

Stabilizing Group Treatment for Complex Posttraumatic Stress Disorder Related to Child Abuse Based on Psychoeducation and Cognitive Behavioural Therapy: A Multisite Randomized Controlled Trial

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Key Words

Randomized controlled trial · Psychotherapy outcome research · Childhood abuse · Posttraumatic stress disorder · Group treatment · Group intervention · Group psychotherapy · Psychoeducation · Cognitive behaviour group therapy · Cognitive behavioural treatment

Abstract

Background: Evidence-based treatments for complex posttraumatic stress disorder (PTSD) related to childhood abuse are scarce. This is the first randomized controlled trial to test the efficacy of psycho-educational and cognitive behavioural stabilizing group treatment in terms of both PTSD and complex PTSD symptom severity. **Methods:** Seventy-one patients with complex PTSD and severe comorbidity (e.g. 74% axis II comorbidity) were randomly assigned to either a 20-week group treatment in addition to treatment as usual or to treatment as usual only. Primary outcome measures were the Davidson Trauma Scale (DTS) for PTSD and the Structured Interview for Disorders of Extreme Stress (SIDES) for complex PTSD symptoms. Statistical analysis was con-

ducted in the intention-to-treat (ITT) and in the completer sample. Subjects were considered responders when scoring at 20 weeks at least 1 standard deviation below pretest findings. **Results:** The 16% attrition was relatively low. After 20 weeks, the experimental condition (large effect sizes) and control condition (medium effect sizes) both showed significant decreases on the DTS and SIDES, but differences between the conditions were not significant. The secondary responder analysis (ITT) revealed significantly more responders on the DTS (45 vs. 21%), but not on the SIDES (61 vs. 42%). **Conclusions:** Adding psycho-educational and cognitive behavioural stabilizing group treatment for complex PTSD related to child abuse to treatment as usual showed an equivocal outcome. Patients in both conditions improved substantially during stabilizing treatment, and while significant superiority on change scores was absent, responder analysis suggested clinical meaningfulness of adding group treatment.

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Introduction

Childhood trauma is associated with a wide array of psychopathology [1]. Childhood physical abuse and rape are far more likely to result in posttraumatic stress disorder (PTSD) than other traumas: nearly 50% compared to 8–20% [2]. Repeated interpersonal trauma is associated with additional symptoms, such as problems in affect regulation, memory and attention, self-perception, interpersonal relations, somatization and systems of meaning [3] also referred to as ‘PTSD with associated features’ (DSM-IV) or complex PTSD [4]. Empirical studies [5–7] as well as neurobiological findings [8, 9] have supported the concept of complex PTSD and have reported a prevalence of 1% [10].

Overall, for PTSD, several treatments such as imaginary exposure and eye movement desensitization and reprocessing have been proven effective [11, 12], although drop-out rates are considerable (e.g. 30% [13]) and the necessity of exposure is under debate [14, 15]. Symptom severity and comorbid borderline personality disorder (BPD) have been associated with higher drop-out rates, and the presence of complex PTSD, anger and child abuse with poor treatment outcome [12, 16–18].

Moreover, results of earlier treatment studies are difficult to generalize to patients with polysymptomatology related to child abuse and comorbid axis II diagnoses [11, 13], due to exclusion criteria and insufficient diagnostics [19–21]. During the last few years, a growing number of studies [15, 22, 24–26] have indicated that cognitive behavioural therapy elements may be effective in the treatment of child abuse-related PTSD, especially in reducing feelings of guilt and shame, which are complex PTSD symptoms. The guideline of the International Society for Traumatic Stress Studies [12] stated that patients with an inability to tolerate strong affects should initially focus on ‘stabilization’, so-called phase-based treatment [27]. However, treatment studies in inadequately diagnosed *complex* PTSD populations demonstrating efficacy in terms of complex PTSD symptom reduction and high compliance are lacking [21, 25]. In the current randomized controlled trial, we hypothesized that adding stabilizing group treatment would be efficacious [28, 29]. We expected that dissociative symptoms (interfering with attention) would be associated with poor outcome, and that comorbid BPD would predict higher drop-out rates.

Methods

Participants

Between June 2005 and February 2006, mental health clinicians referred 121 patients for stabilizing treatment. These patients were informed about the content of the study and the study procedures by clinicians who did a psychiatric intake, which was followed by structured interviews by independent assessors ($n = 90$). The subjects had to meet (1) criteria for PTSD according to the Structured Diagnostic Interview for DSM-IV axis I disorders [26] and (2) for complex PTSD according to the Structured Interview of Disorders of Extreme Stress (SIDES [5]). Furthermore, (3) sexual and/or physical abuse before the age of 16 was required (Structured Trauma Interview [30]). Exclusion criteria were (4) the presence of antisocial personality disorder, (5) current psychotic episode, (6) dissociative identity disorder or (7) severe alcohol or drug dependence or abuse (likely to interfere with attendance) as assessed by Structured Clinical Interviews for DSM-IV axis I and II disorders [31–33]. (8) Subjects currently under exposure treatment or seeking such treatment were also excluded.

All patients signed informed consent forms following oral and written explanations of the procedure. For ethical reasons, patients randomized to the control condition (treatment as usual, TAU) were offered the experimental treatment (EXP) after the test.

The study was conducted at four mental health institutes in the Netherlands. Postmeasurements were completed by September 2006. The period between premeasurement time and the start of treatment was 2 months at most. The study was approved by the Medical Ethical Board of the VU University Medical Centre.

Study Design

The study design was a multicentre randomized controlled trial. The patients were randomly assigned to (1) the EXP group with stabilizing group treatment added to TAU or (2) TAU only. The randomization was performed independently on a 1:1 basis, stratified per site, by a methodologist not involved in the study. Condition assignments were e-mailed to the group leader, who then informed the patient without informing the researchers or assessors. The patients were invited to 3 assessments, 2 at baseline and 1 posterior assessment. All the participants received individual TAU by a psychotherapist, psychiatric nurse or psychiatrist, including medication. TAU was not protocolized but was tailored to the individual needs of the patients and did not include exposure therapy. EXP consisted of 20 additional 2-hour treatment meetings held weekly. The groups comprised 8–12 participants and 2 therapists, who were experienced psychotherapists, psychiatrists or psychiatric nurses who had received training and supervision from the first author. To verify treatment progress and integrity, all the sessions were recorded. The therapists also completed a checklist that measured treatment adherence after every session. These checklists were used to screen for protocol violations throughout the study.

The stabilizing group treatment employed in the present study was focused on decreasing the core symptoms of complex PTSD. Psycho-education aimed at attaining a sense of cognitive mastery by explaining symptoms as adaptations that were once necessary for emotional survival in a context of child abuse. Cognitive behavioural skills focused on identifying and modifying dysfunctional behaviour, thoughts and beliefs about the trauma, in particular the trauma’s meaning for one’s self, relationships,

Table 1. Stabilizing group treatment for complex PTSD related to childhood abuse based on psycho-education and cognitive behavioural therapy: topics per session

Session No.	Session topic
1	Complex PTSD psychology and biology (Me, A)
2	'Safe' sleep (M)
3	Dissociation, re-experiencing (Me, A)
4, 5	Correct recognition of emotions and introduction cognitive model (M, L)
6–9	Skills building: affect regulation, self-care/soothing, relaxation, self-esteem (L)
10	Crisis management
11, 12	CT (false beliefs, thinking errors) (Mc)
13	Anger management (Mc, Me): skills and CT
14, 16, 18	Assertiveness, bodily experiences and sexuality (L, K, B, A): skills and CT
15	Distrust (B): skills and CT
17	Guilt and shame (B): skills and CT
19, 20	Saying goodbye and future (A)

CT = Cognitive techniques. Sessions 1–13 and 20 are mainly based on Zlotnick's protocol [26]; we added sessions 14–19. In parentheses the most contributing primary sources are indicated: Linehan (L) [37]; Matsakis (M) [36]; McKay (Mc) [38]; Meichenbaum (Me) [39]; Korsten (K) [52]; Bouma (B) [53]; authors (A).

future and world view. The aim of these skills was to acquire improved self-regulation, adaptive beliefs, and assertiveness, thereby decreasing avoidance. The focus of the treatment was towards the here-and-now, on positive reinforcement and empowerment. The group format aimed at inducing hope and reframing patients' symptoms as understandable responses to trauma, thereby reducing shame, guilt and isolation. The interaction between group members was limited in order to create a safe place to learn. Sharing individual trauma histories, which could affect other group members, was explicitly discouraged. The treatment manual consisted of a structured, detailed session-by-session script (psycho-educational presentations on a weekly topic, connected skills training and cognitive restructuring, and homework pages) based on a manual by Zlotnick et al. [26, 27, 34]. Three of the authors [35] extended this protocol by inserting additional sessions (14–19) to cover all symptom domains of complex PTSD. Sources included work by Matsakis [36], Linehan [37], McKay et al. [38] and Meichenbaum [39]. Also, some adaptations were made to the existing sessions of Zlotnick's manual (table 1).

Measures

Core Symptoms. The concept of complex PTSD, comprising both PTSD as well as associated complex PTSD features, was captured by two measures: (1) The severity of PTSD was established using the Davidson Trauma Scale (DTS [40]), a well-validated 17-item measure assessing DSM-IV diagnostic criteria on a 5-point Likert scale (range 0–68; Cronbach's $\alpha = 0.88$). (2) The SIDES was used to assess symptom severity for each domain of complex PTSD [8], i.e. affect regulation, memory and attention, self-perception, perception of perpetrator, interpersonal relations, somatization and systems of meaning. The original 48-item version was used for diagnostic assessment, whereas the revised 37-item version by Ford et al. [10] was used for severity assessment after consultation with its author (J. Ford), excluding perception of per-

petrator and somatization items. Each item is rated on a 0–3 scale (range, 0–111) (Cronbach's $\alpha = 0.74$).

Secondary Outcome Measures. (1) The Borderline Personality Disorder Severity Inventory IV [41] is a DSM-IV-based, well-established 70-item semistructured interview that measures the frequency of BPD symptoms (Cronbach's $\alpha = 0.84$). (2) The Dissociative Experiences Scale (DES [42]) is a 28-item measure that records the severity of dissociative symptoms. The items are rated on a 0–100 scale, and a mean score of these 28 items was calculated (Cronbach's $\alpha = 0.93$). The interviews were conducted by trained independent assessors, who were blind to the treatment condition and were audiotaped for use in supervision. Comparability of the assessments was ensured by joint bi-weekly supervision of the assessors by the first two authors.

Power Considerations

The estimated outcomes were based on the study of Zlotnick et al. [26]. In the latter study, the mean improvement in the experimental condition on the DTS was 21 (standard deviation, SD, 22) versus a mean improvement of 2 (SD 26) in the control condition, consisting of TAU. Power calculations showed that each group should comprise at least 26 completers based on the DTS (power = 80% and $\alpha = 0.05$, two-tailed). To allow for participant attrition, we decided to enroll at least 36 patients in each group.

Data Analyses

Demographic and clinical characteristics were analysed for differences between groups at the pretest examination as well as between completers and drop-outs with t tests for continuous variables and χ^2 tests for categorical variables.

Both intention-to-treat analysis (ITT) and completers' analysis were conducted. In the ITT analysis, we applied a 'last observation carried forward' method in which the available pretest score

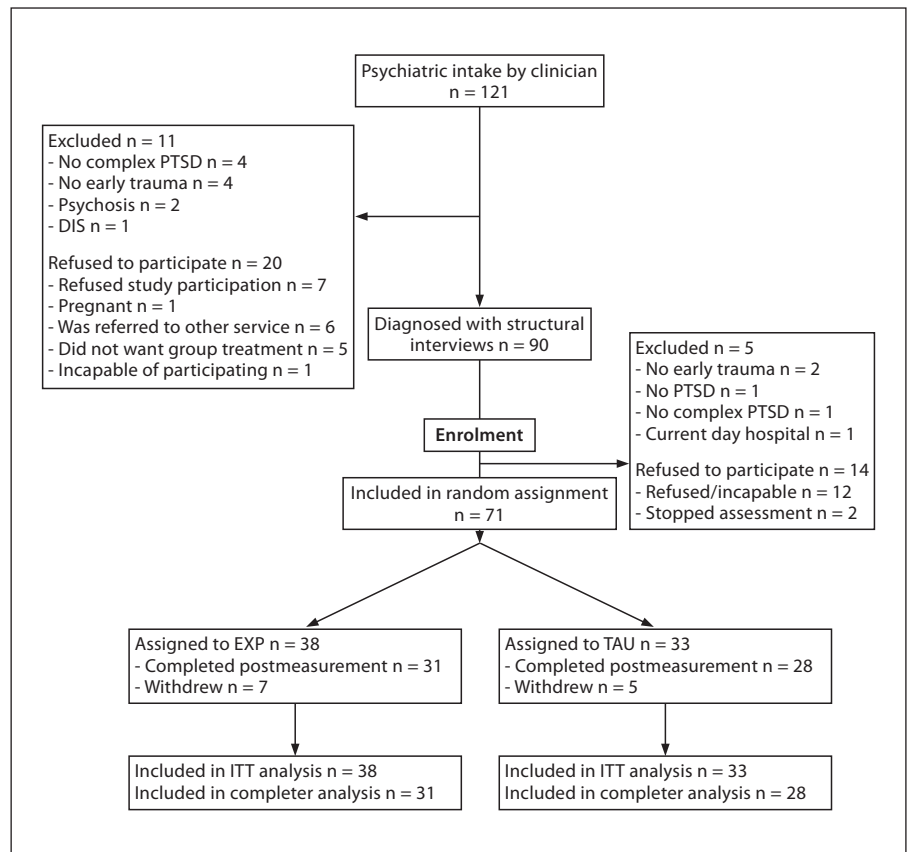


Fig. 1. Flow diagram of a randomized controlled trial comparing TAU with EXP. DIS = Dissociative identity disorder.

was used to account for the subsequent missing posttest score. Two-tailed statistical tests were applied. All computations were carried out with SPSS 15.0.

Within-Condition Analysis. Time effects were analysed for both groups separately, using paired t tests or, when the data violated normality assumptions, Wilcoxon-Mann-Whitney tests. Cohen's *d* effect size was calculated using the formula (mean before treatment – mean after treatment)/SD before treatment. The effect sizes were interpreted as follows: <0.50 = weak or no effect, 0.50–0.80 = moderate effect, >0.80 = large effect [43].

Between-Condition Analysis. Since the assumptions for using ANCOVA or repeated measures mixed models were not met (the postscores appeared to vary non-linearly with the prescores), comparisons between the two groups were based on change scores (pretest scores – posttest scores), which eliminates the influence of differences in pretest scores. If the data appeared to be normally distributed, a 2-sample t test was used; otherwise, a Wilcoxon-Mann-Whitney test was employed.

Responder Analysis. To analyse clinically significant differences between the groups, we used the concept of 'reliable change' by comparing the percentages of the responders on the core measures DTS and SIDES for the two groups. Responders were defined according to the approach by Greeven et al. [44] (based on Jacobsen and Truax [45]) as participants with a posttest score at least 1 SD below the pretest score (22.5 points on DTS, 9.6 points on SIDES). The relative risk was computed as the percentage of

responders in EXP divided by the percentage of responders in TAU. A relative risk above 1.25 indicates clinically meaningful change [46]. The number needed to treat was computed by dividing 100 by absolute risk reduction [= risk (%) non-responding TAU – risk (%) non-responding EXP] [47].

Subgroup Analysis. To examine whether the presence of BPD predicted a higher drop-out rate, χ^2 tests were used. To examine whether dissociation severity was associated with poor outcome, we compared change scores of the two conditions in the severest subgroup, defined by a median split of DES and DTS, using a Wilcoxon-Mann-Whitney test.

Results

Patient Attrition and Baseline Comparability

Of the 90 patients diagnosed by the independent assessors, 71 were included (fig. 1). Table 2 lists the subjects' demographic and clinical status variables. The scores indicated chronic, severe PTSD, borderline and dissociative symptom levels at baseline, with high comorbidity on both axis I and II and frequent use of psychotropic medication. PTSD symptom severity was significantly higher in the

Table 2. Trauma history, demographic and psychiatric status variables at baseline in patients with complex PTSD (n = 71)

	EXP (n = 38)		TAU (n = 33)	
	percentage or mean	SD	percentage or mean	SD
Age, years	40.3	10.7	37.1	10.3
Years of education	9.9	3.1	10.5	3.1
Married or living together	86%		87%	
Employed ¹	8	22%	4	12.5%
Childhood abuse	38	100%	33	100%
Physical	57%		69%	
Sexual	97%		91%	
Adult abuse ²	72%		52%*	
Physical ³	46%		39%	
Sexual ⁴	58%		38%	
History				
Duration of symptoms >10 years ⁵	50%		53%	
Number of previous treatments	1.9	1.5	1.9	1.3
Current other treatments				
SSRI/SNRI	76%		61%	
Sedative/hypnotic	49%		45%	
Antipsychotic	24%		15%	
Current comorbidity DSM-IV axis I				
Mean number of disorders	2.9	1.7	2.6	2.1
Depressive disorder	63%		45%	
Mean number of anxiety disorders	1.7	1.2	1.4	1.2
Social phobia ⁶	50%		36%	
Panic disorder ⁶	45%		39%	
Substance abuse and/or dependence ⁶	18%		21%	
Current comorbidity axis II (SIDP-IV)				
Mean number of disorders	1.2	1.0	1.7	1.4
BPD ⁶	53%		52%	
Avoidant PD ⁶	21%		30%	
Clinical characteristics				
DTS	90	20	80*	23
SIDES	46.1	8.5	43.3	10.6
BPDSI	22.8	7.4	23.8	9.1
DES	24.3	15.8	27.8	15.4

Comparison of EXP and TAU: frequencies (percentages) and means with SD. SSRI/SNRI = Serotonin reuptake inhibitor/serotonin-norepinephrine reuptake inhibitor; PD = personality disorder; BPDSI = Borderline Personality Disorder Severity Index. Adult abuse: $t = 4.23$, $d.f. = 1$; DTS: $t = 1.96$, $d.f. = 69$. * $p \leq 0.05$.

¹ n = 69. ² n = 67. ³ n = 66. ⁴ n = 65. ⁵ n = 68. ⁶ Most prevalent disorders.

EXP group at baseline (table 2). In addition, adult abuse was more frequently reported in EXP. The attrition rate was 16% (overall). The drop-out versus completer analysis on pretest variables revealed no significant differences.

Main Analysis

Within-Group Analysis. The patients improved from pre- to posttreatment assessments significantly in both

EXP and TAU on both core symptom measures (table 3), with overall large effect sizes (>0.80) in EXP and medium (>0.50) effect sizes in TAU.

Between-Group Analysis. On both core symptom measures, no significant differences in change scores were found between EXP and TAU (table 4), only trends ($0.05 < p < 0.10$) in completer analysis (two-tailed). Results were similar when controlling for sites or when

Table 3. Mean scores at pre- and posttherapy testing and effect size on core symptoms – PTSD symptoms (DTS) and complex PTSD symptoms (SIDES) – on completer analysis (CA) and ITT analysis of the EXP and TAU groups

Measure	Condition	CA/ITT	Number	Pretherapy score		Posttherapy score		t- or z- statistic	d.f.	p	Cohen's d
				mean	SD	mean	SD				
DTS	EXP	CA	31	91.4	21.8	66.7	29.4	5.0	30	0.000	1.09
		ITT	38	89.8	20.3	69.6	27.4	4.1 ¹	NA	0.000	1.00
	TAU	CA	29	80.5	23.1	65.5	30.3	3.6	28	0.001	0.65
		ITT	33	79.6	23.5	66.5	29.8	3.5	32	0.001	0.61
SIDES	EXP	CA	31	47.2	8.4	32.5	10.3	7.8	30	0.000	1.75
		ITT	38	46.1	8.5	34.1	10.5	6.6	37	0.000	1.41
	TAU	CA	28	44.3	10.7	35.4	11.7	3.9	27	0.000	0.83
		ITT	33	43.3	10.6	35.8	11.3	3.8	32	0.000	0.72

Paired t- or z-statistic within groups (pre-/posttherapy analysis): t test, unless otherwise indicated.

¹ Mann-Whitney U test.

Table 4. Comparison of EXP versus TAU change scores (pre- minus posttherapy score) in core symptoms during treatment – PTSD symptoms (DTS) and complex PTSD symptoms (SIDES) – based on completer analysis (CA) and ITT analysis

Measure	CA/ITT	EXP			TAU			Difference		t- or z- statistic ¹	d.f.	p
		n	mean	SD	n	mean	SD	mean	95% CI			
DTS	CA	31	24.7	27.3	29	14.9	22.2	9.8	-3.1 to 22.7 ²	1.6 ³	NA	0.10
	ITT	38	20.2	26.4	33	13.1	21.3	6.9	-4.4 to 18.5	1.2	69	0.22
SIDES	CA	31	14.7	10.6	28	8.9	11.9	5.8	-0.7 to 11.7	2.0	57	0.05
	ITT	38	12.0	11.2	33	7.6	11.4	4.4	-0.9 to 9.8	2.0	69	0.10

¹ t test, unless otherwise indicated. ² t test confidence limit. ³ Wilcoxon-Mann-Whitney test, all tests two-tailed.

performing a non-parametric version of ANCOVA (Wilcox's method). The trends in completer analysis were mainly due to the PTSD subscale avoidance ($t = 1.7$; d.f. = 58; $p = 0.10$) and the complex PTSD domains self-perception ($t = 1.1$; d.f. = 58; $p = 0.02$) and systems of meaning ($t = -2.0$; d.f. = 57; $p = 0.06$). On the secondary measures for borderline symptoms (Borderline Personality Disorder Severity Inventory IV; $t = 1.2$; d.f. = 69; $p = 0.22$) and dissociation (DES; Wilcoxon-Mann-Whitney test: $Z = -1.15$; $p = 0.25$) in the ITT population, no significant differences were found.

Responder Analysis. The comparison of the responder rates revealed significant differences in favour of EXP (table 5), on PTSD symptoms, but not on the complex PTSD symptoms. The relative risks above the cut-off for the clinically meaningful change of 1.25 [43] indicated high-

er proportions of responder rates in the experimental condition, reflected in numbers needed to treat of 4.2 (ITT) and 3.2 (completer analysis) on PTSD symptoms (DTS) and 5.3 and 4.2, respectively, on complex PTSD symptoms (SIDES).

Subgroup Analysis

Twenty of the 38 patients in EXP met criteria for BPD. Contrary to our expectation, we found that 19 (95%) of these patients completed treatment, as opposed to 12 of 18 (66%) patients without a borderline personality diagnosis. Thus, BPD was apparently associated with compliance ($\chi^2 = 5.0$; d.f. = 1; $p = 0.02$).

In the severest 'high dissociative, high posttraumatic stress' subgroup (i.e. with DES >24 and DTS >86), a significant difference between the DTS mean change score

Table 5. Comparison of percentage responders in EXP versus TAU with clinically relevant change defined as at least 1 SD progress in core symptoms during treatment – PTSD symptoms (DTS) and complex PTSD symptoms (SIDES) – based on completer analysis (CA) and ITT analysis (two-tailed)

Measure	CA/ITT	EXP		TAU		Relative risk		χ^2	d.f.	p
		n	%	n	%	risk	95% CI			
DTS	CA	17	55	7	24	2.3	1.1–4.8	5.9	1	0.02
	ITT	17	45	7	21	2.1	1.0–4.4	4.4	1	0.03
SIDES	CA	14	74	14	50	1.5	1.0–2.3	3.7	1	0.05
	ITT	14	61	14	42	1.4	0.9–2.3	2.3	1	0.12

of 34 points (SD 23) in EXP and the DTS mean change score of 15 points (SD 28) in TAU was found (Wilcoxon-Mann-Whitney test: $Z = -2.0$; $p = 0.04$).

Discussion

This study on cognitive behavioural stabilizing group treatment in child abuse-related complex PTSD showed equivocal results. Both the experimental condition (large effect sizes) and control condition (medium effect sizes) revealed substantially decreased PTSD and complex PTSD symptoms. However, no significant differences between conditions were found on change scores (ITT), and only the completers' analysis showed trends ($0.05 < p < 0.10$). The secondary responder analysis revealed significantly more responders in EXP on PTSD symptoms, i.e. 45 vs. 21%, but not significantly more on complex PTSD symptoms, i.e. 61 vs. 42% (ITT). Relative risks indicated clinically meaningful change [46].

Compared to earlier studies [15, 16, 19, 23, 25, 26], comorbidity on both axis I and II and symptom severity were high in this population specifically referred to stabilizing treatment. Pre-post effect sizes were comparable to previous studies [26, 29]. Moreover, the 16% attrition observed was low [13, 15]. The subgroup with the highest dissociation and PTSD levels profited equally, and BPD was associated with increased compliance, suggesting the experimental treatment was suitable for these patients.

In view of our ambiguous results, we compared the individual therapists' discipline, the number of individual sessions or changes in prescription of psychotropic medication between conditions, but did not find major differences. Although therapists were all experienced with this population, had completed the training course,

were supervised and passed treatment integrity checks, unexpected replacements resulting in 50% inexperienced group leaders may have negatively influenced the results.

Our power assumptions were based on the study of Zlotnick et al. [26], who found similar improvements in EXP, but no improvement in TAU, in contrast to our findings, which is likely to have reduced power. The improvement in TAU may have been due to general advances [13] or differences between countries [48] in TAU. Also our multisite design, probably thwarting optimal implementation, and the severer pathology differ from those of Zlotnick et al. [26].

Evidently, our study has limitations. Although our groups were comparable with regard to illness duration, medication use, number of previous treatments and general characteristics of TAU, heterogeneity of treatment history and TAU may have biased our results. Our non-blinded study may have overestimated treatment effects. Also, we did not compare the experimental intervention to a gold standard treatment like imaginary exposure or 'pure' cognitive therapy, or an unspecific encounter [49, 50].

The randomized controlled trial reported here is, to our knowledge, the first to use well-diagnosed complex PTSD both as inclusion criterion and core measure. Although Cloitre et al. [51] recently reported effectiveness of stabilization before exposure treatment for child abuse-related PTSD, we consider our results of relevance since there is a paucity of data on treatments for complex PTSD. However, given that our results are inconclusive and provide only modest evidence for the clinical relevance of this treatment, future research should aim to further improve cognitive behavioural stabilizing treatment in women with child abuse-related complex PTSD.

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