

Using Explicit Case Formulation to Improve Cognitive Processing Therapy for PTSD

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We investigated the utility of explicit case formulation (CF) within Cognitive Processing Therapy (CPT) for individuals with posttraumatic stress disorder (PTSD). An uncontrolled pre-posttreatment design was used. Participants attended 12–16 weekly sessions of CPT with explicit CF, where CF guided treatment length and treatment components. Treatment was completed by 19 of the 23 participants who started therapy. Results revealed significant reductions in PTSD and depression severity as well as unhelpful PTSD-related beliefs from pre- to posttreatment (d s between 1.10–1.92) and treatment gains were maintained at 3-month follow-up. Of the participants available at posttreatment for assessment, 69% ($n = 11/16$) met good end-state functioning for PTSD and 62% ($n = 8/13$) did so at follow-up. Finally, 72% ($n = 13/18$) of those interviewed at posttreatment no longer met criteria for PTSD and this was found for 93% of those assessed at follow-up ($n = 14/15$). Treatment, and CF in particular, was found to be acceptable by participants. Explicit case formulation did not interfere with positive outcomes of Cognitive Processing Therapy for PTSD. Further clinical implications and future directions for research are discussed.

Keywords: case conceptualization; cognitive processing therapy; CPT; PTSD

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TRAUMA-FOCUSED COGNITIVE-BEHAVIORAL THERAPY (CBT) is one of the treatments of choice for posttraumatic stress disorder (PTSD) (ACPMH, 2013). Although PTSD treatments are effective, with CBT and other methods resulting in loss of diagnosis in sufferers of between 26%–66% (Bradley, Greene, Russ, Dutra, & Westen, 2005; Cusack et al., 2016), not everyone responds. Across multiple therapy types, meta-analysis shows that 66% of individuals did not show clinically meaningful improvement (Bradley et al., 2005). Another challenge is that despite a number of well-researched PTSD treatment protocols being available to clinicians, uptake continues to be modest even when supported by large-scale dissemination initiatives (e.g., Couineau et al., 2016; Rosen et al., 2016). Barriers identified in the field a number of years ago, for example, the perception that manualized therapy is inflexible or does not address real-world clients and their comorbidities (Becker, Zayfert, & Anderson, 2004), remain (e.g., Cook, Dinnen, Simiola, Thompson, & Schnurr, 2014). We report on an open trial that tested the efficacy of an empirically supported manualized trauma-focused cognitive-behavioral treatment, Cognitive Processing Therapy (CPT), that incorporated explicit use of case formulation (CF). CPT has been subject to more than 10 randomized trials and a number of effectiveness or observational studies (see Tran, Moulton, Santesso, & Rabb, 2016). The goal of the study was to examine whether CF would assist in flexible treatment delivery and address the multiple needs and challenges to good outcomes in complex clients, while at the same time not interfering with CPT's established efficacy.

CF involves the combination of psychological theory and client experience to provide a meaningful description and explanation of the client's presenting issues, and assists both the client and therapist in

identifying targets for intervention (Dudley, Kuyken, & Padesky, 2011). CF is argued to be critical for good clinical practice as it promotes tailoring psychological treatment to enhance treatment outcomes (Tarrrier & Johnson, 2006). Although manualized CBT protocols are typically individualized implicitly (e.g., by targeting a client's specific thoughts and behaviors), *explicit* CF that actively involves the client is not always carried out in the context of manualized CBT protocols.

CF is certainly used in existing PTSD treatments, for example in Ehlers and Clark's Cognitive Therapy for PTSD (Ehlers, Clark, Hackmann, McManus, & Fennell, 2005), and mention is made of CF in an integrated PTSD and alcohol disorder treatment protocol (Sannibale et al., 2013). However, to date it is unclear whether the addition of explicit CF in protocol-driven PTSD therapies helps or hinders therapists. In particular, when treatment within a standard protocol is not resulting in the desired outcomes, it is unknown whether judicious deviations from the protocol, informed by CF, can ameliorate challenges and obstacles to set a client back on a trajectory of recovery. It is important to note that in CPT, like any good CBT, a therapist uses CF to a degree and has some flexibility in relation to the use of some of its materials (worksheets). Recently, two nonprotocol, supportive therapy sessions have been allowed to deal with significant crises (e.g., dealing with reexposure to a trauma, other life stressor) based on the work of Galovski et al. (2012). However, explicit CF can provide guidance for therapists in the face of difficulties during therapy when progress is stalled or derailed (Kuyken et al., 2009), something which CPT does not fully leverage at this time. For example, although both the most recent (and past) CPT manuals discuss how to tackle issues of motivation or treatment nonadherence (Resick, Monson, & Chard, 2014, 2017), deviating beyond the protocol by more than several nonsupportive "crisis" sessions is not encouraged. Indeed, the latest manual version recommends terminating CPT if full commitment by the client doesn't seem possible or other therapies might be indicated (e.g., for anger, panic). At this time it is unknown whether more extensive CF and CF-guided deviations might assist in such circumstances.

There are several reasons to believe that a protocol-driven PTSD intervention such as CPT would benefit from inclusion of explicit CF beyond how CF is currently employed within CPT. First, comorbidity is common among PTSD sufferers and although the effects of CPT generalize to other problems (in particular depressive symptoms; Tran et al., 2016), comorbidity can be associated with poorer treatment outcomes following PTSD treat-

ment, including CPT (e.g., Galovski et al., 2016; Lloyd et al., 2014; Nishith, Nixon, & Resick, 2005). Addressing comorbid issues may require the incorporation of other treatment strategies into the primary treatment of PTSD, which can be guided by CF. Second, the use of collaborative CF may accentuate the therapist-client relationship by enabling the client to be even more actively involved in their treatment (e.g., incorporating their strengths, including the client's explanations and solutions for treatment barriers and lack of progress). Research suggests CF improves therapeutic alliance in other disorders such as psychosis and OCD (Nattrass, Kellett, Hardy, & Ricketts, 2014; Pain, Chadwick, & Abba, 2008). Third, as avoidance is a key symptom of PTSD, a number of clients avoid emotions and discussions of their trauma, both potential impediments to progress in therapy, and avoidance has been implicated in dropout (Bryant et al., 2007). In certain cases, the opportunity to introduce nonprotocol techniques to address therapeutic challenges (e.g., motivational interviewing techniques in the face of ambivalence or lack of engagement, substance reduction techniques when substances are being used to numb emotions), would allow therapy "to get back on track" and maximize successful outcome. Fourth, although successful PTSD treatment frequently reduces other problems (e.g., sleep, depression), this is not always the case or residual symptoms remain (Galovski et al., 2016; Lommen et al., 2016; Nixon & Nearmy, 2011; Pruijsma et al., 2016), thus CF that allows these issues to be also targeted is likely to be beneficial. Fifth, lack of treatment acceptability and client engagement are likely contributors to dropout rates in PTSD treatment, with relatively stable estimates placing these figures between 18%–22% on average, although the actual range of individual studies is broad (Bradley et al., 2005; Imel, Laska, Jakupcak & Simpson, 2013; Swift & Greenberg, 2014). If a collaborative CF process promotes client engagement and increases treatment acceptability, this should also result in increased treatment completion and thus better outcomes. Finally, if deviations from the protocol that are informed by CF result in better outcomes, this would not only reduce the perception among clinicians of a protocol's inflexibility but might increase the likelihood of its uptake.

Accordingly, we tested the efficacy of combining CPT with CF (CPT-CF) in an open trial. The current study represented a necessary first step for piloting the efficacy and feasibility of adding CF to CPT before proceeding to a randomized design (e.g., CPT vs. CPT-CF). We predicted that CPT-CF would lead to significant and clinically meaningful reductions in

PTSD symptoms, would result in good end-state functioning for clients, and that clients would report treatment, and case formulation specifically, helpful. Although these hypotheses lay in the positive direction, the study enabled examination of whether allowing deviations to the protocol *compromised* outcomes, a potential risk when protocols are not closely followed.

Method

PARTICIPANTS

Participants either self-referred to the study or were referred by other services or professionals. Participants had to meet criteria for full or subthreshold PTSD (subthreshold being 1 symptom short of full criteria¹). Exclusion criteria for the study were: (a) inadequate comprehension of English, (b) moderate to severe traumatic brain injury, (c) uncontrolled psychosis, (d) uncontrolled current substance dependence, (e) already in an active, trauma-focused therapy, (f) significant risk of harm (e.g., in current domestic violence situation) or (g) active suicidality. Fifty participants contacted the researchers and 42 were accepted for assessment. Of these participants, 26 were entered into treatment with 16 meeting exclusion criteria ($n = 9$; did not meet criteria for PTSD diagnosis, with 1 also not adequately comprehending English), not attending assessment ($n = 4$), not completing assessment ($n = 1$) or choosing not to undertake treatment ($n = 2$). Nineteen participants were treatment completers, 4 dropped out (1 due to increased employment, 1 reported trauma work distressing, 2 unknown reasons); 1 did not attend the first therapy session, and 2 were withdrawn due for clinical/exclusion reasons.² Of the 24 participants that were accepted for treatment and not withdrawn, all but 3 met a full diagnosis of PTSD and 20 also met criteria for a mood disorder (including 2 with psychotic features), 9 had generalized anxiety disorder, 10 had agoraphobia, 4 had social phobia, 5 had panic disorder, 2 had an eating disorder and 3 met criteria for a substance use disorder. Participants (17 women and 7 men; mean age = 37.37, $SD = 13.08$; mean years of education = 12.79, $SD = 2.59$; White = 18, Minority = 6) presented with a variety

of index traumas including physical nonsexual assault ($n = 6$), child sexual assault ($n = 5$), adult sexual assault ($n = 3$), motor vehicle or bike accident ($n = 4$), murder of a family member ($n = 1$), plane accident ($n = 1$), earthquake ($n = 1$), witnessing serious injury of a family member ($n = 1$), and house fire ($n = 1$). Average time since the occurrence of index traumas was 13.85 years (ranging: 3 months to 40 years; 50% > 10 years) and 78% of participants had experienced multiple traumatic events, including physical assault (38%), sexual assault (42%) and other trauma (46%). The study was approved by the relevant clinical ethics committee.

MEASURES

The following well-established measures were used. The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Weathers, Blake, et al., 2013) and MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1997, for DSM-IV) were used to determine PTSD status and comorbidity. Interviewers were trained by the first author and practiced by coding prior unrelated assessment tapes before undertaking clinical assessments. This process has resulted in good diagnostic accuracy and reliability in our prior studies using this training method, which has achieved diagnostic agreement of 92%–100% for PTSD and 87%–100% for comorbid disorders (e.g., Angelakis, 2014; Nixon et al., 2016). Limited funding precluded extensive interrater checks in the current study, but a random sample of 6 CAPS-5 tapes (~13% of available tapes) demonstrated a kappa coefficient for overall PTSD diagnosis (CAPS) of 1.00 (100% agreement). The correlation between raters for total CAPS severity scores was .96 ($p = .002$).

Participants completed self-report measures: the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; Weathers, Litz, et al., 2013), the depression subscale from the Depression Anxiety and Stress Scale (DASS-21; Lovibond & Lovibond, 1995), the Post-traumatic Cognitions Inventory (PTCI; Foa, Ehlers, Clark, Tolin, & Orsillo, 1999), and the Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001). Trauma history was assessed with a measure adapted from Resick, Nishith, Weaver, Astin, and Feuer (2002). Therapy-process measures included the Credibility/Expectancy Questionnaire (Devilley & Borkovec, 2000), the Working Alliance Inventory short form (WAI-S; Tracey & Kokotovic, 1989) and a brief Case Formulation Evaluation Questionnaire created for the study which assessed whether the CF process was understandable, logical, acceptable and helpful. In relation to the latter, this measure was administered at Sessions 2 and 6 of therapy and at posttreatment. Participants answered questions asking them to indicate their level of agreement from 1 =

¹ Subthreshold participants were included given subthreshold PTSD is still associated with significant clinical impairment, comorbidity, and persistence of symptoms (Cukor, Wyka, Jayasinghe, & Difede, 2010; Mota et al., 2016), and initial evidence suggests similar trajectories in outcome for subthreshold and full PTSD individuals following CPT (Dickstein, Walter, Schumm, & Chard, 2013).

² Data from the withdrawn participants were not included in subsequent analyses. One participant had an eating disorder, the severity of which was not disclosed at pretreatment. It was accompanied by significant weight loss that had begun prior to treatment, and when this was detected, it was determined it required immediate clinical attention thus PTSD treatment was ceased; the other had not disclosed at assessment ongoing relationship violence, and was withdrawn when this was reported during treatment.

totally disagree to 5 = *totally agree* for the following items: (a) I believe that the case formulation process was understandable; (b) I believe that the case formulation process was logical; (c) I believe the case formulation process was acceptable; (d) I believe that the case formulation process was helpful.

PROCEDURE

Following a brief telephone screening, potential participants who met the eligibility criteria completed a pretreatment assessment comprised of diagnostic interviews and self-report measures. Participants who met inclusion criteria commenced weekly therapy sessions. Posttreatment assessments were completed within 2 weeks after treatment had ceased and again at 3 months. All diagnostic interviews were videotaped. Post and 3-month follow-up assessments were conducted by an assessor other than the treating therapist.

THERAPISTS

Nine therapists who were undertaking postgraduate clinical psychology training delivered the therapy. With one exception, therapists saw at least 2 clients. Therapists attended a half-day workshop on CPT delivered by the first author, an accredited CPT trainer, and completed the online CPT course (Medical University of South Carolina, 2009). They received weekly supervision from the first author, which comprised a minimum of 60 hours. Therapy followed the CPT manual that was most current at the time the study was initiated (CPT; Resick et al., 2014), and included the routine use of a trauma account (see *Therapy* below).

THERAPY

Participants were offered up to 16 weekly therapy sessions ($M_{\text{attended}} = 10.79$, $SD = 5.23$). CPT entailed initially providing psychoeducation regarding PTSD and identifying unhelpful cognitions or interpretations (i.e., stuck points) that resulted from or were strengthened by the index traumatic event. These stuck points were challenged through Socratic dialogue and various worksheets and, ultimately, the clients were assisted in creating more balanced and helpful cognitions. A detailed trauma account was written, revised, and read by the clients to assist with emotional processing and identification of further stuck points. During the final sessions, the clients were asked to focus on one theme each week (i.e., safety, trust, power, esteem, intimacy) and correct overgeneralized beliefs related to the theme. CF in this study was based on a modified combination of previous models proposed by Eells (2013), Padesky and Mooney (1990) and Dudley et al. (2011) that was made specific for PTSD presenta-

tions (see Fig. S1 in online materials). CF was incorporated into Session 1 of CPT (Session 1 took 90 minutes to incorporate this) and CF was revisited when necessary throughout treatment. The therapist and client completed CF diagrams collaboratively to better understand the development and maintenance of PTSD for the individual, the client's strengths and goals, and explicit inclusion of the proximal and distal factors that might influence the client's current adjustment; this also provided guidance when it appeared other intervention strategies were required. The initial CF and information collated from the assessment was summarized in the form of a therapeutic letter that was given to the client at the beginning of Session 2. When issues that were hindering treatment progress were detected and/or weekly monitoring indicated a lack of treatment response, CF was used to plan modifications and/or deviations from the CPT protocol to address these, for example with evidence-based strategies or techniques such as CBT for insomnia (Edinger, et al., 2001) or Motivation Interviewing (Miller & Rollnick, 1991). Both the client and therapist determined the decision to deviate and its manner, with the therapist also receiving input from the supervisor. As opposed to nonprotocol sessions in traditional CPT that are typically limited in number and might largely be supportive therapy (although frequently elements of CPT can be integrated in such sessions), CF-driven deviation sessions were specific in focus to the therapy-interfering issue at hand, and, if needed, could be up to 5 sessions, although in most cases only 1 to 2 sessions were required. CPT itself is quite versatile, and a number of clinical challenges, including motivation, can often be addressed through Socratic questioning and cognitive restructuring. In contrast, the CF-driven deviations entailed specific use of non-CPT methods. Modifications (deviations) from protocol were documented and later coded. These modifications were rated as minor (e.g., psychoeducation regarding alcohol misuse or sleep hygiene), moderate (e.g., using motivational interviewing for significant portion of session or more), or major (e.g., in-depth use of non-CPT techniques to address panic attacks).

TREATMENT FIDELITY

Assessment and therapy sessions were videotaped for review for clinical supervision and for assessment of treatment adherence and competency. An independent CPT expert evaluated 12 CF sessions and therapeutic letters and 8 other sessions that were randomly selected for therapy adherence and competency evaluation, using a protocol adapted for this study as well as a 6-item CF rating scale (Page, Stritzke, & McLean, 2008; see online

materials for details of these measures). These ratings showed that therapists delivered on average 92.5% of essential components of CPT, with mean session competence rated at 5.16 ($SD = 1.18$) and overall competence rated at 5.63 ($SD = 0.76$). These scores fell between *good* and *very good* on a 7-point scale (1 = *poor*, 7 = *excellent*). The mean score of 24.36 ($SD = 2.20$) from a total possible score of 30 on the case formulation rating scale reflected that therapists were rated as showing good CF skills (with possible ratings per item ranging between 1 [deficient ability/inadequate] to 5 [high level of ability]).

DATA ANALYSIS

Linear-mixed model (LMM) analyses with planned comparisons were conducted to investigate the effectiveness of CPT-CF treatment as LMM allowed for the estimation of missing data where attrition occurred for continuous variables. All analyses were conducted on the intent-to-treat sample (ITT; completer analyses available on request). Good end-state functioning (GES; i.e., changes in symptom severity of PTSD and depression) was assessed by a Reliable Change Index (RCI), where a change that exceeded 1.96 was considered significant (Jacobson & Truax, 1991) in combination with symptom severity scores falling below 31 (PCL-5; Bovin et al., 2016) and 9 (DASS-D; Lovibond & Lovibond, 1995).³

Results

Table 1 summarizes descriptive and inferential data for outcome measures at all assessment points. Significant main effects of time were observed for all symptom measures. Pairwise comparisons indicated that generally pretreatment to posttreatment and pretreatment to 3-month follow-up changes showed large effects (pre- posttreatment comparisons: CAPS-5: $p < .001$, $d = 1.92$); PCL-5: $p < .001$, $d = 1.91$; DASS-D: $p < .001$, $d = 1.10$; PTCI: $p < .001$, $d = 1.34$; ISI: $p = .006$, $d = 0.83$; pretreatment-follow-up comparisons: CAPS-5: $p < .001$, $d = 2.11$); PCL-5: $p < .001$, $d = 1.59$; DASS-D: $p = .005$, $d = 1.00$; PTCI: $p = .001$, $d = 1.08$; ISI: $p = .004$, $d = 0.97$).⁴

As indicated by RCI analyses at posttreatment (see Table 2), 11 participants (of 16 who were assessed) achieved good end-state functioning (GES) for PTSD (PCL-5) and 8 (out of 14) did so for

depression (DASS-D). At 3-month follow-up RCI analyses showed that 8 participants (of 13 who were assessed) achieved GES for PTSD and 8 of 12 participants for depression. Table 2 also individually documents each participant's loss of PTSD diagnosis at posttreatment and follow-up assessments, as well as the extent of deviation from the CPT protocol as indicated by CF. As seen in Table 2, three clients required what were deemed moderate deviations. For example, in one case this included the use of motivational interviewing around therapy engagement and avoidance, coupled with behavioral strategies to address significant alcohol misuse that was precluding engagement with the trauma memory. In another case it was deemed necessary to address comorbid panic attacks that were interfering with engagement in CPT work and were hypothesized to be reinforcing stuck points in relation to uncontrollability of symptoms and dangerousness of anxiety symptoms.

Although limited by the sample size, we also examined whether those who achieved GES at posttreatment for PTSD differed from those who didn't on relevant pretreatment (e.g., initial symptom severity, comorbidity) and treatment credibility variables that might have revealed differences in initial complexity of participants. We examined posttreatment data as it was most complete for GES (see Table S1, online supplementary materials, for full details). In short, there were no statistically significant differences between groups. Although some of the effect sizes suggested possible differences, given the small sample and extremely wide confidence intervals that would surround these values, we would not interpret the data in this fashion.

Descriptive data for measures of working alliance, treatment credibility and CF evaluation are reported in Table 3. As can be seen, estimated means across assessment points indicated overall positive participant ratings for all three measures; however, no significant changes were observed. This was the case for treatment credibility, $F(1, 8.22) = 0.85$, $p = .383$, $d = 0.24$, working alliance, $F(2, 26.62) = 1.17$, $p = .326$, $d = 0.22$, and CF-evaluation scores, $F(2, 24.71) = 0.24$, $p = .788$, $d = 0.22$. Although underpowered, clients' ratings of usefulness of CF at the beginning and middle of therapy were associated with lower post- and follow-up PTSD severity (CAPS, PCL) even when controlling for initial symptom severity (r s typically from $-.33$ to $-.78$).

Discussion

The large effects observed in PTSD severity reduction in the current study (average $d = 1.88$) were comparable, if not higher, to those of previous research with similar community samples that

³ A GES was not calculated on the CAPS-5 as a recommended cutoff is yet to be established for this measure. RCI was calculated on ITT data but due to challenges in estimating missing data for dichotomous variables, especially with modest sample sizes, analysis was conducted only on available data from the ITT sample.

⁴ Cohen's d was calculated using estimated means from linear mixed model analyses and SD 's from raw data. These values did not differ remarkably from d s based on the available raw mean data however this raw data was subject to missing cases, hence d s were based on estimated means.

Table 1

Estimated Means and Standard Errors for Posttraumatic Stress Disorder Severity, Depression Severity, Unhelpful Beliefs, and Sleep Problems Across Assessments

	Pretreatment	Posttreatment	Follow-up	<i>F</i> (df)
	<i>M</i> (<i>SE</i>)	<i>M</i> (<i>SE</i>)	<i>M</i> (<i>SE</i>)	
CAPS-5	39.58 (2.60)	14.06 (2.96)	14.41 (3.25)	33.45 (2, 34.56)***
PCL-5	47.04 (3.28)	18.21 (3.73)	21.03 (4.33)	31.33 (2, 29.70)***
DASS-D	22.64 (2.30)	10.27 (2.74)	11.64 (3.19)	9.22 (2, 28.31)**
PTCI	148.50 (8.76)	92.95 (10.67)	103.60 (11.57)	14.79 (2, 25.06)***
ISI	16.48 (1.43)	10.84 (1.82)	9.86 (1.91)	6.49 (2, 24.78)**

Note. CAPS-5 = Clinician Administered PTSD Scale for DSM-5; PCL-5 = PTSD Checklist for DSM-5; DASS-D = 21-item Depression Anxiety Stress Scale, Depression subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index. *F* = main effect of time.

* $p < .05$; ** $p < .001$; *** $p < .001$.

Table 2

Good End-State Functioning Status, Loss of PTSD Diagnosis and Extent of Modification to CPT Protocol as Indicated by Case Formulation for Individual Clients

Client	Posttreatment		Follow-Up				Extent of Modification to CPT Protocol
	GES	Lost Dx	GES	GES	Lost Dx	GES	
1	Y	Y	Y	Y	Y	Y	Minor deviation: session addressing crisis situation.
2	Y	Y	Y	Y	Y	Y	Minor deviation: psycho-education and management of sleep disturbance and motivational interviewing regarding homework completion.
3	Y	Y	^b	–	Y	–	Minor deviation: psycho-education regarding perfectionism.
4 ^a	–	–	–	N	–	N	No deviation.
5	Y	Y	Y	Y	Y	Y	No deviation.
6	Y	Y	Y	Y	Y	Y	Moderate deviation: sessions also addressed panic and potential threat of deportation.
7	N	N	N	–	–	–	Moderate deviation: client experienced another (more serious) car accident during therapy, suicidal ideation also managed during therapy.
8	–	N	–	–	–	–	Moderate deviation: ambivalence regarding treatment, significant avoidance and alcohol misuse addressed.
9	Y	Y	Y	Y	Y	Y	No deviation.
10	–	–	–	–	–	–	No deviation.
11	Y	Y	N	–	–	–	Minor deviation: self-harm incident and risky sexual behaviour addressed, motivational interviewing regarding session attendance and homework completion.
12	N	Y	^b	N	Y	N ^c	Minor deviation: client literacy issues managed during therapy.
13 ^a	–	–	–	–	–	–	No deviation.
14 ^a	N	N	N	–	–	–	No deviation.
15	N	Y	N	–	Y	–	Minor deviation: review of therapy progress and CF given modest change in symptoms.
16	–	N	–	N	Y	N	Minor deviation: psycho-education and management of sleep disturbance.
18	Y	Y	Y	N	Y	N	No deviation.
19 ^a	–	–	–	–	–	–	No deviation.
20	Y	Y	Y	Y	Y	Y	No deviation.
21	–	–	–	Y	Y	Y	No deviation.
22	N	N	N	N	N	N	Minor deviations: addressed sleep, behavioural survey re: meaning of abuse.
23	Y	Y	N	–	Y	–	No deviation.
24	Y	Y	Y	Y	Y	Y	No deviation.

Note: GES = Good end-state functioning; Dx = Diagnosis; PTSD GES status based on PCL; Depression GES status based on DASS-D. Client 17 did not attend first treatment session nor participate in assessments, thus is omitted from the table.

^a Dropped out of treatment.

^b Not above cut-off at pretreatment.

^c Depression significantly higher at follow-up than pretreatment.

– Missing data.

Table 3
Estimated Means and Standard Errors for Working Alliance,
Treatment Credibility and Evaluation of Case Formulation
Across Assessments

Measure	Baseline	Mid-treatment	Posttreatment
	<i>M</i> (<i>SE</i>)	<i>M</i> (<i>SE</i>)	<i>M</i> (<i>SE</i>)
WAI-C	70.50 (3.18)	73.79 (3.27)	73.93 (3.41)
Credible ^a	21.79 (1.76)	—	23.62 (2.11)
CF-Eval	17.86 (0.53)	17.88 (0.63)	18.33 (0.65)

Note. *N* = 24. Baseline = treatment session 1 for credibility and session 2 for working alliance and case formulation evaluation. WAI-C = Working Alliance Inventory- Client Version; Credible = Credibility/Expectancy Questionnaire; CF-Eval = Case Formulation Evaluation. Higher scores reflect more favorable reports.

^a Credibility only assessed at baseline and posttreatment.

conducted standard CPT (without CF) (ES range 1.10-1.20; Resick et al., 2008) or flexible CPT (e.g., allowing for more treatment sessions and sessions to address unexpected non-traumatic stressors; ES range 0.86-1.35; Galovski et al., 2012). Further, the majority of clients that were assessed at posttreatment or follow-up no longer met criteria for PTSD (72% and 93%, respectively), keeping in mind that although this data included dropouts (i.e., were ITT data), the figures are based on available scores, and might overestimate outcomes. Good PTSD end-state functioning (i.e., minimal symptoms/full recovery) was seen in 62%–63% of assessed clients at each assessment. These outcomes fall in the middle to upper ranges of the treatment outcomes reported by previous CPT research with similar samples (without CF) (Galovski et al., 2012; Resick et al., 2008), with Resick et al. finding that 55%–60% of their sample had lost their PTSD diagnosis at posttreatment or follow-up. The study dropout rate from therapy starters (17%) was promising and on the low side of the average rate (approximately 26%) seen in some of the randomized CPT studies that used trauma accounts (Galovski et al., 2012, 2016; Monson et al., 2006; Resick & Schnicke, 1992; Resick et al., 2002, 2008).

However, given that the present findings are based on a small-scale pilot study with neither control group nor a CPT only comparison, it cannot be definitively concluded that the client outcomes can be solely attributed to the CF process, especially given that this process was different for every client (as is required by true CF). Nevertheless, the ongoing CF process may have contributed to positive client outcomes by allowing for treatment flexibility (e.g., number of sessions), addressing treatment-interfering issues (e.g., providing nonprotocol treatment for comorbid issues and MI for avoidance) as well as by potentially

accentuating good therapeutic alliance and treatment acceptability. Indeed, working alliance, treatment credibility, and CF acceptability were rated positively by clients across assessment points. The results from this CF-modified CPT intervention are consistent with unpublished data on CPT with veterans that found clients whose therapists returned to the CPT protocol after deviating from CPT to manage clinical crises or other issues were able to still achieve good outcomes relative to those that did not return to address PTSD issues with CPT (Kartel, Couineau, Lloyd, Nixon, & Forbes, 2015).

Five clients met criteria for PTSD at posttreatment, with CPT modified moderately for two of these clients. One of these clients also suffered a more serious MVA during treatment that likely contributed to this outcome. It is worth noting that six clients had further significant stressful events by 3-month follow-up (four of which were Criteria A events), but despite this, scores were generally good for the majority of these clients. Although a 100% success rate is probably unrealistic in treatment studies, what could be altered to improve these outcomes even further is worth considering. Idiosyncratic client complexities may have impeded the clients' progress within treatment and our post-study review of these clients suggested that modifications to CPT could perhaps have been instituted earlier and that these clients might have benefited from additional sessions that specifically addressed the issues that appeared to be interfering with CPT progress, before returning to CPT. In addition, although there is some evidence that CBT-CF may be slightly more advantageous to standard CBT in treating complex presentations (e.g., psychosis; van der Gaag et al., 2014), to date there are no PTSD studies that directly compare standard CBT to CBT-CF and therefore it is still unknown which leads to better outcomes for complex clients. As reported earlier, small sample size limited conclusions as to whether there were meaningful differences between clients who responded and did not in relation to factors typically indicative of complexity (e.g., comorbidity, severity etc.). Another factor is that all of the therapists in this study were *novice* therapists with limited experience in CF, CPT and PTSD, and may have had less experience in flexibly and quickly adapting to clients' idiosyncratic complexities and addressing stalled progress. This is relevant given dropout in adult psychotherapy is moderated by therapist experience (Swift & Greenberg, 2012). Although this was not observed for PTSD treatments in general (Swift & Greenberg, 2014), the latter meta-analysis did not have sufficient numbers of trainees in CBT protocols for this to be properly

assessed. It is worth noting, however, that *other* clients with complex presentations within the current study achieved positive outcomes and the dropout in the present study was lower than the 30% observed in a similar study with trainee therapists (Nixon & Nearmy, 2011). Independent fidelity ratings also indicated that therapy was deemed to be of good quality. Future research will benefit from investigating the factors that moderate CPT-CF treatment outcomes. Related to this, our knowledge of the critical ingredients of CF and how best to train therapists in CF is in its infancy (Waltman & Sokol, 2017). Providing recommendations on how to deviate for every potential scenario is unrealistic yet we need to develop guidelines and methods of evaluating the decisions underlying the use of CF to deviate from protocols. Of course we also need to assess whether such deviations enhance client outcomes.

We acknowledge limitations of the study and highlight directions for future research. First, this was a pilot study and therefore an open trial design. A randomized design is required to investigate whether the CF process adds any benefits for clients or therapists to a standard CPT (and other CBT) treatment. Second, the modest sample size meant that missing data for dichotomous outcomes could not be satisfactorily addressed. Third, although the initial CF diagrams and summary letters created for every client were based on a template, the degree and type of modifications to treatment based on CF of course differed according to individual client need. This makes it difficult to draw conclusions about the specific effects of the CF process as a whole. Future research is needed to address the level of CF application required within different client populations and how different levels of CF application may influence client outcomes, while clearly documenting how and how well CF is being applied. Fourth, the therapists received only a half-day training workshop versus the 2-day workshop that is delivered as part of the CPT roll-out within Veterans Affairs in the U.S. It is possible this could have impacted outcomes in subtle ways that require further research. That said, we note that therapists likely received more supervision than the minimum required by the roll-out standards and that independent evaluation of therapy quality was on par with previous CPT research. Finally, a relatively brief (3-month) follow-up was undertaken although long-term follow-up of CPT indicates posttreatment gains are maintained (Resick, Williams, Suvak, Monson, & Gradus, 2012). Despite these limitations, the study was the first to examine explicit CF within CPT and demonstrated that CF did not appear to dilute the general efficacy of CPT. The study also showed explicit CF was acceptable to clients. Given that CF is

recommended for good clinical practice (Tarrier & Calam, 2002; Tarrier & Johnson, 2006) and taught within clinical psychology training programs, it is imperative that further research is undertaken that will inform best evidence-based practice not only in the field of PTSD, but psychotherapy more broadly.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

Appendix A. Supplementary Data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.beth.2018.04.003>.

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