



Stabilizing group treatment for childhood-abuse related PTSD: a randomized controlled trial

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ABSTRACT

Background: Patients with PTSD related to childhood-abuse often experience additional problems such as emotional dysregulation and interpersonal difficulties. Psychotherapy focused on stabilization of symptoms, emotion-regulation, and skills training has been suggested as a treatment for this patient population, either as preparation for further treatment or as a stand-alone intervention.

Objective: The present study tests the efficacy of treatment using a group-protocol for stabilizing treatment delivered adjunct with conventional individual therapy.

Methods: In a delayed-treatment design with switching replication, a clinically representative sample of 89 patients with PTSD and histories of childhood abuse were randomly assigned to either 20-week stabilizing group treatment or a corresponding waiting-period, both adjunct with conventional individual therapy. After the waiting-period, patients in the control condition were offered group treatment. The primary outcome was psychosocial functioning, measured with interview – assessed Global Assessment of Functioning (GAF), while secondary outcome was self-reported PTSD symptoms. These were measured before treatment, after treatment and at 6 months follow up. The trial was preregistered at Clinical Trials (NCT02450617).

Results: We found large within-group effect sizes in both conditions on GAF and moderate effects on PTSD symptoms. Linear mixed-models did not indicate significant differences in treatment trajectories between conditions.

Conclusion: Stabilizing group treatment focused on emotional-regulation and skills-training does not improve outcomes beyond individual-treatment alone, and should not be recommended as first-line treatment for this patient-group

Tratamiento grupal para estabilización en el tratamiento de estrés postraumático asociado a abuso infantil: Un ensayo clínico aleatorizado

Antecedentes: Los pacientes con trastorno de estrés postraumático (TEPT) asociado a abuso infantil con frecuencia experimentan problemas adicionales como desregulación emocional y dificultades interpersonales. Se ha propuesto a la psicoterapia enfocada en la estabilización de síntomas, la regulación emocional y el entrenamiento en habilidades como un tratamiento para esta población de pacientes, tanto como preparación para algún tratamiento adicional o como una intervención única.

Objetivo: Este estudio evalúa la eficacia del tratamiento empleando un protocolo grupal para estabilización realizado junto con la terapia individual convencional.

Métodos: El estudio contó con un diseño de inicio retrasado del tratamiento con entrecruzamiento de grupos. Los participantes de una muestra clínicamente representativa de 89 pacientes con TEPT y antecedente de abuso infantil fueron aleatorizados ya sea a un tratamiento grupal para estabilización de 20 semanas o a un tiempo de espera de igual duración. Ambos grupos recibieron terapia individual convencional. Luego del tiempo de espera, a los pacientes en el grupo de control se les ofreció el tratamiento grupal. El resultado principal fue el funcionamiento psicosocial, medido en una entrevista empleando la Evaluación Global de Funcionamiento (GAF, por sus siglas en inglés). El resultado secundario fueron los síntomas del TEPT auto-reportados. Estos fueron medidos antes del tratamiento, después del tratamiento y a los 6 meses de seguimiento. El ensayo clínico fue pre-registrado en "Clinical Trials" (NCT02450617).

Resultados: Encontramos tamaños del efecto grandes dentro de los grupos en ambas condiciones con la GAF; además, encontramos tamaños del efecto moderados para los síntomas del TEPT. Los modelos mixtos lineales no mostraron diferencias significativas en las trayectorias del tratamiento entre ambas condiciones.

Conclusiones: El tratamiento grupal para estabilización enfocado en la regulación emocional y en el entrenamiento de habilidades no mejoró los resultados clínicos más allá del tratamiento individual como monoterapia y no debería ser recomendado como un tratamiento de primera línea para este grupo de pacientes.

ARTICLE HISTORY

Received 12 May 2020

Revised 13 November 2020

Accepted 18 November 2020

KEYWORDS

Post-traumatic stress disorder; group psychotherapy; 'childhood abuse; trauma; randomized controlled trial

PALABRAS CLAVE

Trastorno de estrés postraumático; psicoterapia de grupo; abuso infantil; trauma; ensayo clínico aleatorizado


关键词

创伤后应激障碍; 团体心理治疗; 随访研究; 创伤; 随机对照试验

HIGHLIGHT

Stabilizing group treatment focused on emotional-regulation and skills-training does not improve outcomes beyond individual-treatment alone for patients with PTSD after childhood abuse.

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 Supplemental data for this article can be accessed [here](#).

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针对童年期虐待相关PTSD的稳定化团体治疗：一项随机对照试验

背景: 童年期虐待相关PTSD患者经常经历其他问题，例如情绪失调和人际交往困难。已经提出了专注于症状稳定、情绪调节和技能培训的心理学方法，作为对该患者群体的一种治疗方法，可以作为进一步的治疗准备或作为独立的干预措施。

目的: 本研究考查了使用稳定化团体治疗方案辅助传统个体疗法的治疗效果。

方法: 采用交换重复的延迟治疗设计，将89例有童年期虐待史的PTSD患者临床代表性样本随机分配至20周稳定化团体治疗组或相应的等待期组，均辅助传统个体治疗。等待期过后，给予对照状态的患者团体治疗。主要结果是心理社会功能，通过访谈式评估的总体功能评估（GAF），次要结果是自我报告的PTSD症状。在治疗前、治疗后和6个月随访时进行测量。该临床试验进行了预先注册（NCT02450617）。

结果: 我们发现，在两种情况下组内效应均对GAF均具有较大的效应量，而对PTSD症状具有中等效应。线性混合模型并未显示不同条件之间治疗轨迹的显著差异。

结论: 专注于情绪调节和技能培训的稳定团体治疗不能改善个体治疗以外的结果，因此不应该将其推荐为对此患者群体的一线治疗。

Childhood abuse is recognized as a major contributor to the development of mental health difficulties and is associated with a higher prevalence of a wide range of psychiatric disorders (Scott, Smith, & Ellis, 2010). For many, childhood abuse leads to the development of Posttraumatic Stress Disorder (PTSD), either directly as a triggering traumatic event, or indirectly as a heightened vulnerability to develop PTSD after later traumatic experiences (Kessler et al., 2014). Trauma and abuse often occur in the context of other types of adverse childhood events, that are cumulatively associated with disrupted development and a range of somatic and mental health problems (Anda et al., 2006). Patients with histories of childhood abuse therefore often present with other difficulties in addition to severe PTSD symptoms. This is reflected in the proposed category complex PTSD (CPTSD; (Herman, 1992), characterized by interpersonal problems, difficulties in regulating emotions, and negative self-beliefs, in addition to PTSD symptoms, that have an impact on the person's psychosocial functioning. CPTSD was recently included as a distinct diagnostic entity in the 11th revision of the International Classification of Diseases (ICD-11; Cloitre, Garvert, Brewin, Bryant, & Maercker, 2013; Maercker et al., 2013). The diagnosis is not exclusively related to any particular type of event, but research has shown that severe and repeated interpersonal trauma, including childhood abuse, increases the risk of the disorder (Brewin et al., 2017). This nosology remains controversial though, as some argue that multiple trauma exposure and complex presentations are common in all PTSD patients (Resick et al., 2012).

1. Treatment

Studies indicate that patients with PTSD related to childhood trauma experience poorer outcomes from current evidence-based treatments (Dorrepal et al., 2014; Mahoney, Karatzias, & Hutton, 2019). Concerns have been raised that these patients can struggle to tolerate trauma-focused treatment due to difficulties in regulating strong affect, increasing the risk of symptom-exacerbation, drop-out or destructive behaviour (Cloitre et al., 2010;

Mcfetridge et al., 2017). This has led to calls for more personalized multi-component treatments (Cloitre, 2015) and interventions that help patients manage symptoms and improve overall psychosocial functioning and quality of life (Stadtman, Maercker, Binder, & Schnepp, 2018). The risks of symptom-exacerbation and drop-out are disputed though (De Jongh et al., 2016), and recent research shows that childhood trauma does not increase drop-out from trauma-focused treatment (Eftekhari, Crowley, Mackintosh, & Rosen, 2020).

A proposed alternative to trauma-focused treatment recommended by expert guidelines (Cloitre et al., 2012; Mcfetridge et al., 2017) is *stabilizing treatment*, focused on emotion – regulation, stress – management, and skills – training, rather than processing traumatic memories. Stabilizing treatment can be delivered as a preparatory phase before trauma-focused treatment (phase-based treatment; Cloitre, Courtois, Carapezza, Stolbach, & Green, 2011), but has also been suggested as a stand-alone intervention (Courtois, Ford, & Cloitre, 2009).

In mental-health services stabilizing treatment is often offered in a group-format, either alone or conjoint with individual treatment (Dorrepal et al., 2012; Herman & Kallivayalil, 2019; Robertson, Blumberg, Gratton, Walsh, & Kayal, 2013; Stige, 2011; Zehetmair et al., 2018; Zlotnick et al., 1997). The group setting makes it possible to counteract a sense of isolation and offer an opportunity for new interpersonal experiences, while the individual therapy ensures support to handle reactions and experiences from the group (Schwartz, Barkowski, Strauss, Knaevelsrud, & Rosendahl, 2019). To our knowledge, the efficacy of stabilizing group treatment for PTSD has only been investigated in two randomized controlled trials. Zlotnick and colleagues (Zlotnick et al., 1997) in a small study with 48 women with sexual abuse histories, found that stabilizing group treatment was significantly beneficial compared to individual treatment alone in reducing PTSD and dissociative symptoms. Meanwhile, Dorrepal and colleagues (Dorrepal et al., 2012) found that adding stabilizing group treatment did not produce superior outcomes in a multicenter trial with 71 patients diagnosed

with CPTSD and histories of childhood abuse, although within-person effect-sizes were large. Neither of these studies reported follow-up data.

1.1. Study aim

In light of these inconclusive results, there is a need for further empirical investigations of the efficacy of this widely offered treatment format to guide clinical practice. Also, previous investigations have only reported outcomes specifically related to trauma-pathology, such as PTSD, CPTSD, and dissociative symptoms. As it is a stated goal of stabilization-treatment to increase psychosocial functioning, it is important to investigate the effect on this outcome. The current study therefore aims to investigate the efficacy of stabilizing group – treatment, focused on emotion-regulation and interpersonal problems, delivered adjunct with conventional individual treatment, compared to individual-treatment alone. The conventional individual treatment was not trauma-focused. We specifically predicted that the combined treatment would be more effective in increasing psychosocial functioning and alleviating PTSD symptoms than individual treatment alone.

2. Methods

2.1. Participants

Participants were recruited from patients referred to group treatment at an urban outpatient clinic in Oslo, Norway. The clinic accepts referrals from patients with a reported trauma history and trauma-related symptoms, seeking

specialized group treatment. Patients are also required to have planned or ongoing individual treatment at another clinic or practice. Between September 2014 and March 2016, all patients referred for trauma treatment and with presenting problems corresponding with PTSD symptoms were invited to participate at intake. Written informed consent was obtained from all patients followed by structured diagnostic interviews. Inclusion and exclusion criteria were the same as those used by the clinic (Figure 1). To be included in the study patients had to: (a) meet DSM-5 criteria for PTSD; (b) report a history of childhood abuse; (c) be between 18 and 65 years of age. PTSD symptoms did not have to be directly associated with experiences of childhood abuse, but could be related to other traumatic experiences. Exclusion criteria were: (a) acute suicidality; (b) serious substance abuse interfering with treatment; (c) serious psychotic symptoms; (d) current life – crisis interfering with therapy (e.g. ongoing abuse, divorce, court case, somatic disease in spouse or children, etc.); (e) neurological disease, mental disability or life-threatening somatic disease; (f) insufficient competence in Norwegian to be able to participate in a psychoeducational group; (g) a diagnosis of Dissociative Identity Disorder (DID) or Dissociative Disorder Not Otherwise Specified (DDNOS), assessed by DSM-IV Dissociative Disorders-Revised (SCID-D; Steinberg, Cicchetti, Buchanan, & Hall, 1993).¹

The study was funded by Modum Bad Psychiatric Hospital. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the

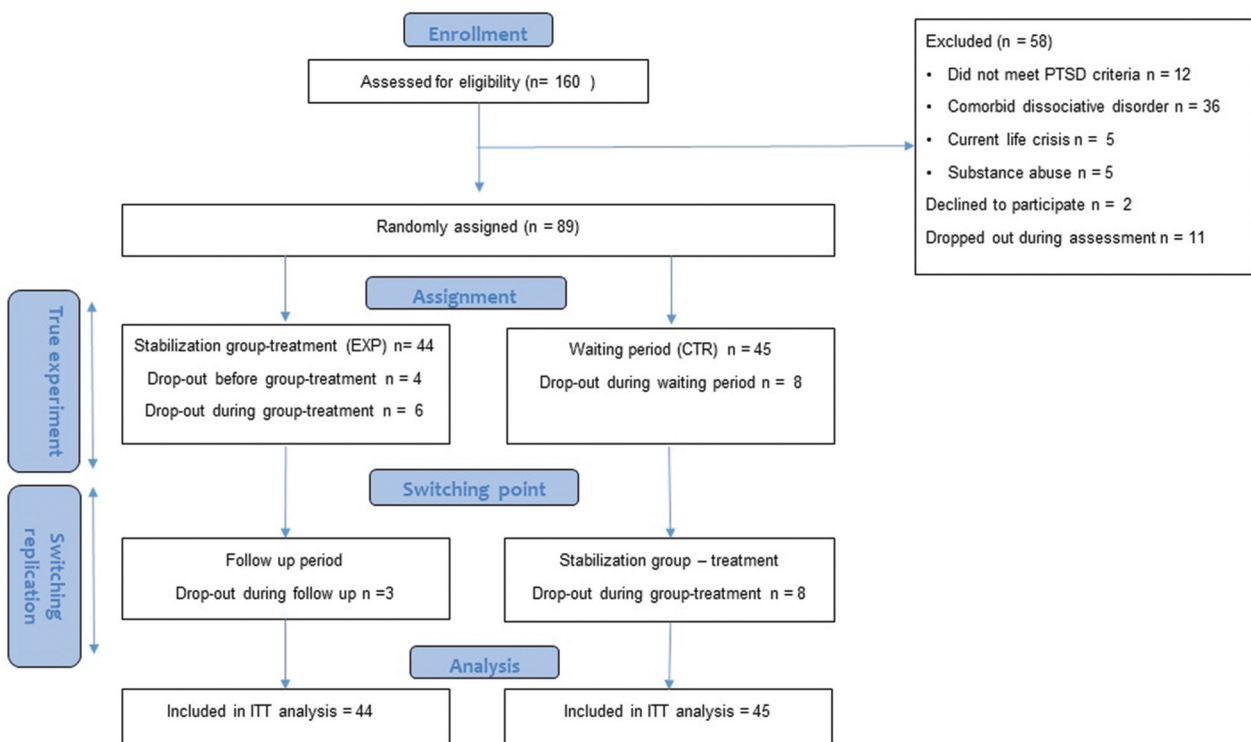


Figure 1. Flow-diagram of randomized trial of stabilizing group treatment with a delayed treatment control group.

Helsinki Declaration of 1975, as revised in 2008. All procedures involving human subjects/patients were approved by the Norwegian Regional Committees for Medical and Health Research Ethics (2013/2350).

2.2. Design and randomization

The study employed a multimethodological design, combining a randomized trial with a delayed treatment control group and multiple time series with switching replication (Heath, Kendzierski, & Borgida, 1982). A delayed-treatment control was believed to be a pragmatic and ethical choice in a clinical setting with referred patients, where a no-treatment control would be difficult. Included patients were randomly assigned to receive stabilizing group treatment immediately (EXP) or after a waiting period (CTR). After the end of group treatment of their corresponding cohort (Switching point), all patients in the control condition were offered the experimental group treatment. All patients received conventional individual treatment conjoint with the group treatment and during the waiting period. Patients were also assessed 6 months after the end of group treatment, to investigate long term effects. This design allows for a 'true experiment' and a quasi-experimental switching replication to infer effectiveness, while also including long-term effects (Figure 1).

Randomization was performed by an independent administrative assistant, not involved in the research group, using random sequences generated from software at www.graphpad.com. To ensure the assignment of nine participants in each treatment group, a blocked randomization procedure with cohorts of 18 was used. One patient withdrew consent after randomization, so one cohort had only 17 subjects, leaving the final sample at 89. Information on condition – assignment was given directly to the patients and therapists, without informing the researchers or assessors. The trial was preregistered at Clinical Trials (NCT02450617).

2.3. Interventions

The stabilizing group treatment focused on psychoeducation and skills – building, primarily to enable patients to cope with PTSD symptoms, strengthen emotional regulation, and increase interpersonal functioning. The treatment is manualized (Bad, 2014) and consists of twenty 90-minute sessions, each with a new topic, exercise and homework. The manual is based on recommendations for stabilization in treatment guidelines for patients with CPTSD (Cloitre et al., 2012; Mcfetridge et al., 2017) and previous work (Dorrepaal et al., 2012) and incorporate elements from cognitive-behavioural therapy and mindfulness interventions. Based on experiences from pilot-groups, the manual carefully introduces topics on trauma, trauma –

reactions, and coping-skills (see supplementary A). Each group had nine participants and two therapists. Sessions were highly structured to increase each participant's sense of safety and predictability. The first part of each session focused on giving each participant time to talk about their experience with the last session's topic and homework, with feedback from the therapists and participants. The second part primarily consisted of psychoeducation, with one of the therapists giving a small lecture about the topic and reviewing next week's homework. Each session also included instructions in different exercises, such as grounding, relaxation, or mindfulness. Exercises were modelled and instructed by one of the therapists, and time was allocated for the patients to practice themselves. Participants had access to written material and audiofiles of exercise – instructions and were tasked with practicing skills between group meetings. The participants were encouraged to share their experiences and thoughts with the group, but not allowed to share details of their trauma-histories to avoid secondary traumatization and affecting other group members (Barrera, Mott, Hofstein, & Teng, 2013; Dorrepaal et al., 2012).

Individual treatment was not protocolled, but delivered as seen fit by the therapists. Therapists were psychologists, psychiatrists, or nurses working in other clinical departments or private practice. Few therapists were trained in trauma-focused treatment (for details see supplementary B). Individual therapists were invited to a meeting at the start of the stabilization group treatment and informed about the rationale and content of the treatment. Patients were encouraged to share written material and discuss their experiences from the group with their therapists.

2.4. Therapists and treatment integrity

Group therapists were experienced psychologists, a psychiatrist or a psychiatric-nurse employed at the clinic. All had previous training and experience with conducting groups based on the manual and participated in weekly group-supervision. After each group – session, both therapists completed a checklist (see supplementary C) that was used to screen for protocol violations. No major violations of fidelity were reported.

3. Measures

3.1. Diagnostic assessment and baseline characteristics

The Post-traumatic Symptom Scale – Interview (PSS-I; Foa, Riggs, Dancu, & Rothbaum, 1993) was used to assess PTSD. Using PSS-I, the

interviewer first establishes a traumatic event before asking about 17 symptoms of PTSD based on DSM-IV. The information and scoring obtained during the interview were used to diagnose patients based on DSM-5 criteria, since the DSM-5 version of PSSI was not published at the start of the study. PSSI has shown good interrater reliability and convergent validity with other measures of PTSD (Foa & Tolin, 2000)

The Mini-International Neuropsychiatric Interview (Sheehan et al., 1998) and **SCID – II** (First, Benjamin, Gibbon, Spitzer, & Williams, 1997) were administered to assess general psychopathology and personality disorders. Both instruments have shown satisfactory psychometric properties and interrater reliability (First et al., 1995; Mordal, Gundersen, & Bramness, 2010).

Childhood Trauma Questionnaire – Short form (CTQ-SF; Bernstein et al., 1994) was used to assess childhood trauma history. CTQ-SF has 28 items scored from 0 (“never true”) to 5 (“very often true”) covering experiences related to five subcategories of abuse: Emotional neglect, physical neglect, emotional abuse, sexual abuse, and physical abuse. Validated cut-off scores for each subcategory (sexual abuse \geq 8, physical abuse \geq 8, physical neglect \geq 8, emotional abuse \geq 10, emotional neglect \geq 15) to classify if participants fulfilled inclusion criteria (i.e. scored above cut-off on at least one category). The Norwegian translation of CTQ-SF has shown good reliability (Dovran et al., 2013).

The International Trauma Questionnaire (ITQ; Cloitre et al., 2018) was used to assess CPTSD. ITQ was developed by members of the ICD-11 Working Group for trauma-related disorders. ITQ consist of 6 items measuring PTSD and 6 items measuring disturbances in self-organization (DSO), that are used in this study. These are scored on a scale from 0 to 4 (0 = ‘not at all’, 1 = ‘a little bit’, 2 = ‘moderately’, 3 = ‘quite a bit’ and 4 = ‘extremely’) to indicate to what degree this symptom has been bothering to the respondent in the last month. The Norwegian translation of ITQ has shown good psychometric properties (Sele, Hoffart, Bækkelund, & Øktedalen, 2020).

Background information and sociodemographic data were registered with a generic form.

3.2. Primary outcome measure

Global Assessment of Functioning – Split version (GAF-S; Karterud, Pedersen, Loevdahl, & Friis, 1998) was used to assess psychosocial functioning. GAF-S is scored between 1 and 100, representing low to high functioning last 7 days. It consists of two subscales that assess global psychosocial functioning and severity of symptoms, and the lowest of these scores are used. GAF-S scores in this study were obtained based on semistructured interviews

conducted by raters blind to randomization. Relevant information from each interview was also conveyed to a second blind rater who gave an independent score, with the mean score of both raters determining the final score. This procedure has been shown to increase the reliability of the GAF scoring (Pedersen, Hagtvat, & Karterud, 2007). Raters had previously completed a web-based feedback training program for GAF-S scoring, shown to further strengthen reliability and validity (Støre-Valen et al., 2015). Interrater reliability between the two independent raters was found to be high (intraclass correlation coefficient (3.1) = 0.88, 95% CI: 0.85– 0.90). GAF scores were collected before treatment, after treatment, and at follow-up.

3.3. Secondary outcome measure

PTSD Symptom Scale – Self-Report (PSS-SR; Foa et al., 1993) assess the severity of PTSD symptoms with 17 self-report items, measuring three symptom dimensions (re-experiences, avoidance, and hyperarousal) Each item is scored, based on frequency and severity of the symptom, on a Likert scale from 0 (not at all or only one time) to 3 (almost always or five or more times a week). PSS-SR has shown satisfactory sensitivity, reliability, internal consistency, and validity. A cut-off score of 14 indicates clinically significant PTSD-symptoms (Coffey, Gudmundsdottir, Beck, Palyo, & Miller, 2006)

Other self-report instruments measuring general psychopathology, interpersonal problems, dissociative symptoms, self-destructive behaviour, and quality of life were collected. These are described in supplementary D, E, and F.

Self-report measures were collected at assessment, before treatment, after treatment and follow-up, via a secure web-based platform (www.checkware.no) in ordinary use at the hospital. Participants were provided with instructions and access-code and could choose to submit their responses at the clinic or in private. Regular reminders were sent to participants that had not completed the measures.

3.4. Individual treatment

To measure the frequency and quality of the individual treatment, both patients and therapists completed a form consisting of items asking about therapist competence, frequency, and length of treatment. Both therapists and patients also completed the *Working Alliance Inventory* (WAI; Hatcher & Gillaspay, 2006) consisting of 12 items measuring the degree of bond, and agreement on goals and tasks between therapist and patient. Both measures were administered at the start and end of treatment.

3.5. Power considerations

To estimate the effect size (δ) to be detected, we relied on Zlotnick et al (1997) who found effect sizes in the range of .80 to 1.10. With a more conservative effect δ at .45 and alpha = .05 (one-tailed), and an analysis of covariance, using the pretreatment score as the covariate with pre – treatment to post-treatment correlation of $r = .70$ (the typical value in psychotherapy research), then 31 patients in each group are needed to achieve power of .80 to detect a statistically significant effect. To account for attrition we therefore chose to recruit participants for five treatment groups of nine patients each, giving a total of 45 patients in each treatment condition.

3.6. Statistical analyses

Demographics, clinical characteristics, and individual treatment- data were analysed for group – differences at pre-treatment with t-tests for continuous variables and chi-square test for categorical data. Non-parametric tests were used if assumptions of normality were not met.

Linear mixed-models (LMM) were used to compare outcome trajectories in the two therapy conditions, with GAF and PSS-SR as outcome variables. This analytical method allows modelling of dependencies in nested data, for instance repeated measures within individual patients. Assumptions of LMM were checked and met. In building the models we started with only a fixed intercept and no random effects. We tested both a linear and nonlinear time-function by fitting a linear-spline model with a knot at the switching point. This model allows for differences in slopes before and after the knot, thereby accommodating the switching-design. Random intercept and slope were added if they significantly improved model-fit, using the Akaike Information Criteria (AIC). Finally, alternative covariance structures of the residuals were tested. Robust Maximum Likelihood (ML) was used for estimation (Fitzmaurice, Laird, & Ware, 2011). Both the linear and spline models were used to investigate differences in treatment trajectories between conditions. The final model chosen, based on the best model fit, includes random intercept with unstructured covariances, but without random slope. Within-group effect sizes were calculated using Hedges's g and interpreted based on classifications by Cohen (Cohen, 1988).

All statistical analyses were carried out using SPSS version 25.

3.7. Missing data

On different time-points between 6% and 42% had insufficient data to calculate GAF and mean PSS-SR scores, including missing scores for patients that dropped out. Rates of missing data were highest for

self-report measures collected at follow-up. Under the assumption of missing at random (MAR), missing data were handled using maximum likelihood estimation in the mixed models. To obtain unbiased estimates of means, standard deviations, and effect sizes we also employed multiple imputations. Twenty datasets for GAF and PSS-SR, with pre-treatment scores as predictors, were generated and pooled estimates were used to calculate means, standard deviations, and effect sizes.

4. Results

4.1. Patient characteristics, attrition, and comparability

In the experimental group, four participants dropped out between allocation and treatment start, six participants dropped out during treatment and three dropped out during follow-up. In the control condition, eight participants dropped out during the waiting period and eight dropped out during group treatment, leaving the total attrition rate at 32.5%. Of the 77 patients that started group treatment, 14 (18%) dropped out during treatment. We observed no significant differences between drop-outs and completers on pre-treatment scores or demographic variables (see supplementary G). Demographical information, treatment history, and prevalence of childhood trauma for the treatment samples can be seen in Table 1. The patients presented severe trauma histories and a high degree of co-occurring psychiatric diagnoses. The majority of the patients were unable to participate in work and had been in contact with mental health services for many years. A majority reported having been diagnosed with PTSD before their participation in this study.

The most prevalent forms of childhood abuse reported were emotional abuse (90.7%) and sexual abuse (75%). Most participants reported being exposed to several types of abuse. Almost all patients reported a history of depression. A little over half of the sample reported disturbances of self-organization consistent with ICD-11 criteria for CPTSD.

Based on statistical analyses we determined that there were no significant differences between the treatment-groups on patient characteristics or pre-scores on outcome variables. There were also no significant differences in patient – reported frequency of individual treatment or therapeutic alliance with individual therapist before or during treatment.

4.2. Treatment Effects

In the mixed-models we investigated if GAF and PSS-SR scores changed over time, and if these measures changed differently in the two groups participating in

Table 1. Sample and group characteristics.

Characteristic	Total (89)	EXP (Fitzmaurice et al., 2011)	CTR (Cohen, 1988)
Demographics			
Age	39.15 (9.9)	38.9(10.05)	39.4 (9.84)
Female gender	84.3%	84.1%	84.4%
Married or partner	48.6%	52.3%	35.1%
College-level education	51.4%	48.6%	54.1%
Living with children	36.1%	40%	32.4%
Occupational status*			
Work incapacity	82.4%	81.1%	83.8%
Student, full or part time	13.7%	11.1%	16.2%
Employed, full- or part-time	27%	27%	27%
Unemployed	2.2%	2.8%	2.7%
Treatment history			
Years since first contact with mental health services	16.16(10.07)	15.52(11.06)	16.84 (9.00)
Inpatient treatment ever	42.2%	44.1%	40%
Inpatient treatment last year	17.2%	17.6%	16.7%
Previous PTSD diagnosis or treatment	59.1%	55.9%	62.5%
Reported childhood abuse			
CTQ mean score	13.82 (3.48)	13.39(3.51)	14.21(3.44)
CTQ – Emotional abuse	90.7%	90.2%	91.1%
CTQ – Physical abuse	58.1%	58.5%	57.8%
CTQ – Sexual abuse	75.3%	72.5%	77.8%
CTQ – Emotional neglect	66.3%	61%	71.1%
CTQ – Physical neglect	68.6%	58.5%	77.8%
Number of CTQ abuse types	3.58 (1.12)	3.39(1.22)	3.76(1.00)
Clinical comorbidity			
MINI Number of comorbid axis-I disorders	5.04(2.15)	5.09 (2.07)	5.00 (2.25)
MINI any depressive disorder (present or lifetime)	91%	95.5%	86.7%
MINI any bipolar disorder (present or lifetime)	4.5%	4.5%	4.4%
MINI severe suicidality (scored above 2)	7.9%	6.8%	8.9%
MINI any anxiety disorder (present or lifetime)	82%	84.1%	80%
MINI substance abuse	11.2%	6.8%	15.6%
MINI any psychotic disorder (present or lifetime)	11.2%	9.1%	13.3%
MINI any eating disorder	9%	6.8%	11.1%
SCID-II Number of comorbid axis-II disorders	0.85 (1.18)	0.954 (1.31)	0.755(1.04)
PSS-I total	33.37 (8.21)	33.8 (8.48)	32.97 (8.04)
ITQ – disturbance of self – organization	56.2%	66.7%	45.9%

Note: Data presented as means (SD) or percentages. CTQ = Childhood Trauma Questionnaire – Short form; PSS-I = Posttraumatic Symptoms Scale – Interview; ITQ = International Trauma Questionnaire

*Participants can belong to more than one category.

stabilization-groups either immediately (EXP) or after a waiting period (CTR). The linear model estimated a significant effect of time for GAF ($t = 6.2$, $p > .001$) and PSS-SR ($t = -2.81$, $p > .05$) indicating significant treatment effects. Means, standard deviations (pre and post), effect sizes, and change trajectories are shown in Figure 2. We observed large within-group effect sizes in both conditions for GAF and medium effects for PTSD symptoms from assessment to follow-up.

However, as reported in Table 2 we observed no significant time x randomization interaction effects (GAF: $t = -1.35$, $p = .18$; PSS-SR: $t = 0.34$, $p = .97$) with a linear model over time. As predicted, the non-linear splines with a knot at the switching point improved model fit, indicating differences in trajectories before and after this time-point. However, neither time – variables were significant in interaction with randomization for GAF or PSS-SR (see Table 2). This indicates that contrary to the hypothesized effect, patients did not have different trajectories of change in both conditions independent of participation in stabilization group treatment.

5. Discussion

5.1. Main findings

The main aim of the present study was to evaluate the efficacy of group-based stabilization therapy focused on emotion regulation and skills-training delivered adjunct with individual therapy. We predicted that participating in stabilization group treatment would more effectively increase psychosocial functioning and reduce PTSD symptoms, than individual therapy alone.

The results show that although patients experienced improvements during the course of treatment, participation in stabilization group treatment did not significantly influence the trajectories of change, compared to individual therapy alone. Effect sizes indicate that most gains were experienced in psychosocial functioning while PTSD symptoms were reduced to a lesser degree. These moderate treatment gains should be interpreted in light of the substantial time and resources invested in the group treatment, involving 20 sessions of 90 minutes. The study therefore does not support the delivery of stabilizing group – treatment as an efficacious

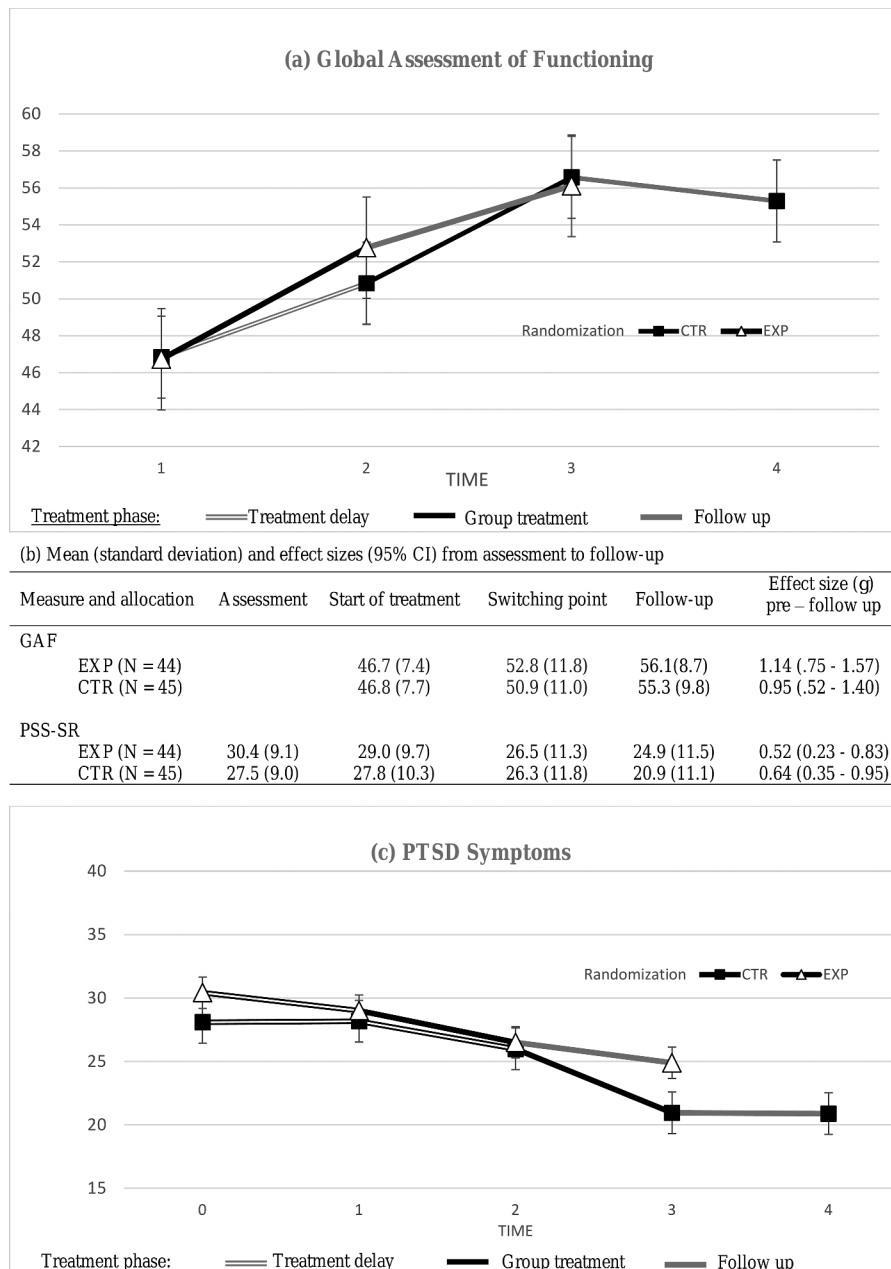


Figure 2. Treatment trajectories of immediate (EXP) or delayed (CTR) stabilizing group treatment measured on Global Assessment of Functioning (GAF) and PTSD Symptoms (PSS-SR). (a) The effect of treatment on primary outcome (GAF) with error bars. (b) The means, standard deviations and effect sizes of outcome measures of both conditions. (c) The effect of treatment on primary outcome (PSS-SR) with error bars.

adjunctive intervention for patients with PTSD related to childhood abuse.

The results from this study are in line with Dorrepaal, Thomaes (Dorrepaal et al., 2012), who similarly did not find significant differences between stabilizing group treatment and treatment as usual. In a recently published meta-analysis, Mahoney and colleagues (Mahoney et al., 2019) similarly observed superior effectiveness of group treatments for PTSD that included trauma-focused interventions, compared to psychoeducational interventions. The results also lend support to recent criticism raised against the phase-based model for treatment of CPTSD (De Jongh et al., 2016). The rationale for stabilization-

treatment is based on the notion that patients with childhood trauma and complex symptom-profiles will have difficulties tolerating an explicit trauma-focus, leading to symptom – exacerbation and adverse effect (Cloitre et al., 2012, 2010). However, trauma-history or symptom profile have been shown to be unrelated to symptom-exacerbations in trauma-focused treatment (Larsen, Wiltsey Stirman, Smith, & Resick, 2016) and does not predict treatment outcome (Minnen & Harned, 2012). In a study of patients with PTSD and psychosis for instance, symptom exacerbations and adverse events were more frequent in the wait-list condition than in the trauma-focused conditions (van den Berg et al., 2016). Such results have led researchers

Table 2. Multilevel mixed-models with GAF and PSS-SR as dependent variables.

Parameter/Outcome		GAF	PSS-SR
Linear Model	Fixed parameters		
	Intercept	42.1**(1.6)[38.9– 45.3]	30.5**(1.6)[27.3– 33.8]
	Randomization	1.2 (2.1) [3.0– 5.4]	–2.4 (2.2) [–6.8– 2.1]
	Time	5.0** (0.8)[3.4– 6.2]	–1.9*(0.6)[–3.2 – –0.5]
	Time *randomization	–1.3 (0.9) [–3.8– 0.6]	0.02 (0.8) [–1.5– 1.6]
	Random parameters		
Intercept	33.3**(7.9)	80.9** (16.2)	
AIC	1583.1	1669.4	
Spline Model	Fixed parameters		
	Intercept	43.6** (3.8)[36.3– 50.1]	30.8**(1.7)[27.5–34.1]
	Randomization	1.6 (4.6)[–7.8– 10.7]	–3.6 (2.3) [–8.1– 0.9]
	Time 1	3.3 (3.3)[–3.4– 9.9]	–2.4* (1.2) [–4.8 – –0.1]
	Time 2	3.1 (2.1)[–0.1– 7.2]	0.01 (1.4) [–3.0– 3.0]
	Time1 *randomization	–1.6 (4.1) [–9.8– 6.5]	2.8 (1.5) [–0.1– 5.8]
	Time2 * randomization	–1.7 (2.4)[–4.9– 4.5]	–2.9 (1.7) [–6.2– 0.4]
	Random parameters		
	Intercept	32.80**(7.8)	80.1** (14.9)
	AIC	1573.8	1657.2

Note. Standard error in parentheses, 95% Confidence Intervals in brackets.

* $p < 0.05$

** $p < 0.01$

GAF = Global Assessment of Functioning; PSS-SR = PTSD Symptom Scale – Self-Report

to contend that stabilization-treatment unnecessarily prolongs treatment for patients and only delays access to effective interventions (De Jongh et al., 2016). The current study adds support to this criticism since the benefits of stabilizing treatment on PTSD symptoms are small. Proponents of phase-based treatments however, argue that a preparatory stabilization-phase also can enhance treatment gains in later trauma-focused treatment (Cloitre, 2015). As with previous studies on group-based stabilization-treatment, this hypothesis cannot be investigated in this study, due to a lack of a control group that is being offered trauma-focused treatment before or after stabilization-treatment.

The observed effects in both conditions in this study indicate that improvement in psychosocial functioning for this patient group does not necessarily hinge on large reductions in PTSD symptoms. Treatments without an explicit trauma – focus may help patients cope with distress and thereby increase functioning, without necessarily reducing symptoms (Stadtman et al., 2018). Contrary to our first hypothesis however, improvements in psychosocial functioning were not directly influenced by group participation, but generally improved over time. Although there is some evidence to suggest that trauma-focused treatments also can improve psychosocial functioning in PTSD, there is a general lack of research focusing on this outcome (Reich, Nemeth, & Acierno, 2019). Future research should investigate interventions that can improve psychosocial functioning and how this relates to improvements in symptoms.

It should be noted that a majority of the group-participants chose to discuss the group topic with their individual therapists, indicating that they found the experience important, and some patients experienced substantial gains during the study period. Also, stabilization treatment might be more effective in different PTSD populations and settings. Eichfeld, Farrell (Eichfeld et al., 2018) for instance

observed very large within-person effect-sizes and remission rates from stabilization-treatment for PTSD in a large study conducted in South-East Asia, albeit without a control condition. In that study, no clients had previous treatment-histories and the authors conclude that stabilization-treatment is effective, safe, and easily disseminated in post-conflict settings. Meanwhile, the current study was conducted in a specialist clinic with patients referred from other mental health clinics. This might have had an impact on the chronicity of the recruited participants, as these patients are usually referred based on lack of progress in previous treatments or perceived complexity by referring clinicians. All patients had previous treatment histories, with a mean of 16 years since their first contact with mental health services.

5.2. Limitations

It is worth noting that the observed effects in the present study contrast the two previous investigations with similar treatments, patient-samples, and research designs (Dorrepal et al., 2012; Zlotnick et al., 1997), who both reported larger effect-sizes in the group-conditions. This should be interpreted in light of some noteworthy differences between the studies. First, the current study recruited a more diverse sample of patients. Both previous investigations included only females, while men were also included in the current study, albeit in small numbers ($N = 8$). We observed smaller treatment gains and higher drop-out rates in male participants, although the small size of this subgroup limited the statistical power to detect significant differences. Furthermore, female-only groups have been shown to be more effective than mixed-gender groups in substance abuse treatment (Prendergast, Messina, Hall, & Warda, 2011), with increased group cohesion and feelings of safety (Greenfield, Cummings, Kuper, Wigderson, & Koro-Ljungberg, 2013), and it is conceivable that this

difference would be equally important for women with abuse-related PTSD. Also, in both previous investigations, all participants fulfilled criteria for Disorders of Extreme Stress (Pelcovitz et al., 1997), an earlier version of CPTSD criteria, while the current study included both patients with and without CPTSD according to ICD-11 criteria. Lastly, the treatment-protocol used is not identical to those used in the previous studies, since these were not available for translation. Although the rationale, content, and broad themes covered are similar, specific adaptations and additions were made, such as the inclusion of mindfulness-focused interventions and less emphasis on cognitive-behavioural interventions.

The results should further be interpreted in light of some other important limitations. Since the individual treatment in both conditions was delivered by therapists in other services than the study-clinic, the content and frequency of this treatment were not protocolled. The use of stabilization interventions in individual therapies might have impacted the differences between conditions. Across conditions, seventy percent of participants reported receiving individual treatment less frequently than once a week, and 45% had to change therapists during the study period primarily due to staff turnover. This might have contributed to a diminished treatment response across conditions. We also experienced more attrition than expected, influencing statistical power to detect treatment differences, although the number of patients in each group at the switching point (34 vs 36) was within the parameters set by the power analysis. Furthermore, the delayed-treatment design makes it impossible to infer differential effects after the end of treatment, since patients in both conditions had received the study treatment at that time-point. Finally, the current study did not control for medication use, which may have confounded results.

5.3. Conclusion

The results of this study do not support offering stabilizing group treatment as an add-on to individual therapy in specialist healthcare settings, for patients with PTSD and experiences of childhood abuse. Together with the results of previous investigations, these results indicate that stabilization groups should primarily be considered if preferred by the patient or if other evidence-based treatments are unavailable. Future studies could investigate if stabilization groups would be better applied to lower levels of care or in settings where large – scale training of therapist in trauma-focused treatments are difficult (Eichfeld et al., 2018). Investigations should also examine if stabilization-treatment can bolster treatment gains from later or concurrent trauma-focused treatment, and increase motivation for trauma-focused interventions in patients who are

reluctant to engage in such treatment. To enable strong inferences, studies should include clear treatment protocols, fidelity ratings, and robust research-designs, including longer follow-up and active treatment-controls.

Note

1. These patients were included in another trial investigating specialized treatment for this diagnostic group.

Disclosure statement

The authors have nothing to disclose.

Funding

The study was funded by Modum Bad Psychiatric Hospital. This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to ethical approval and confidentiality agreements made with participants, but are available from the corresponding author on reasonable request.

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