



Skills Training in Affective and Interpersonal Regulation Narrative Therapy for women with ICD-11 complex PTSD related to childhood abuse in Japan: a pilot study

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ABSTRACT

Background: Skills Training in Affective and Interpersonal Regulation (STAIR) Narrative Therapy (SNT) has shown efficacy in alleviating symptoms of posttraumatic stress disorder (PTSD) and improving emotion regulation and interpersonal skills among individuals with complex trauma, such as childhood abuse. Although this therapy is expected to be effective for patients with complex PTSD (CPTSD), no study has directly assessed diagnostic and symptom outcomes. Moreover, the potential of therapy to achieve good outcomes in non-Western countries remains unclear.

Objective: This pilot study examined the feasibility, safety, and outcomes of SNT for CPTSD among women with a history of childhood abuse in a Japanese clinical setting.

Methods: Ten women aged 21–54 years ($M = 29.1$ years) with childhood-abuse-related ICD-11 CPTSD were enrolled in this study. The International Trauma Interview and International Trauma Questionnaire were administered to diagnose CPTSD and assess its severity. Symptoms of dissociation and depression, difficulties in emotion regulation and interpersonal relationships, quality of life, and negative cognitions were assessed pretreatment, midtreatment (after the STAIR phase), and immediately posttreatment (after the Narrative Therapy phase), in addition to 3 months after treatment.

Results: Seven of the 10 participants completed the treatment. The therapists' adherence to the therapy protocol was 96.4%, ranging from 93.6% to 100% across therapists. Serious adverse events were not observed. Among the seven completers, six at posttreatment and all at follow-up no longer met CPTSD diagnosis. Exploratory analyses using the linear mixed-effects model showed significant improvements at posttreatment and follow-up for almost all the variables.

Conclusions: The results provide preliminary evidence for the feasibility and safety of SNT for CPTSD in a Japanese clinical setting. This study is the first to report the use of SNT for individuals diagnosed with ICD-11 CPTSD using reliable clinician and self-report measures.

Terapia narrativa de entrenamiento de habilidades de regulación afectiva e interpersonal para mujeres con tept-complejo según la cie-11 relacionado con abuso en la infancia en japon: un estudio piloto

Antecedentes: La terapia narrativa (SNT en su sigla en inglés) de Entrenamiento de habilidades en regulación afectiva e interpersonal (STAIR en su sigla en inglés) ha demostrado eficacia en el alivio de los síntomas del trastorno de estrés postraumático (TEPT) y mejorar regulación emocional y las habilidades interpersonales entre individuos con trauma complejo, como el abuso en la infancia. Aunque esta terapia se espera que sea efectiva para pacientes con TEPT complejo (TEPT-C), ningún estudio ha evaluado directamente su estado diagnóstico y síntomas. Además, el potencial de la terapia para alcanzar resultados parecidos en países no Occidentales sigue sin estar claro.

Objetivo: Este estudio piloto examinó la viabilidad, seguridad y resultados de la SNT para TEPTC en mujeres con historia de abuso en la infancia en un contexto clínico japonés.

Métodos: Se inscribieron en este estudio diez mujeres de edad entre los 21–54 años ($M = 29.1$) con TEPT-C según la CIE-11 relacionado con abuso infantil. Se aplicó la Entrevista Internacional de Trauma y el Cuestionario Internacional de Trauma para diagnosticar TEPT-C y evaluar su gravedad. Los síntomas de disociación y depresión, dificultades en la regulación emocional y relaciones interpersonales, calidad de vida y cogniciones negativas se evaluaron durante el pretratamiento, a la mitad del tratamiento (después de la fase STAIR) e inmediatamente postratamiento (después de la fase de Terapia Narrativa), además de a los 3 meses después del tratamiento.

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Trastorno de Estrés Postraumático; TEPT Complejo; Terapia Narrativa STAIR; abuso en la infancia; Entrevista Internacional de Trauma; Cuestionario Internacional de Trauma

关键词

创伤后应激障碍; 复杂性 PTSD; STAIR叙事疗法; 童年期虐待; 国际创伤访谈; 国际创伤问卷

HIGHLIGHTS

- This study examined the feasibility and safety of STAIR Narrative Therapy for women with ICD-11 CPTSD related to childhood abuse in a Japanese clinical setting.
- High therapy adherence was observed.
- No serious adverse events occurred.

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Resultados: Siete de las 10 participantes completaron el tratamiento. La adherencia de los terapeutas al protocolo de la terapia fue del 96.4%, con una variación del 93.6% al 100% entre terapeutas. No se observaron eventos adversos serios. Entre las siete que completaron el tratamiento, seis en el postratamiento y todas al seguimiento ya no cumplían con el diagnóstico de TEPT-C. Los análisis exploratorios que utilizaron el modelo lineal de efectos mixtos mostraron una mejoría significativa en el postratamiento y seguimiento para casi todas las variables.

Conclusiones: Los resultados entregan evidencia preliminar para la viabilidad y seguridad de la SNT para TEPT-C en un contexto clínico japonés. Este estudio es el primero en reportar el uso de la SNT para individuos diagnosticados con TEPT-C según la CIE-11 usando medidas clínicas y de auto-reporte confiables.

日本有关童年期虐待的 ICD-11 复杂性 PTSD 女性的情感和人际调节叙事疗法技能培训：一项试点研究

背景: 情感和人际调节技能培训 (STAIR) 叙事疗法 (SNT) 在减轻创伤后应激障碍 (PTSD) 症状和改善有复杂性创伤 (例如童年期虐待) 个体的情绪调节和人际交往能力方面已显示出疗效。尽管这种疗法对于复杂性 PTSD (CPTSD) 患者预期有效, 但没有研究直接评估其诊断状态和症状。此外, 在非西方国家取得类似结果疗法的潜力仍不清楚。

目的: 本试点研究在日本临床环境中考查了有童年期虐待史女性中 SNT 疗法 CPTSD 的可行性、安全性和结果。

方法: 本研究招募了 10 名年龄在 21–54 岁 (M = 29.1 岁) 且患有童年期虐待相关 ICD-11 CPTSD 的女性。国际创伤访谈和国际创伤问卷用于诊断 CPTSD 并评估其严重程度。在治疗前、治疗中期 (STAIR 阶段后) 和治疗后 (叙事疗法阶段后) 以及疗法后 3 个月评估解离和抑郁症状、情绪调节和人际关系困难、生活质量和负性认知。

结果: 10 名参与者中有 7 名完成了治疗。治疗师对治疗方案的依从率为 96.4%, 从 93.6% 至 100% 不等。没有观察到严重不良事件。在 7 名完成者中, 有 6 名在疗法后和所有随访中均不再符合 CPTSD 诊断。使用线性混合效应模型的探索性分析显示, 几乎所有变量在治疗后和随访中都有显著改善。

结论: 结果为日本临床环境中 SNT 疗法 CPTSD 的可行性和安全性提供了初步证据。本研究首次使用可靠的临床和自我报告测量报告了诊断为 ICD-11 CPTSD 个体中 SNT 的使用。

1. Introduction

Complex posttraumatic stress disorder (CPTSD) is a new diagnosis adopted by the World Health Organization (WHO, 2018) in addition to posttraumatic stress disorder (PTSD) (Maercker et al., 2013) under the general parent category of ‘disorders specifically associated with stress’ in the 11th revision of the International Classification of Diseases (ICD-11). While PTSD and CPTSD may develop following exposure to an extremely threatening or horrific event or a series of events, CPTSD more commonly follows prolonged or repetitive events from which escape is difficult or impossible (WHO, 2018). PTSD comprises three core symptom clusters: re-experiencing trauma, avoidance of trauma reminders, and a heightened sense of threat. CPTSD comprises three PTSD clusters and three additional clusters described as ‘disturbances in self-organization’ (DSO) symptoms: affect dysregulation, negative self-concept, and disturbances in relationships (Maercker et al., 2013). A review of current evidence regarding ICD-11 PTSD and CPTSD supports the construct validity of these diagnoses and clarifies their clinical characteristics (Brewin et al., 2017). Compared with PTSD, CPTSD is more frequently associated with multiple and sustained traumas, higher levels of comorbid symptoms, greater functional impairment, and lower psychological well-being (e.g. Brewin et al., 2017;

Cloitre et al., 2019; Hyland, Shevlin, Fyvie, & Karatzias, 2018).

Treatment for CPTSD remains to be investigated. Recent systematic reviews and meta-analyses have used evidence from clinical trials involving PTSD diagnosed according to the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) to evaluate the potential efficacy of the treatments used for PTSD for the treatment of CPTSD (Coventry et al., 2020; Karatzias et al., 2019; Melton et al., 2020). Karatzias et al. (2019) conducted a systematic review and meta-analysis of randomised controlled trials (RCTs) of PTSD treatments that measured at least one DSO symptom cluster. They found that cognitive behavioural therapy and exposure therapy were effective for PTSD and DSO symptoms. However, the benefits were smaller for all symptom clusters among patients with a history of childhood trauma, which is a patient group representative of those likely to have CPTSD. Another systematic review of psychological and pharmacological interventions for PTSD following complex traumatic events concluded that trauma-focused psychological interventions are effective in reducing PTSD symptoms, anxiety, depression, and sleep problems (Coventry et al., 2020). Moreover, they reported that phase-based interventions that included skills-based strategies and trauma-focused strategies were promising interventions for DSO symptoms. The network meta-analysis, which

compared multiple intervention components and their combination, suggested that multicomponent interventions, which can include phase-based approaches, were the most effective treatment package for managing PTSD in complex trauma (Coventry et al., 2020).

Skills Training in Affective and Interpersonal Regulation (STAIR) Narrative Therapy (SNT), initially developed as a phase-based intervention for childhood abuse survivors, is one of the most tested treatments for patients likely to have CPTSD (Cloitre, Cohen, & Koenen, 2006). The first module (STAIR) includes skill training to develop emotional and interpersonal resources that have been compromised by long-term complex trauma. The second module (Narrative Therapy) employs exposure and cognitive restructuring techniques to alleviate PTSD symptoms. Three RCTs demonstrate the clinical efficacy of SNT for PTSD-related symptoms, dissociation, emotion regulation, and interpersonal relationships (Cloitre, Koenen, Cohen, & Han, 2002; Cloitre et al., 2010; Oprel et al., 2021); moreover, in one benchmark study, flexible application of the protocol was as effective as strict application (Levitt, Malta, Martin, Davis, & Cloitre, 2007). SNT has been reported to be effective, regardless of the level of dissociation (Cloitre, Petkova, Wang, & Lu Lassell, 2012; Hoeboer et al., 2020); therefore, it may be an appropriate treatment for CPTSD. However, research on SNT has been conducted only in Western countries, and not in Japan or other Asian countries. More importantly, no clinical trial has directly assessed CPTSD diagnostic status and symptoms using a structured interview for the ICD-11 CPTSD (i.e. the International Trauma Interview [ITI]; Roberts, Cloitre, Bisson, & Brewin, 2019).

This study aimed to examine the feasibility and safety of SNT for ICD-11 CPTSD in a Japanese clinical setting. Moreover, we aimed to compare participants' symptom changes with previous outcomes from Western countries. We also examined individualised modifications and cultural adaptations of SNT.

2. Methods

2.1 Participants and procedure

We conducted a single-arm study of SNT for ICD-11 CPTSD in a Japanese clinical setting. The study was approved by the ethics committees of the National Center of Neurology and Psychiatry and Hyogo Institute for Traumatic Stress and was conducted in accordance with the Declaration of Helsinki (Clinical Trial Registry ID: UMIN000030889). Written informed consent was obtained from all participants.

Most inclusion and exclusion criteria were similar to those used in a previous RCT on SNT for abuse-related PTSD (Cloitre et al., 2010). The inclusion criteria were being female, being aged 18–65 years, having a principal diagnosis of ICD-11-defined CPTSD related to childhood sexual or physical abuse before age 18, and having Japanese as one's native language. Experiences of childhood abuse and the diagnosis of CPTSD were initially evaluated by psychiatrists (trauma specialists) and then confirmed using the clinician-administered ITI (Roberts et al., 2019), which was recently developed for ICD-11 PTSD and CPTSD. The exclusion criteria were current substance dependence, schizophrenia and related disorders, significant cognitive impairment, untreated bipolar disorder, and acute suicidality requiring hospitalisation or referral to the emergency room in the past 3 months. If candidates received psychotherapy or pharmacological treatment, the treatment continued during SNT if it was not PTSD-focused and was ongoing for at least 3 months before study entry. Patients were asked to make no changes in their psychopharmacological prescriptions, except for sleep medications. However, if symptoms worsened, anti-psychotics and anxiolytics were permitted as temporary abortive medications.

Participants were recruited from urban and rural outpatient mental health clinics and a national hospital, between January 2018 and August 2020. During this recruitment period, 17 individuals were referred to the study, 3 did not meet the inclusion criteria (ICD-11 CPTSD diagnosis), 4 met the exclusion criteria (acute suicidality), and none declined to participate. Ultimately, 10 were enrolled in this study.

2.2 Measures

We used the Childhood Trauma Questionnaire (CTQ; Bernstein et al., 2003) to assess the history of early life maltreatment at baseline. We administered the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) to evaluate the comorbidities and psychiatric conditions that met the exclusion criteria. We assessed comorbid borderline personality disorder (BPD) with the Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II; First, Gibbon, Spitzer, Williams, & Benjamin, 1997).

We evaluated CPTSD diagnosis and severity using the ITI, a two-part semi-structured clinical interview that assesses symptoms of PTSD and DSO. A diagnosis of ICD-11 CPTSD requires that both the PTSD and DSO criteria be satisfied. To meet the PTSD or DSO criteria, the endorsement (score ≥ 2) of at least one of the two items from each of the three symptom clusters associated with PTSD or DSO and functional impairment associated with these symptoms. The

ITI generates severity scores for PTSD (range = 0–24), DSO (range = 0–24), and combined CPTSD (range = 0–48). A previous validity study with a Swedish sample reported good inter-rater agreement (Krippendorff's $\alpha = .76$), satisfactory internal consistency for PTSD (.86) and DSO (.89), and concurrent validity (Bondjers et al., 2019).

The Japanese version of the ITI was translated from English to Japanese by a clinical psychologist (MN) and psychiatrist (YK) and then back-translated to English by a bilingual clinical psychologist (RN-O). Finally, the back-translated English version was sent to and approved by the original authors (Roberts and Cloitre, February 19, 2021). The ITI test version 2.0 (Roberts, Cloitre, Bisson, & Brewin, 2018) was implemented during data collection. However, the diagnosis and severity assessment followed the algorithm of the latest version, version 3.2, with fewer items (Roberts et al., 2019). Independent evaluators administered ITI at pretreatment, posttreatment, and 3 months after treatment.

We assessed:

- self-reported CPTSD symptoms using the International Trauma Questionnaire (ITQ; Cloitre et al., 2018), which has been validated for use in several languages and countries;
- PTSD symptoms with the Posttraumatic Diagnostic Scale (PDS; Foa, 1995);
- dissociative symptoms with the Dissociative Experience Scale-II (DES-II; Carlson et al., 1993);
- emotion dysregulation using the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) and the General Expectancy for Negative Mood Regulation Scale (NMR; Catanzaro & Mearns, 1990);
- interpersonal problems using the short version of the Inventory of Interpersonal Problems (IIP-32; Barkham, Hardy, & Startup, 1996);
- depression with the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996);
- anxiety using the State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, & Lushene, 1970);
- quality of life using the WHO Quality of Life-BREF (WHOQOL-BREF; WHOQOL Group, 1998);
- trauma-related negative thoughts and beliefs with the Posttraumatic Cognitions Inventory (PTCI; Foa, Ehlers, Clark, Tolin, & Orsillo, 1999).

These psychological and clinical measures were implemented at pretreatment, midtreatment (after the STAIR phase), posttreatment, and 3 months after the treatment. Additionally, PDS and BDI-II were used to monitor treatment progress at each treatment session. The details of validated measures, including information on the Japanese versions and the critical values of the reliable change index (RCI) (Jacobson

& Truax, 1991), are included in the supplementary materials.

For feasibility, we recorded dropout rates and participants' reasons for dropping out, therapists' adherence to the therapy protocol using a checklist of key elements (agenda) for each session, and the duration and number of sessions and time per session required for treatment. We defined 'dropout' as when a participant did not complete the entire treatment protocol. To assess safety, therapists recorded the occurrence and course of adverse events (i.e. suicidal ideation, self-harm behaviour, and other medical condition changes that require attention) and serious adverse events (i.e. an adverse event that is life-threatening and requires inpatient hospitalisation or potentially results in permanent impairment), in addition to monitoring the BDI-II (suicidal ideation item) and MINI (suicidal risk section) at each treatment session.

2.3 Treatment

STAIR Narrative Therapy (SNT) is a 16-session manualized treatment delivered in weekly 60 min individual-format sessions (Cloitre et al., 2006). The STAIR module comprises eight sessions focused on skills training for (a) emotion regulation (sessions 1–4), namely, emotional awareness, soothing negative emotions, enhancing positive emotions, coping with dissociation, and distress tolerance, and (b) interpersonal functioning (sessions 5–8), including exploring and revising interpersonal schemas, assertiveness, and flexibility in interpersonal situations. Narrative Therapy is a modified version of prolonged exposure that focuses on processing emotions associated with traumatic memories and identifying interpersonal schemas derived from traumatic experiences. Because flexible application of the protocol is recommended, we allowed a maximum of 25 sessions, considering the maximum number reported in previous studies (Levitt et al., 2007). We considered that the baseline in the latest SNT manual (Cloitre, Cohen, Ortigo, Jackson, & Koenen, 2020) was 18–20 sessions; however, this can be tailored to patients' individual needs. Cloitre, Jackson, and Schmidt (2016) presents a session-by-session description of SNT.

Treatment was delivered by two psychiatrists and four clinical psychologists experienced in trauma treatment, who completed a 2-day workshop led by the treatment developer (Cloitre; September 12–13, 2017). Five therapists were female, and four had experience with more than one case of SNT under session-by-session supervision. To maintain treatment fidelity, four cases, including therapists who were new to SNT, received individual supervision with Dr. Susan Paula, a senior clinical psychologist with extensive experience in psychological interventions, particularly SNT. Three cases were conducted with

full session-by-session supervision, and one case had several on-demand sessions. Supervision primarily entailed guidance on the proper implementation of each treatment module and modifications for specific client problems and conditions. Furthermore, therapists regularly held conferences to review cases and share supervision content.

Table 1 includes the treatment foci and personalised modifications for each participant, as reported by the therapist. Treatment foci were tailored to each individual. In addition to increasing the number of sessions, modifications included providing psychoeducation on comorbid disorders, creating a safety plan before beginning the narrative, emphasising body-focused emotion regulation, attempting empty chair work to soothe the childhood self and deepen self-compassion, and modifying trauma narratives to a written format.

2.4 Statistical analysis

We computed the mean and standard deviation, when appropriate. Linear mixed-effects models (LMMs) were used to examine changes from pre- to posttreatment or follow-up on all outcome measures. Repeated measurements were considered at four time points: pre- (0 weeks), mid- (after the STAIR phase; 17.3 ± 2.4 weeks), and posttreatment (after the Narrative Therapy phase; 37.1 ± 9.4 weeks) and at follow-up (3 months after the treatment; 52.4 ± 10.3 weeks). The dependent variable was ITI CPTSD severity or every other symptom outcome. We then included participants as a random effect. Statistical significance was set at two-tailed $p < 0.05$, and effect sizes for changes in symptom scores between the pre- and posttreatment (or follow-up) were calculated using Cohen's d , where coefficients of 0.2, 0.5, and 0.8 indicate minimum values for small, medium, and large effects, respectively (Cohen, 1988). We calculated the effect size for completers using the formula: $d = (M_{\text{pre}} - M_{\text{post}}) / SD_{\text{pooled}}$, where $SD_{\text{pooled}} = \sqrt{(SD_{\text{pre}}^2 + SD_{\text{post}}^2)/2}$. All statistical analyses were performed using SPSS version 27.0 (IBM Corp., Tokyo, Japan). We determined the loss of CPTSD or PTSD diagnosis after treatment based on whether the participant fully met the CPTSD or PTSD diagnostic criteria, as per the ITI.

3. Results

3.1 Baseline demographic and clinical characteristics

Table 1 summarises each participant's chief complaint, trauma type, and comorbid disorders. Table 2 lists the participants' baseline characteristics. Our sample comprised 10 female patients with CPTSD, aged 21–54 years ($M = 29.1$, $SD = 10.7$). All

participants had experienced long-term, repetitive, and multiple forms of abuse since early childhood. All CTQ sub-scores, except those for physical neglect (moderate), were in the severe range (Table 2). All participants experienced multiple traumas (range = 2–6; $Mdn = 3.5$; assessed using the PDS). Patients presented with a range of 0–4 current comorbid disorders ($Mdn = 2.0$; assessed using MINI), including two who met the diagnostic criteria for BPD using the SCID-II, nine with moderate or severe PTSD (≥ 21 on the PDS; Foa, 1995), and eight with severe depression (≥ 29 on the BDI-II; Beck et al., 1996).

3.2 Feasibility of treatment

Seven of the 10 participants completed the treatment. Of the three participants who dropped out, one experienced panic attacks that prevented her from regularly coming to the clinic (completed treatment up to Session 6), another experienced difficulty continuing after the trauma narrative (completed treatment up to Session 10), and the third was unable to come to the hospital because of the COVID-19 pandemic (completed treatment up to Session 14). The COVID-19 pandemic also led to a 3-month follow-up delay for one of the participants who completed the treatment.

Therapists' adherence to the therapy protocol was 96.4% (1562/1621) based on 114 sessions. Adherence ranged from 93.6% to 100% across the therapists. There was variation in SNT treatment duration ($M = 6.7$, $SD = 2.1$; range = 4–11 months) and number of sessions ($M = 23.9$, $SD = 1.8$; range = 20–25) for completers and mean minutes per session ($M = 71.7$, $SD = 13.9$) for all participants. In certain cases, the sessions were conducted multiple times to accommodate individual needs. For example, during the STAIR phase, Session 3 was sometimes divided into three individual sessions focused on the body, thought, and behaviour, which is standard according to the latest manual (Cloitre et al., 2020). During the Narrative Therapy phase, one session was sometimes split into two, with each session focusing on the trauma narrative and scheme analysis. Up to 25 sessions were allowed; however, there were two cases of additional sessions after the posttreatment assessment. In one case, the patient was required to end sessions because she relocated; in the other case, the therapist determined that additional narrative sessions would be beneficial because the patient experienced multiple traumatic experiences.

3.3 Safety of treatment

Serious adverse events were not observed. Suicidal ideation was defined as a score of ≥ 2 on the BDI-II suicidal ideation item. Six of the 10 patients had suicidal ideation at least once during treatment (six in STAIR and three in Narrative Therapy). None of the

Table 1. Overview of each participant's clinical information and treatment application.

ID (Age)	Chief complaints (symptoms)	Trauma type	Comorbidities (MINI, SCID-II)	Treatment focus	Personalised modifications	Clinically important changes
P1 (20s)	Emotional dysregulation (self-harm and sexual deviance); Compulsion; Guilt; Suicidal ideation	Childhood sexual and emotional abuse	MDD; Social phobia; OCD; GAD	Practice of emotion regulation and assertiveness	Added psychoeducation on OCD; Attempted empty chair work after the narrative to soothe the childhood self and deepen self-compassion	Decreased sense of self-blame and self-harm behaviours; Increased self-esteem and self-compassion
P2 (20s)	Severe dissociation; Sleep disorder (severe nightmare, fear of darkness); Eating disorder; Interpersonal difficulties	Childhood physical, sexual, and emotional abuse and neglect	Dysthymia; Agoraphobia; Bulimia nervosa	Reduction of nightmares and dissociation	Added psychoeducation on sleep and eating; Attempted nightmare prescription to deal with severe nightmares	Decreased episodes of pathological dissociation
P3 (50s)	Emotional numbness; Dissociation; Pervasive self-blame; Interpersonal difficulties (lack of assertiveness)	Childhood physical and emotional abuse and neglect; Traumatic death	Dysthymia; Social phobia	Emotional awareness; Reduction of dissociation; Practice of relaxation and assertiveness	Attempted empty chair work to express her feelings to her deceased mother; Used the responsibility pie to discuss her self-blame	Increased emotional awareness and decreased dissociation; Decreased self-blame; Improved relationship with children; Feeling of being more relaxed around others
P4 (20s)	Intrusive symptoms; Significant fear of men; Feelings of hopelessness	Childhood sexual and emotional abuse; Traumatic death	Agoraphobia	Reduction of PTSD and recurrent depressive symptoms	Added psychoeducation on and treatment for anxiety disorder; Added psychoeducation on avoidance of trauma reminders	Dropped out due to anxiety disorder that made clinic visits difficult
P5 (20s)	Intrusive symptoms; Significant fear of men; Difficulty going out	Childhood physical abuse; Adolescent indecent assault	(None)	Understanding the impacts of abuse; Practice of emotion regulation and interpersonal skills	Emphasized understanding the role of emotions and what it means to feel them	Increased awareness of abuse and emotions; More natural interpersonal relationships
P6 (30s)	Significant insomnia; Memory loss; Headaches	Childhood sexual and physical abuse; Domestic violence	(None)	Understanding the impacts of abuse and PTSD symptoms	(None)	Dropped out after the first trauma narrative (presumably due to the difficulty in ending the relationship with the perpetrator)
P7 (20s)	Severe dissociation; Emotional dysregulation; Interpersonal difficulties	Childhood sexual and physical abuse; Adolescent sexual assault	MDD; Agoraphobia; Psychotic disorder*; BPD	Reduction of dissociation; Practice of interpersonal skills	Emphasized body-focused emotion regulation to feel emotions without dissociation; Added sessions focusing on interpersonal relationships before the last session	Improved family relationships (able to get support and express opinions); Reduced dependence on others; More adjusted distance from people, including the abuser
P8 (20s)	Emotional dysregulation (especially anger); Maltreatment of her own child; Compulsion; Interpersonal difficulties	Childhood physical and emotional abuse; Adolescent indecent assault	Bipolar disorder; Agoraphobia; OCD; GAD; BPD	Emotion regulation, especially anger control; Maintenance of interpersonal relationships	Added anger management over multiple sessions; Provided her husband with psychoeducation on her symptoms and treatment rationale	Improved emotion regulation skills; Communicated her needs without being aggressive; Fewer marital fights
P9 (20s)	Significant fear of the perpetrator; Intrusive symptoms; Emotional numbness	Childhood sexual, physical, and emotional abuse	(None)	Being able to experience emotions; Reduction of PTSD symptoms and negative cognitions	Modified narrative work in written format (she refused to record or listen to her voice); She wrote the narratives and listened to the therapist read them during session and rewrote them for homework	Decreased sense of self-blame; No more risky behaviour based on the schema of 'I don't care what happens to me'; Changed her mind about not getting married or pregnant
P10 (30s)	Depression; Strong sense of helplessness	Childhood physical and emotional abuse; Domestic violence	MDD; Agoraphobia	Reduction of PTSD and recurrent depressive symptoms	Emphasized body-focused emotion regulation; Modified narrative work in written format (she was at a loss for words when recounting traumatic experiences)	Symptoms were not completely improved, but trauma symptoms, depression, and a strong sense of helplessness were reduced

Abbreviations: MINI, Mini-International Neuropsychiatric Interview; SCID-II, Structured Clinical Interview for DSM-IV Personality Disorders; MDD, major depressive disorder; OCD, obsessive-compulsive disorder; GAD, generalized anxiety disorder; PTSD, posttraumatic stress disorder; and BPD, borderline personality disorder.

*P7 met the criteria for psychotic disorder according to the MINI but was not clinically diagnosed with schizophrenia (symptoms were related to PTSD or dissociative disorders). Therefore, the patient was not excluded from the study.

Table 2. Baseline characteristics of the participants ($N = 10$).

Variable	
Age, years: mean (<i>SD</i>)	29.10 (10.65)
Education: <i>n</i>	
Junior high school graduate	2
High school graduate	3
University student	2
University graduate	3
Marital status: <i>n</i>	
Single	6
Married	2
Divorced	2
Current employment: <i>n</i>	
Full-time	1
Part-time	2
Unemployed (including students)	7
Number of current Axis-1 disorders, excluding PTSD: mean (<i>SD</i>)	2.00 (1.67)
Co-occurring BPD: <i>n</i>	2
≥ 1 Suicide attempt, lifetime: <i>n</i>	6
Repeated abuse: <i>n</i>	10
Age of first abuse, years: mean (<i>SD</i>)	3.80 (2.66)
Duration of abuse, years: mean (<i>SD</i>)	12.00 (4.08)
Years since the last incident of abuse: mean (<i>SD</i>)	13.00 (9.84)
Medication, any: <i>n</i>	8
Antipsychotics	4
Antidepressants	4
Anxiolytics	3
Mood stabilisers	0
Hypnotics	3
Childhood Trauma Questionnaire, total score: mean (<i>SD</i>)	79.70 (17.30)
Emotional abuse	18.80 (5.77)
Physical abuse	13.60 (5.95)
Sexual abuse	14.60 (7.96)
Emotional neglect	21.40 (4.86)
Physical neglect	11.30 (2.95)

Abbreviations: *SD*, standard deviation; PTSD, posttraumatic stress disorder; and BPD, borderline personality disorder.

patients had made a concrete plan, self-harmed, or attempted suicide. One patient experienced panic attacks in the STAIR phase, which caused her to drop out. Other adverse events unrelated to treatment were observed as temporal and mild worsening of symptoms triggered by a family quarrel, troubles with friends, anniversary reactions, and an encounter with the perpetrator by chance. Among these, two occurred in STAIR and three appeared in Narrative Therapy.

3.4 Changes in CPTSD diagnosis and clinical scores

Among the seven patients who completed treatment, six no longer met the criteria for a CPTSD or PTSD diagnosis at the treatment end, and none met the criteria for these diagnoses at follow-up. Given that the critical RCI value for the ITQ was calculated to be 5.41 (Cloitre, Hyland, Prins, & Shevlin, 2021), five completers exceeded the value (i.e. reliable improvement), and two did not exceed the value in either direction at posttreatment or follow-up. Two dropouts who completed the midtreatment assessment showed reliable improvements. Individual symptom changes from pre- to posttreatment are shown in Table S1. Of the many outcome measures, only DES-II included patients with reliable symptom exacerbations exceeding the RCI value; five completers and two dropouts

showed reliable improvements, whereas two completers showed reliable exacerbations (Table S1). However, these two patients had lower DES-II scores at follow-up than at pretreatment.

Table 3 shows mean scores for each measure at the four time points. LMMs showed significantly lower ITI CPTSD severity scores posttreatment and at follow-up (both, $p < .001$). Large effect sizes were found for ITI CPTSD severity at posttreatment ($d = 1.69$) and follow-up ($d = 2.14$) and for both PTSD and DSO severity scores (Table 3). LMMs showed significantly lower posttreatment scores for ITQ CPTSD severity ($p = .007$), PDS severity ($p = .002$), DES-II ($p = .021$), DERS ($p = .002$), IIP-32 ($p = .045$), BDI-II ($p < .001$), STAI-Trait ($p = .012$), and PTCI ($p < .001$) and higher scores on the NMR ($p < .001$) and WHO-QOL-BREF ($p = .002$). At posttreatment, effect sizes were large for all these outcomes ($d = 0.92$ – 2.14), except that DES-II had a medium effect size ($d = 0.66$). We calculated large effect sizes at follow-up as well ($d = 1.08$ – 2.22).

4. Discussion

In this pilot study, we examined the feasibility and safety of SNT for CPTSD in a Japanese clinical setting. Seven patients completed the treatment, but three could not, one because of the COVID-19 pandemic. Although we included patients with severe symptoms of CPTSD, dissociation, or depression, no serious adverse events occurred, and the patients could be treated in outpatient settings. Explorative analyses showed significant improvements in CPTSD symptoms, depression, trait anxiety, emotion regulation, interpersonal relationships, quality of life, and post-traumatic negative cognition. These improvements were generally maintained 3 months after treatment.

The dropout rate (30%) is comparable to those of previous studies involving SNT (15.2–30.0%; Cloitre et al., 2002, 2010; Levitt et al., 2007; Oprel et al., 2021) and those reported in a meta-analysis of trauma-focused treatment in patients with childhood-abuse-related PTSD (24%; Ehring et al., 2014). Participants' reasons for dropping out, aside from one who dropped out due to the COVID-19 pandemic, are similar to those reported in a previous study (Levitt et al., 2007): one participant experienced panic attacks related to her traumatic experience, which might have surfaced as gradual exposure that progressed during the STAIR phase. The other participant made substantial progress with symptom changes during the STAIR phase but could not continue working on her trauma narrative. Levitt et al. (2007) similarly reported that some participants in their study refused exposure, although they appeared appropriate for it, and that others completed only the STAIR component because the remainder of the treatment

Table 3. Mean scores (*SD*) for the outcomes at the four time points and within-group effect sizes.

Measure	(Potential range)	Time point				Effect size <i>d</i> (Completers)	
		Pre (<i>n</i> = 10)	Mid (<i>n</i> = 9)	Post (<i>n</i> = 7)	Follow-up (<i>n</i> = 7)	Pre to Post	Pre to Follow-up
ITI (CPTSD)	(0–48)	30.60 (6.90)	–	15.43 (9.74) **	13.29 (8.20) **	1.69	2.14
ITI (PTSD)	(0–24)	13.80 (4.18)	–	6.86 (6.26) **	5.14 (4.34) **	1.30	1.96
ITI (DSO)	(0–24)	16.80 (3.79)	–	8.57 (4.65) **	8.14 (4.60) **	1.77	1.88
ITQ	(0–48)	35.10 (8.99)	28.67 (13.89)	22.00 (14.17) **	19.71 (14.81) **	1.06	1.22
PDS	(0–51)	31.40 (8.57)	26.33 (14.34)	18.43 (13.59) **	17.29 (14.42) **	1.34	1.37
DES-II	(0–100)	36.00 (18.85)	25.67 (22.94)	21.89 (26.72) *	15.87 (19.33) **	0.66	1.14
DERS	(36–180)	135.50 (15.75)	121.44 (27.11)	99.00 (25.36) **	98.86 (25.63) **	1.55	1.54
NMR	(25–125)	44.10 (7.19)	58.22 (15.58) *	70.86 (15.96) **	73.57 (17.15) **	–2.14	–2.22
IIP-32	(0–4)	2.18 (0.56)	2.04 (0.49)	1.63 (0.42) *	1.47 (0.28) **	0.92	1.78
BDI-II	(0–63)	39.90 (12.37)	34.56 (11.85)	19.57 (12.46) **	20.14 (16.16) **	1.81	1.48
STAI (State)	(20–80)	44.20 (8.08)	37.67 (10.30)	37.00 (6.88)	40.29 (7.67)	1.44	0.92
STAI (Trait)	(20–80)	65.80 (6.91)	65.44 (8.03)	54.86 (9.06) *	54.86 (13.93) *	1.49	1.08
WHOQOL	(1–5)	2.37 (0.71)	2.58 (0.68)	2.98 (0.46) **	3.17 (0.67) **	–1.08	–1.20
PTCI	(36–252)	178.90 (33.02)	167.22 (33.93)	122.14 (44.56) **	127.71 (54.02) **	1.49	1.18

Abbreviations: *SD*, standard deviation; ITI, International Trauma Interview; CPTSD, complex posttraumatic stress disorder; DSO, disturbances in self-organization; ITQ, International Trauma Questionnaire; PDS, Posttraumatic Diagnostic Scale; DES-II, Dissociative Experience Scale-II; DERS, Difficulties in Emotion Regulation Scale; NMR, General Expectancy for Negative Mood Regulation Scale; IIP-32, Inventory of Interpersonal Problems; BDI-II, Beck Depression Inventory-II; STAI, State-Trait Anxiety Inventory; WHOQOL, World Health Organization Quality of Life; and PTCI, Posttraumatic Cognitions Inventory.

P-values were derived from linear mixed-effects models. ** $p < .01$, * $p < .05$.

focused on symptoms of another disorder. The drop-out rate and reasons may partly reflect the acceptability of the treatment; however, these were not significantly different from the results of studies conducted in Western countries.

For treatment delivery, therapists provided the treatment with sufficient protocol adherence (96.4%) and modifications to meet the needs of each patient. The number of sessions and time required tended to be longer than in the original protocol. Our result of 20–25 sessions ($M = 23.9$, $SD = 1.8$) is somewhat longer than that of a previous study ($M = 19$, $SD = 3$, range = 12–25; Levitt et al., 2017) that examined the flexible application of SNT for survivors of the 9/11 terrorist attack. This difference could be partly because our sample had a long history of childhood abuse and severe symptoms. Moreover, our protocol allowed therapists to continue with as many sessions as required, following the therapists' and their supervisor's clinical judgment. This could also have led to the increase in the number of sessions observed in our study. As for treatment delivery, the International Society of Traumatic Stress Studies (ISTSS) published a position paper on CPTSD in adults in which it noted the need for individualised treatment, including various tailored therapeutic interventions and long-term treatment, to address the diversity and number of symptoms of CPTSD (ISTSS Guidelines Committee, 2019). Treatment delivery in this study is consistent with this notion, but further studies are needed to determine the optimal treatment duration for CPTSD.

Types of cross-cultural adaptation of trauma-focused treatment have been previously reported (Ennis et al., 2020), such as surface adaptations through translation and deep adaptations through modification of the intervention content to reflect cultural values, which mostly involve therapists as stakeholders. In this study, we translated the manuals and

materials into Japanese and examined whether further modifications were necessary. As shown in Table 1, various modifications were made to meet individuals' needs based on therapists' judgment and the supervisor's advice. However, uniform culture-related modifications were unnecessary, which is consistent with a previous Japanese study on trauma-focused cognitive behavioural therapy designed for traumatised children (Cohen, Mannarino, & Deblinger, 2006; Kameoka et al., 2015). The recommendation for flexible application of treatment modules enabled us to fine-tune and increase the number of sessions, which was also beneficial for Japanese patients with CPTSD. According to therapists' reports, while all treatment elements and rationales were accepted, body-focused emotion regulation was preferred, which could have been because such a physical approach was perceived to be reminiscent of Zen breathing techniques. These techniques are firmly rooted in the Japanese and other East Asian cultures.

In our small sample, no serious adverse events occurred, which is consistent with an RCT that set similar inclusion and exclusion criteria (Oprel et al., 2021). Oprel et al. (2021) reported that serious adverse events were rare in their STAIR and prolonged exposure (STAIR + PE) group, with only one of the 50 patients undergoing brief hospitalisation after a suicide attempt. Our sample included two patients with co-occurring BPD, six patients with a history of suicide attempts, and eight patients with pretreatment suicidal ideation decreased as the STAIR sessions progressed. Emotion dysregulation and dissociation improved after the STAIR phase, which could have helped in the safe implementation of exposure (i.e. Narrative Therapy in our intervention).

All participants who completed the treatment demonstrated decreased CPTSD symptoms and no

longer met the CPTSD diagnosis 3 months after treatment. Our results are consistent with those from the United States, where individuals were treated for PTSD and multiple comorbidities with a range of traumatic exposures (Cloitre et al., 2002, 2010; Levitt et al., 2007). The effect sizes for our study were comparable to those reported in previous RCTs (Cloitre et al., 2002, 2010; Oprel et al., 2021) and a benchmark study (Levitt et al., 2007). For example, the completers' effect sizes of our small sample (PDS: 1.34; BDI-II: 1.81; NMR: 2.14) were comparable with those reported in previous studies of U.S. samples (Modified PTSD Symptom Scale-Self Report: 1.76 and 1.79; BDI: 1.83 and 1.23; NMR: 1.42 and 0.70; Cloitre et al., 2002; and Levitt et al., 2007, respectively). One new result is that our study assessed CPTSD symptoms using the ITI, whereas previous studies assessed PTSD symptoms using the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995). Although the outcomes from the clinician-administered ITI and self-reported ITQ followed the same trend, the ITQ scores were higher than the ITI scores in two cases both before and after treatment. We observed this tendency in older patients; however, whether this was an individual difference or an age-related tendency is unclear because there were very few patient cases. Lastly, there were two cases of increased dissociative symptom scores posttreatment, but these were transient. We cannot say that there was an adverse effect on dissociation; however, there may be a subtype whose dissociative symptoms are less likely to improve.

This study had several limitations. First, the generalizability of the results is limited by the small sample size and exclusion of male participants. Second, therapists differ widely by discipline, and no generalisations can be made about education and training history regarding the discipline's relevance to the feasibility of treatment delivery. Third, due to the pilot nature of our study, we did not include a control group; therefore, we could not make any comparisons with alternative treatments. Fourth, we used ITI version 2.0 for data collection; however, a more recent version, version 3.2, was later developed that contained fewer DSO items and more detailed scoring guidelines. We followed the latest version's algorithm for diagnosis and severity calculation to facilitate future comparisons; however, future studies must implement the final version's procedures. Moreover, when interpreting the follow-up scores, it is important to recall that one case had a follow-up delay and two cases received additional sessions posttreatment. Finally, we did not systematically obtain patient outcomes for the acceptability of SNT; therefore, further examination is needed.

In summary, this is the first report on the use of SNT in individuals diagnosed with ICD-11 CPTSD using reliable clinician and self-report measures. These results provide preliminary evidence of the

feasibility and safety of SNT in Japanese patients with CPTSD. Although our results indicated improvements in traumatic stress symptoms, depression, and other clinically important aspects, it is uncertain whether these findings can be attributed to SNT. Future RCTs are required to test the efficacy of SNT in Japan.

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Data Availability Statement

The data supporting the findings of this study are available from the corresponding author, MN, upon reasonable request. The data are not publicly available because they contain information that can compromise the privacy of research participants.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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