Balancing Clinical Flexibility while Preserving Efficacy in Delivering EBPs for PTSD

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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.\(^1\)
- The lack of integration has had direct implications for the perceived effectiveness of psychological interventions.\(^{1,2,3}\)
- 1990s: Substantial effort to close the scientist-practitioner gap due to a host of economic and political forces\(^{4,5,6}\)
- The pressure to “empirically validate” psychological interventions grew substantially\(^{5,6,7}\)
- The schisms between schools of psychology grew more apparent

\(^{1}\) Messer and Winokur, 1980; \(^{2}\) Messer, 1986; \(^{3}\) Lazarus, 1977; 
\(^{4}\) Goldfried & Wolfe, 1996; \(^{5}\) Hayes & Follette, 1996; \(^{6}\) Goldfried & Wolfe, 1998; 
\(^{7}\) 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 …

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>Move toward Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random assignment</td>
<td>Construct effectiveness question/condition and compare to a more tightly controlled condition</td>
</tr>
<tr>
<td>Control for nonspecific factors</td>
<td>e.g. Patients choose therapist</td>
</tr>
<tr>
<td>Operationalized target outcomes</td>
<td>Treatment success defined more broadly</td>
</tr>
<tr>
<td>Fixed number of sessions</td>
<td>Therapy length determined by patient progress</td>
</tr>
<tr>
<td>Homogenous sample</td>
<td>Increase heterogeneity (comorbidity, patient populations, etc.)</td>
</tr>
<tr>
<td>Strict adherence to manualized treatment</td>
<td>Modifiable depending on variation in client’s life circumstances and response to intervention</td>
</tr>
</tbody>
</table>
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\(^1\)

- Over 50% report suicidal ideation\(^1\)

- The nature of war-related traumas, such as traumatic losses and moral injury, may contribute to clinical complexity\(^2,3\)

- Veterans have high rates of homelessness, unemployment\(^4\)

- Veterans also have compromised physical health conditions, often related to service\(^5\)

- 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\(^6\)

\(^1\) Magruder et al., 2005; \(^2\) Litz et al., 2009; \(^3\) Stein et al., 2012; \(^4\) Fargo et al., 2012; \(^5\) Agha et al., 2000; \(^6\) Alverez, 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.¹

- Data from one VHA clinic suggested that approximately 50% of therapists are modifying treatment protocols in some way to address clinical complexities.²

- However, the patients who received a modified treatment had significantly worse outcomes than standardized therapy.²

- The perception of lack of flexibility in the face of clinical complexity results in providers choosing to use EBPs for PTSD with fewer patients.¹

¹ Kehle-Forbes, et al., 2016; ² Niles, et al., in press;
How can I make this work?

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

Fidelity

-OR-

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

Flexibility
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\(^1,2,3,4\)
- Primarily a cognitive treatment designed to treat PTSD\(^5\)
- One of the therapies for PTSD with the most empirical support to date\(^6,7\)
- 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

\(^1\) ISTSS, 2008; \(^2\) NHRMC, 2013; \(^3\) APA, 2017; \(^4\) VA/DoD, 2017; \(^5\) Resick et al., 2017; \(^6\) Watts et al., 2013; \(^7\) Haagan et al., 2015
## The Development of CPT

<table>
<thead>
<tr>
<th>Clinical Complexity</th>
<th>Modification of original protocol</th>
</tr>
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<tbody>
<tr>
<td>Patient crises, ongoing trauma, major psychosocial stressors</td>
<td>Add emergency sessions, use modified worksheets, rely on other creative ways to move therapy into patient’s lives</td>
</tr>
<tr>
<td>Fixed number of sessions and/or timing and location of sessions</td>
<td>Let patient progress determine the length of therapy. CPT in one week – massed trial CPT via telemental health</td>
</tr>
<tr>
<td>Complex trauma history or a non-combat trauma</td>
<td>Efficacy of CPT has been demonstrated in multiple trauma populations (interpersonal violence, MVA, MST, Veteran, active duty, adolescents, CSA)</td>
</tr>
<tr>
<td>Cross cultural applications</td>
<td>Translated into 11 different languages Tested internationally: Australia, Germany, Israel, Kurdistan, Congo, etc.</td>
</tr>
<tr>
<td>Your study participant doesn’t look like my patient! (comorbidity, ambivalence, cognitive functioning, suicidality or self-harm, TBI)</td>
<td>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.</td>
</tr>
<tr>
<td>Stuck Points</td>
<td></td>
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<tr>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>My client is not ready for trauma-focused therapy</td>
<td></td>
</tr>
<tr>
<td>My clients are more difficult than those in research studies</td>
<td></td>
</tr>
<tr>
<td>My client is too fragile</td>
<td></td>
</tr>
<tr>
<td>Clients will get worse if we talk about their traumas in any detail</td>
<td></td>
</tr>
<tr>
<td>If I use a manual, the “art” of therapy is lost and it will damage rapport with the client</td>
<td></td>
</tr>
<tr>
<td>CPT won’t work with comorbidities (depression, dissociation, substance abuse, personality disorders)</td>
<td></td>
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</tbody>
</table>
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....

- Worse Overall Functioning
- Greater Emotional Distress
- More Frequent Hospitalizations
- More Severe Psychiatric Symptoms
- Decreased Social and Occupational Functioning
- Higher Risk for substance abuse problems and disorders
- Higher Suicide Risk

(Resnick, Bond, & Mueser, 2003; Mueser, Essock, Haines, Wolfe, & Xie, 2004; Switzer et al., 1999; Brekke, Prindle, Woo Bae, & Long, 2001; Walsh et al., 2003; Brekke et al., 2001; Chapple et al., 2004; Hiday et al., 1999; Sells, Rowe, Fisk, & Davidson, 2003; Chapple et al., 2004; Dean et al., 2007; Stumbo, Yarborough, Paulson, & Green, 2015; Carballo et al., 2008)
Challenges to Trauma-focused Therapy in Community Mental Health

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

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

97 Assessed for eligibility
- 11 No information/Ineligible
- 2 Sent to more intensive inpatient treatment
- 2 Interfering substance abuse
- 1 Incarcerated

81 Intent-to-Treat

41 Did not complete treatment
- 32 Dropped out during treatment
  - 19 Unknown/went missing
  - 7 Relapsed/went to inpatient substance treatment
  - 2 Removed from treatment for noncompliance
  - 4 Other
    - 1 Had baby
    - 1 Employed
    - 1 Switched to more convenient clinic
    - 1 Completed JD program

9 Dropped before beginning treatment
- 4 No information
- 2 Became homeless
- 2 Substance abuse relapse
- 1 Incarcerated

40 Completed Treatment
- 16 CPT
- 21 CBT
- 3 MI
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

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male (52%)</td>
<td></td>
</tr>
<tr>
<td>Female (48%)</td>
<td></td>
</tr>
<tr>
<td>Transgender (1%)</td>
<td></td>
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<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>18-65 years (M = 39.26, SD = 10.98)</td>
<td></td>
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<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Black/African-American (74%)</td>
<td></td>
</tr>
<tr>
<td>White/Caucasian (24%)</td>
<td></td>
</tr>
<tr>
<td>Other (1%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Living Situations</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohabitated with a S/O or family member</td>
<td>33%</td>
</tr>
<tr>
<td>Independently</td>
<td>21%</td>
</tr>
<tr>
<td>Homeless</td>
<td>21%</td>
</tr>
<tr>
<td>Therapeutic housing settings</td>
<td>17%</td>
</tr>
<tr>
<td>Hotel or with a friend</td>
<td>9%</td>
</tr>
</tbody>
</table>
## Criminal Offenses

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

12 started MI

1 went to CPT
2 went to CBT
8 dropped out

3 completed MI
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
<table>
<thead>
<tr>
<th>A. Situation</th>
<th>B. Thought (stuck point)</th>
<th>C. Emotion(s)</th>
<th>D. Challenging Thoughts</th>
<th>E. Problematic patterns</th>
<th>F. Alternative Thought</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the event, thought or belief leading to the unpleasant emotion(s).</td>
<td>Write thought(s) related to Column A. Rate belief in each thought below from 0-100% (How much do you believe this thought?)</td>
<td>C. Emotion(s) Specify sad, angry, etc., and rate how strongly you feel each emotion from 0-100%</td>
<td>Use <strong>Challenging Questions</strong> to examine your automatic thoughts from Column B. Is the thought balanced and factual or extreme?</td>
<td>Use the <strong>Problematic Thinking Patterns</strong> sheet to decide if this is one of your problematic patterns of thinking.</td>
<td>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%</td>
</tr>
<tr>
<td>G. Re-rate how much you now believe the thought in Column B from 0-100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>H. Emotion(s) Now what do you feel? 0-100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Changing Beliefs and Feelings Form

1. Stuck point
2. Feelings
3. Questions
4. New thought
5. Change in Feelings

- 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?
Women who received CPT also reported significant and sustained functional improvements
Translating the research into clinical practice

- 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

- **Challenges**
  - Avoidance
    - 1.
    - 2.
  - Engagement
    - 1.
    - 2.
  - Emotional Regulation
    - 1.
    - 2.

- Concurrent Mental & Physical Health Difficulties
  - 1.
  - 2.

- Current Major Stressors
  - 1.
  - 2.

**Well-Being**
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

Deciding to Diverge?—OR—Continue?

- YES
  - Is challenge related to trauma or to the experience of having PTSD?
    - YES
      - Can the challenge be best addressed by trauma-focused therapy?
        - YES
          - Resume CPT
        - NO
          - Formalize Divergence/Specify Return
    - NO
      - Is this challenge a priority such that it makes sense to pause/stop CPT?
        - YES
          - Formalize/Specify
        - NO
          - Continue CPT Concurrent Referral?
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
Please enter your questions in the Q&A box and be sure to include your email address.

The lines are muted to avoid background noise.
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To obtain continuing education credit please return to www.vha.train.org after the lecture.

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FOR PROVIDERS WHO TREAT VETERANS

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Listen to the lecture.

Return to TRAIN for evaluation.

Follow the directions to print certificate.

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CEU Process (for VA employees)

- Registration
  - Register in TMS.
  - (See link under “Web Links” on right here if you have not registered.)

- Attendance
  - Join via TMS and listen to the lecture.

- Posttest
  - Posttest is no longer required for this lecture.

- Evaluation
  - Return to TMS and complete evaluation found in your “To-Do List.”

- Certificate
  - Print certificate from the “Completed Work” section of TMS.

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### Upcoming Topics

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 15</td>
<td>The Continuum of Care for PTSD Treatment</td>
<td>Kelly Phipps Maieritsch, PhD</td>
</tr>
<tr>
<td>September 19</td>
<td>PTSD and Women’s Mental Health</td>
<td>Suzanne Pineles, PhD</td>
</tr>
<tr>
<td>October 17</td>
<td>Dementia Risk in Veterans with PTSD and a History of Blast-Related TBI</td>
<td>David Cifu, MD</td>
</tr>
</tbody>
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For more information and to subscribe to announcements and reminders go to [www.ptsd.va.gov/consult](http://www.ptsd.va.gov/consult)