

Cognitive processing therapy for the treatment of acute stress disorder
following sexual assault: A randomized effectiveness study.

Supplementary Material

(Table S1 at end of document)

Method

Participants

A total of 158 clients were considered for the study. As indicated in Figure 1 (available in main text), the most common reason for exclusion was intellectual/cognitive disability ($n = 24$) followed by suicide risk ($n = 21$). A comparable number of otherwise eligible participants could not make themselves available to be assessed within 4-weeks of their trauma ($n = 22$). One participant was withdrawn from CPT when she was diagnosed with a life-threatening illness requiring immediate treatment. The high level of Caucasian ethnicity reported is representative of the region's demographics.

Procedures

Assessors. Clinical interviews were conducted by licensed PhD-level clinical psychologists or advanced doctoral or masters level trainee psychologists trained by the first author.

Measures. To maximise clients' willingness to honestly report on the Credibility and Expectancy Questionnaire and Working Alliance Inventory, clients enclosed the CEQ and WAI in a sealed envelope. They were informed this would be opened and entered by the project director, not their therapist.

Therapists and Training. Nine female therapists who were regular staff members of Yarrow Place conducted therapy on site and represented approximately 80% of the counselling staff who were available at the initiation of the trial. Therapists were randomized to either CPT or TAU. The two groups were comparable in terms of years of clinical experience (CPT: $M = 11.13$, $SD = 6.91$; TAU: $M = 12.50$, $SD = 4.04$) and years working with sexual assault victims (CPT: $M = 10.63$, $SD = 7.04$; TAU: $M = 12.38$, $SD = 5.15$). All staff had a Bachelor of Social Work qualification, and two staff (one in each treatment condition)

had Masters qualifications. Staff reported working from a feminist model of sexual assault prior to the trial and regarded their orientation as eclectic (using a mixture of therapeutic approaches) although none identified as being specifically cognitive-behavioural. Therapists had not previously delivered CPT and had no allegiance to this mode of therapy prior to training. Due to staff changes, employment status (e.g., part-time), planned absences and current caseloads, uneven numbers of clients were seen by therapists. In the CPT group, the number of clients seen by the four therapists was 1, 3, 9 and 11, respectively. For TAU, the five therapists saw 1, 2, 3, 7 and 9 clients respectively.

Therapists allocated to CPT received a 3-day workshop from R.D.V.N., followed by weekly group consultation of 1-hr initially, then approximately 30 min in the latter stages of the trial. TAU therapists received a briefing regarding the trial but no study-specific training or consultation. TAU (and CPT) therapists did continue to receive their usual supervision in the service. This supervision included monthly supervision with a focus on clinical and administrative issues, monthly clinical review meetings, and informal supervision as required.

Treatment Conditions. CPT is normally delivered over 12 sessions (see Resick et al., 2007) however a modified and abbreviated 6-session format that has previously been trialled (Nixon, 2012) was used. This 6-session manualized format adopted the framework and materials of the CPT manual (Resick et al., 2007) and sessions (90 min duration) were scheduled weekly (the 90min sessions ensured adequate coverage of CPT content). CPT targets specific cognitive themes during the course of therapy, these being unhelpful beliefs regarding safety, trust, power-control, esteem and intimacy. Self-blame is also an important focus of early sessions, and homework is set after each session. Session 1 comprised psycho-education, and describing the rationale and components of treatment. In addition the relationship between thoughts and feelings, Socratic questioning, and challenging unhelpful beliefs were introduced. Session 2 continued cognitive therapy, with the introduction of more

advanced worksheets and with clients being introduced to alternative ways of thinking. The task of writing an account of the traumatic event for homework was also introduced. Session 3 included a review of homework and the reading of the trauma account. Specific exploration of two themes, safety and trust, was undertaken in session. Sessions 4-6 and associated homework continued work on challenging unhelpful beliefs in the domains of power/control, esteem and intimacy. Processing of the traumatic event through a written account continued. Session 6 as the final session, focussed on goals for the future, revision of the treatment rationale and components, and relapse prevention. In order to reflect real-life clinical practice, nonprotocol sessions were allowed; for example, if a client attended with a significant crisis that required clinical attention and that prevented CPT from being conducted in session (e.g., a client coming in distressed after receiving news her employment was to be unexpectedly terminated). Two clients had 1 nonprotocol session each, and one client had 2 nonprotocol sessions.

TAU. TAU session duration was comparable to that of CPT (typically 80min).

Treatment fidelity. Therapy was audiotaped in both conditions. Of the 153 therapy sessions conducted across the two treatment conditions, 22 CPT and 22 TAU sessions (29%) were randomly selected and rated by two independent clinicians with previous CPT fidelity rating experience in clinical trials. Using a CPT fidelity rating form adapted from that used by Resick et al. (2008), they indicated adherence to the 6-12 essential elements of CPT in each CPT session. Adherence to the protocol for these sessions was 90%. This adherence compares favourably with prior CPT research using a similar form that has ranged from 90-93% (Forbes et al., 2012; Galovski, Blain, Mott, Elwood, & Houle, 2012; Monson et al., 2006; Resick et al., 2008). Therapist CPT competence was rated (from *poor* = 1 to *excellent* = 7), with therapists rated as 'satisfactory' or better on 91% of elements, with their global therapist skill (using the same scale) rated as *good* (a score of '5'). CPT and TAU therapists were rated on

important therapeutic factors (i.e. genuineness, warmth, accurate empathy, professional manner) using the same scale. Mean ratings fell in the *very good* to *excellent* range, and effect sizes tended to favor CPT (*ds* ranging from 0 to 0.64; *ps* ranging from .23 to 1.00). CPT and TAU appeared similar in terms of global therapist skill ratings (CPT: $M = 5.14$, $SD = 1.35$; TAU: $M = 5.11$, $SD = 1.27$, $d = 0.02$, $p = .96$). The raters judged how close TAU was to an empirically supported therapy such as CBT (where 1 = *not at all similar* to 7 = *CBT*). The mean rating was 2.22 ($SD = 1.30$). A small number of sessions (5 CPT and 4 TAU) were coded for inter-rater reliability checking. For CPT, 92% interrater agreement was demonstrated for adherence ratings. Similarly, agreement that therapy was performed satisfactorily or better was high, 91%. For TAU, interrater agreement that structured techniques comparable to CPT were not routinely conducted was high (89%) with 1 session resulting in this lower agreement; with this session removed, agreement was 95%. There was perfect interrater agreement that therapy was performed satisfactorily or better, 100%.

Statistical Approach

Simulations indicate that even with small samples and substantial missing data (e.g., sample $N = 50$, 80% missing data), multiple imputation such as MICE demonstrates good performance for addressing missing data (Schafer & Graham, 2002). The imputation model included all baseline symptom measures, treatment group, and outcomes (42 variables in total¹). Relations between and within time were preserved and imputation values were constrained to the range of observed values in nonmissing data. Given the large amount of missing data, 10 instead of 5 complete data sets were computed using 20 iterations (Rubin, 1987), providing efficiency of replacement of approximately 95% (Schafer & Graham, 2002).

¹ Although van Buuren and Groothuis-Oudshoorn (2011) suggest that between 15-25 predictor variables are usually sufficient for models, we used all variables of interest to ensure adequate coverage. However repeating the imputation using only 22 predictors (including the CAPS, PCL, PTCI) resulted in the replication of all findings.

MICE uses Rubin's rules for pooling of statistical parameters (Raghunathan & Dong, 2013; Rubin, 1987). SPSS 20.0 was used for remaining analyses.

Given that we were unable to reach the planned sample size we adopted an analysis and interpretative approach that focussed on effect sizes and the confidence intervals around these effects. Although this approach was driven by the fact our resultant sample size meant the study was underpowered for our original planned null hypothesis significance testing [NHST] methods, it is becoming increasingly recognized that traditional NHST has substantial limitations. NHST, with its resultant focus on p values, is unreliable and uninformative with respect determining the magnitude (if any) of differences in the two treatments under study (see Cumming, 2008; 2014; Faulkner, Fidler, & Cumming, 2008, for detailed discussion of the superiority of effect sizes and confidence intervals versus NHST). Accordingly, we report effect sizes (Cohen's d , ϕ , Cramer's V) and confidence intervals throughout, with Cohen's conventions, albeit relative, indicating 0.2, 0.5 and 0.8 reflect small, medium and large effects respectively for d , and 0.1, 0.3 and 0.5 for ϕ .

Numbers needed to treat (NNT). NNT were calculated from good-end state functioning percentages. The absolute difference of this percentage is inverted to give a figure that indicates the number of clients that would be needed to be treated before a particular event would occur. Low NNT values are good, indicating a particular treatment (e.g., CPT) does not require many clients to be treated for an additional success to be seen (on average) compared with another therapy (e.g., TAU).

Results

Preliminary analyses

Baseline and follow-up participation. There were generally clinically negligible differences (i.e., effect sizes ranged from negligible to small) between groups for baseline

demographic and comorbidity variables (see Table 1 [located in main article]) or for pretreatment symptom severity measures (Table 2 [located in main article]). Those who did not participate in either a posttreatment or follow-up assessment did not differ to a large degree from those who did on demographic, previous assessment symptom severity scores, diagnostic or trauma history variables, with one exception. Those who did not return for any follow-ups had higher baseline self-reported PTSD (PCL), albeit with a wide confidence interval ($d = 0.70$, $CI_{95} [-0.05, 1.45]$, $p = .09$).

Number of sessions. The two groups attended the same number of therapy sessions in the pre-to-posttreatment phase. On average, taking into account nonprotocol sessions, CPT clients attended 3.50 sessions ($SD = 2.38$), as did TAU clients ($M = 3.50$, $SD = 2.39$), $d = < 0.01$, $CI_{95} [-0.58, 0.58]$, $p = 1.00$. As seen in Figure 1 (available in main text), the distribution of sessions attended showed negligible differences (i.e., percentage of clients who attended 1-2 sessions versus 5-6, Cramer's $V = .09$, $\chi^2(3, 46) = 0.33$, $p = .95$). Clients in both groups could attend further sessions following the posttreatment assessment if required. For TAU these sessions typically reflected that therapy was still ongoing given that no time restrictions were placed on how TAU was conducted in the study to ensure it accurately reflected normal treatment in the service. Thus although the two groups had a comparable number of sessions in the pre-posttreatment phase (3.50 sessions), 11 TAU clients had additional sessions between posttreatment and 3-month follow-up compared with only 1 CPT client ($\phi = 0.52$, Fisher's Exact Test, $p < .001$). No CPT clients had additional sessions from the service for the remainder of the trial, whereas 8 and 9 clients respectively were seen for additional sessions either between 3- and 6-month follow-up or between the 6- to 12-month follow-up period ($\phi = 0.48$, Fisher's Exact Test, $p = .001$, and $\phi = 0.52$, $p < .001$), with these clients receiving on average an additional 4-5 sessions in each follow-up interval.

Treatment credibility and expectancy. For treatment credibility and expectancy, TAU showed a small advantage over CPT (credibility - CPT: $M = 21.90$, $SD = 4.51$; TAU: $M = 23.17$, $SD = 3.45$, $d = 0.32$, $CI_{95} [-0.32, 0.96]$, $t(36) = 0.96$, $p = .34$; expectancy - CPT: $M = 67.78$, $SD = 24.87$; TAU: $M = 76.47$, $SD = 17.30$, $d = 0.41$, $CI_{95} [-0.26, 1.08]$, $t(33) = 1.19$, $p = .24$).

Therapeutic alliance. Differences in ratings of therapeutic alliance from both a client and therapist perspective were generally small, with large confidence intervals. Session 2 client rating - CPT: $M = 70.62$, $SD = 8.78$; TAU: $M = 72.88$, $SD = 8.65$, $d = 0.26$, $CI_{95} [-0.47, 0.98]$, $t(28) = 0.71$, $p = .49$; Session 2 therapist rating - CPT: $M = 67.27$, $SD = 8.48$; TAU: $M = 71.82$, $SD = 7.05$, $d = 0.58$, $CI_{95} [-0.13, 1.29]$, $t(30) = 1.66$, $p = .11$; Session 4 client rating - CPT: $M = 78.00$, $SD = 6.93$; TAU: $M = 76.20$, $SD = 8.22$, $d = 0.24$, $CI_{95} [-0.62, 1.10]$, $t(19) = 0.55$, $p = .59$; Session 4 therapist rating - CPT: $M = 70.17$, $SD = 11.09$; TAU: $M = 69.90$, $SD = 10.59$, $d = 0.02$, $CI_{95} [-0.81, 0.86]$, $t(20) = 0.06$, $p = .96$.

Predictors of posttreatment and 12-month outcome

A large number of potential predictors were available, including trauma characteristics, pretreatment symptom severity, treatment credibility and later symptom severity. Many correlations were modest (e.g., $< .15$) with wide confidence intervals that included 0, accordingly we only considered those correlated $\geq .30$ to have clinically meaningful impact. These were then examined within regression analyses, first controlling for group membership.

Not surprisingly, posttreatment CAPS scores were correlated with pretreatment PTSD and depression severity, and with the degree of relationship with the perpetrator (higher symptoms associated with a closer relationship to the perpetrator, e.g., partner or ex-partner).

Pretreatment PCL demonstrated a modest predictive relationship with posttreatment CAPS severity, when also entering group membership, pooled unstandardized coefficient (B) = 0.76,

CI₉₅ [0.03, 1.49], SE = 0.35, $p = .04$. Estimates when additional variables were added to the model (e.g., depressive symptoms) were smaller, with large confidence intervals (e.g., after controlling for group and pretreatment PCL, depression symptoms (BDI), $B = 0.68$, CI₉₅ [-1.28, 2.64]. Prediction of posttreatment outcome (as measured on the PCL) showed the same pattern of findings, that is, after pretreatment severity was controlled, no other variables made meaningful contributions to predicting outcome. In relation to 12-month outcomes, after controlling for group, no demographic or pretreatment severity variables accounted for PTSD severity.

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Table S1

Pooled inferential statistics from imputed datasets on all measures at posttreatment and all follow-ups (2 × 2 ANOVAs)

Measure	Pre- to Posttreatment	Pre- to 3-Month FU	Pre- to 6-Month FU	Pre- to 1-Year FU
CAPS				
Group (G)	$F(0.69, 34.09) = 1.49$	$F(.60, 34.26) = 2.28$	$F(0.60, 31.95) = 3.07$	$F(0.51, 27.16) = 1.78$
Time (T)	$F(0.94, 26.30) = 66.03^{***}$	$F(0.87, 8.24) = 39.48^{***}$	$F(0.95, 20.34) = 33.82^{***}$	$F(0.96, 22.73) = 59.39^{***}$
G × T	$F(0.46, 26.30) = 0.30$	$F(0.18, 8.24) = 0.01$	$F(0.07, 20.34) = 0.00$	$F(0.13, 22.73) = 0.06$
PCL				
G	$F(0.36, 34.75) = 0.19$	$F(0.21, 26.21) = 0.11$	$F(0.23, 31.95) = 0.06$	$F(0.16, 33.28) = 0.04$
T	$F(0.86, 12.13) = 33.12^{***}$	$F(0.68, 17.35) = 22.86^{**}$	$F(0.95, 13.95) = 23.11^{***}$	$F(0.92, 27.87) = 33.37^{***}$
G × T	$F(0.14, 12.13) = 0.24$	$F(0.47, 17.35) = 1.32$	$F(0.29, 13.95) = 0.07$	$F(0.19, 27.87) = 0.09$
PTCI				
G	$F(0.22, 38.42) = 0.57$	$F(0.30, 33.39) = 0.06$	$F(0.25, 36.40) = 0.16$	$F(0.66, 27.51) = 2.94$
T	$F(0.89, 16.33) = 17.80^{**}$	$F(0.70, 28.77) = 8.32^*$	$F(0.46, 25.28) = 4.38$	$F(0.80, 14.50) = 12.66^{**}$
G × T	$F(0.07, 16.33) = 0.02$	$F(0.38, 28.77) = 0.38$	$F(0.49, 25.28) = 0.50$	$F(0.21, 14.50) = 0.92$
BDI-II				
G	$F(0.14, 33.20) = 0.01$	$F(0.08, 27.23) = 0.05$	$F(0.09, 25.65) = 0.08$	$F(0.12, 21.47) = 0.30$
T	$F(0.80, 18.40) = 28.17^{***}$	$F(0.84, 13.14) = 12.23^{**}$	$F(0.79, 17.10) = 10.22^{**}$	$F(0.86, 22.59) = 13.40^{**}$
G × T	$F(0.61, 18.40) = 0.44$	$F(0.32, 13.14) = 0.67$	$F(0.18, 17.10) = 0.25$	$F(0.37, 22.59) = 1.31$

Note. CPT = Cognitive Processing Therapy (n = 24); TAU = Treatment as Usual (n = 22); CAPS = Clinician-Administered PTSD scale; PCL =

Posttraumatic Stress Disorder Check List; PTCI = Posttraumatic Cognitions Inventory; BDI-II = Beck Depression Inventory – 2nd Edition.

* $p < .05$; ** $p < .01$; *** $p < .001$.