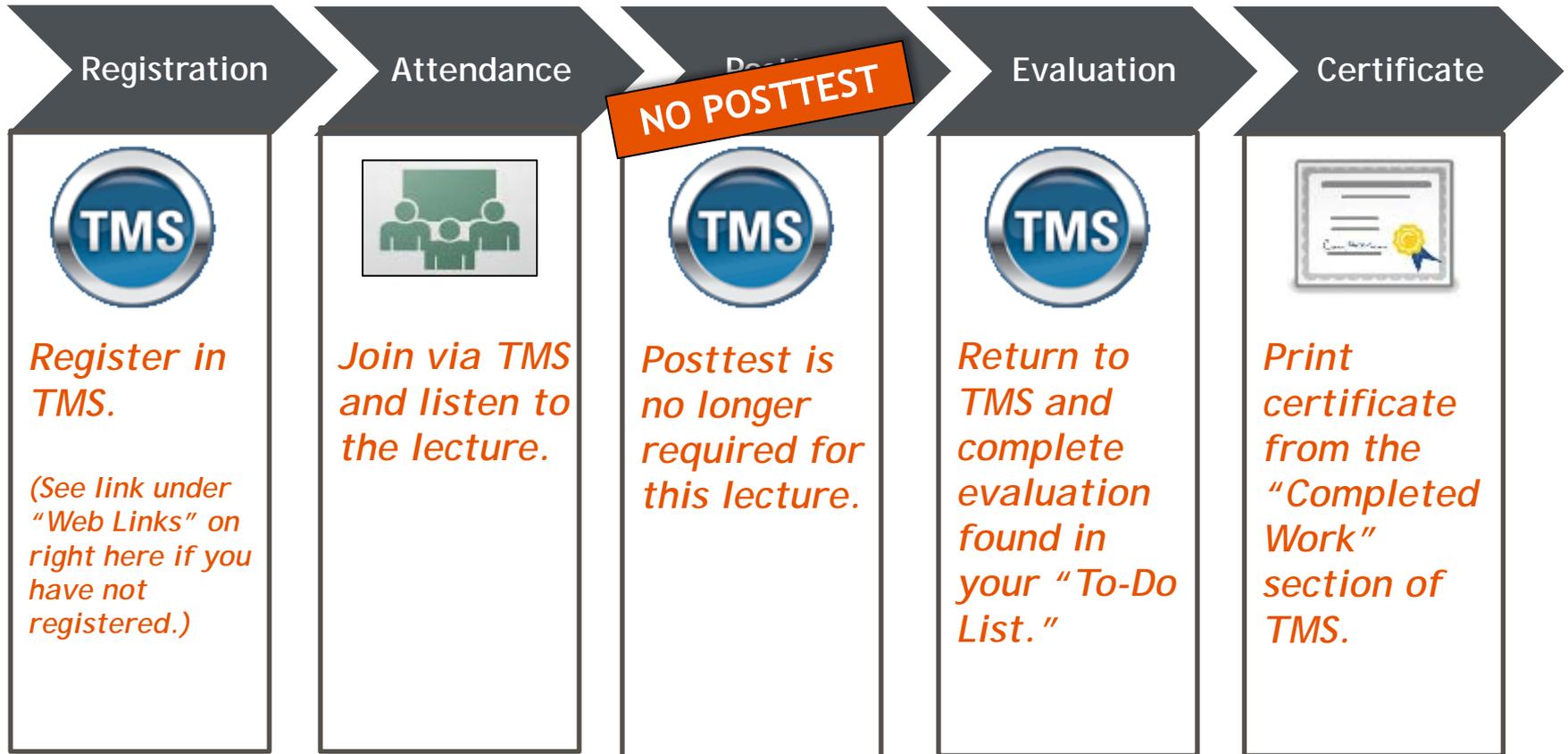
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## UPCOMING TOPICS

*SAVE THE DATE: Third Wednesday of the Month from 2-3PM (ET)*

August 15	The Continuum of Care for PTSD Treatment	Kelly Phipps Maieritsch, PhD
September 19	PTSD and Women's Mental Health	Suzanne Pineles, PhD
October 17	Dementia Risk in Veterans with PTSD and a History of Blast-Related TBI	David Cifu, MD



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