Contents lists available at ScienceDirect

Behaviour Research and Therapy

A randomized controlled trial of a bidirectional cultural adaptation of cognitive behavior therapy for children and adolescents with anxiety disorders

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ARTICLE INFO

ABSTRACT

Background: Cognitive behavior therapy (CBT) programs with ethnic and cultural sensitivity are scarce. This study was the first randomized controlled trial of cognitive behavior therapy for children and adolescents with anxiety disorders using bidirectional cultural adaptation.

Methods: The Japanese Anxiety Children/Adolescents Cognitive Behavior Therapy program (JACA-CBT) was developed based on existing evidence-based CBT for anxious youth and optimized through feedback from clinicians in the indigenous cultural group. Fifty-one children and adolescents aged 8–15 with anxiety disorders were randomly allocated to either a cognitive behavioral treatment (CBT: 122.08 days, $SD = 48.15$) or a wait-list control condition (WLC: 70.00 days, $SD = 11.01$). Participants were assessed at pre-treatment and post-treatment as well as 3 and 6 months after completion of treatment (92.88 days, $SD = 17.72$ and 189.42 days, $SD = 25.06$) using a diagnostic interview, self-report measures of anxiety, depression, cognitive errors, and a parent-report measure of anxiety.

Results: A significant difference was found between the CBT and WLC at post-treatment, specifically 50% of participants in the treatment condition were free from their principal diagnoses compared to 12% in the wait-list condition, χ^2 (1, $N = 51$) = 8.55, $\eta^2 = 0.17$, $p < .01$. In addition, participants in the treatment condition showed significant improvement in clinical severity and child-self reported depression, F (1, 49) = 12.38, $p < .001$, F (1, 47.60) = 5.95, $p < .05$. At post-treatment, Hedge's g between the conditions was large for clinical severity, 1.00 (95% CI = 0.42–1.58), and moderate for the self-report anxiety scale, 0.43 (0.19–1.04), two depression scales, 0.39 (0.22–1.00), 0.48 (0.14–1.09), and the cognitive errors scale, 0.38 (0.24–0.99). Finally, significant improvements in diagnostic status were evident at the 3 and 6-month follow-up assessments when combining the CBT and WLC, $ps < .001$.

Conclusion: The current results support the transportability of CBT and the efficacy of a bidirectional, culturally adapted cognitive behavior therapy in an underrepresented population.

Anxiety disorders are the most prevalent psychological disorders in children and adolescents (Cartwright-Hatton, McNicol, & Doubleday, 2006; Higa-McMillan, Francis, & Chorpita, 2012; Weems & Silverman, 2013). Although fear and anxiety are regarded as a part of normal as well as necessary development, severe anxiety symptoms impair various daily functions in children and adolescents (Essau, Conradt, & Petermann, 2000; Higa-McMillan et al., 2012). Moreover, anxiety disorders in children and adolescents are predictive of later mental health problems broadly, including anxiety disorders, mood disorders, and substance abuse (Seligman & Gahr, 2013; Weems & Silverman, 2013).

Evidence has consistently shown that cognitive behavior therapy (CBT) is an effective psychosocial intervention for anxiety disorders in

children and adolescents. Higa-McMillan and colleagues reviewed 111 treatment outcome studies of anxiety and related problems for children and adolescents from 1967 to mid-2013 (Higa-McMillan, Francis, Rith-Najarian, & Chorpita, 2016). The findings suggested that CBT and exposure-based interventions are "well-established treatments" based on the criteria of the American Psychological Association Task Force (Chambless et al., 1996; 1998). Consistent with these positive findings, a Cochrane review concluded that CBT is superior to wait-list control (James, James, Cowdrey, Soler, & Choke, 2013). The proportion of children in remission from anxiety diagnoses following CBT was 59.4% versus 17.5% for wait-list control, based on the ITT analysis of 26 studies (odds ratio = 0.13, 95% confidence interval [CI] = 0.09 to 0.19). Although the comparison between CBT and active control conditions was not significant, limited numbers of studies using an active control were available. Sensitivity analysis with completer-only participants did in fact reveal a significant difference between CBT and active controls for remission of anxiety diagnoses ($z = 2.98$, $p = .003$). A subsequent meta-analysis supported that CBT produces large effects sizes not only immediately after treatment but also after follow-up assessments ranging from 1 to 89 months after treatment ($M = 11.80$ months, $SD = 16.69$; pre-to post-treatment: $d = 1.05$, 95% CI = 0.94 to 1.15; pre-to follow-up: $d = 1.29$, 95% CI = 1.18 to 1.40) (Sun, Rith-Najarian, Williamson, & Chorpita, 2018). To date, CBT is the most promising psychosocial treatment for anxiety disorders in children and adolescents.

Kazdin (2002) articulated that psychosocial interventions with ethnic and cultural sensitivity are scarce and identified this as a future issue for evidence-based psychosocial intervention. Indeed, although importance of cultural adaptation of psychosocial interventions has been frequently emphasized (Weems & Silverman, 2013), the dissemination of CBT to diverse cultures is still at an experimental stage. Specifically, studies focusing on anxiety disorders in children and adolescents were limited in underrepresented ethnocultural groups and focus almost exclusively on Western and related cultural values (see Essau, Sakano, Ishikawa, & Sasagawa, 2004). Hall and colleagues published a meta-analysis examining cultural adaptations of psychological interventions for a range of psychological disorders in children, adolescents, and adults that included 11 previous meta-analyses and additional trials. The meta-analysis included 13,998 participants, 95% of whom were non-European. Although the results supported the efficacy of culturally adapted interventions ($g = 0.67$) in comparison with no or other interventions (Hall, Ibaraki, Huang, Marti, & Stice, 2016), there were very few studies focused on CBT for Asian children and adolescents. Although 27 studies focusing on youth were included in the meta-analysis, there were only three studies for Jordanian, Chinese American, and Hong Kong Chinese children, specifically. One study which evaluated efficacy of the FRIENDS program (Barrett, 2004, 2005) in Hong Kong indicated that children who completed the 12-week intervention reported a significant decrease in overall anxiety levels (Batra, 2013). However, specific cultural adaptations of the Western program to Chinese children were not reported.

Lau and colleagues also conducted a CBT trial for anxiety in children in Hong Kong (Lau, Chan, Li, & Au, 2010). The study used a group treatment program based on the Coping Cat program (Flannery-Schroeder & Kendall, 1996). In addition, they added several cultural adaptations, specifically, i) translation into the native language, replacing the acronym FEAR in the Coping Cat program with an easy-to-remember Chinese acronym, ii) repackaging from original sixteen 1-h sessions to nine 2-h sessions, iii) enhancing parental involvement by inviting the parents to observe the children's sessions and meet with one of the CBT co-leaders in five sessions (i.e., 1st, 2nd, 5th, 8th, and 9th sessions), and iv) applying a culturally specific analogy (e.g., *kung fu*). The results showed both clinically and statistically significant improvements in children's self-report and parent report anxiety symptoms. Moreover, 65% of children with an anxiety disorder before treatment no longer met the diagnostic criteria after treatment,

according to semi-structured interviews (Kiddie-Schedule for Affective Disorders Schedule; Kaufman, Birmaher, Brent, Rao, & Ryan, 1997).

Although the numbers of previous studies are limited, the outcome supports the transportability of evidence-based psychotherapies for childhood anxiety disorders to Asian countries. It is meaningful to translate and import treatment manuals which already have confirmed efficacy among represented ethnocultural groups. However, the previous studies exclusively focused on *top-down* cultural adaptation in which an existing intervention for one group is modified for application to another group (Hall, Ibaraki et al., 2016). According to the Psychotherapy Adaptation and Modification Framework (PAMF) and Formative Method for Adapting Psychotherapy (FMAP) by Hwang (2006, 2016), reliance on *top-down* approaches might fail to address important aspects of cultural adaptation. Rather, a *bottom-up* approach which is developed within a particular cultural context can address culturally specific concerns (Hall, Ibaraki et al., 2016; Hwang, 2016). Although a *bottom-up* approach is important and indispensable for cultural adaptation, it is not sensible to emphasize exclusive domestic production of psychosocial interventions ignoring the current evidence-based interventions. Thus, an approach that capitalizes on existing evidence-based practices may prove more practical.

For the purposes of this study, we applied an innovative bidirectional approach, one that includes both *top-down* and *bottom-up* approaches and aims to develop a novel treatment that is derived from previous studies but not a simple translation of previous manuals. First, in one direction, treatment components should be selected from existing programs, imported into the concerned cultures, and a pilot protocol set up. Second, in the opposite direction, the provisional protocol should be modified within a particular cultural context and an implemented treatment program would be shaped gradually. The first pathway allows researchers to develop a protocol based on current evidence-based practices specifically for an underrepresented ethnocultural population where availability and accessibility have been limited due to lack of several resources, such as language, proximity, or finance. Meanwhile, as a second pathway, the provisional protocol should be optimized and refined through continuous feedback from indigenous clinical settings in keeping with the theoretical, therapeutic, and conceptual elements of each treatment component. The reciprocal process of cultural adaptation is expected to provide an original protocol which consists of components that are supported by previous clinical trials. Furthermore, it allows flexible application beyond accurate translation works or rigid perseveration of the individual program. Although there have been some studies in the US examining bidirectional cultural adaptions of CBT for adult depression (Hwang et al., 2015), to the best of our knowledge, there are no studies using this approach for children and adolescents.

It is important to show the specific procedure of cultural adaptation from the existing evidence-based psychotherapies to other underrepresented cultures. It is difficult for users of evidence-based practices to decide when, for whom, which aspect, and how to adapt (Cardemil, 2010). Especially for Asian cultures, limited previous studies are available regarding efficacy and effectiveness trials of psychotherapies with cultural adaptation (see, Hall et al., 2016; Pina, Polo, & Huey, 2019) as well as hypothetical models for cultural adaptation (see, Sundell, Ferrer-Wreder, & Fraser, 2014). However, considering the culturally distinct nature of the Asian heritage population, cultural adaptation of cognitive behavior therapy may be even more important than groups such as African American or Latino who are likely to have increased exposure to Western cultures (Hwang, 2016).

The current study examined the efficacy of a culturally adapted CBT program. The current study is the first randomized controlled trial in Japan to examine the efficacy of CBT for children and adolescents with anxiety disorders using a bidirectional approach to cultural adaptation. The main hypothesis of this study states that CBT will be superior to a wait-list control condition regarding absence of principal diagnoses and all diagnoses, and improvement in the severity of principal diagnoses.

We predict that, compared to those in the wait-list condition, participants in the CBT condition will obtain greater treatment gains for all child- and parent-reported measures, including a culturally-specific cognitive measure. In addition, we predicted that the therapeutic gains will be maintained until 6-month follow-up and the outcome will be comparable with the effects observed in previous RCTs in Western countries.

1. Methods

1.1. Participants

Fifty-one children and adolescents in Japan (aged 8–15 years old; $M = 10.90$, $SD = 2.00$) with anxiety disorders participated in this study. The participants were 22 boys and 29 girls from Kansai area, Japan. Exact information about socio economics status (SES) could not be collected, as inquiry about SES in detail to participate in psychosocial services is unusual and unacceptable for Japanese people. However, all participants were from a middle-class background according to the clinical intake information. All families were Japanese in ethnicity and could read/write Japanese. Thirty-one children met DSM-IV-TR criteria for social anxiety disorder, seven for generalized anxiety disorder, nine for specific phobia, one for depression, and three for dysthymia as a principal diagnosis. The four participants with mood disorders (three children aged 9–12 and one adolescent) initially presented for treatment for anxiety related problems, and although they met criteria for additional anxiety diagnoses the initial assessment indicated that the child's depression was more severe. A decision was made to include these children in the trial, given they were seeking help specifically for the child's anxiety. Thirty-eight of the participants (74.51%) had more than one disorder and 23 (45.10%) had three or more anxiety or depressive disorders. No participants had additional comorbid diagnoses.

1.2. Measures

In this study, a multimethod, multi-informant assessment of children is used. The absence of principal diagnoses, determined following a structured interview was the primary outcome measure. In addition, questionnaires for self-reported anxiety, depression, and cognitive errors as well as parent-reported anxiety were used as secondary outcomes.

1.3. Diagnostic interview

The Anxiety Disorders Interview Schedule for DSM-IV (ADIS). The ADIS (Silverman & Albano, 1996) was administered by one of three trained clinical psychologists. The ADIS in this study was translated into Japanese for the purpose of a previous trial in Japan (Ishikawa et al., 2012). One bilingual translator translated the interview from English to Japanese, and another bilingual translator who was also a native speaker back-translated the interview into English. Differences in the two versions were discussed and resolved by joint agreement of both translators. In this study, the evaluators who did not know the allocation of each participant interviewed the child and his/her parents at the pre-, post-, and follow-up assessments. They received a one-day training by clinical psychologists experienced in implementing the ADIS and observed previous interview sessions. Diagnoses were based on information provided by both informants (i.e., composite diagnoses). After completion of all ADIS interviews, another clinical psychologist reviewed all recorded audio and written data for the participants allocated to treatment. Interrater reliability (kappa coefficient) for the presence of disorders was 1.00 for separation anxiety disorder, 1.00 for social anxiety disorder, 0.91 for specific phobia, 0.96 for generalized anxiety disorder, 0.92 for depression, and 0.91 for dysthymia. When any discrepancies were found, the primary and secondary interviewers

discussed the diagnostic status and reached a consensus. Principal diagnoses were determined based on the disorder with the highest severity (Clinical Significance Ratings: CSR) as judged by the clinical psychologists.

1.4. Questionnaires

Secondary outcomes included self-reported anxiety, depression, and cognitive errors as well as parent-reported anxiety. Translated questionnaires, especially one's considered as "gold-standard" for specific symptoms, enable us to make cross-cultural comparisons (Ishikawa et al., 2018). On the other hand, the translated measures might be unfamiliar and incomprehensible when they aim to assess children's internal verbal states. Although several standardized cognitive measures have been developed (e.g., Children's Automatic Thought Scale; Schniering & Rapee, 2002), we used a culturally specific measure for children's cognition in addition to universal psychopathological measures for anxiety and depression.

1.5. Child self-report

Spence Children's Anxiety Scale (SCAS). The SCAS (Spence, 1998) is a 38-item self-report measure of anxiety symptoms designed for children and adolescents. Each item is rated on a 4-point scale in terms of its frequency ranging from 0 (*never*) to 3 (*always*). The total score of all 38 items represents overall anxiety score. Ishikawa and colleagues developed the Japanese version of the SCAS (Ishikawa, Sato, & Sasagawa, 2009) with strong internal reliability coefficients: .94 and .92 for the full-scale scores among children and adolescents, respectively. In addition, the scale has acceptable test–retest reliabilities of 2–4 weeks: $r = .76$ for children and $r = .86$ for adolescents, $ps < .001$ (Ishikawa et al., 2009). Internal consistency of the SCAS in the current sample was .90.

Depression Self-Rating Scale (DSRS). The DSRS (Birleson, 1981) is an 18-item measure of depressive symptoms for children and adolescents between 6 and 15 years of age. The total score of the DSRS represents depressive symptoms and each item is rated on a 3-point scale in terms of its frequency from 0 (*never*) to 2 (*always*). Murata, Shimizu, Mori, and Oushima (1996) translated the English scale into Japanese. The test-retest reliability of Japanese scale was .73 and Cronbach' alpha was .77. Internal consistency of the DSRS in this study was .82.

Child Depression Inventory (CDI). The CDI (Kovacs, 1985) is a 27-item measure for assessment for depression in children and adolescents between 7 and 17 years of age. Whereas the DSRS was commonly used in Japan, the CDI is also applied for international comparison. The CDI has three descriptions which represent each depressive symptom and each item is allocated 0, 1, and 2 points as its severity. Mashida et al. (2009) translated the CDI into Japanese and found that Cronbach's alpha was .83. Internal consistency of the CDI was .86 in the current sample.

Children's Cognitive Error Scale (CCES). The CCES (Ishikawa, 2012) is a 20-item measure for assessing cognitive errors in children and adolescents in Japan. Each item is rated on a 4-point scale in terms of its frequency from 0 (never think so) to 3 (think so very much) and a total cognitive errors score is created by summing each item. The CCES is composed of two parts. The first part shows short vignettes describing possible anxiety-provoking events. Second, children and adolescents were asked to report the degree to which they agreed with the possible interpretations of the vignettes. Explanatory and confirmatory factor analyses revealed that the CCES has a single factor structure (Ishikawa, 2012; Ishikawa & Sakano, 2003). Two-week test-retest reliability of the CCES was $r = .66$, $p < .01$ and Cronbach's alpha was .85 (Ishikawa & Sakano, 2003). Internal consistency of the CCES was .90 in the current sample.

1.6. Parent-report

Spence Children's Anxiety Scale-Parent version (SCAS-P). The SCAS-P (Nauta et al., 2004) is a 38-item parent-report measure of anxiety symptoms for children and adolescents. The items from the original version of the SCAS-P were formulated, as closely as possible, to the corresponding items from the child version of the SCAS. There were 38 items in the SCAS-P scored on a scale from 0 (*never*) to 3 (*always*). The all 38 items are summed to produce an overall anxiety score. Ishikawa and colleagues developed the Japanese version of the SCAS (Ishikawa et al., 2014). Internal reliabilities of the Japanese version were satisfactory for the community and clinical samples (Cronbach's alpha with corrected Spearman Brown coefficients = .96). Internal consistency of the SCAS-P in the current sample was .83.

1.7. Treatment

The Japanese Anxiety Children/Adolescents Cognitive Behavior Therapy program (JACA-CBT), a generic treatment manual focusing on underlying mechanisms among several types of anxiety disorders rather than specific types, has been developed over a decade of research and clinical service delivery. Based on the previous trials (Ishikawa et al., 2012; Ishikawa, Kikuta, & Mitamura, 2013; Ishikawa & Sakano, 2005b; Ishikawa, Shimotsu, & Sato, 2008), the treatment was adapted over 4 phases that are described in detail in Table 1. Each adaptation occurred following pilot testing of the program, allowing feedback from therapists to be incorporated into the next iteration to allow increased suitability for Japanese children. Cultural adaptations and modifications of both context and content were made to JACA-CBT (Stirman, Miller, Toder, & Calloway, 2013; Sundell, Beelmann, Hasson, & Schwarz, 2016). Table 2 shows the components of the JACA-CBT program.

First, the JACA-CBT addressed six contextual adaptations; population (for whom the treatment is developed), personnel (who provides the treatment), setting (where the treatment is provided), format (individual or group, family or child-parent), dosage (how many sessions are prepared), and procedure (how to recruit) (Stirman et al., 2013; Sundell et al., 2016). Clearly, the targeted population was specific to Japanese children and adolescents through all phases of adaptation. Because it is uncommon in Japanese culture for children to be seen by a health professional without a parent present, parents were in the same room as their child receiving the explanation and discussing each topic. In clinical trials in Western countries that used generic treatment manuals, parents and children are typically seen separately (e.g., Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008), or a mix of working together and separately (e.g., Hudson et al., 2009). Consistent with existing Western manuals, treatment was provided once per week and homework was assigned between the sessions. However, treatment length was shorter - eight sessions - compared with 16 sessions for Coping Cat (e.g., Kendall, 1994) and 10 sessions for Cool Kids (e.g., Hudson et al., 2009). Considering the hectic schedule for Japanese children and adolescents, a flexible schedule was applied for supplemental sessions to allow the families to catch up on any missed sessions and homework. Due to the flexible schedule, all participants completed eight sessions. Children and adolescents, as well as their parents, were invited to attend a booster session after they completed eight sessions. Cognitive behavior therapy for children and adolescents is not yet common practice in Japan (Ishikawa et al., 2016a,b). Considering the lack of readiness of families, we decided to prepare a minimum number of mandatory sessions and supplement with up to three subsequent booster sessions. Booster sessions mainly focused on the family's implementation of the in vivo exposures in their daily life. A booster session was provided once per one to three months and until six months after the completion of therapy depending on the needs of each participant. Mean number of booster sessions that were provided for participants was 2.61 (*SD* = 1.74) and more than half of the treatment completers (52.17%) attended two or three booster sessions until 6 months (range = 0–6). Finally, given the treatment protocol was found to be effective in also reducing depressive symptoms (Ishikawa et al., 2012;; Ishikawa et al., 2013), this study included children and adolescents who had depressive disorders as their principal diagnoses in addition to anxiety disorders.

Second, in terms of content cultural adaptation (Stirman et al., 2013; Sundell et al., 2016), the JACA-CBT tailored materials as well as adjusting elements and time-management through four-phase. The vignettes of anxiety situations and emotional descriptions were collected based on bottom-up approach during Phase 1. Culturally specific illustrations and a culturally specific acronym were prepared to be more attractive and acceptable to Japanese children at Phase 2. In addition, different versions for children and adolescents were also developed at Phase 3 considering the significant transition for Japanese children from elementary to junior high school. The modification had been implemented through Phase 4, such as adding a detailed explanation for adolescents about several types of cognitive errors based on onsite survey results, and shortening the amount of time for cognitive restructuring for the children's version through feedback from local clinical psychologists. To emphasize and encourage the exposure session, at Phase 3, the habituation model of anxiety was introduced based on the One Session Treatment for specific phobia in children and adolescents (Öst & Ollendick, 1999) and a treatment manual for children with school refusal (Kearney & Albano, 2007). The habituation model was mentioned in one treatment manual (Hudson et al., 2009) but not another (Kendall, 1994). Instead, at Phase 4, cognitive restructuring for younger children was shortened by including a culturally specific acronym, based on feedback from practitioners. In addition, given that most clients referred to the clinic had social anxiety disorder, the majority of vignettes in this program were changed to socially relevant situations. In the last phase, relaxation was added to JACA-CBT as a compulsory topic considering that Asian individuals tend to show their anxiety as physical symptoms (e.g., Hwang, 2016). Finally, the time frame of the JACA-CBT was reordered considering the balance of each component. Each session was 60 min in length which is consistent with the cultural norms in the country, but extended up to 120 min for in vivo exposure to ensure sufficient time for habituation. All treatment protocols comprise multiple treatment components, however the balance was adapted for Japanese culture. Given there is no clear boundary between "thoughts" and "feelings" in the Japanese language system, the program was adjusted to spend less time on cognitive restructuring and more time for habituation or relaxation which were concepts more familiar to Japanese families.

1.8. Therapists

Two qualified Japanese clinical psychologists, SI and KK implemented JACA-CBT in a clinical psychology center within the university. To assess the adherence of the sessions, 20% of the program sessions were extracted randomly and evaluated by independent raters based on the treatment manual. Treatment adherence was evaluated by independent raters who were enrolled in a masters or doctoral course of clinical psychology. They evaluated treatment adherence of each therapist according to the specific manual that included dichotic checklists for mandatory components (range: 11–16) for each session. As a result, overall adherence was 99.8% and the two therapists were comparable, 99.6% and 100%, respectively.

1.9. Procedure

Participants were recruited using advertisements displayed at schools, public mental health clinics and in newspapers and websites between 2012 and 2015. Following a brief phone screening, 79 children and adolescents participated in a pre-treatment assessment conducted by clinical psychologists. The diagnosticians explained the study to

Table 1

A cultural adaptation/modification of Japanese Anxiety Children/Adolescents Cognitive Behavior Therapy (JACA-CBT) program.

Phase	Major adaptation/modification	Way of adaptation	Main results of testing of the program
Phase 1			Ishikawa and Sakano (2005b)
i)	Therapeutic components from previous CBT programs in Western countries (e.g. Barrett, 1998; Kendall, 1994) had been reviewed and a detailed protocol was developed as a provisional version of the JACA-CBT.	Top-down	The study aimed to develop a cognitive behavioral therapy (CBT) program for children and adolescents with anxiety disorders in Japan. As a result, a provisional version of the JACA-CBT program was developed. In addition, a case study for a 14 year-old boy reported that anxiety symptoms and cognitive errors improved post-treatment and 2-month follow-up.
ii)	Vignettes in which children tend to feel anxiety, were extracted from an onsite survey for Japanese children and adolescents (Ishikawa & Sakano, 2003).	Bottom-up	
iii)	Emotional descriptions which were used in the program, were collected and developed based on another onsite survey about self-statements for children and adolescents in Japan (Ishikawa & Sakano, 2005a).	Bottom-up	
Phase 2			Ishikawa et al. (2008)
iv)	More familiar and cultural specific illustrations were drawn by a professional illustrator.	Bottom-up	The pilot study examined the preliminary efficacy of a group version of the JACA-CBT program. Participants were 12 children with anxiety disorders. Nine children (75%) were free from their principal diagnoses. There were significant improvements for self-report anxiety as well as cogntive errors.
v)	A culturally relevant acronym to assist the children in remembering the skills was also developed through feedback from clinical psychologists that some children had difficulties learning the components.	Bottom-up	
Phase 3			Ishikawa et al. (2012)
vi)	Two versions of the program were developed to accommodate the child's developmental stage. Specifically one child version was developed for elementary school students and an adolescent version for junior high school students.	Bottom-up	The study examined group and individual JACA-CBTs based on a quasi-experimental design. Three months following treatment, 20 of the 33 children and adolescents (60.9%) no longer met criteria for their principal anxiety disorders and 16 (48.5%) were free from all anxiety disorders. Self-report anxiety, depression, and cognitive errors also decreased significantly from pre- to post-treatment. Individual and group formats were comparable excepting on one self-report measure. Specifically, individual treatment was superior to group on one measure of self-reported depression.
vii)	Explanation of habituation of anxiety was added to understand how exposure works for overcoming anxiety (e.g., Kearney & Albano, 2007; Öst & Ollendick, 1999). The adaptation was not culturally specific, rather simply introduced from the other CBT protocols to enhance motivation for exposures.	Top-down	
viii)	Cognitive restructuring for elementary school children was changed to a simpler format including self-instruction and a role-play task for using the other person's perspective. This change was made based on further feedback from clinical psychologists regarding the difficulty of the cognitive components.	Bottom-up	
ix)	The vignette examples of anxious children were updated to accommodate the high numbers of children and adolescents who had social anxiety symptoms. For example, the cognitive components vignette was changed to a social situation (i.e., your friend who always leaves school with you, said that she could not go home with you). The adaptation was based on feedback from clinical psychologists as well as empirical data.	Top-down Bottom-up	
Phase 4			Ishikawa et al. (2013)
x)	Based on further feedback from clinical psychologists, relaxation training was included as a compulsory topic instead of an optional. Emprically, Asian children including Japanese childre tend to show anxiety as physical symptoms. The instructions have been developed based on the previous CBT programs in Western countries.	Top-down Bottom-up	The pilot study evaluated whether there was augmented treatment gain from adding a parental component. Twelve Japanese children with anxiety disorders participated in JACA-CBT with parental components. Three months following treatment, 6 children (50.00%) no longer met criteria for their principal anxiety disorders. A significant treatment effect was found for depression scale, but not for both self- and parent-report anxiety scales. From this preliminary study, there were no clear results to suggest separate sessions for parents should be added to the standard CBT program for children and parents.
xi)	Standard session times were shortened from 90 to 60 min considering cultural norms of school-aged children and adolescents (students in elementary and junior high schools are used to lessons up to 60 min). However, 90–120 min were preserved for in vivo exposures based on the theoretical implication of the previous CBT programs in Western countries (i.e., exposure is considerd a core component for CBT protcol).	Top-down Bottom-up	
xii)	The order of the cognitive components session was modified for adolescents because the second session was short and the third was relatively long. Thus the session order was modified to allow consistent session length. Finally, session schdule was prepared flexibly depending on each participant to complete all sessions.	Bottom-up	
xiii)	Based on the previous two studies (Ishikawa et al., 2012; Ishikawa et al., 2013), the subsequent study would include participants who has depression in addition to anxiety disorders.	Bottom-up	

children and parents and invited the parents to complete the consent form. After completion of informed consent from parents, they received assent from children. The diagnosticians conducted a joint interview with children and parents using the ADIS-IV-P/C (Silverman & Albano, 1996). Joint interviews with parents and children were conducted for two reasons: to reduce the burden of their attendance and because this is the social norm. Reliability of this format of the ADIS for principal diagnoses was 93.33% (Kappa = .91) in the previous study (Ishikawa et al., 2013). Clinical psychologists asked parents and children

separately for severity of symptoms and used a composite rating after completion of the interview. To be included in the study, participants had to (a) be between 7 and 15 years of age, (b) attend the program with their parents, (c) have an anxiety disorder as determined through the ADIS, (d) not fulfill criteria for PTSD, disruptive behavioral disorders, substance abuse, mental retardation, pervasive developmental disorder, or a psychotic disorder, and (e) agree to discontinue other forms of therapy for the duration of the study. Six participants had been prescribed medications, but no one was taking medications at the time

Table 2
Program components of the JACA-CBT.

No.	Children version	Adolescent version
1	Let's think about your problem! (Psychoeducation)	
2	Catch your feeling! (Psychoeducation)	
3	Pick your thoughts up! (Cognitive restructuring)	Try to think flexibly! (Cognitive restructuring)
4	Try to think flexibly! (Cognitive restructuring)	Capture irrational thoughts! (Cognitive restructuring)
5	Try to think more flexibly ! (Cognitive restructuring)	
6	Built your anxious staircase! (Anxiety hierarchy)	
7	Take a challenge of your staircase! (In vivo exposure, Relaxation)	
8	Review and party! (Homework exposure)	

Note: JACA-CBT = Japanese Anxiety Children/Adolescents Cognitive Behavior Therapy program.

of the pre-assessment, and there were no participants who received other psychotherapies during the study. Finally, 51 children and adolescents were randomly allocated to either the treatment condition of cognitive behavior therapy (CBT: $n = 26$) or a wait-list control condition (WLC: $n = 25$). Fig. 1 shows a CONSORT flow chart of this study. Given the two age-specific versions of the program (i.e., for children aged 8–12 in elementary school and adolescents aged 12–15 in junior high school), participants were allocated to condition randomly by use of a random number generator with block randomization by age. An independent person produced a random number and allocated each condition. All procedures performed in studies involving human

participants were in accordance with the ethical standards and approved by the institutional review board of the first author (#15015). The trial had been pre-registered in the UMIN clinical trials (UMIN000008724). The recruitment of the trial was started on 20th August 2012 and the follow-up was completed on 31st March 2017 based on completion of prerequisite sample size.

Participants in the treatment condition were provided eight treatment sessions one to two weeks after the pre-treatment assessment ($M = 122.08$ days, $SD = 48.15$). In the wait-list control condition, participants visited our clinic two months after the pre-treatment assessment for a second assessment session ($M = 70.00$ days, $SD = 11.01$). As a result, the wait-list duration was shorter than that of treatment phase for the CBT condition, after which the children in the WLC condition started to participate in the CBT program as outlined above ($M = 112.29$ days, $SD = 33.32$). A participant in the CBT condition did not attend the post-assessment as the parents did not respond to calls from the research team. Another participant in WLC participated in another treatment program before completion of the wait-list period and was thus due to this protocol breach excluded from the follow-up analysis. Participants in both conditions completed a 3- and 6-month follow-up assessment after the end of the treatment ($M = 92.88$ days, $SD = 17.72$ and $M = 189.42$ days, $SD = 25.06$).

1.10. Data analysis

The primary research question was to examine whether a bidirectional culturally adapted CBT program can ameliorate the principal
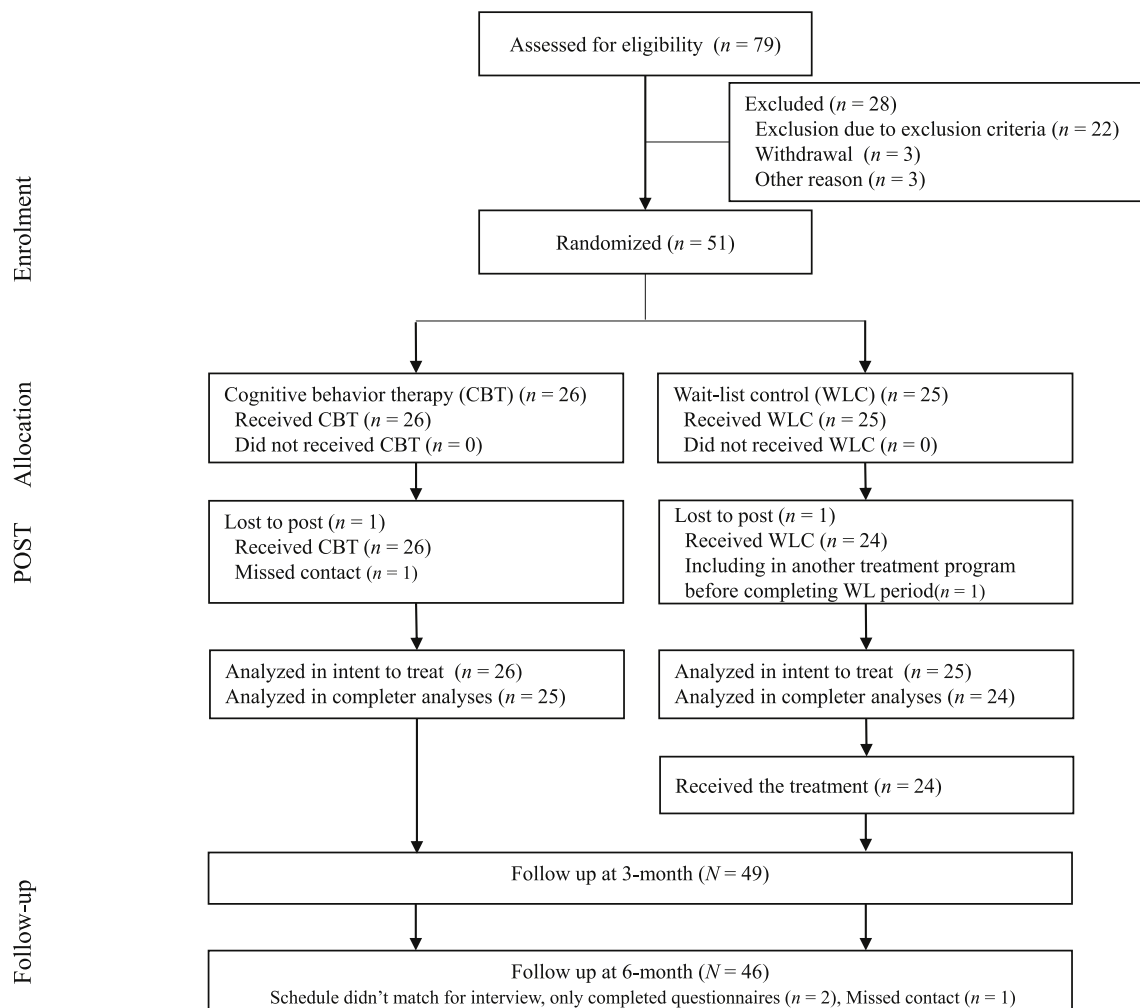

Fig. 1. CONSORT flow chart of this study.

Table 3
Demografic data across conditions.

Characteristics		CBT (n = 26)		WLC (n = 25)	
Female (%)		18	(69.23)	11	(44.00)
Age, mean (SD)		10.88	(2.27)	10.92	(1.73)
Grade(%)					
elementary school	3	8	(30.77)	4	(16.00)
	4	5	(19.23)	6	(24.00)
	5	2	(7.69)	6	(24.00)
	6	3	(11.54)	3	(12.00)
junior high school	7	2	(7.69)	2	(8.00)
	8	4	(15.38)	2	(8.00)
	9	2	(7.69)	2	(8.00)
Principle diagnosis (%)					
	SAD	0	(0.00)	0	(0.00)
	SoP	15	(57.69)	16	(64.00)
	SP	3	(11.54)	6	(24.00)
	GAD	5	(19.23)	2	(8.00)
	Dep	1	(3.85)	0	(0.00)
	Dys	2	(7.69)	1	(4.00)
No. of comorbid disorders(%)					
	1	6	(23.08)	7	(28.00)
	2	10	(38.46)	5	(20.00)
	3-	10	(38.46)	13	(52.00)

Note: CBT = treatment condition of cognitive behavior therapy; Dep = depression; Dys = dysthymia; GAD = generalized anxiety disorder; OCD = obsessive-compulsive disorder; PD = panic disorder; SAD = separation anxiety disorder; SoP = social phobia; SP = specific phobia; WLC = wait-list control condition.

diagnoses of Japanese children and adolescents seeking treatment for anxiety. Therefore, the proportion of participants who no longer met criteria for the principal diagnosis at post-treatment in the CBT and WLC, was examined using a χ^2 test. In addition, we compared absence of all anxiety diagnoses at post-treatment. Based on the diagnostic free proportions in the CBT and wait-list control conditions reported by James et al. (2013; 59.4% vs. 17.5%), G*Power (Faul, Erdfelder, Buchner, & Lang, 2009) calculated that the required sample size was $N = 25$ for a single arm when power $1 - \beta$ was 0.90 and type I error was 5%. All diagnostic data were analyzed using the intent-to-treatment (ITT) sample, and the completer sample was also used to conduct supplementary analyses. Missing diagnostic data for the ITT analyses of diagnostic data were handled using the last-observation-carried-forward (LOCF) method. A mixed model analysis was conducted for diagnostic severity (CSR) for the ADIS and all child- and parent-rated questionnaires. MANOVAs comparing symptoms of participants without missing data and those with partial missing data were not significant. As a result, missing data of secondary outcome were handled by multiple imputation method. Logarithmic conversions were conducted for all secondary measures that showed positive skewness. Skewness was mainly observed in the data at 6-month follow-up, due to improvement. In the model, two main effects of condition (CBT, WLC) and time (pre, post) as well as the interaction (condition by time) were entered as a fixed effect, and subject was imputed as a random effect. When significant group differences in the any secondary outcomes at pre-treatment were found, the model included the pre-treatment scores of the scale as a covariate for analyses of the remaining secondary outcomes. When any significant interactions were found, post-hoc analyses were conducted between conditions at each time and within condition. Effect sizes of Hedge's g and 95% confidence interval (CI) for all continuous variables and eta-squared for χ^2 test were calculated based on the ITT analyses using the LOCF methods. In terms of secondary outcomes, a clinically significant change was examined based on a Reliable Change Index (RCI; Jacobs & Truax, 1991) and a non-dysfunctional range. The RCI was calculated based on standard errors of pre-treatment scores. When the RCI was greater than 1.96, the children were considered to show clinically meaningful change. Clinical cutoff points were applied to set a non-dysfunctional range when obtained.

Nevertheless, mean scores within 1SD range were adopted as non-dysfunctional range (Jacobs & Truax, 1991). In addition, several thresholds were set when the previous studies suggested different criteria depending on gender and age. As a result, different cutoff points corresponding to age and gender were set for the SCAS (children: boys: 33, girls: 26, adolescents: boys: 26, girls: 41) and the CCES (children: boys: 33, girls: 40, adolescents: boys: 27, girls: 45) while unified clinical cutoff points were applied for the CDI (24) and the DSRS (16). For the SCAS-P, we applied a single threshold (21) based on the mean and standard deviation, given our previous study suggested there was no significant difference between age and gender in Japanese children (Ishikawa et al., 2014). When a participant met both criteria; showing greater than 1.96 for RCI and falling in a non-dysfunctional range, the children were classified as showing clinically significant improvement. Finally, since this study could not examine differences between the CBT and WLC at follow-up phases due to the wait-list control group receiving treatment following the post assessment period, mixed model analyses for time (pre, 3-month, 6-month) were also conducted to examine follow-up effects after combining CBT and WLC. The model included time as a fixed effect and subject as a random effect. To exclude natural time effect, post scores for WLC condition (i.e., after the wait-list period) were included as pre-scores in this model. Given that there were three assessment-points for follow-up analyses, multiple comparisons with Bonferroni correction were conducted for post-hoc analyses to examine which time would be significantly different. Clinically significant improvement was also examined for all participants at 3- and 6-months follow-up assessments.

2. Results

2.1. Preliminary analyses

Children in the treatment and wait-list control conditions were compared on demographic data (Table 3). There were no significant differences between the CBT and WLC in terms of gender, χ^2 (1, N = 51) = 3.31, p > .06, age, t (49) = 0.62, p > .95, severity of the principal diagnosis, t (49) = 1.04, p > .30, and numbers of diagnoses, t (49) = 0.74, p > .46. In addition, all dimensional outcomes except the SCAS-P were not different at pre-treatment, SCAS: F (1,49) = 0.09, DSRS: F (1,49) = 2.20, CDI: F (1,49) = 0.22, CCES: F (1,49) = 0.38, SCAS-P: F (1,49) = 9.41, p < .01.

2.2. Primary outcome[1]

Table 4 shows the number of children who were free from their principal diagnoses in the treatment and wait-list control condition at pre-, post-, 3-month, and 6-month follow-up assessment. A significant difference was found between the CBT and WLC at post-treatment assessment for the ITT analysis, χ^2 (1, N = 51) = 8.55, $\eta^2 = 0.17$, p < .01. Specifically, 13 children and adolescents in treatment condition were free from their principal diagnoses compared to three in the wait-list condition (50% versus 12%). In terms of remissions rates of all anxiety disorders, four participants in the CBT condition were free from all diagnoses compared to one in the control condition. There were no significant differences in the remission rates for all diagnoses between

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[1] We found the same results for completer analyses for principal diagnoses, χ2 (1, N = 49) = 8.69, η2 = 0.18, p < .01 and for any diagnoses of anxiety disorders, χ2 (1, N = 49) = 0.67, η2 = 0.01, p > .41. We also examined the proportion of participants who were free from the principal anxiety disorders (excluding four participants who had depressive disorders as principal diagnoses). Significant differences were found for ITT and completer analyses, χ2 (1, N = 47) = 5.63, η2 = 0.12, χ2 (1, N = 45) = 5.75, η2 = 0.13, ps < .05, respectively. Specifically, 10 children and adolescents (43.5% for ITT; 45.5% for completers) in treatment condition were free from their principal diagnoses compared to 3 (12.5% for ITT; 13.0% for completers) in the wait-list condition

Table 4
Diagnostic outcome.

		CBT	WLC	CBT + WLC	
		Post	Post	3-month	6-month
Proportion free of principal diagnosis					
ITT	n	13/26	3/25	26/51	34/51
	%	(50.00)	(12.00)	(50.98)	(66.67)
Compeleter	n	13/25	3/24	26/49	34/46
	%	(52.00)	(12.50)	(53.06)	(73.91)
ITT	n	4/26	1/25	17/51	25/51
Proportion free of any diagnosis					
	%	(15.38)	(4.00)	(33.33)	(49.02)
Completer	n	4/25	1/24	17/49	25/46
	%	(16.00)	(4.17)	(34.69)	(54.35)

Note: CBT = treatment condition of cognitive behavior therapy; CCES = Children's Cognitive Error Scale; CDI = Children's Depression Inventory; DSRS = Depression Self-Rating Scale; SCAS = Spence Children's Anxiety Scale; SCAS-P = Spence Children's Anxiety Scale-Parent vesion; WLC = wait-list control condition.

the CBT and WLC at post-treatment.

Clinical severity ratings (CSR) of principle diagnoses in the ADIS were examined between the two groups. Significant main effects of condition and time were found, F (1, 49) = 13.57, $p < .001$, F (1, 49) = 25.72, $p < .001$, respectively. A significant interaction between condition and time was found, F (1, 49) = 12.38, $p < .001$. Specifically, children and adolescents in the treatment condition showed significant improvement on clinical severity (CSR) from pre-to post-treatment ($p < .001$) whereas those in the wait-list condition did not show any improvement. In addition, there was a significant difference between the conditions at post-treatment, $p < .001$. Effect size of CSR for ITT sample at post-treatment was 1.00 (Hedge's g 95% CI = 0.42–1.58).

2.3. Secondary outcome[2]

A mixed model was examined for the remaining secondary outcome measures after controlling for pre-treatment scores of the SCAS-P, whereas the original model was applied for the SCAS-P (Table 5). There were no main effects of condition for all secondary outcomes. Significant main effects of time were found for the SCAS, DSRS, CDI, CCES, and SCAS-P (F (1, 47.89) = 16.68, $p < .001$, F (1, 47.58) = 5.14, $p < .05$, F (1, 47.62) = 11.03, $p < .01$, F (1, 48.54) = 7.24, $p < .01$, and F (1, 47.53) = 14.90, $p < .001$, respectively. While significant interactions between time and condition were evident on the CDI, F (1, 47.60) = 5.95, $p < .05$ and SCAS-P, F (1, 47.53) = 8.24, $p < .01$, there were no interactions for the remaining scales. Post-hoc analyses revealed that CBT only improved depressions scores (CDI) from pre-to post treatment, $p < .001$. However, there were no significant differences between CBT and WLC at both assessments. In terms of the SCAS-P, a significant difference of condition was found at pre-treatment, $p < .05$: CBT showed a significant decrease in parent-reported anxiety from pre-to post-treatments, $p < .001$. Effect size of Hedge's g between the CBT and WLC at post-treatment were SCAS = 0.43 (95% CI = 0.19–1.04), DSRS = 0.39 (95% CI = 0.22–1.00), CDI = 0.48 (95% CI = 0.14–1.09), CCES = 0.38 (95% CI = 0.24–0.99), and SCAS-P = 0.15 (−0.45–0.76), respectively. The proportions of participants showing clinically significant improvement did not differ between CBT and WLC at post-treatment (Table 6).

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[2] The mixed model of the CSR after controlling the pre-scores of the SCAS-P also showed significant main effect of condition and time as well as the interaction of time and conditions, F (1, 47.84) = 16.17, F (1, 49.33) = 27.39, F (1, 49.32) = 13.21, $ps < .001$

2.4. Follow-up primary outcome

Finally, we examined follow-up outcomes at 3 and 6 months after treatment, combining the CBT and WLC. All three participants who recovered from their principal diagnosis during the wait-list period still received the active treatment, as they still had either additional clinical anxiety disorders ($n = 2$) or subclinical symptoms ($n = 1$), and thus all wait-list participants were included in the analyses examining outcomes 3 and 6 months after the completion of the treatment program. Twenty-six participants at 3-month (50.98%) and 34 at 6-month (66.67%) were free from their principal diagnoses. In addition, 25 children and adolescents (49.02%) did not meet criteria for any diagnoses at 6-month follow-up. Significant improvements in diagnostic status were evident from pre-to 3-month, and 6-month, χ^2 (1, $N = 51$) = 34.89, χ^2 (1, $N = 51$) = 51.00, $ps < .001$, respectively. Neither serious harm nor unintended side effects were reported in both conditions at post, 3 month or 6-month follow-up assessments through parental interviews.

2.5. Follow-up secondary outcome

In addition, significant time effects were found for all the secondary outcomes, SCAS: F (2, 94.55) = 35.36, DSRS: F (2, 95.26) = 30.81, CDI: F (2, 94.48) = 16.71, CCES: F (2, 94.52) = 14.81, SCAS-P: F (2, 95.08) = 54.67, $ps < .001$, respectively. Post-hoc analyses showed that the scores significantly decreased from pre-treatment to both 3-month and 6-month for the SCAS, DSRS, CDI, CCES, and SCAS-P, $ps < .001$, respectively ($p < .01$, pre to 3-month for the CDI and the CCES). Further improvements from 3- to 6-month were also found for the SCAS, $p < .01$, DSRS, $p < .05$, and SCAS-P, $p < .05$. For the clinically significant change, around half of the children and adolescents showed clinically significant improvement at the 3-month follow-up assessment (SCAS = 48.98%, DSRS = 46.94%, CDI = 42.86%, CCES = 57.14%, SCAS-P = 53.06%), and more than 55% at 6-month follow-up (SCAS = 75.00%, DSRS = 66.67%, CDI = 56.25%, CCES = 62.50%, SCAS-P = 75.00%).

3. Discussion

The current study investigated the efficacy of cognitive behavior therapy for children and adolescents with anxiety disorders based on a bidirectional cultural adaptation approach. The Japanese Anxiety Children/Adolescents Cognitive Behavior Therapy program (JACA-CBT) consisted of an original protocol which was developed within the Japanese culture and has been amended according to feedback from indigenous clinicians in the country over the past decade. The JACA-CBT ameliorated the presence and severity of principal anxiety and depressive diagnoses in children and adolescents. The results support the transportability of CBT and efficacy of a bidirectional, culturally adapted treatment to populations in an underrepresented culture of CBT.

The favorable primary outcome results are comparable with previous international studies. For example, one meta-analysis showed the remission rate of anxiety disorders was 59.4% for CBT versus 17.5% for controls (James et al., 2013). The Child/Adolescent Anxiety Multimodal Study (CAMS), which is the largest randomized multi-site clinical trial for children and adolescent with anxiety disorders, revealed that 59.7% participants responded to CBT at post-treatment based on clinical global impression scores (Walkup et al., 2008). The current results are also on par with previously reported remission rates of the principal anxiety diagnosis at post-treatment using the ADIS, for example, 64% in the USA (Kendall et al., 2008), 45.1% in Australia (Hudson et al., 2009), and 35.4% in Norway (Wergeland et al., 2014). Finally, although a different interview was used, the outcome of this study is similar to results of a trial conducted in Hong Kong which showed 65% children were free from their anxiety disorder (Lau et al., 2010).

Table 5
Means and standard errors for dependent measures across conditions.

		CBT				WLC				ES (post)
		Pre	Post	3-month	6-month	Pre	Post	3-month	6-month	Hedge's g (95% CI)
CSR	n	26	25	25	24	25	24	24	24	1.00
	M	6.31	3.08	2.38	1.43	6.72	6.00	2.70	1.57	(0.42–1.58)
	SE	(0.49)	(0.50)	(0.49)	(0.52)	(0.50)	(0.51)	(0.52)	(0.52)	
SCAS	n	26	25	25	24	25	24	24	24	0.43
	M	37.36	28.28	27.85	20.20	41.58	35.95	23.83	18.57	(0.19–1.04)
	SE	(3.55)	(3.55)	(3.48)	(3.55)	(3.63)	(3.97)	(3.70)	(3.70)	
DSRS	n	26	25	25	24	25	24	24	24	0.39
	M	16.85	14.00	14.08	12.36	16.74	16.50	11.43	8.87	(0.22–1.00)
	SE	(1.44)	(1.54)	(1.47)	(1.47)	(1.47)	(1.50)	(1.54)	(1.54)	
CDI	n	26	25	25	24	25	24	24	24	0.48
	M	18.75	14.64	15.31	14.40	18.87	19.05	15.00	12.61	(0.14–1.09)
	SE	(1.78)	(1.75)	(1.71)	(1.75)	(1.82)	(1.86)	(1.82)	(1.82)	
CCES	n	26	25	25	24	25	24	24	24	0.38
	M	22.88	15.72	17.31	14.04	21.96	21.13	13.83	12.17	(0.24–0.99)
	SE	(2.59)	(2.65)	(2.59)	(2.65)	(2.65)	(2.70)	(2.76)	(2.76)	
SCAS-P	n	26	25	25	24	25	24	24	24	0.15
	M	35.58	25.42	22.04	15.56	26.25	27.57	17.48	15.04	(-0.45–0.76)
	SE	(2.47)	(2.57)	(2.47)	(2.52)	(2.57)	(2.62)	(2.62)	(2.62)	

Note: CBT = treatment condition of cognitive behavior therapy; CCES = Children's Cognitive Error Scale; CDI = Children's Depression Inventory; CSR = clinical severity rating of principle diagnoses; DSRS = Depression Self-Rating Scale; SCAS = Spence Children's Anxiety Scale; SCAS-P = Spence Children's Anxiety Scale-Parent vesion; SE = standard error; WLC = wait-list control condition.

Table 6
Proportion of participants showed clinical significance change.

		CBT			WLC			Chi square (post)
		Post	3-month	6-month	Post	3-month	6-month	p
	Responders	25	25	24	24	24	24	
SCAS	n	14	10	18	9	14	18	1.68
	%	56.00	40.00	75.00	37.50	58.33	75.00	.20
DSRS	n	9	8	15	5	15	17	1.38
	%	36.00	32.00	62.50	20.83	62.50	70.83	.24
CDI	n	10	11	14	4	10	13	3.27
	%	40.00	44.00	58.33	16.67	41.67	54.17	.07
CCES	n	14	13	14	7	15	16	3.60
	%	56.00	52.00	58.33	29.17	62.50	66.67	.06
SCAS-P	n	8	12	21	5	14	15	0.78
	%	32.00	48.00	87.50	20.83	58.33	62.50	.38

Note: CBT = treatment condition of cognitive behavior therapy; CCES = Children's Cognitive Error Scale; CDI = Children's Depression Inventory; DSRS = Depression Self-Rating Scale; SCAS = Spence Children's Anxiety Scale; SCAS-P = Spence Children's Anxiety Scale-Parent vesion; WLC = wait-list control condition.

Clinician-rated severity and child-reported depression were consistent with diagnostic data, showing improvements in symptoms in the CBT condition compared to wait-list. In contrast, there was no significant difference between the CBT and WLC on child self-reported anxiety. For both groups, a marked improvement in symptoms was observed. Previous studies have also indicated similar inconsistencies between diagnostic data and child-reported measures, where assessments using diagnosticians (unaware of treatment condition) are more sensitive to treatment differences. For example, individual and family CBT were superior to a non-specific intervention in diagnostic remission rates, whereas there were no significant differences for self-reported measures (Kendall et al., 2008; Suveg et al., 2009). Similarly, Hudson et al. (2009) showed significant treatment effects on clinician and parent reported symptoms but not on self-reported symptoms. One possibility is that social desirability might influence children's reporting, resulting in all children, regardless of treatment, reporting improved symptoms at the post assessment (Dadds, Perrin, & Yule, 1998). Alternatively, the children and adolescents might become more aware of their anxiety through the treatment and as a result, they could report more accurately following treatment. Especially, appropriate knowledge about child and adolescent mental health has not been

disseminated in Japan (e.g., Ishikawa, Sasagawa, Chen, & Essau, 2016). Otherwise, the treatments may not be sufficiently potent to result in improvements in child-reported symptoms, over and above normal fluctuations in symptoms. However, based on effect sizes, all self-reported measures showed that cognitive behavior therapy, compared to no-treatment, improves anxiety, depression, and cognitive errors with moderate magnitude, indicating the absence of differences on child-reported anxiety may have occurred due to limited power. In summary, the ethnically and culturally sensitive cognitive behavioral program successfully showed therapeutic gains in line with the previous studies according to diagnostic status and severity of principle diagnoses as well as magnitude of therapeutic changes.

This study included a high rate of participants with a principal diagnosis of social anxiety disorder (61%). This is noteworthy, because social anxiety disorder does not yield equivalent treatment gains as other types of anxiety disorders when a generic CBT is applied. For example, Hudson et al. (2015) compared treatment outcomes of a group family-based cognitive behavioral therapy for 842 children and adolescents with a range of different anxiety disorders. Based on diagnostic data, results indicated that children with a diagnosis of social anxiety disorder experienced poorer diagnostic outcomes than children with

other anxiety disorders. Given this, we would have expected to see poorer overall remission rates in a sample made up of primarily socially anxious children. However, the proportion of children free from principal diagnoses in the current study (50%) was on a par with outcome rates previously reported for children diagnosed with non-social anxiety disorders (e.g., separation anxiety disorder: 42.2%; generalized anxiety disorder: 52.7%; and specific phobia: 42.1%; Hudson et al., 2015) and was markedly higher than remission rates for children with social anxiety disorder (22.3%; Hudson et al., 2015).

Thus, given the protocol targeted a range of anxiety disorders and the current study included high rates of social anxiety disorder, the remission rates of the JACA-CBT are promising. Although speculative, a treatment based on bidirectional cultural adaptation might produce improved therapeutic gains for an underrepresented population with culturally relevant symptoms. Since it is an important aspect for cultural adaptation and modification to understand and address ethnic differences in expression of distress (Hwang, 2006; 2016), an adapted treatment can consider culturally specific symptoms and tackle with these problems inherently especially when it includes a *bidirectional* approach.

The current sample also included children with depression and dysthymia as a principal diagnosis. It is not uncommon to include participants with depressive disorders in a treatment study of anxiety disorders yet it is less common, even in transdiagnostic approach to anxiety and depression, to include children whose depression is more severe than the anxiety (see Ollendick, Fraire, & Spence, 2014). Moreover, although evidence-based psychosocial treatment has been established for adolescents with depression, it has not been established for children (Weersing, Jeffreys, Do, Schwartz, & Bolano, 2017). Nevertheless, given that all participants with depressive disorders were free from their principal diagnosis at 6-month follow-up (in addition to significant improvements of the CDI), the current results provide preliminary evidence that the JACA-CBT might also ameliorate depressive symptoms due to its sensitivity of culturally specific symptoms.

There are some limitations in this study as well as implication for future research. First, this study could not determine the follow-up effects of cognitive behavior therapy in a controlled design due to the need to provide treatment to children in the wait-list condition. Although significant time effects were found at 6 months, future studies should examine the long-term impact of CBT beyond 6 months by including an active control condition. Second, despite including a culturally specific measure of cognition, this study failed to include culturally specific measures of psychopathology. Although the current study did not find stronger effects on the culturally sensitive measure, future research would benefit from determining whether using culturally sensitive measures of symptoms may track treatment gain more effectively. Third, this study used composite diagnoses from a joint parent and child interview rather than independent diagnostic status from separate child and parent interview, based on common practice within the culture. A separate interview before treatment was not considered possible for children in Japan especially those with anxiety symptoms. However, due to presence of their parents, children may have under-reported their symptoms and may have been embarrassed or worried about reporting their true experience (Dadds et al., 1998; Joiner Schmidt, & Schmidt, 1996). In addition, the study did not measure inter-rater reliability of CSRs for the ADIS. Future studies should explore different modalities that may be appropriate for clinical interviews with children and adolescents in Japan. Finally, despite conducting random allocation to groups, there were pre-treatment differences between conditions in parent-reported anxiety using the SCAS-P. This is likely the result of a small number of parents in the wait-list condition who reported very low pre-treatment anxiety scores, despite reporting clinical levels of anxiety in the interview. Although the analyses conducted in this study examined change in symptoms and thus showed significant differences in the slope between the two treatment groups, future studies employing a larger sample would be important to replicate these findings in a sample with no pre-treatment differences. Further exploration of the false negative rate of the SCAS-P in a sample of Japanese children is warranted.

Despite these limitations, this study suggests that CBT based on bidirectional cultural adaptation can be efficacious for children and adolescents with anxiety disorders in an Asian country. The JACA-CBT includes both context and content cultural adaptations that have been performed over a decade. This study provides evidence that, when clinicians can tailor the materials, adjust time and dosage, and select adequate components, cognitive behaviour therapy is transportable to other cultural populations independent from the representative culture where evidence-based practices have been established. Based on multicultural approaches to ethnocultural diversity (Hall, Yip, & Zárate, 2016), insights gained with research conducted with underrepresented ethnocultural groups offer new perspectives on other (i.e., represented) groups. In addition to providing evidence that cognitive behavioral treatment is efficacious for anxiety disorders in Japanese children and adolescents, this study also shows that a culturally sensitive psychosocial treatment can ameliorate anxiety symptoms in an underrepresented ethnocultural population.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee (Doshisha University # 1304) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

References

Barrett, P.,M. (1998). Evaluation of cognitive-behavioral group treatment for childhood anxiety disorders. *Journal of Clinical Child Psychology, 27,* 459–468.

Barrett, P. M. (2004). *FRIENDS for life! for children. Participant workbook and leaders manual.* Brisbane, Australia: Australian Academic Press.

Barrett, P. M. (2005). *FRIENDS for life! for youth. Participant workbook and leaders manual.* Brisbane, Australia: Australian Academic Press.

Batra, P. (2013). *Evaluation of the Hong Kong FRIENDS intervention program for childhood anxiety (Unpublished doctoral dissertation)*Hong Kong: Alliant International University.

Birleson, P. (1981). The validity of depressive disorder in childhood and the development of self-rating scale. *Journal of Child Psychology and Psychiatry, 22,* 73–88.

Cardemil, E. V. (2010). Cultural adaptations to empirically supported treatments: A research agenda. *Scientific Review of Mental Health Practice, 7,* 8–21.

Cartwright-Hatton, S., McNicol, K., & Doubleday, E. (2006). Anxiety in neglected population: Prevalence of anxiety disorders in pre-adolescent children. *Clinical Psychology Review, 26,* 817–833.

Chambless, D. L., Baker, M. J., Baucom, D. H., Beutler, L. E., Calhoun, K. S., Crits-Christoph, P., ... Woody, S. R. (1998). Update on empirically validated therapies, II. *Clinical Psychologist, 51,* 3–16.

Chambless, D. L., Sanderson, W. C., Shoham, V., Johnson, S. B., Pope, K. S., Crits-Christoph, P., et al. (1996). An update on empirically validated therapies. *Clinical Psychologist, 49,* 5–18.

Dadds, M. R., Perrin, S., & Yule, W. (1998). Social desirability and self-reported anxiety in

children: An analysis of the RCMAS lie scale. *Journal of Abnormal Child Psychology, 26*, 311–317.

Essau, C. A., Conradt, J., & Petermann, F. (2000). Frequency, comorbidity, and psychosocial impairment of anxiety disorders in German adolescents. *Journal of Anxiety Disorders, 14*, 263–279.

Essau, C. A., Sakano, Y., Ishikawa, S., & Sasagawa, S. (2004). Anxiety symptoms in Japanese and in German children. *Behaviour Research and Therapy, 42*, 601–612.

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41*, 1149–1160.

Flannery-Schroeder, E., & Kendall, P. (1996). *Cognitive-behavioral therapy for anxious children: Therapist manual for group treatment.* Ardmore: Workbook Publishing.

Hall, G. C. N., Ibaraki, A. Y., Huang, E. R., Marti, C. N., & Stice, E. (2016). A meta-analysis of cultural adaptations of psychological interventions. *Behavior Therapy, 47*, 993–1014.

Hall, C. C. N., Yip, T., & Zárate, M. A. (2016). On becoming multicultural in a monocultural research world; A conceptual approach to studying ethonocultural diversity. *American Psychologist, 71*, 4–51.

Higa-McMillan, C. K., Francis, S. E., & Chorpita, B. F. (2012). (3rd ed.). *Child psychopathology*(pp. 345–428). New York: Guilford.

Higa-McMillan, C. K., Francis, S. E., Rith-Najarian, L., & Chorpita, B. F. (2016). Evidence base update: 50 years of research on treatment for child and adolescent anxiety. *Journal of Clinical Child and Adolescent Psychology, 45*, 91 -11.

Hudson, J. L., Rapee, R. M., Deveney, C., Schniering, C. A., Lyneham, H. J., & Bovopoulos, N. (2009). Cognitive-behavioral treatment versus an active control for children and adolescents with anxiety disorders: A randomized trial. *Journal of the American Academy of Child & Adolescent Psychiatry, 48*, 533–544.

Hudson, J. L., Rapee, R. M., Lyneham, H. J., McLellan, L. F., Wuthrich, A. M., & Schniering, C. A. (2015). Comparing outcomes for children with different anxiety disorders following cognitive behavioural therapy. *Behaviour Research and Therapy, 72*, 30–37.

Hwang, W. C. (2006). The psychotherapy adaptation and modification framework: Application to Asian Americans. *American Psychologist, 61*, 702–715.

Hwang, W. C. (2016). *Culturally adapting psychotherapy for Asian heritage populations: An evidence-based approach.* Cambridge, MA: Elsevier Academic Press.

Hwang, W. C., Myers, H., Chiu, E., Mak, E., Butner, J., Fujimoto, K., et al. (2015). Culturally adapted cognitive behavior therapy for depressed Chinese Americans: A randomized controlled trial. *Psychiatric Services, 66*, 1035–1042.

Ishikawa, S. (2012). Cognitive errors, anxiety, and depression in Japanese children and adolescents. *International Journal of Cognitive Therapy, 5*, 38–49.

Ishikawa, S., Hida, N., Kishida, K., Ueda, Y., Nakanishi, Y., & Kaneyama, Y. (2016a). The empirical review of academic activities regarding cognitive behavioral therapies for children and adolescents in Japan: Before and after the World Congress of Behavioral and Cognitive Therapies in 2004. *Kobe. Japanese Journal of Cognitive Therapy, 9*, 34–43.

Ishikawa, S., Kikuta, K., & Mitamura, T. (2013). Parent-child cognitive behavior therapy for children and adolescents with anxiety disorders. *Journal of Japanese Clinical Psychology, 31*, 364–375.

Ishikawa, S., Motomura, N., Kawabata, Y., Tanaka, H., Shimotsu, S., Sato, Y., et al. (2012). Cognitive behavioural therapy for Japanese children and adolescents with anxiety disorders: A pilot study. *Behavioural and Cognitive Psychotherapy, 40*, 271–285.

Ishikawa, S., & Sakano, Y. (2003). Cognitive error and trait anxiety in children: Development of a children's cognitive error scale. *Japanese Journal of Behavior Therapy, 29*, 145–157.

Ishikawa, S., & Sakano, Y. (2005a). Investigation on the relationship between self-statement and anxiety symptoms in childhood. *Japanese Journal of Behavior Therapy, 31*, 45–57.

Ishikawa, S., & Sakano, Y. (2005b). The practice study of the cognitive behavioral therapy for children with anxiety symptoms. *Japanese Journal of Behavior Therapy, 31*, 71–84.

Ishikawa, S., Sasagawa, S., Chen, J., & Essau, C. A. (2016b). Prevention program for depression among children and adolescents in Japan: Challenges and opportunities. In R. H. Shute, & P. T. Slee (Eds.). *Mental health and wellbeing through schools: The way forward* (pp. 157–170). New York: Routledge.

Ishikawa, S., Sato, H., & Sasagawa, S. (2009). Anxiety disorder symptoms in Japanese children and adolescents. *Journal of Anxiety Disorders, 23*, 104–111.

Ishikawa, S., Shimotsu, S., Ono, T., Sasagawa, S., Kondo-Ikemura, K., Sakano, Y., et al. (2014). A parental report of children's anxiety symptoms in Japan. *Child Psychiatry and Human Development, 45*, 306–317.

Ishikawa, S., Shimotsu, S., & Sato, Y. (2008). Short-term and group cognitive behavior therapy for children with anxiety disorders. *Japanese Journal of Psychiatric Treatment, 23*, 1481–1490.

Ishikawa, S., Takeno, Y., Sato, Y., Kishida, K., Yatagai, Y., & Spence, S. H. (2018). *Psychometric properties of the Spence Children's Anxiety Scale with adolescents in Japanese high schools.* School Mental Health https://doi.org/10.1007/s12310-017-9242-3.

Jacobs, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*, 12–19.

James, A. C., James, G., Cowdrey, F. A., Soler, A., & Choke, A. (2013). Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database of Systematic Reviews, 6*, CD004690. https://doi.org/10.1002/14651858.CD004690.

pub3.

Joiner, T. E., Schmidt, K. L., & Schmidt, N. B. (1996). Low-end specificity of childhood measures of emotional distress: Differential effects for depression and anxiety. *Journal of Personality Assessment, 67*, 258–271.

Kaufman, J., Birmaher, B., Brent, D. A., Rao, U., & Ryan, N. D. (1997). Schedule for affective disorders and schizophrenia for school age children, present and lifetime version (K-SADS-PL): Initial reliability and validity data. *Journal of the American Academy of Child & Adolescent Psychiatry, 36*, 980–988.

Kazdin, A. E. (2002). The state of child and adolescent psychotherapy research. *Child and Adolescent Mental Health, 7*, 53–59.

Kearney, C. A., & Albano, A. M. (2007). *When children refuse school: A cognitive-behavioral therapy approach therapists guide.* New York: Guilford.

Kendall, P. C. (1994). Treating anxiety disorders in children: Results of randomized clinical trial. *Journal of Consulting and Clinical Psychology, 62*, 100–110.

Kendall, P. C., Hudson, J. L., Gosch, E., Flannery-Schroeder, E., & Suveg, C. (2008). Cognitive-behavioral therapy for anxiety disordered youth: A randomized clinical trial evaluating child and family modalities. *Journal of Consulting and Clinical Psychology, 76*, 282–297.

Kovacs, M. (1985). The children's depression inventory (CDI). *Psychopharmacology Bulletin, 21*, 995–998.

Lau, W., Chan, C. K., Li, J. C., & Au, T. K. (2010). Effectiveness of group cognitive behavioral treatment for childhood anxiety in community clinics. *Behaviour Research and Therapy, 48*, 1067–1077.

Mashida, N., Ogata, A., Ozono, S., Koseki, S., Sato, H., Ishikawa, S., et al. (2009). Development of a Japanese version of the children's depression inventory (CDI). *Japanese Journal of Behavior Therapy, 35*, 219–232.

Murata, T., Shimizu, A., Mori, Y., & Oushima, S. (1996). Childhood depressive state in the school situation: Consideration from the Birleson's scale. *Saishin Seishin Igaku, 1*, 131–138.

Nauta, M. H., Scholing, A., Rapee, R. M., Abbott, M., Spence, S. H., & Waters, A. (2004). A parent-report measure of children's anxiety: Psychometric properties and comparison with child-report in a clinic and normal sample. *Behaviour Research and Therapy, 42*, 813–839.

Ollendick, T. H., Fraire, M. G., & Spence, S. H. (2014). Transdiagnostic treatments: Issues and commentary. In J. Ehrenreich-May, & B. C. Chu (Eds.). *Transdiagnostic treatments for children and adolescents: Principles and practice* (pp. 405–419). New York: Guilford.

Öst, L.-G., & Ollendick, T. H. (1999). *Manual for the One Session Treatment (OST) of specific phobia in children and adolescents.* (Unpublished manual).

Pina, A. A., Polo, A. J., & Huey, S. J. (2019). Evidence-based psychosocial interventions for ethnic minority youth: The 10-year update. *Journal of Clinical Child and Adolescent Psychology.* https://doi.org/10.1080/15374416.2019.1567350.

Schniering, C. A., & Rapee, R. M. (2002). Development and validation of a measure of children's automatic thoughts: The children's automatic thoughts scale. *Behaviour Research and Therapy, 40*, 1091–1109.

Seligman, L. D., & Gahr, J. L. (2013). Course and outcome of child and adolescent anxiety. In C. A. Essau, & T. H. Ollendick (Eds.). *Treatment of childhood and adolescent anxiety disorders* (pp. 44–67). London: Wiley-Blackwell.

Silverman, W. K., & Albano, A. M. (1996). *Anxiety disorders interview schedule for DSM-IV: Child version.* New York: Oxford University Press.

Spence, S. H. (1998). A measure of anxiety symptoms among children. *Behaviour Research and Therapy, 36*, 545–566.

Stirman, S. W., Miller, C. J., Toder, K., & Calloway, A. (2013). Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implementation Science, 8*, 65.

Sundell, K., Beelmann, A., Hasson, H., & Schwarz, U. T. (2016). Novel programs, international adoptions, or contextual adaptations? Meta-analytical results from German and Swedish intervention research. *Journal of Clinical Child and Adolescent Psychology, 45*, 784–796.

Sundell, K., Ferrer-Wreder, L., & Fraser, M. W. (2014). Going global: A model for evaluating empirically-supported family-based interventions in new contexts. *Evaluation & the Health Professions, 37*, 203–230.

Sun, M., Rith-Najarian, L. R., Williamson, T. J., & Chorpita, B. F. (2018). Treatment features associated with youth cognitive behavioral therapy follow-up effects for internalizing disorders: A meta-analysis. *Journal of Clinical Child and Adolescent Psychology.* https://doi.org/10.1080/15374416.2018.1443459.

Suveg, C., Hudson, J. L., Brewer, G., Flannery-Schroeder, E., Gosch, E., & Kendall, P. C. (2009). Cognitive-behavioral therapy for anxiety-disordered youth: Secondary outcomes from a randomized clinical trial evaluating child and family modalities. *Journal of Anxiety Disorders, 23*, 341–349.

Walkup, J. T., Albano, A. M., Piacentini, J., Birmaher, B., Compton, S. N., Sherrill, J. T., et al. (2008). Cognitive behavioral therapy, sertraline, or a combination in childhood anxiety. *New England Journal of Medicine, 359*, 2753–2766.

Weems, C. F., & Silverman, W. K. (2013). Anxiety disorders. In T. P. Beauchaine, & S. P. Hinshaw (Eds.). *Child and adolescent psychopathology* (pp. 513–541). (2nd ed.). New Jersey: Joh Wiley & Sons.

Weering, V. R., Jeffreys, M., Do, M. T., Schwartz, K. T. G., & Bolano, C. (2017). Evidence base update of psychosocial treatments for child and adolescent depression. *Journal of Clinical Child and Adolescent Psychology, 46*, 11–43.

Wergeland, G. J. H., Fjermestad, K. W., Marin, C. E., Haugland, B.,S. M., Bjaastad, J. F., Oeding, K., et al. (2014). An effectiveness study of individual vs. group cognitive behavioral therapy for anxiety disorders in youth. *Behaviour Research and Therapy, 57*, 1–12.