Symptom Exacerbations in Trauma-Focused Treatment: Cause for Concern or Par for the Course?

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Poll Question #1

- What is your primary role in the VA?
  - Student, trainee, or fellow
  - Clinician
  - Researcher
  - Administrator, manager, or policy-maker
  - Other

Trauma-focused treatments

- Front-line treatment for PTSD
- Under-utilized relative to their efficacy and the prevalence of PTSD

The concern with exacerbations

- Some populations (e.g. CSA, comorbidities) can't tolerate trauma-focused treatment
- Trauma-focused treatments will make PTSD worse
- Trauma-focused treatments could increase patient distress
- Patients will then drop out or be worse off than when they started

Past Studies

- Imaginal exposure not linked to exacerbations (Foa et al 2002)
- Drop-out rates same across active PTSD treatments (Hembree et al 2003)
- Two studies of pre-to-post treatment worsening
  - Some got worse on the wait list; none got worse in trauma-focused treatment (Jayawickreme et al 2013; Ehlers et al 2014)
- Two studies of within-treatment exacerbations
  - 30% of sample in an active trauma group (Mott et al 2013)
  - 22% of sample had depression spikes (Keller et al 2014)

Study 1

An examination of symptom exacerbations in a clinical trial sample (Larsen et al., 2015)

Study 1 Questions

1. How common are symptom exacerbations in trauma-focused treatments for PTSD?
2. What predicts symptom exacerbations?
3. Do symptom exacerbations predict worse post-treatment outcomes or dropout?

Larsen, Wiltsey Stirman, Smith, & Resick (2016) Symptom exacerbations in trauma-focused treatments: Associations with treatment outcome and non-completion. Behavior Research and Therapy, 77, 68-77.

Methods—Participants

- Two RCTs of CBT for PTSD
  - CPT
  - CPT-C
  - PE
- Female survivors of interpersonal violence
- Completed at least 4 therapy sessions

Demographics

- N = 192 (PE = 60; CPT = 98; CPT-C = 34)
- Age *M* = 34 years
- 78% White, 19% African-American
- Marital status
  - 44% single
  - 25% married or cohabiting
  - 30% separated, widowed, or divorced
- Years since assault *M* = 11

Methods - Treatments

- Prolonged Exposure (PE)– 9 sessions
  - Psychoeducation
  - Breathing retraining
  - In vivo exposure
  - Imaginal exposure and emotional processing
- Cognitive Processing Therapy (CPT) – 12 sessions
  - Recognizing and challenging dysfunctional trauma-related beliefs
  - Write trauma narrative
- CPT-C does not include the written narrative

Methods—Measures

- CAPS
  - Pre- and post-treatment
- PTSD Symptom Scale/Posttraumatic Diagnostic Scale
  - Pre, post, and weekly during treatment (every other session)

- Defining exacerbations:
  - Change greater than 6.15 points on PDS/PSS (Foa et al., 2002)

Results - Frequencies

- Frequency overall
  - CPT 28.6%
  - CPT-C 14.7%
  - PE 20%
- Frequency between sessions 2 and 4
  - CPT 13.4%
  - CPT-C 2.9%
  - PE 15.0%

CPT vs. CPT-C $\chi^2(N = 131) = 2.89$, $p = .089$;
PE vs. CPT-C $\chi^2(N = 94) = 3.32$, $p = .068$
CPT vs. PE $\chi^2(N = 157) = 0.08$, $p = .78$

Predictors of exacerbations

- Potential predictors
  - Demographics
  - Trauma-related variables
  - Treatment type
  - Diagnostic variables
  - Avoidance symptom cluster
- None were significant predictors
  - Marginal significance:
    - Childhood Sexual Abuse
    - Alcohol abuse

Post-Treatment Outcomes

- Do exacerbations cause worse post-treatment outcomes? **Yes and no…**
- **Yes**: Those who experienced an exacerbation were more likely to retain a PTSD diagnosis, and were likely to continue to have higher PTSD symptom scores over the course of treatment
- **No**: Those who experienced an exacerbation showed (large) significant pre-to-post treatment improvement, ending with scores within non-PTSD population norms

Dropout

- Unrelated to symptom exacerbations
- Unrelated to PDS/PSS early sessions

Large exacerbations (2x)

- N=14 (7% of sample)
- Slightly more likely to drop out
- Comparable pre-to-post changes

Conclusions from Study I

- A minority of patients experience symptom exacerbations
- Exacerbations ***do not preclude*** positive outcomes
- Clients can tolerate such treatments
- Symptom exacerbations may be a normal part of treatment, and are less common than sudden gains

Poll Question #2

- To what extent do these findings mirror your own clinical experience?
  - I've noticed symptom exacerbations like this AND worry about them
  - I've noticed symptom exacerbations like this and DON'T worry about them
  - I haven't noticed exacerbations like this
  - I avoid doing trauma-focused therapy because of worries about these exacerbations
  - Other/not applicable

Study 2

CPT provided by newly-trained clinicians

Study Team

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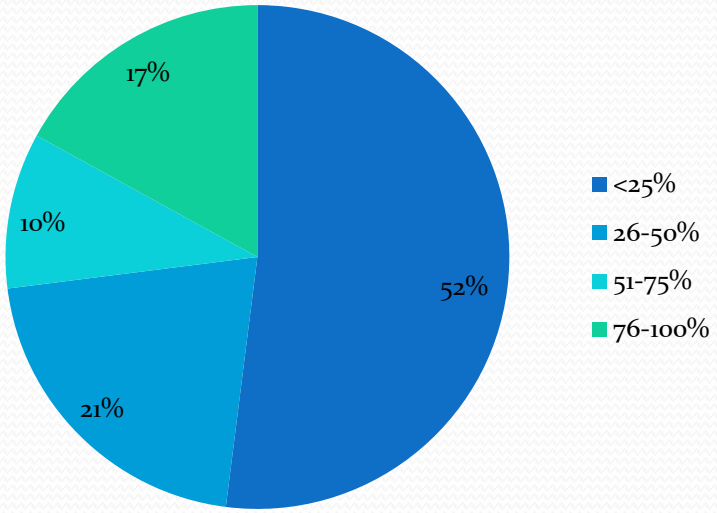
Design

- Hybrid-III design (Curran et al., 2012)
- RCT of 3 different post-workshop consultation strategies
  - Fidelity assessment only (No consultation)
    - Written feedback on a randomly selected session 6 months after workshop
    - Potential to become a CPT Provider
  - Standard Consultation
    - Weekly group consultation with a CPT expert
    - Discussion of cases
    - No use of work samples
  - Technology-enhanced Consultation
    - Weekly group consultation with a CPT expert
    - Review of segments of audio recorded sessions
    - Review of worksheets, stuck point logs, etc

Therapists and Settings

- N=134
- 23 Clinics
  - 10 Operational Stress Injury Clinics
  - 3 Canadian Forces Clinics
  - 3 Hospitals (multiple sub-clinics at three of the clinics)
  - 7 Community-based clinics
- 37 Private Practitioners (provide services to Veterans)
- 78% Urban Clinics, 16% Suburban, 5% Rural
- Mean Caseload: 28 (SD=23)

- % Caseload with PTSD

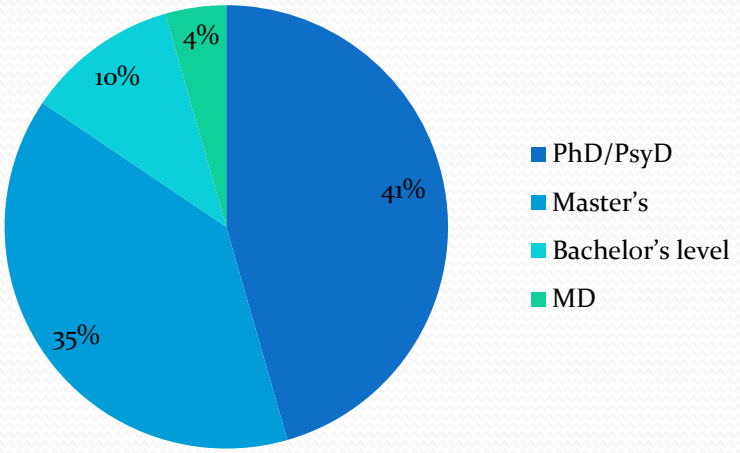


Therapists

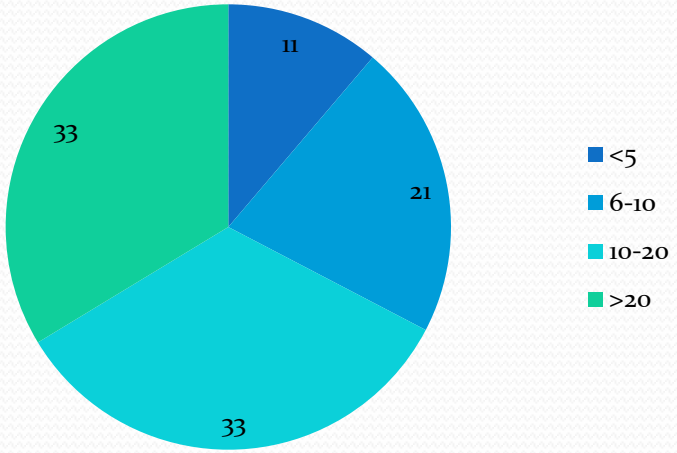
Mean Age= 47 (SD=11)

72% Female, 27% Male

<u>Degree</u>



52% had prior CBT supervision



Client participants

- N=188
- Age M=35, SD=11
- Education M=12, SD=2
- 53% Female
- Race/Ethnicity
  - 88% White
  - 4% Native Canadian
  - 3% Asian
  - 2% Black
  - 3% Other
  - <1% Hispanic/Latino

  Marital Status
  - 36% Single/Divorced/Widowed
  - 58% Married/In a Committed Relationship
- Veteran Status
  - 70% of males and 17% of females were in military or were veterans

Client Diagnoses

Diagnosis	%
PTSD	98
Major Depressive Disorder	56
Substance Abuse or Dependence	12
Anxiety Disorder	17
Bipolar Disorder	5
Eating Disorder	4
ADHD	5
Borderline PD	14
Other PD	10

No differences in client demographic or diagnostic characteristics between conditions

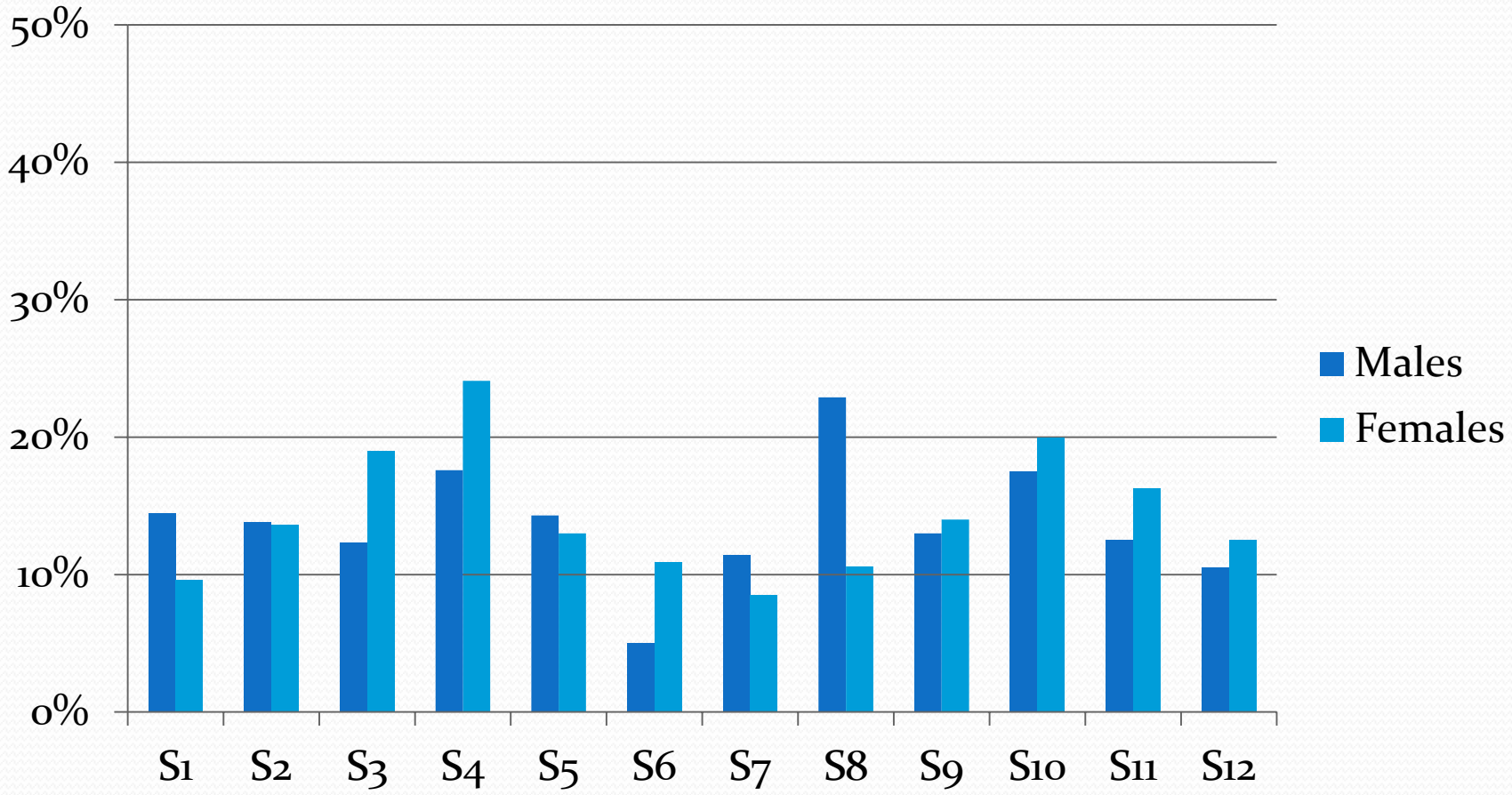
Study Procedures

- Therapists completed CPT workshop
- Therapists in all condition knew fidelity would be rated
- Those in consultation received weekly consultation for 6 months
- Therapists delivered CPT
- Enrolled clients completed PCL-IV at every session.

Symptom Exacerbation

- Defined as an increase greater than 5.71 on the PCL between adjacent sessions.
- 65.6% reported at least one instance of symptom exacerbations during treatment.
- Of those who reported them, the average was 1 session with symptom exacerbations (range = 0 – 4).
- Symptom exacerbations occurred on average in 14% of sessions in which PCLs were available (or median = 11% of available sessions).

Exacerbations by Session



Why the difference?

- Different measure, 5.71 points for exacerbation
- Differences in clinical training
- Differences in discipline and training background
- Very limited exclusion criteria
- Differences in supervision/consultation

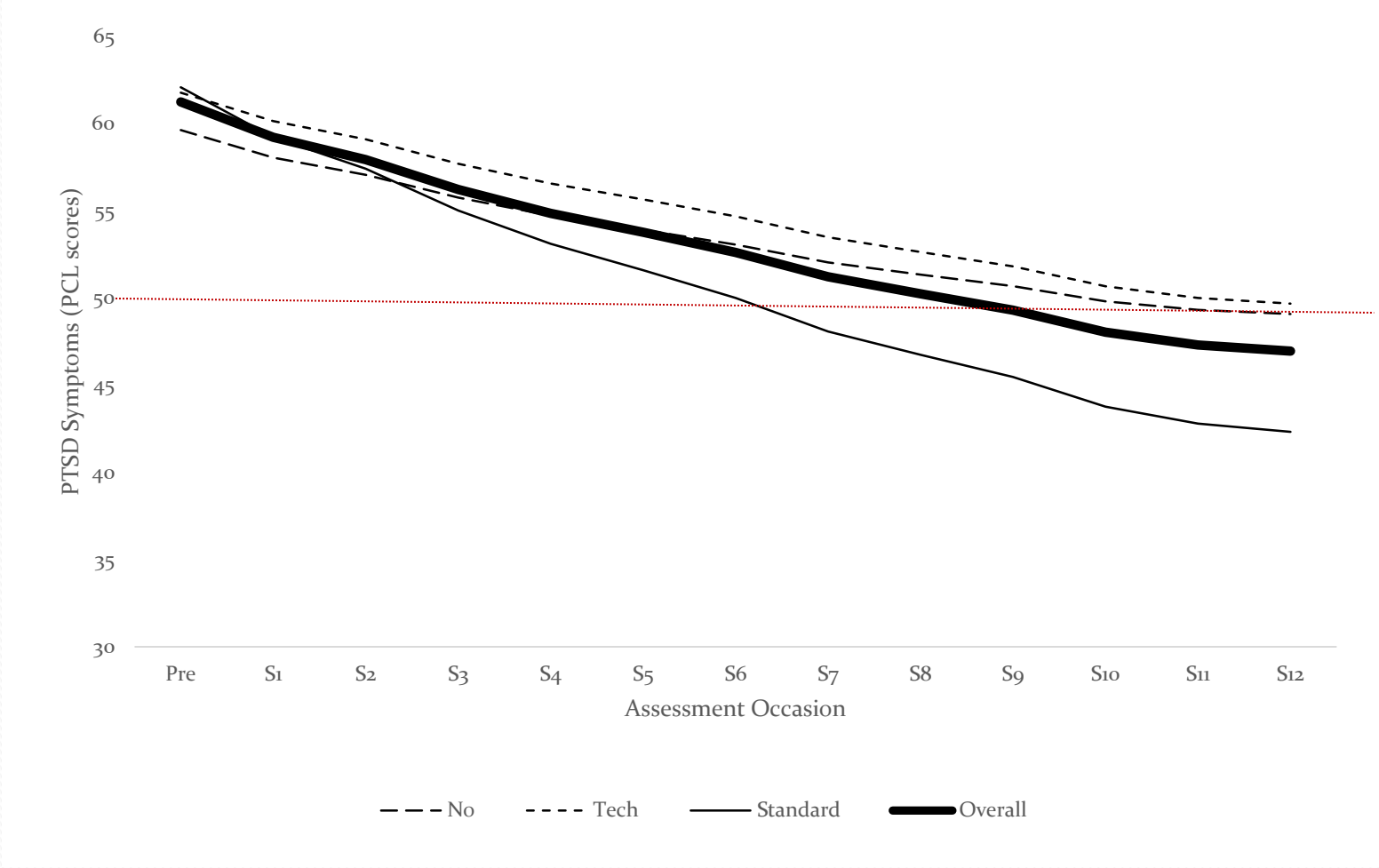
Fidelity

	Mean	SD	Range
Adherence	2.26	.49	0-3
Competence	2.82	.80	0-6

Predictors of Exacerbation

Predictors	Model 1 OR (95% CI)	Model 2 OR (95% CI)	Model 3 OR (95% CI)	Model 4 OR (95% CI)
Age	1.03 (.99, 1.06)	1.03 (.99, 1.06)	1.03 (.99, 1.06)	1.03 (.99, 1.06)
Gender	1.39 (.61, 3.19)	1.66 (.66, 4.18)	1.64 (.65, 4.17)	1.49 (.56, 3.93)
Education	1.02 (.88, 1.19)	1.03 (.88, 1.21)	1.03 (.88, 1.21)	1.03 (.88, 1.21)
Marital Status	1.20 (.59, 2.46)	.94 (.41, 2.17)	.94 (.40, 2.17)	.92 (.39, 2.18)
Military Status	1.14 (.49, 2.65)	1.38 (.54, 3.50)	1.41 (.55, 3.61)	1.38 (.54, 3.54)
Depression	n/a	1.39 (.62, 3.08)	1.38 (.62, 3.09)	1.37 (.61, 3.09)
Anx Disorder	n/a	.62 (.21, 1.79)	.62 (.21, 1.82)	.66 (.21, 2.05)
SU Disorder	**n/a**	**.27* (.08, .90)**	**.26* (.07, .89)**	**.23* (.06, .83)**
Personality DO	n/a	.61 (.23, 1.60)	.60 (.22, 1.61)	.59 (.21, 1.60)
Session 1 PCL	n/a	n/a	1.01 (.97, 1.04)	1.01 (.97, 1.05)
Consultation				
None vs Tech	n/a	n/a	n/a	.49 (.19, 1.29)
None vs Standard	n/a	n/a	n/a	.45 (.02, 13.90)

Overall PTSD Change



Effect Sizes

CPT in RCTs	No Consultation	Tech-enhanced	Standard	Full Sample
1.69[1] (95% CI=1.27-2.11)	**.95**	**1.09**	**1.78**	**1.29**

[1]Watts et al., 2013

Exacerbations predicting dropout?

- Participants with symptom exacerbations were significantly **LESS** likely to drop out of treatment prior to completing at least 8 sessions

- Looking at sessions 1 – 7 individually, the likelihood of treatment drop out was not related to the presence of symptom exacerbations; all χ^2 (1)< 1.7, all ps > .05.

- People who had an exacerbation in any given session were no more likely to drop out than they were to finish treatment

Predictors of Symptom Change

Predictors	B (95% CI)
Age	.59 (-.22, .46)
Gender	-.97 (-9.99, 3.40)
Education	-.43 (-1.41, .90)
Marital Status	-.88 (-8.08, 3.10)
Military Status	.31 (-5.36, 7.37)
Depression	.66 (-3.91, 7.80)
Anx Disorder	-1.51 (-13.93, 1.89)
SU Disorder	-.09 (-9.45, 8.66)
Personality DO	-.57 (-7.74, 4.28)
Session 1 PCL	-.81 (-.39, .17)
Consultation Condition	
None vs. Tech	.39 (-5.44, 8.08)
None vs. Standard	-1.04 (-10.33, 3.19)
Total Exacerbations	.81 (-1.68, 3.99)

Predictors	B (95% CI)
Age	.67 (-.20, .40)
Gender	-.95 (-9.78, 13.41)
Education	-.46 (-1.47, .92)
Marital Status	-1.03 (-8.46, 2.66)
Military Status	.36 (-5.37, 7.79)
Depression	.75 (-3.81, 8.41)
Anx Disorder	-1.59 (-14.20, 1.57)
SU Disorder	-.17 (-9.61, 8.10)
Personality DO	-.65 (-7.96, 4.02)
Session 1 PCL	-.89 (-.40, .15)
Consultation Condition	
None vs. Tech	.28 (-5.76, 7.69)
None vs. Standard	-1.15 (-10.71, 2.85)
Early Exacerbations	-.24 (-4.41, 3.46)

Exacerbations and Treatment Response

- ITT sample: Mean PCL reduction of 15.28 points (*d*=1.29)
- Mean post-treatment PCL-IV
  - No Exacerbations=39.0 (18.4)
  - Exacerbations=45.22 (15.69)
- Number and presence of exacerbations did not predict treatment response (PCL<50 at post-treatment), χ^2 (4)< 3.97, p=.41
- 66% of people who experienced an exacerbation had a PCL below 50 at session 12.

Worsening of Symptoms?

- 5.4% reported worse PCLs scores at session 12 compared to session 1 (worse > 5.71 symptom increase).
- Number of symptom exacerbations in early sessions (sessions 1 – 5) did not predict overall worsening; OR = 1.22 (.40, 3.68)
- Effects on Symptom Trajectories
  - Using piece-wise latent growth curve model (sessions 1 – 5 vs 5 – 12)
  - Number of exacerbations in early sessions did not predict linear slope for PCL scores during session 6 – 12; standardized effect = -.27, p = .19
  - Standardized effect estimates for symptom change during sessions 1-5 = -.47 and during sessions 5 – 12 = -.67 (both sig)
- Consultation Condition did not predict significant differences for symptom change nor for number of exacerbations for sessions 1 – 5.

Conclusions

- Exacerbations may be common in practice
- They don’t mean people won’t improve
- We still know little about what predicts them
- May be related to decreased avoidance or to non-treatment related factors

Clinical Considerations

- Important to differentiate between therapies that produce symptom increases in the short term and those that are truly harmful
- Potential drawbacks of not engaging in trauma-focused treatments
- We can normalize symptom increases but reassure that clients that people *still get better*

Questions? Comments?

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Reference:

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