The Effectiveness of Combining Cognitive Processing Therapy with a Case Formulation Approach in the Treatment of Posttraumatic Stress Disorder – A Randomised Controlled Trial

by

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CONTENTS

ABSTRACT

Objective: This thesis examined the combination of Cognitive Processing Therapy (CPT) with a case formulation approach (CPT+CF) to investigate its efficacy on improving client outcomes in terms of symptom reduction and increased therapy engagement (i.e. reduced dropout rates). I also tested whether several factors thought to contribute to treatment outcomes including client complexity, therapeutic alliance and degree of deviation from the CPT protocol, moderated the effect of treatment condition and PTSD and related outcomes.

Method: A randomised controlled trial design was used comparing CPT+CF with CPT alone (N = 93). CPT+CF consisted of the standard CPT protocol with the inclusion of a case formulation approach (both diagrammatic and narrative in format) which guided planned deviations should this be deemed necessary. Deviations from the protocol were recorded and coded for each session. Participants were assessed at pretreatment, posttreatment and at 6-month follow-up. PTSD and depression were assessed at every session, as were participants' judgements of overall wellbeing and session satisfaction. In order to measure complicated client presentations, a checklist of 30 variables which prior research had indicated might negatively influence treatment outcomes was developed. PTSD and depression were the main outcomes of interest with levels of complication and therapeutic alliance tested as hypothesised moderators of change. Linear mixed modelling analyses were used to examine change in symptom scores with maximum likelihood estimation for missing data. Response to treatment and good end-state functioning was assessed by a reduction in symptom severity of PTSD and depression using reliable change indices and relevant cut-offs for the measures of interest.

Results: Both conditions evidenced significant improvements on primary (PTSD and depression) and secondary treatment outcomes (posttrauma cognitions, sleep, substance use, emotional regulation). Effect sizes for PTSD measures for the intent-to-treat sample (ITT)

were large ranging between 2.50 and 3.66 across time points, and this was also seen for loss of PTSD diagnosis (which ranged between 80% and 94.7%) and good end-state (ranging between 71.9% and 85.7%). Contrary to expectations, there was no significant difference in dropout between the two groups (CPT: 19.1%; CPT+CF: 15.2%). Although there were no moderating effects of either client complexity or therapeutic alliance over time between the treatment conditions, there was a tentative suggestion that those not showing initial treatment response may have benefited if allocated to CPT+CF where deviations could be put in place, relative to receiving CPT alone. Examination of the utility of the case formulation approach suggested that although it was appreciated by participants in that group (borne out by qualitative and quantitative analyses), this did not translate to group level differences on outcomes between the two treatment conditions.

Conclusion: The findings replicate previous randomised controlled trials of CPT that demonstrate CPT is a highly effective therapy for PTSD. The findings are consistent with the small number of head-to-head comparisons between individualised case formulation approaches with standard manualised treatment, which have typically observed comparable outcomes between a formulation approach and standard protocol treatment. Further research is required to determine under which conditions deviating or augmenting standard PTSD treatments might confer additional benefits for PTSD sufferers.

DECLARATION

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Marja Elizabeth

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CHAPTER 1: LITERATURE REVIEW

Introduction

Lifetime exposure to a traumatic event is common, with 50-75% of people having been exposed to at least one traumatic event (Creamer, Burgess, & McFarlane, 2001; Mills et al., 2011). Although most people will not suffer long-term problems as a result, a significant minority develop posttraumatic stress disorder (PTSD), a condition characterised by re-experiencing of the traumatic event, avoidance of trauma-related stimuli and reminders, negative cognitions and mood, and increased arousal or reactivity (American Psychiatric Association, [APA], 2013).

As will be elaborated later, trauma-focused cognitive behavioural therapy (CBT) has long been the standard approach for the treatment of PTSD (Australian Centre for Posttraumatic Mental Health [ACPMH], 2013; Forbes et al., 2007; National Institute for Health and Care Excellence [NICE], 2018). Although CBT approaches have good efficacy in the treatment of PTSD, as will be highlighted, non-response to treatment and dropout rates remain substantial, and our understanding of what predicts good versus poor response to treatment is still in its infancy. Evidence-based therapies for PTSD tend to be manualised thus it is possible that for some clients, the focus of adhering to a manualised treatment approach, without being able to also target the many comorbid and complicating issues that accompany PTSD (e.g., motivation and avoidance issues, anxiety and mood disorders, personality disorders and substance abuse), contributes to a less than optimal treatment program.

Although we have a number of effective treatments for PTSD, further research is required to improve our understanding of how to optimally treat complex clinical cases and improve therapy response rates. A suggested way forward to address both potential barriers associated with manualised therapies and client complexity has been to ‘flex’ the therapy by allowing deviations from the standard treatment protocol based on individual client needs

(Galovski, Blain, Mott, Elwood, & Houle, 2012). One method to achieve this is through case formulation, otherwise known as case conceptualisation. Briefly, case formulation is an approach whereby a therapist and client work collaboratively to obtain a shared understanding of the presence and maintenance of a client's issues at the commencement of therapy, with the formulation used to select and guide the treatment approach, as well as providing a framework and rationale for addressing challenges which impede treatment outcomes (Aston, 2009; Kuyken, Padesky, & Dudley, 2009; Tarrier & Calam, 2002).

My PhD research examines the combination of an established PTSD treatment, Cognitive Processing Therapy (CPT) with a case formulation approach (CPT+CF). CPT helps an individual challenge and modify unhelpful beliefs and to develop a current understanding of why a traumatic event occurred and the impact on cognitions about self, other people and the world. Specifically, I tested its efficacy on improving participant outcomes in terms of symptom reduction and increased therapy engagement (i.e., reduced dropout rates), in a randomised design, comparing it against CPT alone. I also tested whether several factors thought to contribute to treatment outcomes, for example, client complexity, therapeutic alliance and degree of deviation from the CPT protocol, moderated the effect of treatment condition and clients' PTSD and related outcomes.

In this chapter I review the PTSD treatment literature with a focus on the factors that influence treatment succuss and discuss the role of complicated or complex presentations. Additionally, I examine the potential usefulness of case formulation to improve current PTSD treatments. I then describe the study method of the randomised trial (Chapter 2), report the results for main treatment findings and the factors that moderate outcome, including client complexity and the role of deviations throughout therapy (Chapters 3 and 4, respectively) before finally discussing these findings, their implications, and outlining avenues for further research (Chapter 5).

Posttraumatic Stress Disorder

Prevalence and Comorbidity

Estimates vary somewhat, however surveys indicate the lifetime prevalence of PTSD in adults in the United States and Canada as ranging from 6.1% to 9.2%, with estimates of PTSD over a 12-month period ranging from 3.5% to 4.7% (Kessler, Berglund, et al., 2005; Kessler, Chiu, Demler, & Walters, 2005; Van Ameringen, Mancini, Patterson, & Boyle, 2008). Population surveys cross-nationally indicate lower lifetime prevalence rates by country income level, with high income countries having twice (5%) the proportion of PTSD cases than lower-low middle income (2.1%) and upper-middle income countries (2.3%) (Koenen et al., 2017). In Australia prevalence of PTSD in the Australian population is estimated at 4.4% over a 12-month period, with lifetime prevalence rates estimated to be approximately 7.2% (McEvoy, Grove, & Slade, 2011). Prevalence estimates based on DSM-5 criteria have been reported as slightly lower than those reported for DSM-IV with a same event PTSD lifetime prevalence rate of 8.3% and the past 12-month estimate as 4.7% (Kilpatrick et al., 2013).

It has been suggested that PTSD can spontaneously remit in untreated individuals, with a recent meta-analysis of 42 studies (N = 81,642) suggesting remission rates of 51.7% if PTSD is in a relatively acute stage (i.e. diagnosed within five months of the trauma), and lower remission (36.9%) if diagnosed after five months following trauma (Morina, Wicherts, Lobbrecht, & Priebe, 2014). Variability of remission was high however, ranging between 8-89% in the reported studies, indicating that for a significant portion of individuals, remission does not occur without formal intervention. As such, the individual and societal impacts of PTSD are considerable. As will be discussed, PTSD has a high level of comorbidity, frequently occurring with depression, anxiety and substance use. It has also been linked with other physical health conditions including diabetes and cardiovascular disease (Watson, 2019). The economic impacts of PTSD have been estimated as substantial and include

medical and psychological health care, pharmacology and lost productivity with, for example, the annual cost of sexual assault in the US estimated at $402 billion (AUD) (Peterson, DeGue, & Lokey, 2017) and the annual cost of PTSD in Northern Ireland over $366 million (AUD) (Ferry, Brady, Bunting, Murphy, Bolton, & O'Neill, 2015).

It has long been known that the presence of other comorbid disorders with PTSD is the norm, not the exception. For example, in the nineties, the National Veteran's Readjustment Study (Kulka, 1990) reported that 99% of Vietnam veterans with PTSD had experienced another psychiatric diagnosis compared with 41% without PTSD, with particularly high rates for alcohol abuse or dependence (75%), generalised anxiety disorder (44%) and depression (20%) (Jordan et al., 1991). Subsequent large-scale epidemiological studies and reviews of both veteran and non-veteran populations continue to demonstrate that PTSD is highly comorbid with other conditions including anxiety disorders, mood disorders and substance use disorders (Creamer et al., 2001; Kessler, Chiu, et al., 2005; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995).

PTSD can also be accompanied by comorbid personality disorders, with individuals with PTSD more likely than trauma controls to meet criteria for borderline, schizotypal and narcissistic personality disorders, and women more likely to meet criteria for obsessive-compulsive personality disorder (Pietrzak, Goldstein, Southwick, & Grant, 2011; Shea et al., 2000). The most studied comorbidity has been with borderline personality disorder (BPD), however comorbidity rates vary across studies with differences in sample types (e.g. clinical versus non-clinical samples) and methodological and assessment differences making overall comparison of studies difficult (Pagura et al., 2010; Scheiderer, Wood, & Trull, 2015). A recent review of BPD-PTSD literature estimated that individuals with a diagnosis of BPD who also have comorbid PTSD ranges between 30-70%, and likewise between 22-24% of people with a primary diagnosis of PTSD are estimated to have comorbid BPD (Frias &

Palma, 2015). Additionally, a large-scale survey (N = 34,653) reported that of individuals with BPD, 30.2% had comorbid PTSD, and 24.2% of those with PTSD were also diagnosed with BPD (Pagura et al., 2010).

In addition to comorbidity with other disorders, PTSD is frequently accompanied by other significant clinical problems including suicidal ideation and suicide attempts, with research indicating that over 50% of people with PTSD will have thoughts of suicide, and between 20-30% will have made a suicide attempt (Nepon, Belik, Bolton, & Sareen, 2010; Panagioti, Gooding, Pratt, & Tarrier, 2015). A number of studies have found that both PTSD alone and PTSD comorbid with other conditions heighten suicide risk. For example, results from the National Comorbidity Survey indicate that individuals with PTSD are six times more likely to attempt suicide (Kessler, Borges, & Walters, 1999) and more recently a Danish national study reported a 5.3 times greater risk of suicide in individuals with a diagnosis of PTSD (Gradus et al., 2010). This risk exacerbates when PTSD is comorbid with other conditions including depression (Krysinska & Lester, 2010; Oquendo et al., 2003; Rojas, Bujarski, Babson, Dutton, & Feldner, 2014), panic disorder (Nepon et al., 2010), alcohol abuse (Kachadourian, Pilver, & Potenza, 2014; Rojas et al., 2014) or a personality disorder (Nepon et al., 2010).

Maladaptive behaviours such as reckless driving, unsafe sex, binge drinking and other risky behaviours are also frequently seen at higher rates in those with PTSD relative to those without PTSD (Ashwick, Syed, & Murphy, 2018; Contractor & Weiss, 2019; Kachadourian et al., 2014; Weiss, Walsh, DiLillo, Messman-Moore, & Gratz, 2019), with these behaviours now considered a symptom of PTSD in the latest iteration of DSM (i.e., DSM-5).

PTSD therefore is rarely treated on its own, with complicating factors making predictors of treatment outcome difficult. Over the years there has been significant debate as

to what constitutes a more 'complex' or 'complicated' client presentation, and whether and how these factors might contribute to the type and/or sequence of treatment options.

PTSD and Complex PTSD

As noted, there has been substantial, and often heated debate, as to whether certain trauma types or number of traumas result in different or more severe PTSD or whether the traditional PTSD diagnosis (as described by the DSM) truly captured all trauma survivor's experiences. As a result, the term 'complex' has been used to distinguish both trauma type (e.g. 'complex trauma') and the resulting effects (e.g. 'complex PTSD'). For example, individuals who experienced trauma typically interpersonal in nature (such as childhood sexual abuse, war, domestic violence, kidnapping or torture) or who present with repeated or prolonged traumatic events over years have been described as having experienced '*complex trauma*' (Cloitre et al., 2011; Herman, 1992). The term '*complex PTSD*' was used by some authors to describe a symptom profile originating from a complex trauma presentation, distinguishable from PTSD and defined by high levels of avoidance, hyperarousal and ruptures in relationship attachments causing significant emotional difficulties and distress (Cloitre, Petkova, Su, & Weiss, 2016; Lee, 2016), as well as disturbances in self-regulatory capacities including emotion regulation difficulties, relational disturbances, dissociation, adversely affected belief systems and somatic distress (Ben-Ezra et al., 2018; Cloitre et al., 2011; van der Kolk, Roth, Pelcovitz, Sunday, & Spinazzola, 2005).

Debate has continued as to the necessity of a Complex PTSD diagnosis and whether there is a distinct complex PTSD presentation, or whether the hallmark features actually describe other personality features (e.g. borderline personality disorder) (Frost, Hyland, Shevlin, & Murphy, 2018; Knefel, Tran, & Lueger-Schuster, 2016; Kulkarni, 2017; Resick et al., 2012). Currently, two distinct classification systems operate worldwide: the Diagnostic and Statistical Manual of Mental Disorders (DSM) currently in its 5th edition (APA, 2013)

and the International Classification of Diseases (ICD) which recently published its 11th edition (World Health Organization [WHO], 2018). Whilst the DSM-5 recognises only a singular diagnosis for PTSD, the ICD-11 for the first time separates out PTSD into two sibling conditions: 'PTSD' and 'Complex PTSD' (i.e., CPTSD).

In the DSM-5, there are four symptom clusters and a total of 20 individual symptoms of PTSD: re-experiencing symptoms (e.g. memories, dreams, flashbacks; triggered psychological distress); avoidance symptoms (effort to avoid memories, thoughts, feelings, or people, places and situations); negative cognitions and mood (about self, other people or the world, self-blame, loss of interest in activities and difficulty experiencing positive emotions) and arousal and reactivity symptoms (e.g. sleep disturbances, irritability, concentration issues, hypervigilance, exaggerated startle responses and reckless behaviour) (APA, 2013). In addition, the DSM-5 includes a dissociative subtype for PTSD that involves depersonalisation (feeling of detachment, unreality of self, body or time) and derealisation (surroundings seem unreal, distant or distorted) symptoms. The ICD-11 classification shares similarities with the symptom clusters in DSM-5, however it is presented in a more narrative format as a set of features rather than distinct symptoms or diagnostic criteria (Cloitre et al., 2018). The ICD-11 describes the PTSD condition as consisting of re-experiencing, avoidance and a sense of threat, with the separate complex condition, CPTSD adding disturbances in self-organisation to these PTSD core symptoms. These further symptoms include issues in: (1) affect regulation (difficulty regulating emotions, heightened reactivity and anger outbursts, or conversely feeling numb or dissociated); (2) beliefs about oneself as diminished, defeated or worthless, accompanied by feelings of shame, guilt or failure, and (3) difficulties in sustaining relationships and in feeling close to others (WHO, 2018). Application of the revised ICD-11 approach has been somewhat problematic, with the broad narrative format seen as open to ambiguity and varying interpretations even by its proponents (Karatzias et al., 2018; WHO,

2018). As a way forward, authors have suggested identification of 12 symptoms across both sibling conditions to capture the symptom clusters of PTSD (re-experiencing, avoidance and sense of threat) alongside the disturbances in self-organisation (dysregulation, negative self-concept and relationship disturbance) (Cloitre et al., 2018).

However it is important to note that the experience of complex trauma does not automatically result in Complex PTSD (Courtois, 2004; Resick et al., 2012), and that clients can have complicated clinical presentations in the absence of multiple or repeated trauma (Gerger, Munder, & Barth, 2014; Olatunji, Cisler, & Tolin, 2010), with many of the emotional regulatory problems argued to be hallmark features of complex PTSD also seen in clients diagnosed with PTSD, and indeed make up some of the DSM-5 classification criteria (Karatzias et al., 2018; WHO, 2018). These issues become relevant when considering the topic of how best to treat individuals with PTSD following trauma.

In the next section I briefly discuss current recommendations for evidence-based practice for PTSD, followed by sections that examine the challenges and barriers to optimal outcomes, including predictors of good and poor treatment response.

Treatment for PTSD – Cognitive Processing Therapy

For more than a decade trauma-focused therapies including cognitive behaviour therapy and eye movement desensitisation and reprocessing therapy (EMDR) have been the recommended front line treatments for PTSD as set out by a number of international guidelines and supported by a number of meta-analyses (Creamer et al., 2001). Recent guidelines have not only restated the overall efficacy for trauma-focused CBT interventions, but have recommended that these be based on a validated manual, with individual sessions (typically 8-12) having good evidence both clinically and in respect to cost effectiveness (Asmundson et al., 2019; ACPMH, 2013; Bradley, Greene, Russ, Dutra, & Westen, 2005; Forbes et al., 2007; Haagen, Smid, Knipscheer, & Kleber, 2015; Lenz, Haktanir, & Callender,

2017; NICE, 2018; Tran & Gregor, 2016; US Department of Veterans Affairs, 2017; Watts et al., 2013).

Included as one of the recommended interventions is Cognitive Processing Therapy (CPT), a manualised form of trauma-focused cognitive behavioural therapy initially developed for rape victims with chronic PTSD which has also been used successfully with other traumatic events (NICE, 2018). CPT is based on the cognitive model of PTSD, which theorises that PTSD becomes persistent when individuals appraise the trauma as a serious, current and future threat, through a pattern of maladaptive appraisals of the trauma and a distorted representation of the trauma memory (Ehlers & Clark, 2000).

The effectiveness of CPT has been illustrated within large scale meta-analyses that included other PTSD interventions, as well as when CPT was solely examined (Cusack et al., 2016; Tran, Moulton, Santesso, & Rabb, 2016; Watts et al., 2013). For example Cusack et al. reported large effect sizes for PTSD symptom reduction after CPT (Cohen's d = 0.85 to 1.95) over four trials (N = 299) where effect sizes favoured the intervention compared with either waitlist (3 trials or usual care [1 trial]), and a loss of diagnosis was observed in 44% more clients treated with CPT than for the control groups; Tran et al. observing similar outcomes (Tran et al., 2016). In addition to being effective in treating PTSD, Tran et al.'s meta-analysis of 10 RCT and six observational studies (total N = 1,865) observed CPT resulted in significant reductions in symptoms of depression and anxiety. Results from both randomised and open trials have demonstrated that CPT is effective across a range of trauma groups including interpersonal assault survivors, adult survivors of childhood abuse, veterans and active duty personnel, torture survivors, and in both Western and non-Western settings (Cusack et al., 2016). CPT has also been shown to be effective in a range of modalities including traditional weekly face-to-face therapy (Resick et al., 2008)), intensive therapy, i.e. CPT delivered over one week or several weeks (Bryan et al., 2018; Held et al., 2019; Zalta et

al., 2018), group therapy (Bass et al., 2013; Chard, 2005; Kaysen et al., 2013; Monson et al., 2006; Resick, Nishith, Weaver, Astin, & Feuer, 2002; Steenkamp, Litz, Hoge, & Marmar, 2015), telehealth (Ashwick, Turgoose, & Murphy, 2019; Lamp, Avallone, Maieritsch, Buchholz, & Rauch, 2019; Turgoose, Ashwick, & Murphy, 2018), and group telehealth (Kuester, Niemeyer, & Knaevelsrud, 2016; Morland et al., 2015; Wierwille, Pukay-Martin, Chard, & Klump, 2016). In spite of these positive findings, as discussed next, not all clients improve following CPT (or other EBPs for PTSD), and a substantial amount of research has been undertaken to better understand what might moderate clients' outcomes.

Challenges to Optimal Therapy Outcomes

Treatment Response and Dropout

Despite the efficacy of CPT for PTSD, dropout across RCTs and open trials has ranged from 4% to 50% (Morland, Hynes, Mackintosh, Resick, & Chard, 2011) with the average rate in the vicinity of 20-30% which is comparable to meta-analytic studies of PTSD treatment in general that indicate approximately 20% will prematurely terminate therapy (Chard, Schumm, Owens, & Cottingham, 2010; Davis, Walter, Chard, Parkinson, & Houston, 2013; Jak et al., 2019; Jeffreys et al., 2014; Mott et al., 2014; Resick et al., 2017; Resick et al., 2002; Resick & Schnicke, 1992). Although not ideal, this rate is still purportedly lower than for TF-CBT in routine clinical settings, with attrition rates for military samples for example cited as 2 to 6 times greater than the average rate found in clinical trials (Steenkamp & Litz, 2013).

In addition, treatment non-response rates following PTSD therapy have been reported as ranging between 25-50%, with residual impairments in many individuals (Goetter et al., 2015). However there is variability in what constitutes treatment response in studies (e.g., loss of diagnosis versus clinically meaningful symptom reduction). CPT is not immune to these issues, and in methodologically rigorous trials that have included good supervision of

therapists, there is a wide range of non-response to PTSD treatments generally, with reports of 4% to 45% of clients failing to either lose their PTSD diagnosis or demonstrate a reliable treatment response (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Brady, Warnock-Parkes, Barker, & Ehlers, 2015; Lonergan, 2014; Schottenbauer, Glass, Arnkoff, Tendick, & Hafter Gray, 2008).

Despite a reasonable amount of research to date, it is fair to say that the factors associated with poor treatment outcomes and dropout rates for PTSD treatments in general, as well as CPT, are still not well understood, with differences in methodologies across studies making comparison of nonresponse and dropout rates difficult, and a number of mixed findings evident in the literature (Galovski et al., 2012; Resick et al., 2002; Resick et al., 2015). Despite these challenges, a brief summary of findings relevant to the present thesis follows.

Predictors and Moderators of PTSD Treatment Dropout and Outcomes

A range of client factors such as gender, age, ethnicity, education levels, social problems, marital status, social support, comorbid psychiatric conditions, personality disorders, substance abuse, perseverative thinking, trauma cognitions, pain, sleep, emotional dysregulation and trauma characteristics (e.g., trauma type, symptom severity, time since trauma, number of traumas) may all play a part in accounting for the variance in treatment outcomes (Nixon et al., 2020). However as concluded by a number of authors, there are few reliable predictors across studies (Brady et al., 2015; Schottenbauer et al., 2008). Other factors also exist, including the client's family and social support, the treatment protocol being used, therapist fidelity to the treatment protocol, therapeutic alliance, therapist inexperience, the environment in which the treatment is delivered, intensity of treatment or logistical factors such as transport and lack of child care (Brady et al., 2015); however the importance of these for PTSD outcomes is unclear with limited research to date (Schottenbauer et al., 2008).

In respect to demographic variables, research studies and large scale meta-analytic reviews of trauma-focused CBT have indicated that generally females have more favourable outcomes than males (Blain, Galovski, & Robinson, 2010; Tarrier, Sommerfield, Pilgrim, & Faragher, 2000; Wade et al., 2016; Watts et al., 2013) and younger age has been associated with poorer outcomes (Alvarez et al., 2011; Dickstein, Walter, Schumm, & Chard, 2013; Garcia, Kelley, Rentz, & Lee, 2011; Mott et al., 2014; Rizvi, Vogt, & Resick, 2009), however again, the research is mixed with other studies finding no difference in treatment outcomes as a function of either gender or age across both veteran and non-veteran populations. (Falkenstein, C'de Baca, Belon, & Castillo, 2017; Phelps et al., 2018; Straud, Siev, Messer, & Zalta, 2019; Swift & Greenberg, 2014). Education level has sometimes been associated with dropout rates in some studies (i.e. the higher the education the less likelihood for dropout) (Cui et al., 2016; Rizvi et al., 2009) with other studies finding no relationship between the two (Falkenstein et al., 2017; Hale, Rodriguez, Wright, Driesenga, & Spates, 2019; van Minnen, Arntz, & Keijsers, 2002). Similarly, non-Caucasian ethnicity has sometimes (Keefe et al., 2018; Walling, Suvak, Howard, Taft, & Murphy, 2012), but not always (Falkenstein et al., 2017; Gros, Price, Yuen, & Acierno, 2013; Holliday, Holder, Williamson, & Suris, 2017) been associated with higher dropout rates. Research has indicated a consistent link between higher levels of PTSD symptoms and low levels of social support (Brewin, Andrews, & Valentine, 2000; Dodson & Beck, 2017; Ozer, Best, Lipsey, & Weiss, 2003), with factors such as social alienation, marital distress and low emotional and informational support moderators of treatment outcomes (Gros et al., 2013; Price, Gros, Strachan, Ruggiero, & Acierno, 2013). Overall, military populations have been found to have poorer treatment outcomes and worse PTSD remission rates at posttreatment than civilian samples (Bisson et al., 2007; Bradley et al., 2005; Steenkamp et al., 2015; Straud et al., 2019).

As noted above, PTSD is highly comorbid with a number of conditions. The effect of these on treatment outcomes however has been mixed. As an example, higher levels of pretreatment depression have sometimes (Brady et al., 2015; Ehlers et al., 2013) but not always (Asamsama, Dickstein, & Chard, 2015; Liverant, Suvak, Pineles, & Resick, 2012; Stein, Dickstein, Schuster, Litz, & Resick, 2012; Taylor et al., 2001) been associated with poor treatment response. Similar mixed findings exist in the case of comorbid anxiety with higher levels of anxiety at pretreatment (Rosenkranz & Muller, 2011) and presence of generalised anxiety disorder associated with less PTSD symptom improvement in some studies (Tarrier et al., 2000), with the opposite found in others (i.e., where higher anxiety was associated with treatment gains) (Feeny, Zoellner, & Foa, 2002; Lloyd et al., 2014).

Studies have also indicated that individuals with one or more personality disorders are less likely to achieve good end-state functioning with CBT treatment (Forbes et al., 2002) however other studies have reported that participants with a personality disorder show equivalent gains in PTSD therapy as compared to those without (Clarke, Rizvi, & Resick, 2008; Dorrepaal et al., 2013; Hembree, Cahill, & Foa, 2004; Holder, Holliday, Pai, & Suris, 2017; Walter, Bolte, Owens, & Chard, 2011).

Substance abuse has also been linked with poorer outcomes and risk of dropout (Read, Brown, & Kahler, 2004; van Minnen et al., 2002), however, results from a meta-analysis of 156 RCTs of the efficacy of PTSD treatments indicated that although the majority (73.7%) of trials excluded participants based on substance use status (Leeman et al., 2017), those which reported findings regarding substance abuse status and PTSD found that substance use did not impede treatment outcomes or retention, a finding which has been reported in other studies (Leeman et al., 2017; Roberts, Roberts, Jones, & Bisson, 2015).

In terms of trauma type and number of traumas, experience of trauma at an early age, interpersonal trauma (Ehlers et al., 2013) and multiple traumas (≥ 4 traumatic events) (Karam

et al., 2014) have all been linked with greater functional impairment, increased comorbidity and increased symptom severity. This in turn has been linked with reduced treatment outcomes (Garcia et al., 2011; Zandberg, Rosenfield, Alpert, McLean, & Foa, 2016).

Participants identified as having complex PTSD have also been noted as having less favourable outcomes, however the majority of studies report findings prior to the introduction of the CPTSD definition in the ICD-11 and tested the moderating effect of trauma type (particularly child sexual abuse) (Dorrepaal et al., 2014) or dissociative symptoms (Armour, Elklit, Lauterbach, & Elhai, 2014; Boyd et al., 2018) than CPTSD per se. Other emotional regulation issues, including numbing and anger, have also been identified as negatively moderating outcomes in some studies (Gobin et al., 2017; Lloyd et al., 2014; Taylor et al., 2001) but not others (van Minnen et al., 2002). A significant amount of research has also been conducted examining the types of pretrauma cognitions that strongly predict outcomes, given a shift of cognition is the primary goal of trauma-focused CBT and positive alterations in trauma-related cognitions predict improvements in PTSD symptoms (Dondanville et al., 2016; Iverson, King, Cunningham, & Resick, 2015; Kleim et al., 2013; Scher, Suvak, & Resick, 2017; Schumm, Dickstein, Walter, Owens, & Chard, 2015). Higher levels of guilt and self-blame have been observed as predictors of change in some studies (Holliday, Holder, & Suris, 2018; Phelps et al., 2018), however in others these were not found to be predictors of treatment outcomes nor dropout rates (Falkenstein et al., 2017; Stayton, Dickstein, & Chard, 2018; van Minnen et al., 2002).

In addition, other factors including treatment credibility (i.e., whether the client believes the therapy will work) and expectancy (i.e., belief that the therapy will result in symptom improvement) as well as therapeutic alliance (i.e., the strength of the relationship between client and therapist) have all been linked to treatment outcomes, however as per the literature on other treatment predictors, the results are not definitive (Berke et al., 2019).

Given the mixed nature of evidence that using individual characteristics are weak moderators of treatment outcomes, some authors have suggested combining several individual weak measures to create a single strong moderator (Karatzias et al., 2019; Wallace, E., & Kraemer, 2013; Wallace & Smagula, 2018). For example, Delgadillo and colleagues proposed a combination approach to identify client complexity based on individual characteristics to predict depression and anxiety outcomes, finding that complex cases are defined by the presence of measurable factors mapping onto clinical (e.g. symptom severity, comorbidity), demographic (e.g. age, ethnicity, gender), characterological (e.g. personality disorder diagnosis or traits, interpersonal problems) and dispositional (e.g. expectancy, readiness to change) domains which have a cumulative detrimental effect on treatment outcomes (Delgadillo, Huey, Bennett, & McMillan, 2017).

In the PTSD context, preliminary studies have undertaken this approach, with Cloitre et al. combining baseline client characteristics: PTSD symptoms, depression, dissociation and interpersonal problems to construct a symptom burden scale, which when combined with factors associated with 'emotion regulation strength', (e.g. anger management and general emotion regulation) generated a moderator score which significantly predicted the course of symptoms differentially across three treatment conditions (Cloitre et al., 2016).

Similarly, a meta-analysis by Gerger et al. (2014) compared specific interventions (i.e. using a standardised format and directly addressing the trauma or PTSD symptoms) versus non-specific interventions (i.e. did not necessarily focus on the PTSD symptoms with therapists free to select from a range of techniques or use non-verbal techniques [e.g. relaxation strategies]). The study focused on clients with complex clinical conditions, the latter defined as having at least two of the following four clinical characteristics: (a) duration of symptoms lasting more than 6 months; (b) presence of multiple problems (e.g., comorbid mental disorders, being in an ongoing violent relationship, and being a refugee); (c) presence

of a complex psychological traumatisation (i.e. childhood, multiple, or intentional trauma); and (d) the presence of a formal PTSD diagnosis according to DSM-III/IV criteria. The results indicated that for complex client groups, there was only a small superiority of specific over non-specific interventions while for non-complex clinical problems the specific interventions were superior. The complexity of clinical problems therefore, was found to be the most relevant predictor of efficacy between the interventions types as compared with any other moderator (Gerger et al., 2014).

In summary, the traditional approach of searching for a single treatment moderator, which ultimately tends to have only a small effect, has been seen as limited in informing clinical practice and as such, although not the focus of the present study, research efforts are underway in an attempt to more accurately predict which client, trauma and other characteristics influence treatment outcomes. As noted above, there are a number of variables related to the individual (i.e. demographic factors, comorbidities, social support), the trauma (type, frequency, severity) and other factors (e.g. negative self-concept, cognitions, emotional regulation, sleep, pain) which are said to impact PTSD treatment. These factors individually and/or combined contribute to a complexity of presentation which may adversely affect outcomes and require a more flexible approach to the delivery of current treatments.

CPT and Trauma-Focused Therapy for Complex Clients

Of relevance to the present study, some PTSD treatment guidelines indicate that for clients with complex presentations, enhanced CBT treatment, stabilisation methods, combined and/or phase-based approaches and other interventions are recommended in order to deal with the severity of symptoms and comorbidities in order to improve outcomes (ACPMH, 2013; Cloitre et al., 2016). Other authors however reject a sequenced approach to treatment, citing efficacious results with single focus trauma-focused therapies (including CPT) without a period of stabilisation or regulatory control interventions (De Jongh et al., 2016). The recent

NICE guidelines support this approach, noting that for people with PTSD and complex needs, the PTSD should be treated first, despite comorbidities, unless these form a barrier to treatment engagement, in which case it is recommended the therapist assist the person to manage these barriers alongside PTSD treatment (NICE, 2018). This approach aligns with that adopted by the authors of the CPT protocol, who note that even with the high rates of comorbidity with PTSD, particularly depression, anxiety, dissociation and some personality disorders, that there is often no need to deal with these independently as they remit alongside PTSD in the course of treatment (Resick, Monson, & Chard, 2014). Further, as many of the symptoms associated with other disorders may be PTSD-relevant (e.g., avoidance, obsessive checking, negative cognitions and mood), these may resolve with the standard treatment. As discussed previously, there have been good outcomes with clients who complete CPT having presented with more complex issues, including traumatic brain injury, substance use, personality disorders and psychiatric comorbidities (Chard, Schumm, McIlvain, Bailey, & Parkinson, 2011; Resick et al., 2017; Wieferink, de Haan, Dijkstra, Fledderus, & Kok, 2017), as well as with clients who present with other risk factors such as suicidal ideation. For example, a recent RCT (N = 108) of veterans receiving either group CPT or a non-trauma focused therapy found that for participants with active suicidal ideation at pretreatment this significantly decreased across both treatments and was maintained at 12-month follow-up (Bryan et al., 2016). These were similar to findings of an earlier study comparing CPT and PE in a sample of civilian women having experienced sexual assault (N = 163) where suicidal ideation decreased in both groups at posttreatment and was maintained over a follow-up period of 5-10 years. (Gradus, Suvak, Wisco, Marx, & Resick, 2013). In addition, a recent review indicates that unless there are high priority safety issues (in which case a two-month period of stabilisation is recommended), when a client presents with PTSD as the primary issue, trauma-focused treatment should be offered in the first instance, even in the presence of

other comorbidities including substance use and/or personality disorders, given the research indicates that effective PTSD treatment is likely to reduce symptoms associated with comorbid disorders (Goodnight, Ragsdale, Rauch, & Rothbaum, 2019).

Despite the existence of good treatments for PTSD, as noted above, the dropout rates from CPT and other trauma-focused therapies remains unacceptably high, and although all the mechanisms underlying dropout and non-response are not yet fully understood, client complexity might play a part in moderating treatment outcomes. Concerns have been raised by clinicians about the use of manualised protocols, for example, that they are restrictive, leaving little flexibility for the therapist to individualise treatment and address immediate concerns (Galovski et al., 2012; Hembree et al., 2003; Kendall, Chu, Gifford, Hayes, & Nauta, 1998; Schottenbauer et al., 2008). This has been noted particularly in respect to clients with complex needs (Addis, Wade, & Hatgis, 1999; Borntrager, Chorpita, Higa-McMillan, Daleiden, & Starace, 2013; Rosen et al., 2016). For example, Gray et al. surveyed 461 trauma professionals regarding their beliefs and use of evidence-based trauma-focused protocols and found that while over 80% of the respondents held favourable views, 36.4% also felt that empirical research findings were not generalisable to unique or complex cases (Gray, Elhai, & Schmidt, 2007). Results from a more recent survey supported this finding (N = 159), observing that although therapists' perceptions of the usefulness of CPT was high, concerns remained about its applicability to complicated clients with severe psychiatric comorbidities, cognitive limitations and level of readiness to engage in trauma-focused treatment (Cook, Simiola, Hamblen, Bernardy, & Schnurr, 2017).

As such, a number of studies are focusing on ways to deliver manualised protocols such as CPT more flexibly, including adjusting the length of therapy (Galovski et al., 2012), varying the intensity (Bryan et al., 2018), adding components such as education and treatment planning sessions (DeViva, Bassett, Santoro, & Fenton, 2017), adding motivational strategies

(e.g., collaborative care) (Grubbs et al., 2015); addressing comorbidities specifically and separately (Angelakis & Nixon, 2015), combining CPT with treatment for other issues such as smoking (Dedert et al., 2019; Dedert et al., 2016); simplifying content and themes based on cultural and/or literacy factors (Kaysen et al., 2013) and utilising a case formulation approach to individualise therapy depending on client's issues and need (Nixon & Bralo, 2019).

Although the studies above have generally reported positive outcomes, modifying protocols which have demonstrated treatment outcomes in their original form is associated with a degree of risk, given it remains unclear which therapy elements can be changed and which are in effect core elements to which the clinician should adhere in order to avoid diluting treatment efficacy. As such, more research is needed as to how much to individualise and 'flex' established evidence-based protocols without compromising effective treatment outcomes. These modifications are now discussed, and where applicable, their relevance to complex and/or nonresponding clients highlighted.

Modifications to Trauma-Focused Therapies

As previously discussed, there is an ongoing need to refine evidence-based treatments for PTSD in order to improve outcomes and reduce treatment barriers. This has led to modifications through changing *how* a therapy is delivered, and/or *what* is delivered. At the minor end of this spectrum have been changes to the method of delivery (e.g,. telehealth vs. in person, group vs. individual treatment; treatment location, e.g. residential; outpatient; in home treatment) (Alvarez et al., 2011; Fortney et al., 2015; Grubbs et al., 2015; Morland et al., 2011; Morland et al., 2015; Peterson et al., 2018; Resick et al., 2017; Sloan, Feinstein, Gallagher, Beck, & Keane, 2013), largely as a means to address access issues and cost effectiveness.

Changing the length of treatment has also occurred, with mixed results. For example, intensifying delivery and shortening treatment time has demonstrated good results in TF-CBT

approaches (Ehlers et al., 2014; Galovski et al., 2012; Gutner, Suvak, Sloan, & Resick, 2016; Hendriks, de Kleine, Broekman, Hendriks, & van Minnen, 2018; Resick et al., 2017; Sijbrandij et al., 2007; Sloan, Marx, Lee, & Resick, 2018; Van Woudenberg et al., 2018), including CPT, with a recent small study by Bryan et al. piloting the delivery of CPT over a two-week period. The study (N = 20) resulted in higher treatment completion rates (100%) than typically seen, accompanied by 69.2% of participants demonstrating clinically significant change (Bryan et al., 2018). Several studies have examined flexible length CPT, with treatment delivered over a longer period of time. For example, Chard et al. adapted CPT for sexual abuse survivors offering both group and individual therapy over a 17-week period (Chard, Weaver, & Resick, 1997) and Galovski et al. allowed 'stressor sessions' as treatment breaks to deal with significant psychosocial stressors or emergencies, extending therapy to 18 weeks if necessary (Galovski et al., 2012). Although both these studies resulted in large long-term treatment gains, adding additional sessions does not necessarily mean greater improvement. In Galovski et al., the majority of treated participants (58%) achieved good end-state prior to the usual 12-session CPT protocol, with only 8% remaining retaining their PTSD diagnosis at the end of the treatment (session 18). A recent study of both PE and CPT found that the strongest predictor of change was *early* change, with participants who had experienced at least 20% reduction of symptoms before session eight twice as likely to achieve subsequent meaningful change (Sripada, Ready, Ganoczy, Astin, & Rauch, 2019). Additionally, research into the use of PE has indicated that extending therapy for too long may have a *negative* impact on outcomes, with the finding that participants who achieved meaningful change had significantly fewer sessions than those who did not, leading to the authors' recommendation that for those participants whose symptoms have not improved or have worsened by session eight, the treatment plan be changed or re-conceptualised (Ready, Lamp, Rauch, Astin, & Norrholm, 2018).

Other minor modifications to CPT specifically have also been made in terms of both the format of therapy materials as well as the content of the treatment protocol. For example, changes to language used, use of interpreters, simplification of worksheets and homework assignments and use of culturally appropriate examples to take into account cultural differences or literacy levels have all been trialled with good success (Bass et al., 2013; Marques et al., 2019; Pearson, Kaysen, Huh, & Bedard-Gilligan, 2019; Rosner et al., 2019; Schulz, Resick, Huber, & Griffin, 2006; Valentine et al., 2017). CPT has also been simplified and modified to take into account developmental differences in clients. For example, in a recent RCT of CPT for adolescents (N = 88), researchers used a 15-session CPT protocol and added a planning and preparation phase to increase motivation (five sessions); emotion regulation training prior to the commencement of CPT (six sessions); and four sessions on developmental tasks. Of interest is that despite these additions, changes in PTSD occurred during the CPT phase, with no differences in improvement in the first two added phases (motivation and emotional regulation). This adds weight to the argument that stabilisation phases are not necessarily essential, even in a complex trauma group such as this one (Rosner et al., 2019), although in this case, definitive evidence would require comparison against a standard CPT intervention without modifications, not simply a waitist control. Another modified version of CPT has been recently trialled (N = 100), this time for veterans with a traumatic brain injury (SMART-CPT) with modifications to the protocol including psychoeducation about TBI and PTSD and added compensatory strategies for attention, memory and executive functioning, in addition to simplification of language and homework sheets. No significant differences between the standard CPT and the modified version were found on PTSD symptoms following treatment, however there were greater improvements in attention/working memory, verbal learning/memory and executive functioning in the SMART-CPT approach (Jak et al., 2019).

Other studies have also added one or several pretreatment sessions consisting of psychoeducation and motivational techniques, primarily to promote engagement, however results have indicated that motivational techniques did not reduce dropout rates or accentuate symptom reductions (Blain, 2013; DeViva et al., 2017). Other recent content inclusions to CPT have served to address issues identified within particular cultural groups, with CPT modified to include sessions on relationships, safer sex and substance use with a sample of Native American women (N = 73) (Pearson et al., 2019). In this study there were large effects on improving PTSD and high risk sexual behaviour, and moderate to large effects on alcohol use, however given the study was randomised against a waitlist group, it is unclear as to whether CPT alone without the additional information would have achieved the same results.

More significant modifications to CPT have included concurrent treatment options to address either comorbidities or client complexities. For example, Galovski and colleagues used hypnosis to improve sleep problems before beginning CPT to determine if this would then augment PTSD recovery. Although they found there was improved sleep following the hypnosis intervention, recovery from PTSD was no faster when the treatments were combined (Galovski et al., 2016). Research into treating concurrent PTSD and smoking has also been conducted, however no differences in smoking cessation were found with CPT combined with smoking cessation treatment as to treatment without CPT (Dedert et al., 2019). In relation to another comorbidity, a recent study targeting depression (MDD) with comorbid PTSD (N = 50) which compared CPT alone, CPT followed by behavioural activation (BA) and BA followed by CPT found all conditions demonstrated clinically significant improvements on PTSD and MDD, (ES of 1.25 - 2.84 for PTSD; 0.56 - 1.51 for MDD); however there were larger improvements at posttreatment and follow-up, as well as a lower dropout rate when PTSD was targeted *first* (i.e., CPT followed by BA) suggesting the addition of depression-focused sessions before PTSD treatment did not enhance outcomes (Angelakis, 2014).

There have also been adaptations to the structure of CPT since its development. In a seminal dismantling study where the full CPT protocol was compared with its constituent parts (CPT-C: that is, without the written trauma account; and CPT-W: i.e., written account without cognitive therapy) the authors found that all three conditions showed substantial improvements in PTSD symptoms and depression but the CPT-C group showed faster improvements than CPT and greater improvement than the CPT-W condition (Resick et al., 2008; Resick et al., 2014). In addition, the CPT-C group had a lower dropout rate (22% compared with 26% for CPT-W and 34% for CPT). The efficacy of a CPT-C only approach was replicated with a sample of male veterans with comorbid traumatic brain injury and PTSD in a residential treatment setting, with large effect size reductions on PTSD symptoms posttreatment (Chard et al., 2011). As a result of these and other findings (Resick et al., 2017), the use of a trauma account in CPT is now considered as optional. When considering flexible delivery of CPT, it is also worth noting, as outlined by Resick et al. (2017), that the treatment approach is already quite flexible, with CPT offered in several different formats (individual, group, group + individual), with or without the trauma account (CPT alone (CPT); CPT + trauma account (CPT-A)) and adapted for particular client groups or comorbidities (CPT for sexual abuse (CPT-SA), SMART-CPT for clients with a TBI). In addition, sessions can be run with some flexibility. For example, agenda setting at the beginning of each session allows for non-trauma related material to be introduced on occasion if clearly indicated. Similarly, the addition of a small number of non-protocol or 'stressor' sessions can help to deal with crisis issues if they arise, and simplified worksheets and material are available for clinicians to use both in the standard delivery of CPT as well when delivering CPT in non-Western settings (Resick, Monson, & Chard, 2017).

The studies reviewed above demonstrate that CPT can be modified in a number of ways without losing its efficacy. Some of these studies comprised samples or settings that

could be construed as ‘complicated’. Despite this, further improvements to our PTSD interventions are required given there is still limited data at present to help clinicians at the commencement of therapy to predict which clients may not achieve good outcomes or dropout prematurely. Additional research is also necessary because apart from one study that examined the effect of including the addition of stressor sessions to target clinical or life emergencies that may occur in a client’s life (Galovski et al., 2012), there have been no studies on the impact of making changes to the CPT protocol *throughout* therapy, or determining when and how deviations from the standard CPT protocol might be needed to address treatment resistance or to keep people engaged in therapy. One potential way forward may be the explicit use of case formulation, in order to target potential barriers to therapy and to provide further flexibility to the CPT protocol and guide any deviations.

Case Formulation – A Way Forward?

Case formulation, or case conceptualisation, is a process by which therapist and client work to obtain a shared understanding of a client’s issues and an explanation of how they are maintained in order to individualise treatment protocols, to provide focus within interventions, and to enhance treatment outcomes (Aston, 2009; Bieling & Kuyken, 2003; Kuyken et al., 2009; Persons, 2006; Tarrier & Calam, 2002). Although the approach is considered a cornerstone of good clinical practice, surprisingly, very little research has been conducted as to what makes for a good case formulation, its critical ingredients, and how it affects clinical outcome (Aston, 2009; Bieling & Kuyken, 2003; Bucci, French, & Berry, 2016; Ghaderi, 2011).

There is some agreement that case formulations should have some key elements, including describing presenting problems, understanding developmental history and causal factors, identifying maintaining factors, potential issues or barriers to therapy and to guide the type and sequence of interventions (Bieling & Kuyken, 2003; Dudley, Kuyken, & Padesky,

2011; Kuyken et al., 2009). A more recent review has also identified the importance of incorporating protective factors or strengths into written conceptualisations (Easden & Kazantzis, 2017).

Case formulation involves both a *content* component, i.e. identifying problems, goals, obstacles and treatment plans and a *process* component, i.e. how this information is elicited both initially and as therapy progresses (Eels, 2007). Ideally the process is a collaborative one involving both therapist and client, however not all case formulation processes are conducted jointly and to date there is very little research as to whether collaborative case formulation is superior to therapist only formulation (Kuyken et al., 2009). Most commonly, formulations involve either the creation of a diagram which highlights the interrelationships between a problem and it's causal mechanisms (Kuyken et al., 2009) or use of a written process, such as a case formulation letter from the therapist to the client.

As noted however, there is very little research as to the many ways formulations can be developed, what is included, how they are utilised during therapy, the overall benefits and the effect on outcomes.

The Efficacy of Case Formulation in Non-PTSD Disorders

Research in non-PTSD samples has suggested that in the context of CBT therapies, case formulation can have positive effects (Allen et al., 2016; Chadwick, Williams, & Mackenzie, 2003; Ghaderi, 2006; Lundkvist-Houndoumadi, Thastum, & Hougaard, 2015; Nattrass, Kellett, Hardy, & Ricketts, 2015; Persons, 2006; Persons, Beckner, & Tompkins, 2013; Rogers, Reinecke, & Curry, 2005), however how these effects are defined and the attribution to formulation specifically is unclear. Positive effects include whether case formulation achieves symptom change; whether the addition of explicit case formulation achieves superior treatment outcomes to treatment as usual; and/or acceptability of the formulation process.

Very few head-to-head comparisons between individualised case formulation approaches compared with standard manualised treatment have been conducted. A recent review of the literature (Easden & Kazantzis, 2017) identified that of the small number of studies which compared a formulation driven treatment group and standardised manualised treatment (n = 5), the lack of consistent criteria to define the formulation driven group and lack of clarity as to how these groups differed from the control groups, made comparisons difficult. However, of the randomised trials reported, there were comparable outcomes between a formulation process and standard treatment or a moderate difference favouring formulation (Chadwick et al., 2003; Esbjorn et al., 2015; Ghaderi, 2006; Nelson-Gray, Herbert, Herbert, Sigmon, & Brannon, 1989; Persons, Bostrom, & Bertagnolli, 1999; Persons, Roberts, Zalecki, & Brechwald, 2006).

Conversely, some authors have suggested that standardised groups are more successful than those which use individualised approaches but result in *too* much flexibility and adaptation (Eifert, Schulte, Zvolensky, Lejuez, & Lau, 1997). For example, a randomised trial of 120 patients with phobias receiving individual treatment, standardised exposure therapy or a control group found the standardised group showed a significantly larger change (Schulte, Kunzel, Pepping, & Schulte-Bahrenberg, 1992).

In addition to showing some promise in regard to treatment outcomes, some studies have reported benefits in the perceived utility of the process. For example, Nattrass et al. (2015) examined a case formulation approach for clients with obsessive-compulsive disorder (N = 29) and found that the alliance during the post-formulation phase improved. Similarly a qualitative analysis of clients with depression and/or anxiety (N = 10) noted positive outcomes for clients including feeling more understood by their therapist, assisting their own understanding of their problems and supporting them to move forward (Redhead, Johnstone, & Nightingale, 2015). Other studies have found more varied reactions to the process. For

example, Chadwick et al. in investigating the impact of case formulation on therapeutic alliance and treatment outcomes with clients with psychosis (N = 13) found a mix of positive, neutral and negative effects, with case formulation overall rated as more positively by therapists, rather than clients (Chadwick et al., 2003). Similarly, a qualitative study (N = 7) with clients with depression found all the participants initially viewed the case formulation negatively, finding it difficult to understand or receive, however this negativity dissipated over time (Kahlon, Neal, & Patterson, 2014). This finding was similar to that reported by Morberg Pain et al. (2008) who assessed client and therapist experience of collaborative case formulation in CBT for psychosis (N = 13) and found that while 40% of participants reported negative feelings after the formulation, including increased feelings of sadness, hopelessness, worry and difficulty in processing the formulation, overall participants were equally as positive as they were negative about the process (Morberg Pain, Chadwick, & Abba, 2008).

The usefulness of the case formulation letter has also had mixed results. An early small study of cognitive analytic therapy (N = 4) where the therapist and client write a joint formulation letter prior to a diagrammatic reformulation found no effect on therapeutic alliance or treatment outcomes, despite clients reporting that it had considerable impact upon them and the process of therapy (Evans & Parry, 1996). Similar findings have also been reported in later studies (Shine & Westacott, 2010) and more recently in a randomised trial with clients with depression (N = 95), where a comparison of cognitive analytic therapy with or without a narrative reformulation (i.e. the joint formulation letter) found the letter had no effect on depression outcomes, therapeutic alliance or ratings of helpfulness of therapy (Kellett et al., 2018). Conversely, a recent study in the treatment of anorexia nervosa provides some support for a written formulation, reporting that some aspects of the formulation including the use of a developmental perspective and formulating the letter in a respectful and

reflective tone predicted treatment satisfaction and improvements in symptoms respectively (Allen et al., 2016).

Case Formulation and PTSD

Despite the mixed evidence in relation to the usefulness of case formulation, there is reason to think that case formulation could improve current PTSD treatments. As described above, PTSD is a disorder that is accompanied by high levels of comorbidity, as well as avoidance or ambivalence regarding treatment components (e.g., discussion of the traumatic experience, avoidance of strong emotions). Typically participants in CPT study samples possess many of the characteristics which have been noted as contributing to client complexity (e.g. comorbidities, multiple traumas, childhood trauma, personality disorders, etc.). However rarely, or almost never have these trials examined what to do when clients are not responding throughout treatment and the protocol is rarely deviated from and when deviations occur, they have been relatively minor (e.g. use of more simplified worksheets; additional stressor sessions). In the face of clinical complexity, good case formulation could assist therapists in determining when and how standard PTSD protocols might need to be added to or deviated from when barriers to effective therapy are identified, or when client progress appears to be less than optimal.

Although mention is made of the use of case formulation in some research trials for PTSD (e.g., Ehlers et al., 2013; Sannibale et al., 2013) and some authors have focused on the importance of a case formulation approach for PTSD (Fernando & Lampo, 2018; Kerig, Sink, Cuellar, Vanderzee, & Elfstrom, 2010; Lee, 2016; Padmanabhanunni & Edwards, 2015; Waltman, 2015; Zayfert & Becker, 2007), these studies have typically been single case reports, where often the type or level of formulation used is not specified. Additionally, whether its use results in superior outcomes compared with protocol driven treatment with minimal formulation is unknown.

A recent small-scale pilot study suggests that using explicit case formulation to guide deviations in PTSD treatment may be viable (Nixon & Bralo, 2019). This uncontrolled, open trial ($N = 23$), employed a single group pre-posttest design with a three-month follow-up. The case formulation process utilised went beyond the case conceptualisation process already inherent in the standard CPT protocol, which predominantly focuses on the importance of assessing how a client has made meaning of the traumatic event/s and how to use key CPT elements to identify and address factors thought to lead to the maintenance of a client's PTSD (e.g., use of an Impact Statement to identify and begin processing stuck points). Explicit case formulation as used by Nixon and Bralo (2019) involved a more wide-ranging approach to not only describe and explain how PTSD has developed and is maintained for that individual, but also to identify barriers and past and current factors which might impact recovery, as well as specifically highlighting client strengths and resources. The formulation was used both at the outset of therapy and throughout treatment as a guide, particularly for those clients with more complex presentations or who may not have been on track for a good outcome. Importantly the work of Nixon and Bralo allowed the introduction of other treatment methods and techniques when indicated by the formulation (e.g., use of behavioural experiments to test stuck points/negative beliefs). Results indicated significant reductions in PTSD (72% at posttreatment and 93% of those at three-month follow-up no longer met criteria for PTSD) (Nixon & Bralo, 2019).

Aims and Hypotheses

In summary, we do not know whether case formulation really helps in PTSD treatment, although a number of authors have suggested that it should help with more complex clients. Accordingly, I tested this proposal by conducting a randomised trial comparing CPT alone with CPT plus explicit case formulation (CPT+CF) in adults with PTSD. Participants received up to 15 sessions of therapy and were followed up at

posttreatment as well as 6-month follow-up. Based on the literature reviewed I had several key hypotheses.

It was hypothesised that participants in both treatment groups would demonstrate a reduction in PTSD symptoms; however if case formulation contributes to a greater treatment success then participants in the CPT+CF treatment would show a greater reduction in PTSD at posttreatment and follow-up, be more likely to achieve good end-state functioning, and show lower dropout. A number of secondary outcomes were also assessed (e.g., depression, substance use, sleep etc.). It was anticipated that CPT+CF participants would similarly show better outcomes in these domains.

As reviewed earlier, concerns have been raised by some clinicians regarding the adequacy of short-term PTSD therapies for more complex clients (Galovski, 2012; Gray et al., 2007). Given that case formulation has been proposed to improve outcomes by better individualising therapy for clients' specific problems and fostering better client-therapist relationships (Nattrass et al., 2015; Redhead et al., 2015) it was hypothesised that participant outcomes would be moderated in the following way:

1. Participants with complex presentations would exhibit less reduction in PTSD symptoms than those without a complex presentation, however this discrepancy would be smaller in the CPT+CF group than in the CPT alone treatment group;
2. Participants who report a lower therapeutic alliance (as rated by the participant) would exhibit less reduction in PTSD than those who report a greater therapeutic alliance however this discrepancy would be reduced in the CPT+CF group compared with CPT alone.

CHAPTER 2: METHOD[1]

Participants

Participants were recruited from a range of sources including agencies such as Yarrow Place Rape and Sexual Assault Counselling Service, Victim Support Services (VSS), South Australia Police Service (SAPOL) and other emergency services, and community mental health services. Participants also self-referred after seeing advertisements located at universities, throughout the community, and from community service announcements placed in local newspapers.

Inclusion criteria required participants to be over 18 years of age, to have been directly or indirectly exposed to a Criterion A traumatic event as defined by DSM-5 four or more weeks prior to inclusion in the study, to meet full diagnostic criteria for PTSD, with scores ≥ 25 on the Clinician Administered PTSD Scale (CAPS-5; (Weathers et al., 2018) and ≥ 31 on the PTSD Checklist (PCL-5; (Weathers et al., 2013), to be able to attend weekly therapy and demonstrate good English language proficiency. If on psychotropic medication, participants had to have been on a stable dose for the preceding six weeks. Exclusion criteria for the study were: participant was at imminent risk of harm (self or to others), significant cognitive impairment, uncontrolled bipolar or psychosis, or concurrently engaged in therapy specifically related to treatment of their PTSD symptoms. Personality disorders and severe substance use were not exclusions (unless risk was apparent). Participants with severe substance issues were admitted to the study provided they agreed to reduce or cease their substance usage during treatment.

The study was registered with the Australian New Zealand Clinical Trials Registry (Trial ID 12617000064303) and ethics was obtained through the Women and Children's Health Network Human Research Ethics Committee (HREC/16/WCHN/113).

[1] The Consort guidelines (Moher et al., 2012) have been followed in the reporting of relevant information throughout the thesis.

A total of 223 people contacted the researcher and were initially screened for eligibility via a brief phone interview (see Figure 2.1 for participant flow). Of those, 46 did not respond to further contact made by email and/or phone and 68 were not eligible or not interested in participating in the study following contact being made. Of those who could be contacted; 30 did not meet the requirement for a Criterion A trauma; eight could not attend weekly sessions due to either employment issues or were living interstate; eight were in current trauma-focused therapy and wished to continue with their own therapist, two were not safe (in current domestic violence relationships and therefore referred to crisis support services); 11 were for other reasons (e.g., wanted to be paid for participation; were calling for a family member; were calling for work opportunities) and nine gave no reason for no longer being interested in participating. Of the participants who attended a face-to-face assessment for diagnostic interviews, 16 were deemed ineligible for the following reasons: sub-threshold or non-PTSD (n = 12); current and significant alcohol dependence not identified at the initial phone screening (n = 1); comprehension issues due to limited English ability at interview (n = 1) and withdrew voluntarily post full assessment because no longer interested (n = 2).

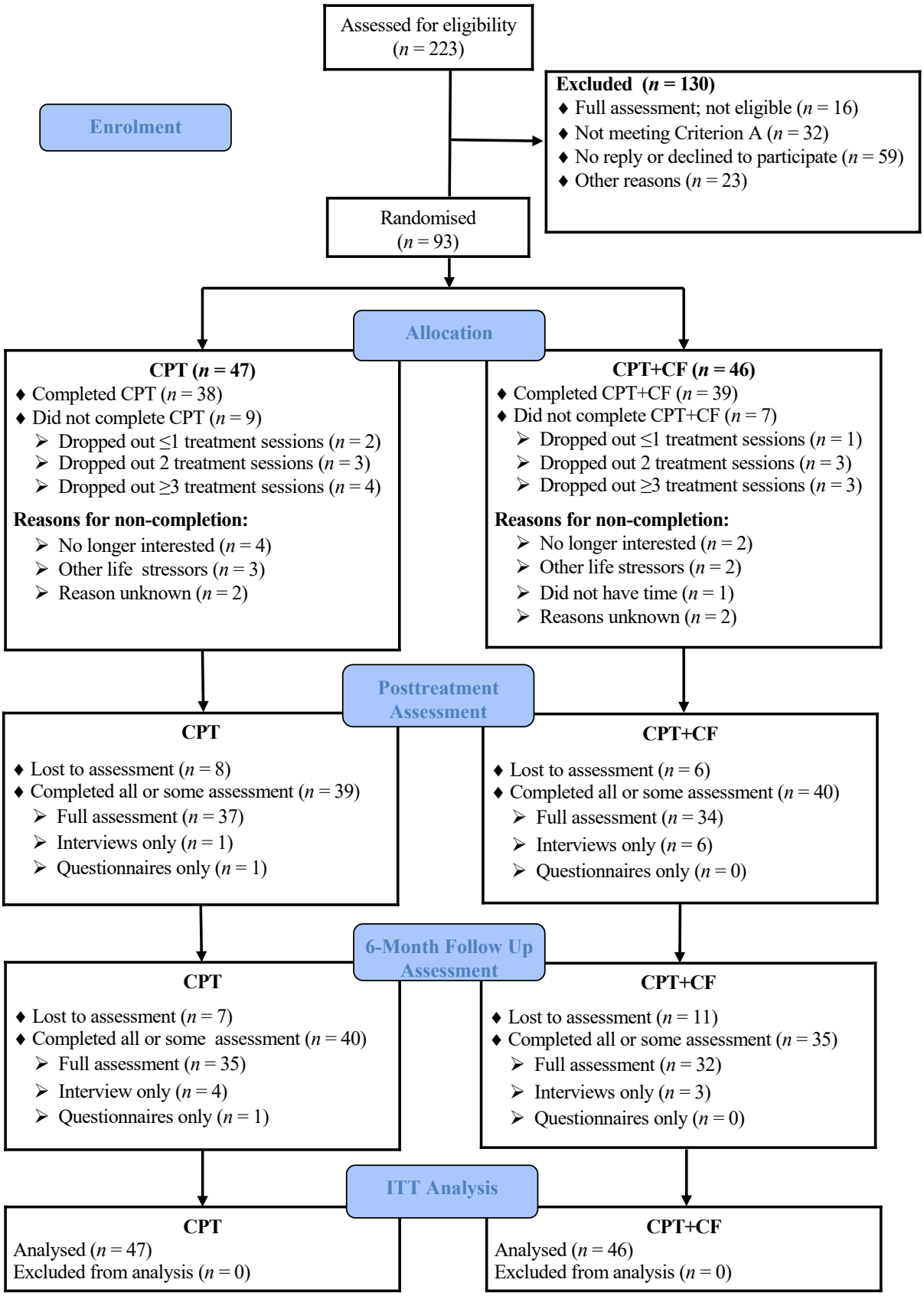


Figure 2.1. Flow chart of participant progression. CPT= Cognitive Processing Therapy; CF= Case Formulation; ITT=Intent to Treat.

Table 2.1

Participant Demographic and Pretreatment Trauma and Symptom Characteristics for Intent-to-Treat Sample

Characteristics *M* (SD) or *n* (%)	CPT (*n* = 47)	CPT+CF (*n* = 46)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Age (years)	43.38 (13.78)	43.26 (12.65)	$t = 0.04$	.965	0.01 [-0.40, 0.42]
Female	31 (66%)	31 (67.4%)	$\chi^2 = 0.02$	> .999	0.02 [-0.19, 0.23]
White ethnicity	37 (78.7%)	35 (76.1%)	$\chi^2 = 4.66$	.458	0.22 [0.12, 0.38]
Education (years)	15.57 (3.67)	14.24 (2.95)	$t = 1.90$	.046	0.40 [-0.01, 0.81]
Currently employed	30 (63.8%)	30 (65.2%)	$\chi^2 = 0.02$	> .999	0.01 [-0.20, 0.21]
First responder	7 (14.9%)	13 (28.3%)	$\chi^2 = 2.46$	.136	0.16 [-0.03, 0.37]
Income					
Less than $10,000	3 (6.4%)	5 (10.9%)			
$10,001 – 30,000	13 (27.7%)	10 (21.7%)			
$30,001 – 50,000	4 (8.5%)	5 (10.9%)	$\chi^2 = 2.10$	.835	0.15 [0.12, 0.43]
$50,001 – 70,000	12 (25.5%)	8 (17.4%)			
$70,001 – 90,000	2 (4.3%)	2 (4.3%)			
More than $90,000	13 (27.7%)	16 (34.8%)			
Marital status					
Single	10 (21.3%)	12 (26.1%)			
Married/cohabiting	22 (46.8%)	22 (47.8%)	$\chi^2 = 9.27$	.099	0.32 [0.21, 0.51]
Divorced/separated/widower	12 (25.5%)	5 (10.9%)			
Relationship not living together	3 (6.4%)	7 (15.2%)			

Characteristics *M* (SD) or *n* (%)	CPT (*n* = 47)	CPT+CF (*n* = 46)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Index Trauma					
Child sexual abuse	5 (10.6%)	10 (21.7%)			
Adult sexual assault	7 (14.9%)	3 (6.5%)	χ^2 =6.81	.657	0.27 [0.25, 0.55]
Child physical abuse	4 (8.5%)	4 (8.7%)			
Adult physical assault	7 (14.9%)	6 (13%)			
Motor vehicle accident	6 (12.8%)	3 (6.5%)			
Witness death	8 (17%)	11 (23.9%)			
Serious injury/threat of death	3 (6.4%)	3 (6.5%)			
Physical assault	4 (8.5%)	2 (4.3%)			
Traumatic loss	2 (4.3%)	1 (2.2%)			
Home invasion/rape	1 (2.1%)	3 (6.5%)			
Interpersonal trauma	29 (61.7%)	29 (63%)	χ^2 =0.02	> .999	0.01 [-0.17, 0.22]
Years since index trauma	17.37 (16.18)	15.99 (15.78)	t = 0.42	.677	0.09 [-0.32, 0.50]
Current comorbid diagnoses (MINI)					
Major Depressive Disorder	32 (68.1%)	27 (58.7%)	χ^2 = 0.88	.394	0.10 [-0.31, 0.11]
Panic Disorder	21 (44.7%)	15 (32.6%)	χ^2 = 1.43	.289	0.12 [-0.32, 0.08]
Agoraphobia	18 (38.3%)	13 (28.3%)	χ^2 = 1.05	.380	0.11 [-0.31, 0.10]
Mania or Hypomania	4 (8.5%)	3 (6.5%)	χ^2 = 0.13	> .999	0.04 [-0.23, 0.16]
Social Anxiety Disorder	13 (27.7%)	15 (32.6%)	χ^2 = 0.27	.656	0.05 [-0.16, 0.27]
Obsessive-Compulsive Disorder	10 (21.3%)	5 (10.9%)	χ^2 = 1.86	.260	0.14 [-0.35, 0.06]
Generalised Anxiety Disorder	20 (42.6%)	18 (39.1%)	χ^2 = 0.11	.834	0.04 [0.24, 0.16]
Alcohol abuse or dependence	18 (38.3%)	22 (47.8%)	χ^2 = 0.86	.406	0.10 [-.10, 0.29]
Substance abuse or dependence	4 (8.5%)	6 (13.0%)	χ^2 = 0.50	.523	0.07 [-0.14, 0.27]
Psychotic Disorder	1 (2.1%)	3 (6.5%)	χ^2 = 1.09	.361	0.11 [-0.11, 0.26]
Eating Disorder	4 (8.5%)	3 (6.5%)	χ^2 = 0.13	> .999	0.038 [-.23, 0.18]
Comorbid conditions (Total)	3.09 (2.03)	2.83 (1.90)	t = 0.64	.527	0.13 [-.28, 0.54]

Characteristics *M* (SD) or *n* (%)	CPT (*n* = 47)	CPT+CF (*n* = 46)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Current suicidality	28 (59.6%)	30 (65.2%)	$\chi^2 = 0.12$	.830	0.04 [-.18, 0.25]
Suicidal Behaviour Disorder	13 (27.7%)	12 (26.1%)	$\chi^2 = 0.03$	> .999	0.02 [-.23, 0.19]
Any hospitalisation pretrauma	8 (17.0%)	2 (4.3%)	$\chi^2 = 3.89$	.091	0.21 [0.01, 0.36]
Any hospitalisation posttrauma	20 (42.6%)	10 (21.7%)	$\chi^2 = 4.61$	.046	0.22 [0.18, 0.41]
Symptom Measures					
CAPS-5 severity	43.04 (9.24)	41.96 (7.71)	$t = 0.62$	.540	0.13 [-0.28, 0.54]
PCL-5	51.89 (11.05)	48.48 (10.40)	$t = 1.53$	.128	0.32 [-0.09, 0.73]
DASS-D	23.32 (11.51)	23.87 (10.94)	$t = 0.23$	.816	0.05 [-0.36 - 0.46]
PTCI	149.09 (35.59)	133.67 (39.04)	$t = 1.98$	.051	0.41 [-0.002, 0.82]
ISI	16.38 (6.56)	15.64 (5.66)	$t = 0.58$	.565	0.12 [- 0.29, 0.53]
DERS	104.09 (24.23)	97.31 (21.75)	$t = 1.41$	.162	0.29 [- 0.12, 0.70]
AUDIT	7.09 (7.81)	6.58 (6.18)	$t = 0.35$	.731	0.07 [- 0.34, 0.48]
CUDIT	1.26 (4.72)	1.22 (4.70)	$t = 0.03$	.973	0.01 [-0.40, 0.41]
DUDIT	1.38 (3.63)	2.89 (7.49)	$t = 1.22$	.227	0.26 [-0.15, 0.67]
CCPC (Total)	11.68 (4.46)	10.24 (4.70)	$t = 1.50$	.136	0.31 [-0.10, 0.72]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPR = Complicated Client Presentation Checklist.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large; for φ: 0.1 = small, 0.3 = medium, and 0.5 = large.

Demographic information, trauma history and baseline comorbidity and symptom levels are contained in Table 2.1. Across the whole sample, participants identified their worst trauma experience (i.e., index trauma) as childhood sexual abuse (16.1%), witnessing death of another person (20.4%), adult domestic violence (14%), childhood physical abuse (8.6%), adult sexual assault (10.8%), and home invasion and/or associated rape (4.3%). There were no significant differences between the groups in relation to the type of index trauma or trauma history. The average length of time since the index trauma was 16.69 years (*SD* = 15.9), ranging from one-month posttrauma to 55 years. The majority of the participants had experienced multiple traumas in their lifetime including a serious motor vehicle accident (80.6%), fire, explosion or natural disaster (65.6%), physical assault by a family member or someone known (63.4%), physical assault by a stranger (51.6%), assault with a weapon (48.4%), sexual assault by a family member or someone known (51.6%), sexual assault by a stranger (33.7%), childhood sexual assault (41.3%) and life-threatening illness (45.7%). The average number of trauma types experienced was 7.66 (SD = 3.50).

Comorbid conditions were assessed using the MINI International Neuropsychiatric Interview 7.0.2 for DSM-5 (Sheehan, 2016). Participants were assessed for major depressive disorder, mania, hypomania, bipolar disorder, panic disorder, agoraphobia, social anxiety disorder, obsessive-compulsive disorder, alcohol use disorder, substance use disorder, any psychotic disorder, anorexia nervosa, bulimia nervosa, binge eating disorder and generalised anxiety disorder. The suicide module was also used to assess current risk of suicide and suicidal behaviour disorder. There were no significant differences between groups for comorbid condition type or for total number of conditions. As expected, the majority (91.4%) of participants had an additional diagnosis, with the most common comorbidities being MDD (63.4%), alcohol abuse disorder (43%), generalised anxiety disorder (40.9%), panic disorder (38.7%), agoraphobia (33.3%) and social anxiety disorder (30.1%). Almost two thirds of

participants (62.4%) reported currently having thoughts and/or feelings of suicide with 29% rated in the moderate to severe range. There was no significant difference between groups in pretrauma hospitalisations, however there was a significant difference between groups in hospitalisations posttrauma with more participants in the CPT group reporting hospitalisations posttrauma (p = .032, d = 0.22, 95% CI d = [0.18, 0.41]. Additionally, there was a significant difference in education at pretreatment, however as reported in the Supplementary information (Table S1) education did not differentiate whether participants completed treatment or not. Overall therefore, findings suggest that at pretreatment, the CPT only group were slightly more complicated in regard to higher symptom severity, more comorbidities and more posttrauma hospitalisations.

Both groups were comparable in respect to the credibility/expectancy of treatment. This was seen at pretreatment (CPT alone: M = 39.70, SD = 8.22; CPT+CF: M = 42.00, SD = 7.17, t(90) = 1.43, p = .157, d = 0.30), as well as at posttreatment (CPT alone: M = 47.76, SD = 8.11; CPT+CF: M = 47.86, SD = 7.54, t(70) = 0.05, p = .957, d = 0.01), and follow-up (CPT alone: M = 48.00, SD = 6.40; CPT+CF: M = 47.89, SD = 5.51, t(65) = 0.08, p = .941, d = 0.02), where participants were asked to reflect on how they now felt about the treatment in terms of how believable, convincing and logical the treatment is and their expectancy that the treatment would benefit them. Linear mixed modelling demonstrated there was no significant group by time interaction (F(2, 128.20) = 0.75, p = .475) however credibility/expectancy did increase significantly over time, (F(2, 128.20) = 34.76, $p < .001$; see Supplementary Analyses Table S4 and S5). Analysis for the completer sample revealed no significant differences between groups at pretreatment (CPT alone: M = 40.61, SD = 7.56; CPT+CF: M = 41.87, SD = 7.14, t(75) = .76, p = .452, d = 0.17), as well as at posttreatment (CPT alone: M = 49.29, SD = 4.24; CPT+CF: M = 47.86, SD = 7.54, t(68) = .98, p = .332, d = 0.23), and follow-up (CPT alone: M = 48.73, SD = 5.14; CPT+CF: M = 47.89, SD = 5.51, t(63) = .63, p

= .529, d = 0.16). As seen with the ITT sample, credibility/expectancy of treatment showed a significant overall interaction for time (F(2, 122.79) = 46.53, p < .001) but no significant main effect for group (F(1,68.21) = 0.19, p = .662) nor group by time (F(2,122.79) = 1.64, p = .197; see Supplementary Analyses Tables S6 and S7).

All participants were offered up to 15 sessions of treatment, with no significant difference overall in the average number of treatment sessions attended (CPT: M = 11.28, SD = 4.16; CPT+CF: M = 11.35, SD = 4.41, t(91) = 0.08, p = .936, d = .02). Participants were categorised as early therapy completers if they had a PCL-5 score of ≤ 10 for three consecutive sessions and both participant and therapist agreed it was appropriate to complete treatment. Treatment *dropouts* were differentiated from early completers if they terminated their treatment before the 15 sessions, did not show a clinically significant change on the PCL-5, and the therapist was of the opinion the participant still required therapy. The overall dropout rate was 17.2% (n = 16) with 77 participants completing treatment. There were no significant differences in the dropout rate between the two groups (CPT = 9; CPT+CF = 7; Fishers Exact Test [FET] p = 0.785; φ = .05). Dropouts had significantly higher symptom scores than treatment completers on most baseline measures including PTSD (PCL-5: p = .025, d = 0.63, 95% CI d = [0.08, 1.17]), depression (p = .025, d = 0.64, 95% CI d = [0.10, 1.19] and posttraumatic cognitions (p = .006, d = 0.79, 95% CI d = [0.24, 1.34] and scored higher on the complicated client checklist (p = .021, d = 0.66, 95% CI d = [0.11, 1.21]. Effect size differences for pretreatment measures ranged from 0.04 to 0.79 (see Supplementary Table S1 for details). Dropouts also had more pretreatment comorbid conditions than completers including significant differences when totalling all comorbid conditions (p = .021, d = 0.66, 95% CI d = [0.011, 1.21]. Of the dropouts, 10 (62.5%) had completed three or less treatment sessions with the overall average 3.56.

There was a significant difference on pretreatment PTSD severity (PCL-5) for those participants who did not complete any form of posttreatment assessment (M = 58.93, SD = 8.34) versus those who did complete later assessments (M = 48.66, SD = 10.50), $t(91)$ = 3.47, p =.001, d = 1.01). For follow-up assessments, there was also a significant difference for pretreatment PTSD severity (PCL-5) for those who did not complete any 6-month assessment (M = 54.95, SD = 8.71) compared with those who did (M = 49.07, SD = 11.01), $t(91)$ = 2.11, p =.038, d =0.55). However there were no significant differences between the groups in terms of who engaged in posttreatment assessments, with good retention in both groups (CPT: 83%, CPT+CF: 87%, χ^2 = .288, p = .592).

Power

My key hypothesis was that treatment complexity would moderate outcome over time. We used an a-priori analysis with G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) to determine the sample size. The repeated measures ANOVA (within-between interaction) option was chosen to approximate linear mixed modelling (LMM) which is not included in G-Power and given there is no established strategy for conducting power analyses for the specific analyses I conducted. This demonstrated that 54 participants in total were needed to be able to detect just under a medium effect (f = .2, 80% power, alpha = .05, 3 groups which included the moderator, 3 assessments, r between measurements = .5, nonsphericity correction = 1). A sample size of 60 was set as the recruitment target, however recruitment was more successful than anticipated, thus data collection was continued in the event the differences between conditions were smaller than expected. Recruitment ceased so that I could submit my PhD on time.

Measures[2]

The main outcome variables of PTSD symptoms and depression were measured using the Clinician Administered PTSD Scale (CAPS-5), the PTSD Checklist (PCL-5) and the depression subscale of the Depression, Anxiety and Stress Scale (DASS-21-D). Secondary outcomes relevant to PTSD (e.g. trauma cognitions, emotional regulation, sleep etc.) were also measured. In addition, measures were used to develop the Complicated Client Presentation Checklist which was developed for the purposes of this study using a range of factors which research has indicated may adversely affect client outcomes. All measures used are described below.

Clinical Interviews

Clinician Administered PTSD Scale for DSM-5 (Weathers et al., 2018). The CAPS-5 is an established interview-administered diagnostic interview for PTSD consistent with the criteria as set out by the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (APA, 2013). It assesses PTSD symptoms plus associated features such as dissociation, global ratings of distress, impairment, validity of responses and improvement since previous administrations. The CAPS-5 assesses both frequency/amount and intensity of symptoms on a five-point scale ranging from Absent (0) through to Extreme/Incapacitating (4), with the maximum possible total score being 80. The CAPS-5 total severity score has high internal consistency (α = .88), strong interrater reliability (ICC = .91) and high test-retest reliability (ICC = .78). It also demonstrates good convergent validity with total severity score strongly correlated with the CAPS-IV (r = .83) and the PTSD Checklist for DSM-5 (r = .66) (Weathers et al., 2018). In the current study, Cronbach's α for the CAPS-5 severity at pretreatment was .74. A CAPS-5 severity score of ≥ 25 was the clinical cut-off used for study inclusion (Schnurr et al., 2015).

[2] Unless otherwise stated, all measures were administered at pretreatment, posttreatment, and 6-month follow-up. PTSD outcomes (symptom severity, diagnosis) were considered the primary outcomes of interest.

MINI International Neuropsychiatric Interview 7.0.2 for DSM-5 (MINI; (Sheehan, 2016). The MINI is a structured diagnostic interview for a number of the major psychiatric disorders described in both the DSM and International Classification of Diseases (ICD-11). For the purposes of this research all modules were used except those for PTSD (assessed using the CAPS-5) and antisocial personality disorder. This version of the MINI is based on DSM-5 criteria, for which psychometric information is yet to be published, but the prior version of the MINI demonstrated strong properties, for example, test-retest reliability between .79 and .93 and interrater reliability above .75 (Sheehan et al., 1997).

Trauma Interview. A semi-structured clinical interview was used to gather information relevant to the study such as demographics, details of the trauma, social support, family mental health history and past and current psychological and medical status. The interview was administered at the pretreatment assessment.

Questionnaires

Posttraumatic Stress Disorder Checklist (Weathers et al., 2013). The PCL-5 is a 20-item self-report rating scale that assesses PTSD symptoms. Participants indicate how much each PTSD symptom has bothered them in the past month on a 5-point scale ranging from 0 – *Not at all* to 4 – *Extremely*. It was administered at each assessment point as well as prior to each treatment session (the latter administrations requiring participants to indicate symptoms over the past week). PCL-5 scores have strong internal consistency (α = .96), test-retest reliability (r = .84), convergent and discriminant validity and structural validity (Bovin et al., 2016). In the current study, Cronbach's α for the PCL-5 at pretreatment was .81.

Depression, Anxiety and Stress Scale (Lovibond & Lovibond, 1995a). The DASS-21 is a self-report, short-form version of the 42-item DASS that measures depression, anxiety and stress symptoms. Each construct is rated by seven items with participants asked the degree to which the statement applied from 0 – *Did not apply to me at all* to 3 – *Applied very*

much, or most of the time. It was administered at each assessment session and also at each treatment session. The Depression subscale of the DASS-21 is reported on in the analysis of results. The Depression scale has good internal consistency (α = .82) with an overall internal consistency for the scale at .93 (Henry & Crawford, 2005). In the current study, Cronbach's α for the DASS-21 at pretreatment was .90.

Outcome Rating Scale (Miller & Duncan, 2000). The ORS is a four-item rating scale measuring an individual's personal, relationships, social and overall wellbeing over the previous week. It was designed as a diagnostic measure to track participant change throughout therapy, and consecutive scores below a cut-off have been shown to predict risk of treatment nonresponse and dropout (Miller, Duncan, Brown, Sparks, & Claud, 2003). Participants mark their functioning on a blank line (measuring 10 cm), which ranges from low levels (score = 0) to high levels (maximum = 10). Accordingly, total scores can range from 0 to 40, with a score of 25 the clinical cut-off. The ORS has strong internal consistency (α = .97), high test-retest reliability (r = .80), and moderate concurrent validity of .69 (Bringhurst, Watson, Miller, & Duncan, 2006). The ORS was included in the study as a secondary item of interest; that is, whether this briefer measure indexed participant change in a similar fashion to that documented by weekly administration of the PCL-5. Participants completed the ORS at the beginning of every therapy session.

Trauma History. This questionnaire administered at pretreatment assessment is an adaptation of the Life Events Checklist (LEC-5; Weathers et al., 2013), and was used to assess the frequency and severity of previous traumatic experiences. It contains 19 items listing various traumatic events, with an additional item allowing for any other traumatic event to be specified. For each item participants note how often the event occurred by circling a number between 0 to 6, indicating a range from *never*, through to *more than 20 different*

times. For each item listed as having been experienced, the severity of the incident or worst incident was self-reported on a scale of 0 to 10 (0 = *no distress*, 10 = *extremely distressing*).

Posttraumatic Cognitions Inventory (Foa, Ehlers, Clark, Tolin, & Orsillo, 1999). The PTCI is a 36-item measure assessing unhelpful trauma-related beliefs an individual can have after a traumatic experience. Each item is scored across a scale from 1 (*Totally Disagree*) to 7 (*Totally Agree*), with a total score ranging from 36 to 252 (higher scores indicate more problematic thinking). In a sample of traumatised subjects without PTSD the median score was 49.0 and for traumatised subjects with PTSD the median score was 133.0 (Foa et al., 1999). The measure has three subscales: negative cognitions about the self (21 items), negative cognitions about the world (7 items) and self-blame (5 items), which show good internal consistency (total score, α = .97; Self, α = .97, World, α = .88, Self-Blame, α = .86) and test-retest reliability (Spearman Rho: total score, P = .74, Self, P = .75, World, P = .89, Self-Blame, P = .89) (Foa et al., 1999). In the current study, Cronbach's α for the PTCI at pretreatment was .95. The total score is reported in the present study and pursuant to Foa, a score of 133+ has been used as indicating trauma with PTSD.

Insomnia Severity Index (Morin, Belleville, Belanger, & Ivers, 2011). The ISI is a seven-item scale designed to assess the nature, severity, and impact of insomnia and used to monitor sleep treatment response in adults. Items include level of satisfaction/dissatisfaction with current sleep pattern, how worried/distressed an individual is about their current sleep problem and to what extent it interferes with daily functioning. Scores are added to obtain a final score (range 0 to 28). Score categories indicate level of clinically significant insomnia where 0-7 = *none*, 8-14 = *subthreshold*, 15-21 = *moderate severity clinical insomnia* and 22-28 = *severe clinical insomnia*. The measure has been found to have strong internal consistency across both community and clinical samples (α of .90 and .91 respectively) with moderate improvement indicated by an ISI change score of -8.4 points (95% CI: -7.2, -9.5)

and marked improvement an average change score of -9.9 (95% CI: -8.7, -11.0) (Morin et al., 2011). In the current study, Cronbach's α for the ISI at pretreatment was .88.

Alcohol Use Disorders Identification Test (AUDIT; Babor, de la Fuente, Saunders, & Grant, 1992). The AUDIT is an extremely widely used and studied 10-item screening tool developed by the World Health Organization to assess alcohol consumption, drinking behaviour, and alcohol-related problems. It has excellent psychometric and validity properties (Allen, Litten, Fertig, & Babor, 1997). A score of 0-7 indicates Low-risk, 8-15 a Risky or hazardous level, 16-19 High-risk or harmful level and 20 or more High-risk and Almost certainly dependent. In the current study, Cronbach's α for the AUDIT at pretreatment was .87.

Cannabis Use Disorders Identification Test - Revised (Adamson et al., 2010). The CUDIT, modelled on the AUDIT, is a 10-question, self-report screening instrument developed to accurately assess cannabis consumption, cannabis problems (abuse), dependence and psychological features. Questions 1-7 are scored on a 0 to 4 scale from *Never* to *Daily or Almost Daily* and Question 8 regarding whether an individual has ever thought about cutting down or stopping cannabis use is scored 0 = *Never*, 2 = *Yes, but not in the past 6 months* and 4 = *Yes, during the past 6 months*. A total score of 8+ indicates a hazardous level of cannabis use with a score of 12+ indicating possible cannabis use disorder. The measure has strong internal consistency (α = .91) and test-retest reliability (r = .87) (Adamson et al., 2010). In the current study, Cronbach's α for the CUDIT at pretreatment was .95.

Drug Use Disorders Identification Test (DUDIT; Berman, Bergman, Palmstierna & Schlyter, 2002, 2005). Modelled on the AUDIT, the DUDIT is an 11-item self-administered screening instrument for drug-related problems, giving information on the level of drug intake and selected criteria for substance abuse/harmful use and dependence. The tool

is gender specific with a score of 6+ indicating drug-related problems for men and 2+ for women, and 24+ an indication of highly probably heavily dependent on one or more drugs for both genders. A review of the measure reports internal consistency reliability estimates as high (α > .90) (Hildebrand, 2015). In the current study, Cronbach's α for the DUDIT at pretreatment was .93.

Difficulties in Emotional Regulation Scale (DERS; Gratz & Roemer, 2004). The DERS is 36-item self-report questionnaire designed to assess multiple types of emotion dysregulation including difficulties in engaging in goal-directed behaviour, impulse control difficulties, lack of emotional awareness, lack of emotional clarity and limited access to emotional regulation strategies. Example items include: *When I'm upset, I feel like I'm weak*; *When I'm upset, my emotions feel overwhelming;* and *I have no idea how I'm feeling*. Participants indicate the degree to which they have maladaptive regulation strategies for each item on a response scale that ranges from 1 (*Almost Never / 0-10% of the time*) to 5 (*Almost Always / 91-100% of the time*). Possible total scores range from 36 to 180, with higher scores indicating more difficulties with emotional regulation. The measure has high internal consistency (α > .93) and good overall test-retest reliability (.88, p < .01) (Gratz & Roemer, 2004). In the current study, Cronbach's α for the DERS at pretreatment was .93.

Structured Clinical Interview for DSM 5 - Personality Disorders (First, Williams, S., & Spitzer, 2016). The SCID-5SPQ is a 106-item self-report screening tool, which is generally used to guide a subsequent clinical interview using the SCID-5-PD to diagnose personality disorders. The SCID-5 screening measure was used to index traits of the 10 DSM-5 personality disorders (Avoidant (*7 items*), Dependent (*8 items*), Obsessive-Compulsive (*9 items*), Paranoid (*8 items*), Schizotypal (*13 items*), Schizoid (*6 items*), Histrionic (*8 items*), Narcissistic (*17 items*), Borderline (*15 items*) and Antisocial (*15 items*)). Time constraints precluded formal assessment of personality disorders, however the SCID-5SPQ was used as a

proxy for measuring borderline personality disorder and contributed to the measurement of client complexity (discussed below). In the current study, Cronbach's α for the SCID-5SPQ at pretreatment was .92.

Assessment of Quality of Life-8D (AQoL-8D; Richardson et al., 2009). The AQoL is a health-related quality of life instrument which has 35 questions assessing across eight health dimensions: Independent Living, Happiness, Mental Health, Coping, Relationships, Self-Worth, Pain and Senses. The measure has high test-retest reliability (Cronbach's α = .96) (Richardson et al., 2014). In the current study, Cronbach's α for the AQoL-8D at pretreatment was .93.

Complicated Client Presentation Checklist (CCPC). At the time the study was initiated, there was no available measure that indexed the complexities seen in PTSD clients.[3] Accordingly the CCPC was developed, comprising of 30 variables which prior research has indicated might negatively influence treatment outcomes (items scored dichotomously). The checklist included items indexing gender, social support, PTSD severity, PTSD dissociative subtype, trauma type and frequency, comorbid conditions, substance use, suicidality, personality factors, insomnia, emotional regulation and pretrauma cognitions. Items were assigned a score of '1' as follows: participant was male (Blain et al., 2010; Wade et al., 2016); reported their social support as 0, 1 or 5 on a scale where 0 = '*No social support'*, 1 = '*A little supportive*' and 5 = '*Not applicable (Have not told anyone)*' (versus 2 = '*Somewhat supportive*', 3 = '*Quite supportive*' or 4 = '*Very supportive*') (Brewin et al., 2000; Ozer et al., 2003); CAPS-5 was 60+ and/or PCL-5 55+; met PTSD dissociative subtype (as per the CAPS-5); had more than four lifetime traumas (Karam et al., 2014); had experienced childhood sexual assault; had experienced prolonged and repeated trauma (e.g. domestic

[3] The ICD-11 Complex PTSD diagnosis was not released until after the beginning of the study and even so, client presentations can still be challenging or complicated in the absence of a Complex PTSD diagnosis.

violence or as a first responder, emergency services worker or war veteran) and/or interpersonal trauma; had current suicidal ideation at the '*moderate*' or '*severe'* range (as per the MINI); had a comorbid condition (as per the MINI) of: major depressive disorder; generalised anxiety disorder; panic disorder; agoraphobia; mania; obsessive-compulsive disorder; or an eating disorder (each scored as 1 if present); were assessed as having alcohol abuse and/or dependence as '*severe*' on the MINI and/or a score of 16+ on the AUDIT ('*severe*' or '*extremely severe*'); were assessed as having a score of 8+ on the CUDIT indicating abuse and/or dependence as '*severe*' or '*extremely severe*'; other drug misuse/abuse (including prescription) as assessed on the MINI; had positively endorsed the requisite number of screening questions to meet personality disorder types (SCID-5-SPQ); had negative trauma cognitions greater than the median score for PTSD clients (PTCI 133+); were assessed as '*severe*' or above for sleep difficulties (i.e., an ISI score of 22+); and had high levels of emotional regulation difficulties (defined as a score of ≥ 108 on the DERS, which represents an average score of 3+ ('*about half of the time*' and above at the individual item level). Accordingly, total scores on the CCPC could range from 0 to 30, with higher scores reflecting more complex and potentially therapy-interfering issues. Internal reliability of the measure was .75 (Cronbach's alpha). Correlations between the CCPC and other pretreatment symptom measures ranged from r = .40 (DASS-Depression) to .47 for (CAPS-5/PCL-5), suggesting that the measure was not simply a proxy for symptom severity. See Appendix A for CCPC.

Therapy Process Measures

Case Formulation Evaluation. As no standard measure exists to evaluate the usefulness or acceptability of case formulation from a client's perspective, a modified version of that used by Nixon and Bralo (2018) was adopted for the present study. It consisted of five items with which the participant rated the case formulation process as understandable, logical,

acceptable, helpful and a good summary of their current difficulties, using a 5-point scale ranging from *Totally Disagree* (1) to *Totally Agree* (5). These items were totalled for analyses. Two qualitative questions were also added which asked participants to detail what was *least* and *most* liked about the case formulation process. The measure was only used for the CPT+CF group, and administered in session 2, at posttreatment, and at 6-month follow-up. See Appendix C for Case Formulation Evaluation. In the current study, Cronbach's α for the case formulation evaluation at Session 2 was .84.

Therapeutic Letter Evaluation. For the same reasons as above, a measure was developed to evaluate the therapeutic letter used in CPT+CF (discussed further under *Treatment*). It comprised five items describing the participant's view of the therapeutic letter as understandable, logical, acceptable, helpful and a good summary of their current difficulties, using a 5-point scale (1 = *Totally Disagree*, 5 = *Totally Agree*). Again, two qualitative questions asked the participant what was *least* and *most* liked about the therapeutic letter. It was used for the CPT+CF group in session 4, and at post and 6-month follow-up assessment. See Appendix D for Therapeutic Letter Evaluation. In the current study, Cronbach's α for the therapeutic letter evaluation at Session 4 was .89.

Brief Revised Working Alliance Inventory (Mallinckrodt & Tekie, 2016). A revised version of the original 36-item WAI (Horvath & Greenberg, 1989) was used to measure therapeutic alliance (16-items). It contains two subscales designed to assess alliance between a client and therapist regarding agreement on the *tasks/goals* of treatment and the strength of the *bond* between therapist and client. The response scale ranges from 1 (*Rarely or Never*) to 5 (*Always*) with a higher range score indicating a better alliance. The original scale had high internal consistency of the total scale and subdomains (total score, α = .91; subdomains ranging from .81 to .90) and test-retest reliability of .93 (Paap & Dijkstra, 2017) with the authors noting that the Br-WAI performs better than the full scale WAI

(Mallinckrodt & Tekie, 2016). It was used at sessions 2, 6 and 10 and at posttreatment and follow-up assessments. In the current study, Cronbach's α for the WAI at Session 2 was .88.

Credibility/Expectancy Questionnaire (Devilly & Borkovec, 2000). This 6-item questionnaire measures clients' expectancies that treatment will be helpful and perceived credibility of the treatment. Items included: *At this point how logical does the therapy offered to you seem? How confident would you be in recommending this treatment to a friend who experiences similar problems?* and *By the end of the therapy period, how much improvement in your trauma symptoms do you think will occur*? Higher scores reflect higher credibility and expectancy of treatment success. The reported internal consistency for the total scale ranges between .79 and .90 for the expectancy factor, between .81 and .86 for the credibility factor and between .84 and .85 for the total scale. It also possesses good test-retest reliability (.82 for expectancy and .75 for credibility over one-week period) (Devilly & Borkovec, 2000). The measure was used at the end of Session 1 (psychoeducation session and presentation of treatment rationale) and at posttreatment and follow-up assessments. In the current study, Cronbach's α for the questionnaire at Session 1 was .81.

Session Rating Scale (SRS; Miller & Duncan, 2000). The SRS is a four-item rating measure that participants completed at the end of each treatment session and served as a brief measure of alliance and satisfaction with therapeutic progress. It comprises three related components measuring the relationship bond between therapist and client, agreement on the goals of therapy and agreement on the tasks. The fourth item measures an overall rating for the session. At the positive end of the scale participants could indicate: "*I felt heard, understood, and respected"*, "*We worked on and talked about what I wanted to work on and talk about*", "*The therapist's approach is a good fit for me*" and "*Overall, today's session was right for me*", with responses at the negative end of the scale indicating the opposite. Like the

Outcome Rating Scale, items are scored on a 0 to 10 scale, with higher ratings indicating greater satisfaction. Total scores can range between 0 and 40. Test-retest reliability over six administrations (a period between three and six months) was .64, and validity has been demonstrated by correlation with other alliance measures such as the Helping Alliance Questionnaire II (r = .48) (Duncan et al., 2003).

Deviations from the Protocol

All deviations from the CPT protocol were documented using a form created for the purpose and completed by the therapist immediately after each session (See Appendix E). The form detailed what was covered in the session according to the standard CPT protocol, and the nature of any deviation and time spent. Deviations were coded as *no deviation*, *minor*, *moderate* or *major*. Deviations were also differentiated by type into those that were crisis/emergency deviations and those which were a deviation from the CPT protocol. Examples are as follows. A crisis deviation included any safety planning or risk assessment required for suicidal ideation and/or domestic violence issues. They also included any instances where an additional trauma occurred throughout treatment which warranted discussion. These crisis deviations were also coded for 'level' of deviation, which indicated the length of time needed, from a minor discussion up to needing an entire session. A CPT deviation was any deviation from the protocol itself. A minor deviation was defined as between 5-10 minutes and/or may have included psychoeducation or information about non-trauma related topics (e.g., sleep); a moderate deviation was between 11-30 minutes and could involve additional information and/or treatment strategies such as behavioural activation, motivational interviewing, or behavioural experiments. A major deviation involved in-depth development or discussion of a non-CPT related technique such as a behavioural experiment or therapeutic strategies to address panic. A major deviation generally would involve the entire session (decision rules for making deviations are outlined in sections below).

Procedures

After making contact with the researcher, participants were screened via phone by myself to ensure they met basic eligibility requirements. Following provision of an Information sheet outlining the research and obtaining informed consent, an in-person interview was conducted and structured interviews (CAPS-5, MINI, Trauma Interview) completed. The therapist who was allocated to each participant was responsible for conducting the pretreatment assessment interviews and used the process to establish rapport. Participants completed pretreatment questionnaires and were then randomised into treatment. In order to ensure the two treatment groups were comparable on key baseline characteristics that might influence treatment outcomes, minimised randomisation (Hu, Hu, Ma, & Rosenberger, 2014) was used to allocate to condition. Thus randomisation was stratified by gender, whether the index trauma was interpersonal or not, the number of current comorbidities ($\geq$ 4) and a CAPS-5 severity score of $\geq$ 40. Participants were randomised by an individual external to the study so that personnel conducting pretreatment assessments and providing the treatment were unaware of group allocation ratios, and to ensure treatment allocation was not influenced by the pretreatment assessment. Additional information about therapists and assessors is detailed below.

Posttreatment assessments were conducted two weeks after the end of therapy and the follow-up assessment was conducted six months post therapy. Participants who had dropped out of therapy prior to completion were assessed at the scheduled completion date *should* they have completed treatment. Participants were given a $20 gift voucher for completing the 6-month follow-up. The proportion of data returned is reported in the results. Data was collected throughout the study with the last participants finishing therapy in December 2018 and final data collection at the end of July 2019.

Treatment

Cognitive Processing Therapy (CPT)

The study followed the latest CPT manual (Resick et al., 2017). CPT comprises of 12 sessions of material, with most sessions of 60 minutes duration, however number of sessions is flexible depending on client progress. Initial sessions included an overview of treatment, rationale for CPT, and psychoeducation about PTSD and cognitive theory. The client completed an Impact Statement focusing on *why* they believed their traumatic event occurred and the effect on their life, particularly focusing on issues of safety, trust, power/control, esteem and intimacy. Problematic thinking about the traumatic event, or 'stuck points' were derived from the Impact Statement.

In subsequent sessions the connection between events, thoughts and feelings are introduced. Now optional in CPT, clients can also write a detailed description of the event through use of a Trauma Account. In this study, determination of whether a Trauma Account would be used was guided by supervision and whether it was deemed clinically advantageous to introduce the account (i.e., when a client was highly avoidant of strong emotions surrounding the event). Given that a Trauma Account is a standard CPT tool, use of a Trauma Account was not considered a deviation for the purposes of the study. In subsequent sessions, clients continue to work through their stuck points as they related to the traumatic event, with the therapist using a variety of techniques including Socratic questioning and challenging questions, and identifying patterns of problematic thinking. From session 7 to 11, the modules addressing safety, trust, power and control, esteem and intimacy were introduced which addressed problematic beliefs about each theme. In the penultimate session, clients were asked to write another Impact Statement, which reflected their *current* thinking, and in the final session this was compared with their original statement. This process provides an opportunity to highlight changes in thinking and treatment gains, as well as identifies residual

stuck points that might require further work. In the present study, up to 15 sessions were offered in the CPT alone condition to enable any residual stuck points to be addressed after the five modules had been discussed, and allowed for sessions where emergency, non-protocol deviations might have occurred.

Cognitive Processing Therapy/Case Formulation (CPT+CF)

CPT+CF followed the format described above in relation to the CPT component, but differed with the inclusion of a case formulation approach (Kuyken et al., 2009) that guided planned deviations from the CPT protocol. For participants randomised to the CPT+CF group, the initial therapy session was 90 minutes to allow for the case formulation process. The case formulation process was introduced to participants in Session 1 with a diagram that mapped PTSD symptoms to the participant's index trauma (see Figure 2.2). See Appendix B for a therapist version with additional prompts.

In order to individualise the formulation and ensure that other presenting issues were identified, past experiences, both distal and proximal, that might be relevant were also included in the diagram (e.g., the experience of severe childhood neglect might have also influenced the unhelpful or core beliefs of a participant who experienced domestic violence in adulthood). Participant's capabilities and strengths and resources were also discussed and documented. This explicit case formulation was conducted collaboratively with the participant, and a copy provided to them following the session. The case formulation could be revisited as needed, especially in the context of treatment gains not being observed during therapy (as tracked by the weekly administration of the PCL-5 and DASS-21).

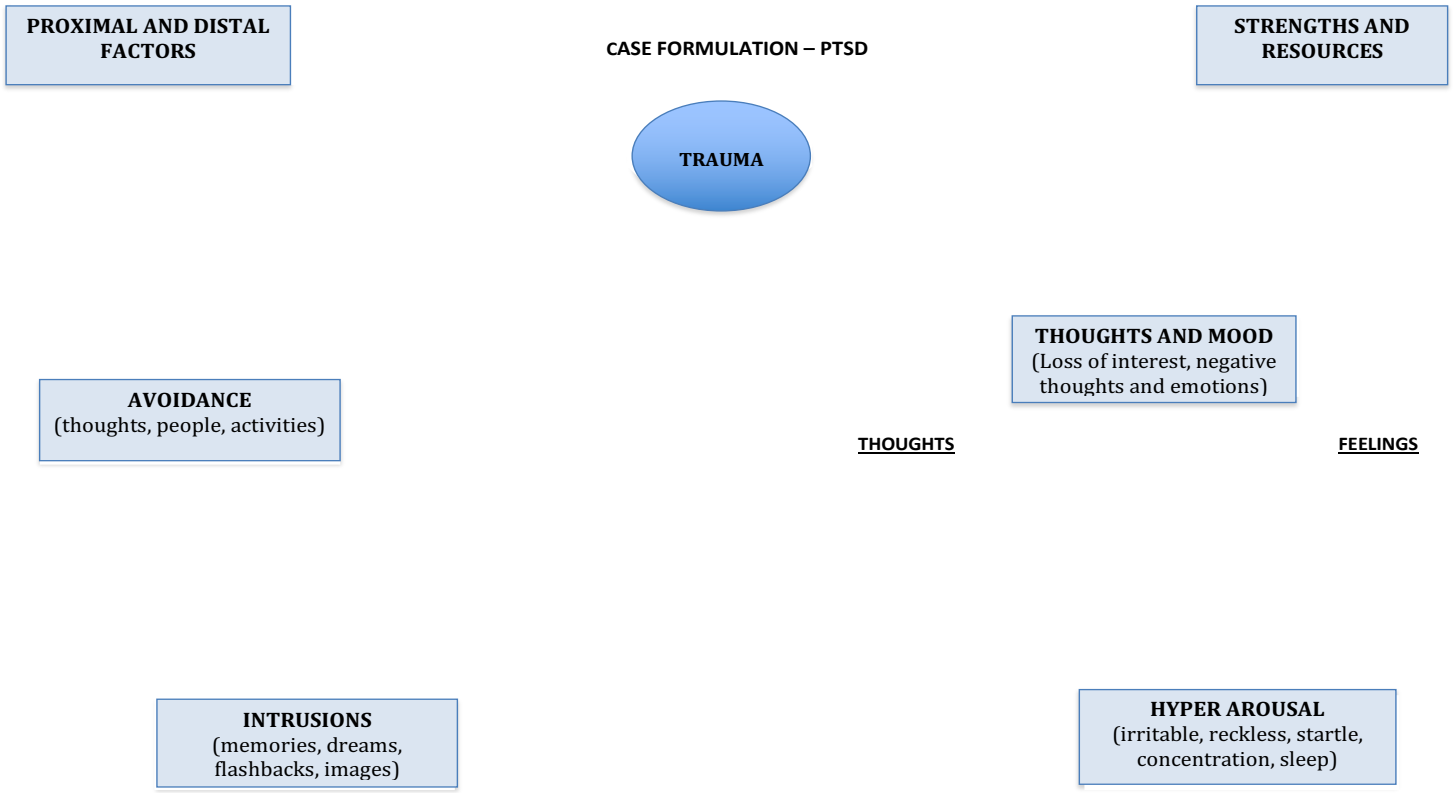


Figure 2.2. PTSD Case Formulation Diagram – Client Version

Thus, this formulation assisted in guiding the therapist to barriers in treatment and to help with decisions such as whether to target a particular issue (e.g., motivation, homework noncompliance) or comorbidity (e.g., substance abuse, chronic pain) that might be interfering with treatment. Participants in the CPT+CF group also received a therapeutic letter following Session 3. The letter was presented to the participant as a part of the case formulation process, with the rationale that it was a summary of the therapists' understanding of the factors leading to the development of PTSD in the participant, and their view of the participant's goals, strengths and resources. The letter allowed for checking of the participant's understanding and agreement with the accuracy of the case formulation, allowed opportunity for amendments, and was intended to strengthen the client-therapist relationship (see Appendix F for an example).

The CPT+CF group also allowed for a more flexible approach to delivery of the CPT protocol. In circumstances where treatment gains were not being made or therapy-interfering behaviours were present, major deviations from the therapy could occur. These included: the introduction of behavioural experiments and experiential exercises to test assumptions and challenge beliefs that did not appear to be shifting through use of typical CPT cognitive techniques and worksheets; the use of distress tolerance techniques and sessions focused on managing distress when significant emotional dysregulation was evident; motivational interviewing to address ambivalence or noncompliance with therapy; and sessions on addressing relationship issues which may have been contributing barriers to treatment progression. As reported earlier, deviations were recorded following every session. The explicit goal of the CPT+CFT approach was to ensure a trauma-focus to therapy, thus where deviation from the CPT protocol occurred, the ultimate goal of treatment was to return to addressing PTSD symptoms using CPT, or to use additional techniques to enhance standard methods of CPT (e.g., behavioural experiments to complement Challenging Belief

Worksheets). Where other interventions were introduced to assist with this goal (e.g., targeting of alcohol use that was interfering with engaging in trauma-specific work), these additional interventions were CBT-based. Up to 15 sessions were offered for the CPT+CF group.

Therapists

Therapists (n = 7) were undertaking Masters or PhD level clinical psychology training and consisted of six females and one male. The largest number of participants were seen by myself as the lead researcher, a registered psychologist trained in the CPT protocol and case formulation approach (n = 36) with other therapists maintaining a caseload of between two to 12 participants each. Therapists received weekly group and individual supervision from Professor Nixon and participants were seen in the Flinders University Posttraumatic Stress Clinic. Therapists worked across both treatment conditions, however they were under clear instructions to follow protocol and to not use any deviation in the CPT only group. This was reiterated in supervision and all therapists were aware that a sample of tapes would be rated for fidelity (as discussed below).

All therapists completed the Medical University of South Carolina's online CPTWeb program prior to commencement of therapy and attended a CPT workshop conducted by Professor Nixon. Therapists also had access to video recordings of previous therapy sessions for additional learning and reference. All therapy sessions were recorded and periodically reviewed as part of supervision.

Treatment Fidelity

All therapy sessions were recorded (audio or video). Budget considerations limited the extent of evaluation, however a total of 24 sessions (2.3%) were rated for fidelity by an independent accredited CPT trainer (See Appendix G for Therapist Adherence and Competence Protocol). Given the importance of evaluating therapist's skills with CPT+CF

participants and the variability of deviations that could occur in this condition, one third of the sessions were randomly selected from the CPT only group, and two-thirds from the CPT+CF group. Within the CPT+CF tapes, half of the selected sessions reflected participants who had no to low deviations and the other half contained sessions with moderate to high deviations, however the independent rater had no a priori knowledge of the type or reason for deviations. Mean session competence was assessed for the particular sessions coded, with scores rated on a 7-point scale (1 = *poor*, 7 = *excellent*) with overall competence rated based on eight essential but not unique elements of therapy (e.g. empathy, warmth, agenda setting, homework setting and review, structuring of time).

Ratings showed that for the CPT only group, therapists delivered 100% of essential components of CPT, with mean session competence rated at 4.75 (*SD* = 0.58) and overall competence rated at 6.03 (*SD* = 0.54). For the CPT+CF group, therapists delivered 84.5% of essential elements of CPT, with mean session competence rated at 5.13 (*SD* = 0.65) and overall competence rated at 5.60 (*SD* = 0.51). The lower adherence score for CP+CF is to be expected given that modifications occurred in this group. Modifications noted by the rater included that the therapist: tailored the terminology or CPT worksheets to make them easier for the participant to understand (2/16); skipped or removed elements of the session (2/16); re-ordered elements of the protocol (4/16); lengthened the session (5/16); repeated an activity or content (3/16); and introduced non-CPT techniques or methods (3/16). The degree of modification was also rated with scores ranging between being considered minor and major modifications (*M* = 2.00, *SD* = 0.71). The rater also indicated the degree of justification for the modifications (*M* = 5.33, *SD* = 1.11), with scores falling between the satisfactory and excellent range, indicating that overall modifications and departures from the protocol was considered good to very good. One case formulation diagram was assessed and given an overall rating of ‘good’ (21/30) where each item was rated on a 5-item scale with possible

ratings ranging between 1 (no evidence of factors/poor integration) to 5 (high level of conceptualisation). In sum, although the rater questioned whether some aspects of modification were required (e.g., some of the repeated content sessions) and the rater did not have the full context of a participant's therapy (i.e., did not watch all sessions of a participant), it appeared that modifications were generally deemed clinically appropriate and executed with reasonable competence.

Assessors

Assessors (n = 6) who had no knowledge of the participants' details, treatment allocation or stage of treatment reached were used at posttreatment and follow-up assessments. Assessors did not reassess the same participant. Assessors (and therapists who completed pretreatment assessments) were trained in the CAPS-5 through the online training available from the US Department of Veterans Affairs PTSD: National Center for PTSD. Additional training in the CAPS-5 and MINI was provided by myself, and assessors also viewed prior administrations of interviews.

Statistical Analyses

Analysis of Treatment Outcomes

Linear mixed effects modelling analyses were used to examine changes in symptom scores and moderation hypotheses, with maximum likelihood estimation for missing data. Response to treatment and good end-state functioning was assessed by a reduction in symptom severity of PTSD and depression, stress and anxiety using reliable change indices (Jacobson & Truax, 1991) and relevant cut-offs for the measures of interest. Categorical outcomes (PTSD status, response to treatment, good end-state function, dropouts) were analysed using chi-square analyses. Data was analysed with IBM SPSS version 25.0 (IBM Corp, 2017).

Cohen's *d* was used as the measure of effect size for the difference between group means with the sample pooled standard deviation used as the measure of variability for calculation of both the point estimate and the associated 95% confidence interval.

Response to treatment was defined when participants demonstrated a reliable change on the PCL-5 and this was accompanied by a total score below the cut-off of 31 (Blevins, Weathers, Davis, Witte, & Domino, 2015); good end-state (i.e., recovery from PTSD) was conservatively defined as a reliable change and a score at or below a cut-off of 17 on the PCL-5 (P. Schnurr – personal communication, 23 December, 2016). The significant RCI equated to an 18-point change on the PCL-5, which based on the *M* and the *SD* of the PCL-5 in the current sample, was comparable to a within-group *d* of 0.50. This effect size is consistent with recent empirical analysis of what constitutes meaningful clinical change on the CAPS-5 and PCL-5 (Stefanovics, Rosenheck, Jones, Huang, & Krystal, 2018). For depression (DASS-D), response to treatment was defined as an 8-point change (i.e., reliable change), with good end-state indexed by both reliable change and a score of 6 or below (Henry & Crawford, 2005; Lovibond & Lovibond, 1995a).

Analyses are reported for the intent-to-treat sample (ITT) with treatment completers reported in the supplementary materials.

CHAPTER 3: MAIN RESULTS

Aims and Analysis

In my examination of whether the addition of a case formulation approach to CPT improved outcomes for participants, or whether standard CPT was sufficient to achieve positive treatment outcomes, I had hypothesised in Chapter 1 that:

1. Participants in both the CPT alone and CPT+CF groups would have a significant reduction in PTSD symptoms (on the CAPS-5 and PCL-5) and would show reductions in secondary outcomes (e.g., depression, substance use, sleep, etc.).
2. Participants in the CPT+CF group would have a greater reduction in PTSD at posttreatment and follow-up and demonstrate better good end-state functioning relative to those in CPT only.
3. Fewer participants in the CPT+CF group would drop out of treatment than CPT alone participants.

Given that this study also examined factors that might contribute to treatment outcomes, I also hypothesised that participant outcomes would be moderated in the following ways:

4. Participants with complex presentations would exhibit less reduction in PTSD symptoms than those without a complex presentation, however this discrepancy would be smaller in the CPT+CF group than in the CPT alone treatment group.
5. Participants who reported a lower therapeutic alliance (as rated by the participant) would exhibit less reduction in PTSD than those who reported a greater therapeutic alliance however this discrepancy would be reduced in the CPT+CF group compared with CPT alone.

The findings in relation to the above hypotheses are reported in this chapter, with post-hoc analyses detailed in Chapter 4.

Data Screening and Analysis Strategy

Before analysis, data was screened for missing values as well as normality and outliers. Missing data included data that was missing due to participant dropout where no data was available for individual sessions and/or posttreatment and follow-up. Main outcome variables (CAPS-5, PCL-5 and DASS-D) were normally distributed for both groups at pretreatment. Although some variables were significantly skewed at other assessment intervals, analysis on transformed and untransformed data resulted in the same outcomes, hence the latter are reported. A similar pattern was observed for secondary variables.

Analysis was conducted on the intent-to-treat sample (completer analyses are reported in Supplementary Analyses). The analysis strategy adopted, calculation of effect sizes, and definitions of treatment response and good end-state functioning were detailed in Chapter 2.

Preliminary Analyses

As a reminder, preliminary analyses for the major outcome variables (i.e. CAPS-5, PCL-5, DASS-D, PTCI, ISI, DERS, AUDIT, CUDIT, DUDIT and CCPC) have already been reported in Chapter 2 for the intent-to-treat sample, with completer statistics located in Supplementary Analyses Table S1.

Primary and Secondary Outcomes from Pre- to 6-Month Follow-Up

Using a linear mixed modelling approach, I analysed pretreatment to posttreatment and 6-month follow-up changes on the main outcome measures (CAPS-5, PCL-5, DASS-D, PTCI, ISI, DERS, AUDIT, CUDIT and DUDIT) using a 2 (Condition: CPT, CPT+CF) × 3 (Time: pretreatment, posttreatment, 6-month follow-up) mixed design.

My first prediction (Hypothesis 1) was that participants in both the CPT alone and CPT+CF groups would have a reduction in PTSD symptoms (CAPS-5 and PCL-5) and improvements in secondary outcomes (e.g., depression, substance use, sleep, etc.). This hypothesis was supported with significant reductions from pre- to posttreatment assessment

and pre- to follow-up assessment with large effects for participants in both conditions on most measures (CAPS-5, PCL-5, DASS-D, PTCI, ISI, DERS) and small effect sizes for others (AUDIT, DUDIT and CUDIT). See Table 3.1 for descriptives, effect sizes and inferential statistics. Unless otherwise noted, all pre-post and pre-6-month changes were statistically significant. Exceptions to this were for the CUDIT and DUDIT which can be explained by the timeframe of the instructions for these measures, which assess cannabis and drug use over the past 12 months.

Of more interest was whether significant interactions were observed, that is, were better outcomes achieved in CPT+CF relative to CPT alone over time (Hypothesis 2)? Overall, this was not observed for the continuous variables (see Table 3.1, and Supplementary Analyses Table S2 for inferential statistics). That is, overall group by time interactions were nonsignificant for both PTSD and secondary variables (*p*s > .22), indicating that contrary to expectations, both groups had similar outcomes over time. As seen in Table 3.2, between group effect sizes were small to medium on the main outcome measures (CAPS-5, PCL-5, DASS-D) at all time points.

Table 3.1

Model Estimates, Within-Group Effect Sizes [and 95% Confidence Intervals] and Type 3 Fixed Effects of Time, Group and Group by Time from Pre- to Posttreatment and 6-Month Follow-up – Intent to Treat Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[1a]	*M*	*SE*	*Cohen's d [95% CI)*[1a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
CAPS-5	1	43.04	1.37		41.96	1.11										
	2	8.92	1.53	3.66 [1,67, 5.64]	13.50	2.26	2.50 [0.10, 4.91]									
	3	11.79	2.06	2.83 [0.50, 5.16]	11.06	2.03	3.15 [1.02, 5.29]	362.92	2,152.49	< .001	.41	1, 93.71	.525	2.32	2, 152.49	.102
PCL-5	1	51.89	1.63		48.48	1.58										
	2	10.29	2.00	3.57 [1.09, 6.05]	9.17	2.32	3.26 [0.63, 5.89]									
	3	13.71	2.74	2.77 [-0.19, 5.72]	12.44	2.24	3.16 [0.63, 5.69]	384.99	2,143.31	< .001	.37	1,90.05	.544	.58	2,143.31	.563
DASS-D	1	23.32	1.75		23.87	1.60										
	2	4.84	1.40	1.79 [-0.40, 3.94]	5.83	1.55	1.74 [-0.52, 4.00]									
	3	9.02	2.09	1.19 [-1.39, 3.76]	7.00	1.63	1.65 [-0.65, 3.94]	103.98	2,140.14	< .001	.03	1,85.07	.870	.49	2,140.14	.611
PTCI	1	149.09	5.12		133.67	5.87										
	2	71.79	5.68	2.22 [-5.27, 9.71]	72.59	6.89	1.52 [-7.26,10.29]									
	3	87.86	7.69	1.51 [-7.20,10.22]	80.87	6.67	1.37 [-7.23, 9.97]	133.15	2,136.35	< .001	.26	1,89.16	.615	2.97	2,136.35	.055
ISI	1	16.38	0.97		15.64	0.84										
	2	9.78	0.97	1.03 [-0.35, 2.41]	8.68	1.03	1.19 [-0.10, 2.49]									
	3	8.52	1.19	1.16 [-0.31, 2.62]	8.99	1.19	1.09 [-0.28, 2.45]	61.09	2,137.60	< .001	.10	1,91.09	.757	.96	2,137.60	.387
DERS	1	104.09	3.44		97.31	3.21										
	2	69.95	2.97	1.56 [-3.12, 6.24]	66.46	3.57	1.42 [-3.34, 6.17]									
	3	71.71	4.11	1.33 [-3.93,6.58]	65.7	2.86	1.62 [-2.76, 6.01]	84.20	2,138.76	< .001	1.51	1,86.59	.223	.31	2,138.76	.736

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group x Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
AUDIT	1	7.09	1.16		6.58	0.92										
	2	4.76	0.88	0.34 [-1.13, 1.81]	4.83	0.69	0.31 [-0.88, 1.50]									
	3	5.08	0.89	0.29 [-1.18, 1.77]	4.66	1.02	0.32 [-1.02, 1.66]	8.72	2,133.58	< .001	.28	1,87.62	.600	.24	2,133.58	.787
CUDIT	1	1.26	0.66		1.22	0.69										
	2	1.24	0.76	0.01 [-1.00, 1.01]	0.31	0.32	0.24 [-0.59, 1.07]									
	3	0.56	0.27	0.19 [-0.61, 0.98]	0.84	0.64	0.09 [-0.87, 1.05]	0.37	2,131.06	.690	.06	1,84.57	.815	1.16	2,131.06	.318
DUDIT	1	1.34	0.53		2.89	1.08										
	2	1.43	0.96	0.02 [-1.03, 0.99]	0.54	0.32	0.40 [-0.88, 1.68]									
	3	0.83	0.36	0.17 [-0.50, 0.83]	0.97	0.67	0.31 [-1.09, 1.70]	1.56	2,131.59	.215	.37	1,80.68	.546	.65	2,131.59	.196

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPR = Complicated Client Presentation Checklist. T1 = Pretreatment, T2 = Posttreatment; T3 = 6-month Follow-up

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large. All pre-post and pre-6-month changes were statistically significant, with the exception of CUDIT and DUDIT (see main text).

Table 3.2

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] at Pre-, Posttreatment, and 6-Month Follow-up – Intent to Treat Sample

		CPT		CPT+CF		
Measure	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI]*[a]
CAPS-5	Pretreatment	43.04	1.37	41.96	1.11	0.13 [-1.60, 1.86]
	Posttreatment	8.92	1.53	13.50	2.26	0.37 [-3.10, 2.36]
	Follow-up	11.79	2.06	11.06	2.03	0.06 [-2.79, 2.90]
PCL-5	Pretreatment	51.89	1.63	48.48	1.58	0.32 [-1.86, 2.50]
	Posttreatment	10.29	2.00	9.17	2.32	0.07 [-2.96, 3.09]
	Follow-up	13.71	2.74	12.44	2.24	0.09 [-3.45, 3.62]
DASS-D	Pretreatment	23.32	1.75	23.87	1.60	0.05 [-2.35, 2.25]
	Posttreatment	4.84	1.40	5.83	1.55	0.13 [-2.18, 1.92]
	Follow-up	9.02	2.09	7.00	1.63	0.18 [-2.47, 2.83]
PTCI	Pretreatment	149.09	5.12	133.67	5.87	0.41 [-7.21, 8.04]
	Posttreatment	71.79	5.68	72.59	6.89	0.05 [-8.76, 8.65]
	Follow-up	87.86	7.69	80.87	6.67	0.17 [-9.91, 10.24]
ISI	Pretreatment	16.38	0.97	15.64	0.84	0.12 [-1.13, 1.38]
	Posttreatment	9.78	0.97	8.68	1.03	0.19 [-1.26, 1.64]
	Follow-up	8.52	1.19	8.99	1.19	0.07 [-1.71, 1.58]
DERS	Pretreatment	104.09	3.44	97.31	3.21	0.29 [-4.42, 5.00]
	Posttreatment	69.95	2.97	66.46	3.57	0.16 [-4.47, 4.79]
	Follow-up	71.71	4.11	65.47	2.86	0.30 [-4.72, 5.31]
AUDIT	Pretreatment	7.09	1.16	6.58	0.92	0.07 [-1.37, 1.52]
	Posttreatment	4.76	0.88	4.83	0.69	0.03 [-1.16, 1.09]
	Follow-up	5.08	0.89	4.66	1.02	0.08 [-1.24, 1.40]
CUDIT	Pretreatment	1.26	0.66	1.22	0.69	0.01 [-0.95, 0.97]
	Posttreatment	1.24	0.76	0.31	0.32	0.25 [-0.59, 1.10]
	Follow-up	0.56	0.27	0.84	0.64	0.10 [-0.75, 0.55]
DUDIT	Pretreatment	1.34	0.53	2.89	1.08	0.27 [-1.46, 0.93]
	Posttreatment	1.43	0.96	0.54	0.32	0.20 [-0.83, 1.23]
	Follow-up	0.83	0.36	0.97	0.67	0.05 [-.077, 0.68]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPR = Complicated Client Presentation Checklist.

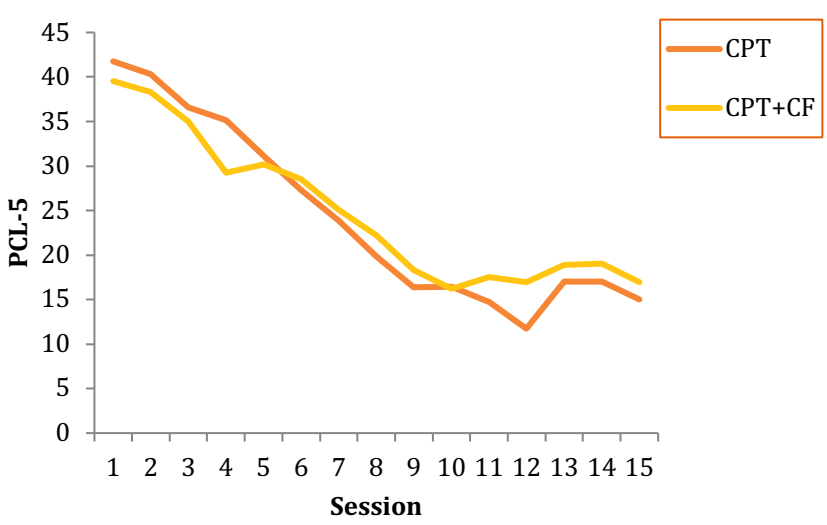
[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large

Session by Session Data

PCL-5 and DASS. PTSD and depression were measured every session, thus I could examine the trajectory of change over the course of treatment (Figure 3.1 and Supplementary Analyses Table S8). These results replicated the findings above; that is, PTSD and depression symptoms reduced significantly over time, $F(14, 819.44) = 11.38$, $p < .001$, and $F(14, 787.22) = 4.79$, $p < .001$, respectively, however the Group by Time interaction was not significant for PTSD, $F(14, 819.44) = 1.01$, $p = .445$, nor depression, $F(14,787.22) = 0.83$, $p = .638$.

ORS and SRS. The ORS and SRS were also measured at every session, thus I could also examine their trajectory of change over the course of treatment (Figure 3.2 and Supplementary Analyses Table S9). Complementing the PCL-5 and DASS-D findings, when participants reported general adjustment on the ORS (a general wellbeing measure), improvements over time were observed ($F(14, 769.85) = 6.79$, $p < .001$), but no differential response was observed, i.e. treatment condition was nonsignificant as was condition by time, $F(1, 132.83) = 0.07$, $p = .789$, and $F(14, 769.85) = 1.03$, $p = .425$ respectively.

Similarly for the SRS, a client satisfaction and quasi-alliance measure, improvements were observed over time ($F(14, 679.99) = 2.51$, $p = .002$), but there were no significant interactions for condition or condition by time, $F(1, 114.94) = 0.98$, $p = .324$, and $F(14, 679.99) = 0.52$, $p = .921$.



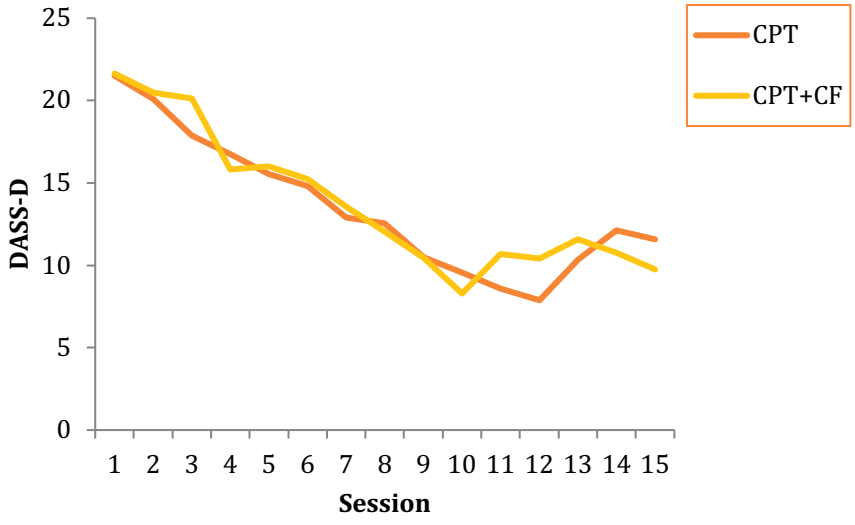
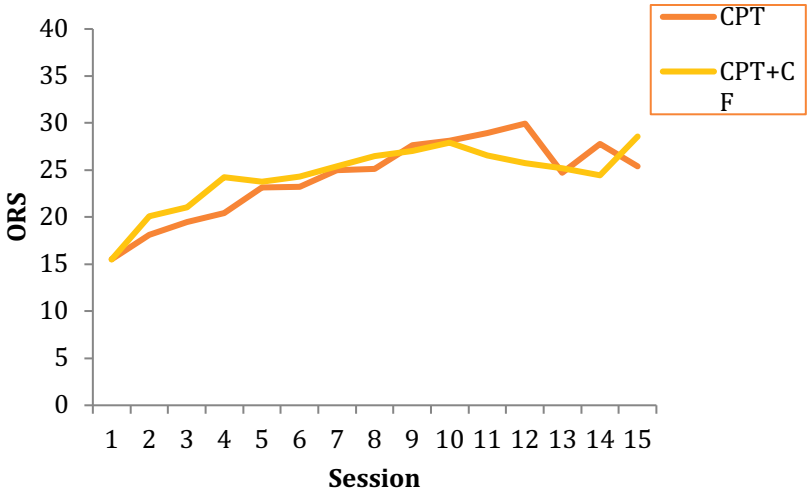


Figure 3.1. Session-by-session data for PCL-5 and DASS-D.



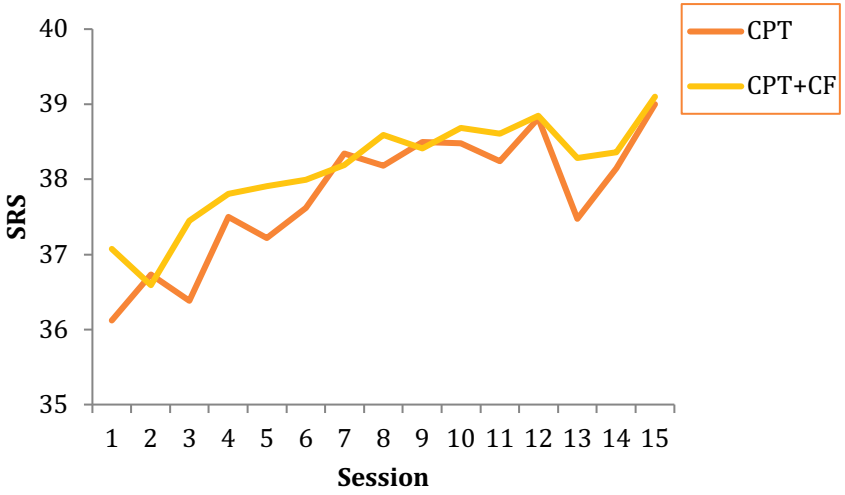


Figure 3.2. Session-by-session data for Outcome Rating Scale (ORS) and Session Rating Scale (SRS). Note the SRS Y-axis has been adjusted to reflect that SRS scores typically range from a minimum of 35 and maximum of 40.

Diagnostic, Treatment Response, and Good End-State Outcomes

As a reminder, a Reliable Change Index (Jacobson & Truax, 1991) was calculated to examine response to treatment and good end-state functioning. PTSD treatment response was defined by a significant RCI and a PCL-5 score below a clinical cut-off, in this case 30 and below (Bovin et al., 2016), with good end-state functioning (GES) defined by a significant RCI and a PCL-5 score of 17 and below. This latter cut-off has been adopted by several large-scale PTSD trials in the USA (P. Schnurr – personal communication, 23 December, 2016). For depression, response to treatment was indicated by an 8-point change (i.e. reliable change) with good end-state indexed by a reliable change *and* a score of 6 and below (Henry & Crawford, 2005; Lovibond & Lovibond, 1995a).

Table 3.5 summarises the proportion of participants who had a treatment response, loss of diagnosis, as well as the proportion who reached good end-state functioning in each treatment condition. Hypothesis 2 predicted that more participants in the CPT+CF group would show improvements on these categorical outcomes than CPT alone participants. As detailed below, there were no significant differences between groups on any of the measures at either posttreatment or follow-up, therefore there was no support for the hypothesis that the case formulation condition would achieve better outcomes. It is important to note that in relation to depression outcomes, only those who were above the moderate severity cut-off/had an initial diagnosis of depression were included in analyses. Outcomes for the completer sample are summarised in Supplementary Analyses Table S10.

Table 3.5

Diagnostic and Clinical Response to Treatment Outcomes

Outcome (%, n)	CPT	CPT+CF	χ^2	*p*	φ [g]
Posttreatment					
PTSD Response [a]	86.8% (33/38)	91.4% (32/35)	0.39	.531	.07
PTSD Loss of Diagnosis [b]	94.7% (36/38)	80.0% (32/40)	2.58	.088	.22
PTSD GES [c]	81.6% (31/38)	85.7% (30/35)	0.23	.634	.06
Depression Response [d]	89.3% (25/28)	88.9% (24/27)	0.002	> .999	.01
Depression Loss of Diagnosis [e]	84.0% (21/25)	79.2% (19/24)	0.19	.725	.06
Depression GES [f]	67.9% (19/28)	66.7% (18/27)	0.01	> .999	.01
6-month follow-up					
PTSD Response	86.5% (32/37)	87.1% (27/31)	.005	> .999	.01
PTSD Loss of Dx	84.6% (33/39)	88.6% (31/35)	0.25	.740	.06
PTSD GES	73.0% (27/37)	71.9% (23/32)	<0.01	> .999	.01
Depression Response	79.3% (23/29)	83.3% (20/24)	0.14	> .999	.05
Depression Loss of Dx	84.6% (22/26)	72.2% (13/18)	1.00	.451	.15
Depression GES	65.5% (19/29)	58.3% (14/24)	0.29	.776	.07

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; *p* values are Fisher's Exact Test (2-sided value).
[a] Response to treatment defined by a change of more than 18 points on the PTSD Checklist (PCL-5) and total score of less than 31.
[b] On the Clinician Administered PTSD Scale (CAPS-5).
[c] GES = good end-state defined as a change of more than 18 points on the PCL-5 at or below a cut-off of 17 on the PCL-5.
[d] Response defined by 8-point change on the Depression Anxiety and Stress Scale – Depression Subscale (DASS – D).
[e] On the MINI; [f] GES = score of 6 or below on the DASS-D.
[g] Effect size conventions for φ: 0.1 = small, 0.3 = medium, and 0.5 = large.

Dropout

Hypothesis 3 predicted that there would be fewer dropouts for the CPT+CF condition than for CPT alone. However this was not supported, with no significant difference in the proportion of the dropouts in the CPT alone group (19.1%) compared to the CPT+CF condition (15.2%), FET $p = .785$, $\varphi = .05$.

Does Clinical Complexity Moderate Outcomes?

Linear mixed modelling was conducted, with the Complicated Client Presentation Checklist (CCPC) score (the creation of which was detailed in Chapter 2) used as a continuous variable to index complexity, and the CAPS-5, PCL-5 and DASS-D measures being the main outcomes of interest. For ease of interpretation, the findings are reported graphically in Figures 3.3–3.5, where "Average Complication" reflects the mean CCPC score, and "Low Complication" 1 *SD* below and "High Complication" 1 *SD* above the average score. Full inferential statistics are reported in Supplementary Analyses Table S15.

In terms of PTSD outcome as measured by the CAPS-5, there was a significant 3-way interaction between group, time and complexity, $F(2, 151.884) = 3.84$, $p = .024$. Graphically (Figure 3.1) this suggested that contrary to prediction, individuals with high levels of complexity in CPT alone had lower PTSD severity at posttreatment than the CPT+CF group, however unpacking this interaction further did not reveal statistically significant findings. Specifically, examining the time by complexity interaction separately for each group (i.e., pre- to posttreatment change) demonstrated this change was not significant (CPT alone: $p = .056$; CPT+CF: $p = .071$). Furthermore, examination of Figure 3.3 (and formal analysis) shows this difference was reduced and no longer significant by 6-month follow-up ($p = .807$). Three-way interactions were not observed when PTSD was indexed with the PCL-5, $F(2, 150.91) = .21$, $p = .811$, nor for depression outcomes (DASS-D), $F(2, 142.66) = .30$, $p = .739$. Thus, the hypothesis that individuals with clinical complexity would have better outcomes

when in the receipt of CPT+CF was not supported. Interestingly there was also no evidence of complexity by time interactions, with those characterised by higher complexity having relatively similar outcomes as those with lower complexity.

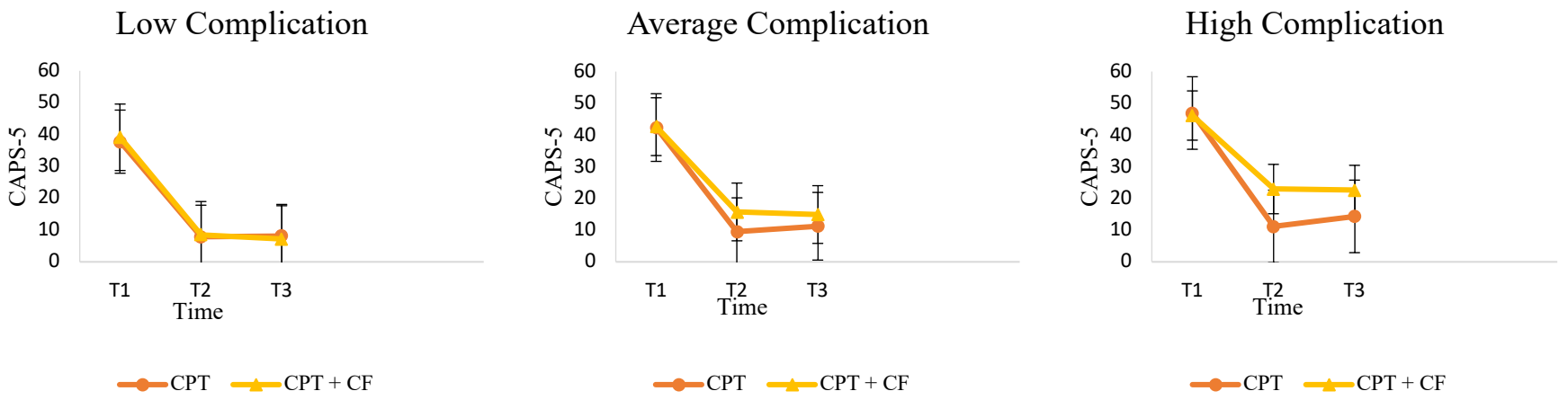


Figure 3.3. Complicated client presentation as a moderator of change following CPT versus CPT+CF for Clinician Administered PTSD Scale. Error bars reflect standard errors.

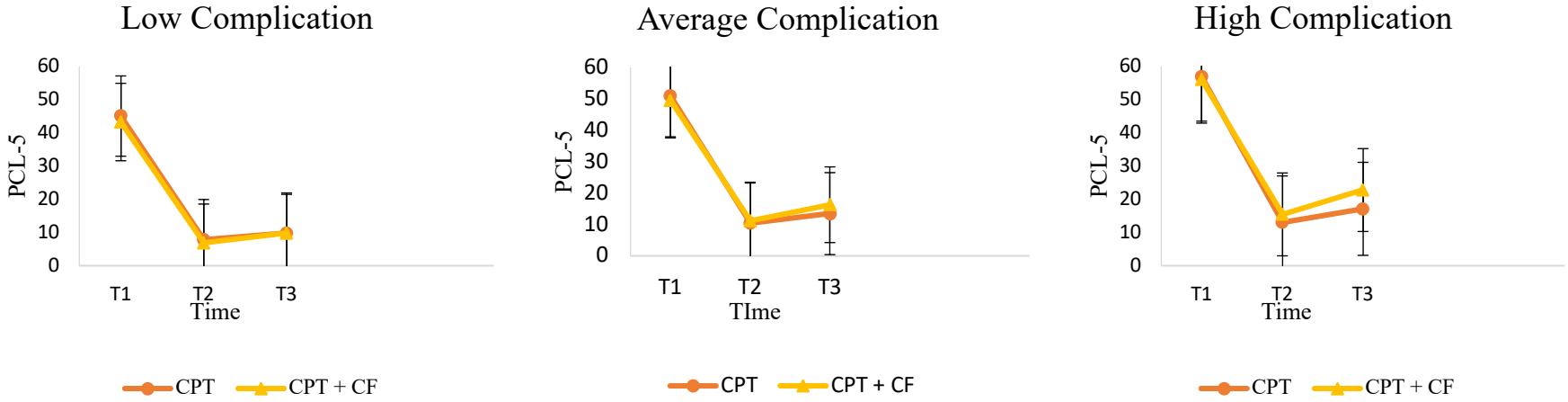


Figure 3.4. Complicated client presentation as a moderator of change following CPT versus CPT+CF for PTSD Checklist. Error bars reflect standard errors.

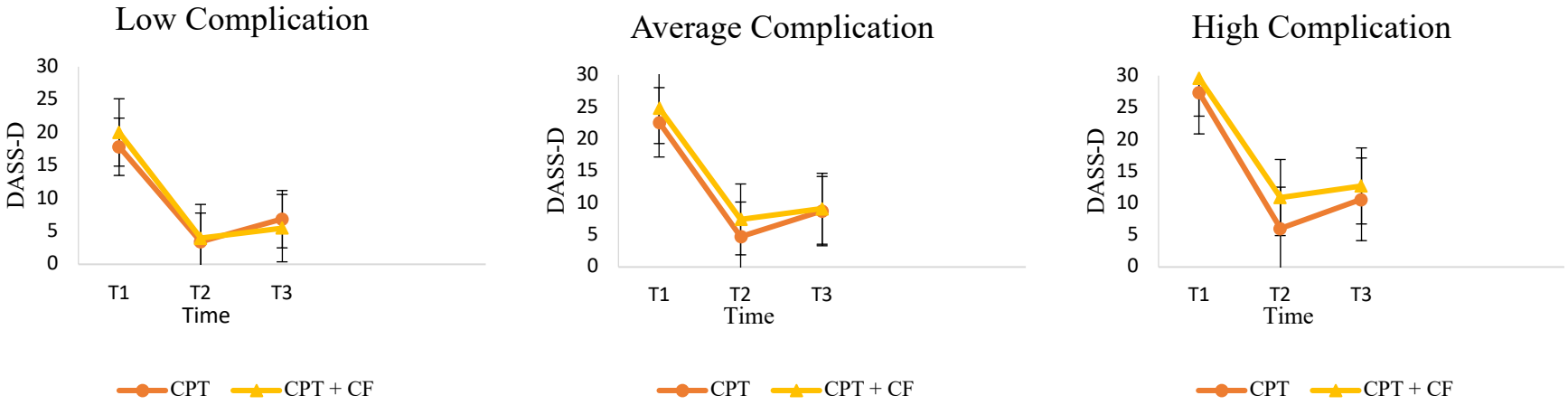


Figure 3.5. Complicated client presentation as a moderator of change following CPT versus CPT+CF for Depression subscale of the Depression, Anxiety and Stress Scale. Error bars reflect standard errors.

Does Therapeutic Alliance Moderate Outcomes?

Linear mixed modelling was conducted, with the WAI and the CAPS-5, PCL-5 and DASS-D measures being the main outcomes of interest. As the WAI was administered several times during therapy, the first administration of the WAI (at session 2) was used as the moderator, given that alliance may change over treatment, with this first time point establishing a baseline level without significant treatment effects. The findings are reported graphically in Figure 3.6 for the significant 2-way interactions for the CAPS-5 as described below, where "Average Alliance" reflects the mean total Time 1 WAI score, and "Low Alliance" 1 *SD* below and "High Alliance" 1 *SD* above the average score. Full inferential statistics are reported in Supplementary Analyses Tables S16, S17 and S18.

WAI Total: In terms of PTSD outcome as measured by the CAPS-5, there was a significant 2-way interaction between group and level of alliance (total WAI score), $F(1, 84.31) = 4.48$, $p = .037$, but no significant 3-way interaction, $F(2, 143.55) = 1.83$, $p = .165$. This significant group by alliance interaction seemed driven by the fact that overall CAPS-5 scores were constant in the CPT alone group regardless of level of alliance, whereas scores were higher in the CPT+CF group compared with CPT when alliance was low.

There were no significant 2-way interactions between time and WAI total for the PCL-5, $F(2, 133.90) = 2.36$, $p = .099$ nor was there a significant 3-way interaction for group, time and WAI total, $F(2, 133.90) = 0.17$, $p = .846$. There were no significant findings for either time or group by time interactions on the DASS-D, $F(2, 130.84) = 0.95$, $p = .388$), and $F(2, 130.84) = 0.39$, $p = .676$, respectively.

WAI Task/Goals: Similarly to the overall scale, there was a significant 2-way interaction between group and WAI Task/Goal on the CAPS-5, $F(1, 85.09) = 5.16$, $p = .026$ but no significant 3-way interaction, $F(2, 144.26) = 0.60$, $p = .548$ and no significant 2-way interactions or 3-way interactions group for the PCL-5 or DASS-D outcome variables.

WAI Bond: As above, there was a significant 2-way interaction between group and time, $F(2, 144.71) = 3.25$, $p = .042$ on the CAPS-5, but no significant 3-way interaction, $F(2, 144.10) = 2.70$, $p = .070$ and no significant findings for the PCL-5 or DASS-D outcome variables.

Outcomes for Treatment Completers

Full details of these analyses are reported in the Supplementary Analyses. Briefly, these findings demonstrated a similar pattern to those observed in the intent-to-treat sample. That is, large and significant reductions in PTSD and secondary outcomes were observed, however with one exception, there were no differential outcomes as a result of treatment group, nor were PTSD or depression outcomes moderated by complexity or alliance. The single exception was a significant group by time interaction on the PTCI as detailed in Supplementary Analyses Table S2.

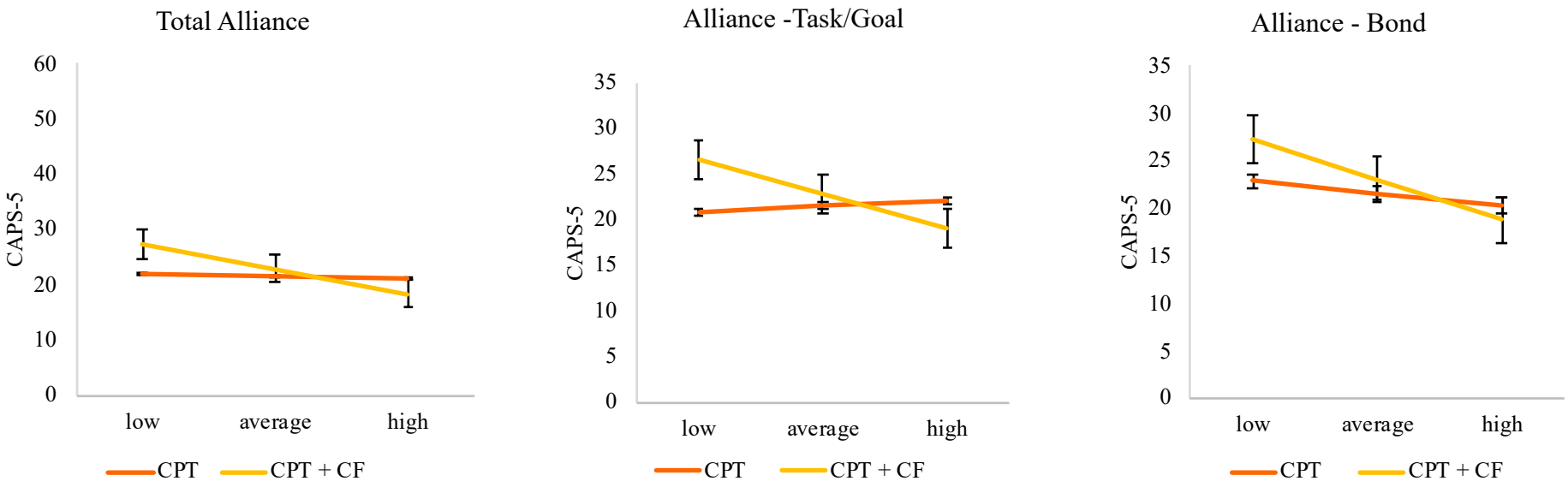


Figure 3.6. Working Alliance – Two-way interaction between working alliance and treatment group for Clinician Administered PTSD Scale. Error bars reflect standard errors.

Adverse Events

No significant study-related adverse events (e.g., suicide attempt, psychiatric hospitalisation) were reported throughout the study. One participant had a hospital admission due to an unrelated mental health disorder, however this same participant completed treatment with good end-state functioning (CAPS-5, PCL-5 and DASS-D). Another participant reported a psychiatric hospital admission due to stalking/contact from an abusive ex-partner and withdrew during therapy, however reported to the researcher resolution of those stressors several months after their withdrawal from therapy. Using reliable change index analyses (i.e., Jacobson, & Truax, 1991), there were no reliable increases of PTSD symptoms (CAPS-5, PCL-5) between pretreatment and posttreatment nor between pretreatment and follow-up assessment. There was an increase for depressive symptoms (DASS-D) between pretreatment and 6-month follow-up assessment for one participant (related to a concurrent court case). Transient increases were seen between sessions during therapy (i.e. between S1-S2, S3-S4, etc.) on PTSD symptoms for some participants (on the PCL-5, CPT: 15 occasions, CPT+CF: 21 occasions) and for depression (on the DASS-D, CPT: 8 occasions, CPT+CF: 10 occasions). On all occasions PTSD symptoms had (significantly) reduced at the next measurement point. On seven occasions depression symptoms reduced after two measurement points.

Summary

Overall, therapy was effective for both groups, with participants evidencing substantial and clinically meaningful changes in PTSD and associated symptoms after therapy and at 6-month follow-up. Contrary to predictions, superior outcomes were not observed in the CPT+CF group relative to CPT alone. Post-hoc analyses were conducted to explore this unexpected finding and are detailed in the next chapter.

CHAPTER 4: SECONDARY ANALYSES

Comparing Deviations Between Groups

As detailed in Chapter 2, each session was rated for therapy protocol deviation according to type (i.e., crisis/emergency deviation or CPT deviation) and level (range 0 = none, 1 = minor deviation, 2 = moderate deviation and 3 = major deviation). As with previous CPT research (Galovski et al., 2012) and inherent with the pragmatics of running a clinical trial, some non-protocol sessions were conducted to address crises. I examined whether different rates of such sessions, as well as deviations that addressed clinical issues (e.g., motivation, other clinical problems) occurred between groups, possibly impacting on the results reported in the previous chapter.

In total, 59.6% of participants in the CPT only group and 71.3% in the CPT+CF group had any deviation across treatment, but this difference was not significant (p = .276). There were also no significant differences in the proportion of participants in each group who received a crisis deviation (CPT: 23.4%; CPT+CF: 21.7%, $p > .999$). Not surprisingly given the research design, there was a significant difference between groups for CPT deviations, with 44.7% of CPT group participants having any form of deviation and 69.6% for CPT+CF (p = .021). Breaking this down further, there were no significant differences between the groups in terms of whether minor deviations occurred (i.e., deviation coded 0 or 1), remembering this encompassed off topic discussions either related to current stressors in a participant's life, or other issues which might have been impacting therapy (e.g., motivation, avoidance, eating issues, sleep, pain) and which took less than 5-10 minutes (CPT: 40.4%; CPT+CF: 56.5%, p = .148). However, as expected, there were significant differences between groups for the number of participants who had moderate-major level deviations (coded 2 or 3), which included longer amounts of time for planned interventions for the CPT+CF condition when required (e.g., addressing

problematic substance use, addressing significant motivational issues, etc.) (CPT: 23.4%; CPT+CF: 43.55%, p = .049).

I conducted independent samples t-tests to compare the treatment groups for *number* of deviation sessions according to type (Table 4.1). A significant difference was revealed for the number of moderate-major CPT deviations across treatment, $t(76.04) = 2.02$, $p = .047$, $d = 0.42$), but no others. For treatment completers, there were no significant differences between groups for any type of deviation at any level.

Table 4.1

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] for Number of Deviations across Treatment – Intent to Treat Sample

	CPT		CPT+CF		
Deviation	*M*	*SD*	*M*	*SD*	*Cohen's d [95% CI]*[a]
Crisis	0.47	0.95	0.33	0.73	0.17 [-0.01, 0.34]
CPT low	1.23	2.30	1.30	1.70	0.24 [-0.30, -0.18]
CPT moderate-major	0.49	1.16	1.13	1.82	0.42 [-0.73, -0.11]
Total CPT	1.70	2.91	2.41	3.05	0.24 [-0.84, 0.37]
Total All	2.19	2.96	2.76	3.39	0.19 [-0.81, 0.44]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation. CPT low = none-minor deviation; CPT moderate-major = moderate-major deviation; Total CPT = Total CPT deviations across treatment; Total All = Total CPT and crisis deviations across treatment.
[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

In short, apart from the planned moderate-major CPT deviations, which were expected, there were no major differences between the groups in terms of crisis or minor deviations that would account for the lack of difference in outcomes between the groups as reported in Chapter 3.

Do Deviations Help when Clients are Nonresponding?

Most of the analyses reported so far collapse data across the entire sample, or compare CPT and CPT+CF regardless of participant progress during therapy. However, if a participant was progressing well in CPT+CF, there was no reason to deviate, thus analyses so far do not identify whether a differential effect is observed between CPT and CPT+CF when we take into account participants who are not demonstrating change during treatment, a situation that CPT+CF was predicted to address better than CPT only.

Accordingly, I first determined whether individuals had made a reliable change on the PCL-5 from pretreatment to session 6 (i.e., a significant RCI) and then conducted linear mixed model analyses for the main outcomes of interest. Specifically of interest was the 3-way interaction between group (CPT; CPT+CF), time (Pre, post, FU) and RCI (RCI by S6: yes, no). If CPT+CF improves outcomes for those not responding to therapy, we would expect better outcomes for those who had NOT shown a significant RCI by session 6 in the CPT+CF group relative to those in CPT.

At this time, it is unclear in the traumatic stress field at which point a client can be determined to be on a trajectory for a poor outcome and thus changes to therapy should be considered. For example, in unpublished data (Nixon et al., 2020), clients who have made a reliable change by session 6 often demonstrate excellent outcomes. However, a significant number of clients also achieved good outcomes by the end of CPT, but had not shown a significant RCI by session 6. Other studies that have collapsed trauma-focused therapies such as CPT and PE in analyses suggest that changes to the therapy approach be considered after 7 to 8 sessions if a reliable response has not been observed (Litz et al., 2019; Ready et al., 2018; Sripada et al., 2019). In addition to this, in the present study modifications could occur earlier than session 6 if the clinician felt this was

required. I therefore repeated analyses to also examine those who had/had not made a reliable change from either pretreatment to session 4 and from pretreatment to session 8. Because these results essentially replicated the findings using session 6 RCI data, only the latter is reported as follows (see Table 4.2 for inferential statistics).

Results indicate that for PTSD symptoms reported on the CAPS-5, there was not a significant 3-way interaction for group, time and reliable change (RC). Unsurprisingly there was a significant time by RC interaction. Unpacking this interaction (see Table 4.3 for descriptives) indicated greater reductions were demonstrated by those who showed early changes (significant RCI) compared with those who did not evidence such change.

The same pattern of findings was observed on the PCL-5. Findings on the DASS-D showed that the 3-way interaction of group, time and RC did not reach statistical significance (p = .053), and in addition, there was not a significant interaction between Time and RC (p = .487). See Table 4.2.

Table 4.2

Linear Mixed Modelling Effects –Pretreatment to Session 6 Reliable Change – Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	75.593	.505	.480
Time	2	135.429	334.612	.000
S6 RC	1	75.593	20.256	.000
Group x Time	2	135.429	1.465	.235
Group x s6RC	1	75.593	.000	.986
Time x S6 RC	2	135.429	10.370	.000
Group x Time x S6 RC	2	135.429	.772	.464
PCL-5				
Group	1	73.360	2.686	.105
Time	2	127.877	357.033	.000
S6 RC	1	73.360	19.199	.000
Group x Time	2	127.877	.147	.864
Group x S6 RC	1	73.360	.181	.672
Time x S6 RC	2	127.877	12.574	.000
Group x Time x S6 RC	2	127.877	1.990	.141
DASS-D				
Group	1	72.272	1.255	.266
Time	2	127.566	85.321	.000
S6 RC	1	72.272	11.927	.001
Group x Time	2	127.566	1.115	.331
Group x S6 RC	1	72.272	.984	.325
Time x S6 RC	2	127.566	.723	.487
Group x Time x S6 RC	2	127.566	3.008	.053

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; S6 RC = Reliable change from Pretreatment to session 6 on the PCL-5 (coded yes/no).

Table 4.3

CAPS-5 Severity from Pretreatment to Posttreatment and 6-Month Follow-up for Participants with a Session 6 Reliable Change – Intent-to-Treat Sample

		CPT				CPT+CF			
		S6 RC		No S6 RC		S6 RC		No S6 RC	
Measure	T	*M*	*SE*	*M*	*SE*	*M*	*SE*	*M*	*SE*
CAPS-5	1	43.11	1.93	44.39	2.83	39.80	2.28	42.21	2.34
	2	6.27	2.00	17.69	2.99	5.90	2.28	19.68	2.34
	3	7.85	1.99	20.88	2.94	7.58	2.37	16.91	2.44
PCL-5	1	52.36	2.25	50.15	3.30	45.95	2.66	48.21	2.73
	2	5.94	2.37	18.74	3.40	3.42	2.77	15.71	2.84
	3	7.20	2.36	28.38	3.54	8.11	2.93	19.71	2.93
DASS-D	1	22.29	1.94	26.15	2.85	20.30	2.29	24.95	2.35
	2	2.98	2.06	9.34	2.94	2.46	2.40	9.48	2.46
	3	4.88	2.04	19.04	3.07	6.69	2.54	8.53	2.54

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; S6 RC = Reliable change from Pretreatment to session 6 on the PCL-5; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up. Pairwise comparisons demonstrated significant differences between those who had a reliable change at S6 and those who did not on the CAPS-5 and PCL-5 at both posttreatment and 6-month follow-up (*p*s < .007). For the DASS-D there were significant differences at post treatment for the CPT+CF group ($p = .042$) but not the CPT group (p = .078) and at 6-month follow-up for the CPT group ($p < .001$) but not the CPT+ CF group ($p = .610$).

Another way to address the issue of whether CPT+CF conveyed benefits for those not responding was to investigate outcomes when significant modifications occurred in treatment. The rationale for this examination was that such modifications would be enacted when barriers to good outcome were identified, typically reflecting clients were not improving (based on weekly PCL-5 scores). These analyses were exploratory, and as will be later discussed, caution exercised in their interpretation given the number of potential analyses conducted (and risk of Type I error). A series of analyses were conducted on the subsets of participants for whom: there was any deviation from the therapy (regardless of level of deviation); there was moderate-major deviation of any type

(i.e., crisis, CPT-related); and there was a moderate-major CPT deviation (outcomes are reported in full in Supplementary Analyses Tables S23 to S25 for intent-to-treat sample and in Supplementary Analyses Tables S26 to S28 for completer sample). An exemplar is summarised below where participants were included if at least one deviation occurred during treatment (Table 4.5 and 4.6). In this case, a significant 3-way interaction was observed for depression outcomes as measured by the DASS-D (and statistically non-significant outcomes on the CAPS-5 and PCL-5). Unpacking the significant interactions indicated greater reductions were demonstrated by those who showed significant changes by Session 8 (RCI) compared with those who did not evidence such change by that session. As seen in the appendices, although the pattern of findings in regard to these 3-way interactions was not always consistent (e.g., they were not universally significant for both PTSD and depression outcomes), there was a suggestion that differential outcomes occurred between the treatment conditions based on progress during therapy and deviations.

Table 4.5

Model Estimates, Means, Standard Errors and Type 3 Fixed Effects of Time, Group and Group by Time from Pre- to Posttreatment and 6-Month Follow-up for Any Deviation from Therapy by Session 8 Reliable Change - Intent to Treat Sample

		Model estimates and effect sizes								Type III fixed effects								
		CPT				CPT+CF												
		S8 RC		S8 No RC		S8 RC		S8 No RC		Group × time			RC × time			Group × RC × time		
Measure	T	*M*	*SE*	*M*	*SE*	*M*	*SE*	*M*	*SE*	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
CAPS-5	1	42.65	2.58	45.11	3.55	40.05	2.39	43.00	3.76									
	2	8.13	2.63	19.21	3.86	8.80	2.38	27.75	3.76									
	3	8.59	2.58	25.04	3.75	11.33	2.42	24.08	4.19	2.63	2,93.88	.077	8.11	2,93.88	.001	1.83	2,93.88	.166
PCL-5	1	51.71	2.90	54.56	3.99	47.20	2.68	51.13	4.23									
	2	8.50	2.95	23.66	4.38	5.00	2.73	29.54	4.65									
	3	10.15	2.97	29.95	4.48	11.08	2.85	33.12	5.12	1.19	2,88.63	.310	11.31	2,88.63	< .001	0.83	2,88.63	.439
DASS-D	1	20.59	2.49	29.33	3.42	21.00	2.30	30.25	3.63									
	2	3.61	2.55	13.50	3.82	2.72	2.35	20.32	4.09									
	3	6.63	2.56	23.74	3.87	8.44	2.47	13.13	4.50	1.76	2,88.12	.178	0.89	2,88.12	.414	3.28	2,88.16	.042

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; S8 RC = Reliable change from Pretreatment to session 8 on the PCL-5; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up.

Table 4.6

Estimated Means, Standard Errors, Within-Group and Between-Group Effect Sizes [and 95% Confidence Intervals] from Pre- to Posttreatment and 6-Month Follow-up for Any Deviation from Therapy by Session 8 Reliable Change - Intent to Treat Sample

		Pretreatment		Posttreatment		Follow-up		Within-group Effect Sizes		Between-group Effect Sizes		
								Pre-Post	Pre-Follow-up	Pretreatment	Posttreatment	Follow-up
	Group	*M*	*SE*	*M*	*SE*	*M*	*SE*	*Cohen's d*	*Cohen's d*	*Cohen's d*	*Cohen's d*	*Cohen's d*
	CPT											
CAPS-5	RC	42.65	2.58	8.13	2.63	8.59	2.58	3.94 [1.68, 6.19]	3.74 [1.39, 6.08]	0.26 [-3.16,2.63]	1.25 [-4.14, 1.63]	1.67 [-4.84, 1.49]
	No RC	45.11	3.55	19.21	3.86	25.04	3.75	2.55 [-2.16, 7.25]	1.83 [-3.10, 6.76]			
	CPT+CF											
	RC	40.05	2.39	8.80	2.38	11.33	2.42	3.00 [0.29, 5.70]	2.82 [0.18, 5.46]	0.40 [-2.78, 1.98]	1.57 [-5.46, 2.32]	1.07 [-5.14, 3/01]
	No RC	43.00	3.76	27.75	3.76	24.08	4.19	1.05 [-5.32, 7.42]	1.35 [-5.10, 7.81]			
PCL-5	CPT											
	RC	51.71	2.90	8.50	2.95	10.15	2.97	4.14 [1.44, 6.85]	4.08 [1.44, 6.73]	0.25 [-3.78, 3.28]	1.30 [-5.09, 2.49]	1.63 [-5.65, 2.38]
	No RC	54.56	3.99	23.66	4.38	29.95	4.48	2.17 [-4.43, 8.76]	1.54 [-5.82, 8.91]			
	CPT+CF											
	RC	47.20	2.68	5.00	2.73	11.08	2.85	4.73 [2.31, 7,16]	3.68 [0.97, 6.40]	0.37 [-3.79, 3.06]	2.15 [-6.04, 1.74]	1.92 [-6.03, 2.19]
	No RC	51.13	4.23	29.54	4.65	33.12	5.12	1.36 [-5.95, 8.68]	1.28 [-5.49, 8.03]			
DASS-D	CPT											
	RC	20.59	2.49	3.61	2.55	6.63	2.56	1.73 [-2.81, 6.27]	1.32 [-3.59, 6.22]	0.77 [-4.28, 2.74]	1.21 [-3.92, 1.49]	1.59 [-5.51, 1.96]
	No RC	29.33	3.42	13.50	3.82	23.74	3.87	1.42 [-3.73, 6.57]	0.44 [-5.50, 6.37]			
	CPT+CF											
	RC	21.00	2.30	2.72	2.35	8.44	2.47	2.29 [0.11, 4.46]	1.31 [-1.35, 3.97]	0.87 [-4.31, 2.58]	2.53 [-4.90, 0.16]	0.50 [-3.87, 2.87]
	No RC	30.25	3.63	20.32	4.09	13.13	4.50	0.83 [-4.71, 6.37]	1.46 [-4.10, 7.03]			

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; RC = Reliable change from Pretreatment to session 8 on the PCL-5.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Participants' Views of the Case Formulation Process and Therapeutic Letter

A linear mixed modelling approach was utilised to see if there were any significant differences over time for the CPT+CF participants' views on the usefulness of the case formulation process. As a reminder, the CF process included both a diagrammatic formulation and a written formulation via a therapeutic letter from the therapist to the participant with quantitative and qualitative data regarding usefulness of both of these methods collected at Session 2 (case formulation diagram), Session 4 (therapeutic letter), posttreatment and at 6-month follow-up. Changes over time were significant for the perceived usefulness of the case formulation discussion and diagram from pretreatment to posttreatment with participants rating the formulation as less useful at posttreatment ($p < .001$) and between pretreatment and 6-month follow-up ($p = .011$) and posttreatment and 6-month follow-up ($p < .001$), however there were no significant changes over time for the therapeutic letter (See Table 4.7).

Table 4.7

Model Estimates, Within-Group Effect Sizes [and 95% Confidence Intervals] and Type 3 Fixed Effects of Time for Case Formulation Diagram and Therapeutic Letter - Intent to Treat Sample

		Model estimates and effect sizes			Type III fixed effects		
		CPT+CF			Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*
Diagram	1	21.16	0.41				
	2	18.00	0.45	1.14 [0.52, 1.75]			
	3	22.69	0.48	0.59 [-1.78, 0.003]	55.66	2, 72.53	< .001
Letter	1	23.53	0.33				
	2	23.79	0.34	0.12 [-0.62, 0.37]			
	3	23.94	0.04	0.20 [0.68, 0.29]	0.64	2,64.85	.529

Note. CPT+CF = Cognitive Processing Therapy plus Case Formulation; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Although it was not the focus of the thesis, some qualitative analysis of participants' perception of the usefulness of case formulation and the therapeutic letter was undertaken using NVivo (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018). Each response to the qualitative questions was coded into themes at the three time points with each quotation linked to multiple codes as appropriate. Themes were then compared across timepoints to examine changes in themes that might be the result of treatment. These results are reported in Supplementary Analyses S29 and S30. Quantitative data, supplemented by the qualitative data, indicates that the therapeutic letter was well received consistently across treatment (Pretreatment scores rating: Range 16-25; Posttreatment: Range 19-25; Follow-up: Range 20-25, with 0 = "totally disagree" and 25 = "totally agree" in respect to whether the letter or diagram, as applicable, was understandable, logical, acceptable, helpful or a good summary). Participants most commonly commented that the letter was validating, a good summary of their issues, that they felt understood and listened to. Although the case formulation was also generally well received, as noted above participants tended to rate it as less useful at posttreatment than at pretreatment and follow-up assessment (Pretreatment: Range 15-25; Posttreatment: Range 10-25; Follow-up: Range 15-25). Qualitative analysis suggested that posttreatment participants were sometimes confused by the diagram or its purpose or had forgotten having done it earlier in treatment. See Supplementary Analysis.

Summary

In summary, as expected there were significant differences between the CPT and CPT+CF groups in the number of moderate-major deviations which were made across treatment and a tentative suggestion that those who were showing clear treatment responses during treatment may have had better outcomes in regard to PTSD symptoms and depression. Despite analysis suggesting the case formulation approach was

appreciated by participants in that group, secondary analyses did not identify any context or subgroup in which CF resulted in better outcomes relative to the CPT alone condition. These and the main findings from Chapter 3 are discussed next in Chapter 5 (Discussion).

CHAPTER 5: DISCUSSION

This thesis examined whether the addition of a case formulation approach to CPT would result in superior client outcomes and reduced dropout rates. Additionally, it examined whether factors that have been associated with treatment outcomes including client complexity and therapeutic alliance moderated outcomes in either of the treatment groups and investigated the impact of deviating from the treatment protocol.

This chapter begins by discussing the effects of treatment condition on PTSD symptoms, depression and secondary outcome measures. I then focus on client complexity and therapeutic alliance as moderating factors, with the effects of deviating from the protocol then examined. Finally, research strengths and limitations are addressed, including the theoretical and clinical implications of my findings, and directions for future research.

Summary of Treatment Outcomes

As noted previously, very few head-to-head comparisons of individualised case formulation approaches compared with standard manualised treatment in non-PTSD samples have been conducted, and my PhD represents the first randomised controlled trial to test the efficacy of an explicit case formulation approach combined with CPT in the treatment of PTSD.

As hypothesised, participants in both treatment groups demonstrated significant reductions in PTSD symptoms, as well as secondary outcomes at posttreatment and 6-month follow-up. Effect sizes for PTSD measures were large ranging between 2.50 and 3.66 across time points, and this was also seen for loss of PTSD diagnosis (which ranged between 80% and 94.7%) and GES (ranging between 71.9% and 85.7%). Treatment effect sizes for secondary measures were also large including depression (ranging between 1.19 and 1.79), trauma cognitions (1.37 to 2.22), emotional regulation (1.42 to

4.11) and sleep (1.03 to 1.19). Effect sizes for substance abuse were small to moderate (ranging between 0.01 and 0.31).

Contrary to prediction, dropout was similar between groups, and overall the findings indicated that case formulation did not result in superior outcomes, nor were there differential outcomes between groups moderated by complexity, therapeutic alliance, or by how much deviation occurred, although with the latter, there was some hint to indicate that some deviations may have had some positive effects, which will be discussed later. In sum, similar to previous CPT randomised controlled trials (Galovski et al., 2016; Jak et al., 2019; Monson et al., 2006; Resick et al., 2017), good outcomes were achieved.

Why Did Case Formulation Not Result in Superior Outcomes?

As raised in the Introduction, there is only a modest literature outside of the PTSD field that has compared a formulation driven approach with standardised manualised treatment. This literature is also characterised by contrasting findings, with some research indicating comparable outcomes (Emmelkamp, Bouman, & Blaauw, 1994; Esbjorn et al., 2015; Nattrass et al., 2015; Persons et al., 1999; Persons et al., 2006) and other findings suggesting standard delivery of treatment protocols was superior (Schulte et al., 1992). In the one non-PTSD randomised trial where case formulation was found to have *benefits* over the standard manual, these were moderate effects and limited by a small sample size and a lack of blinding, with the author delivering all the treatment and undertaking the assessments at each assessment point (Ghaderi, 2006). Although there has not been a substantial amount of PTSD-case formulation literature, a pilot study that tested explicit case formulation with CPT showed promising results (Nixon & Bralo, 2019), however this was an uncontrolled open trial where all participants received the CPT+CF treatment protocol.

A number of explanations for my null findings could be considered. Although the results from the study seem to align with the literature in non-PTSD trials which indicate limited support for the superiority of individualisation over standardised therapy, those studies had key differences from the present design in that they compared a manualised approach with a non-manualised approach which was based on CBT case formulation principles, which were individualised depending on clinical priority. For example, Persons et al. (1999) compared manualised CBT for depression with an approach where other higher priority issues were addressed using adjunct therapy and an open-ended number of sessions. In that study, 22% of the non-manualised group received adjunct therapy, with an average session number of 34.8 (compared with 20 sessions in the manualised group). In the non-manualised group, interventions were also provided more flexibly; their order was changed from the prescribed protocol and some interventions were emphasised over others with treatment decisions made using an individualised, collaborative case formulation approach. In comparison, in the present study, both groups were more similar in terms of how treatment was conducted, including a maximum of 15 sessions, and those randomised to CPT+CF still received a form of manualised CPT, with deviations not enacted unless indicated because of poor or slow response to treatment. Another key difference in the present study was that apart from the CPT+CF participants engaging in an initial collaborative case formulation diagram, receiving a therapeutic letter, and a small subset receiving planned deviations if their PTSD symptoms were not decreasing throughout therapy, for the majority of the participants, both treatment conditions were largely the same with no substantial differentiation, and appeared to result in similar outcomes. This is similar to the finding by Ghaderi (2006) who also reported a lack of differentiation between the treatment groups with a wide range of individualisation in the standardised condition, possibly resulting in both groups

receiving interventions that shared more similarities than differences. Finally, there has been some criticism of those studies which observed superior effects of manualised treatment given their focus on a single disorder, with case formulation argued to be more valuable for complex or comorbid cases (Mumma & Fluck, 2016). However consistent with the literature that indicates PTSD is typically associated with high levels of comorbidity, the sample in the present study demonstrated reasonably high levels of complexity (with an average of 3.06 additional comorbid diagnoses), thus this does not explain the current null findings, as expanded upon below.

Although it was hypothesised that case formulation would benefit those with more complicated presentations, the results from this study indicated that complexity did not moderate treatment outcomes, with those participants characterised with higher complexity having similar outcomes to those with lower complexity regardless of whether they received CPT+CF or not. It is possible, however, that the combined complexity measure created for the study did not appropriately index the factors that have been argued by clinicians (and somewhat supported by some empirical findings) to contribute to clinical challenges in successfully treating PTSD. However, it is important to note that there is no gold standard measure of complexity at present, and that the measure designed for this study did index the factors which are most commonly cited as problematic in the field, with this measure comprising a total frequency of these factors, rather than relying on a single factor, for example, experience of childhood sexual abuse, as a moderator.

Additionally, as noted previously, the literature on the effect of complexity on treatment outcomes has been mixed and the suggested treatment approaches to address these complexities has been the source of some debate. This study appears to provide further support for the premise that CPT works well for clients both with or without

complex presentations, without the need to address comorbidities separately and independently, in accordance with not only the NICE guidelines (2018) and the authors of the CPT protocol (Resick, Monson & Chard, 2014), but in accordance with a recent review which notes that aside from safety issues requiring a period of stabilisation, trauma-focused treatment should be offered in the first instance *despite* complexity and comorbidities (Goodnight et al., 2019).

Also contrary to my hypotheses, there was no significant difference in dropout rate between the two treatment groups and no significant difference in the number of treatment sessions attended by participants in either group, again demonstrating that both treatment groups could achieve positive outcomes for participants in similar timeframes. The overall dropout rate of 17.2% in this study was at the lower end of the range reported in a recent meta-analysis of CPT outcomes (approximately 15-30%; Tran et al., 2016), was comparable to a 15% rate reported in a recent trial of non-veteran adults (Butollo, Karl, Konig, & Rosner, 2016), and better than the rate reported in a CPT trial that also comprised therapy modifications (e.g., Jak et al., 2019) which reported a non-completion rate of 47%. There were, however, some significant differences in baseline characteristics between treatment completers and those who dropped out of therapy, including higher scores on the complicated client presentation checklist, more pretreatment comorbidities and higher symptom severity, which aligns with research which indicates that clients with more complex or complicated presentations or who have greater PTSD severity may sometimes find it more difficult to complete therapy as planned (Najavits, 2015). Therefore retaining people in therapy should be a primary goal of PTSD therapy, illustrated by the fact that the majority of dropouts in this study (62.5%) completed three or fewer treatment sessions, which did not allow for all case formulation components to be delivered (i.e. the therapeutic letter was provided after session 3). Additionally,

dropout at those very early stages in therapy meant that deviations, which may have been useful for nonresponsive clients, were less likely to have occurred in conjunction with substantive case formulation-led deviations. For example, moderate-major CPT deviations between sessions 1 to 3 occurred only for four participants.

As has been noted, if and how case formulation can contribute to retention and treatment outcomes is still unclear. This is exacerbated by a lack of a unified understanding of the components of case formulation and how it can be most effectively utilised throughout therapy. As discussed in the Introduction, there appears to be a lack of clarity about what case formulation actually is or should be, how formulation-driven CBT operates at the practical level, or how it differs from competently delivered 'standard' CBT (see Easden & Kazantzis, 2017, for discussion). Almost all case formulation research has been with very small samples or focused on individual case studies and we have limited data on the inter-rater reliability of formulations, which makes measurement difficult (Flinn, Braham, & das Nair, 2015; Flitcroft, James, Freeston, & Wood-Mitchell, 2007). In addition, there is very little research about how to *effectively* apply a case formulation to a case, with different therapists with the same formulation possibly selecting different treatment targets, as well as different interventions to address these targets. The present study is not immune to these issues, some of which may have contributed to the lack of superiority of the case formulation approach. Consistent with previous qualitative research (e.g., Nattrass et al., 2015; Redhead et al., 2015) where participants reported case formulation helped them feel understood, and assisted them to understand better their issues and to 'move forward', participants in my study reported that the formulations helped make linkages and connections with symptoms, provided an overarching framework for understanding and helped them feel listened to and validated. Given there was no significant difference in treatment outcomes however, the

formulations used in this study may have had utility in describing symptoms and providing insight and understanding into the maintenance factors of PTSD for participants, but may have had limited value in guiding deviations for the therapist when treatment stalled. Although the formulation-driven deviations were assessed by an independent rater in this study, without coding every case formulation diagram and letter and every client session it is difficult to ascertain whether the deviations made were the most appropriate in terms of both timing and suitability.

My prediction that case formulation would interact with therapeutic alliance to result in superior outcomes was not supported. As previously discussed, there are mixed findings in the literature in regard to the link between therapeutic alliance and treatment outcomes. A recent meta-analytic review concluded that the majority of studies examining the relationship between alliance and outcomes showed that alliance was predictive of or associated with symptom reduction (Ellis, Simiola, Brown, Courtois, & Cook, 2018) however other studies have reported that a strong therapeutic alliance is not a predictor in PTSD samples (Forbes et al., 2008; van Minnen et al., 2002). In this study, as PTSD symptoms went down, scores on the SRS for participants in both groups increased, therefore as people felt better, they rated the value of the sessions, including the alliance with the therapist, more highly. However overall alliance was not a moderator of outcomes according to treatment group over time, with no significant 3-way interaction found. Although it was beyond the scope of this thesis to examine the links between alliance, complexity and treatment outcome using multilevel modelling, my analyses did show there was a group by alliance interaction with participants with low alliance (as measured by the WAI) having higher CAPS-5 scores in the CPT+CF group. Although this did not affect outcomes over time, this finding might indicate that there

was an aspect of the case formulation diagram or letter (or the process) which those participants with low alliance reacted against.

In summary, analyses indicated that the addition of explicit case formulation did not significantly reduce symptoms of PTSD or other secondary measures; nor did CPT+CF perform better than standard CPT even for clients with complex presentations, nor differentially affect dropout rate compared to using the standardised manualised approach. Although there was not a difference between groups in terms of dropouts, they were characterised by higher levels of clinical complexity and symptom severity. Clearly then, a different approach is needed to keep people in therapy, particularly in the early stages and even if it is not entirely clear as to which modifications are the most effective, it is possible that a guided approach to modifying manualised therapy when symptoms are not reducing is still warranted.

Do Deviations Assist When Participants Are Not Responding?

As noted above, when things are going well in CPT, there is no need to deviate from the standard protocol, with the majority of participants reaching a good outcome, even in the face of increasing complexity. The more difficult questions to answer, however, are how to determine how early in therapy should one intervene when therapy is not progressing well or as expected, and in such cases, what should that intervention entail?

Although the results from this study indicate that there were greater reductions in PTSD symptoms at the end of treatment for those participants who showed changes as early as session 4 relative to those who do not evidence such early change, this does not necessarily mean that early lack of change will predict an unfavourable outcome nor that deviation from the standard therapy is warranted at that early stage. Thus although a strong predictor of change is early change (Sripada et al., 2019) and on average CPT

studies demonstrate that symptoms decline steadily during therapy (at the group level) (Galovski et al., 2012; Resick et al., 2008), this is not always the case and early change is not always a prerequisite for positive outcome. For example, a recent analysis of responder types categorised by treatment trajectory found that although clear responders to therapy (i.e. those who demonstrated a reliable decrease in PTSD symptoms by session 6) could be distinguished by session 4, a number of individuals who did not show this early change still evidenced very good outcomes by posttreatment, albeit more slowly (Nixon et al., 2020). As reported in the Results, although tentative, there was some evidence from this study that certain deviations occurring through therapy may have had a beneficial outcome for CPT+CF participants who had not made reliable changes relative to CPT participants. As emphasised here and in the earlier chapter, these findings are considered tentative, and qualified by the obvious power issues that accompany smaller sample sizes, particularly for analyses that examined whether moderate-major CPT deviations occurred across treatment (with cell sizes for CPT: n = 11; CPT+CF, n = 20).

These results may provide some indication that deviating from therapy when clinically indicated could possibly result in improved outcomes. However, as noted by Nixon et al. (2020) and others (Resick et al., 2014), deviating from an evidence-based protocol too early can result in clients not receiving a full dose of appropriate therapy, while continuing with a treatment protocol in the face of non-response is equally problematic (Ready, Lamp, Rauch, Astin, & Norrholm, 2018). In addition, therapists' ability to predict outcome using clinical judgement alone in the absence of statistical or actuarial outcome monitoring has been noted as often inaccurate (Boswell, Kraus, Miller, & Lambert, 2015), with such inaccuracy also seen when clinicians are asked to make predictions about likelihood of treatment non-response (Hannon et al., 2005; Hatfield,

McCullogh, Frantz, & Krieger, 2010). Also, where case formulation has been used for the purpose of guiding treatment, research has indicated that the quality of formulation decreases with increasing problem complexity, and that individualised formulations were not often associated with treatment decisions (Groenier, Pieters, Witteman, & Lehmann, 2014). Therefore, while it may be indicated that something should be done, it is not sufficient to rely on clinical judgement alone when deciding whether to deviate, how to deviate and with whom. Currently, there is no empirically based decision-making framework about how to modify treatment in the face of PTSD non-response, and when deviations are made, it is not always clear whether they are being done effectively, with the right people and targeting the right outcome (Goodnight et al., 2019; Nixon et al., 2020).

Limitations

Although adequately powered to detect treatment effects and the main interactions of interest (i.e., group x time), it is likely that my study was not sufficiently powered to detect small effects between those responding and not responding during treatment, or to examine, for example, whether deviations to address substance use were more effective than when the identified issue to be addressed was depression or motivation. To address these issues more sophisticated power methods to accommodate both analyses of subsets of participants and nested data could be utilised in the future.

In addition, almost two thirds of the treatment sessions were conducted by novice therapists, with limited experience in the use of case formulation, which may have led to some inconsistencies in how formulations were developed and subsequently utilised. Also, the diagrammatic case formulation used in this study may have benefited from additional prompts on the therapist's sheet to assist with explicit identification of past proximal and distal factors (e.g. past life experiences) as well as potential barriers to

therapy (e.g. work related stress, comorbidities) that could then be documented on the formulation. A more explicit consideration of comorbidities and their interrelationship with the maintenance of PTSD may be more beneficial in terms of secondary outcomes (e.g. pain, sleep). Despite this, therapists generally achieved good outcomes across both treatment conditions, and as mentioned previously, the dropout rate was low. This is consistent with other studies that have used novice therapists administering an explicit case formulation approach (Nixon & Bralo, 2019).

In addition, although there was a shared understanding of what constituted a deviation from therapy, with planned deviations occurring under supervision, there was still some potential variability in how therapists completed the form used to document deviations from protocol, which may have led to some inconsistency in coding. This was alleviated somewhat by separating deviations into crisis driven deviations and CPT deviations, which allowed for better coding of deviation type and level, but nonetheless still relied heavily on individual therapists assessing their own level of deviation and there was not objective observation or a comparison of therapist reports to observer reports.

In addition, although a sample of treatment sessions and a case formulation were coded for fidelity, there were insufficient funds for inter-rater reliability of diagnostic interviews. Although a limitation, it should be noted that all assessors had done online training for the CAPS-5, all received training for administration of the MINI and were monitored through supervision. This training method has been used consistently across studies conducted in the Flinders Posttraumatic Stress Research Unit and where inter-rater reliability was conducted has resulted in good outcomes (Nixon, 2012).

Although the follow-up period of six months was good for a study of this type, given the ongoing PTSD symptom reduction noted in the CPT+CF group over time, a longer follow-up would have been beneficial.

Finally, as has been mentioned earlier, the complicated client presentation checklist was a new measure developed specifically for the study, and the combination of these variables (versus examining them as separate moderators) is a relatively new approach in the PTSD literature (but see Cloitre et al., 2016 and Gerger et al., 2014).

Strengths

There were a number of strengths to my study. It was conducted in accordance with CONSORT guidelines for randomised trials and included independent randomisation of participants, assessors at posttreatment and 6-month follow-up assessments who were unaware of participants' treatment details (i.e., treatment condition, stage of treatment), and who did not assess the same participant at subsequent follow-ups. For a research trial conducted within the timelines of a PhD, the 6-month follow-up interval should also be viewed as a strength. Additionally, the fidelity and quality of not only CPT but also case formulation was assessed (and found to be good-to-excellent), leading to confidence that therapy was more than adequately delivered. The use of diagnostic interviews for both PTSD and other comorbid conditions at pretreatment allowed for a comprehensive examination of these disorders, which provided a thorough description of the sample, an important factor when making generalisations from the findings. Additionally, a range of self-report measures that indexed other common comorbid problems (e.g., alcohol abuse, insomnia) allowed the effects of treatment to be evaluated beyond PTSD and depression outcomes. Finally, the definition of good end-state functioning for PTSD chosen in this trial (PCL-5 < 17) met

the recent standards being set for PTSD trials of this type, resulting in clear demarcation of participants who remitted completely from PTSD and those who did not.

Theoretical and Clinical Implications

Although case formulation has been cited as underpinning CBT since the mid-90s, there is very little research on the types of formulations, how they should be used throughout therapy, and the overall benefits and effect on outcomes. PTSD is a disorder with high levels of comorbidity, characterised by substantial avoidance, and in the case of interpersonal trauma in particular, can have significant negative impacts in relation to trust and relationships, which includes the therapeutic relationship. With the exception of one open trial (Nixon & Bralo, 2019), explicit collaborative case formulation in the context of PTSD research has thus far been limited to individual case examples (Kerig et al., 2010; Kramer, 2009; Lee, 2016; McCarthy & Petrakis, 2011; Padmanabhanunni & Edwards, 2015), and although positive results were noted, how case formulation actually benefits clients remains unclear. For example, it is possible the benefit lies primarily in the therapist having a better understanding of how a client's individual experience of PTSD is maintained through the formulation, rather than the individual client. As such, although case formulation may assist in guiding treatment decisions, in some circumstances this approach may possibly be more useful when undertaken by the therapist for their own conceptualisation of the case rather than always needing to be a shared, collaborative process. This is aligned with research which indicates that nonspecific therapy factors (e.g. alliance) have been theorised to be as important, if not more so, than specific protocols or treatment types (Wampold et al, 2010; Miller & Duncan, 2000) however such models may require further scrutiny given the results of this study suggest that personalising through case formulation did not influence outcome for the majority of clients. In addition, despite a list of factors which have been noted as

contributed to poorer treatment outcomes, we still do not have a good model nor theory for why some people do not get better with PTSD treatment.

My research also replicates previous trials by demonstrating that CPT alone is effective in treating individuals with complicated presentations and that deviations from therapy may not always be warranted (Chard et al., 2011; Gradus et al., 2013; Resick, Suvak, & Wells, 2014), but also extends such findings by examining in detail how deviations influence treatment success and through a more rigorous examination of how client complexity might influence outcomes. This has important implications for the treatment of PTSD in routine clinical settings, given concerns are often raised that clients in those settings are more difficult to treat or require periods of stabilisation prior to treatment commencement (Cook, Thompson, Simiola, Wiltsey Stirman, & Schnurr, 2018; Gray et al., 2007). In this study exclusion criteria were kept to a minimum and the sample demonstrated high rates of comorbidity, which suggests that the findings are generalisable to a clinical setting. The lack of adverse events reported in this study, despite the complexity of client presentations, indicate that addressing the trauma first even in the presence of comorbidities including suicidal ideation is not contraindicated which may address clinician concerns about using trauma-focused approaches even with clients who may present at some risk. This study, as others, notes that risk level in respect to suicidal ideation can actually decrease with treatment (Holliday et al., 2018). In addition, given the positive outcomes found with administering CPT alone without deviation, with the average number of sessions delivered being 11.32, my study adds to the substantial body of CPT literature that indicates many clients, including those with clinical complexity, can benefit from a relatively short-term treatment. Clients do need an adequate dose of therapy, given that those who dropped out before 5-6 sessions did not benefit as much as those who completed the full course of therapy, which replicates other

work (Nixon et al., 2020) and reinforces the need to keep clients engaged as active participants throughout treatment.

In summary, although the addition of case formulation in this study did not achieve superior results, it did not adversely affect outcomes either. Formulation remains an integral part of CBT approaches in clinical practice and can provide a shared understanding between therapist and client, and/or between therapists on the development and maintenance of mental health conditions and the identification of strengths and barriers. This study adds to the literature noting that for the most part, CPT does not need to be modified. However, there is also some suggestion that for clients with complex presentations deviations may be beneficial, and in those cases pressing on with CPT when there are clear barriers or risks of dropout would be imprudent. Case formulation in these circumstances provides both a justification for therapy deviations, and a guide for an appropriate therapeutic approach.

Directions for Future Research

As has been noted, criticism levelled towards case formulation research has included the observation that although the process is generally considered indicative of good practice, the type and quality of the formulations are often not described, nor is the acceptability of the formulation process often evaluated. My research indicates that while generally considered useful, there may have been some variability in how the different types of formulations were accepted by clients, with some quantitative and qualitative differences reported between the diagrammatic case formulation and the therapeutic letter. Although there was no effect on outcome, these findings add weight to the view that the utility of different *forms* of case conceptualisation should be tested in further research (Easden & Kazantzis, 2017). In addition, as suggested above, it may be that case formulation is primarily a tool which serves therapists' needs rather than that of clients,

although collaborative case formulation traditionally involves both parties (Kuyken et al., 2009). As such, further research could investigate whether non-collaborative case formulation can assist the therapist independent of the client, particularly in guiding any treatment deviations.

In addition, although it is clear that when therapy is not progressing well deviating from standard treatment protocols may be indicated, the individual nature of deviations can make replicability of study findings difficult. As has been noted, whenever adaptations are made, there needs to be careful characterisation of the types of adaptation so that an association can be made with outcome (La Bash, Galovski, & Stirman, 2019). Further research into treatment modifications made during therapy may also benefit from an improved understanding of how to detect non-response in a reliable and accurate fashion, so that treatment decisions are made on the basis of agreed non-response indicators (for example, reliable change indices measured during therapy) and agreed treatment deviations are utilised to address specific issues (e.g. motivational interviewing to address avoidance).

Summary and Final Conclusions

Although case formulation did not result in superior outcomes in this study, there was some possible indication that deviating from treatment protocols when clients were not responding may have been beneficial. The challenge for future research is to determine what sort of deviations are warranted, how early (or late) these deviations should occur, and to develop an empirically derived method upon which to base the decision-making processes used to guide treatment.

In conclusion, my study replicates numerous randomised controlled trials of CPT, underscoring it as an effective treatment for PTSD, with good treatment outcomes achieved for the majority of clients in less than 12 sessions, even for those individuals who presented with high levels of complication. As such, it is a highly generalisable trial with important implications for clinical practice and provides a strong base for subsequent research to further examine how we can improve our treatments for those who suffer from PTSD.

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SUPPLEMENTARY ANALYSES

Table S1

Participant Demographic and Pretreatment Trauma and Symptom Characteristics for Completer Sample

Characteristics *M* (SD) or *n* (%)	Completers (*n* = 77)	Non-Completers (*n* = 16)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Age (years)	43.35 (13.50)	43.19 (11.78)	$t = 0.05$	.964	0.01 [-0.55, 0.53]
Female	49 (63.6%)	13 (81.3%)	$\chi^2 = 1.85$	.247	0.14 [-0.31, 0.05]
White ethnicity	58 (75.3%)	14 (87.5%)	$\chi^2 = 1.79$	.877	0.14 [0.09, 0.27]
Education (years)	14.87 (3.16)	15.19 (4.42)	$t = 0.40$	.694	0.09 [-0.45, 0.63]
Currently employed	51 (66.2%)	9 (56.3%)	$\chi^2 = 0.58$	.567	0.08 [-0.13, 0.29]
First responder	20 (26.0%)	0 (0%)	$\chi^2 = 5.29$	.019	0.24 [0.16, 0.33]
Income					
Less than $10,000	7 (9.1%)	1 (6.3%)			
$10,001 – 30,000	17 (22.1%)	6 (37.5%)			
$30,001 – 50,000	7 (9.1%)	2 (12.5%)			
$50,001 – 70,000	17 (22.1%)	3 (18.8%)	$\chi^2 = 2.69$	.747	0.17 [0.13, 0.42]
$70,001 – 90,000	4 (5.2%)	0 (0%)			
More than $90,000	25 (32.5%)	4 (25%)			
Marital status					
Single	17 (22.1%)	5 (31.3%)			
Married/cohabiting	39 (50.6%)	5 (31.3%)			
Divorced/separated/widower	11 (14.3%)	5 (31.3%)	$\chi^2 = 4.36$	.498	0.22 [0.13, 0.47]
Relationship not living together	9 (7.8%)	1 (6.3%)			

Characteristics *M* (SD) or *n* (%)	Completers (*n* = 77)	Non-Completers (*n* = 16)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Index Trauma					
Child sexual abuse	10 (13.0%)	5 (31.3%)			
Adult sexual assault	9 (11.7%)	1 (6.3%)			
Child physical abuse	6 (7.8%)	2 (12.5%)			
Adult physical assault	9 (11.7%)	4 (25.0%)			
Motor vehicle accident	8 (10.4%)	1 (6.3%)	χ^2 =10.69	.298	0.34 [0.31, 0.59]
Witness death	19 (24.7%)	0 (0.0%)			
Serious injury/threat of death	5 (6.5%)	1 (6.3%)			
Physical assault	5 (6.5%)	1 (6.3%)			
Traumatic loss	2 (2.6%)	1 (6.3%)			
Home invasion/rape	4 (5.2%)	0 (0%)			
Interpersonal trauma	45 (58.4%)	13 (81.3%)	χ^2 =2.93	.099	0.18 [-0.34, 0.002]
Years since index trauma	14.88 (15.70)	22.56 (16.39)	t = 1.75	.084	0.49 [-0.06, 1.03]
Current comorbid diagnoses (MINI)					
Major Depressive Disorder	48 (62.3%)	11 (68.8%)	χ^2 = 0.24	.778	0.05 [-0.25, 0.16]
Panic Disorder	28 (36.4%)	8 (50.0%)	χ^2 = 1.04	.399	0.11 [-0.32, 0.11]
Agoraphobia	23 (29.9%)	8 (50.0%)	χ^2 = 2.42	.149	0.16 [-0.37, 0.05]
Mania or Hypomania	6 (7.8%)	1 (6.3%)	χ^2 = 0.05	> .999	0.02 [-0.21, 0.16]
Social Anxiety Disorder	22 (28.6%)	6 (37.5%)	χ^2 = 0.50	.552	0.07 [-0.28, 0.12]
Obsessive-Compulsive Disorder	12 (15.6%)	3 (18.8%)	χ^2 = 0.10	.718	0.03 [-0.28, -0.17]
Generalised Anxiety Disorder	27 (35.1%)	11 (68.8%)	χ^2 = 6.22	.013	0.26 [-0.45, -0.06]
Alcohol abuse or dependence	33 (42.9%)	7 (43.8%)	χ^2 = 0.004	> .999	0.01 [-0.21, 0.19]
Substance abuse or dependence	5 (6.5%)	5 (31.3%)	χ^2 = 8.46	.012	0.30 [-0.54, -0.02]
Psychotic Disorder	3 (3.9%)	1 (6.3%)	χ^2 = 0.18	.537	0.04 [-0.29, 0.12]
Eating disorder	5 (6.5%)	2 (12.5%)	χ^2 = 0.69	.346	0.09 [-0.35, 0.13]
Comorbid conditions (Total)	2.75 (2.01)	3.94 (1.39)	t = 2.25	.008	0.62 [0.07, 1.17]

Characteristics *M* (SD) or *n* (%)	Completers (*n* = 77)	Non-Completers (*n* = 16)	Test	*p*	*ES*[a] *d or φ [95% CI]*
Current suicidality	46 (59.7%)	13 (81.3%)	$\chi^2 = 2.64$	.154	0.17 [-0.33, 0.03]
Suicidal Behaviour Disorder	18 (23.4%)	7 (43.8%)	$\chi^2 = 2.780$	.122	0.17 [-0.40, 0.04]
Any hospitalisation pretrauma	7 (9.1%)	3 (18.8%)	$\chi^2 = 1.29$	.368	0.12 [-0.38, 0.120]
Any hospitalisation posttrauma	25 (32.5%)	5 (31.3%)	$\chi^2 = 0.01$	> .999	0.01 [-0.20, 0.21]
Symptom Measures					
CAPS-5 severity	42.09 (8.31)	44.50 (9.32)	*t* = 1.03	.304	0.28 [-0.26, 0.82]
PCL-5	49.07 (10.88)	55.69 (8.84)	*t* = 2.28	.025	0.63 [0.08, 1.17]
DASS-D	22.44 (11.10)	29.47 (9.96)	*t* = 2.28	.025	0.64 [0.10, 1.19]
PTCI	136.84 (36.05)	165.67 (39.30)	*t* = 2.80	.006	0.79 [0.24, 1.34]
ISI	15.48 (6.01)	18.80 (6.07)	*t* = 1.95	.054	0.55 [0.01, 1.10]
DERS	99.38 (22.92)	107.93 (23.94)	*t* = 1.31	.192	0.37 [-0.17, 0.91]
AUDIT	6.88 (6.99)	6.60 (7.44)	*t* = 0.14	.887	0.04 [-0.58, 0.50]
CUDIT	0.81 (0.10)	3.47 (8.81)	*t* = 1.16	.266	0.74 [0.19, 1.30]
DUDIT	1.57 (0.61)	4.93 (1.94)	*t* = 1.66	.116	0.41 [-0.13, 0.95]
CCPC (Total)	10.49 (4.41)	13.47 (4.97)	*t* = 2.34	.021	0.66 [0.11, 1.21]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPC = Complicated Client Presentation Checklist.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large; for φ: 0.1 = small, 0.3 = medium, and 0.5 = large.

Table S2.

Model Estimates, Within-Group Effect Sizes [and 95% Confidence Intervals] and Type 3 Fixed Effects of Time, Group and Group by Time from Pre- to Posttreatment and 6-Month Follow-up – Completer Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI]*[a]	*M*	*SE*	*Cohen's d [95% CI]*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
CAPS-5	1	43.24	1.50		40.97	1.15										
	2	8.72	1.61	3.65 [1.49, 5.80]	12.62	2.17	2.61 [0.20, 5.02]									
	3	11.05	1.95	3.03 [0.62, 5.43]	11.06	2.03	3.06 [0.83, 5.29]	357.62	2,140.48	< .001	.15	1,77.70	.703	2.79	2,140.48	.065
PCL-5	1	51.13	1.83		47.05	1.64										
	2	9.57	2.13	3.49 [0.75, 6.22]	9.17	2.32	3.15 [0.42, 5.89]									
	3	12.06	2.47	3.01 [0.04, 5.99]	12.44	2.24	3.03 [0.38, 5.69]	390.17	2,130.55	< .001	.12	1,74.63	.732	1.49	2,130.55	.230
DASS-D	1	22.32	1.84		22.56	1.76										
	2	5.09	1.49	1.69 [-0.66, 4.03]	5.83	1.55	1.64 [-0.68, 3.96]									
	3	8.74	2.16	1.13 [-1.64, 3.89]	7.00	1.63	1.52 [-0.86, 3.90]	90.53	2,128.89	< .001	.00	1,72.74	.952	.30	2,128.89	.742
PTCI	1	146.39	5.17		127.54	6.06										
	2	71.04	5.70	2.32 [-5.19, 9.83]	72.59	6.89	1.40 [-7.54, 10.34]									
	3	83.30	7.19	1.94 [-5.57, 9.45]	80.87	6.67	1.24 [-7.55, 10.02]	127.28	2,128.37	< .001	.29	1,74.37	.595	4.31	2,128.37	.016[4]
ISI	1	15.76	1.12		15.21	0.82										
	2	9.57	1.07	0.94 [-0.58, 2.45]	8.68	1.03	1.18 [-0.09, 2.45]									
	3	8.09	1.21	1.10 [-0.51, 2.71]	8.99	1.19	1.06 [-0.31, 2.43]	56.79	2,130.27	< .001	.00	1,76.27	.994	1.03	2,130.27	.361

[4] Unpacking of the interaction revealed the significant finding was likely driven by the higher pretreatment mean for CPT group, resulting in a larger pre- to posttreatment change, with no significant differences between groups at follow-up.

		Model estimates and effect sizes						Model estimates and effect sizes								
		CPT			CPT+CF			Time			Group			Group × Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
DERS	1	104.24	3.92		94.64	3.34										
	2	69.57	3.14	1.60 [-3.37, 6.57]	66.46	3.57	1.34 [-3.44, 6.12]									
	3	69.14	3.64	1.54 [-3.74, 6.81]	65.47	2.86	1.54 [-2.85, 5.94]	85.19	2,130.55	< .001	1.67	1,74.94	.201	1.10	2,130.55	.338
AUDIT	1	6.97	1.26		6.80	1.00										
	2	4.83	0.94	0.31 [-1.25, 1.88]	4.83	0.69	0.37 [-0.84, 1.58]									
	3	0.35	0.18	1.16 [-0.16, 2.48]	0.44	0.22	1.36 [0.26, 2,45]	8.81	2,127.79	< .001	.05	1,72.23	.823	.23	2,127.79	.798
CUDIT	1	0.68	0.36		0.54	0.30										
	2	0.54	0.30	0.07 [-0.39, 0.53]	0.31	0.31	0.13 [-0.30, 0.55]									
	3	0.53	0.28	0.08 [-0.37, 0.53]	0.84	0.64	0.11 [-0.78, 0.56]	.57	2,119.85	.570	.25	1,64.65	.616	.56	2,119.85	.572
DUDIT	1	0.79	0.33		2.33	1.16										
	2	0.51	0.25	0.16 [-0.25, 0.56]	0.54	0.32	0.33 [-0.91, 1.57]									
	3	0.62	0.35	0.08 [-0.38, 0.55]	0.97	0.67	0.23 [-1.16, 1.61]	1.80	2,99.57	.171	1.08	1,49,07	.304	.97	2,99.57	382

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPC = Complicated Client Presentation Checklist. T1 = Pretreatment, T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d* 0.2 = small, 0.5 = medium, and 0.8 = large. Unless otherwise noted, all pre-post and pre-6-month changes were statistically significant.

Table S3

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] at Pre-, Posttreatment, and 6-Month Follow-up for Main Treatment Variables – Completer Sample

		CPT		CPT+CF		
Measure	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
CAPS-5	Pretreatment	43.24	1.50	40.97	1.15	0.27 [-1.58, 2.13]
	Posttreatment	8.72	1.61	12.62	2.17	0.33 [-3.01, 2.35]
	Follow-up	11.05	1.95	11.06	2.03	.001 [-2.76, 2.760
PCL-5	Pretreatment	51.13	1.83	47.05	1.64	0.38 [-2.02, 2.78]
	Posttreatment	9.57	2.13	9.17	2.32	0.03 [-3.05, 3.12]
	Follow-up	12.06	2.47	12.44	2.24	0.03 [-3.31, 3.26]
DASS-D	Pretreatment	22.32	1.84	22.56	1.76	0.02 [-2.52, 2.47]
	Posttreatment	5.09	1.49	5.83	1.55	0.08 [-2.19, 2.03]
	Follow-up	8.74	2.16	7.00	1.63	0.16 [-2.53, 2.84]
PTCI	Pretreatment	146.39	5.17	127.54	6.06	0.54 [-7.28, 8.36]
	Posttreatment	71.04	5.70	72.59	6.89	0.04 [-8.83, 8.74]
	Follow-up	83.30	7.19	80.87	6.67	0.06 [-9.58, 9.70]
ISI	Pretreatment	15.76	1.12	15.21	0.82	0.09 [-1.26, 1.44]
	Posttreatment	9.57	1.07	8.68	1.03	0.15 [-1.31, 1.60]
	Follow-up	8.09	1.21	8.99	1.19	0.13 [-1.79, 1.53]
DERS	Pretreatment	104.24	3.92	94.64	3.34	0.43 [-4.61, 5.46]
	Posttreatment	69.57	3.14	66.46	3.57	0.16 [-4.51, 4.82]
	Follow-up	69.14	3.64	65.47	2.86	0.19 [-4.37, 4.76]
AUDIT	Pretreatment	6.97	1.26	6.80	1.00	0.02 [-1.55, 1.60]
	Posttreatment	4.83	0.94	4.83	0.69	0.00 [-1.14, 1.14]
	Follow-up	0.35	0.18	0.44	0.22	0.08 [-0.35, 0.19]
CUDIT	Pretreatment	0.68	0.36	0.54	0.30	0.07 [-0.39, 0.53]
	Posttreatment	0.54	0.30	0.31	0.31	0.13 [-0.30, 0.55]
	Follow-up	0.53	0.28	0.84	0.64	0.11 [-0.78, 0.56]
DUDIT	Pretreatment	0.79	0.33	2.33	1.16	0.29 [-1.48, 0.91]
	Posttreatment	0.51	0.25	0.54	0.32	0.02 [-0.42, 0.38]
	Follow-up	0.62	0.35	0.97	0.67	0.12 [-0.84, 0.61]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; MINI = MINI International Neuropsychiatric Interview; CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; PTCI = Posttraumatic Cognitions Inventory; ISI = Insomnia Severity Index; DERS = Difficulties in Emotional Regulation Scale; CCPC = Complicated Client Presentation Checklist.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S4

Model Estimates, Within-Group Effect Sizes [and 95% Confidence Intervals] and Type 3 Fixed Effects of Time, Group and Group by Time from Pre- to Posttreatment and 6-Month Follow-up for Credibility/Expectancy – Intent-to-Treat Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
Credibility	1	21.83	0.64		22.02	0.62										
	2	25.16	0.61	0.81 [-1.69, 0.07]	24.74	0.67	0.67 [-1.57, 0.23]									
	3	25.11	0.56	0.83 [-1.68, 0.03]	25.02	0.58	0.79 [-1.64, 0.67]	24.15	2, 24.21	< .001	.01	1,74.75	.942	0.13	124.21	.881
Expectancy	1	17.87	0.73		19.98	0.59										
	2	22.59	0.78	0.97 [-2.01, 0.08]	23.11	0.67	0.79 [-1.66, 0.08]									
	3	22.91	0.62	1.13 [-2.09, 0.18]	22.88	0.55	0.80 [-1.61, 0.01]	30.81	2,134.84	< .001	1.85	1,82.23	.177	1.53	134.84	.221
Total	1	39.70	1.20		42.00	1.07										
	2	47.76	1.33	0.99 [-2.73, 0.76]	47.86	1.28	0.80 [-2.42, 0.82]									
	3	48.00	1.08	1.33 [-2.67, 0.01]	47.89	0.97	0.90 [-2.36, 0.56]	34.76	2,128.20	< .001	0.52	1,78.41	.472	0.75	128.20	.475

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; Credibility = Credibility Subscale; Expectancy = Expectancy Subscale; Total = Total Credibility and Expectancy; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S5

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] at Pre-, Posttreatment, and 6-Month Follow-up for Credibility/Expectancy – Intent-to-Treat Sample

		CPT		CPT+CF		
Measure	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
Credibility	Pretreatment	21.83	0.64	22.02	0.62	0.05 [-0.92, 0.83]
	Posttreatment	25.16	0.61	24.74	0.67	0.11 [-0.78, 1.00]
	Follow-up	25.11	0.56	25.02	0.58	0.03 [-0.76, 0.82]
Expectancy	Pretreatment	17.87	0.73	19.98	0.59	0.47 [-1.39, 0.45]
	Posttreatment	22.59	0.78	23.11	0.67	0.12 [-1.13, 0.89]
	Follow-up	22.91	0.62	22.88	0.55	0.01 [-0.80, 0.82]
Total	Pretreatment	39.70	1.20	42.00	1.07	0.30 [-1.88, 1.28]
	Posttreatment	47.76	1.33	47.86	1.28	0.01 [-1.82, 1.80]
	Follow-up	48.00	1.08	47.89	0.97	0.02 [-1.42, 1.45]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; Credibility = Credibility Subscale; Expectancy = Expectancy Subscale; Total = Total Credibility and Expectancy.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S6

Model Estimates, Within-Group Effect Sizes [and 95% Confidence Intervals] and Type 3 Fixed Effects of Time, Group and Group by Time from Pre- to Posttreatment and 6-Month Follow-up for Credibility/Expectancy – Completer Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
Measure	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
Credibility	1	22.31	0.62		22.03	0.66										
	2	25.91	0.27	1.22 [-1.90, -0.54]	24.74	0.67	0.67 [-1.59, 0.26]									
	3	25.47	0.40	0.99 [-1.73, -0.25]	25.02	0.58	0.79 [-1.67, 0.09]	28.81	2,118.51	< .001	1.43	1,63.54	.236	0.49	2,118.51	.615
Expectancy	1	18.29	0.80		19.85	0.64										
	2	23.37	0.54	1.22 [-2.20, -0.23]	23.11	0.67	0.82 [-1.73, 0.09]									
	3	23.27	0.58	1.18 [-2.18, -0.17]	22.88	0.55	0.84 [-1.68, 0.01]	40.71	2,126.27	< .001	0.09	1,71.39	.767	2.41	2,126.27	.094
Total	1	40.61	1.23		41.87	1.14										
	2	49.29	0.72	1.41 [-2.88, 0.06]	47.86	1.27	0.82 [-2.49, 0.85]									
	3	48.73	0.90	1.25 [-2.81, 0.30]	47.89	0.97	0.93 [-2.43, 0.58]	46.53	2,122.79	< .001	0.19	1,68.21	.662	1.64	2,122.79	.197

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; Credibility = Credibility Subscale; Expectancy = Expectancy Subscale; Total = Total Credibility and Expectancy; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S7

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] at Pre-, Posttreatment, and 6-Month Follow-up for Credibility/Expectancy – Completer Sample

		CPT		CPT+CF		
Measure	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI]*[a]
Credibility	Pretreatment	22.31	0.62	22.03	0.66	0.32 [-0.56, 1.21]
	Posttreatment	25.91	0.27	24.74	0.67	0.39 [-0.32, 1.10]
	Follow-up	25.47	0.40	25.02	0.58	0.16 [-0.53, 0.85]
Expectancy	Pretreatment	18.29	0.80	19.85	0.64	0.35 [-1.35, 0.65]
	Posttreatment	23.37	0.54	23.11	0.67	0.07 [-0.77, 0.92]
	Follow-up	23.27	0.58	22.88	0.55	0.12 [-0.66, 0.91]
Total	Pretreatment	40.61	1.23	41.87	1.14	0.17 [-1.81, 1.47]
	Posttreatment	49.29	0.72	47.86	1.27	0.23 [-1.20, 1.67]
	Follow-up	48.73	0.90	47.89	0.97	0.16 [-1.14, 1.45]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; Credibility = Credibility Subscale; Expectancy = Expectancy Subscale; Total = Total Credibility and Expectancy; T1 = Pretreatment; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S8

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] for Session-by-Session Data for PCL-5 and DASS-D – Intent to Treat Sample

		CPT		CPT+CF		
Measure	Session	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
PCL-5	1	41.75	2.06	39.53	2.21	0.15 [-2.81, 3.12]
	2	40.33	1.97	38.33	2.45	0.13 [-2.93, 3.19]
	3	36.60	2.52	35.00	2.99	0.09 [-3.74, 3.92]
	4	35.14	2.70	29.24	2.98	0.32 [-3.61, 4.26]
	5	31.12	2.71	30.15	3.08	0.05 [-3.96, 4.07]
	6	27.27	3.09	28.54	2.81	0.07 [-4.18, 4.04]
	7	23.83	3.13	25.11	3.18	0.19 [-4.19, 4.56]
	8	19.80	2.96	22.19	3.14	0.13 [-4.35, 4.10]
	9	16.35	2.61	18.31	2.78	0.12 [-3.86, 3.61]
	10	16.47	2.67	16.21	2.68	0.02 [-3.70, 3.73]
	11	14.71	2.46	17.50	2.98	0.20 [-3.51, 3.10]
	12	11.73	2.26	16.97	2.99	0.36 [-3.97, 3.25]
	13	17.00	3.11	18.88	3.51	0.12 [-4.81, 4.57]
	14	17.00	2.89	19.00	3.69	0.14 [-4.92, 4.65]
	15	15.00	3.38	16.94	3.46	0.14 [-4.92, 4.64]
DASS-D	1	21.51	1.60	21.64	1.87	0.01 [-2.42, 2.39]
	2	20.09	1.75	20.49	1.67	0.04 [-2.40, 2.33]
	3	17.86	1.97	20.14	1.88	0.18 [-2.85, 2.49]
	4	16.76	1.98	15.80	1.86	0.08 [-2.59, 2.74]
	5	15.56	2.03	16.00	1.97	0.04 [-2.81, 2.74]
	6	14.79	1.96	15.23	2.01	0.04 [-2.78, 2.71]
	7	12.90	2.08	13.58	2.05	0.05 [-2.92, 2.81]
	8	12.55	2.20	12.05	1.87	0.04 [-2.81, 2.89]
	9	10.50	2.16	10.44	1.97	0.01 [-2.84, 2.85]
	10	9.56	1.83	8.29	1.80	0.12 [-2.40, 2.63]
	11	8.59	1.70	10.69	2.05	0.20 [-2.79, 2.40]
	12	7.88	1.83	10.40	2.23	0.22 [-3.02, 2.58]
	13	10.32	2.60	11.58	2.43	0.11 [-3.59, 3.37]
	14	12.13	2.69	10.76	2.33	0.13 [-3.32, 3.58]
	15	11.57	3.36	9.76	2.54	0.16 [-3.88, 4.20]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S9

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals] for Session-by-Session Data for ORS and SRS – Intent to Treat Sample

		CPT		CPT+CF		
Measure	Session	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
ORS	1	15.52	1.16	15.50	1.26	0.002 [-1.67, 1,68]
	2	18.11	1.27	20.11	1.36	0.23 [-2.05, 1.60]
	3	19.45	1.55	21.06	1.69	0.15 [-2.40, 2.09]
	4	20.41	1.59	24.22	1.69	0.36 [-2.63, 1.91]
	5	23.13	1.70	23.76	1.67	0.06 [-2.40, 2.28]
	6	23.20	1.83	24.34	1.84	0.10 [-2.64, 2.44]
	7	24.96	1.83	25.42	1.80	0.05 [-2.58, 2.48]
	8	25.16	1.93	26.52	1.88	0.12 [-2.76, 2.53]
	9	27.64	1.83	27.03	1.88	0.06 [-2.52, 2.63]
	10	28.10	1.81	27.92	1.71	0.02 [-2.43, 2.46]
	11	28.96	1.92	26.57	1.81	0.22 [-2.38, 2.82]
	12	29.94	1.89	25.72	2.04	0.39 [-2.33, 3.11]
	13	24.74	2.56	25.17	2.38	0.04 [-3.46, 3.39]
	14	27.78	2.14	24.42	2.55	0.32 [-3.08, 3.73]
	15	25.43	2.86	28.57	2.71	0.30 [-4.15, 3.56]
SRS	1	36.12	0.86	37.07	0.47	0.20 [-1.18, 0.78]
	2	36.73	0.53	36.59	0.50	0.04 [-0.67, 0.75]
	3	36.38	0.95	37.45	0.45	0.22 [-1.27, 0.83]
	4	37.50	0.91	37.81	0.39	0.07 [-1.06, 0.92]
	5	37.22	0.55	37.91	0.53	0.20 [-0.95, 0.54]
	6	37.62	0.57	37.99	0.46	0.11 [-0.84, 0.61]
	7	38.34	0.41	38.19	0.50	0.06 [-0.55, 0.66]
	8	38.18	0.46	38.59	0.39	0.16 [-0.75, 0.44]
	9	38.50	0.35	38.41	0.43	0.04 [-0.51, 0.59]
	10	38.48	0.36	38.68	0.49	0.08 [-0.67, 0.51]
	11	38.24	0.40	38.61	0.40	0.17 [-0.71, 0.38]
	12	38.81	0.29	38.85	0.34	0.02 [-0.48, 0.43]
	13	37.47	0.62	38.28	0.72	0.26 [-1.22, 0.70]
	14	38.15	0.55	38.36	0.54	0.09 [-0.85, 0.67]
	15	39.00	1.03	39.10	0.30	0.04 [-0.10, 0.89]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; ES = Effect Size; ORS = Outcome Rating Scale; SRS = Session Rating Scale.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S10

Diagnostic and Clinical Response to Treatment – Completer Sample

Outcome (%, n)	CPT	CPT+CF	χ^2	*p*	φ [g]
Posttreatment					
PTSD Response [a]	88.6% (31/35)	91.4% (32/35)	0.16	> .999	.05
PTSD Loss of Diagnosis [b]	94.4% (34/36)	82.1% (32/39)	2.72	.156	.19
PTSD GES [c]	82.9% (29/35)	85.7% (30/35)	0.11	.999	.04
Depression Response [d]	88.5% (23/26)	88.9% (24/27)	0.002	.999	.01
Depression Loss of Diagnosis [e]	83.3% (20/24)	82.6% (19/23)	0.004	> .999	.01
Depression GES [f]	65.4% (17/26)	66.7% (18/27)	0.01	> .999	.01
6-month follow-up					
PTSD Response	88.6% (31/35)	87.1% (27/31)	0.03	> .999	.02
PTSD Loss of Dx	86.5% (32/37)	88.6% (31/35)	0.07	> .999	.03
PTSD GES	77.1% (27/35)	71.9% (23/32)	0.25	.780	.06
Depression Response	77.8% (21/27)	83.3% (20/24)	0.25	.731	.07
Depression Loss of Dx	84.0% (21/25)	72.2% (13/18)	0.88	.455	.14
Depression GES	66.7% (18/27)	58.3% (14/24)	0.38	.575	.09

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; p values are Fishers Exact Test (2-sided value).

[a] Response to treatment defined by a change of more than 18 points on the PTSD Checklist (PCL-5) and total score of less than 31; [b] On the Clinician Administered PTSD Scale (CAPS-5); [c] GES = good end-state defined as a change of more than 18 points on the PCL-5 at or below a cut-off of 17 on the PCL-5; [d] Response defined by 8 point change on the Depression Anxiety and Stress Scale – Depression Subscale (DASS – D); [e] On the MINI; [f] GES = score of 6 or below on the DASS-D.

[g] Effect size conventions for φ: 0.1 = small, 0.3 = medium, and 0.5 = large.

Table S11

Means, Standard Errors and Within-Group Effect Sizes [and 95% Confidence Intervals across Time Points for Working Alliance Inventory – Intent to Treat Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
WAI	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
Task/goal	1	34.19	0.51		34.09	0.49										
	2	37.78	0.54	1.06 [-1.79, -0.33]	38.03	0.50	1.24 [-1.94, -0.54]									
	3	37.00	0.69	0.75 [-1.57, 0.07]	38.19	0.48	1.33 [-2.02, -0.65]	47.02	2,137.66	< .000	0.28	1,85.98	.600	0.61	2,137.66	.544
Bond	1	32.47	0.61		32.33	0.49										
	2	35.81	0.67	0.82 [-1.70, 0.06]	35.94	0.66	1.01 [-1.79, -0.23]									
	3	35.03	0.76	0.60 [-1.55, 0.36]	35.84	0.78	0.92 [-1.77, 0.08]	31.16	2,142.88	< .000	0.24	1,92.72	.624	0.40	2,142.88	.670
Total	1	66.66	1.02		66.42	0.87										
	2	73.60	1.11	1.02 [-2.49, 0.46]	73.97	1.05	1.26 [-2.57, 0.06]									
	3	72.03	1.39	0.71 [-2.35, 0.93]	74.03	1.16	1.24 [-2.61, 0.13]	45.29	2,140.87	< .000	0.30	1,89.99	.587	0.54	2,140.87	.585

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; WAI = Working Alliance Inventory; T1 = Session 2; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S12

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals across Time Points for Working Alliance Inventory – Intent to Treat Sample

		CPT		CPT+CF		
WAI	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
Task/goal	1	34.19	0.51	34.09	0.49	0.03 [-0.67, 0.73]
	2	37.78	0.54	38.03	0.50	0.08 [-0.81, 0.65]
	3	37.00	0.69	38.19	0.48	0.34 [-1.18, 0.50]
Bond	1	32.47	0.61	32.33	0.49	0.04 [-0.73, 0.81]
	2	35.81	0.67	35.94	0.66	0.03 [-0.96, 0.89]
	3	35.03	0.76	35.84	0.78	0.18 [-1.25, 0.89]
Total	1	66.67	1.02	66.42	0.87	0.04 [-1.28, 1.36]
	2	73.60	1.11	73.97	1.05	0.06 [-1.56, 1.44]
	3	72.03	1.39	74.03	1.16	0.27 [-2.06, 1.53]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; WAI = Working Alliance Inventory; T1 = Session 2; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S13

Means, Standard Errors and Within-Group Effect Sizes [and 95% Confidence Intervals across Time Points for Working Alliance Inventory – Completer Sample

		Model estimates and effect sizes						Type III fixed effects								
		CPT			CPT+CF			Time			Group			Group × Time		
WAI	T	*M*	*SE*	*Cohen's d [95% CI)*[a]	*M*	*SE*	*Cohen's d [95% CI)*[a]	*F*	*dfs*	*p*	*F*	*dfs*	*p*	*F*	*dfs*	*p*
Task/goal	1	34.28	0.58		34.31	0.54										
	2	38.29	0.43	1.29 [-2.00, -0.57]	38.03	0.50	1.17 [-1.89, -0.45]									
	3	37.77	0.46	1.10 [-1.83, -0.36]	38.19	0.48	1.26 [-1.98, -0.55]	55.39	2,126.24	< .000	0.004	1,70.79	.949	0.21	2,126.24	.807
Bond	1	32.39	0.69		32.64	0.54										
	2	36.14	0.66	0.92 [-1.86, 0.02]	35.94	0.66	0.90 [-1.74, -0.07]									
	3	35.68	0.64	0.82 [-1.75, 0.11]	35.84	0.78	0.82 [-1.73, 0.08]	39.75	2,132.71	< .000	0.05	1,77.56	.831	0.01	2,132.71	.989
Total	1	66.68	1.17		66.95	0.96										
	2	74.43	0.10	1.17 [-2.69, 0.35]	73.97	1.05	1.15 [-2.54, 0.24]									
	3	73.44	1.03	1.01 [-2.56, 0.54]	74.03	1.16	1.13 [-2.59, 0.32]	56.63	2,130.04	< .000	0.01	1,74.86	.933	0.07	2,130.04	.932

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; WAI = Working Alliance Inventory; T1 = Session 2; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S14

Means, Standard Errors and Between-Group Effect Sizes [and 95% Confidence Intervals across Time Points for Working Alliance Inventory – Completer Sample

		CPT		CPT+CF		
WAI	Time	*M*	*SE*	*M*	*SE*	*Cohen's d [95% CI)*[a]
Task/goal	1	34.28	0.58	34.31	0.54	0.01 [-0.78, 0.76]
	2	38.29	0.43	38.03	0.50	0.09 [-0.56, 0.74]
	3	37.77	0.46	38.19	0.48	0.16 [-0.81, 0.49]
Bond	1	32.39	0.69	32.64	0.54	0.07 [-0.92, 0.79]
	2	36.14	0.66	35.94	0.66	0.05 [-0.87, 0.97]
	3	35.68	0.64	35.84	0.78	0.04 [-1.03, 0.95]
Total	1	66.68	1.17	66.95	0.96	0.04 [-1.52, 1.44]
	2	74.43	0.10	73.97	1.05	0.08 [-1.35, 1.50]
	3	73.44	1.03	74.03	1.16	0.09 [-1.61, 1.42]

Note. CPT = Cognitive Processing Therapy; CPT+CF = Cognitive Processing Therapy plus Case Formulation; WAI = Working Alliance Inventory; T1 = Session 2; T2 = Posttreatment; T3 = 6-month Follow-up.

[a] Effect size conventions for Cohen's *d*: 0.2 = small, 0.5 = medium, and 0.8 = large.

Table S15

Linear Mixed Modelling Effects – Clinical Complexity as a Moderator – Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	89.465	.743	.391
Time	2	148.632	57.805	.000
CCPC	1	93.210	27.672	.000
Group x Time	2	148.632	1.485	.230
Group x CCPC	1	93.210	2.969	.088
Time x CCPC	2	151.884	.461	.631
Group x Time x CCPC	2	151.884	3.838	.024
PCL-5				
Group	1	91.631	.370	.545
Time	2	146.050	40.997	.000
CCPC	1	96.665	21.343	.000
Group x Time	2	146.050	.014	.986
Group x CCPC	1	96.665	.608	.438
Time x CCPC	2	150.909	1.551	.215
Group x Time x CCPC	2	150.909	.210	.811
DASS-D				
Group	1	83.187	.092	.763
Time	2	138.582	6.639	.002
CCPC	1	86.738	13.305	.000
Group x Time	2	138.582	.327	.721
Group x CCPC	1	86.738	.521	.472
Time x CCPC	2	142.657	1.603	.205
Group x Time x CCPC	2	142.657	.303	.739

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; CCPC = Complicated Client Presentation Checklist.

Table S16

Linear Mixed Modelling Effects – Total Alliance as a Moderator – Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	84.826	4.715	.033
Time	2	143.991	.767	.466
WAI-all	1	84.311	6.892	.010
Group x Time	2	143.991	2.222	.112
Group x WAI-all	1	84.311	4.477	.037
Time x WAI-all	2	143.548	2.760	.067
Group x Time x WAI-all	2	143.548	1.827	.165
PCL-5				
Group	1	81.449	2.122	.149
Time	2	134.589	.156	.856
WAI	1	80.666	6.379	.014
Group x Time	2	134.589	.235	.791
Group x WAI-all	1	80.666	2.289	.134
Time x WAI-all	2	133.901	2.356	.099
Group x Time x WAI-all	2	133.901	.168	.846
DASS-D				
Group	1	76.678	.396	.531
Time	2	131.614	2.733	.069
WAI-all	1	75.958	7.843	.006
Group x Time	2	131.614	.471	.625
Group x WAI-all	1	75.958	.372	.544
Time x WAI-all	2	130.837	.954	.388
Group x Time x WAI-all	2	130.837	.393	.676

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Total Time 1.

Table S17

Linear Mixed Modelling Effects – Alliance as a Moderator (Task/Goal Subscale) – Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	85.392	5.410	.022
Time	2	144.542	1.565	.213
WAI-task/goal	1	85.085	2.661	.107
Group x Time	2	144.542	.831	.438
Group x WAI-task/goal	1	85.085	5.158	.026
Time x WAI-task/goal	2	144.264	2.232	.111
Group x Time x WAI-task/goal	2	144.264	.604	.548
PCL-5				
Group	1	83.529	3.028	.086
Time	2	136.328	.131	.877
WAI-task/goal	1	82.747	3.133	.080
Group x Time	2	136.328	.136	.873
Group x WAI-task/goal	1	82.747	3.234	.076
Time x WAI-task/goal	2	135.648	2.685	.072
Group x Time x WAI-task/goal	2	135.648	.094	.910
DASS-D				
Group	1	78.730	.236	.628
Time	2	133.604	3.205	.044
WAI-task/goal	1	77.976	4.028	.048
Group x Time	2	133.604	.312	.732
Group x WAI-task/goal	1	77.976	.214	.645
Time x WAI-task/goal	2	132.812	1.509	.225
Group x Time x WAI-task/goal	2	132.812	.253	.777

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Task/Goal Subscale Time 1.

Table S18

Linear Mixed Modelling Effects – Alliance as a Moderator (Bond Subscale) – Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	85.770	2.534	.115
Time	2	144.714	.568	.568
WAI-bond	1	85.026	8.063	.006
Group x Time	2	144.714	30253	.042
Group x WAI-bond	1	85.026	2.311	.132
Time x WAI-bond	2	144.104	2.537	.083
Group x Time x WAI-bond	2	144.104	2.704	.070
PCL-5				
Group	1	82.044	.782	.379
Time	2	135.275	1.242	.292
WAI-bond	1	81.271	7.055	.010
Group x Time	2	135.275	.315	.730
Group x WAI-bond	1	81.271	.903	.345
Time x WAI-bond	2	134.617	1.717	.184
Group x Time x WAI-bond	2	134.617	.226	.798
DASS-D				
Group	1	77.607	.332	.566
Time	2	132.435	2.499	.086
WAI-bond	1	76.935	8.593	.004
Group x Time	2	132.435	.512	.600
Group x WAI-bond	1	76.935	.305	.583
Time x WAI-bond	2	131.754	.337	.715
Group x Time x WAI-bond	2	131.754	.422	.657

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Bond Subscale Time 1.

Table S19

Linear Mixed Modelling Effects – Clinical Complexity as a Moderator – Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	75.675	.022	.883
Time	2	136.34	52.874	.000
CCPC	1	76.114	21.409	.000
Group x Time	2	136.34	1.010	.367
Group x CCPC	1	76.114	.693	.408
Time x CCPC	2	136.894	.727	.485
Group x Time x CCPC	2	136.894	3.014	.052
PCL-5				
Group	1	75.474	.000	.983
Time	2	130.212	41.798	.000
CCPC	1	76.571	18.685	.000
Group x Time	2	130.212	.040	.961
Group x CCPC	1	76.571	.118	.732
Time x CCPC	2	131.277	.863	.424
Group x Time x CCPC	2	131.277	.273	.762
DASS-D				
Group	1	71.458	.002	.963
Time	2	126.475	5.235	.007
CCPC	1	72.473	11.031	.001
Group x Time	2	126.475	.476	.623
Group x CCPC	1	72.473	.204	.653
Time x CCPC	2	127.671	1.461	.236
Group x Time x CCPC	2	127.671	.433	.649

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; CCPC = Complicated Client Presentation Checklist.

Table S20

Linear Mixed Modelling Effects – Alliance as a Moderator – Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	74.738	2.129	.149
Time	2	135.685	.256	.774
WAI-all	1	74.545	4.931	.029
Group x Time	2	135.685	1.711	.185
Group x WAI-all	1	74.545	2.032	.158
Time x WAI-all	2	135.479	2.734	.069
Group x Time x WAI-all	2	135.479	1.344	.264
PCL-5				
Group	1	72.003	1.120	.294
Time	2	126.175	.272	.762
WAI-all	1	71.683	5.182	.026
Group x Time	2	126.175	.203	.816
Group x WAI-all	1	71.683	1.191	.279
Time x WAI-all	2	125.876	4.278	.016
Group x Time x WAI-all	2	125.876	.119	.888
DASS-D				
Group	1	69.592	.200	.656
Time	2	124.094	2.283	.106
WAI-all	1	69.238	7.186	.009
Group x Time	2	124.094	.720	.489
Group x WAI-all	1	69.238	.192	.662
Time x WAI-all	2	123.706	.640	.529
Group x Time x WAI-all	2	123.706	.646	.526

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Total Time 1.

Table S21

Linear Mixed Modelling Effects – Alliance as a Moderator (Task/Goal Subscale) – Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	75.081	2.722	.103
Time	2	136.052	1.120	.329
WAI-task/goal	1	74.930	1.638	.205
Group x Time	2	136.052	.731	.483
Group x WAI-task/goal	1	74.930	2.627	.109
Time x WAI-task/goal	2	135.888	1.382	.255
Group x Time x WAI-task/goal	2	135.888	.541	.584
PCL-5				
Group	1	73.262	2.137	.148
Time	2	127.349	.019	.981
WAI-task/goal	1	72.831	2.335	.131
Group x Time	2	127.349	.263	.769
Group x WAI-task/goal	1	72.831	2.250	.138
Time x WAI-task/goal	2	126.951	3.325	.039
Group x Time x WAI-task/goal	2	126.951	.187	.830
DASS-D				
Group	1	71.075	.182	.671
Time	2	125.751	2.954	.056
WAI-task/goal	1	70.603	4.235	.043
Group x Time	2	125.751	.450	.639
Group x WAI-task/goal	1	70.603	.178	.675
Time x WAI-task/goal	2	125.230	1.283	.281
Group x Time x WAI-task/goal	2	125.230	.390	.678

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Task/Goal Subscale Time 1.

Table S22

Linear Mixed Modelling Effects – Alliance as a Moderator (Bond Subscale) – Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5				
Group	1	74.982	.926	.339
Time	2	135.916	.143	.837
WAI-bond	1	74.725	6.279	.014
Group x Time	2	135.916	2.340	.100
Group x WAI-bond	1	74.725	.837	.363
Time x WAI-bond	2	135.651	3.392	.037
Group x Time x WAI-bond	2	135.651	1.805	.168
PCL-5				
Group	1	72.124	.212	.647
Time	2	126.355	.978	.379
WAI-bond	1	71.981	6.063	.016
Group x Time	2	126.355	.130	.878
Group x WAI-bond	1	71.981	.244	.623
Time x WAI-bond	2	126.186	4.100	.019
Group x Time x WAI-bond	2	126.186	.045	.956
DASS-D				
Group	1	70.064	.069	.794
Time	2	124.526	2.058	.132
WAI-bond	1	69.848	7.314	.009
Group x Time	2	124.526	.755	.472
Group x WAI-bond	1	69.848	.061	.805
Time x WAI-bond	2	124.329	.162	.851
Group x Time x WAI-bond	2	124.329	.674	.511

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; WAI-all = Working Alliance Inventory Bond Subscale Time 1.

Table S23

Linear Mixed Modelling Effects – Any Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	54.927	1.720	.195
Time	2	96.649	189.997	.000
S4 RC	1	54.927	18.444	.000
Group x Time	2	96.649	3.410	.037
Group x s4RC	1	54.927	3.359	.072
Time x S4 RC	2	96.649	6.173	.003
Group x Time x S4 RC	2	96.649	3.941	.023
PCL-5 Session 4				
Group	1	56.172	.387	.537
Time	2	94.574	209.632	.000
S4 RC	1	56.172	28.902	.000
Group x Time	2	94.574	1.366	.260
Group x s4RC	1	56.172	1.387	.244
Time x S4 RC	2	94.574	5.383	.006
Group x Time x S4 RC	2	94.574	2.402	.096
DASS-D – Session 4				
Group	1	54.957	1.226	.273
Time	2	94.914	51.779	.000
S4 RC	1	54.957	29.105	.000
Group x Time	2	94.914	.555	.576
Group x s4RC	1	54.957	.411	.524
Time x S4 RC	2	94.914	.097	.908
Group x Time x S4 RC	2	94.914	2.705	.072
CAPS-5 Session 6				
Group	1	52.869	.528	.471
Time	2	93.392	192.524	.000
S6 RC	1	52.869	13.570	.001
Group x Time	2	93.392	.585	.559
Group x S6 RC	1	52.869	.015	.904
Time x S6 RC	2	93.392	7.084	.001
Group x Time x S6 RC	2	93.392	.629	.535
PCL-5 Session 6				
Group	1	51.705	2.417	.126
Time	2	88.520	231.239	.000
S6 RC	1	51.705	13.743	.001
Group x Time	2	88.520	.100	.904
Group x S6 RC	1	51.705	.260	.612
Time x S6 RC	2	88.520	10.432	.000
Group x Time x S6 RC	2	88.520	1.625	.203

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	52.046	.874	.354
Time	2	89.773	54.201	.000
S6 RC	1	52.046	12.491	.001
Group x Time	2	89.773	.903	.409
Group x S6 RC	1	52.046	1.735	.194
Time x S6 RC	2	89.773	.105	.901
Group x Time x S6 RC	2	89.773	2.350	.101
CAPS-5 Session 8				
Group	1	54.176	.172	.680
Time	2	93.883	152.117	.000
S8 RC	1	54.176	18.141	.000
Group x Time	2	93.883	2.630	.077
Group x S8 RC	1	54.176	.094	.760
Time x S8 RC	2	93.883	8.111	.001
Group x Time x S8 RC	2	93.883	1.830	.166
PCL-5 Session 8				
Group	1	53.449	.007	.934
Time	2	88.633	181.567	.000
S8 RC	1	53.449	25.350	.000
Group x Time	2	88.633	1.187	.310
Group x S8 RC	1	53.449	.524	.472
Time x S8 RC	2	88.633	11.306	.000
Group x Time x S8 RC	2	88.633	.830	.439
DASS-D – Session 8				
Group	1	51.064	.012	.912
Time	2	88.116	36.240	.000
S8 RC	1	51.064	23.442	.000
Group x Time	2	88.116	1.758	.178
Group x S8 RC	1	51.064	.092	.763
Time x S8 RC	2	88.116	.890	.414
Group x Time x S8 RC	2	88.116	3.283	.042

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S24

Linear Mixed Modelling Effects – Any Moderate-Major Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	36.994	.266	.609
Time	2	62.243	96.649	.000
S4 RC	1	36.994	11.003	.002
Group x Time	2	62.243	2.683	.076
Group x s4RC	1	36.994	.379	.542
Time x S4 RC	2	62.243	4.083	.022
Group x Time x S4 RC	2	62.243	2.306	.108
PCL-5 Session 4				
Group	1	37.769	.406	.528
Time	2	60.551	104.699	.000
S4 RC	1	37.769	23.744	.000
Group x Time	2	60.551	1.870	.163
Group x s4RC	1	37.769	.212	.648
Time x S4 RC	2	60.551	4.622	.014
Group x Time x S4 RC	2	60.551	2.833	.067
DASS-D – Session 4				
Group	1	37.618	.375	.544
Time	2	62.001	28.948	.000
S4 RC	1	37.618	20.904	.000
Group x Time	2	62.001	1.458	.241
Group x s4RC	1	37.618	.521	.475
Time x S4 RC	2	62.001	.083	.921
Group x Time x S4 RC	2	62.001	3.485	.037
CAPS-5 Session 6				
Group	1	35.089	.717	.403
Time	2	60.324	105.455	.000
S6 RC	1	35.089	8.387	.006
Group x Time	2	60.324	.725	.488
Group x S6 RC	1	35.089	.252	.619
Time x S6 RC	2	60.324	6.239	.003
Group x Time x S6 RC	2	60.324	.900	.412
PCL-5 Session 6				
Group	1	34.193	1.287	.264
Time	2	55.833	133.987	.000
S6 RC	1	34.193	8.365	.007
Group x Time	2	55.833	.312	.733
Group x S6 RC	1	34.193	.375	.544
Time x S6 RC	2	55.833	11.332	.000
Group x Time x S6 RC	2	55.833	1.249	.295

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	35.625	.617	.437
Time	2	58.320	31.821	.000
S6 RC	1	35.625	4.941	.033
Group x Time	2	58.320	.984	.380
Group x S6 RC	1	35.625	.796	.378
Time x S6 RC	2	58.320	1.295	.282
Group x Time x S6 RC	2	58.320	1.379	.260
CAPS-5 Session 8				
Group	1	35.804	.012	.913
Time	2	60.372	97.742	.000
S8 RC	1	35.804	14.369	.001
Group x Time	2	60.372	1.832	.169
Group x S8 RC	1	35.804	.455	.504
Time x S8 RC	2	60.372	6.728	.002
Group x Time x S8 RC	2	60.372	.848	.433
PCL-5 Session 8				
Group	1	34.238	.033	.857
Time	2	54.356	118.671	.000
S8 RC	1	34.238	17.849	.000
Group x Time	2	54.356	1.450	.243
Group x S8 RC	1	34.238	1.093	.303
Time x S8 RC	2	54.356	8.025	.001
Group x Time x S8 RC	2	54.356	.235	.792
DASS-D – Session 8				
Group	1	33.658	.103	.750
Time	2	55.576	23.329	.000
S8 RC	1	33.658	14.169	.001
Group x Time	2	55.576	.999	.375
Group x S8 RC	1	33.658	.125	.726
Time x S8 RC	2	55.576	.862	.428
Group x Time x S8 RC	2	55.576	1.444	.245

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S25

Linear Mixed Modelling Effects – Any Moderate-Major CPT Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Intent to Treat Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	23.481	1.042	.318
Time	2	41.411	80.981	.000
S4 RC	1	23.481	5.701	.025
Group x Time	2	41.411	3.646	.035
Group x s4RC	1	23.481	2.912	.101
Time x S4 RC	2	41.411	1.195	.313
Group x Time x S4 RC	2	41.411	3.022	.060
PCL-5 Session 4				
Group	1	23.672	3.310	.082
Time	2	38.970	120.400	.000
S4 RC	1	23.672	15.481	.001
Group x Time	2	38.970	3.402	.043
Group x s4RC	1	23.672	5.041	.034
Time x S4 RC	2	38.970	3.529	.039
Group x Time x S4 RC	2	38.970	2.149	.130
DASS-D – Session 4				
Group	1	20.446	1.949	.178
Time	2	36.791	25.389	.000
S4 RC	1	20.446	10.602	.004
Group x Time	2	36.791	2.007	.149
Group x s4RC	1	20.446	.065	.801
Time x S4 RC	2	36.791	.005	.995
Group x Time x S4 RC	2	36.791	4.056	.026
CAPS-5 Session 6				
Group	1	22.919	.153	.700
Time	2	40.694	72.413	.000
S6 RC	1	22.919	1.398	.249
Group x Time	2	40.694	1.917	.160
Group x S6 RC	1	22.919	.981	.332
Time x S6 RC	2	40.694	3.376	.044
Group x Time x S6 RC	2	40.694	1.128	.334
PCL-5 Session 6				
Group	1	23.081	.667	.422
Time	2	35.941	133.716	.000
S6 RC	1	23.081	1.283	.269
Group x Time	2	35.941	1.710	.195
Group x S6 RC	1	23.081	1.795	.193
Time x S6 RC	2	35.941	10.807	.000
Group x Time x S6 RC	2	35.941	1.080	.350

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	22.963	.339	.566
Time	2	37.942	20.931	.000
S6 RC	1	22.963	2.588	.121
Group x Time	2	37.942	1.427	.253
Group x S6 RC	1	22.963	.043	.837
Time x S6 RC	2	37.942	.394	.677
Group x Time x S6 RC	2	37.942	1.489	.239
CAPS-5 Session 8				
Group	1	22.363	.581	.454
Time	2	39.273	76.396	.000
S8 RC	1	22.363	6.406	.019
Group x Time	2	39.273	3.421	.043
Group x S8 RC	1	22.363	.451	.509
Time x S8 RC	2	39.273	3.898	.029
Group x Time x S8 RC	2	39.273	1.627	.210
PCL-5 Session 8				
Group	1	20.389	1.461	.241
Time	2	33.030	118.219	.000
S8 RC	1	20.389	8.718	.008
Group x Time	2	33.030	3.578	.039
Group x S8 RC	1	20.389	2.190	.154
Time x S8 RC	2	33.030	7.855	.002
Group x Time x S8 RC	2	33.030	.554	.580
DASS-D – Session 8				
Group	1	21.158	1.329	.262
Time	2	37.224	18.586	.000
S8 RC	1	21.158	6.090	.022
Group x Time	2	37.224	1.620	.211
Group x S8 RC	1	21.158	.896	.355
Time x S8 RC	2	37.224	.850	.435
Group x Time x S8 RC	2	37.224	1.067	.354

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S26

Linear Mixed Modelling Effects – Any Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	51.112	1.248	.269
Time	2	92.284	183.727	.000
S4 RC	1	51.112	14.190	.000
Group x Time	2	92.284	3.694	.029
Group x s4RC	1	51.112	2.723	.105
Time x S4 RC	2	92.284	5.664	.005
Group x Time x S4 RC	2	92.284	3.207	.045
PCL-5 Session 4				
Group	1	51.938	.757	.388
Time	2	88.790	217.456	.000
S4 RC	1	51.938	26.596	.000
Group x Time	2	88.790	1.925	.152
Group x s4RC	1	51.938	1.184	.282
Time x S4 RC	2	88.790	6.063	.003
Group x Time x S4 RC	2	88.790	1.754	.179
DASS-D – Session 4				
Group	1	50.192	1.478	.230
Time	2	87.850	46.244	.000
S4 RC	1	50.192	25.851	.000
Group x Time	2	87.850	.425	.655
Group x s4RC	1	50.192	.341	.562
Time x S4 RC	2	87.850	.029	.972
Group x Time x S4 RC	2	87.850	2.178	.119
CAPS-5 Session 6				
Group	1	50.329	.267	.607
Time	2	91.511	193.793	.000
S6 RC	1	50.329	11.720	.001
Group x Time	2	91.511	.651	.524
Group x S6 RC	1	50.329	.100	.753
Time x S6 RC	2	91.511	6.214	.003
Group x Time x S6 RC	2	91.511	.393	.676
PCL-5 Session 6				
Group	1	49.499	1.433	.237
Time	2	85.685	244.856	.000
S6 RC	1	49.499	10.906	.002
Group x Time	2	85.685	.034	.967
Group x S6 RC	1	49.499	.033	.858
Time x S6 RC	2	85.685	10.443	.000
Group x Time x S6 RC	2	85.685	.922	.402

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	49.286	.608	.439
Time	2	85.944	49.380	.000
S6 RC	1	49.286	10.726	.002
Group x Time	2	85.944	.763	.469
Group x S6 RC	1	49.286	1.311	.258
Time x S6 RC	2	85.944	.339	.714
Group x Time x S6 RC	2	85.944	2.064	.133
CAPS-5 Session 8				
Group	1	52.490	.102	.751
Time	2	92.667	151.087	.000
S8 RC	1	52.490	18.372	.000
Group x Time	2	92.667	2.711	.072
Group x S8 RC	1	52.490	.045	.832
Time x S8 RC	2	92.667	7.738	.001
Group x Time x S8 RC	2	92.667	1.825	.167
PCL-5 Session 8				
Group	1	51.586	.001	.971
Time	2	87.338	178.477	.000
S8 RC	1	51.586	24.114	.000
Group x Time	2	87.338	1.118	.332
Group x S8 RC	1	51.586	.573	.453
Time x S8 RC	2	87.338	11.293	.000
Group x Time x S8 RC	2	87.338	.806	.450
DASS-D – Session 8				
Group	1	49.554	.000	.984
Time	2	86.551	34.980	.000
S8 RC	1	49.554	22.067	.000
Group x Time	2	86.551	1.801	.171
Group x S8 RC	1	49.554	.044	.834
Time x S8 RC	2	86.551	.962	.386
Group x Time x S8 RC	2	86.551	3.326	.041

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S27

Linear Mixed Modelling Effects – Any Moderate-Major Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	34.140	.110	.742
Time	2	59.730	95.991	.000
S4 RC	1	34.140	8.306	.007
Group x Time	2	59.730	20632	.080
Group x s4RC	1	34.140	.180	.674
Time x S4 RC	2	59.730	3.669	.031
Group x Time x S4 RC	2	59.730	1.843	.167
PCL-5 Session 4				
Group	1	34.570	.494	.487
Time	2	56.514	114.643	.000
S4 RC	1	34.570	20.004	.000
Group x Time	2	56.514	2.471	.094
Group x s4RC	1	34.570	.319	.576
Time x S4 RC	2	56.514	5.486	.007
Group x Time x S4 RC	2	56.514	1.971	.149
DASS-D – Session 4				
Group	1	33.927	.397	.533
Time	2	56.937	25.971	.000
S4 RC	1	33.927	18.293	.000
Group x Time	2	56.937	1.009	.371
Group x s4RC	1	33.927	.389	.537
Time x S4 RC	2	56.937	.215	.807
Group x Time x S4 RC	2	56.937	3.003	.058
CAPS-5 Session 6				
Group	1	32.834	.409	.527
Time	2	58.513	105.663	.000
S6 RC	1	32.834	7.011	.012
Group x Time	2	58.513	.780	.463
Group x S6 RC	1	32.834	.091	.764
Time x S6 RC	2	58.513	5.584	.006
Group x Time x S6 RC	2	58.513	.498	.610
PCL-5 Session 6				
Group	1	32.082	.563	.458
Time	2	53.006	155.005	.000
S6 RC	1	32.082	6.047	.020
Group x Time	2	53.006	.553	.579
Group x S6 RC	1	32.082	.053	.819
Time x S6 RC	2	53.006	13.223	.000
Group x Time x S6 RC	2	53.006	.923	.403

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	32.980	.364	.551
Time	2	54.606	29.002	.000
S6 RC	1	32.980	3.936	.056
Group x Time	2	54.606	.524	.595
Group x S6 RC	1	32.980	.504	.483
Time x S6 RC	2	54.606	2.283	.112
Group x Time x S6 RC	2	54.606	1.188	.313
CAPS-5 Session 8				
Group	1	34.456	.002	.966
Time	2	59.206	96.500	.000
S8 RC	1	34.456	14.408	.001
Group x Time	2	59.206	1.889	.160
Group x S8 RC	1	34.456	.359	.553
Time x S8 RC	2	59.206	6.388	.003
Group x Time x S8 RC	2	59.206	.811	.449
PCL-5 Session 8				
Group	1	32.799	.012	.914
Time	2	53.426	116.123	.000
S8 RC	1	32.799	16.651	.000
Group x Time	2	53.426	1.337	.271
Group x S8 RC	1	32.799	1.199	.281
Time x S8 RC	2	53.426	8.100	.001
Group x Time x S8 RC	2	53.426	.246	.783
DASS-D – Session 8				
Group	1	32.507	.050	.825
Time	2	54.447	22.310	.000
S8 RC	1	32.507	13.133	.001
Group x Time	2	54.447	.979	.382
Group x S8 RC	1	32.507	.196	.661
Time x S8 RC	2	54.447	.919	.405
Group x Time x S8 RC	2	54.447	1.527	.226

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S28

Linear Mixed Modelling Effects – Any Moderate-Major CPT Deviation from Therapy by Reliable Change Points at Different Stages of Treatment - Completer Sample

	df1	*df2*	*F*	*p*
CAPS-5 Session 4				
Group	1	21.952	.564	.461
Time	2	39.763	78.189	.000
S4 RC	1	21.952	4.779	.040
Group x Time	2	39.763	3.372	.044
Group x s4RC	1	21.952	2.066	.165
Time x S4 RC	2	39.763	1.102	.342
Group x Time x S4 RC	2	39.763	2.580	.088
PCL-5 Session 4				
Group	1	23.226	2.872	.104
Time	2	38.468	117.301	.000
S4 RC	1	23.226	14.484	.001
Group x Time	2	38.468	3.698	.034
Group x s4RC	1	23.226	4.489	.045
Time x S4 RC	2	38.468	3.852	.030
Group x Time x S4 RC	2	38.468	2.159	.129
DASS-D – Session 4				
Group	1	19.491	1.905	.183
Time	2	35.438	24.737	.000
S4 RC	1	19.491	10.283	.005
Group x Time	2	35.438	1.976	.154
Group x s4RC	1	19.491	.067	.799
Time x S4 RC	2	35.438	.005	.995
Group x Time x S4 RC	2	35.438	4.009	.027
CAPS-5 Session 6				
Group	1	22.919	.153	.700
Time	2	40.694	72.413	.000
S6 RC	1	22.919	1.398	.249
Group x Time	2	40.694	1.917	.160
Group x S6 RC	1	22.919	.981	.332
Time x S6 RC	2	40.694	3.376	.044
Group x Time x S6 RC	2	40.694	1.128	.334
PCL-5 Session 6				
Group	1	23.081	.667	.422
Time	2	35.941	133.716	.000
S6 RC	1	23.081	1.283	.269
Group x Time	2	35.941	1.710	.195
Group x S6 RC	1	23.081	1.795	.193
Time x S6 RC	2	35.941	10.807	.000
Group x Time x S6 RC	2	35.941	1.080	.350

	df1	*df2*	*F*	*p*
DASS-D – Session 6				
Group	1	22.963	.339	.566
Time	2	37.942	20.931	.000
S6 RC	1	22.963	2.588	.121
Group x Time	2	37.942	1.427	.253
Group x S6 RC	1	22.963	.043	.837
Time x S6 RC	2	37.942	.394	.677
Group x Time x S6 RC	2	37.942	1.489	.239
CAPS-5 Session 8				
Group	1	22.363	.581	.454
Time	2	39.273	76.396	.000
S8 RC	1	22.363	6.406	.019
Group x Time	2	39.273	3.421	.043
Group x S8 RC	1	22.363	.451	.509
Time x S8 RC	2	39.273	3.898	.029
Group x Time x S8 RC	2	39.273	1.627	.210
PCL-5 Session 8				
Group	1	20.389	1.461	.241
Time	2	33.030	118.219	.000
S8 RC	1	20.389	8.718	.008
Group x Time	2	33.030	3.578	.039
Group x S8 RC	1	20.389	2.190	.154
Time x S8 RC	2	33.030	7.855	.002
Group x Time x S8 RC	2	33.030	.554	.580
DASS-D – Session 8				
Group	1	21.158	1.329	.262
Time	2	37.224	18.586	.000
S8 RC	1	21.158	6.090	.022
Group x Time	2	37.224	1.620	.211
Group x S8 RC	1	21.158	.896	.355
Time x S8 RC	2	37.224	.850	.435
Group x Time x S8 RC	2	37.224	1.067	.354

Note. CAPS-5 = Clinician-Administered PTSD Scale; PCL-5 = Posttraumatic Stress Disorder Check List for DSM-5; DASS–D = Depression Anxiety and Stress Scale – Depression Subscale; s4RC = Reliable change from Pretreatment to session 4 on the PCL-5; s6RC = Reliable change from Pretreatment to session 6 on the PCL-5; s8RC = Reliable change from Pretreatment to session 8 on the PCL-5.

Table S29

Qualitative Analysis Coding and Example Comments for Case formulation Diagram – Most Useful and Least Useful Elements

Node	Subnode	Explanation	Example Comment
Most	Linkages	Linkages between symptoms and PTSD	*"A visual representation of the links between the areas and the way in which they are interrelated"*
	CBT TFA	How thoughts, feelings and actions link	*"Connecting thoughts and feelings, clearer idea of how I am thinking and feeling"*
	Framework	Provided framework to understand issues	*"The simple structure allowed me to see all my issues in a more approachable light"*
	Externalise	Having problem on paper; out of mind	*"Getting a lot of thoughts that race around my head down on paper"*
	Help	Therapist helping; collaborative process	*"The way that things were explained several times when I didn't understand"*
	Understand	Helped understand symptoms	*"Helped to understand my reasons for behaviour and anxiety, panic, hypervigilance and startle reactions"*
	Avoidance	Facing issues; break through avoidance	*"It made me think about things I had purposefully buried"*
	Strengths	Highlighting of strengths and resources	*"Helped me to focus on my strengths! Made me feel good about myself"*
	Normalising	Process helped to feel normal	*"Maybe only that it allowed me to realise all of these things are normal for someone with PTSD"*
Least	Nothing	Nothing was 'least useful'	*"I didn't find anything un-useful"*
	Confusing	Process was confusing	*"Too much overuse of 'psychobabble' and labelling. Not useful to clients"*
	Too early	Too early in therapy to comment	*"Nothing yet as we have only just started the process"*
	Format	Could include other aspects; e.g. culture	*"Cultural factors should be taken into consideration more"*
	Remember	Could not remember the process	*"I don't recall much about doing it, if anything it wasn't entirely clear to me what it was about"*
	Time	Not enough time to complete the process	*"Time (ran out of)"*
	Confronting	Process emotionally confronting	*"Looking back it was a bit confronting. To draw out from me all the issues that going through this process did"*

Note. Subcode of 'nothing' included comments where participants wrote in the field, even if the response was N/A or Nil. Responses that were left blank were not coded.

Table S30

Qualitative Analysis Coding and Example Comments for Therapeutic Letter - Most Useful and Least Useful Elements

Node	Subnode	Explanation	Example Comment
Most	Validating	Felt validated by the letter/therapist	*"It validated me and the understanding of my description of my situation"*
	Summary	Letter was a good summary of issues	*"Summarising the experience brings it into a relatable sphere"*
	Understood	Felt understood by the therapist	*"(Therapist) understood me and my situation well which would have helped me open up as well as I did"*
	Listened	Felt listened to by the therapist	*"Actually made me happy in a sense that someone (my counsellor) was listening to me and gave me hope"*
	Change	Helped see change; encourage change	*"It made me critically think about my situation and how I was going forward"*
	Ideas	Helped structure ideas	*"Helped to have someone write out my experiences logically, can get jumbled in my head"*
	Strengths	Highlighted strengths and goals	*"Set out my strengths. Made me believe it was possible to reduce the effect that PTSD has had and is having"*
	Cared	Felt cared for by the therapist	*"Reflected exactly the things we have spoken about - made me feel cared for. It seemed really kind."*
	Encouraging	Felt encouraged; therapist encouraging	*"It was a boost to my self esteem. It also made me feel like my therapist cared for me and my issue"*
	Logical	Set out a logical way to look at PTSD	*"The letter set down in a clear and logical manner the issues which I have been dealing with"*
Least	Nothing	Nothing was 'least useful'	*"I think the letter was perfectly useful"*
	Confronting	Reading the letter confronting, difficult	*"A smack in the face about what was happening"*
	Confusing	Found the letter or purpose confusing	*"I'm not really sure of the purpose of it or why it was written/presented at the time it was"*
	Structure	Tone of letter or way it was written	*"A bit formal language"*

Note. Subcode of 'nothing' included comments where participants wrote in the field, even if the response was N/A or Nil. Responses that were left blank were not coded.

APPENDICES

Appendix A – Complicated Client Presentation Checklist

COMPLICATED CLIENT PRESENTATION CHECKLIST

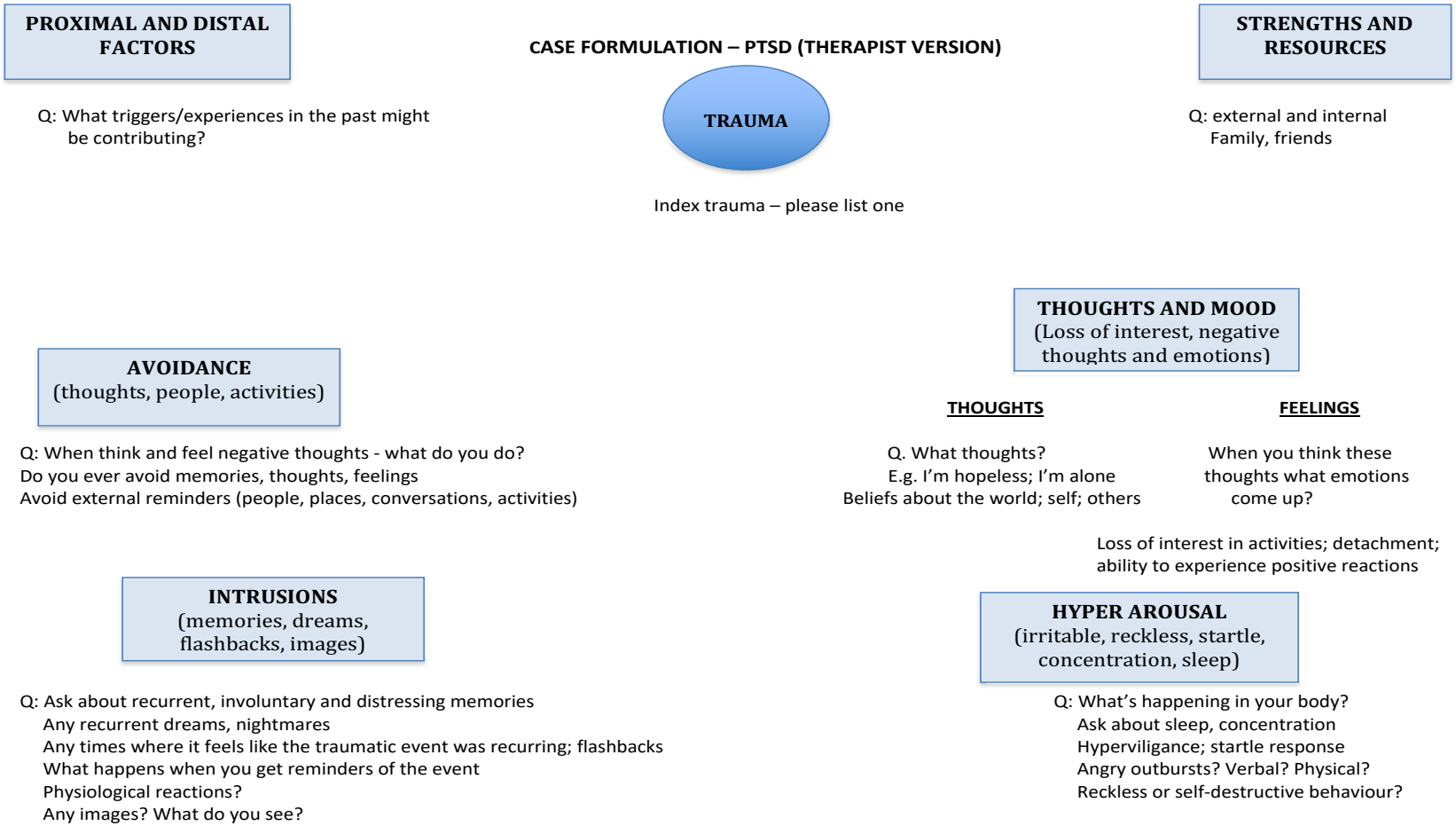
Has the client been assessed as having or self-reports any of the following at pre-treatment phase as current:

Scoring:

- *Score each YES as 1.*
- *Score each NO as 0.*

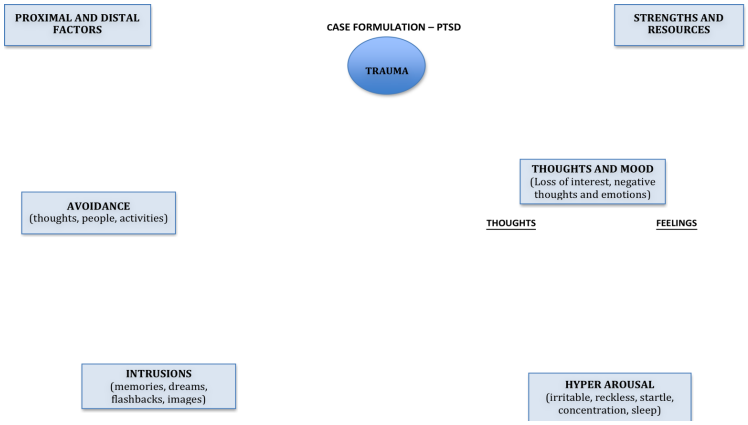
FACTOR	YES	NO
Demographic Factors		
1. Male		
2. Low social support (Trauma History 0, 1 or 5)		
Trauma Factors		
3. CAPS-5 score above 60 and/or PCL-5 score above 55		
4. Dissociative subtype		
5. CSA		
6. Prolonged and repeated trauma and/or Interpersonal		
7. More than four lifetime traumas		
Cormorbidities		
8. Alcohol abuse and/or dependence assessed as severe on MINI and/or severe or extremely on AUDIT (16+)		
9. Cannabis abuse and/or dependence assessed as severe or extremely on CUDIT (8+)		
10. Other drug misuse/abuse (including prescription) as assessed on MINI		
11. MDD current (MINI) and/or DASS-D severe and above (21+)		
12. Suicidality current (MINI)		
13. Generalised anxiety (MINI)		
14. Panic disorder (MINI)		
15. Agoraphobia (MINI)		
16. Mania		
17. Obsessive-compulsive		
18. Eating disorder (MINI)		
Personality Disorder (SCID-PDSQ)		
19. Borderline (5+)		
20. Narcissistic (5+)		
21. Avoidant (4+)		
22. Schizotypal (5+)		
23. Schizoid (4+)		
24. Paranoid (4+)		
25. Histrionic (5+)		
26. Obsessive-compulsive (4+)		
27. Dependent (5+)		
Other Issues		
28. Sleep issues (severe on ISI 22+)		
29. Emotional regulation (Higher range difficulties assessed on DERS 108+)		
30. Trauma cognitions (PTCI) – Trauma with PTSD (133+)		
TOTAL		

Appendix B – Case Formulation Diagram – Therapist Version



Appendix C – Client Case Formulation Evaluation

Client Case Formulation Evaluation



At the start of your therapy you completed a case formulation with your therapist based on the template as shown above. Below is a list of statements about the case formulation you completed. Please indicate your level of agreement for each of the following items using the following rating scale:

Totally Disagree	*Disagree*	*Don't know*	*Agree*	*Totally Agree*
1	2	3	4	5

(a) I believe that the case formulation process was understandable.

1 2 3 4 5

(b) I believe that the case formulation process was logical.

1 2 3 4 5

(c) I believe that the case formulation process was acceptable.

1 2 3 4 5

(d) I believe that the case formulation process was helpful.

1 2 3 4 5

(e) I believe that the case formulation process was a good summary of my current difficulties.

1 2 3 4 5

Please indicate what you found most useful about the Case Formulation process?

Please indicate what you found least useful in the Case Formulation process?

Appendix D – Therapeutic Letter Evaluation

Therapeutic Letter Evaluation

At the start of your therapy your therapist gave you a therapeutic letter focusing on your strengths, goals, and way forward for therapy. Below is a list of statements about the therapeutic letter you received.

Please indicate your level of agreement for each of the following items using the following rating scale:

Totally Disagree	*Disagree*	*Don't know*	*Agree*	*Totally Agree*
1	*2*	*3*	*4*	*5*

(a) I believe that the therapeutic letter was understandable.

1 2 3 4 5

(b) I believe that the therapeutic letter was logical.

1 2 3 4 5

(c) I believe that the therapeutic letter was acceptable.

1 2 3 4 5

(d) I believe that the therapeutic letter was helpful.

1 2 3 4 5

(e) I believe the therapeutic letter was a good summary of my current difficulties.

1 2 3 4 5

Please indicate what you found most useful about the therapeutic letter?

Please indicate what you found least useful about the therapeutic letter?

Appendix E – Deviations from Protocol Form

Posttraumatic Stress Disorder Treatment Study

Deviations from protocol form

Subject ID#:_____ **Therapist:**_____

Instructions: For each session, please indicate whether there was any deviation from the standard session protocol. Please include the time taken for the deviation in minutes, and indicate **specifically** what was done (see sections at end of form).

Treatment Session # **(N.B. actual treatment session, not CPT session)**
Date:_____

Please tick what from the standard protocol was covered in the session?

- Psychoeducation about PTSD ☐
  - PTSD symptom clusters ☐
  - Trauma recovery and FFF response ☐
  - Cognitive theory ☐
  - Types of emotions ☐
- Impact Statement 1 ☐
- Connections between thoughts, feelings, emotions ☐
- Identification of stuck points ☐
- ABC Worksheets ☐
- Trauma Account 1 ☐
- Trauma Account 2 (i.e., continued work on same Trauma) ☐
- Trauma Account (i.e., processing new trauma) ☐
- Responsibility v Blame ☐
- Challenging Questions Worksheets ☐
- Problematic Thinking Worksheets ☐
- Challenging Beliefs Worksheet ☐
- Safety Issues Module ☐
- Trust Issues Module ☐
- Power/Control Issues Module ☐
- Esteem Issues Module ☐
- Intimacy Issues Module ☐
- Impact statement 2 ☐

Time taken in minutes for standard session information: **minutes**

Was there any deviation from the standard protocol? *YES* ☐ *NO* ☐

If yes, please provide <u>detail</u> about the deviation:
(e.g. discussion regarding pros and cons of attending therapy, as client presented with increasing ambivalence about therapy. Thus substantial time spent using motivational interviewing techniques'.
Time spent: 30 min)

Time taken in minutes for deviation: **minutes**

Appendix F – Therapeutic Letter Example

DATE

Dear NAME,

Thank you for attending your assessment appointment on the _____and your subsequent therapy sessions on the_____. I greatly appreciate your courage and honesty in talking with me about some of the events that have had such an impact on your life.

Struggling with the trauma of witnessing your father physically assault your mother for almost 40 years had led you to believe that there was something inherently wrong with you for not being able to 'move on' in all this time. In approaching your 50th birthday, you decided that you wanted to finally start getting the enjoyment out of your life that others around you seemed to have. You told me that you saw my treatment study as an opportunity to work on some of the issues that seemed to be holding you back from living the life that you would like to be living.

After your initial assessment appointment, we found that you were suffering from Posttraumatic Stress Disorder (PTSD). The PTSD has had an impact on almost every aspect of your life. It has impacted your ability to form and maintain relationships with family members, friends and partners. It has had an impact on your career and your ability to stay in one job. You also told me how recently how your PTSD symptoms have prevented you from doing leisure activities that brought you enjoyment in the past.

The PTSD has remained with you in the form of distressing thoughts and beliefs ('I will ultimately end up alone'), emotions (sadness and anger), physical reactions (hands and thighs shaking), imagery (being alone in a cold dark house disconnected from the world) and avoidance behaviours (avoiding your partner and watching TV). We talked about how these avoidance behaviours can work in the short term to give you a sense of control and relief, but create a vicious cycle that ultimately maintains the PTSD in the long term. Negative past experiences, such as being threatened by your brother, have further helped to maintain this vicious cycle.

Despite the PTSD, we have discussed how you show strength everyday by going to work and maintaining a certain level of functioning. You also told me how you provide support to your friends in their times of need and how you love your loyal dogs with all of your heart. Your close friends, partner and especially your dogs are there to provide support for you as well.

In our last session we discussed the goals that you would like to achieve during therapy. Being able to make decisions in an efficient way and take action in your life rather than waiting and watching opportunities pass you by seemed quite important to you. Spending time doing more activities that give you enjoyment and less time avoiding were some other important goals. I was pleased to hear that you had already begun working on these goals by starting to read for enjoyment, which left you with less time for TV (an avoidance strategy for you at this time). You also began to decrease your avoidance by facing your emotions (allowing yourself to cry) and by speaking up in a stressful staff meeting.

I commend your courage in starting to face the fears that have been haunting you for quite some time, despite feeling so anxious about doing so. I look forward to working with you to build on your strengths and skills to help you on the path to reach your goals.

Yours sincerely,

Appendix G – Therapist Adherence and Competence Protocol

Cognitive Processing Therapy (CPT):
Therapist Adherence and Competence Protocol

Adapted for CPT + CF RCT by R.D.V. Nixon & M. Elizabeth 2019

from:

Trial of CPT in VVCS by Del Lloyd, ACPMH, 2009

which was adapted from

Cognitive Processing Therapy for Military-Related Posttraumatic Stress Disorder
White River Junction VA Medical and Regional Office Center
Dartmouth Medical School

Candice M. Monson, Ph.D.,
Clinical Research Career Development Awardee
Jennifer L. Price, Ph.D., Study Coordinator

Originally Adapted from:
Pallavi Nishith, Ph.D and Patricia A. Resick, Ph.D
University of Missouri at St. Louis
Department of Psychology
Center for Trauma Recovery

Cognitive Processing Therapy:
Therapist Adherence and Competence Protocol

Therapist:_____

Participant#:_____ Rater: _____ Rating Date: _____

Instructions (Part I - Part IV):

Adherence: For each item, assess **if the therapist demonstrated the particular behavior** described in the item. If so, put a check (X) on the first line next to the item. For e.g., in session 1, item 1, if the therapist educated the client about PTSD, the rated item would look like:

X
____ ____ 1. Therapist educated the client about PTSD.

Competence: For each item, assess **how well the therapist carried out the particular behavior** described in the item. Use the rating scale described below to assign a number on the second line next to the item. For e.g., in session 1, item 1, if you think the therapist did a barely adequate job in educating the client about PTSD, then you would assign the number 2 on the second line next to the item. The rated item would now look like:

X 2
____ ____ 1. Therapist educated the client about PTSD.

Rating Scale for Assessing Competence:

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satis-factory	Good	Very Good	Excellent

Please don't leave any items blank. For all items assess therapist competency, taking into account client's presenting problems, their difficulty level, and the stage of therapy.

Use N/A for Not Applicable ratings of Adherence/Competence.

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Part I. Unique and Essential Elements specific to each session:

Session 1: Introduction and Education Phase:

____ ____1. Therapist educated the client about PTSD.
____ ____2. Therapist presented the treatment rationale using the Information Processing Theory and gave the handout on stuck points.
____ ____3. Therapist presented the client with an overview of the 12-session treatment.
____ ____4. Therapist asked client to write an Impact statement for homework.
____ ____5. Therapist completed Case Formulation Sheet with client [FOR CASE FORMULATION GROUP note additional detailed scoring questions of CF on last page].

Session 2: Finding stuck points:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist had client read his/her impact statement.
____ ____3. If the client did not do the homework, the therapist had client describe meaning of events orally.
____ ____4. Therapist assisted the client in identifying Stuck Points in the statement.
____ ____5. Therapist helped client differentiate between thoughts and feelings and introduced the ABC sheet and Identifying Emotions worksheet to help client with this.
____ ____6. Therapist asked client to fill out at least one ABC sheet a day with examples, past or current, related to the trauma, for homework.

Session 3: Working with Events, Thoughts and Feelings:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. If client had not done Impact Statement in previous session, therapist had client read his/her impact statement.
____ ____3. Therapist reviewed ABC sheets with client, and helped him/her further differentiate between thoughts and feelings.
____ ____4. Therapist reviewed trauma related ABC worksheet with client and explored the stuck point of self-blame, using Socratic questioning.
____ ____5. Therapist asked client to continue daily monitoring of the ABC worksheets but this time all related to the trauma for homework.

Session 4: Processing the Index Event:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist addressed client's assimilated stuck points, using Socratic dialogue to help the client address self-blame.
____ ____3. Therapist helped client differentiate between blame/intent, responsibility and the unforeseeable (Handout).

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

____ ____4. Therapist introduced Challenging Questions Sheet to help client challenge stuck points (Handout).
____ ____5. Therapist asked the client to challenge at least one stuck point a day, using the Challenging Questions Sheet, for homework.

Session 5: Using the Challenging Questions Worksheet:
____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist reviewed the Challenging Questions Sheet to address stuck point of self -blame.
____ ____3. Therapist introduced the Problematic Patterns of Thinking Worksheet.
____ ____4. Therapist helped client generate possible examples of problematic thinking patterns, trauma and non-trauma related, using the worksheet.
____ ____5. Therapist asked the client to identify stuck points and find examples for each problematic thinking pattern, for homework.

Session 6: Problematic Patterns of Thinking Worksheet:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist and client reviewed midway PCL-5 and treatment progress.
____ ____3. Therapist and client reviewed the problematic thinking patterns sheet to address trauma-related stuck points.
____ ____4. Therapist introduced the Challenging Beliefs Worksheet.
____ ____5. Therapist asked the client to identify stuck points and confront them using the challenging beliefs worksheet for homework.

Session 7: Challenging Beliefs Worksheets and Introduction to Modules:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist provided an overview of the five specific themes/modules that will be discussed in the remaining sessions.
____ ____3. Therapist introduced the first of five problem areas: Safety issues related to Self and Others (Handout).
____ ____4. Therapist asked the client to identify stuck points, one of which had to relate to Safety and confront them using the challenging beliefs worksheet for homework.

Session 8: Processing Safety and Introducing Trust:
____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist reviewed the Challenging Beliefs Worksheet with regard to Safety and to other stuck points.
____ ____3. Therapist introduced the second of five problem areas: Trust issues related to Self and Other (Handout).
____ ____4. Therapist asked the client to identify stuck points, of which one had to relate to trust, and confront them using the challenging beliefs worksheet for homework.

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Session 9: Processing Trust and Introducing Power/Control:

____ ____1. Therapist checked/ reviewed homework
____ ____2. Therapist reviewed the Challenging Beliefs Worksheet with the client to challenge trauma-related trust stuck points and generate alternative beliefs.
____ ____3. Therapist discussed judgment issues that may arise from stuck point related to trust, and discussed client's social support systems using the Trust Star (Handout).
____ ____4. Therapist introduced the third of the five problem areas: Power/Control issues related to Self and Others (Handout).
____ ____5. Therapist asked the client to complete a Trust Star example for homework.
____ ____6. Therapist asked client to identify stuck points, of which one had to relate to power/control issues, and confront them using the challenging beliefs worksheet for homework.

Session 10: Power/Control Issues:

____ ____1. Therapist checked/ reviewed homework
____ ____2. Therapist reviewed the clients Trust Star.
____ ____3. Therapist discussed the connection between power/control and self-blame, and helped client challenge faulty cognitions related to this area using the power/control Handout.
____ ____4. Therapist introduced the fourth of the five problem areas: Esteem issues related to self and others (Handout).
____ ____5a. Therapist asked the client to identify stuck points, of which one had to relate to esteem issues, and confront them using the challenging beliefs worksheet, for homework.
____ ____5b. Therapist asked the client to practice giving and receiving compliments for homework.
____ ____5c. Therapist asked the client to do at least one nice thing for themselves each day for homework.

Session 11: Review of Esteem and Intimacy Issues:

____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist helped client identify esteem issues and assumptions and challenge them using Challenging Beliefs Worksheet.
____ ____3. Therapist discussed clients' reactions to giving and receiving compliments and engaging in a pleasant activity.
____ ____4. Therapist introduced the fifth of the five problem areas: Intimacy issues related to self and others (Handout).
____ ____5a. Therapist asked the client to identify stuck points, one of which had to relate to intimacy issues, and confront them using the challenging beliefs worksheet for homework.
____ ____5b. Therapist asked the client to rewrite the impact statement for homework.

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

____ ____5c. Therapist asked the client to continue to give and receive compliments for homework.
____ ____5d. Therapist asked the client to continue to do at least one nice thing for him-/herself each day for homework.

Session 12: Processing Intimacy and the Final Impact Statement:
____ ____1. Therapist checked/ reviewed homework.
____ ____2. Therapist helped client identify any remaining stuck points and confront them using the Challenging Beliefs Worksheet.
____ ____3. Therapist had client read the rewritten impact statement.
____ ____4. Therapist involved the client in reviewing therapy and progress.
____ ____5. Therapist discussed initial goals for therapy, helped client identify goals for the future, and helped him/her delineate strategies for meeting them.

Part II: Essential but not Unique Elements:

Therapist established good rapport by demonstrating:
____ ____1a. Genuineness
____ ____1b. Warmth
____ ____1c. Accurate Empathy
____ ____2. Therapist engaged with the client in a professional manner.
____ ____3. Therapist set an agenda at the beginning of the session, in an atmosphere of collaboration and mutual understanding.
____ ____4. Therapist reviewed the homework with the client, using the CPT homework review form.
____ ____5. Therapist structured therapy time efficiently, and was able to keep the focus of the session on issues decided upon in setting the agenda.
____ ____6. Therapist elicited feedback about the client's reactions to the therapy and/or the therapist as part of the closing portion of the session.
____ ____7. Therapist assigned homework in a clear and specific manner.
____ ____8. Therapist asked the client about anticipated problems with completing homework, and problem solved to resolve them.

1. Please give a rating of the therapist's <u>overall skills</u> as demonstrated on this tape segment.

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satis-factory	Good	Very Good	Excellent

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Part III: Modifications:

1. Check all that apply:

- ❑ The therapist tailored the terminology or CPT worksheets to make them easier for the client to understand or use.
- ❑ The therapist skipped or removed elements of this session
- ❑ The therapist re-ordered elements of the protocol (e.g., employed a strategy that typically occurs in a later session or introduces a concept, form, or intervention that should have been introduced in an earlier session)
- ❑ The therapist shortened the session (less than 45 minutes)
- ❑ The therapist lengthened the session (more than 60 minutes)
- ❑ The therapist did CPT, but loosened the structure of the session
- ❑ The therapist repeated an activity or concept covered in a previous session that was not intended to be repeated or reviewed in this session
- ❑ The therapist introduced non-CPT techniques or methods (e.g., psycho-education re sleep, set up a behavioural experiment, discussed alcohol use or monitoring):
  a) Please detail the nature of the modification or deviation:

_____

_____

_____

_____

How much time did this modification take up (in minutes)? _____

Given the content of the modification and time spent on it, how large a modification was this? (tick one)

- ○ Minor (e.g., superficial psycho-education re sleep or alcohol use, and/or only took a 5-10min)
- ○ Moderate (e.g., spent time developing behavioural activation strategies, some time spent another technique such as motivational interviewing, and/or took some time 11-30min)
- ○ Major (e.g., in-depth development or discussion of behavioural experiment or other non-CPT technique, e.g., for panic strategies and/or took majority of session (31min or more)

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Justification and adequacy of departure from CPT Protocol

2. Please write down any additional comments that you may have regarding the ratings on this tape including any departures from the protocol and the adequacy with which the therapist dealt with the problems that led to the departure.

_____

_____

_____

_____

_____

_____

_____

1	2	3	4	5	6	7
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Case Formulation Scoring Criteria

Take into account both CF conducted in Session 1 with client as well as written therapeutic letter (circle option from 1 – 5 for each question).

1. Problem List

	All relevant problems noted; clearly distinguishing between primary and secondary issues
	Most relevant problems noted; but no evidence of distinguishing between primary and secondary issues
	Some relevant problems noted; but also some irrelevant problems noted AND at least one primary problem missing
	NA

2. Predisposing Factors

	Predisposing variables noted; and clearly linked to specific problem in problem list
	Predisposing variables noted; but these are not clearly linked to specific problem in problem list
	No evidence of considering predisposing variables
	NA

3. Precipitating Factors

	Precipitating event(s) noted; and clearly linked to specific problem in problem list
	Precipitating event(s) noted; but not clearly linked to specific problem in problem list
	No evidence of considering precipitating events
	NA

4. Perpetuating Factors

	Perpetuating factors noted (e.g., core beliefs); and clearly linked to specific problem in problem list
	Perpetuating factors noted; but not clearly linked to specific problem in problem list
	No evidence of considering perpetuating factors
	NA

5. Provisional Conceptualisation

	Well integrated hypothesis that links relevant problems with predisposing, precipitating and perpetuating factors; provides a good explanation of the patient's presenting problem(s)
	A hypothesis that presents a plausible but incomplete explanation of the patient's presenting problem(s)
	A poorly integrated explanation of the patient's presenting problem(s)
	NA

6. Problems potentially hindering treatment and strengths and assets

	Potential problems, strengths and assets noted; clearly linked to presenting problems OR specific aspects of treatment plan
	Potential problems, strengths and assets noted; but not clearly linked to presenting problems OR treatment plan
	No evidence of considering potential problems and strengths and assets
	NA