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A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of Well Parent Japan in routine care in Japan: The training and nurturing support for mothers (TRANSFORM) study

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Background: Well Parent Japan (WPJ) is a new hybrid group parent training programme combining sessions to improve mothers' psychological well-being with a culturally adapted version of the New Forest Parenting Programme (NFPP). This study investigates the effectiveness and cost-effectiveness of WPJ against treatment as usual (TAU) within Japanese child mental health services. **Methods:** TRANSFORM was a pragmatic multi-site randomised controlled trial (RCT) with two parallel arms. Altogether 124 mothers of 6–12-year-old children with DSM-5 ADHD were randomised to WPJ (n = 65) or TAU (n = 59). Participants were assessed at baseline, post-treatment and three-month follow-up. The primary outcome was parent-domain stress following intervention. Secondary outcomes included maternal reports of child-domain stress, parenting practices, parenting efficacy, mood, family strain, child behaviour and impairment. Objective measures of the parent–child relationship were collected at baseline and post-treatment. Data analysis was intention to treat (ITT) with treatment effects quantified through analysis of covariance (ANCOVA) via multilevel modelling. An incremental cost-effectiveness ratio (ICER) assessed WPJ's cost-effectiveness. **Results:** WPJ was superior to TAU in reducing parent-domain stress post-treatment (adjusted mean difference = 5.05, 95% CI 0.33 to 9.81, p = .036) and at follow-up (adjusted mean difference 4.82, 95% CI 0.09 to 9.55, p = .046). Significant WPJ intervention effects were also observed for parenting practices, parenting efficacy and family strain. WPJ and TAU were not significantly different post-intervention or at follow-up for the other secondary outcomes. The incremental cost of WPJ was 34,202 JPY (315.81 USD). The probability that WPJ is cost-effective is 74% at 10,000 JPY (USD 108.30) per one-point improvement in parenting stress, 92% at 20,000 JPY (216.60 USD). The programme was delivered with high fidelity and excellent retention. **Conclusions:** WPJ can be delivered in routine clinical care at modest cost with positive effects on self-reported well-being of the mothers, parenting practices and family coping. WPJ is a promising addition to psychosocial interventions for ADHD in Japan.
Keywords: ADHD; parent training; Japan; New Forest Parent Programme; Parent Stress Management.

Introduction

Attention-deficit hyperactivity disorder (ADHD) is a common neurodevelopmental disorder characterised by elevated levels of inattention, impulsivity and hyperactivity. It has a prevalence of 5% (Polanczyk, Silva de Lima, Lessa, Biederman & Rohde, 2007) in childhood with symptoms persisting into adulthood for many (Simon, Czobor, Balint, Meszaros & Bitter, 2009). ADHD is associated with increased levels of parenting stress, less effective parenting practices, disruptions to the parent–child relationship (Peasgood et al., 2021) and significant financial burden (Daley, Jacobson, Lange, Sorensen & Walldorf, 2019). Access to effective and acceptable treatment is critical to addressing the burden of ADHD.

Recommended treatments for ADHD include pharmacotherapy and psychosocial interventions (Coghill et al., 2021). Not all families favour using medication for ADHD or struggle to contrast its risks and benefits (Flood, Hayden, Gavin, & McNicholas, 2019). In Japan, adherence to pharmacotherapy for ADHD is generally poor with early discontinuation (Ishizuya et al., 2021), and psychosocial interventions are recommended ahead of medication (Saito & Iida, 2022).

A broad range of psychosocial interventions exist for ADHD, and the available evidence favours parent training (Daley et al., 2018; Sibley et al., 2023).

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Meta-analyses report mild-to-moderate symptom reduction (Daley et al., 2014; Hornstra et al., 2023) together with significant improvements in parenting skills, parenting efficacy and quality of the parent–child relationship, based on parent reports (Daley et al., 2014; Dekkers et al., 2022). These effects are often maintained beyond the treatment period (Doffer et al., 2023; Rimestad, Lambek, Christiansen & Hougaard, 2019). Internationally, behavioural parent training is recommended as the first treatment for younger children and in combination with pharmacotherapy for older children (National Institute for Health and Care Excellence, NICE, 2018).

As parent training programmes use parents as agents of change to help their children, it is critical that parents are psychologically robust and supported to undertake this role. This is especially important as parental mental health is often impacted by their child's ADHD as highlighted by the developmental–transactional model of ADHD (Johnston & Chronis-Tuscano, 2015). However, to date, very few interventions have directly targeted parental well-being (depression: Chronis-Tuscano, Gamble, Roberts & Pelham, 2006; 2013; parenting stress: Treacy, Tripp, & Baird, 2005). The stigma that surrounds ADHD in Japan together with Japanese cultural values of sensitivity to interpersonal cues, self-monitoring and harmony increases the vulnerability of Japanese families dealing with ADHD (Armstrong-Hough, 2018). This is especially true for Japanese mothers who carry greater responsibility for parenting and may be judged responsible for their child's behavioural difficulties (Murayama, Ito, Teruyama, & Tsujii, 2018; Thompson et al., 2017).

The need to support children with neurodevelopmental disorders and their families is recognised in Japanese legislation (The Japanese Ministry of Health, Labour and Welfare, MHLW, 2004). Three levels of parent training are currently promoted: (1) *Parent Programme* to teach parents to observe their child's developmental needs and behaviours; (2) *Parent Training* to teach parents behavioural techniques/strategies based on social learning theory and applied behaviour analysis; and (3) *Applied Parent Training*, that is disorder specific (MHLW, 2020). Currently, there are no *Applied Parent Training* programmes targeting the complex needs of Japanese families with children with ADHD.

To address the need for specialist parent training for ADHD in Japan, we developed Well Parent Japan (WPJ). This 13-session programme incorporates a culturally adapted version of the empirically supported New Forest Parenting Programme (NFPP; Thompson et al., 2009; Thompson et al., 2017; Shimabukuro et al., 2017) and five sessions designed to enhance parents' knowledge of ADHD and improve their psychological well-being to prepare them to support their children with ADHD (Treacy et al., 2005). The programme is designed for group administration to strengthen participants' social support networks and address the limited availability of specialised therapists in Japan.

The programme's efficacy has been demonstrated in a proof-of-concept study (Shimabukuro et al., 2017) and a small wait-list control randomised control trial (RCT) (Shimabukuro et al., 2020). Here, we test the programme's effectiveness and cost-effectiveness against treatment as usual (TAU) in routine psychiatric care across three trial sites in Japan. The primary outcome is mother's parent-domain parenting stress, that is, perceived stress in the parent–child dyad arising from the characteristics of the parent, given WPJ's strong focus on the emotional well-being of participating mothers. This is the first large-scale RCT of a specialist parent training programme for ADHD undertaken in Japan.

Cost-effective data collection and analyses are included to obtain realistic estimates of the cost of delivering WPJ in clinical practice together with its economic value. The collection and analyses of such data are not yet routine in parent training research, and we are not aware of any such previous analyses in Japan. Thus, the current study offers the first cost and cost-effectiveness analysis of a specialist parent training programme in Japan.

Methods

The study protocol is published (JMIR Res Protoc 2022;11(4): e32693), and the trial is registered with the International Trial Registry (ISRCTN66978270) http://isrctn.org. Ethical approval for the study was obtained from each intervention site (University of Fukui Hospital Medical Research Ethics Review Committee #20170085; The Ethical Committee of Kurme University – health care and medical ethics #19052; Medical Research Ethics Review Committee National Hospital Organisation Ryukyu Hospital #31-5) and the OIST Graduate University Human Subjects Research Review Committee (HSR-2019-014). The full statistical analysis plan (SAP) is available online with the trial registration with relevant sections included in Appendix S1. Trial recruitment took place from July 2019 to April 2021, data collection from August 2019 to March 2022. The data collection period was extended due to suspension of programme delivery at two sites due to COVID-19 (see Protocol violations).

Study design and participants

A multi-site pragmatic RCT was conducted to test the superiority of WPJ over TAU in child and adolescent mental health services at three hospital sites in Japan (Fukui, Fukuoka and Okinawa). We recruited mothers of 6–12-year-old children with a DSM-5 clinical[1] diagnosis of ADHD.

Inclusion criteria for mothers were fluency in Japanese and parenting an elementary school child diagnosed with ADHD. As a pragmatic trial, comorbidity in the child, including autism spectrum disorder (ASD), was permitted unless the child had very little pragmatic speech or a functional intellectual

[1]As a pragmatic trial, there were no researcher checks (questionnaires or structured diagnostic interviews) of the children's ADHD diagnostic status.

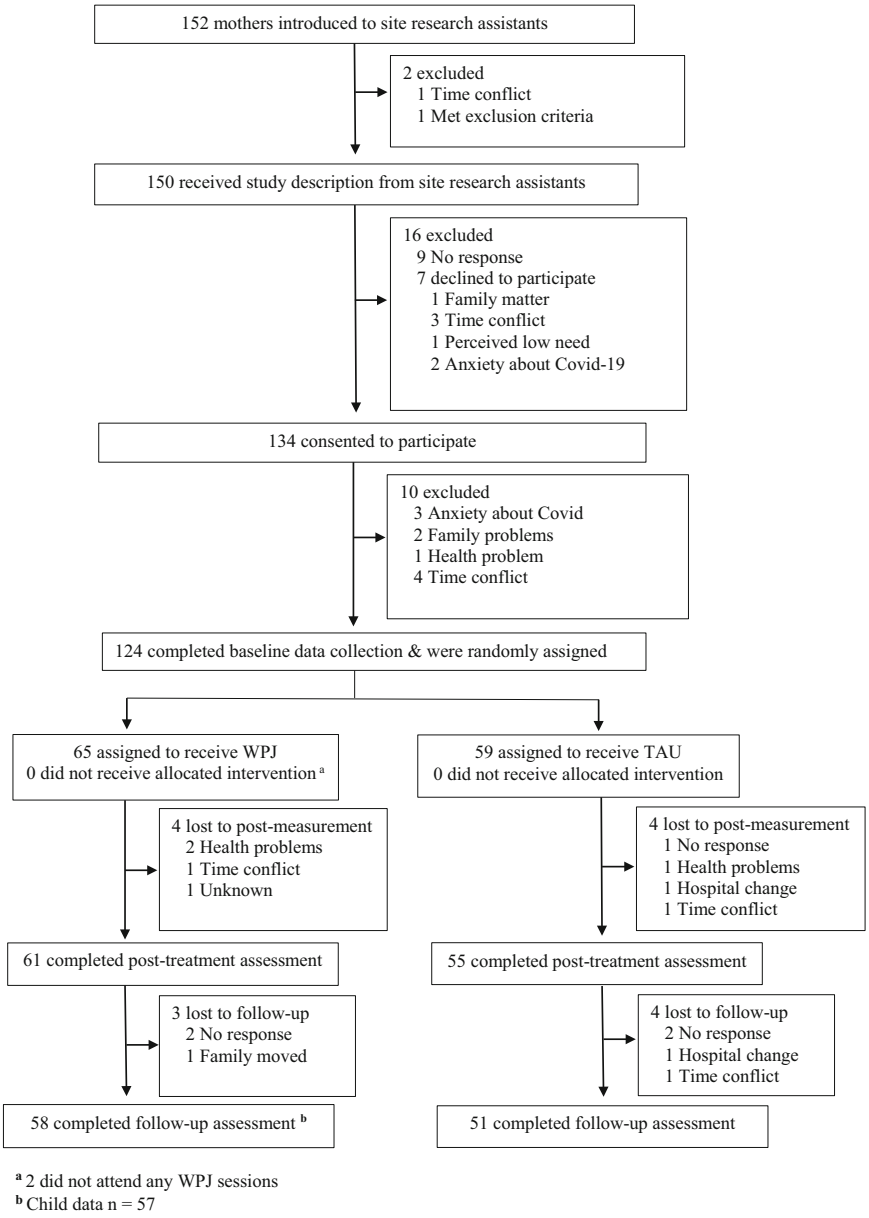

Figure 1 Trial profile (CONSORT diagram)

disability, as identified by the treating clinician. Medication for ADHD symptom management was permitted and recorded via parent report and medical records. Referring doctors were asked to exercise clinical judgement regarding mothers' suitability for a group-delivered intervention (e.g. the absence of serious mental health difficulties and cognitive delays). Mothers were not eligible to participate if they were currently or had recently (within the last two months) participated in another parenting programme.

Mothers were introduced to the study by their child's treating physician,[2] who briefly explained the study and confirmed their eligibility. Those expressing interest were referred to the site research assistant for a detailed verbal and written explanation. Mothers agreeing to participate provided written consent for their own and their child's participation. Written consent from teachers was obtained by mail, and the child's assent at the first face-to-face assessment session. The CONSORT diagram (Figure 1) shows participant flow through the study.

Randomisation and blinding

When sufficient participants were recruited at a site (minimum 12), they were randomised to a study arm using block randomisation. Mothers were allocated with equal probability to WPJ or TAU. Randomisation was carried out by DD[3] using an EXCEL random number generator following baseline data collection. Mothers were informed of study arm allocation by the site research assistant. Site staff were not blind to allocation; researchers at the main trial site (OIST) and the trial statistician were aware of allocation by ID number only. Research staff coding observational data were blind to participants' trial arm and data collection time point.

Procedure

Prior to randomisation (baseline), at post-treatment (14 weeks) and follow-up (26 weeks), mothers were asked to complete and

[2]Four mothers self-referred to the study from other services.

[3]DD had no role in participant recruitment, treatment implementation or data collection.

return questionnaires about their child and themselves and participate in face-to-face interviews about their child's medical and educational service use.[4] At baseline and at post-treatment, they engaged in a pasta making task with their child (parent–child interaction) and talked about their child for 5 min (5-min speech sample, FMSS). Data collection was managed by the research assistant at each site, with questionnaire data and recordings returned to the main trial site for scoring/coding and database entry. These data were identified by ID number only. Each data collection site maintained a linking table that was not shared with the main trial site.

Mothers assigned to WPJ completed the 13-week programme while those assigned to TAU had no contact with the research teams until the post-treatment data collection, which took place between weeks 14 and 16. Follow-up data collection took place between weeks 26 and 28. No mothers had contact with the researchers from the post-treatment to follow-up assessments.

Well Parent Japan

Well Parent Japan (WPJ) is a 13-session group-delivered intervention for mothers of children with ADHD. Sessions are scheduled weekly for 2 h. Session content includes psychoeducation about ADHD, four sessions addressing mothers' psychological well-being (stress management, cognitive restructuring, problem-solving and communication skills) followed by eight sessions of behaviour management incorporating the core components of NFPP, adapted to the Japanese context (Shimabukuro et al., 2017; Thompson et al., 2017). Mothers unable to attend a group session are offered an individual catch-up session (30–60 min) before the next group session. In the trial, a maximum of two catch-up sessions were provided per participant.

At each site, WPJ was delivered by two trained group leaders (five licensed clinical psychologists and one occupational therapist) to groups of 6–8 mothers, according to the WPJ group leaders manual. Group leaders checked coverage at the end of each session, presenting any missed information at the beginning of the next session. All group sessions were recorded, with permission, to assess fidelity of WPJ delivery. Twenty-six sessions (22%) were randomly[5] selected for blind (to study site and wave) review against the group leader's manual for major and minor session content. Checks were carried out by a research assistant familiar with WPJ but not involved in the study.

For the trial, Adverse Events (AEs) were defined as any undesirable event that led to harm or distress that occurred during engagement with WPJ. There were no adverse events during delivery of WPJ. Reporting procedures are outlined in Appendix S1.

TAU included all services provided to families of children with ADHD during the period of the study. Participants in both arms were permitted to access all available hospital/educational services, except for participating in another parenting programme.[6] Hospital service use was recorded from the child's medical file (see Table S1) and indicated that TAU included medical appointments, psychological consultation with treating doctors (mother alone, mother and child), assessment and diagnostic-related appointments with doctors and psychologists, psychologist provided counselling (mother and child alone and together), cognitive training, occupational therapy and speech therapy. Although not all services were available at each participating site, recorded use is consistent with the researchers understanding of TAU, for ADHD, in Japanese hospitals.

All mothers received a 2000 JPY[7] (18.47 USD) voucher for the baseline and week 14 assessment visits and a 1,000 JPY (9.23 USD) voucher for the week 26 face-to-face service utilisation interview. Mothers in the WPJ arm received a 1,000 JPY voucher for each session attended to help cover travel and inconvenience costs. Teachers received a 1,000 JPY voucher each time they completed the study questionnaires.

Outcomes

Detailed descriptions of the outcome measures are provided in the published study protocol (Shimabukuro et al., 2022) and in Appendix S1. The primary outcome measure for the trial was change in parent-domain stress on the Japanese Parent Stress Index (PSI, Abidin, 1983; Narama et al., 1999) from baseline to week 14 for statistical analysis and baseline to week 26 for the economic analysis.

Secondary outcomes were reported changes in PSI child-domain stress; over-reactivity and laxness scores on the Parenting Scale (PS, Arnold, O'Leary, Wolff & Acker, 1993; Itani, 2010); parenting efficacy and satisfaction from the Parent Sense of Competence scale (PSOC, Chuang, Nagatomo, Shimabukuro & Tripp, 2019; Gibaud-Wallston & Wandersman 1978 cited in Johnston & Mash, 1989); Parent Locus of Control (PLOC, Campis, Lyman & Prentice-Dunn, 1986) including responsibility for child's behaviour, perceived efficacy,[8] control of child behaviour and child control of mothers behaviour; Beck Depression Inventory (BDI-II, Beck, Steer & Brown, 1996, Kojima et al., 2002) scores; perceived family strain from the Family Strain Index (FSI, Riley et al., 2006); mothers reports of child ADHD and oppositional defiant disorder (ODD) symptom severity (sum of item ratings from the Japanese translation of the SNAP, Inoue et al., 2014; Swanson, 1992); relationship quality and academic performance from the Vanderbilt Assessment Scale (NICHQ https://tinyurl.com/bde67f5j; Wolraich et al., 2003); and child impairment from the Impairment Rating Scale (Fabiano, Pelham, Waschbusch & Gnagy, 2006). These measures were completed at baseline and weeks 14 and 26.

Blinded observer ratings of parent–child interactions (positive parenting (positive affect, emotional support, parent scaffolding); negative parenting (negative affect, rejection/invalidation, coerciveness) and negative child affect (withdrawal, child negative affect)) during the pasta making task (System for Coding Interactions and Family Functioning, Lindahl & Malik, 2000; and System for Coding Interactions in Parent–Child Dyads, Lindahl & Malik, 1996) and maternal expressed emotion from the revised FMSS (R-FMSS, Daley, Sonuga-Barke & Thompson, 2003) were recorded at baseline and week 14.

Planned teacher outcomes (see Shimabukuro et al., 2022) were excluded following a COVID-19-related protocol violation.

Statistical analyses

Parent-domain parenting stress scores at week 14 informed our sample size calculation. A power calculation indicated 112

[4]Post-intervention collection of service use data was implemented after the first wave of WPJ groups to improve mothers recall/recording but is not included in data analysis.

[5]Subject to the following constraints: inclusion of two recordings of each WPJ session, at least eight sessions from each site and each wave of data collection.

[6]Behavioural parent training programmes were not available at two of the sites, and are not routinely offered through Japanese hospitals.

[7]Using the average exchange rate over the study period September 2019 to December 2021: 1 USD = 108.3 JPY.

[8]The baseline correlation between the PSOC and PLOC efficacy scales is significant, but small $r = -.233$, $p < .01$, $N = 124$.

participants were required to detect a 0.5 standardised effect size with 80% power at two-tailed 5% significance, assuming a correlation of 0.35 between baseline and follow-up. The proposed effect size was based on the previous WPJ RCT (Shimabukuro et al., 2020) and expert opinion to take a slightly conservative approach to avoid underpowering the trial. Adjusting for a 15% attrition rate, the target sample was inflated to 132. The Stata *sampi* command was used for the power analysis.

All analyses were conducted on an intention-to-treat (ITT) basis. Data imputation ensured inclusion of all randomised participants in the ITT analyses. The statistical analysis plan was finalised prior to the data being locked for analysis. Treatment effect estimates, at post-intervention (week 14) and three-month follow-up (week 26), and their 95% confidence intervals (CIs) were quantified through analysis of covariance by means of multilevel modelling with baseline scores, treatment arm, follow-up time and the interaction of arm × time included as covariates and participant as a level two unit. Exploratory data analyses indicated trivial variability in outcome measures across sites; therefore, site was not included as a higher-level analytical unit in these analyses. *Blimp 3.0* software (Keller & Enders, 2022) was used to impute missing data under a missing-at-random assumption with analytical model after exploration of the effect of the observed data on missing outcome values.

Various sensitivity analyses, such as modelling with observed data only, were conducted to check the robustness of treatment effect estimates sensitive to missingness and other data assumptions. Stata software (version 17; StataCorp, 2021) was used for all data analyses, except imputation of missing data.

Economic evaluation

The resources involved in delivering the intervention, that is, staff time (programme delivery and preparation), consumables and therapist supervision, were recorded from time sheets and receipts. This allowed the intervention cost to be calculated. Personal health care utilisation costs were estimated from maternal reports using the Japanese Health Economic Cost [JHEC] developed for this study with reference to the Client Service Receipt Inventory (Beecham & Knapp, 1992). Mothers reported the costs of medical and educational service utilisation at baseline and three-month follow-up (26 weeks).

Costs were estimated from both societal and personal perspectives, as recommended by the NICE (2018). Costs included ADHD and non-ADHD medical, educational service and WPJ implementation costs (treatment group). As total costs were only available via the JHEC interview, final reported costs are based on maternal reports only. Mothers were asked to provide medical receipts for the 3 months prior to the start of WPJ and the 3 months after WPJ finished (in Japan, medical receipts are routinely kept for tax deduction purposes). To check the accuracy of this information, treating hospitals provided copies of their own invoices. The association between maternal-provided costs and hospital records of ADHD-related medical costs was large and significant ($r = .80$, $p < .001$; 95% CI 0.76 to 0.83), confirming the accuracy of maternal information.

Cost-effectiveness was gauged by the incremental cost-effectiveness ratio (ICER), that is, the difference in the total cost of WPJ and TAU in the 3 months before and after implementation of WPJ divided by the difference in their effects on parent-domain parenting stress (cost of WPJ – cost of TAU)/(effect of WPJ – effect of TAU). A complete case analysis was carried out, that is, without the use of imputation, and thus cost estimates are based on $N = 108$. However, where no response was received for questions about service use on the JHEC, in an otherwise complete questionnaire, no cost was assumed. WPJ therapist training costs were not included in the cost analysis. This is a one-off cost that would distort the recurrent cost of implementing WPJ.

Bootstrapping was used to calculate 95% confidence intervals for the ICER, with individual-level resampling (Briggs, Wonderling & Mooney, 1997). The net benefit approach (Behan et al., 2020) was used to estimate the probability of cost-effectiveness at various willingness-to-pay thresholds and the cost-effectiveness acceptability curve generated. Costs are presented in Japanese yen (JPY) and US dollars (USD), using the average exchange rate over the study period.

Intervention costs reflect average salary costs for clinical psychologists in the Japanese healthcare system. Staff time allocated to prepare and clean the intervention room increased significantly for the second and third waves of WPJ delivery during the COVID-19 pandemic. These were adjusted to the average times before the pandemic.

Results

Sample characteristics

Altogether 152 mothers of children with ADHD were referred for a detailed description of the trial. The study was described to 150 mothers. Consent was obtained from 134 mothers, across the three sites, before recruitment closed, 124 of whom participated in baseline data collection and were randomised to WPJ or TAU, an attrition rate of 7.5% (see Figure 1). Amongst these, 38 (30.6%) mothers were from the Fukui site and 43 (34.7%) each from the Kurume and Okinawa sites. Sixty-five (52.4%) mothers were randomised to WPJ and 59 (47.6%) to TAU. One hundred and sixteen (93.5%) mothers participated in the post-intervention assessment (93.8% for WPJ group, 93.3% for TAU), while 109 (87.9%) engaged at follow-up (87.7% for WPJ, 86.4% for TAU). Baseline demographic and clinical characteristics and outcome scores are summarised in Table 1. Changes to the children's ADHD medication use during the trial are reported in Table S2.

Primary outcome: Parent reported parent-domain parenting stress

The modelled mean difference in the change (reduction) score in parenting stress between WPJ and TAU was significant at week 14 (adjusted mean difference 5.05, 95% CI 0.33 to 9.81, $p = .036$). The difference was also significant at week 26 (adjusted mean difference 4.82, 95% CI 0.09 to 9.55, $p = .046$), see Figure 2 and Table 2. The reduction in parent-domain parenting stress was significantly larger for mothers in the WPJ arm. Sensitivity analysis showed that treatment effects estimates are robust across various data scenarios (see Table S3).

Secondary outcomes

Amongst the secondary outcomes, the modelled mean difference in change scores between WPJ and TAU was significant immediately post-intervention (week 14) for parent over-reactivity (adjusted mean

Table 1 Parent and child demographic characteristics and baseline primary and secondary outcome measures

Variable	WPJ (N = 65)	TAU (N = 59)
Mothers age in years, *M* (*SD*)	40.20 (5.91)	39.76 (4.98)
Education, *n* (%)		
Junior High School	4/65 (6)	4/59 (7)
High School	27/65 (42)	18/59 (31)
Two-year College	13/65 (20)	11/59 (19)
Technical/Vocational	10/65 (15)	15/59 (25)
Four-year University	9/65 (14)	10/59 (17)
Graduate School	2/65 (3)	1/59 (2)
Employment status, *n* (%)		
Full-time employment	22/65 (34)	14/59 (24)
Part-time employment	20/65 (31)	33/59 (56)
Student	18/65 (28)	9/59 (15)
Not working	5/65 (8)	3/59 (5)
Married or cohabitating, *n* (%)	56/65 (86)	47/59 (80)
Number of children in family		
1–2	37/65 (57)	36/59 (61)
>2	28/65 (43)	23/59 (39)
Conners Adult ADHD Rating Scale, *M* (*SD*)	57.90 (15.98)	55.40 (15.37)
Child with ADHD age in years, *M* (*SD*)	8.66 (1.63)	8.58 (1.64)
Male children, *n* (%)	57/65 (88)	49/49 (83)
Comorbid Autism diagnosis (*n* %)	45/65 (69)	35/59 (59)
Autism quotient above cut-off (*n* %)	27/65 (34)	16/59 (27)
Child taking medication for ADHD (*n* %)	22/65 (34)	23/59 (39)
Child education, *n* (%)		
Regular classroom	23/65 (35)	28/59 (47)
Special classroom	12/65 (18)	5/59 (8)
Mixed	30/65 (46)	26/59 (44)
Parent Stress Index, *M* (*SD*)		
Parent-domain stress	111.95 (23.56)	111.90 (22.71)
Child-domain stress	106.60 (16.05)	104.42 (18.37)
Family Strain Index, *M* (*SD*)	6.91 (4.03)	6.63 (3.68)
Parenting Scale, *M* (*SD*)		
Over-reactivity	41.55 (11.62)	40.20 (10.51)
Laxness	24.94 (6.71)	24.61 (6.27)
PSOC, *M* (*SD*)		
Efficacy	16.68 (5.06)	17.59 (4.53)
Satisfaction	34.09 (6.74)	33.63 (7.20)
PLOC, *M* (*SD*)		
Responsibility	31.97 (5.17)	31.61 (5.26)
Efficacy	26.03 (4.12)	25.19 (4.08)
Parent Control Child Behaviour	31.05 (5.25)	29.93 (5.19)
Child Control of Mother's Behaviour	20.77 (3.66)	20.90 (3.70)
BDI, *M* (*SD*)	13.22 (9.15)	14.56 (11.00)
Baseline parent–child interaction		
Positive parenting	9.49 (2.66)	9.54 (2.57)
Negative parenting	3.35 (0.81)	3.44 (1.05)
Negative child affect	2.83 (1.43)	2.46 (0.73)
Expressed emotion		
Positive comments	1.40 (1.33)	1.31 (1.39)
Negative comments	1.91 (1.65)	1.83 (1.61)
ADHD symptom severity, *M* (*SD*)		
Inattention	17.94 (5.32)	16.15 (5.36)
Hyperactivity/Impulsivity	11.38 (6.33)	9.51 (5.33)
ODD symptom severity, *M* (*SD*)	9.55 (5.78)	7.83 (5.65)
Impairment, *M* (*SD*)	17.06 (7.00)	17.32 (8.06)
Vanderbilt		
Academic performance	7.64 (2.41)	7.81 (2.54)
Social performance	8.20 (1.84)	8.52 (1.86)

BDI, Beck Depression Inventory II; Impairment, Impairment Rating Scale; ODD, oppositional defiant disorder; PLOC, Parent Locus of Control; PSOC, Parent Sense of Competence; TAU, Treatment as usual; WPJ, Well Parent Japan.

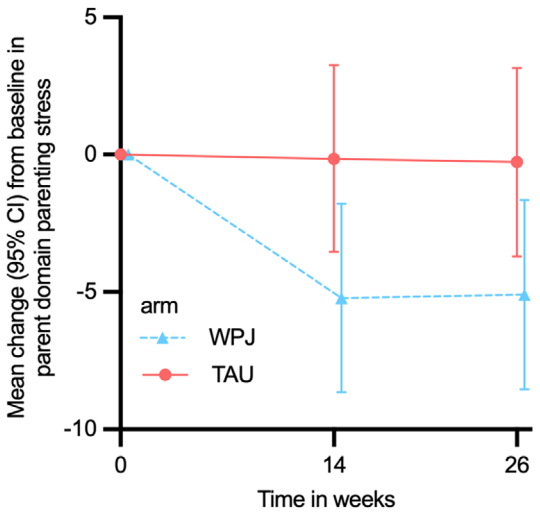

Figure 2 Mean change [95% CI] in parent-domain parenting stress on the Parent Stress Index immediately post-intervention and at three-month follow-up. Data are of all participants (N = 124) included in the intention-to-treat analysis. Error bars show 95% CIs

difference 7.51, 95% CI 4.50 to 10.53, $p < .001$); parenting efficacy measured with the PSOC (adjusted mean difference −3.15 95% CI −4.63 to 1.67, $p < .001$) and the PLOC (adjusted mean difference 2.24; 95% CI 1.01 to 3.46, $p < .001$); parent sense of control over child behaviour (adjusted mean difference 2.95, 95% CI 1.24 to 4.66, $p = .001$) and perception of child control of mothers behaviour (adjusted mean difference 0.92, 95% CI 0.06 to 1.77, $p = .035$). For these outcomes, improvement was greater for WPJ. At follow-up (week 26) differences were significant for parent over-reactivity (adjusted mean difference 5.00, 95% CI 2.16 to 7.84, $p = .001$) and parenting efficacy (PSOC adjusted mean difference −2.60, 95% CI −4.22 to 0.97, $p = .002$; PLOC adjusted mean difference 2.01, 95% CI 0.87 to 3.16, $p = .001$). The mean difference in change scores for family strain was significant at week 26 (adjusted mean difference 1.53, 95% CI 0.53 to 2.53, $p = .003$). Mothers in the WPJ group reported significantly less family strain than those in TAU.

The mean difference in change scores for WPJ and TAU was not significant at week 14 or week 26 for all remaining self-report measures, that is, child-domain

Table 2 Multilevel modelling of changes in scores from baseline to follow-up for WPJ versus TAU: ITT analysis

Variable	Mean change from baseline [95% CI]		Change difference [95% CI]	*p*-Value
	WPJ ($N = 65$)	TAU ($N = 59$)		
PD PSI				
Week 14	−5.22 [−8.64, −1.79]	−0.15 [−3.55, 3.26]	5.05 [0.33, 9.81]	.036
Week 26	−5.09 [−8.54, −1.65]	−0.27 [−3.70, 3.16]	4.82 [0.09, 9.55]	.046
CD PSI				
Week 14	−3.48 [−5.41, −1.56]	−2.32 [−5.01, 0.37]	1.16 [−2.27, 4.60]	.507
Week 26	−2.94 [−5.56, −0.32]	−2.23 [−4.59, 0.13]	0.71 [−2.15, 3.57]	.624
Family strain				
Week 14	−1.08 [−1.80, 0.36]	−0.65 [−1.36, 0.05]	0.42 [−0.59, 1.44]	.413
Week 26	−1.77 [−2.50, 1.04]	−0.24 [−0.97, 0.49]	1.53 [0.53, 2.53]	.003
PS o-reactivity				
Week 14	−7.54 [−10.27, −4.80]	−0.02 [−1.26, 1.22]	7.51 [4.50, 10.53]	.000
Week 26	−5.51 [−7.50, 3.53]	−0.51 [−2.35, 1.32]	5.00 [2.16, 7.84]	.001
PS laxness				
Week 14	−2.57 [−3.66, 1.48]	−0.94 [−2.27, 0.40]	1.63 [−0.36, 3.62]	.109
Week 26	−0.89 [−2.32, 0.53]	−0.82 [−1.94, 0.30]	0.08 [−1.29, 1.44]	.913
PSOC efficacy				
Week 14	3.20 [2.20, 4.20]	0.05 [−1.30, 1.40]	−3.15 [−4.63, 1.67]	.000
Week 26	2.99 [2.01, 3.98]	0.40 [−0.69, 1.48]	−2.60 [−4.22, 0.97]	.002
PSOC sat				
Week 14	1.36 [−0.10, 2.81]	0.36 [−0.59, 1.31]	−1.00 [−3.12, 1.12]	.357
Week 26	0.82 [−1.28, 2.91]	0.42 [−0.66, 1.49]	−0.40 [−2.81, 2.01]	.746
PLOC resp				
Week 14	0.42 [−1.19, 1.65]	−0.19 [1.34, 0.95]	−0.61 [−2.67, 1.45]	.562
Week 26	0.23 [−1.19, 1.65]	−0.20 [−1.31, 0.90]	−0.43 [−2.51, 1.64]	.684
PLOC efficacy				
Week 14	−1.35 [−2.13, 0.57]	0.89 [0.31, 1.47]	2.24 [1.01, 3.46]	.000
Week 26	−1.14 [−1.85, 0.42]	0.88 [0.07, 1.68]	2.01 [0.87, 3.16]	.001
PLOC parent C				
Week 14	−2.47 [−3.50, 1.45]	0.47 [−0.73, 1.67]	2.95 [1.24, 4.66]	.001
Week 26	−0.61 [−1.90, 0.69]	0.62 [−0.38, 1.63]	1.23 [−0.32, 2.77]	.119
PLOC child C				
Week 14	−0.45 [−1.02, 0.13]	0.47 [−0.28, 1.22]	0.92 [0.06, 1.77]	.035
Week 26	−0.24 [−1.13, 0.66]	0.71 [0.17, 1.24]	0.95 [−0.32, 2.21]	.142
BDI				
Week 14	−2.22 [−3.22, 1.22]	−1.72 [−3.68, 0.24]	0.50 [−1.59, 2.59]	.639
Week 26	−2.32 [−4.16, 0.48]	−1.39 [−3.43, 0.66]	0.93 [−1.68, 3.54]	.485
Pasta +ve P				
Week 14	−0.10 [−0.76, 0.57]	−0.87 [−1.75, 1.01]	−0.77 [−1.95, 0.41]	.159
Pasta −ve N				
Week 14	0.12 [−0.33, 0.58]	0.01 [−0.29, 0.30]	−0.12 [−0.66, 0.42]	.612
Pasta −ve C				
Week 14	0.08 [−0.19, 0.34]	0.06 [−0.28, 0.40]	−0.02 [−0.47, 0.44]	.934
EE +ve				
Week 14	−0.22 [−0.64, 0.21]	−0.08 [−0.54, 0.39]	0.14 [−0.52, 0.80]	.619
EE−ve				
Week 14	−0.83 [−1.27, −0.38]	−0.67 [−1.05, −0.28]	0.16 [−0.47, 0.78]	.554
SNAP inatt				
Week 14	−1.77 [−2.70, 0.84]	−1.76 [−2.91, 0.61]	0.01 [−1.53, 1.54]	.994
Week 26	−1.99 [−2.93, 1.05]	−0.99 [−2.30, 0.32]	1.00 [−0.94, 2.94]	.311
SNAP hyper				
Week 14	−0.65 [−1.37, 0.08]	−1.53 [−2.38, 0.68]	−0.89 [−1.86, 0.09]	.076
Week 26	−1.15 [−1.99, 0.32]	−1.21 [−2.09, 0.32]	−0.05 [−1.47, 1.36]	.940
SNAP ODD				
Week 14	−1.81 [−2.45, 1.16]	−1.56 [−2.62, 0.50]	0.25 [−0.83, 1.32]	.652
Week 26	−2.07 [−2.76, 1.38]	−1.07 [−2.11, 0.03]	1.00 [−0.35, 2.35]	.148
Impairment				
Week 14	−2.85 [−4.66, 1.04]	−2.35 [−3.59, 1.12]	0.50 [−1.64, 2.64]	.648
Week 26	−3.23 [−4.75, 1.71]	−2.40 [−4.16, 0.63]	0.83 [−1.34, 3.01]	.452
Vanderbilt social				
Week 14	0.20 [−0.28, 0.69]	0.22 [−0.15, 0.59]	0.02 [−0.64, 0.68]	.957
Week 26	0.42 [−0.02, 0.85]	0.10 [−0.34, 0.53]	−0.32 [−0.89, 0.26]	.277
Vanderbilt academic				
Week 14	0.08 [−0.40, 0.56]	0.29 [−0.22, 0.79]	0.20 [−0.63, 1.03]	.634
Week 26	0.11 [−0.40, 0.61]	0.20 [−0.30, 0.70]	0.09 [−0.70, 0.88]	.820

BDI, Beck Depression Inventory II score; CD PSI, child-domain Parent Stress Index; EE +ve, positive comments during 5 min speech sample; EE−ve, negative comments during 5 min speech sample; Family strain, Family Strain Index; Impairment, Impairment Rating Scale score; ITT, Intention to Treat; Pasta +ve P, positive parenting during pasta task; Pasta −ve C, negative child affect during pasta task; Pasta −ve P, negative parenting during pasta task; PD PSI, parent-domain Parent Stress Index; PLOC child C, Parent Locus of Control child control of parent; PLOC efficacy, Parent Locus of Control efficacy scale; PLOC Parent C, Parent Locus of Control parent control of child behaviour; PLOC resp, Parent Locus of Control responsibility scale; PS laxness, Parenting Scale laxness; PS o-reactivity, Parenting Scale over–reactivity; PSOC efficacy, Parent Sense of Competence Efficacy scale; PSOC sat, Parent Sense of Competence satisfaction scale; SNAP hyper, Swanson, Nolan and Pelham ADHD scale hyperactivity/impulsivity symptom severity; SNAP inatt, Swanson, Nolan and Pelham ADHD scale inattention symptom severity; SNAP ODD, Swanson, Nolan and Pelham ADHD scale oppositional defiant disorder symptom severity; TAU, Treatment as usual; Vanderbilt academic, Vanderbilt academic performance score; Vanderbilt social, Vanderbilt social performance score; WPJ, Well Parent Japan.

stress (PSI), laxness (PS), parenting satisfaction (PSOC), sense of responsibility for child behaviour (PLOC) and mood (BDI-II), and mothers reports of child behaviour, that is, ADHD and ODD symptom severity (SNAP), relationship quality and academic performance (Vanderbilt Assessment Scale) and impairment (please see Table 2 for details of these results). Mean differences in change scores for the objective measures of parent–child interaction quality (pasta making task) and mother's expressed emotion (R-FMSS) were not significant post-intervention (week 14). The multilevel modelling results for all outcome measures are presented in Table 2, with standardised mean differences (Cohen's *d*) reported in Table S4.[9] Modelled changes scores using observed data are presented in Table S5, with the means, standard deviations, medians and minimum and maximum values for the observed data at each time point presented in Table S6.

Fidelity of programme delivery and parent attendance

The fidelity check for WPJ delivery showed the average coverage of major content points, across the 26 reviewed sessions, was 95.2% (90.4% to 98.3% across sites). For minor content, the average coverage was 80.3% (75.3% to 86.8%).

The overall group attendance rate for WPJ was 80.5% (Okinawa = 81.9%; Fukui = 81.2%; Kurume = 78.3%), increasing to 85.7% (88.3%; 89.6%; 79.4%) including catch-up sessions. Participation rates dropped in the third wave of the trial at the height of the COVID-19 pandemic in Japan (wave 1 = 95.5%; wave 2 = 94.1%; wave 3 = 66.7%). Thirty-five mothers (53.9%) received all 13 sessions, 53 (81.5%) at least 11 sessions and 56 (86.2%) at least 8 sessions. Seven mothers (10.8%) received fewer than seven sessions, including two mothers who did not attend any WPJ sessions. Altogether 75 catch-up sessions were offered, of which 44 (58.7%) were utilised.[10]

Protocol deviations

Five[11] protocol violations were recorded. The first three were due to the COVID-19 pandemic: (a) during the third wave of WPJ groups, programme delivery was suspended at two sites (for 13 and 16 weeks) due to hospital and community centre closures. A review session was held at both sites to remind participants of previously covered content before resumption of WPJ sessions; (b) the cost-effectiveness interview following the third WPJ group was carried out by telephone at one site; (c) teacher data were excluded from analyses: school closures and online learning made it impossible for teachers to accurately rate child behaviour. In addition, delays in programme delivery prevented the same teacher from rating children's behaviour across all three time points; (d) one participant was identified as the paternal grandmother of a child with ADHD, she was the child's primary caregiver; (e) four mothers self-identified their interest in participating in the RCT, all received a detailed explanation of the study from the site research assistants, who confirmed their eligibility with the site PI.

Cost-effectiveness analyses

WPJ intervention costs. Table 3 summarises the costs of intervention delivery based on weekly diaries completed by the group leaders. Published national costs usually include capital costs, staff time, training and travel; however, costs presented here are recurrent costs only. Therapist travel costs were not included as it was expected that once implemented the intervention would be delivered within their regular place of work. The mean intervention cost per participant was 31,143 JPY (287.56 USD). Non-recurrent costs, including therapists' training, are presented in Table S7.

Service utilisation costs for children of participating mothers. Table 4 summarises the service utilisation costs for children in both trial arms before and after intervention, including ADHD-related and non-

[9]Included to facilitate comparison with findings from other parent training programs for ADHD reported in the literature.

[10]The maximum number of catch-up sessions available per participant was 2. Mothers continued to be offered catch-up sessions until this limit was reached.

[11]Although not technically a protocol violation, initiation of the second wave of WPJ groups and data collection was delayed by 5 months across all sites.

Table 3 Recurring costs for delivery of WPJ

Cost source	Units (h)/group leader, mean (*SD*)	Total units	Unit cost (JPY)[a]	Total cost (JPY)[b]
Participant handouts/materials		65.00	1,550/person	101,205
Running sessions	26.23 (1.13)	472.17	1,846/h	871,620
Reviewing manual	7.69 (4.10)	138.50	1,846/h	255,671
Make-up sessions	1.95 (1.11)	35.08	1,846/h	64,764
Additional consultation	1.38 (1.37)	24.75	1,846/h	45,689
Dealing with unexpected events	0.45 (0.67)	8.08	1,846/h	14,922
Preparing and cleaning room	7.50 (3.31)	135.00	1,846/h	249,210
Participation in supervision	6.43 (5.16)	115.73	1,846/h	213,644
Provision of supervision	3.84 (5.30)	69.18	3,000/h	207,550
Total costs				2,024,274
Cost per randomised participant				31,143

JPY, Japanese yen; USD, United States dollar; WPJ, Well Parent Japan.
[a]Unit cost for group leaders based average salary for a licensed clinical psychologist with 5 years' clinical experience; for WPJ trainer based on average salary for a licensed clinical psychologist with more than 10 years' clinical experience.
[b]Using the average exchange rate over the study period from September 2019 to December 2021: 1 USD = 108.3 JPY.

ADHD-related health and educational service costs. Intervention costs for WPJ are also presented. For all utilisation costs, the differences between the two arms at baseline were substantial but not statistically significant, reflecting the wide variation between participants. The total cost, that is, change in utilisation costs from baseline to follow-up plus the cost of the intervention received increased by 18,267 JPY (168.67 USD) in WPJ and decreased by 15,935 JPY (147.14 USD) in TAU. Thus, the WPJ intervention resulted in 34,202 JPY (315.81 USD) incremental costs.

Table 4 Child medical and educational service utilisation costs (mean cost per capita, JPY[a]) for WPJ versus TAU (based on available data)

	WPJ (n = 57)		TAU (n = 51)	
Cost source	At baseline	At follow-up	At baseline	At follow-up
ADHD-related hospital services	28,895	22,507	30,793	26,381
Non-ADHD-related hospital services	11,325	8,591	14,095	8,041
Educational services	5,103	1,350	10,616	5,147
Total	45,323	32,447	55,504	39,569
WPJ		31,143		
Total + WPJ	45,323	63,590	55,504	39,569
Change in total mean cost		18,267		−15,935
Incremental cost		34,202		

JPY, Japanese yen; TAU, treatment as usual; WPJ, Well Parent Japan.
[a]Using the average exchange rate over the study period September 2019 to December 2021: 1 USD = 108.3 JPY.

Table 5 Change in parent-domain stress scores from baseline to follow-up for WPJ and TAU (based on available data)

	Baseline		Follow-up		Change	
Treatment arm	*M*	*SD*	*M*	*SD*	*M*	*SD*
WPJ (n = 54)	111.3	21.4	106.0	24.1	−5.3	16.1
TAU (n = 50)	111.0	23.5	110.8	22.1	−0.2	12.6
Difference	0.3		−4.8		−5.1	

TAU, Treatment as usual; WPJ, Well Parent Japan.

Cost-effectiveness. The cost-effectiveness analysis included cases for whom service utilisation costs were available at both baseline and week 26. Parent-domain stress change scores from baseline to follow-up for these mothers are presented in Table 5. The WPJ group showed a 5.3 point reduction in parent-domain parenting stress over this period while for TAU the reduction was 0.2 points, indicating a 5.1 point improvement related to WPJ. The point estimate of the ICER is 6,707 JPY (61.93 USD), calculated by dividing the 34,202 JPY incremental cost of WPJ by the 5.1 point incremental effect.[12]

Bootstrapping and cost-effectiveness acceptability curve. The 1,000 replication bootstrap yielded a 95% CI for the ICER of −80,948 to 94,362 JPY. Figure 3A depicts the incremental cost-effectiveness plane, based on bootstrapping, plotting a combination of the incremental effect (improvements in parent-domain stress) and the incremental cost. A substantial portion of the points fell within the northeast quadrant of the plane, indicating that WPJ was both costlier and more effective than TAU in most cases; that is, WPJ tended to have favourable impact on parenting stress with incremental costs.

Figure 3B presents the cost-effectiveness acceptability curve, showing the probability of WPJ being cost-effective at different willingness-to-pay (WTP) thresholds, to obtain a 1-point improvement in parenting stress. For example, if the WTP is set at

[12]Personal costs N = 108; parenting stress change scores N = 104.

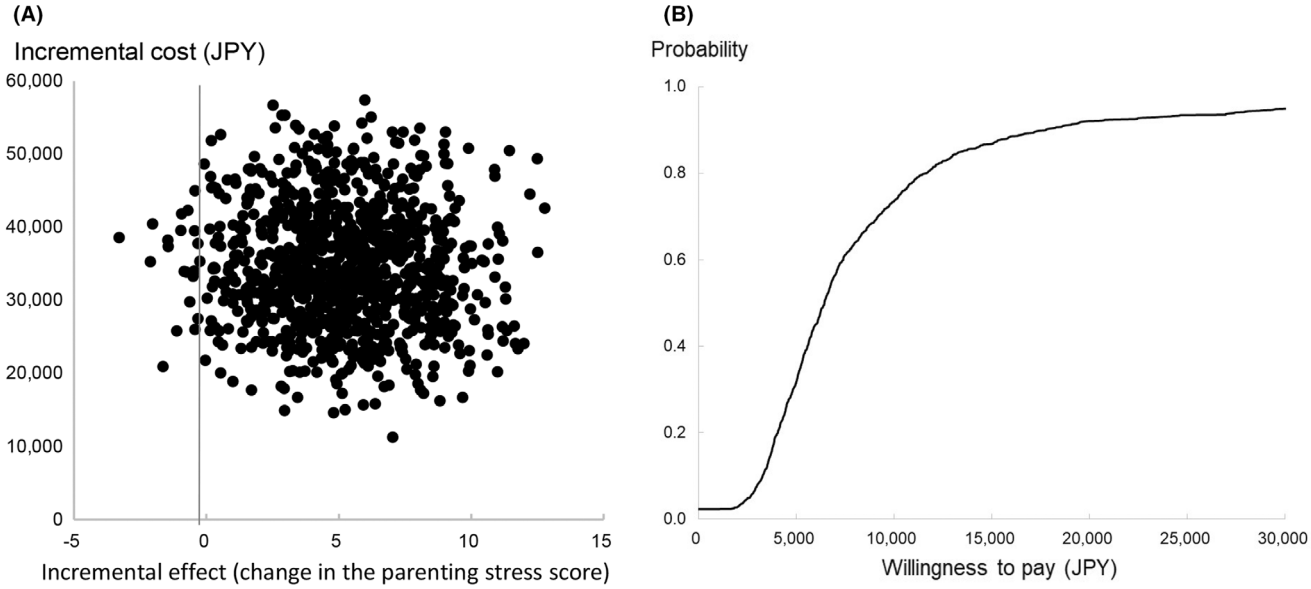

Figure 3 (A) 1,000 replication bootstrap cost-effectiveness plane. (B) Cost-effectiveness acceptability curve

10,000 JPY (108.30 USD), then WPJ would be cost-effective with a probability of 74%; if set at 20,000 JPY (216.60 USD), the probability would rise to 92%.

Discussion

This is the first multi-site RCT of a specialist behavioural parent training programme for ADHD in Japan. The findings demonstrate a pattern of significant and positive advantages of WPJ over TAU delivered in routine clinical care. Participation in WPJ was associated with significant and lasting improvements in parental well-being, including parent-domain parenting stress, the primary outcome and parenting practices. Family strain continued to decline post-intervention. WPJ showed no advantage over TAU for child ADHD symptoms. The cost of delivering the intervention was moderate and therefore cost-effective.

The positive impact of WPJ on maternal self-report of parent-domain parenting stress, parenting practices, parenting efficacy and family strain is consistent with the findings of our earlier proof-of-concept and RCT studies (Shimabukuro et al., 2017, 2020) and of similar magnitude to those reported in a recent meta-analysis of parent outcomes following parent training (Dekkers et al., 2022). The significant group differences were driven by improvements in the WPJ arm, rather than a deterioration in TAU, suggesting intervention-related changes in maternal and family functioning. These changes were not captured by the study's brief observational measures immediately post-intervention. Contrary to the results of previous trials with the NFPP (e.g. Abikoff et al., 2015; Lange et al., 2018), and recent meta-analytic findings (Hornstra et al., 2023), the effects of WPJ on child outcomes were not significant. Maternal ratings of child ADHD and ODD symptoms and impairment were lower following WPJ; however, the effects were moderate, at best, and not significantly different from those seen with TAU.

Sample characteristics may have contributed to these non-significant findings. As a pragmatic trial, inclusion criteria were deliberately broad and did not require research confirmation of the diagnosis of ADHD. The resulting sample included *very* high rates of comorbid autism, limited ODD symptoms, and lower ADHD symptom severity than our previous studies, the latter possibly reflecting higher medication use in the current study, that is, twice the rate. Floor effects would have reduced the opportunity for ADHD and ODD symptom reduction across groups, and we cannot rule out the possibility that mothers had already adjusted their interaction styles to accommodate their children's autism. Previous trials of the NFPP in Europe and the United States excluded autism, while our first RCT with WPJ permitted only mild autism symptoms. Children in the current study were also older than in earlier NFPP trials (Abikoff et al., 2015; Lange et al., 2018; Thompson et al., 2009). It is also possible that COVID-19 lockdowns made it more difficult for mothers to continue using the skills they learned in WPJ. It will be important to explore these hypotheses using sensitivity analyses in future manuscripts.

Despite its length, WPJ was relatively inexpensive to deliver (cf. Sonuga-Barke et al., 2018; Tran et al., 2018) at a unit cost of 31,143 JPY (287.56 USD) per family[13] and demonstrates significant effects on parent and family well-being and parenting practices, making it cost-effective even at modest willingness-to-pay thresholds. These costs reflect the

[13]Based on the cost of providing WPJ to 65 mothers: nine separate groups with two group leaders per group.

recurrent cost of delivery, excluding therapist training or commuting costs. Costs were adjusted in this way to offer a realistic estimate of the cost of implementing WPJ in routine clinical care in Japan. These delivery costs also reflect salary levels of psychologists within the Japanese healthcare system.

Trial challenges

In line with the experiences of researchers and clinicians worldwide, the COVID-19 pandemic impacted trial execution and contributed to protocol violations. National and regional lockdowns led to delays in implementation of the intervention overall, together with site-specific interruptions. This impacted data collection schedules at post-intervention and follow-up for both trial arms. It disrupted careful planning that would have ensured teacher reports from baseline to follow-up were provided within the same school year by the same teacher. However, even if we had allowed different teachers to provide pre- and post-intervention ratings, school closures and the resulting online education made it impossible for teachers to provide accurate reports of child behaviour leading to teacher data being dropped from the study. Pandemic-related anxiety influenced recruitment and engagement. Some mothers were reluctant to join in treatment offered within hospital-based settings, with COVID-19 anxiety cited as a reason for discontinuing the trial. For others, local regulations prevented parents crossing regional boundaries to access the intervention. The impact of these disruptions, and the pandemic itself, on intervention effects will be explored in future analyses/manuscripts.

Recruiting families to the trial was difficult beyond the problems posed by COVID-19. Stigma surrounding mental health remains high in Japan and Japanese culture does not promote talking about one's feelings and problems outside the family (Armstrong-Hough, 2018; Thompson et al., 2017). Specialist interventions for ADHD are not widely available in Japan and thus are less familiar to families. Getting time off work to attend WPJ groups was challenging at times, with mothers often taking annual leave to attend sessions. Within each site group, sessions were timed to be as inclusive as possible, including offering groups at weekends. Considering the COVID-19 and non-COVID-19-related difficulties faced by participating mothers, the study's high retention rates are encouraging and suggest participating mothers were satisfied with WPJ. However, we did not directly collect maternal satisfaction data or their use of the taught strategies in the current study.

The trial faced other methodological challenges beyond recruitment. Due to budgetary constraints, objective behavioural measures were not collected at follow-up. On reflection, this is unfortunate as positive intervention effects on family functioning continued to develop post-intervention. That said, we question the value of EE as a proxy measure for parent–child interaction quality (Daley et al., 2003, McCarty, Lau, Valeri, & Weisz, 2004) in this study. Within Japanese culture, individuals are taught to hold emotions inside and to avoid specific expressions, regardless of their valence, to maintain harmony (Leersnyder, Boiger & Mesquita, 2013). The low baseline levels of EE and absence of change across intervention arms may be measurement artefacts.

Health economics is still a new discipline in Japan, and it was challenging to be one of the first studies to implement cost-effectiveness assessments here. Substantial adjustments were required to the CSRI health economic interview to adapt it to Japan's complex healthcare point system (Chino, 2007; Sakai, 2008). While Japanese mothers were willing to answer questions about health-related expenses, there were extensive costs and payments for them to monitor. The strong association between maternal reports and hospital invoice data for ADHD-related costs is reassuring. We did not include a global quality of life measure as we were already measuring more specific elements of quality of life in both the mother and child, and the overall level of assessment was demanding. However, this does limit our ability to calculate quality of adjusted life years (QUALY's).

Conclusions

Well Parent Japan offers the first parenting programme specialised for ADHD in Japan. Developed through early co-production with consumers, Japanese parents and therapists. WPJ is well received and tolerated by participating mothers, evidenced by the high retention rates despite the COVID-19 pandemic. The programme is effective, leading to significant improvements in participants' well-being, parenting practices and family coping. The significant differences between WPJ and TAU were driven exclusively by improvements in the WPJ arm. These improvements were achieved during a global pandemic with a child sample highly comorbid for autism, underlining the robustness of the programme's effects. While it was culturally appropriate to offer support for maternal well-being prior to asking mothers to be the agent of change for their child, the current design did not empirically test the extent to which targeting maternal well-being helped mothers to help their child. These issues could be subsequently explored through moderator analysis, but ultimately a dismantling design would be the only comprehensive way to explore this issue.

The cost-effectiveness analyses showed intervention costs to be modest and the programme cost-effective. While the relatively low cost of WPJ may be affordable for many Japanese families, it will be important to ensure future insurance coverage for behavioural parenting interventions to incentivise hospitals to invest in training and WPJ provision.

Considering the continuing stigma associated with seeking support for mental health difficulties in Japan, delivery of WPJ in community settings should be considered.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Table S1. Clinic records of child/family mental health service utilisation in the three months prior to and following WPJ across the three intervention sites: observed data.

Table S2. Medication status and medication changes for children from baseline to follow-up: ADHD medications only.

Table S3. Modelled change scores from baseline to follow-up for WPJ versus TAU using robust SE and per-protocol analyses.

Table S4. Cohen's *d* for WPJ versus TAU at week 14 and week 26 using the ITT imputed data.

Table S5. Modelled changes scores from baseline to follow-up for WPJ versus TAU using *observed* data.

Table S6. Summary statistics for outcome variables at baseline, week 14 and week 26 for WPJ versus TAU using available data.

Table S7. Non-recurrent costs of implementing WPJ.

Appendix S1. Supplemental methods.

Figure S1. Consort checklist.

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Data availability

An anonymised copy of the trial paper observed data will be archived with the Okinawa Institute of Science and Technology Graduate University data repository. Requests for access to the data will be considered on a case-by-case basis, subject to Japanese law.

Trial registration

The study was retrospectively registered with ISRCTN after the first of three waves of participant recruitment. Trial registration number: ISRCTN66978270 (https://www.isrctn.com/ISRCTN66978270).

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Key points

- Behavioural parent training is recommended in the management of ADHD.
- WPJ offers the first parenting programme specialised for ADHD in Japan.
- WPJ targets parent well-being together with parenting behaviours.
- WPJ is superior to TAU leading to significant improvements in parent well-being, parenting practices and family strain.
- WPJ is relatively inexpensive to deliver and cost-effective.

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