Spotlight on Women's Health Cyberseminar Series

Sponsored by the VA Women's Health Research Network

IMPROVING MENTAL HEALTH TREATMENT ENGAGEMENT AMONG WOMEN VETERANS WITH SEXUAL TRAUMA HISTORIES: FINDINGS FROM TWO RANDOMIZED CLINICAL TRIALS

Suzannah Creech, PhD and Ursula Kelly, PhD, APRN, FAANP, FAAN

Thursday, February, 17 1:00pm - 2:00 ET

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VISN 17 CENTER OF EXCELLENCE for Research on Returning War Veterans

The University of Texas at Austin Psychiatry Dell Medical School

OBJECTIVES

- Provide background and rationale for the **Safe and Healthy Experiences** (SHE; PI: Creech) and **Project Stress-Less** (PI: Kelly) studies.
- Describe study methods and results
- Discuss implications and next steps

PREVALENCE OF SEXUAL ASSAULT AMONG WOMEN

21%

24%

38% MST

- ✓ **Bisexual women (1 in 2)**
- ✓ **Racial/ethnic minority women**

Less likely to disclose

CONSEQUENCES OF SEXUAL ASSAULT

- Include PTSD, alcohol misuse[1] and repeat exposure to violence including intimate partner violence[2]
- Include stigma, shame, self blame, "rape-myths" that inhibit disclosure and care seeking[3]
  - Can be enhanced for some women veterans at VA due to military context of assault, care environment including persons like perpetrator
  - Can intersect with experiences of institutional racism, homophobia[4,] betrayal
- Population economic burden of sexual assault 3.1 trillion over lifetime of survivors[5] and substantial economic and intangible costs to survivors and their offspring[6]

1. Dworkin ER. 2020; 2. Tjaden P, Thoennes N. 2006: 3. Kennedy AC, Prock KA. 2018;Edwards KM, Turchik JA, Dardis CM, Reynolds N, Gidycz CA. 2011; 4. Bryant-Davis T, Chung H, Tillman S. 2009; 5. Peterson C, DeGue S, Florence C, Lokey CN. 2017; 6. Loya RM. 2015; Post LA, Mezey NJ, Maxwell C, Wibert WN. 2002; Guedes A, Bott S, Garcia-Moreno C, Colombini M. 2016

MST AND TREATMENT ENGAGEMENT

- Underutilization, attrition and delayed care remain concerns for a subset of women veterans with sexual assault histories
- Stigma[1] , distrust, concerns about provider compassion, privacy, shame, continuity of care[2,] and institutional betrayal[3] barriers to seeking care including mental health care.
- 2.1 times greater odds of delaying or forgoing care[4] if MSA history.
- MST was associated with current PTSD or depression symptoms, but not VHA mental health service use.[5]
- Mental health literacy, shame and stigma can inhibit those with sexual assault from seeking mental health treatment[6]
- Clear need to address barriers to initiation and utilization of mental health care associated with assault history

1.Altarum Institute. 2015; 2. Monteith LL, Bahraini NH, Gerber HR, et al. 2020; 3. Kelly, U. (2021). 4. Washington DL, Bean-Mayberry B, Riopelle D, Yano EM. 2011; 5. Calhoun PS, Schry AR, Dennis PA, 2018; 6. Evans EA, Tennenbaum DL, Washington DL, Hamilton AB. 2019; Koblinsky SA, Schroeder AL, Leslie LA. 2017; Mattocks K, Casares J, Brown A, et al. ; Hamilton AB, Frayne SM, Cordasco KM, Washington DL 2013

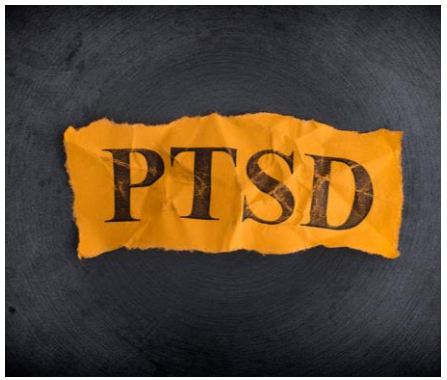
PTSD: TREATMENT & ENGAGEMENT

Trauma-focused therapies

49% - 76%

~ 50%

30% - 40%



COMPLEMENTARY AND INTEGRATIVE HEALTH (CIH) IN VA

THE SHE TEAM

Suzannah Creech, PhD

SHE:

- Central Texas VA women health providers and mental health clinicians.
- Brown university and Providence VA
- Co-Investigators: Caron Zlotnick, Tracie Shea, Lindsay Orchowski, Carey Pulverman, Golfo Tzilos, Chris Kahler
- Staff: Katy Roe, Molly Shin, Morgan Bennett, Laura Osbourne

- **Hundreds of women Veterans who participated in the studies and/or provided input and inspiration.**

DISCLOSURES AND ACKNOWLEDGEMENTS

Funding Statements
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Acknowledgements
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Disclaimer
The contents of this article do not represent the views of the U.S. Department of Veterans Affairs or the United States Government. All authors approved this manuscript and this submission.

Conflicts of Interest
The authors report no conflicts of interest.

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The University of Texas at Austin
Psychiatry
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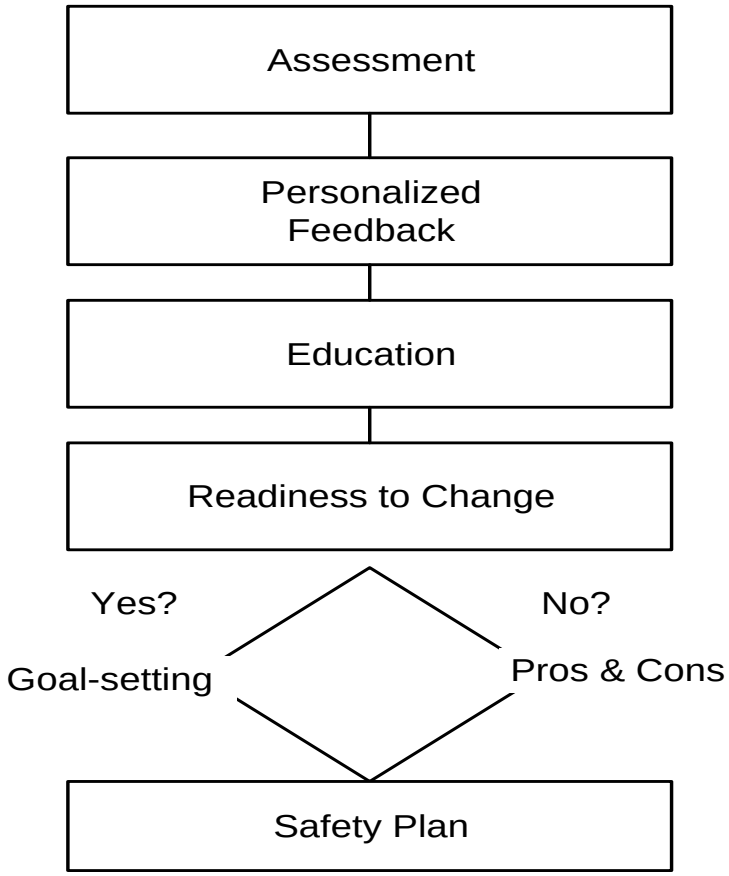
COMPUTERIZED INTERVENTION IN PRIMARY CARE FOR WOMEN WITH SEXUAL ASSAULT HISTORIES AND PSYCHOSOCIAL HEALTH RISKS

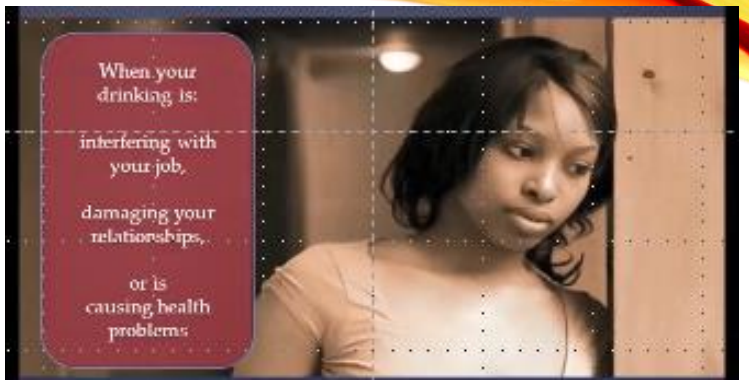
- We developed **Safe and Healthy Experiences (SHE)** to address barriers to treatment seeking for lifetime sexual assault and related health concerns of PTSD, hazardous drinking, and IPV

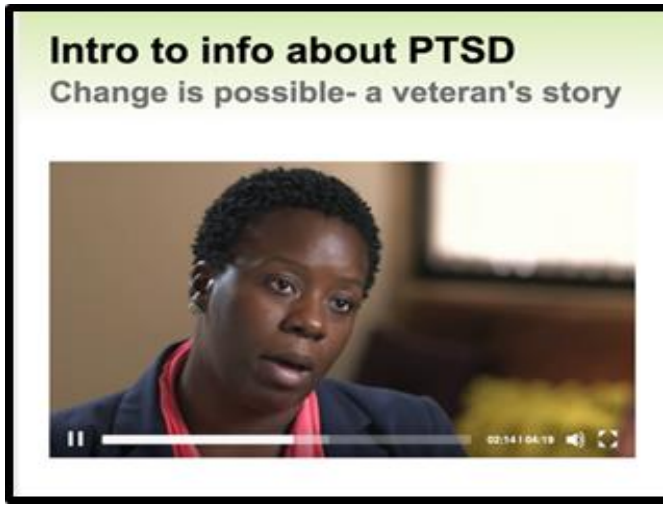
- "I am going to do three things. First, I'm going to share a little information with you about PTSD, or posttraumatic stress disorder, and steps you can take to be healthy.
- Second, you can tell me what you think, and what you want to do.
- And third, we can talk about how I might be able to help with your goals."



SHE COMPONENTS

Informational Videos	Empowerment videos depicting real women Veterans or actors who tell stories of how alcohol use, PTSD or IPV affected their lives, how they were able to reduce alcohol use, IPV, or PTSD and the positive outcomes of these changes.
Motivational Strategies	The narrator elicits behavior change by encouraging participants to explore and resolve ambivalence. e.g., pros and cons of taking steps towards change.
Personalized Safety Plan	Participants are offered tailored advice/information to reduce risk.
Goal setting	Participants are asked to select one goal for reducing their risk of alcohol use/PTSD /IPV.
Referrals	Participants are provided IPV, alcohol use and VA primary care resources. Importance of referrals emphasized.
Summary	Handouts, empowerment messages evoking video content, and referral resources. They are offered assistance contacting a program of their choice.





RCT AIMS AND DESIGN

- RCT of SHE compared to a screen and referral only control condition.
- Primary outcomes 1) change in health risks (screening positive for PTSD, IPV, or alcohol misuse); and 2) treatment initiation and utilization. Secondary outcomes: participant satisfaction with the intervention and the software.
- Setting: VA women's primary care clinic. Patients screened and the provided intervention in private room in the clinic on an iPad.
- Inclusion: self-identified female gender, 18-65, history of sexual assault (defined as at least one incident of unwanted lifetime sexual contact), and at least one current psychosocial health risk (PTSD, hazardous drinking, and/or IPV)
- Measures: PCL5, AUDIT, Composite Abuse Scale, Treatment Services Review, Chart review, Client Satisfaction Ques.

SAMPLE DEMOGRAPHICS

- N = 153
- Participant ages ranged from 24 to 65 with a mean of 43.55 (*SD* = 10.10).
- 10% lesbian or bisexual
- 15% Hispanic; 47.7% African American; 6.5% Biracial; 1.3% Asian, 1.3% Native American/Alaska Native; 7% Hawaiian/Pacific Islander; 35.3% White
- Mean scores at baseline for PTSD ~50, AUDIT ~5.69, IPV ~13

Sexual Trauma History	*N*	%
Unwanted sexual contact childhood	89	58.2
Any adulthood sexual assault	118	100
Adulthood sexual assault	11	7.2
Sexual assault in military	107	69.9

FEASIBILITY & ACCEPTABILITY

- Follow-up completion rate at 4-months was between 85-89%,
- Participants who received SHE reported high satisfaction ratings with the software and the treatment content.
- Therefore the study procedures were determined to be acceptable and feasible for study in a larger sample.

Mean Ratings on Satisfaction with the SHE Intervention	**M (SD)**
Satisfaction with CIAS Software Scale (SCSS)[a]	
How much did you like it?	4.39 (.84)
How interesting was it?	4.33 (.99)
Was it easy to use?	4.84 (.45)
How understandable was it?	4.82 (.46)
How respectful of you was it?	4.88 (.35)
How annoyed by it were you?*	3.52 (1.40)
How interested are you in using the software again in the future?	4.14 (1.06)
Ratings on the Client Satisfaction Questionnaire (CSQ)[b]	
How would you rate the quality of the service you received?	3.63 (.49)
Did you get the kind of services you wanted?	3.41 (.54)
To what extent has our program met your needs?	2.95 (.79)
If a friend were in need of similar help, would you recommend our program?	3.41 (.54)
How satisfied are you with the amount of help you received?	3.21 (.74)
Have the services you received helped you to deal more effectively with your problems?	3.07 (.73)
In an overall, general sense, how satisfied are you with the services you received?	3.26 (.69)
If you were to seek help again, would you come back to our program?	3.31 (.60)

INTENT TO TREAT: PRIMARY OUTCOMES

- IPV and symptom scores: There was no effect of the SHE intervention on scale scores or clinical cut-off (yes/no) for PTSD, alcohol misuse or IPV reported during the 4 month follow-up (all p's > .05).
- Mental health treatment: At both two and four-month follow-ups, women in the SHE group had higher rates of treatment initiation and utilization as measured by chart review [X^2 (1, n = 153) = 4.38, p = .036, r_s = .16], and self-report [X^2 (1, n = 130) = 5.89, p = .015, r_s = .21]
- Adjusting for baseline service use, receiving the SHE intervention compared to control was also associated with greater odds of being classified in a higher level of treatment receipt, odds ratio [OR] = 2.17, 95% CI [1.11, 4.24], p = .02.

RCT RESULTS TREATMENT UTILIZATION

	Control			
Treatment Frequency	Chart review baseline, n/N (%)	Chart review follow-up, n/N (%)	Treatment Services Review baseline, n/N (%)	Treatment Services Review follow-up, n/N (%)
Never	29/77 (37.66)	22/77 (28.57)	22/76 (28.95)	19/67 (28.36)
Up to once monthly	28/77 (36.36)	26/77 (33.77)	25/76 (32.89)	19/67 (28.36)
>monthly up to weekly	16/77 (20.78)	23/77 (29.87)	22/76 (28.95)	23/67 (34.33)
More than weekly	4/77 (5.19)	6/77 (7.79)	7/76 (9.21)	6/67 (8.96)
	Intervention			
Never	25/76 (32.89)	10/76 (13.16)	17/76 (22.37)	10/63 (15.87)
Up to once monthly	29/76 (38.16)	31/76 (40.79)	23/76 (30.26)	15/63 (23.81)
>monthly up to weekly	18/76 (23.68)	23/76 (30.26)	26/76 (34.21)	24/63 (38.10)
More than weekly	4/76 (5.26)	12/76 (15.79)	10/76 (13.16)	14/63 (22.22)

COMPLETER ANALYSES

Completer Analyses of Impact of Treatment Utilization Group on Change in Clinical Outcomes				
PTSD symptoms				
Treatment over the follow-up	Baseline	Follow-up	Change	Main effect
Zero/less than monthly	44.52 (17.65)	40.57 (20.00)	3.95	F 1,98 = 5.28, *p* = .025
Monthly/weekly	54.87 (13.90)	45.28 (16.87)	9.59	
Alcohol misuse				
	Baseline	Follow-up	Change	Main effect
Zero/less than monthly	7.17 (3.22)	6.22 (3.04)	.95	F 1, 34 = 1.89, *p* = .17
Monthly/weekly	7.56 (3.68)	4.11 (2.84)	3.45	
Partner Violence				
	Baseline	Follow-up	Change	Main effect
Zero/less than monthly	9.16 (10.61)	5.70 (11.0)	3.46	F 1,71 = 6.51, *p* = .01
Monthly/weekly	23.96 (24.05)	6.53 (11.42)	17.53	

- Those who used more treatment over the follow-up period evidence greater reductions in PTSD and experiences of IPV from baseline to post-treatment.

SUMMARY

- Results demonstrate initial feasibility and acceptability of SHE
- Promising results for mental health treatment utilization and potentially for clinical change in a highly diverse sample of women veterans
- Findings lend support to the growing evidence that digital health technologies can overcome both provider and patient barriers to addressing highly sensitive and stigmatized conditions without adding cost and in a time-efficient manner.

LIMITATIONS

- Powered for medium effect size whereas behavioral interventions tend to have a small effect size
- Underpowered to test mediation models
- Short follow-up
- Lack of specificity in our measurement of the type of mental health treatment received

FUTURE DIRECTIONS

- Multi-site hybrid type I trial with longer follow-ups and a larger sample to test mediation models for clinical change
- Measures change to align with clinical reminders
- Online delivery
- Expansion of modules and to active duty and other populations
- Expansion to men

PUBLICATIONS

- **Open trial outcomes manuscript**: Creech, S. K., Pulverman, C. S., Shin, M. E., Roe, K. T., Tzilos Wernette, G., Orchowski, L. M., ... & Zlotnick, C. (2021). An open trial to test participant satisfaction with and feasibility of a computerized intervention for women veterans with sexual trauma histories seeking primary care treatment. *Violence against women*, *27*(3-4), 597-614.

  https://tinyurl.com/425yrfk3

- **RCT primary outcomes manuscript:** Creech, S.K., Pulverman, C.S., Kahler, C.W. *et al*. Computerized Intervention in Primary Care for Women Veterans with Sexual Assault Histories and Psychosocial Health Risks: a Randomized Clinical Trial. *J GEN INTERN MED* (2021). https://doi.org/10.1007/s11606-021-06851-0

  https://tinyurl.com/4wwws8bz

IMPLICATIONS

- Digital intervention for stigmatized populations may overcome societal barriers such rape myths and systemic racism that contribute to barriers to treatment.
- Yet investigation of digital interventions in stigmatized and marginalized groups lags.
- Our vision is that SHE will be a model intervention template for screening and intervening to address barriers to treatment engagement for a variety of highly sensitive and highly stigmatized health conditions.
- The ultimate goal is an intervention that is easily scalable and easily integrated into organized VA and military healthcare settings and leverages immediate digital connection to accessible treatment referrals.

THE PROJECT STRESS-LESS TEAM

- Atlanta VAHCS, VAHCS Portland, and VA mental health clinicians.
- Dave Emerson, TCTSY facilitators, the Center for Trauma and Embodiment
- Co-Investigators: Melinda Higgins, Amit Shah, Meghna Patel, Tavi Ioachimescu, Kelly Skelton, Bekh Bradley, Belle Zacarri, Jennifer Loftis
- Terri Haywood, Project Manager
- Numerous study staff, nursing and medical students, and volunteers who contributed to the study
- The VA Women's Health PBRN who served as multi-site consultants
- **Hundreds of women Veterans who participated in the study and/or provided input and inspiration.**

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Disclaimer
The contents of this article do not represent the views of the U.S. Department of Veterans Affairs or the United States Government. All authors approved this manuscript and this submission.

Conflicts of Interest
The authors report no conflicts of interest.

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PROJECT STRESS-LESS

STUDY AIMS

- **To evaluate the effectiveness of Trauma Center Trauma Sensitive Yoga (TCTSY) compared to gold standard psychotherapy (CPT) among women Veterans who experienced MST**

Primary Aim 1	in reducing symptoms of PTSD, chronic pain, and insomnia
Primary Aim 2	in improving quality of life and social functioning
Primary Aim 3	on biological (cytokines) and psychophysiological markers (mechanisms of action of yoga for PTSD)

- Today, I am presenting results related to PTSD and depression outcomes, study attrition and treatment completion.

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METHODS

- **Design:** initially single-site 4-year RCT; added Portland VAHCS in year 4 with project mod; THEN
  - COVID-19 related shut-downs one month after enrollment started in PDX.
- **Sample:**
  - Women veterans with current PTSD related to MST enrolled at Atlanta or Portland Healthcare System. (N=201)
    - Atlanta (n=103) (9 cohorts)
    - Portland (n=28) (1 cohort) virtual study procedures and interventions
- **Data Collection:**
  - Timepoints: Baseline, mid-intervention, 2-weeks and 3-months post-intervention
  - Phase 2: invited study participants for quantitative follow up; subset of qualitative interviews
- **Interventions:** group delivery, weekly, in person then virtual during COVID-19 pandemic
- **Measures**: CAPS-5, PCL-5, BDI-II, MINI for DSM-5
- **Data Analysis:** Multilevel linear models (MLM) were used to model the longitudinal measures to compare changes over time between the two groups

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INTERVENTIONS

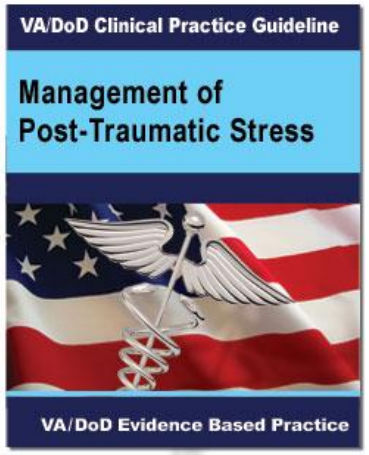
Trauma Center Trauma Sensitive Yoga (TCTSY)[1]

- 10 weeks; 60-minute sessions
- 2 TCTSY certified facilitators
- Hatha Style Yoga
  - Components: physical forms, controlled breathing, mindfulness (interoception)

Trauma Center Trauma Sensitive Yoga, www.traumasensitiveyoga.com

Cognitive Processing Therapy (CPT)

- 12 weeks; 90-minute sessions
- 2 VA clinicians
  - Certified in CPT
- Developed within VA
- CBT-based therapy
  - Talk therapy

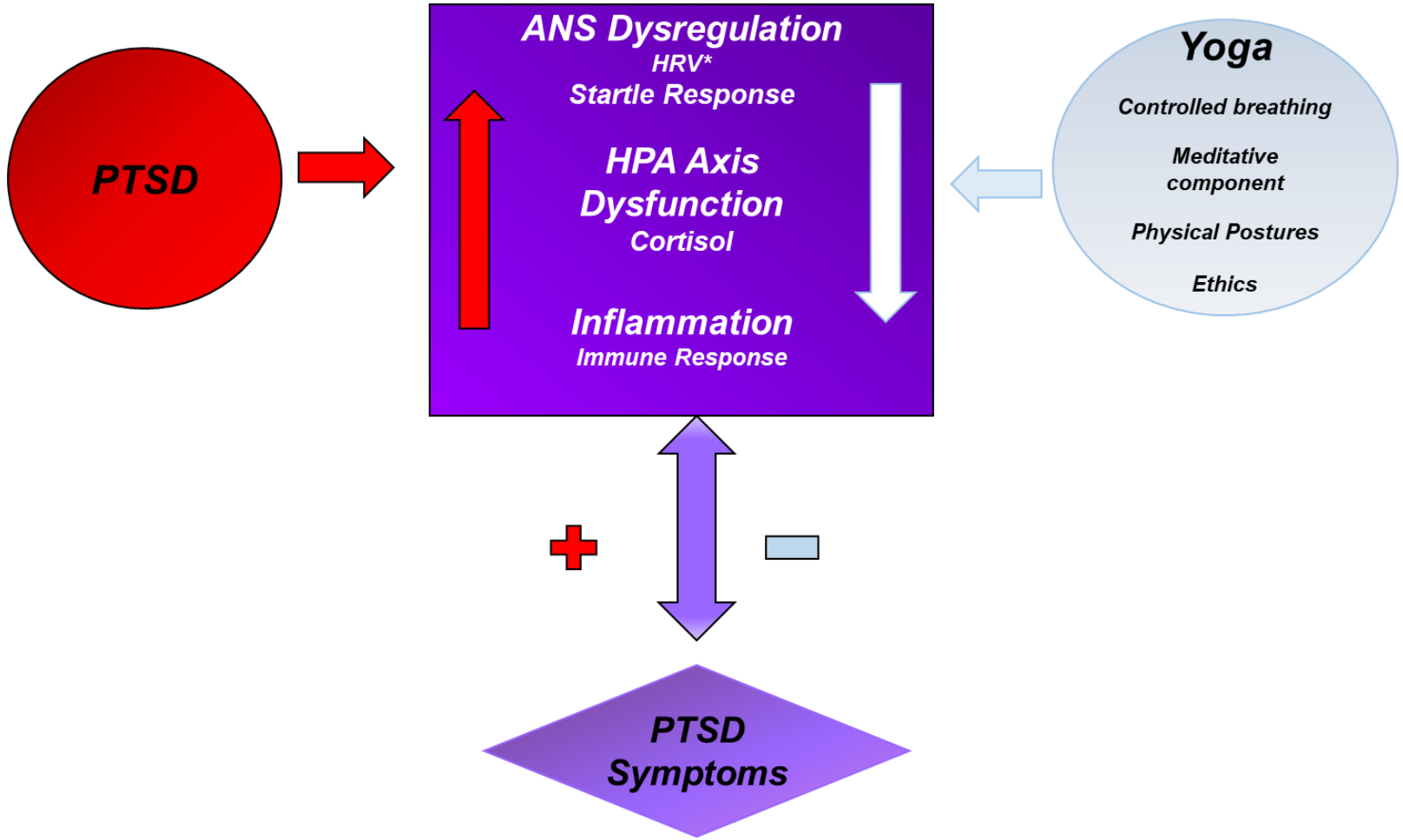


https://www.healthquality.va.gov/guidelines/MH/ptsd/

WHY YOGA?

Trauma, the Brain and Body

Psychoneuro-immunology (PNI)



ANS=autonomic nervous system; HPA=hypothalamic-pituitary-adrenal; HRV=heart rate variability

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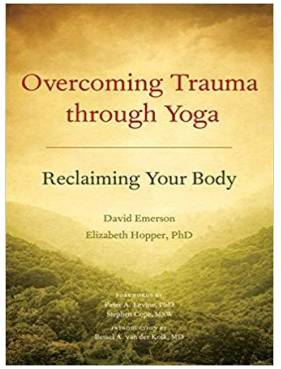
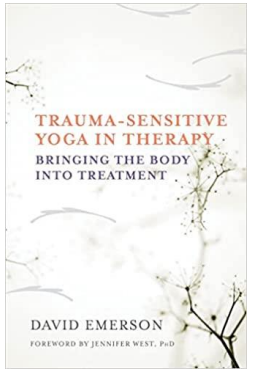
WHY TCTSY?





Clinical intervention for complex trauma or chronic, treatment-resistant PTSD

TCTSY is Theory-Driven

- Trauma theory, attachment theory, neuroscience, Hatha yoga
- Trauma happens to the body first
- Body to brain rather than brain to body

Themes/Therapeutic Goals of TCTSY

- Interoception (internal experience)
- Non-coercion
- Present moment experience
- Practice making choices
- Taking effective action
- Creating safety within the body

Emerson, D. (2015). Trauma-Sensitive Yoga in Therapy: Bringing the Body into Treatment. New York: W.W. Norton and Company, Inc.
Emerson, D., & Hopper, E. (2012). Overcoming trauma through yoga: Reclaiming your body. North Atlantic Books.

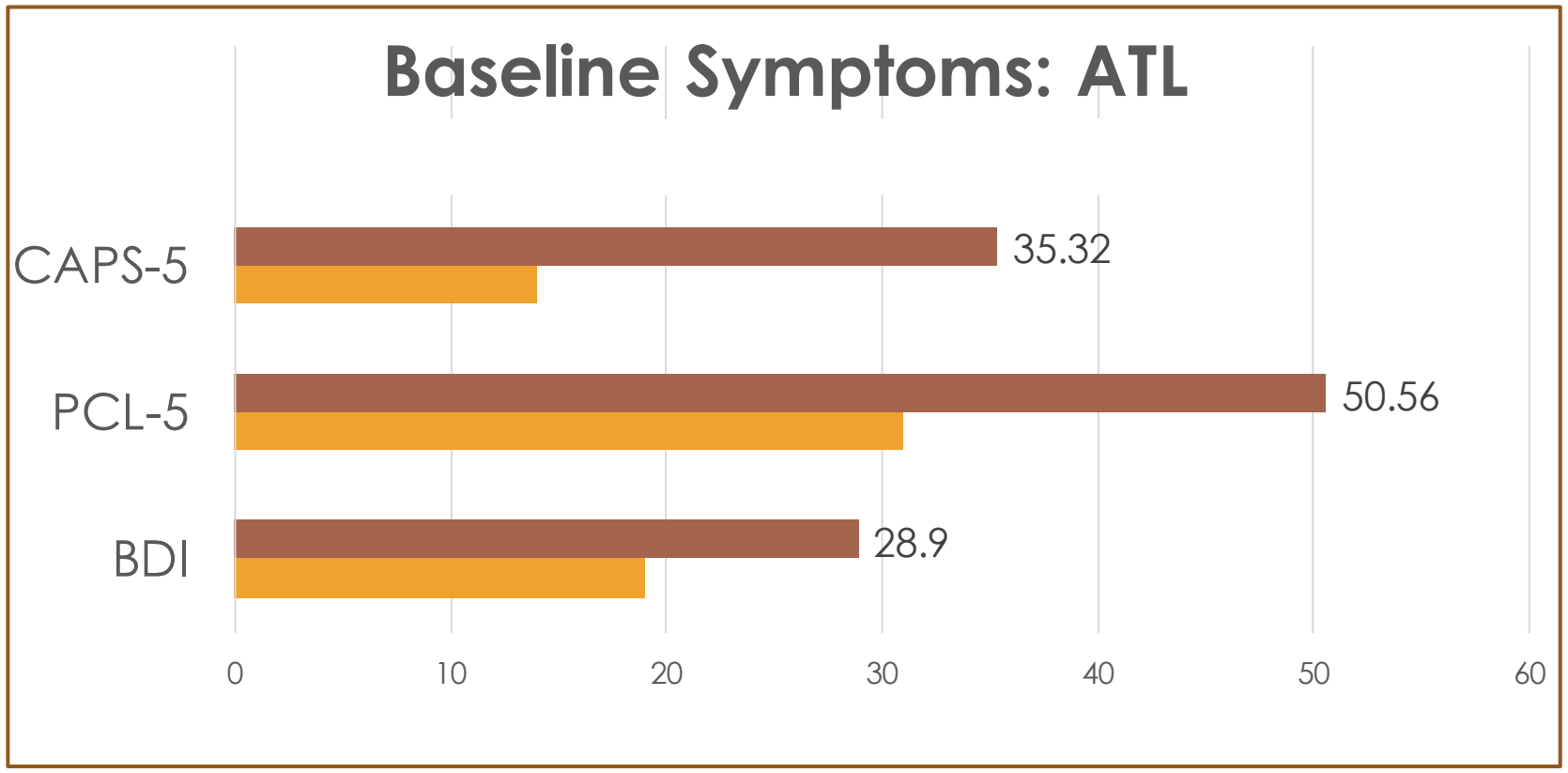
RESULTS: SAMPLE DESCRIPTION (INTENT TO TREAT)

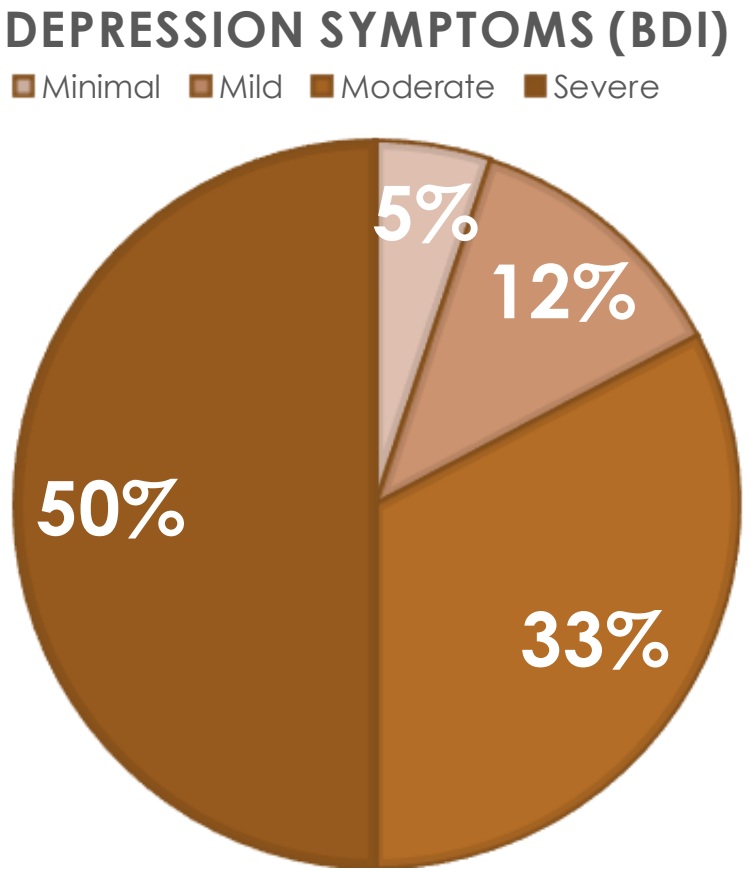
*** p ≤ 0.001
* p = 0.014

Demographics Characteristics by Site

	Pacific Northwest (N=28)	Southeast (N=103)
	Mean (SD)	*Mean (SD)*
Age	47.5 (11.7)	48.43 (11.2)
Demographic	n (%)	n (%)
Education		
12 years (high school)	2 (7.1)	16 (15.5)
13-16 years (college)	19 (67.9)	80 (77.7)
17-20 years (college)	7 (25)	7 (6.8)
Race		
Black, AA	2 (7.1)	**93 (90.3)*** **
Asian	-	1 (1.0)
White	**24 (85.8)*** **	1 (1.0)
Mixed	1 (3.6)	7 (6.8)
American Indian/Alaska Nat.	1 (3.6)	
Relationship Status		
Non-partnered	15 (53.6)	72 (69.9)
Married/Partnered	13 (46.4)	31 (30.1)
Household Monthly Income		
Less than $2K/mo	5 (17.9)	**44 (43.1)***
$2K/mo or more	**23 (82.1)***	58 (56.9)
Employment		
Less than full-time	21 (75)	71 (68.9)
Full-time	7 (25)	32 (31.1)

RESULTS


Baseline Symptoms: ATL
CAPS-5
PCL-5
BDI
35.32
50.56
28.9
0
10
20
30
40
50
60


DEPRESSION SYMPTOMS (BDI)
Minimal
Mild
Moderate
Severe
5%
12%
50%
33%

SUICIDALITY : BASELINE CHARACTERISTICS

n=103	YES	Suicidality Rating (for YES)	N (%)
SUICIDALITY (PAST MONTH)	n=33 **32%**		15 **(45.5)**
			5 **(15.2)**
			13 **(39.4)**
Suicide Attempt (Lifetime)	n= 25 **24.3%**		

ATTRITION in ATL

ATTRITION FROM SCREENING TO BASELINE VISIT

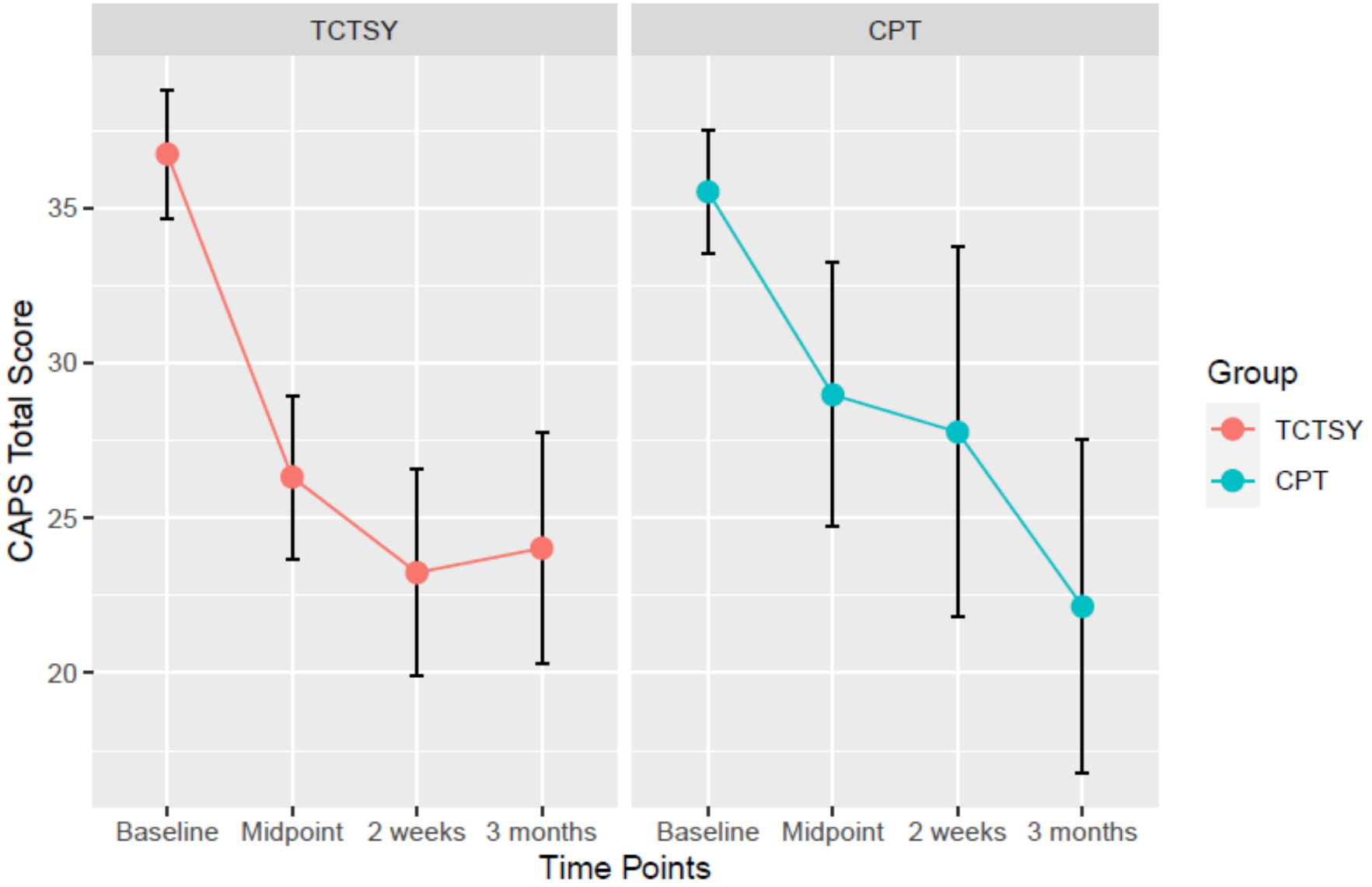
32%

AFTER RANDOMIZATION PRIOR TO FIRST INTERVENTION SESSION (ATL)

TCTSY: 10%
CPT: 20%

PTSD SYMPTOMS

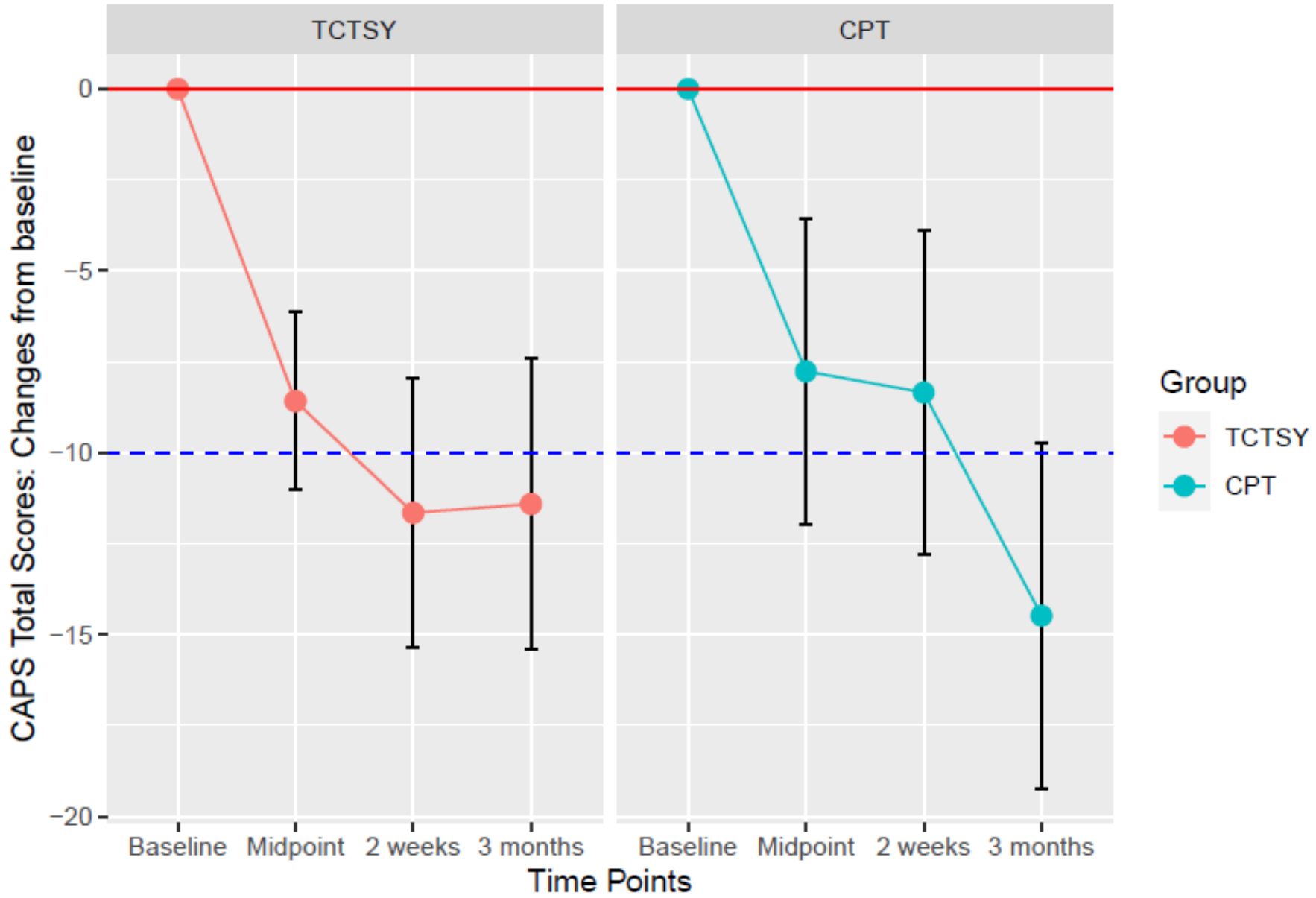
CAPS-5 TOTAL SCORES GROUP CHANGES OVER TIME (+/- 95% CI)



- Time is significant ($p < .001$)
  - Both groups significantly decreased over time
- No group effect (no difference between groups at end of study)

PTSD SYMPTOMS

CAPS-5 TOTAL SCORES CHANGES FROM BASELINE OVER TIME BY GROUP (+/- 95% CI)



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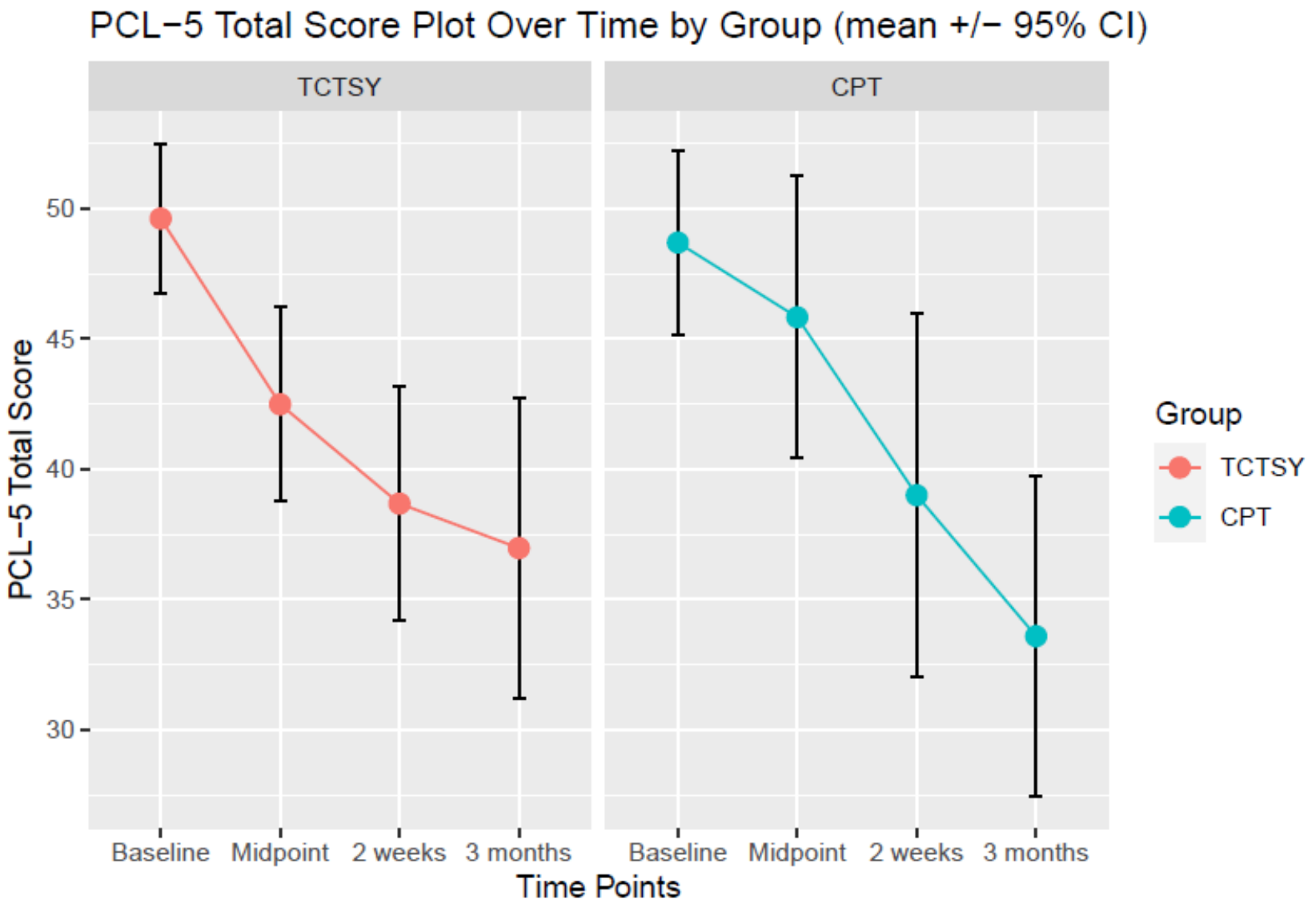
PTSD SYMPTOMS

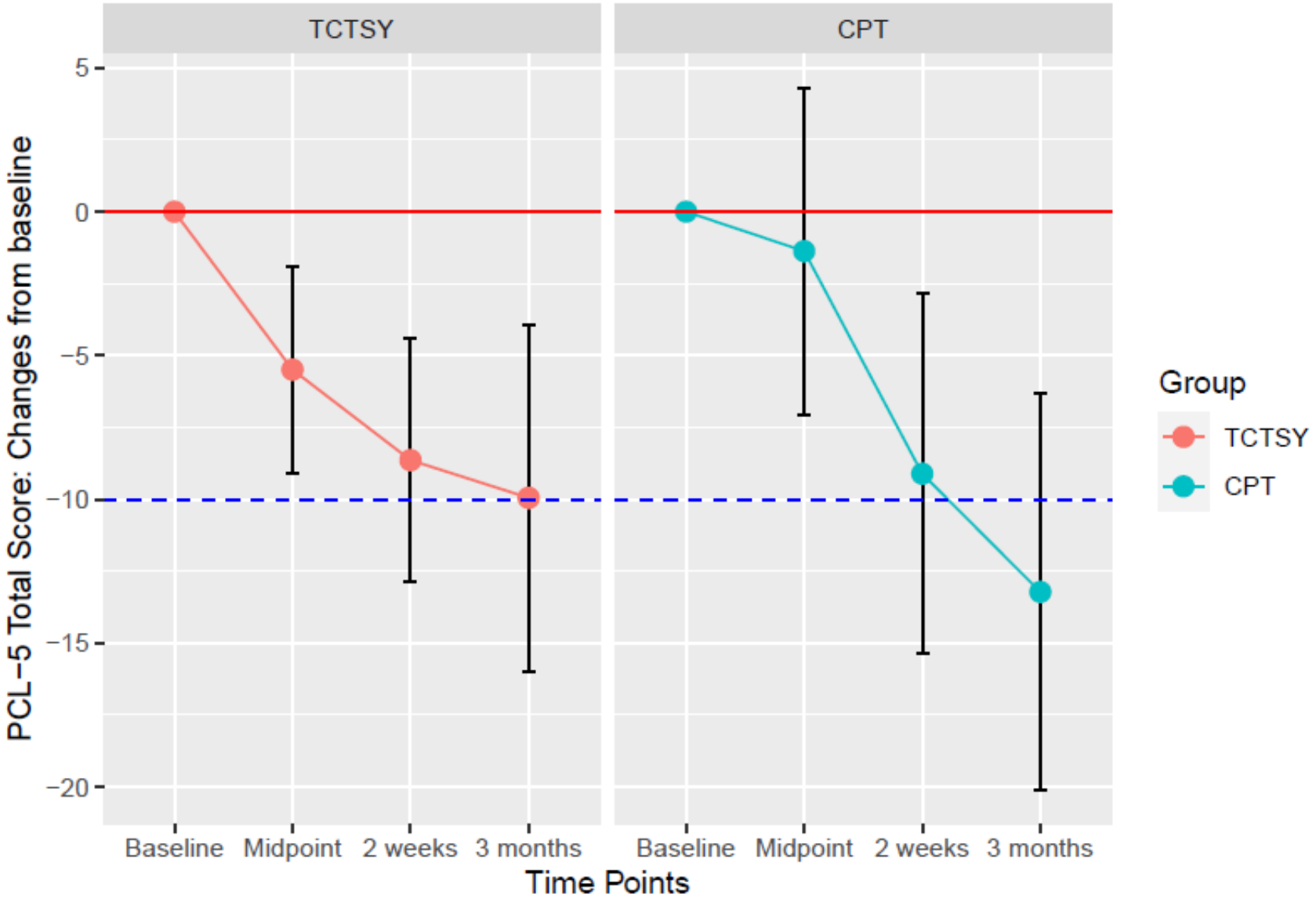
PTSD SYMPTOMS PCL-5 TOTAL SCORE GROUP MEANS OVER TIME



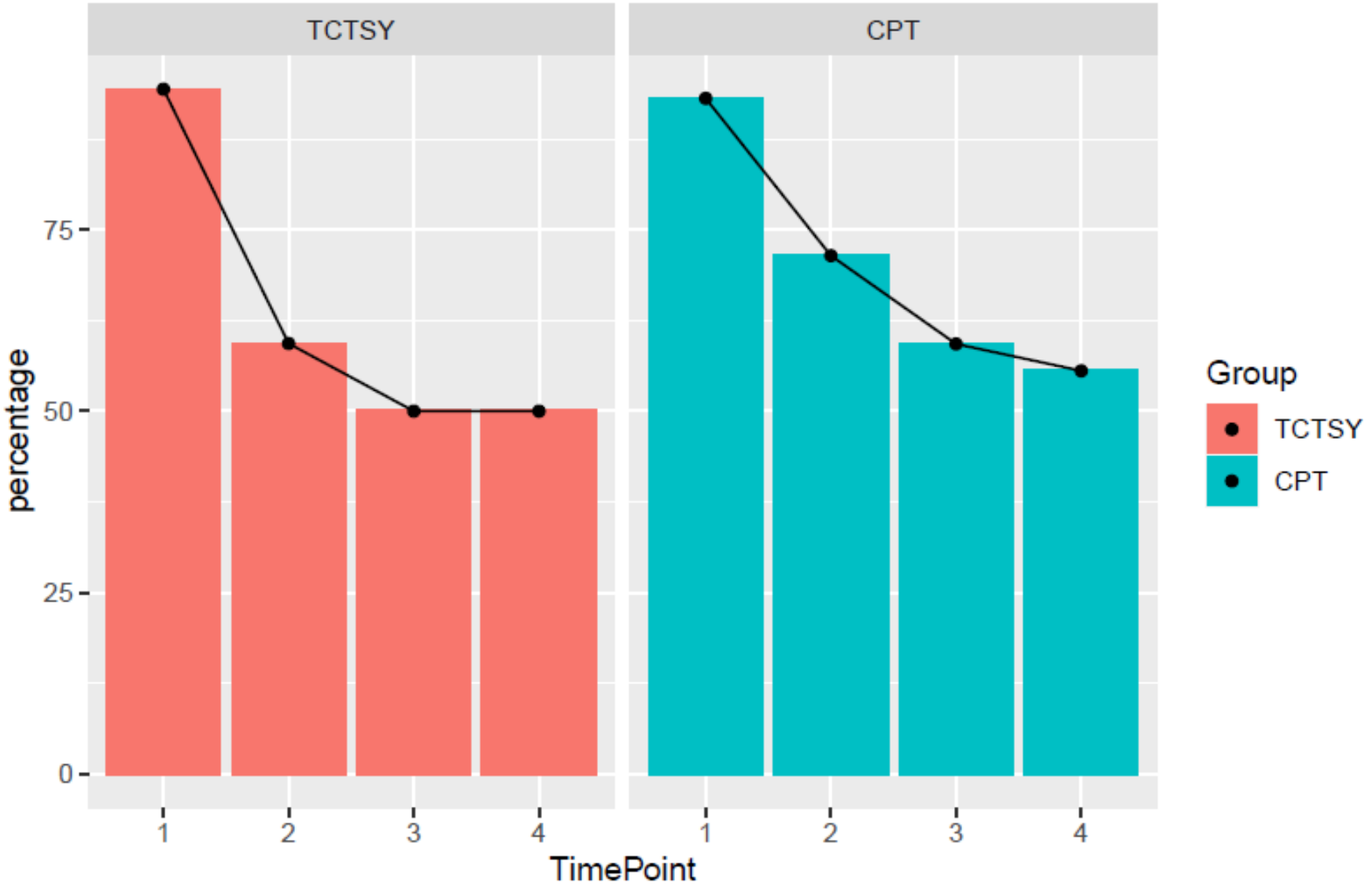
- Time is significant ($p < .001$)
  - Both groups significantly decreased over time
- No group effect (no difference between groups at end of study

PTSD SYMPTOMS

PCL-5
TOTAL SCORES
CHANGE SCORES
OVER TIME BY GROUP
(+/- 95% CI)

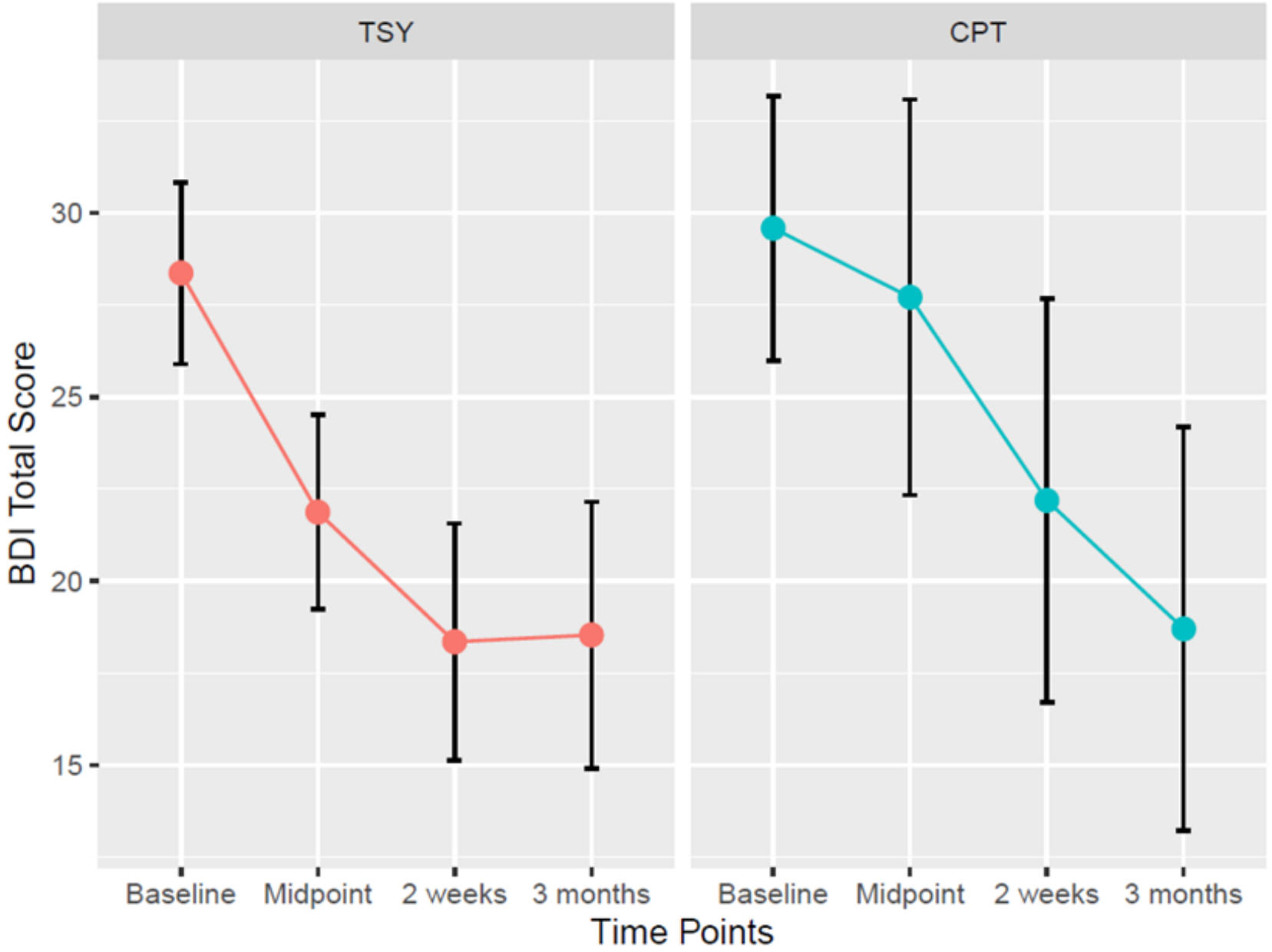


PERCENTAGE MEETING PTSD DX CRITERIA (CAPS-5) BY GROUP OVER TIME



RESULTS: DEPRESSION SYMPTOMS

BDI Mean Scores by Group (+/- 95% CI)



TREATMENT COMPLETION (ATL)

TCTSY: Attendance at ≥ 7/10 sessions

CPT: Attendance at ≥ 8/12 sessions

TCTSY: 60%

CPT: 38%

LIMITATIONS

- Attrition in the study was high (study procedures and intervention sessions), similar to what we see in clinical practice.

- Neither intervention was effective for everyone.

- **The last Atlanta cohort and the one PDX cohort occurred during the first few months of the COVID-10 pandemic and in the context of the political election, the racial justice movement, and unprecedented climate change events.**

DISCUSSION

- **TCTSY resulted in equivalent improvement in PTSD symptoms as CPT 3-mos post-intervention.**

- **TCTSY had higher retention than CPT (90% v. 80%) following randomization.**
  - Neither was universally preferred by study participants at randomization.

- **TCTSY had a 22% higher treatment completion rate than CPT.**
- Symptom trajectories varied:
  - TCTSY had earlier symptom improvement than CPT, then levelled off.
  - CPT had slower symptom improvement that continued at all time points.
  - Neither was sufficient for all individuals in treatment outcomes.

- **Co-occurring depression symptoms improved significantly in both groups.**

IMPLICATIONS

- TCTSY is an additional option for treatment of PTSD related to sexual trauma beyond current EBTs.
- Engagement and treatment completion was higher in TCTSY than CPT.
- Having an additional evidence-based option provides Veterans' choice in treatments
  - Non-cognitively based; bottom up versus top down approach.
- This choice might lead to increased initial and sustained engagement in treatment.

FUTURE DIRECTIONS

- Multi-site hybrid type 2 trial to determine how to scale up TCTSY as an intervention within the VA and continue to evaluate effectiveness.
- RCT to examine TCTSY as a precursor or adjunct to trauma-focused therapy.
- TCTSY for PTSD related to MST for men Veterans and non-VA using Veterans.

PUBLICATIONS

Systematic Review of Objective Markers of Yoga's Poential Mechanisms of Action:

Kelly, U. A., Evans, D. D., Baker, H., & Noggle Taylor, J. (2018). Determining psychoneuroimmunologic markers of Yoga as an intervention for persons diagnosed with PTSD: A systematic review. *Biological Research for Nursing*, *20*(3), 343–351. https://doi.org/10.1177/1099800417739152

RCT Interim Results for Primary Site:

Kelly, U., Haywood, T., Segell, E., & Higgins, M. (2021). Trauma-sensitive yoga for PTSD in women Veterans who experienced military sexual trauma: Interim results from a randomized-controlled trial. *Journal of Alternative and Complementary Medicine, 27*(S1): pp. 45-59. doi.org/10.1089/acm.2020.0417

https://www.liebertpub.com/doi/10.1089/acm.2020.0417?utm_source=Adestra&utm_medium=email&utm_term=&utm_content=ReadMore-&utm_campaign=JICM+FP+January+12+2022 (Open access link)

Virtual Protocol pivot due to COVID:

Zaccari, B., Loftis, J., Haywood, T., Hubbard, K, Clark, J., & Kelly, U. Synchronous Telehealth Yoga and Cognitive Processing Group Therapies for Women Veterans with PTSD: A Multisite Randomized Controlled Trial Adapted for COVID-19. *Telemedicine and e-Health (in press)*.

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Thank you!

Questions and comments?

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