Trials

STUDY PROTOCOL

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Efficacy of behavioural parent training on attachment security in children with attention deficit hyperactivity disorder: a randomised controlled trial

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Abstract

Background Behavioural parent training (BPT) is a psychosocial intervention designed for children with attention deficit hyperactivity disorder (ADHD). BPT programs teach parents to use effective commands or rules whilst encouraging them to pay careful attention to their child's appropriate behaviour. In this study, we will investigate the efficacy of BPT on parental stress, mothers' sense of emotional closeness to their children, and children's attachment security to their mothers. We will also examine the effects of BPT on children's internalising and externalising symptoms, ADHD symptoms, and sensitivity to rewards and punishments compared to usual care alone. The use of bias-prone assessment tools limits the ability of previous studies to assess effectiveness. Therefore, in this study, the child's attachment security will be assessed in a structured interview conducted by assessors blinded to group allocation, and brain changes will be assessed using magnetic resonance imaging.

Methods This randomised controlled clinical trial will aim to compare the efficacy of BPT to routine clinical care for 60 children with ADHD. Participants will be randomised, with stratification by medication status for ADHD (medicated or non-medicated). The BPT intervention group will receive parent training weekly for 10 weeks in a group of six or less. The primary outcome measure will be changes in parental stress. Furthermore, the key secondary outcome measure will be the child's attachment security, which will be assessed in an interview conducted by assessors blinded to group allocation. We will also evaluate changes in neural connectivity in both children and mothers using magnetic resonance imaging. Other secondary outcomes will include child behavioural problems, ADHD symptoms, emotional regulation, child sensitivity to rewards and punishments, parental behaviour, and the child and parent's social support network following the completion of 10 sessions.

Discussion This study represents the first randomised controlled trial exploring the efficacy of BPT on child attachment security and mothers' sense of emotional closeness to their children. It aims to provide robust evidence to assist parents of children with ADHD in making appropriate treatment decisions.

Trial registration UMIN000038693. Registered on November 9, 2019.

Keywords RCT, Behavioural parent training, ADHD, Attachment, MRI

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Administrative information

Note: the numbers in curly brackets in this protocol refer to the SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

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Name and contact information for the trial sponsor {5b}	Investigator-initiated clinical trial; Ayaka Ishii-Takahashi (principal investigator) ayayak-tky@umin.ac.jp (A.I-T.)
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Introduction

Background and rationale {6a}

Attention deficit hyperactivity disorder (ADHD) is one of the most common childhood neurodevelopmental disorders, characterised by maladaptive and persistent inattention, impulsivity, and hyperactivity impairing children's functioning. Behavioural parent training (BPT) is a psychosocial intervention for children with ADHD based on the principles of operant conditioning [1]. It teaches parents effective commands, rules, and positive reinforcement, encouraging them to pay attention to desired behaviours whilst ignoring undesirable ones. The effectiveness of BPT in children with ADHD has been extensively studied, yielding somewhat inconsistent results. A Cochrane review [2] found that BPT was associated with improved parenting stress scores and general behaviour of children in the parent training group. However, it did not demonstrate a significant effect of BPT on core symptoms of ADHD. Similarly, another meta-analysis reported no significant effect of psychological interventions, including parent training, on ADHD symptoms [3]. In contrast, other studies have demonstrated that psychological interventions can lead to significant improvements in externalising symptoms [4–9].

In this study, we will examine the effects of BPT on parenting stress, children's internalising and externalising scores, ADHD symptoms, and sensitivity to rewards and punishments compared to routine clinical care (RCC) alone. We will also explore parent–child attachment patterns. Notably, 'attachment' refers to the predisposition to comfort and security, and its development is thought to be influenced by the child's nurturing environment [10]. A higher rate of insecure attachment patterns has been consistently observed in children with ADHD compared to those without [11]. Many factors, including limited external support, limited knowledge of effective parenting skills, and chronic illness of the child, are believed to lead to undesirable parenting styles [11], which may further contribute to insecure attachment patterns of the child.

Moreover, improving parenting skills through parent training may lead to secure attachment patterns [11].

Attachment-focused interventions can also improve the overall health of children with chronic illnesses [12]. Notably, parenting style not only influences attachment patterns but is also linked to children with secure attachment being more likely to seek support from caregivers and their surrounding environment. This tendency to seek support may further lead to an improved overall environment for the upbringing of the child.

A recent magnetic resonance imaging (MRI) study of typically developing children indicated that those with secure attachment demonstrated increased functional connectivity in the temporal-limbic region compared to children with insecure attachment. In addition, the child attachment security scores were negatively associated with the caudate-prefrontal connectivity but positively associated with the putamen-visual area connectivity [13]. However, the neurobiology associated with attachment patterns in children with ADHD has not yet been studied. We hypothesise that when the mothers of insecurely attached children receive parent training, the child's attachment security may improve, leading to brain connectivity patterns that increasingly resemble those exhibited by securely attached children.

In our preliminary study, we observed positive effects of parent training intervention on mothers' sense of emotional closeness to their children with ADHD [14]. However, whilst medication treatments exhibit strong efficacy for ADHD symptoms, there is no evidence of their effects on parent–child attachment patterns. Therefore, this randomised controlled trial (RCT) will assess the effects of BPT on attachment security between parents and children along with its neural mechanisms using MRI. In addition, we will explore the extent to which social support systems of mothers and children contribute to attachment security and its associated brain regions. Therefore, this study aims to provide high-quality evidence to aid parents of children with ADHD in selecting the most suitable treatment for their children.

We hypothesise that BPT could be effective in reducing children's problem behaviours, parenting stress, and mother's sense of emotional closeness to their children. We also hypothesise that BPT would affect the neural mechanisms associated with attachment stability in children.

Objectives {7}

This study aims to examine the efficacy of BPT for parents of children with ADHD compared to the routine clinical care (RCC) group. The primary aim will be to evaluate changes in total parenting stress in mothers. The secondary aims will be changes in the security of child attachment, assessed by a blinded coder, and changes in neural connectivity in both children and mothers using MRI. Other secondary outcomes include subscales of parenting stress, child behavioural problems, ADHD symptoms, child emotional regulation, child's sensitivity to rewards and punishments, parental behaviour, as well as child and parent social support network. These will all be assessed after the completion of 10 BPT sessions.

Trial design {8}

In this randomised controlled clinical trial, BPT + RCC is compared to RCC. The allocation ratio is 1:1. The superiority of BPT + RCC compared to RCC will be tested.

Methods

Study setting {9}

The participants will be recruited from an outpatient unit at the University of Tokyo Hospital in Tokyo, Japan.

Eligibility criteria {10}

Participants

The eligible participants in this study are individuals diagnosed with ADHD and their mothers. Before the final inclusion, both written and verbal informed consent will be obtained from all mothers in the study. We will also obtain written and verbal informed assent from all children.

Inclusion criteria

The study comprises participants and their mothers meeting the following criteria during the screening process.

For children with a diagnosis of ADHD:

1. A diagnosis of ADHD based on the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria by a child psychiatrist, with a requirement of scoring higher than the 80th percentile on the ADHD Rating Scale-IV (ADHD-RS-IV) [15]. For children with a current diagnosis of ADHD who are on medication, symptoms will be assessed whilst they are receiving treatment.
2. Primary school children between the ages of 8–12 at the time of participation in the study.
3. A full IQ score greater than 70 on the Wechsler Intelligence Scale for Children-IV Japanese version (WISC-IV) [16] with no intellectual delays.
4. Participants with following comorbid disorders are eligible to participate: oppositional-defiant, behavioural, tic, learning, minor anxiety, or emotional disorders.
5. Following a detailed explanation of the study, with a good understanding of the research, those who provide free and voluntary written consent.

6. Those who obtain permission to participate in the research from the attending physician.

For mothers of children with ADHD:

1. Aged between 20 and 60 years of age.
2. Mother of a child with a diagnosis of ADHD.
3. Those who can reliably participate in the 10 training sessions and psychological assessments.
4. Those who can communicate in Japanese.
5. Those who can visit the University of Tokyo Hospital and research-related facilities during the research period and have a contactable phone number or an email address.

Exclusion criteria

For children with ADHD:

1. Those with severe autism spectrum disorder are assessed to be severely autistic on the Childhood Autism Rating Scale (CARS) [17].
2. Comorbid diagnosis of schizophrenia or bipolar disorder.
3. Suffering from intellectual delays (full IQ score less than 70 on the WISC-IV).
4. Those who clinically require immediate pharmacological treatment for depression, intense anxiety, tension, and/or agitation.
5. Those who are currently participating in a psychological/social intervention (e.g. psychotherapy, behavioural therapy, cognitive behavioural therapy) for treatment purposes at another institution at the time of participation in the study.
6. Those who are deemed unfit to participate in the study by the principal investigator.

For mothers of children with ADHD:

1. Those who present with schizophrenia, bipolar disorder, serious alcohol dependence, or substance dependence.
2. Those who clinically require immediate pharmacological intervention for depression, high levels of anxiety, tension, or agitation.
3. Those who are currently participating or intending to participate in a psychological/social intervention (e.g. psychotherapy, behavioural therapy, cognitive behavioural therapy) for treatment purposes at another institution at the time of participation in this study.
4. Those who scored under 70 on the Japanese Adult Reading Test (JART) [18].
5. Those who are pregnant at the time of participation in the study or have plans to become pregnant during the study period.
6. Those who are deemed unfit to participate in the research by the principal investigator.

Who will take informed consent? {26a}

Information and consent forms approved by the Ethics Committee (approval number 2019180NI) will be provided to the participants. A document outlining the exclusion criteria will be provided to the mother, which will then be returned via mail to the University of Tokyo Hospital and the principal investigator will assess and determine the eligibility of the participants. Once they were deemed suitable to participate, a thorough explanation of the study will be given in person by the principal investigator at the University of Tokyo Hospital in verbal and written forms. After answering any questions, free and voluntary written consent will be obtained.

Participants will be promptly informed if new information regarding efficacy and safety may affect their consent status or when there are changes in the implementation plan that may affect their consent. The participant's wish to participate in the study or not will be confirmed. The Ethics Committee will approve the revised information sheet and consent forms in advance, and renewed consent will be further obtained from the participants.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Additional consent will be obtained if stored data are to be used in a new study upon completion of the study.

Interventions

Explanation for the choice of comparators {6b}

Psychiatrists are instructed to provide routine care, including supportive counselling, psychoeducation, pharmacotherapy, and crisis management, whenever necessary. RCC involves face-to-face appointments. This study will allow usual care for children with ADHD. Any changes in doses and names of the prescribed medications will be recorded.

Intervention description {11a}

Participants will be allocated to a small group of six or less. Two psychologists or child psychiatrists will conduct the manualised 90-min BPT training sessions administered over 10 sessions. Participants will remain in the same group throughout the 10 sessions.

Parent training teaches parents effective strategies and establishes a structure for better management of children. Through role plays, participants are taught how

to intervene effectively when potential problem behaviours occur and are further encouraged to apply these techniques at home through homework and summary sheets. The BPT to be utilised in this study is based on parent training conducted by Barkley [19–22] but modified to suit the Japanese culture. Whilst it utilises methods of classic behavioural therapy, it is delivered using the University of Tokyo Hospital's original textbook. The BPT Manual consists of the following chapters: step 1: categorising behaviours, step 2: attend to the desirable behaviour, step 3: make 'praising' a habit, step 4: ignore undesirable behaviours, step 5: make plans to 'ignore', step 6: how to give effective instructions, step 7: how to make 'praise and compliment charts', step 8: implementing 'praise and compliment charts' and setting boundaries, step 9: adjusting the environment, step 10: review (Table 1).

The quality of the program will be monitored through video recordings and by psychologists and child psychiatrists who attend the sessions. Personal training sessions for up to three missed sessions can be conducted, allowing the participants to rejoin the next group session to minimise the dropout rate.

Criteria for discontinuing or modifying allocated interventions {11b}

If the principal investigator and co-investigators determine that the participant cannot continue for any reason,

Table 1 Agenda of each parent training session

Parent Traning sessions	Session content	Detail
1st	Categorising behaviours	Psychoeducation of the ABC theory of behaviour and the power of attention. Categorise children's behaviour into one of three: desirable behaviour, undesirable behaviour, and unacceptable behaviour, and learn how to respond differently to each behaviour.
2nd	Attend to the desirable behaviour	When praising (giving positive attention to) 'desirable behaviour,' children's sense of self-affirmation and self-efficacy increase, and they become more motivated and cooperative. Learn tips and variations of 'praise', the most important skill in parent training.
3rd	Make 'praising' a habit	Spot 'desirable behaviour' in their everyday lives. Learn to break down children's behaviours and recognise how many opportunities arise for praise through various actions.
4th	Ignore undesirable behaviours	Remove attention from 'undesirable behaviours' and wait for 'desirable behaviours' to occur. Learn to praise immediately after the desirable behaviour occurs. Learn the trick of 'removing attention'.
5th	Make plans to 'ignore'	To 'remove attention' more smoothly, make a plan in advance. Identify situations where 'undesirable behaviour' occurs, consider how you will respond when that behaviour occurs, and prepare accordingly.
6th	How to give effective instructions	Provide clear instructions when the previous skills alone do not lead to the 'action you want them to take'. Learn tips and variations on how to give instructions.
7th	How to make 'praise and compliment charts'	Learn how to make a 'praise and compliment chart', a chart for praising children. The participants create a 'Pilot Praise and Compliment chart' by arranging the list of desirable behaviours by time. Using this chart, carefully observe the children's behaviour and confirm that the behaviours listed are appropriate.
8th	Implementing 'praise and compliment charts' and setting boundaries	Based on what was confirmed in the 'Pilot Praise and Compliment Chart,' create the 'Praise and Compliment Chart'. Learn how to use the 'praise and compliments chart'. Whenever possible, use the existing skills to deal with 'undesirable behaviour,' but when it is still difficult or when an unacceptable behaviour occurs, present the rules for setting limits. This involves giving 'consequences' as responsibilities that the child must take when warnings are given but instructions are not followed.
9th	Adjusting the environment	Learn to understand the characteristics of ADHD and how to adjust the environment to suit the child and learn how to work with the school. Participants will share their own experiences and ideas.
10th	Review	Review what has been learned in the previous sessions. Discuss what changes have been made at home through the parent training. At the completion ceremony, participants will make a 'bouquet of flowers for themselves' and praise each other for having completed the Parent Training.

the participants will be withdrawn from the study. The date and time of discontinuation/withdrawal and the reasons for it will be recorded in the participant's medical charts and case registration sheet.

Detailed discontinuation criteria

1) When the participant wishes to discontinue the study or withdraw their consent.
2) When it is revealed, after registration, that the participant was not eligible to participate.
3) When it is determined that continued participation in MRI scans or parent training may aggravate the underlying conditions.
4) The parent training sessions can be missed for inevitable reasons (such as a child's fever) for up to three sessions. However, if they are missed four times and cannot make up these with personal sessions, the participant will be withdrawn from the study, and their participation will be discontinued. There will be three supplementary sessions 30-min each, to supplement the three missed sessions.
5) When it is difficult to continue the study due to worsening complications.
6) When it is difficult to continue the study due to adverse events
7) If this study is suspended.
8) If the principal investigator deems it appropriate for the participants to discontinue the study for any other reasons.

In any of the above cases, the reason for discontinuation will be indicated on the medical chart and the case registration sheet.

Strategies to improve adherence to interventions {11c}

After each BPT session, participants will receive an email with feedback and a reminder about homework assignments. If participants miss a session, they can receive up to three make-up sessions. Participants who complete the study will receive a payment of 5000 yen/MRI at a later date via bank transfer.

Relevant concomitant care permitted or prohibited during the trial {11d}

(1) Concomitant medication (therapy): This study will allow usual care for children with ADHD. Any changes in doses and names of the prescribed medications will be recorded.
(2) Contraindication of concomitant medication (therapy): During the study participation, if another psychosocial therapy is also used in combination for children with ADHD or their mother, participants will be excluded.
(3) Combined cautionary medication (therapy): If the children with ADHD or their mother have received psychosocial treatment similar to this study in the past or currently, participants will be excluded from the study.
(4) Compatible medication (therapy): Medications for children with ADHD or their mothers that are not prescribed for the treatment of ADHD, such as remedies for allergies and colds, can be used concomitantly during study participation.

Provisions for post-trial care {30}

Upon completion of the study, efforts will be made to ensure that the best prevention, diagnosis, and treatment are provided based on the study results. Mothers in the control group of the BPT may participate in the parent training sessions, if desired, following the completion of the research.

Outcomes {12}

Clinical assessment procedures

The BPT study will consist of three periods: pre-intervention, intervention, and post-intervention periods (Table 2). A psychologist will conduct each parent training session as the leader, and three psychologists/child psychiatrists will rotate as sub-leaders. Most measures will be treated as continuous variables, but categorical variables will also be used for the child attachment interview (CAI) [23], which includes the categories: secure and insecure (dismissing, preoccupied, and disorganised). All assessments, except MRI images and CAI scores, will be assessed by a non-blinded assessor.

Primary outcome measures

The change in the percentile score of the total Parenting Stress Index (PSI) score [24, 25] before and after the intervention will serve as the primary outcome, as our preliminary trial demonstrated a significant decrease immediately following the intervention in the BPT + RCC group which was further maintained at the follow-up, 3 months after the intervention [14].

Key secondary outcome measures

The subscale of the PSI related to the mother's difficulty in feeling attached to their child (PSI-P7: attachment) will be selected as the key secondary outcome measure. The quantitative assessment of the security of the child's attachment will be performed using the CAI, which evaluates the level of security (emotional openness, balance of positive and negative references, and use of examples) and level of insecurity (preoccupied anger, idealisation,

Table 2 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagrams

Time point		Study Period									
		Enrollment			Allocation	Post-allocation					
		pre-intervention				intervention			post-intervention		
						T1: 0w		T2: 10w		T3: 24w	
Enrollment											
Eligibility screen	screened with : ADHD-RS; WISCⅣ; CARS; mother screened with: JART	x									
Informed consent		x									
Allocation					x						
Interventtion											
BPT+RCC group							x(BPT+RCC)		x(RCC）		
RCC group							x(RCC）		x(RCC）		
Baseline assessment											
children	DN-CAS; DH-c; SRS; PAQ-C	x									
mothers	DH-p; AQ; ASRS	x									
Assessments											
children's report	on them: CAI; KSS; DSRSC; KiINDL-C; SSN-C; SPP; PANAS-C					x		x		x	
	on their mothers:PPI-C					x		x		x	
mother's report	on them: PSI; PPI-P; BIS-11; BIS/BAS; PPI-P; WHO QOL26; SSN-P					x		x		x	
	on their child: ADHD-RS; CBCL; SNAP; KINDL-P; ARI; SPSRQC					x		x		x	
CGI						x		x		x	
MRI											
children						x		x		x	
mothers						x		x		x	

BPT:Behavioural parent training; RCC:Routtine clinical careADHD-RS: ADHD Rating Scale; WISC-Ⅳ: Wechsler Intelligence Scale for Children-Ⅳ-Japanese version; CARS: Childhood Autism Rating Scale; DN-CAS:Das-Naglieri Cognitive Assessment System; DH-c Questionnaire for children assessing their dominant hand; PAQ-C: Physical Activity Questionnaire for Older ChildrenJapanese version; DH-p Questionnaire for adults assessing their dominant hand; JART :Japanese Adult Reading Test; AQ: Autism-Spectrum Quotient; ASRS: Adult ADHD Self-Report Scale; CAI: Child Attachment Interview-Japanese; KSS: Kerns Security Scale-Japanese version; DSRSC: Depression Self-Rating Scale for Children; Kindle-C: Questionnaire for Measuring Health-Related Quality of Life; SSN-C: Social support network-child; SPP: Self perception profile; PANAS-C Positive and Negative Affect Scale for Children; PPI-C: Parental perception Index-Children–Japanese version; PSI: Parenting Stress Index– Japanese version; PPI-P: Parental perception Index-Children–Japanese version; BIS-11 Barratt Impulsiveness Scale version 11; BIS/BAS: Behavioral Inhibition System/Behavioral Activation System; PPI-P Parental perception Index-Parent–Japanese version; WHO QOL26 WHO Quality of Life; DH-p; SSN-P Social support network-parent; ADHD-RS ADHD Rating Scale; CBCL: Child Behavior Checklist; SNAP :Swanson; Nolan; and Pelham Questionnaire–Japanese version; Kindle-P; ARI: Affective Reactivity Index; SPSRQC: Sensitivity to Punishment and Sensitivity to Reward Questionnaire for Children–Japanese version; SRS: Social

and dismissal). The Kerns Security Scale (KSS), assessed by children, will also serve as a key secondary outcome measure [26, 27].

Other secondary outcome measures

The Child Behaviour Checklist [28] scores reported by the mothers will be used to assess externalising and internalising problems in the children. The ADHD-RS-IV total score and its subscale scores ('Inattention' and 'Impulsivity and Hyperactivity') will be implemented to assess and evaluate ADHD symptoms before and after the intervention. The PSI subscales will be used to assess parenting stress before and after the intervention. More specifically, the subscales within two main domains, the parent domain (P1: role restriction, P2: isolation, P3: spouse/parenting partner relationship, P4: competence, P5: depression, P6: postpartum depression, P7: attachment, P8: health) and the child domain (C1: reinforces parent, C2: mood, C3: acceptability, C4: distractibility/hyperactivity, C5: adaptability, C6: demandingness, and C7: sensitivity) will be analysed to help understand the full picture of the stress that is experienced.

The Parent Perception Inventory (assessed by children: PPI-C [29], assessed by parents: PPI-P) [30] will also be used to measure positive and negative parenting behaviour on a five-point scale (ranging from 'never' to 'a lot') before and after the intervention. The Sensitivity to Punishment and Sensitivity to Reward Questionnaire for Children (SPSRQ-C) [31] will be administered before and after the intervention to assess the effects of BPT on sensitivity to rewards and punishments in children with ADHD. SPSRQ-C will be administered to caregivers to assess child sensitivity to punishment and reward, including fear/shyness, anxiety, drive, responsiveness to social approval, and impulsivity/fun-seeking. We will also assess parent sensitivity to punishment and reward using the Behavioural Inhibition System/Behavioural Activation System (BIS/BAS) [32]. We will assess the child's emotional dysregulation using the Affective Reactivity Index (ARI) [33] and positive and negative emotions using the Positive and Negative Affect Scale for Children (PANAS-C) [34].

Other secondary outcome measures include the following: child's depressive symptoms, assessed using the Depression Self-Rating Scale for Children (DSRS-C) [35]; child's oppositional symptoms, assessed using the Swanson, Nolan, and Pelham Questionnaire–Japanese version (SNAP) [36]; child's self-recognition, evaluated using the Self-Perception Profile (SPP) [37]; child's QOL, determined using the Questionnaire for Measuring Health-Related Quality of Life (KINDL) [38]; parent's QOL, assessed using WHO QOL26 [39]; parent's impulsivity, assessed using the Barratt Impulsiveness Scale (BIS) version 11 [40]; child's social network (number of members and quality); parent's social network (number of members and quality), Clinical Global Impression (CGI) [41]; and MRI images, including T1-weighted image, diffusion weighted tensor imaging, resting functional MRI image, functional MRI during watching movie, and T2- weighted image, before

and after the intervention. For collecting social network data, we will use the concentric circle technique, hierarchical mapping and social network interviews [42–44].

At baseline, we will assess the child executive function using the Das-Naglieri Cognitive Assessment System (DN-CAS) [45], the child's autistic trait (SRS) [46], child's exercise habit using the Physical Activity Questionnaire for Older Children-Japanese version (PAQ-C) [47], parent's ADHD symptoms using the adult ADHD Self-Report Scale (ASRS) [48], and parent autistic trait using the Autism-Spectrum Quotient (AQ) [49] to evaluate their association with the BPT intervention. We will also assess the child's dominant hand (using the questionnaire for dominant hand [DH-c]) [50] and the parent's dominant hand (DH-p) [51] to use as covariates in evaluating MRI data.

Safety measures

No adverse events have been reported from conducting parent training in the past. In this study, the researcher will interview the mother to provide them with an opportunity to report any concerns or adverse experience following the intervention freely.

Participant timeline {13}

The parent training study will consist of three periods: pre-intervention, intervention, and post-intervention periods. The diagram of this clinical trial is presented in Table 2.

Parent training sessions will be conducted over 10 weeks, and questionnaires, the CAI, and MRI will be completed before and after the full intervention. The baseline assessment will be conducted within 12 weeks prior to the intervention. The pre-intervention and post-intervention assessments will be conducted within 1 month of the initiation and completion of the intervention, respectively. The follow-up period will be 3 months (15 weeks following the completion of the intervention), during which the questionnaires, CAI, and MRI scan will be completed.

Participants regularly taking psychotropic medications for treatment will be requested to maintain a stable dosage throughout the intervention. A follow-up interview will be conducted 3 months after the completion of the interventions. Interviews and symptom assessments will be undertaken during week 0 (pre-intervention), week 10 (post-intervention), and week 22 (follow-up). The participants assigned to the RCC group will be required to continue their usual treatment with their primary doctors.

Sample size {14}

In this study, the difference between the intervention group and the control group is assumed to be 12 points, with the standard deviation assumed to be 15.5 for both groups. This difference was calculated based on our previous study [14], which demonstrated that the PSI scores decreased by 3–13 points following the intervention. A total of 56 cases (28 in each group) will be required to detect this difference with a significance level of 5% (two-tailed) and 80% power using a two-sample *t*-test with equal variance. Considering approximately a 5% dropout rate, the target sample size will be 60 participants (30 in each group).

Recruitment {15}

Recruiting will target individuals who can physically and mentally endure the MRI scans and interviews and who are willing to provide consent to participate in the research. The target sample includes children with ADHD and their mothers. For children with ADHD in the control group, recruitment will be conducted via personal connections, the Department of Child Psychiatry website, and brochures at collaborating research facilities. Recruiting will also be performed via brochures available at The University of Tokyo Hospital.

A document outlining the exclusion criteria will be provided to the mother and will be returned via mail or in person. Questionnaires will be sent via mail or provided in person when the participants visit the outpatient ward, and participants will be asked to return them upon completion via mail or in person. If the inclusion criteria are met, consent will be re-obtained at the University of Tokyo to participate in this research.

Following the presentation of the information sheet, those who express interest in research participation will be provided with more detailed information, and then written consent will be obtained. Subsequently, potential participants will be assessed to determine whether they meet the inclusion criteria. If they meet the inclusion criteria for participation in the study, their intention to participate in the study will be re-confirmed.

The principal investigator at the University of Tokyo Hospital was responsible for all aspects of local organisation including identifying potential recruits and obtaining consent.

Assignment of interventions: allocation

Sequence generation {16a}

The statistician will generate the allocation sequence using computer-generated random numbers and apply the stratification based on whether the children are using medication or not. The principal investigator will

provide a verbal and written explanation to the mother and child and obtain written consent to participate in the research. The statistician, who is responsible for conducting the statistical analysis and will have no interaction with the participants, will determine the allocation procedure to eliminate any potential biases. Participants will be divided into stratified blocks depending on the intake of medication (Concerta, Strattera, Intuniv) for ADHD. Notably, blinding the report of the primary outcome measures is not feasible, as the parents completing the questionnaires will be receiving the intervention. However, those who will conduct the CAI will be blinded to which groups the participants are assigned to.

Concealment mechanism {16b}

We will use the sequentially numbered, opaque, sealed envelopes (SNOSE) technique.

Implementation {16c}

The statistician, who is responsible for conducting the statistical analysis and does not have interaction with the participants, will determine the allocation sequence to eliminate any potential biases. Two child psychiatrists will enrol participants, whilst the principal investigator will assign participants to interventions and reveal randomisation status to participants.

Assignment of interventions: blinding

Who will be blinded {17a}

Participants will not be blinded due to the nature of the intervention where the allocation of the group is apparent to the participants. However, the statistician and the researcher coding and analysing the CAI will be blinded. Two researchers who will preprocess the MRI data will also be blinded.

Procedure for unblinding if needed {17b}

After completion of the RCT, the principal investigator will reveal the allocation data to the statistician.

Data collection and management

Plans for assessment and collection of outcomes {18a}

A psychologist or psychiatrist will be trained to assess the social support network through administering it to three individuals. The CAI will be conducted by a psychologist or child psychiatrist trained and approved by Mukai, the certified coder for the CAI.

The following questionnaires have been standardised in English and translated in Japanese but not yet standardised or validated in Japanese: PANAS-C, PAQ-C, Parent Perception Index-Children-Japanese version (PPI-C), Parent Perception Index-Parent-Japanese version (PPI-P), SNAP, and SPSRQ-C-Japanese version.

Plans to promote participant retention and complete follow-up {18b}

A personal training session for up to three missed sessions will be arranged, ensuring that the participants rejoin the subsequent group session to prevent dropouts. Currently, there have been no reports of adverse reactions resulting from parent training; however, participation in the RCT could increase maternal anxiety or frustration when assigned to the control group. Therefore, participants assigned to the control group will be provided with the opportunity to participate in a parent training session following the study period.

Data management {19}

The data entered will always be cross-checked by another person, which will be checked again by the principal investigator at the end. As the University of Tokyo is the principal research facility, a table of correspondence between anonymised IDs at each facility will be created and stored. When a participant is included in the study at the University of Tokyo, informed consent and end-of-trial dates will be recorded in the secure storage in the hospital server, and signed paper forms will be stored in a locked room within our hospital. All research data, including patient material, will be archived for 5 years following the final publication of the articles.

Confidentiality {27}

Names, dates of birth, video recordings of the participant's interview, audio data, and other information obtained from questionnaires and consent forms constitute private information. As this research will be conducted on children with ADHD, it is necessary to obtain detailed information on treatment and diagnosis from medical records. In addition, the email address and telephone number of the patient's parent/guardian are needed to inform the patient of the date of the visit, and address information is required to send questionnaires when necessary.

The data will be anonymised with a corresponding table under the supervision of the principal investigator, and a unique number will be assigned to each participant. The participants will complete the questionnaires after affixing a research ID without including their names. For medical information, the name and medical ID are used and stored in the electronic medical record, which the researcher then transcribes onto a form with the research ID. Correspondence sheets containing personal information, such as name and date of birth, will be kept in a locked storage room. No identifiable information about each patient will be included in any publications.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A (Biological specimens will not be collected).

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

For the evaluation of outcome measures, the following between-group analyses of the intention-to-treat (ITT) population will be performed for both efficacy and safety measures. All randomised participants will be analysed as the ITT population, excluding cases with no valid data. We may consider per protocol set as a subgroup of the ITT analysis group that fully adheres to the protocol for the primary endpoints.

For the primary outcomes, the change in the total percentile score of the PSI immediately after and 3 months following the intervention will be analysed using a random-effects model with fixed effects of baseline score, time, group, and time-group interaction, along with individual random effects. Adjusted mean differences between groups at each time point (least square means) will be reported along with their 95% confidence intervals. Moreover, comparisons between groups will be performed using a *t*-test for changes immediately after and 3 months after the intervention. For continuously variable secondary outcome measures, analysis using a random effects model and *t*-test will be performed, similar to the primary outcome measures. For categorically variable secondary outcome measures, a chi-squared test will be performed on the contingency tables of groups and outcome variables. For the safety evaluation analysis, even if the same adverse event occurs multiple times in the same participant, it will be counted as one, and the incidence rate and 95% confidence interval will be presented for each adverse event.

MRI

Brain anatomy (T1 weighted), structural connectivity (DTI), and functional connectivity (rsfMRI) will undergo processing using accepted pipelines, allowing quality control to follow current best practice. In exploratory analyses, we will determine if anatomic homophily and functional synchrony are associated with measures of mother–child attachment and other forms of emotional closeness. We will also explore if these measures of neural synchrony change as a result of the behavioural intervention.

Interim analyses {21b}

Interim analyses will not be conducted.

Methods for additional analyses (e.g. subgroup analyses) {20b}

For subgroup analysis, the groups will be divided according to their medication status: medication vs. no medication.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Mixed models do not require imputations for missing data because they naturally handle missing data under missing at random assumption; therefore, we do not plan to explicitly handle (i.e. weighting or imputing) missing values.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

There is no plan to share the participant-level dataset. When the primary outcome results are published, the full protocol will also be submitted. However, the datasets analysed during the current study and the statistical code will be available from the corresponding author on reasonable request, as is the full protocol. In such cases, the accessing of data by a third party will likely require further approval from the ethics committee.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The current study is a monocentre study designed, performed, and coordinated at the University of Tokyo Hospital. Day to day support for the trial is provided by each of the following staffs.

Principal investigator: supervises the trial, takes medical responsibility of the patients, conducts trial registration, coordinates the participants' visits, writes annual safety reports, identifies potential recruits, takes informed consent, ensures follow-up is conducted according to protocol.
Data manager: organises data acquisition, safeguards quality of data.
BPT program facilitator: facilitates and coordinates the BPT program.
Study psychologists: data acquisition, conducting psychological testing and CAI.
CAI coder: codes and assesses the CAI.

Biostatistician: analyses data after trial completion.

The principal investigator, the data manager, the BPT program facilitator, and the study psychologists will meet weekly.

CAI coder and the biostatistician will meet with the principal investigator twice a year.

There is no trial steering committee, stakeholder, or any public involvement group for this study.

Composition of the data monitoring committee, its role and reporting structure {21a}

The Ethics Committee decided that the trial does not need a data monitoring committee due to the trial not using medication (only behavioural training for mothers of children with ADHD).

Adverse event reporting and harms {22}

The researcher will interview the mother for any adverse events, although no adverse events have been reported from conducting parent training in the past. All adverse events, if any, and the causality to the study treatment will be recorded. The adverse events will be reported following the procedures outlined by the IRB at the University of Tokyo Hospital.

Frequency and plans for auditing trial conduct {23}

The study's sponsor (AMED) will audit the procedures twice a year.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

All modifications will be submitted to the IRB, in writing, for review, and permission will be sought to proceed. If the modification affects the participant in any way, the participant will be informed of the change, and if necessary, an additional consent form will be completed to obtain consent. Each time an amendment is made, the online study registry will be updated accordingly.

Dissemination plans {31a}

The results of this study, including positive and negative results, are planned to be published in a peer-reviewed journal. If participants wish to receive the results of the study, they will be eligible to receive a summary of the results.

Discussion

Parents raising children with ADHD often experience high levels of stress. Importantly, various reviews have indicated that measures assessing the effectiveness of parent training lack objectivity, as they are often based on parental reports. Therefore, in this study, highly objective measures will be used to assess the intervention's efficacy in addition to parental and child self-reports. A semi-structured interview conducted by assessors blinded to group allocation will evaluate children's attachment security, whilst MRI images will be used to demonstrate neurological changes associated with the intervention. Moreover, changes in the mother's perception represent an important outcome for BPT [47]. Therefore, we will also consider parenting stress and the mother's sense of emotional closeness to her child as primary outcomes in this trial. This study aims to provide parents of children with ADHD with the most informed evidence-based treatment choice by conducting the first randomised controlled trial investigating the efficacy of BPT on attachment security and mother's sense of emotional closeness to their children and understanding the impact of this intervention not only on children but also on parents.

Limitations

There are a few limitations to consider. First, allocation to the control group may worsen the mother's parenting stress as participants are likely to request immediate participation in parent training. This possible delay in training could impair patient inclusion or increase the dropout rate in the control group. However, we aim to minimise this dropout issue via better and thorough explanations of the study's goals and design to the participants, particularly emphasising that all participants would have the opportunity to join the intervention program upon completion of the study. Second, we recruited only mothers of children with ADHD and not fathers. The reason for this was due to the likely difficulties for fathers to participate in all 10 BPT sessions as indicated in a previous review [52]. Whilst the current study targeted mothers, the child's attachment security towards their father was also assessed to explore the effects of the intervention on the child's relationship with their father. Following the conclusion of the current study, it is hoped that a program that will encourage inclusion of fathers can be developed so that the effectiveness of BPT can be assessed for both parents. Third, this trial commenced prior to the COVID-19 pandemic, initially conducting in-person BPT sessions. However, when the state of emergency was declared in Tokyo in March 2020, these sessions shifted to an online format due to the restrictions imposed to prevent the spread of COVID-19. Finally, the follow-up period is relatively short (3 months), and further investigation is needed to assess long-term efficacy, and also to understand potential need for booster sessions.

Strengths

The novelty of this trial lies in the utilisation of BPT for improving attachment security in children with ADHD. Furthermore, the use of MRI images to explore the efficacy of the intervention aims to provide a more objective tool to assess its efficacy, particularly in contrast to previous studies using subjective assessment tools. This study is expected to provide information on the potential neurological mechanisms of attachment security of children with ADHD, and the use of RCT will help provide conclusive evidence of the efficacy of BPT. These results can ultimately provide promising avenues for developing an objective marker to evaluate the efficacy of BPT in children with ADHD.

Trial status

The current protocol is version 7 of 04–12-2023. Participant recruitment began on 29 November 2019. Participant recruitment is estimated to be completed around 31 March 2027.

Abbreviations

ADHD-RS	ADHD Rating Scale
AQ	Autism-Spectrum Quotient
ARI	Affective Reactivity Index
ASRS	Adult ADHD Self-Report Scale
BIS-11	Barratt Impulsiveness Scale version 11
BIS/BAS	Behavioural Inhibition System/Behavioural Activation System
CAI	Child attachment interview-Japanese
CARS	Childhood Autism Rating Scale
CBCL	Child Behaviour Checklist
CGI	Clinical Global Impression
DH-c	Questionnaire for dominant hand-child
DH-p	Questionnaire for dominant hand-parent
DN-CAS	Das-Naglieri Cognitive Assessment System
DSRSC	Depression Self-Rating Scale for Children
JART	Japanese Adult Reading Test
KINDL	Questionnaire for Measuring Health-Related Quality of Life
KSS-F	Kerns Security Scale-Japanese version
KSS-M	Kerns Security Scale-Japanese version
PANAS-C	Positive and Negative Affect Scale for Children
PAQ-C	Physical Activity Questionnaire for Older Children-Japanese version
PPI-C	Parental Perception Index-Children–Japanese version
PPI-P	Pareto Priority Index-Parent-Japanese version
PSI	Parenting Stress Index–Japanese version
WHO QOL26	Quality of Life QOL of parents
SES	Socio-Economic State A simplified socio-economic status scale
SSN-C	Social support network-child
SSN-M	Social support network-mother

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Not applicable.

Authors' contributions {31b}
AI-T is the chief investigator; she conceived the study and led the proposal and protocol development. RY, PS, SG, KT, AS, LK, and TM contributed to the study design and the development of the proposal. TK was the lead trial methodologist. JH contributed to the development of the parent training method. YK contributed to setting up the recruitment method. All authors read and approved the final manuscript.

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Availability of data and materials {29}
Authors at The University of Tokyo Hospital will have access to the final trial dataset, as well as the research collaborators for pre-arranged specific data that were agreed at the onset of this study. The authors of this protocol will also have access to the data. The anonymised data will be shared with the researcher processing the MRI data to facilitate image processing and data analysis, as well as with the researcher coding CAI to facilitate coding. For statisticians analysing outcomes, the full dataset will be shared once data collection is complete. Any data required to support the protocol can be supplied on request; however, the accessing of data by a party that is not currently approved by the ethics committee will likely require further ethics approval.

Declarations

Ethics approval and consent to participate
The Ethics Committee of the Hospital of Tokyo University approved this study (approval number: 2019180NI). Written informed consent to participate will be obtained from all mothers and written informed assent to participate will be obtained from all children with ADHD.

Consent for publication
We are willing to provide a model consent form on request.

Competing interests
The authors declare that they have no competing interests.

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References

1. Pelham W, Wheeler T, Chronis-Tuscano A. Empirically supported treatments for attention deficit hyperactivity disorder. J Clin Child Psychol. 1998;27:190–205.
2. Zwi M, Jones H, Thorgaard C, York A, Dennis JA. Parent training interventions for attention deficit hyperactivity disorder (ADHD) in children aged 5 to 18 years. Cochrane Database Syst Rev. 2011;2011(12):CD003018-CD.
3. Sonuga-Barke EJ, Brandeis D, Cortese S, Daley D, Ferrin M, Holtmann M, et al. Nonpharmacological interventions for ADHD: systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. Am J Psychiatry. 2013;170(3):275–89.
4. Bor W, Sanders MR, Markie-Dadds C. The effects of the Triple P-Positive Parenting Program on preschool children with co-occurring disruptive behavior and attentional/hyperactive difficulties. J Abnorm Child Psychol. 2002;30(6):571–87.
5. Corcoran J, Dattalo P. Parent involvement in treatment for ADHD: a meta-analysis of the published studies. Res Soc Work Pract. 2006;16(6):561–70.
6. Pisterman S, Firestone P, McGrath P, Goodman JT, Webster I, Mallory R, et al. The role of parent training in treatment of preschoolers with ADDH. Am J Orthopsychiatry. 1992;62(3):397–408.

7. Anastopoulos AD, Shelton TL, DuPaul GJ, Guevremont DC. Parent training for attention-deficit hyperactivity disorder: its impact on parent functioning. J Abnorm Child Psychol. 1993;21(5):581–96.
8. Coates J, Taylor JA, Sayal K. Parenting interventions for ADHD: a systematic literature review and meta-analysis. J Atten Disord. 2015;19(10):831–43.
9. Sonuga-Barke EJ, Sergeant JA, Nigg J, Willcutt E. Executive dysfunction and delay aversion in attention deficit hyperactivity disorder: nosologic and diagnostic implications. Child Adolesc Psychiatr Clin N Am. 2008;17(2):367–84, ix.
10. Bowlby J. Attachment and loss. Vol 1. Attachment. New York: NY: Basic Books; 1969.
11. Storebo OJ, Rasmussen PD, Simonsen E. Association between insecure attachment and ADHD: environmental mediating factors. J Atten Disord. 2016;20(2):187–96.
12. Dehghani-Arani F, Besharat MA, Fitton VA, Aghamohammadi A. Efficacy of an attachment-based intervention model on health indices in children with chronic disease and their mothers. Admin Policy Mental Health Mental Health Serv Res. 2018;45(6):900–10.
13. Choi EJ, Taylor MJ, Hong S-B, Kim C, Yi S-H. The neural correlates of attachment security in typically developing children. Brain Cogn. 2018;124:47–56.
14. Ishii-Takahashi A, Kawakubo Y, Hamada J, Nakajima N, Kawahara T, Hirose A, et al. Changes in child behavioral problems and maternal attachment towards children with attention-deficit/hyperactivity disorder following behavioral parent training: a pilot study. Psychiatry Clin Neurosci. 2023;77(7):412–3.
15. Tanaka Y, Ichikawa H, Ono K. Standardization of the Japanese versions of the ADHD-RS [ADHD-RS評価スケールの日本版標準化に向けて]. Clinical Psychiatry [精神医学]. 2016;58(4):317–26.
16. The Japanese WISC-IV Publication Committee, Trans. (2010). Technical and interpretive manual for the Japanese version of the Wechsler Intelligence Scale for Children. 4th ed. Tokyo: Nihon Bunka Kagakusha. https://doi.org/10.1037/t15174-000.
17. Kurita H, Miyake Y, Katsuno K. Reliability and validity of the Childhood Autism Rating Scale—Tokyo version (CARS-TV). J Autism Dev Disord. 1989;19(3):389–96.
18. Matsuoka K, Kim Y, Hiro H. Miyamoto Y, Fujita K, Tanaka K, Katsuki N. The development of National Adult Reading Test (JART)-Japanese version [In original Japanese: 日本語版 National Adult Reading Test (JART) の作成]. Clin Psychiatry [精神医学]. 2002;44(5):503–511).
19. Barkley RA. Defiant children. New York, USA: Guilford press; 1987.
20. Barkley RA. Defiant children: a clinician's manual for assessment and parent training. 3rd ed. New York, USA: Guilford press; 2013.
21. Forehand RL, McMahon RJ. Helping the noncompliant child: a clinician's guide to parent training. New York: Guilford Publications; 1981.
22. Whitham C. Win the whining war & other skirmishes: a family peace plan. Los Angeles: Perspective Publishing; 1991.
23. Mukai T, Koyama N, Ishii-Takahashi A, Tokuda W, Mori C. Measuring attachment representations in middle childhood in Japan: validation of the child attachment interview [児童期における愛着の測定: child attachment interviewの妥当性の検討]. Jpn J Dev Psychol [発達心理学研究]. 2024;35(1):39–52.
24. Abidin R, Flens JR, Austin WG. The parenting stress index. Charlottesville: Lawrence Erlbaum Associates Publishers; 2006.
25. Narama MK, Yuriko. Araki, Akiko. Maru, Mitsue. Nakamura, Nobue. Takeda, Junko. Shirahata, Noriko. Kudo, Yoshiko. Validity and reliability of the Japanese version of the Parenting Stress Index [日本版Parenting Stress Index (PSI)の信頼性・妥当性の検討]. J Child Health [小児保健研究]. 1999;58(5):610-6.
26. Kerns KA, Tomich PL, Aspelmeier JE, Contreras JM. Attachment-based assessments of parent–child relationships in middle childhood. Dev Psychol. 2000;36(5):614–26.
27. Nakao T, Murakami T. Measuring attachment security in middle childhood: construction of a Japanese version of the Kerns Security Scale (KSS) [児童期中期におけるアタッチメントの安定性を測定する試み: カーンズ・セキュリティ・スケール (KSS) の日本語版作成]. The Japanese Journal of Developmental Psychology [発達心理学研究]. 2016;27(1):72–82.
28. Funabiki Y, Murai T. Standardization of the Japanese version of the child behavior checklist/6–18 [ASEBA 行動チェックリスト (CBCL: 6–18歳用) 標準値作成の試み]. Jpn J Child Adolesc Psychiatry [児童青年精神医学とその近接領域]. 2017;58:175–84.
29. Watanabe N. Forgiveness in Japanese children and adolescents: dispositional, emotional, and parental influence. [dissertation]. George Mason University; 2011. Available from: https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=dcdcfbb81316e6387a6d95db86a40850981e3f2d.
30. Hazzard A, Andrew C, Margolin G. Children's perceptions of parental behaviors. J Abnorm Child Psychol. 1983;11(1):49–60.
31. Colder CR, Trucco EM, Lopez HI, Hawk LW Jr, Read JP, Lengua LJ, et al. Revised reinforcement sensitivity theory and laboratory assessment of BIS and BAS in children. J Res Pers. 2011;45(2):198–207.
32. Takahashi Y, Yamagata S, Kijima N, Shigemasu K, Ono Y, Ando J. Gray's temperament model: development of Japanese version of BIS/BAS scales and a behavior genetic investigation using the twin method. Japanese Journal of Personality. 2007;15(3):276–89.
33. Stringaris A, Goodman R, Ferdinando S, Razdan V, Muhrer E, Leibenluft E, Brotman MA. The Affective Reactivity Index: a concise irritability scale for clinical and research settings. J Child Psychol Psychiatry. 2012;53:1109–17.
34. Sato A, Yasuda A. Development of the Japanese version of positive and negative affect schedule (PANAS) scales [日本語版PANASの作成]. Jpn J Pers [性格心理学研究]. 2001;19:138–9.
35. Murata T, Shimizu A, Mori Y, Ohshima S. Depression in elementary school children. An evaluation using Birleson's depression self-rating scale for children [学校における子どものうつ病 Birlesonの小児期うつ病スケールからの検討(解説)]. Saishin Seishin Igaku [最新精神医学]. 1996;1:131–8.
36. Inoue Y, Ito K, Kita Y, Inagaki M, Kaga M, Swanson JM. Psychometric properties of Japanese version of the Swanson, Nolan, and Pelham, version-IV Scale-Teacher Form: a study of school children in community samples. Brain Dev. 2014;36:700–6.
37. Maeshiro K, Sugawara M, Sakai A, Sugawara K. Construction of revised versions of the self-perception profile for children, adolescents and college students in Japan. Shinrigaku Kenkyu. 2007;78(2):182–8.
38. Furushou J, Shibata R, Nemoto Y, Matsuzaki K. Application and interpretation for questionnaire for measuring health-related quality of life for children-KINDLR——[子どものQOL尺度 その理解と活用 心身の健康を評価する日本語版KINDL R]. Tokyo: Shindantochiryousya [診断と治療社]; 2014.
39. Tazaki M, Nakane A, eds. World Health Organization. WHO/QOL-26 Manual [WHOが開発した"生活の質"を測る調査票]. Tokyo: Kaneko Shobo [金子書房]; 1997.
40. Someya T, Sakado K, Seki T, Kojima M, Reist C, Tang SW, Takahashi S. The Japanese version of the Barratt Impulsiveness Scale, 11th version (BIS-11): its reliability and validity. Psychiatry Clin Neurosci. 2001;55(2):111–4.
41. Guy W. ECDEU assessment manual for psychopharmacology. Rockville: US Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, National Institute of Mental Health, Psychopharmacology Research Branch, Division of Extramural Research Programs; 1976.
42. Antonucci TC. Measuring social support networks: hierarchical mapping technique. Generations. 1986;10(4):10–2.
43. Tracy EM, Whittaker JK. The social network map: assessing social support in clinical practice. Fam Soc. 1990;71(8):461–70.
44. Roll A. Koehly L. One social network, two perspectives: social networks of people with down syndrome based on self-reports and proxy reports. J Appl Res Intellect Disab. 2020;33:1188–98.
45. Maekawa H, Nakayama T, Okazaki S. The Das-Naglieri cognitive assessment system: Japanese edition. Tokyo: Nihon Bunka Kagakusha [日本文化科学社]; 2007. (in Japanese).
46. Kamio Y, Tsujii H, Inada N, Inokuchi E, Kuroda M, Koyama T, Uno Y, Okudera T, Ichikawa H, Takagi A. Validation of the Japanese version of the social responsiveness scale: a comparison with PDD-Autism Society Japan rating scales (PARS) [対人応答性尺度 (Social Responsiveness Scale; SRS) 日本語版の妥当性検証-広汎性発達障害日本自閉症協会評定尺度 (PDD-Autism Society Japan Rating Scales; PARS) との比較]. Clin Psychiatry [精神医学]. 2009;51(11):1101–9.
47. Isa T, Sawa R, Torizawa K, Murata S, Saito T, Ebina A, Kondo Y, Tsuboi Y, Fukuta A, Misu S, Ono R. Reliability and validity of the Japanese version of the Physical Activity Questionnaire for Older Children. Clinical medicine insights. Pediatrics. 2019;13.

48. Uchiyama S, Ohnishi M, Nakamura K, Takebayashi K, Ninomiya T, Suzuki K, Tsujii M, Mori N. Epidemiological study of adult ADHD in Japan - characteristics of adult ADHD self report scale-screener (ASRS-screener) positive group [日本における成人期ADHDの疫学調査 : adult ADHD self report scale-screener (ASRS-screener)陽性群の特長について. J Child Brain Develop [子どものこころと脳の発達]. 2012;3:23–33.
49. Wakabayashi A, Tojo Y, Baron-Cohen S, Wheelwright S. The Autism-Spectrum Quotient (AQ) Japanese version: evidence from high-functioning clinical group and normal adults. Shinrigaku Kenkyu. 2004;75:78–84.
50. Okada N, Kasai K, Takahashi T, Suzuki M, Hashimoto R, Kameyama T, Hiramatsu K, Saito O, Niwa S. Questionnaire for dominant hand-Japanese version for studies of biological psychiatry[日本人を対象とした生物学的精神医学研究のための利き手尺度]. Jpn J Biolog Psychiatry [日本生物学的精神医学会誌]. 2014;25(2):118–9.
51. Daley D, van der Oord S, Ferrin M, Danckaerts M, Doepfner M, Cortese S, et al. Behavioral interventions in attention-deficit/hyperactivity disorder: a meta-analysis of randomized controlled trials across multiple outcome domains. J Am Acad Child Adolesc Psychiatry. 2014;53(8):835–47 e5.
52. Fabiano GA. Father participation in behavioral parent training for ADHD: review and recommendations for increasing inclusion and engagement. J Fam Psychol. 2007;21(4):683–93. https://doi.org/10.1037/0893-3200.21.4.683. PMID: 18179340

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