

## Effectiveness of trauma-focused cognitive behavioral therapy for Japanese children and adolescents in community settings: a multisite randomized controlled trial

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### ABSTRACT

**Background:** Trauma-focused cognitive behavioural therapy (TF-CBT) is an efficacious treatment model for children and adolescents with trauma-related disorders. However, few studies have been conducted in community settings, and there have been no randomized controlled trials in Asian countries.

**Objective:** To evaluate the effectiveness of TF-CBT in regular community settings in Japan through comparison with a waitlist with minimal services control condition.

**Method:** Thirty Japanese children and adolescents with posttraumatic stress disorder symptoms (22 females, eight males, mean age = 13.90, range = 6–18) were randomly assigned to 12 sessions of TF-CBT or the waitlist control condition. The primary outcome measure was the Kiddie Schedule for Affective Disorders and Schizophrenia score assessed by blinded evaluators one month later.

**Results:** The mean number of sessions was 12 (range: 11–13) in the TF-CBT group and 4.87 (range: 3–7) in the control group. Intention to treat analysis showed that the TF-CBT group achieved significantly greater symptom reduction than did the control group. The effect size (Cohen's *d*) between the TF-CBT and control groups was 0.96 ( $p = .014$ ) for posttraumatic symptoms and 1.15 ( $p = .004$ ) for depressive symptoms. However, the TF-CBT group did not show better results than the control group with regard to improvements in anxiety symptoms, psychosocial functioning, and behavioural problems.

**Conclusions:** The findings provided preliminary evidence of the effectiveness of TF-CBT for treating youth with trauma in community mental health facilities. TF-CBT in the Japanese context proved identical to the original, demonstrating that it is also suitable for use with children and adolescents in non-Western settings.

### Efectividad de la terapia cognitivo conductual centrada en el trauma para niños y adolescentes japoneses en entornos comunitarios: un ensayo controlado, aleatorizado, y multisitio

**Antecedentes:** La Terapia Cognitivo Conductual Centrada en el Trauma (TF-CBT en su sigla en inglés) es un modelo de tratamiento eficaz para niños y adolescentes con trastornos relacionados con el trauma. Sin embargo, hasta la fecha solo se han realizado unos pocos estudios en entornos comunitarios y no se han realizado ensayos controlados aleatorios en países asiáticos.

**Objetivo:** Este estudio buscó evaluar la efectividad de la TF-CBT en entornos comunitarios regulares en Japón, en comparación con el tratamiento habitual (TAU en su sigla en inglés).

**Métodos:** Treinta niños y adolescentes japoneses (22 mujeres, 8 hombres, promedio de edad = 13.90, rango = 6-18) fueron asignados aleatoriamente a 12 sesiones de la TF-CBT o al grupo TAU. La medida de resultado primaria fue el puntaje K-SADS (Calendario Kiddie para Trastornos Afectivos y Esquizofrenia) evaluado por evaluadores cegados un mes después del tratamiento.

**Resultados:** El análisis de 'intención de tratar' mostró que el grupo TF-CBT logró una reducción significativa de síntomas, mayor que el grupo control. El tamaño del efecto (*d* de Cohen) entre el grupo TF-CBT y el grupo TAU fue de 0.96 ( $p = .014$ ) para los síntomas postraumáticos y 1.15 ( $p = .004$ ) para los síntomas depresivos.

**Conclusión:** Los hallazgos revelaron que la TF-CBT es eficaz para tratar a jóvenes traumatizados en centros comunitarios de salud mental y podría implementarse con éxito en Japón.

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### PALABRAS CLAVE

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### 关键词

临床试验; 童年期创伤; 父母/照顾者; PTSD; RCT; TF-CBT

### HIGHLIGHTS

- TF-CBT was superior to the waitlist with minimal services condition in terms of improving PTSS and depressive symptoms in Japanese youth with trauma in a community setting.
- The Japanese TF-CBT proved identical to the original, and is suitable for use with children and adolescents with trauma in non-Western settings.

## 聚焦创伤认知行为疗法在日本社区儿童和青少年的有效性:一项多点随机对照试验

**背景:** 聚焦创伤认知行为疗法 (TF-CBT) 对于患有创伤相关疾病的儿童和青少年是一种有效的治疗模型。但是, 至今仅有少量研究在社区环境中进行, 并且在亚洲国家未进行任何随机对照试验。

**目的:** 本研究旨在评估与常规治疗 (TAU) 相比, TF-CBT在日本常规社区环境中的有效性。

**方法:** 将30名日本儿童和青少年 (22名女性, 8名男性, 平均年龄为 13.90岁, 范围为6–18岁) 随机分配至TF-CBT或TAU组接受12个疗程。主要结果指标是治疗后一个月由盲测员评估的K-SADS (《学龄儿童情感障碍和精神分裂症问卷》) 得分。

**结果:** ‘意向处理’分析表明, TF-CBT组的症状减轻程度明显高于对照组。TF-CBT组和TAU组间的效应量 (Cohen's *d*) 对于创伤后症状和抑郁症状分别为0.96 ( $p = .014$ ) 和1.15 ( $p = .004$ )。

**结论:** 研究结果表明, TF-CBT可有效治疗社区精神卫生机构中遭受创伤的青年, 并且可以在日本成功实施。

## 1. Introduction

Worldwide, a significant number of children and adolescents experience traumatic events (Copeland, Keeler, Angold, & Costello, 2007; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995). In Japan, the annual number of consultations for child abuse and neglect at child guidance centres has increased approximately 60-fold over the past 20 years (Cabinet Office, 2014). Furthermore, the country has experienced several catastrophic mass traumatic events, such as the Great East Japan Earthquake and tsunami in 2011 (Ministry of Education, Culture, Sports, Science and Technology, 2012). Clinically significant posttraumatic stress symptom (PTSS) levels have been reported with respect to a wide variety of traumatic events (Kawakami, Tsuchiya, Umeda, Koenen, & Kessler, 2014), and studies have identified an association between trauma and increased numbers of anxiety and mood disorders (Famularo, Fenton, Kinscherff, & Augustyn, 1996).

Given the damaging effects of severe PTSS and other trauma-related symptoms that children and adolescents may develop in the aftermath of a traumatic event, evidence-based treatments are imperative. In this regard, trauma-focused cognitive behavioural therapy (TF-CBT) (Cohen & Mannarino, 1996; Deblinger, Lippman, & Steer, 1996) has been the subject of extensive scientific evaluation (International Society for Traumatic Stress Studies, 2019). Approximately 20 randomized controlled trials have been completed for children and adolescents with experience of diverse traumatic events, including multiple and complex traumatic experiences from different cultures and countries, across the developmental span of 3–18 years of age (Cohen, Mannarino, & Deblinger, 2017). Cohen, Deblinger, Mannarino, and Steer (2004) showed that TF-CBT provided to children was significantly superior to child-centred therapy for improving posttraumatic stress disorder (PTSD), depression, and behavioural problems (effect size = .46–.70). Furthermore, they found that this model was superior for improving parental depression, emotional distress, and parenting skills (effect size = .46–.81).

Although TF-CBT was developed in the United States, its applicability has been examined in Australia, Norway, the Democratic Republic of the Congo, the Netherlands, Zambia, and Germany (Cohen et al., 2017). In Asia, the feasibility of TF-CBT has been reported in Japan, where Kameoka et al. (2015) found that 35 children and adolescents aged 3–17 years showed significant improvements in PTSS and psychosocial functioning following therapy (pre- to post-treatment effect sizes, 1.24 and 1.96, respectively). However, no randomized controlled trials have been conducted in Asia.

While empirical research on TF-CBT has been conducted in academic settings, few studies have focused on community clinics. Jensen et al. (2014) found that 156 youth with trauma aged 10–18 years receiving TF-CBT through Norwegian community mental health services reported significantly lower levels of PTSS, depression, and general mental health problems compared to therapy as usual ( $n = 79$ , effect size = .45–.54). Goldbeck, Mueche, Sachser, Tutus, and Rosner (2016) reported that 76 children and adolescents aged 7–17 years receiving TF-CBT in German outpatient clinics showed significant improvements in PTSS, depression, and behavioural symptoms compared to a waitlist group ( $n = 83$ , effect size = .32–.56).

The primary aim of the present study is to investigate the hypothesis that TF-CBT is superior to a waitlist with minimal services condition in reducing PTSS, depression, anxiety, behavioural problems, and psychosocial dysfunction in Japanese children and adolescents in a community setting. Improvements in therapy will result in improved mental health and quality of life in patients, as well as reduced anxiety in caregivers.

## 2. Methods

### 2.1. Procedure

A single-blind, parallel group, randomized controlled trial was conducted, with the independent evaluators blinded to the treatment condition to maintain

objectivity. All work was conducted with the formal approval of the Institutional Review Boards of the Hyogo Institute for Traumatic Stress and the Tokyo Metropolitan Institute of Medical Science, and the clinical trial has been registered as legislation requires (name of registry: the University hospital Medical information Network centre; URL: [https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr\\_view.cgi?recptno=R000012501](https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000012501); registration number: UMIN000010699). All legal guardians as well as the patients themselves provided written informed consent to participate.

The target sample included children and adolescents aged 6–18 years who were referred to a community treatment centre or a psychiatric clinic in Japan between June 2013 and April 2018. The community treatment centre is a victim support centre in a large metropolitan area, while the psychiatric clinic is in a suburban city. No recruitment advertising was conducted, and normal referral procedures were followed, since all participants were referred for treatment. Assessment was conducted at baseline and one month after treatment for both groups. All assessments at each facility were conducted by independent evaluators. Participants received 5000 Japanese yen as compensation for each assessment.

To be eligible for the study, children and adolescents had to have experienced at least one traumatic event that met Criterion A of the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV (American Psychiatric Association, 1994), leading to at least one symptom in each of the three PTSD clusters (re-experiencing, avoidance, and hyper-arousal), as well as psychosocial dysfunction in accordance with the DSM-IV. In addition, the youth were required to have a non-offending caregiver or a care worker in the children's home who was willing to participate in the parental treatment component of the study. Children and adolescents who were currently taking psychotropic medication had to have been on a stable medication regimen for at least eight weeks prior to study admission.

Exclusion criteria were based on TF-CBT application criteria (Cohen et al., 2017). Youth were excluded if they had a current diagnosis of a psychotic disorder, substance use disorder, suicidal ideation, severe aggressive behaviours, and/or antisocial behaviour resulting in significant impairment in adaptive functioning that would prevent them from participating in the treatment. They were also excluded if their parent or primary caregiver who would be participating in the treatment had such a disorder. Furthermore, children and adolescents were excluded if they and/or their parent had a documented developmental disorder such as autism spectrum disorder or severe intellectual disability, which might have resulted in insufficient response to cognitive intervention. These exclusion criteria were evaluated by responsible clinicians. Finally, the

children and adolescents could not be receiving any other trauma-focused therapy outside of the study.

To avoid bias, we standardized assessment measures and employed independent evaluators and allocation managers who were blinded to allocation. If the inclusion criteria were met and consent was provided, the children and adolescents were randomly assigned to either the TF-CBT or waitlist control group. An independent allocation manager created a computer-generated allocation schedule, which was based on the minimization method of balancing three variables: gender, age ( $\leq 12$  or  $> 12$ ), and trauma type (single or chronic) based on the index trauma. Program providers were unaware of the allocation sequence. Intervention allocation could not be masked from the children and adolescents or the program providers. However, the youth and their caregivers were told that they would be assigned by a computer system to weekly treatment for 12 weeks or treatment at their own pace for 12 weeks, and that there was no evidence of which condition would be more effective. They were also reassured that they could receive another type of treatment after the initial treatment if they desired (Figure 1).

## 2.2. Participants

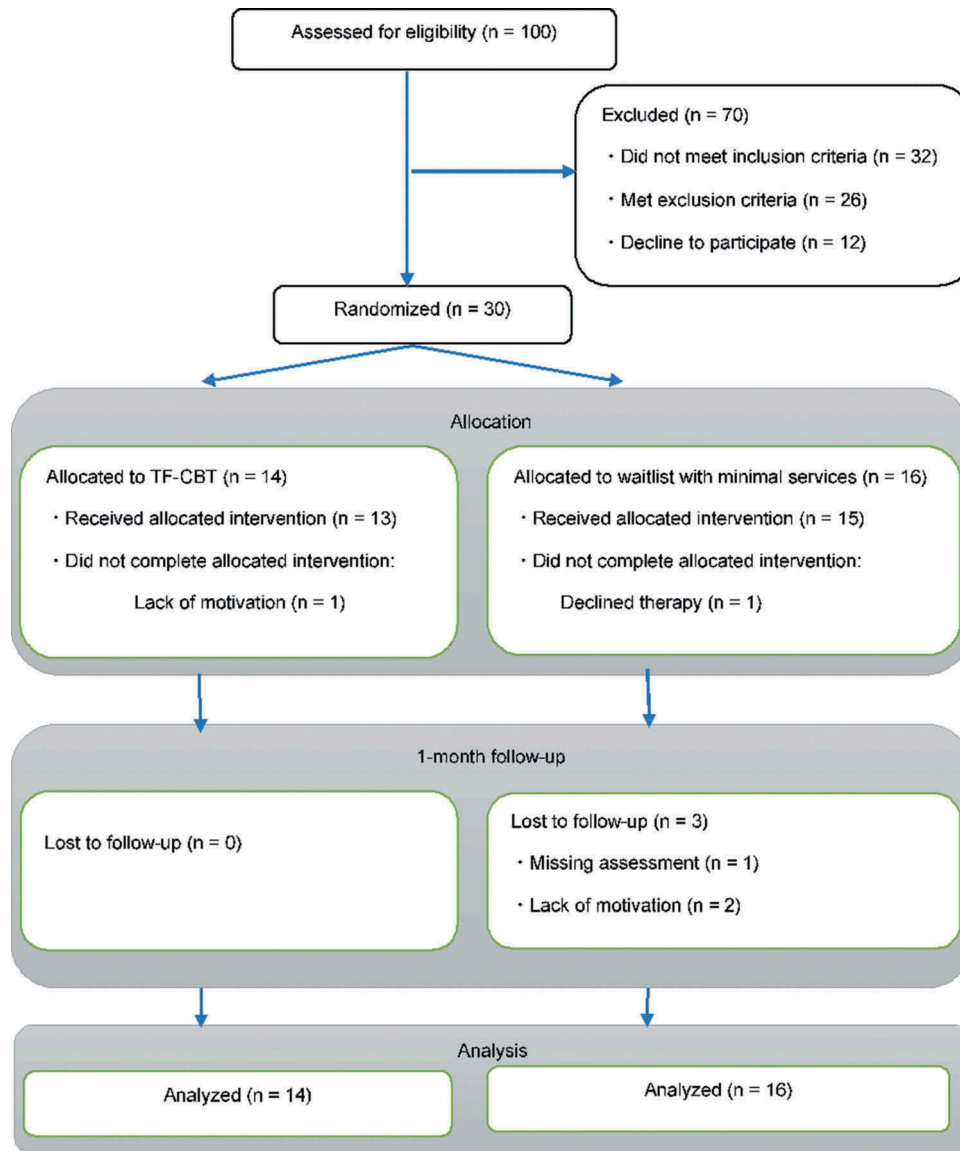
Of the 100 children and adolescents screened for eligibility, 70 were excluded. Thirty-two participants and their caregivers did not meet the inclusion criteria (11 did not have at least one symptom in each PTSD cluster; 21 caregivers were not inclined to participate). Twenty-six children and adolescents and their caregivers met the exclusion criteria (six children and adolescents had severe aggressive behaviours, 10 showed severe depression with suicidal ideation, four caregivers showed severe aggressive behaviour, and six caregivers had severe depression). Twelve children and adolescents and their caregivers declined to participate. Three children had been taking psychotropic medication (one in the TF-CBT group was taking atomoxetine, and two in the control group were taking herbal medicine).

The final sample comprised 30 children and adolescents (22 females, eight males, mean age = 13.90, range = 6–18). There were no significant differences in basic characteristics between the TF-CBT and control groups ( $p = .356, .544, .877, .961, \text{ and } .626$  for age, gender, total number of trauma experiences, trauma experience type, and psychotropic medication, respectively) (Table 1).

## 2.3. Treatment

### 2.3.1. TF-CBT

TF-CBT is a short-term, component-based intervention that involves 12 weekly 90–100-minute sessions (Cohen et al., 2017). The therapeutic components include psychoeducation, parenting skills, relaxation,



**Figure 1.** Flowchart of participants in the study. TF-CBT: trauma-focused cognitive behavioural therapy.

affective expression and modulation, cognitive coping skills, trauma narration and processing, in vivo mastery of trauma reminders, conjoint child-parent sessions, and the enhancement of safety and future development. Each component is offered in parallel or conjoint sessions to the child and caregiver.

The therapy sessions were conducted by two psychologists and one child psychiatrist, who treated three children and adolescents (therapist A), one child (therapist B), and 10 children and adolescents (therapist C), respectively. All therapists have completed the certified TF-CBT training. Two of them (therapists A and C) are certified regional TF-CBT trainers. All the therapy sessions were video or audio recorded and coded by employing the TF-CBT Brief Practice Checklist (Cohen et al., 2017, p. 327). Treatment fidelity was verified using the Brief Practice Checklist by certified regional TF-CBT trainers (therapists A and C). Therapist A verified the fidelity of TF-CBT that was conducted by therapist C,

and therapist C verified the fidelity of TF-CBT conducted by therapists A and B. The checklist contains 10 items (rated present vs. absent) that follow the treatment components. The core components that had to be completed in order for therapy to be defined as TF-CBT were as follows: psychoeducation, relaxation skills, affect expression and modulation, instruction in the cognitive triangle, working through the trauma narration, working with dysfunctional thoughts, and the parenting component. Based on these criteria, TF-CBT for all participants, except one who dropped out, reached an acceptable level of fidelity.

### 2.3.2. Waitlist condition

The same therapists as those conducting TF-CBT were in charge of the waitlist with minimal services condition. Here, they were asked to provide the 90–100-minute treatment they considered most suitable for 12 weeks. The number of sessions was

**Table 1.** Characteristics and group comparisons.

	TF-CBT ( <i>n</i> = 14)		Waitlist control ( <i>n</i> = 16)		Statistics
	<i>M</i> or <i>n</i>	<i>SD</i> or %	<i>M</i> or <i>n</i>	<i>SD</i> or %	
Age ( <i>M</i> , <i>SD</i> )	13.36	3.46	14.50	2.82	$t_{28} = .940$
Gender: Male ( <i>n</i> , %)	3	21.4	5	31.3	$\chi^2(1) = .368$
Female	11	78.6	11	68.8	
Total number of trauma experiences ( <i>M</i> , <i>SD</i> )	3.14	1.55	3.06	1.25	$t_{28} = .156$
Trauma experience type	8	57.1	9	56.2	$\chi^2(1) = .002$
Single ( <i>n</i> , %)	6	42.9	7	43.8	
Multiple	6	42.9	7	43.8	
Child index trauma ( <i>n</i> , %)					
Car accident	2	14.3	0	0	
Crime victim	1	7.1	1	6.3	
Physical abuse	1	7.1	2	12.5	
Sexual abuse (intra or out of family)	9	64.3	12	75.0	
Traumatic death	1	7.1	1	6.3	
Psychotropic medication ( <i>n</i> , %)	1	7.14	2	12.5	$\chi^2(1) = .238$
Participating caregiver ( <i>n</i> , %)					
Biological mother	8	57.1	9	56.2	
Biological mother and father	3	21.4	3	18.8	
Biological father			1	6.3	
Grandmother	1	7.1			
Care worker in the home	2	14.3	3	18.8	

TF-CBT: trauma-focused cognitive behavioural therapy.

generally client-directed. It was considered ethically problematic to make the participants in this group attend weekly sessions, owing to the fact that previous research (Cohen et al., 2004) has demonstrated TF-CBT's superiority to child-centred therapy (the usual treatment). However, not providing any services could be considered ethically problematic as well. Therefore, the control group received minimal services according to the needs of the children, adolescents, and their families. All the youth and their caregivers received individual treatment in both parallel and conjoint sessions. Youth safety was monitored by the study therapists. The therapists provided general psychoeducation on childhood trauma, and the youth and their caregivers learned some relaxation skills. Young people and their families were not encouraged to discuss and/or write about the details of traumatic experiences. Therefore, core components of TF-CBT (trauma narration and in vivo mastery) were not included in this condition. All therapy sessions in the waitlist control group were audio recorded. However, they were not coded.

## 2.4. Measures

The following instruments were used to assess psychiatric symptomatology in the children and adolescents and their caregivers at baseline and one month after treatment.

### 2.4.1. Primary outcome measure

The youth's PTSD symptoms were assessed using the PTSD section of the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children/Parent and Lifetime Version) (K-SADS-PL; Kaufman et al., 1997). This instrument is a semi-structured diagnostic interview in which the child and caregiver respond

independently to questions about the child's exposure to 11 trauma types and PTSD symptoms listed in the DSM-IV. For analysis purposes, caregiver and child/adolescent consensus ratings were used, and if there was a discrepancy between the reports, the interviewer made the decision based on his or her clinical judgement. The numbers of K-SADS symptoms in each cluster were summed up. Validity was established in relation to the psychiatric interview and interrater reliability for children on the PTSD diagnosis (interrater agreement: 93–100%, test-retest reliability:  $\kappa = .63$  to  $.67$ ).

In the present study, this measure was independently administered by two clinical psychologists who were blinded to the treatment conditions. These two assessors' intraclass correlation coefficients for the total K-SADS score and its subscales of re-experience, avoidance, and hyper-arousal were .97, .99, .96, and .86, respectively. The PTSD diagnosis was the same in all 10 interviews (Kappa = 1.00). The Cronbach's alpha coefficients of the total scale and its subscales of re-experience, avoidance, and hyper-arousal were .72, .48, .69, and .39, respectively.

### 2.4.2. Secondary outcome measures for children and adolescents

The level of psychosocial functioning was assessed with the Children's Global Assessment Scale (CGAS; Shaffer et al., 1983). The intraclass correlation coefficient was .84, and test-retest reliability was .85. The reliability of the Japanese version was .74 (Yamauchi, Fujiwara, Okuyama, & Ida, 2013). PTSS was assessed by children and adolescents' reports using the UCLA-PTSD Reaction Index for DSM-IV. Test-retest reliability was .86 and the coefficient alpha range was .86–.91 (UCLA PTSD-RI; Steinberg, Brymer, Decker, & Pynoos, 2004). The Japanese version had an internal consistency of .91 and test-retest

reliability of .76 (Fujimori et al., 2014). In this sample, the Cronbach's alpha coefficient was .86.

The Child Behaviour Checklist/4–18 (CBCL; Achenbach, 1991) is a 118-item caregiver rating scale that assesses children's externalizing and internalizing behavioural problems. Internal consistency for the internalizing subscale was .88 and for the externalizing subscale was .92. Test-retest reliability was .89. The reliability coefficients of the Japanese version were good, with Cronbach's alpha between .67 and .89 (Itani et al., 2001). In the present study, Cronbach's alpha coefficients of the total scale and its internalizing and externalizing subscales were .92, .90, and .90, respectively.

The Depression Self-Rating Scale for Children (DSRSC; Birlleson, 1981) was employed to assess the youth's depressive symptoms. The test-retest reliability of the scale was .80, with a reliability coefficient of .65–.95. In the Japanese version used in the current study, Cronbach's alphas for test-retest reliability and overall reliability were .79 and .77, respectively (Murata, Shimizu, Mori, & Ousima, 1996). In this sample, Cronbach's alpha coefficient was .84.

The Spence Children's Anxiety Scale (SCAS; Spence, 1998) is a 38-item self-report questionnaire that assesses multiple symptoms of childhood anxiety disorders based on the DSM-IV. The internal consistency reliability of the overall scale was .92. The reliability coefficient of the Japanese version was .92, and the test-retest reliability coefficient was .76 (Ishikawa, Sato, & Sasagawa, 2009). In the current study, Cronbach's alpha coefficient was .91.

### 2.4.3. Secondary outcome measures for caregivers

The Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996) is a self-report instrument that, in this study, was used to measure caregivers' depression severity. Cronbach's alpha coefficient in the initial sample was .92 and test-retest reliability was .93. The Japanese version employed in this study also had high internal reliability (.87) and good validity (Kojima et al., 2002). In this sample, Cronbach's alpha coefficient was .88.

The State-Trait Anxiety Inventory (STAI) is a widely used self-report measure (Spielberger, Gorsuch, & Lushene, 1970) that has demonstrated high internal consistency (.83 to .92) and test-retest reliability (.40 to .81). The reliability coefficients of the Japanese version ranged between .86 and .87, and the test-retest reliability ranged from .42 to .82 (Iwamoto et al., 1989). In the current study, Cronbach's alpha coefficients of the overall tool and its subscales of trait and state anxiety were .96, .93, and .95, respectively.

The World Health Organization Quality of Life scale (WHOQOL) was employed to examine each caregiver's quality of life (QoL). The 26-item version includes four domains: physical, psychological, social,

and environmental (WHOQOL Group, 1998). The internal consistency of the four domains of the scale ranged from .66 to .80. The reliability of the Japanese version was .97 (Tazaki et al., 1998). In this sample, Cronbach's alpha coefficients of the complete tool and its subscales of overall, physical, psychological, social, and environmental were .94, .75, .84, .84, .52, and .86, respectively.

## 2.5. Data analysis

In accordance with a previous study conducted outside of the US (King et al., 2000) as well as with our own pilot study (Kameoka et al., 2015), we calculated the sample size based on the following assumptions regarding the primary outcome. We assumed an effect size of  $d = .6$  for the control group and  $d = 1.2$  for the TF-CBT group, suggesting an effect size of about 0.6 between conditions. Assuming power = .85, alpha = .05, two comparison groups, two measurement time points, and  $t$ -tests, including within- and between-group interactions, we needed 14 participants per condition (28 total). Compensation for a possible clustering effect (8%) raised the required sample size to 30 participants.

Baseline group differences with respect to age, gender, total number of trauma experiences, trauma experience type, and psychotropic medication were assessed using independent samples  $t$ -tests for continuous variables and  $\chi^2$  tests for categorical data. The primary and secondary outcome analyses used an intention to treat model by employing the last-observation-carried-forward procedure to replace missing values owing to participants dropping out of the study. We calculated delta scores for the total number of K-SADS symptoms, K-SADS subscales, CGAS, UCLA-PTSD-RI, DSRSC, SCAS, CBCL total score, CBCL externalizing and internalizing scores, BDI-II, STAI, and QoL subscales for pre- and post-treatment periods, and used independent samples  $t$ -tests to compare the intervention and control groups. Effect sizes (Cohen's  $d$ ; Cohen, 1988) were calculated for within-group pre-post comparisons and between-group comparisons of delta scores for primary and secondary outcomes. Two-sided  $p$ -values less than .05 were regarded as statistically significant. All computations were performed using STATA version 15 (Stata Corp., College Station, TX).

## 3. Results

### 3.1. Retention

Thirty youths and their caregivers (three from the victim support centre and 27 from the psychiatric clinic) were randomly assigned to either the TF-CBT ( $n = 14$ , 86% from the psychiatric clinic) or waitlist control group ( $n = 16$ , 94% from the psychiatric clinic). Of all

the youth, 66.7% met all DSM-IV PTSD criteria. One participant in each group dropped out (7.1% in the TF-CBT group, 6.3% in the control group). In the control group, three participants were not available at the one-month follow-up (Figure 1). The mean number of sessions was 12 (range: 11–13) in the TF-CBT group and 4.87 (range: 3–7) in the control group. In the TF-CBT group, the mean number of sessions of trauma narration was three (range: 1–5). A mean of 1.2 sessions (range: 1–2) were conducted conjointly, and the rest were conducted separately with the caregiver. Between-group differences in baseline scores were not significant for any of the assessment scales ( $p = .171-.949$ ). No harm or unintended effects occurred in either group to interrupt the therapy. The data of those effects was collected base on their records retrospectively.

### 3.2. Treatment effects

The TF-CBT group showed symptom improvement on all assessment scales, compared to the control group. Adjusted means significantly differed between the TF-CBT and control groups for PTSS and depressive symptoms: K-SADS total,  $p = .014$ ,  $d = .96$ , 95% confidence interval (CI), 0.20 to 1.72; UCLA-PTSD-RI,  $p = .022$ ,  $d = .89$ , 95% CI, .12 to 1.63; DSRSC,  $p = .004$ ,  $d = 1.15$ , 95% CI, 0.37 to 1. The number of participants receiving TF-CBT meeting the K-SADS PTSD diagnosis from pre-treatment to post-treatment decreased from 10 to three (70% remission), whereas in the control group, this number decreased from 10 to nine (10.0% remission). However, there were no significant between-group effects for children/adolescents' anxiety symptoms as depicted by the SCAS, psychosocial functioning as depicted by the CGAS, and behavioural problems as depicted by the CBCL. Effect sizes ranged from 0.35 to .70 (small to medium).

There were no significant effects of treatment condition on caregivers' depressive symptoms as depicted by the BDI-II, anxiety symptoms as depicted by the STAI, or QoL as depicted by the WHOQOL, with effect sizes ranging from .34 to .76 (small to medium) except for the social domain of the WHOQOL, which was .07 (Table 2).

## 4. Discussion

The results of this study revealed the significant superiority of TF-CBT over the waitlist with minimal services condition in relation to improving PTSS and depressive symptoms in Japanese children and adolescents with trauma in a community setting. The assessment scale effect sizes were substantial. The result regarding the superiority of TF-CBT is in accordance with previous research conducted by its developers, wherein the same measure – the

K-SADS – was used to assess PTSS in a community setting. Deblinger et al. (1996) made a comparison between TF-CBT and the community control group. Their study, the inclusion criteria for PTSS was also the presence of a total of three PTSS, including at least one symptom of avoidance or re-experience. In that study, the between-group effect size of PTSS for the K-SADS was 0.99, while in this study it was 0.96. In their examination of children with trauma, Cohen et al. (2004) made a comparison between TF-CBT and child-centred therapy. Eighty-nine percent of the children in that study met all DSM-IV PTSD diagnostic criteria at pre-treatment, and more than twice as many CCT as TF-CBT children continued to meet full PTSD DSM-IV criteria at post-treatment (21%, 46%, in TF-CBT and CCT, respectively). In the current study, 67% of the youth met the PTSD diagnostic criteria at pre-treatment, and three times as many participants in the waitlist with minimal services condition as those undergoing TF-CBT continued to meet all PTSD criteria at post-treatment.

A few recent studies conducted in community settings in Norway (Jensen, Holt, & Ormhaug, 2017; Jensen et al., 2014) and Germany (Goldbeck et al., 2016) have also demonstrated the effectiveness of TF-CBT. The control groups in these studies were treatment as usual and waitlist (Norway and Germany, respectively). When compared to these studies, larger effect sizes of PTSS and depressive symptom scores were revealed in the present study (PTSS: .46–.51, .5, and .77–.96; depressive symptoms: .54, .32, and 1.15, in the Norwegian, German, and current study, respectively). These differences can be due to different measures, sample sizes, dropout rates, and cultural differences. However, in the present study, the effect size for PTSS in the control group (.54) was smaller than that reported in the German study (.88). This result might have raised the effect size of this study.

Contrary to our expectations, the TF-CBT group was not significantly superior to the control group with regard to improvements in anxiety symptoms, psychosocial functioning, and behavioural problems. However, the effect sizes of these measures in the current study were almost identical to those in the two prior studies noted above (anxiety symptoms: .3, .2, and .57, in the Norwegian, German, and present study, respectively; behavioural problems: .42 and .70 in the German and present study, respectively). Regarding behavioural problems, externalizing problems showed the smallest change in the TF-CBT group (pre-post effect size: .32). Moreover, behavioural problems (both externalizing and internalizing) remained in the average clinical range ( $T > 60$ ) at post-treatment. This is similar to previous studies (Goldbeck et al., 2016). As Deblinger, Mannarino,

Table 2. Within- and between-group comparisons.

	TF-CBT (n = 14)						Waitlist control (n = 16)						Between groups		
	Baseline		1 month		Pre-post % reduction	d <sup>1</sup>	Baseline		1 month		Pre-Post % reduction	d <sup>2</sup>	d <sup>3</sup>	95%CI	
	M	SD	M	SD			M	SD	M	SD					
Primary															
K-SADS score															
Total	12.64	2.34	7.07	4.38	44.1	1.59	11.56	3.05	9.69	3.84	16.2	.54	.96*	[.20, 1.72]	
Re-experiencing	4.43	1.22	2.29	1.68	48.4	1.46	4.00	1.26	3.19	1.56	20.3	.57	.77*	[.02, 1.51]	
Avoidance	4.07	1.59	2.14	1.56	47.4	1.22	3.63	1.54	3.00	1.67	17.2	.39	.77*	[.02, 1.51]	
Hyper-arousal	4.14	1.03	2.64	1.74	36.2	1.05	3.94	1.12	3.50	1.32	11.1	.36	.77*	[.02, 1.51]	
Secondary-self															
CGAS	55.86	7.01	64.79	10.91	-16.0	-.97	53.75	8.39	59.06	6.85	-9.9	-.69	.38	[-.35, 1.10]	
UCLA	37.00	10.66	21.43	13.41	42.1	1.29	35.69	14.53	30.63	15.84	14.2	.33	.89*	[.12, 1.63]	
DSRSC	20.07	7.47	11.57	7.56	42.3	1.13	19.06	6.42	16.75	7.56	12.1	.33	1.15**	[.37, 1.92]	
SCAS	49.64	17.66	34.93	22.35	29.6	.73	48.94	21.60	44.44	24.26	9.2	.20	.57	[-.17, 1.30]	
CBCL															
Total <sup>a</sup>	72.79	10.56	66.00	11.87	9.3	.60	67.14	6.93	64.79	7.07	5.0	.34	.70	[-.11, 1.48]	
Externalizing <sup>b</sup>	65.64	10.96	62.07	11.18	5.4	.32	59.93	10.89	58.73	10.08	2.6	.11	.35	[-.40, 1.09]	
Internalizing	74.64	10.84	67.14	12.38	10.0	.64	69.81	10.74	66.56	9.22	4.7	.32	.58	[-.16, 1.30]	
Secondary-caregiver															
BDI-II	21.07	7.86	14.43	10.12	31.5	.73	16.56	10.42	14.94	12.43	9.8	.14	.62	[-.12, 1.36]	
STAI															
State anxiety	52.43	11.09	46.21	13.93	11.9	.49	51.56	11.55	48.27	13.84	5.8	.26	.35	[-.38, 1.09]	
Trait anxiety	55.57	12.63	50.64	14.40	8.9	.36	51.75	10.34	50.25	11.62	2.9	.14	.40	[-.33, 1.12]	
WHOQOL															
Overall	5.43	2.24	5.71	1.94	-5.3	-.14	5.56	1.26	5.44	1.26	2.2	.10	.34	[-.38, 1.06]	
Physical	20.29	5.33	21.71	5.40	-7.0	-.27	21.19	4.20	19.94	5.17	5.9	.27	.63	[-.11, 1.36]	
Psychological <sup>c</sup>	17.00	4.20	18.71	5.04	-10.9	-.37	17.13	4.06	16.81	3.78	1.8	.08	.76	[.00, 1.52]	
Social	9.64	2.34	10.00	3.11	-3.7	-.13	9.69	1.40	9.94	1.48	-2.6	-.17	.07	[-.65, 0.78]	
Environmental	24.07	6.78	25.50	6.87	-5.9	-.21	25.50	4.03	24.69	4.91	3.2	.18	.52	[-.22, 1.24]	

<sup>a</sup>Two missing values in the waitlist control group, <sup>b</sup>one missing value in the waitlist control group, <sup>c</sup>one missing value in the TF-CBT group, TF-CBT: trauma-focused cognitive behavioural therapy; K-SADS: Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children/Parent and Lifetime Version; CGAS: Children's Global Assessment Scale; UCLA: UCLA-PTSD Reaction Index for DSM-IV; DSRSC: Depression Self-Rating Scale for Children; SCAS: Spence Children's Anxiety Scale; CBCL: Child Behaviour Checklist/4-18 years old; BDI-II = Beck Depression Inventory II; STAI: State-Trait Anxiety Inventory; WHOQOL: WHO Quality of Life scale; d<sup>1</sup>: pre-post effect size in the TF-CBT group; d<sup>2</sup>: pre-post effect size in the waitlist control group; d<sup>3</sup>: effect size between TF-CBT and waitlist control group; \*, p < .05; \*\*, p < .01; \*\*\*, p < .001.



Cohen, Runyon, and Steer (2011) showed, trauma-focused parenting and coping skill building should be the initial focus for improving traumatic behavioural problems.

Similarly, we found no significant differences in the caregivers' depression, anxiety, or QoL. The effect size for caregivers' depressive symptoms in this study (.51) was similar to that reported by Cohen et al. (2004) (.38). Therefore, these non-significant results may be explained by the small sample size. Further studies with larger samples are recommended.

Our findings suggest that, despite cultural differences, the original Western TF-CBT is also suitable for children with trauma and their families in non-Western settings. In Japanese culture, negative feelings (anxiety, fear, shame, anger, etc.) are generally undesirable, and overt expression tends to be avoided. From this perspective, TF-CBT programs that guide children and adolescents and their families to re-experience the negative emotions accompanying trauma would seem particularly unacceptable. However, the families in our sample were faithful to the therapy in its entirety. In addition, our participants' treatment dropout rates were low compared to other TF-CBT studies (Goldbeck et al., 2016; Jensen et al., 2014). This cultural flexibility suggests that TF-CBT may be a promising treatment program that can be applied globally.

The results of this study must be viewed in light of important limitations. First, the sample size was small, which did not allow the investigation of whether TF-CBT is more effective in some subgroups than others. This aspect should be examined in future studies. Second, the K-SADS, which is a conventional semi-structured diagnostic interview, could be limited in evaluating the severity of PTSS. Third, the responses of the waitlist control group with minimal services were not coded. Additionally, the mean number of sessions in the control group was less than half that the TF-CBT group, which might have contributed to the difference in outcomes. A comparison that equates the amount or therapist contact should be examined in future studies. Furthermore, the same therapists conducted both TF-CBT and oversaw the waitlist with minimal services condition. Therefore, the control group in this study might have been more trauma-informed than waitlist groups in the real-world setting in Japan. Finally, the therapists were not randomized and the number of cases that each therapist was assigned was not uniform. In this regard, the results demonstrated an unexpected treatment facility bias. There were significant differences in the reduction of PTSS as demonstrated by the K-SADS scores in the TF-CBT group conducted at both facilities. The mean reduction numbers of the total K-SADS scores and the scores of its

subscales of re-experience, avoidance, and hyperarousal in TF-CBT conducted in the victim support centre were 7.5, 2.5, 2.5, and 2.5, respectively, whereas those for the psychiatric clinic were 5.3, 2.1, 1.8, and 1.3, respectively.

Despite these limitations, this study documents preliminary evidence of the effectiveness of TF-CBT in Japan. We anticipate that our findings will promote the dissemination and application of TF-CBT in Asia and throughout the world.

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