NEW RESEARCH

Effect of Parent Training on Health-Related Quality of Life in Preschool Children With Attention-Deficit/Hyperactivity Disorder: A Secondary Analysis of Data From a Randomized Controlled Trial

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Objective: School-age children with attention-deficit/hyperactivity disorder (ADHD) have reduced health-related quality of life (HRQoL), but it is unclear whether this is also true for preschool children. It is unknown whether parent training (PT) improves HRQoL. This study compared HRQoL in preschool children with ADHD with age-matched children from the general population; examined whether PT improves HRQoL; and tested if treatment-related changes in HRQoL were mediated by improvements in ADHD, parent efficacy, and family stress.

Method: Parents of 164 children age 3–7 years with an ADHD diagnosis participated in a randomized controlled trial comparing the New Forest Parenting Programme and treatment as usual. Measures of HRQoL, ADHD, parent efficacy, and family stress were completed at baseline, post-treatment, and 36-week follow-up. Child baseline HRQoL was compared with two general population-based reference groups. PT effects were analyzed using linear models and mediation analyses.

Results: Preschoolers with ADHD had lower HRQoL than the reference groups. The New Forest Parenting Programme, but not treatment as usual, was associated with improvement in psychosocial HRQoL at posttreatment (change 2.28, 95% CI [0.78, 3.77]) and at 36-week follow-up (change 2.05, 95% CI [0.56, 3.54]). This difference between treatment arms was not statistically significant. Parent efficacy and family stress scores at posttreatment significantly mediated improvements in HRQoL at 36-week follow-up; ADHD scores at posttreatment did not.

Conclusion: ADHD negatively impacts HRQoL in early childhood. PT for ADHD has the potential to improve HRQoL independently of its effects on ADHD symptoms.

Clinical trial registration information: A Controlled Study of Parent Training in the Treatment of ADHD in Young Children (D'SNAPP); http://clinicaltrial.gov/; NCT01684644.

Key words: attention-deficit/hyperactivity disorder, health-related quality of life, parent training, preschool children

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Attention-deficit/hyperactivity disorder (ADHD) is a common childhood neurodevelopmental disorder. Onset is usually in early childhood, and the disorder often persists into adolescence and adulthood.[1] ADHD impairs many aspects of the child's life emotionally, socially, and academically.[2] ADHD in preschool children is more likely to manifest as hyperactivity/impulsivity,[3,4] and if symptoms persist over time into school,[5] this can lead to academic underachievement; low self-esteem; and poor relationships with peers, teachers, and parents.[3,6,7] In the long-term, preschool ADHD can increase the risk of criminality[8,9] and the development of comorbidities such as anxiety or depression.[7,10,11] Moreover, it was recently estimated that elevated symptoms of hyperactivity in preschool children is associated with a 17-fold increase in social, educational, clinical, and family-borne costs in adolescence/early adulthood.[12]

Lower levels of parent-reported and child self-reported health-related quality of life (HRQoL) are well documented in school-age children with ADHD compared with children without the disorder[13,14]; however, the literature on preschool ADHD is minimal.[15] HRQoL is a multidimensional concept representing an "individual's subjective perception of the impact of his/her health status of disease and treatment, on physical, psychological and social function."[16] It is not known if the link between ADHD and low

HRQoL is already present in preschool, but it is possible that this is not the case because of developmental differences between preschool and school-age children.[17,18] Furthermore, school entry might impact HRQoL in children with ADHD secondary to new relationships and demands.

The focus of ADHD treatment trials has increasingly been on everyday functional outcomes in addition to ADHD symptom reduction.[13,15] HRQoL indexes clinical improvements by providing a global evaluation of the impact treatment has on several domains, such as everyday functioning, relationships with peers, and overall well-being.[19] Pharmacological treatments for ADHD, such as atomoxetine and methylphenidate, have been shown to improve HRQoL in school-age children with ADHD.[20–23] International clinical guidelines recommend nonpharmacological interventions, including parent training (PT), as first-line treatment for preschool ADHD, and to the best of our knowledge, no studies have examined whether nonpharmacological treatments, including PT, improve HRQoL.

We recently reported the initial results from a large multicenter randomized controlled trial[24,25] comparing a specialist PT program for preschool ADHD, the New Forest Parenting Programme (NFPP),[26] and nonpharmacological treatment as usual (TAU) in the treatment of preschool children with ADHD referred to specialist ADHD hospital-based services in Denmark (D'SNAPP study).[25] The NFPP was shown to be superior not only to TAU with regard to the primary outcome, ie, ADHD-symptoms[25] (effect size $d = 0.30$, 95% CI [−0.54, −0.08]), but also to increased levels of parenting efficacy (Parenting Sense of Competence efficacy subscore [PSOC-efficacy] effect size $d = 0.32$, 95% CI [0.10, 0.53]) and family strain (Family Strain Index [FSI] effect size $d = -0.29$, 95% CI [−0.53, −0.05]).

In this article, we report a secondary reanalysis of the D'SNAPP data.[25] Our aims were to compare the children's baseline HRQoL with HRQoL in children from two different age-matched general population reference groups; examine whether receiving PT is associated with improvement of the child's HRQoL and if there is a difference between PT and TAU in this regard; and test if potential HRQoL improvements are mediated by improvements in ADHD, parent efficacy, and family stress. Based on the existing literature and the fact that both the NFPP and TAU in the current study had significant active treatment components, we predicted that preschool children with ADHD would have significantly reduced HRQoL compared with normal populations; nonpharmacological treatment in general would show positive effects on HRQoL, ie, both the NFPP and TAU, but that this effect would be stronger in the NFPP; and reductions in ADHD symptom scores and family stress and improvements in parent efficacy would statistically mediate treatment-related improvements in HRQoL.

METHOD

Study Sample

The current study included children from the D'SNAPP study.[25] The study design has been described in detail elsewhere.[24,25] The D'NSAPP study was approved by the ethics committee for the Central Denmark Region (No. 1-10-72-140-12) and by the Danish Data Protection Agency (No. 1-16-02-611-15). Written informed consent was obtained from parents of all participating children.[25]

In brief, children were recruited from three different ADHD preschool clinics (3–7 years old) in the Danish Child and Adolescent Mental Health Services. Exclusion criteria were intellectual disabilities (IQ < 70), autism spectrum disorder diagnosis, already receiving pharmacological and/or psychological treatment for ADHD, severe parental psychiatric disorder (ie, untreated psychosis, bipolar or severe depressive disorder), and severe social adversity in the home (ie, active child protection involvement). In the D'SNAPP study, 164 children and their parents were randomly assigned to either NFPP (n = 88) or TAU (n = 76). Parents completed measures of child ADHD symptoms, parent efficacy, family stress, and HRQoL at baseline (T1, week 0), posttreatment (T2, week 12), and 36-week follow-up (T3, week 48). The study sample was representative of Danish children of the same age who received an ADHD diagnosis during the same period as the recruitment period with regard to relevant sociodemographic characteristics, such as parents' age, educational level, and employment status.[25] Only children whose parents filled out the HRQoL questionnaire at baseline were included in the current study.

Measures

HRQoL. Parents completed the Child Health Questionnaire–Parent Form 28 (CHQ-PF28), a generic parent-reported HRQoL measure for children and adolescents.[27] It is validated for children age 5–18 years and consists of 13 unique physical and psychosocial domains (see Table S1, available online, for different domains) based on 28 Likert-type scale items (eg, "very often" to "never").[27] These domains measure different aspects of the child's functioning, well-being, and social relationships. According to the CHQ user manual,[27] each domain is standardized on a 0–100 continuum, where a higher score corresponds to better quality of life. Scores can further be calculated to form two summary scales, Psychosocial Summary Scale

(PsS) and Physical Summary Scale (PhS), using means and standard deviations from the combined general U.S. population available in the instructions manual. To simplify scoring, PsS and PhS scores are standardized using a linear T score transformation (mean [SD] = 50 [10]). We calculated z-scores for PsS and PhS to compare with scores in the reference group. Internal consistency of the scales in the current study was adequate, ie, at baseline, Cronbach α was 0.83 for PsS and 0.77 for PhS.

Child ADHD Symptoms. Parents completed the ADHD Rating Scale (ADHD-RS) IV–Preschool Version.[28,29] This scale includes 18 items, each rated by one of the parents on a 4-point Likert-type scale from 0 ("not at all") to 3 ("very often"). The scale generates a total score (0–54 points), and a higher score corresponds to more frequent and severe ADHD symptoms.[29,30] In earlier studies, internal consistency has been estimated to be adequate, and the test-retest reliability has been estimated to be high.[28]

Parent Efficacy. The PSOC[31] was used to measure parental self-efficacy. The scale includes 17 items, each rated on a 6-point Likert-type scale from 1 ("strongly disagree") to 6 ("strongly agree"). The scale generates two dimensions, satisfaction and efficacy; only the efficacy dimension was used in the current study. A higher score reflects a stronger feeling of competence, problem-solving ability, and parenting capability.

Family Stress. The FSI[32] was used to assess levels of family stress in the context of living with a child with ADHD. The scale is a 6-item parent-report questionnaire with a higher score indicating greater impairment in family functioning.

Treatment Conditions

The NFPP is an individually delivered program specifically developed for parents of preschool children with ADHD.[33] It includes five core elements: psychoeducation about ADHD in preschool children to improve parents' understanding of their child's behavior; scaffolding to help parents work from their child's level of development; promoting proactive parent–child interaction to support child development and reduce parent stress; play-based strategies to improve the child's attention, impulsivity, and self-regulation; and guidance in the use of specific behavioral strategies to improve behavior and ADHD symptoms.[25,33] Parents received eight sessions over 12 weeks delivered individually by a trained NFPP therapist (psychologists [n = 2], nurse specialist [n = 1], or preschool teacher [n = 1]).

TAU consisted of a standard package of psychoeducation by specialized staff (psychologists [n = 3] and nurse specialists [n = 3]) delivered in a group format. Parents were offered three to four group sessions of 2 to 3 hours over a 12-week period. Some parents were offered individual sessions in addition to or instead of group intervention.[25] The sessions included education about ADHD in preschool children, including how ADHD impacts play and development and interrupts daily routines. Parents were also offered practical advice on how to support their child.

Reference Groups

Data on HRQoL from two different general population reference groups were used for comparison. Reference group 1 consisted of 10,651 children age 4–11 years participating in a 2015 Dutch general population study by Houben-van Herten *et al.*[34] Permission to use the data was granted from the first author (mail correspondence with Houben-van Herten). The data were categorized according to gender and age, and only data on the subgroups of children age 4–5 years (n = 2,584) and 6–7 years (n = 2,608) were used for comparison with our clinical sample.[34] From this point on, these subgroups will be referred to as subgroup I (girls 4–5 years of age, n = 1,249), subgroup II (boys 4–5 years of age, n = 1,355), subgroup III (girls 6–7 years of age, n = 1,295), and subgroup IV (boys 6–7 years of age, n = 1,313). Reference group 2 consisted of American children age 5–18 years drawn from the general population to obtain normative data. The data were available for comparison in the CHQ manual.[27] To achieve the most relevant comparison, we used only data on children age 5–7 years (n = 73) from the American reference group.

Statistical Analysis

All children with CHQ-PF28 data at T1 constituted the final study sample and were included in the analyses. For our first aim in this study, we compared HRQoL (ie, the CHQ-PF28 data) assessed at T1 in the study sample with HRQoL in the two reference groups, using observed descriptive data on all subdomains. The mean score for the two CHQ-PF28 summary scales, PsS and PhS, in the study sample was compared with the mean scores from the reference groups, using z-scores to perform a two-sample t test. Because none of the reference groups included data for 3-year-old children, a sensitivity analysis was performed excluding data on the 3-year-olds in our sample.

For our second aim, to examine whether receiving PT is associated with improvement of the child's HRQoL, we used a mixed model with a random intercept for each child. First, we examined the overall change in CHQ-PF28 summary scores from T1 to T2 and T1 to T3 with time, gender, and age as covariates. This was to study whether

nonpharmacological treatment in general improved the HRQoL of the children. Second, to compare the individual change in the two treatment arms and the difference between these changes, we fitted a model with time, gender, age, treatment group, and their interaction as the independent variables. A mixed model implicitly assumes that data are missing at random and uses all available observations and accounts for correlation within persons. The assumptions underlying the mixed models were checked by graphical inspection of the distribution of the random intercepts and the residuals. Furthermore, we calculated the effect size using standardized measure for Cohen's *d* for changes in summary scores over time in each treatment group.

Finally, for our third aim, to test if potential HRQoL improvements are mediated by improvements in ADHD, parent efficacy, and family stress, following the method proposed by Preacher and Hayes,[35] we used the Stata command -sureg- to explore if the effect of treatment on HRQoL measured at T3 was mediated by ADHD-RS, PSOC-efficacy, and FSI scores at T2. To perform the analysis, we conducted the following steps: First, the proposed intervening variable was regressed on treatment assignment. Second, the outcome, HRQoL (we examined only PsS) measured at T3 was regressed on treatment assignment and on the proposed intervening variable. To make a causal interpretation more plausible, we adjusted for baseline values of the mediator being examined (ie, ADHD-RS, PSOC-efficacy, or FSI) and the dependent variable HRQoL in both regressions. A nonparametric bootstrap analysis, using 5,000 replications, was used to generate bias-corrected (BC) 95% CI. The indirect effect of group assignment on PsS at T3 can be interpreted as the increase we would expect to see in PsS at T3 while holding X constant and increasing the mediator (ADHD-RS, PSOC-efficacy, or FSI) at T2 to whatever value it would attain under a unit increase of X. If zero is not contained in the BC 95% CI for the indirect effect, a statistically significant indirect effect is judged to be present. All analyses were performed in STATA 15.1 (Stata Statistical Software: Release 15; StataCorp LLC, College Station, Texas).

RESULTS

Attrition

CHQ-PF28 was available for 160 of 164 children at T1. Of these, 85 were randomly assigned to NFPP and 75 to TAU. At T2, parents of 143 children (89% of 160 children) completed the questionnaire, and at T3, parents of 144 children (90%) completed the questionnaire (Figure 1).

Baseline Characteristics

Baseline characteristics of the 160 children included in the current study sample are shown in Table 1. The mean (SD) child age was 5.80 (1.04) years, and the majority were boys (72.50%). The mean (SD) ADHD-RS score was 34.42 (9.49). More than half of the children lived with both of their parents (66%), and most of the parents had a high school education or higher (79% of mothers, 69% of fathers) and were employed (74% of mothers, 65% of fathers).

HRQoL of Preschool Children With ADHD

Mean CHQ-PF28 scores for preschool children with ADHD and the subgroups from reference group 1 (the Dutch population study) are displayed in Figure 2, divided in four groups based on age and gender according to reference group 1. In general, children with ADHD scored lower than children from the reference subgroups in all domains. The differences were most pronounced with regard to the psychosocial subdomains, whereas there was less difference in the physical subdomains. This overall pattern was reflected in the summary scores where the mean PsS was significantly lower for the children with ADHD compared with the reference subgroups (all $p < .01$). The corresponding analyses on the mean PhS did not show any statistically significant differences between the study sample subgroups and the reference subgroups (all $p > .05$).

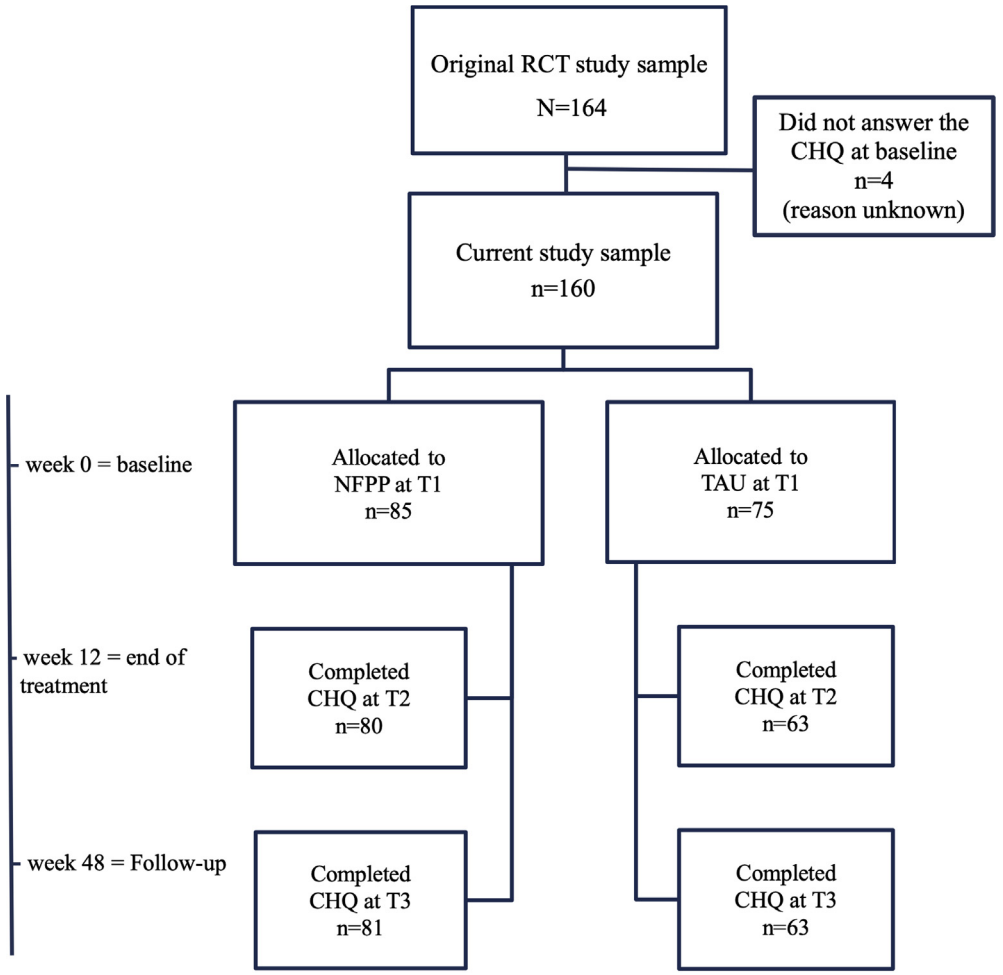
Sensitivity analyses excluding the 3-year-olds (the age that was not represented in the reference group) did not change the results. The comparison with reference group 2 had the same outcomes, ie, children with ADHD scored significantly lower on the psychosocial domains (mean [SD] PsS for the study sample children age 5–7 years versus reference group 2: 38.07 [10.72] versus 52.10 [7.90], $p < .001$) (see Table S2, available online), but not in the physical domains.

HRQoL After Treatment

Table 2 shows adjusted mean changes from T1 to T2 and T1 to T3 for the ADHD-RS, PSOC-efficacy, FSI, and CHQ summary scales. For the whole study sample, a statistically significant improvement was observed in PsS at T2 and at T3, but the same improvement was not observed for PhS (Table 2). As in the primary analysis in the D'SNAPP study, a significant decrease was observed for the ADHD-RS and FSI and an increase was observed for PSOC-efficacy from T1 to T2 and from T1 to T3 (Table 2).

Divided into treatment arms, a significant improvement was observed in PsS for the NFPP group, but not for the group that received TAU (Table 2). For the PhS,

FIGURE 1 Flowchart of Study Sample



Note: *Reason for dropouts between T1 and T2 and T2 and T3 is unknown. CHQ = Child Health Questionnaire; NFPP = New Forest Parenting Programme; RCT = randomized controlled trial; TAU = treatment as usual; T1 = baseline; T2 = posttreatment; T3 = 36-week follow-up.*

there were no significant changes for either of the treatment arms from T1 to T2 or from T1 to T3. The adjusted change in PsS score over time for the two treatment arms is illustrated in Figure S1 (available online). There was no statistically significant difference between the change in PsS from T1 to T2 for the two treatment arms, NFPP versus TAU (2.57, 95% CI [−5.56, 0.42], $p = .09$), or from T1 to T3 (2.64 [−5.62, 0.35], $p = .08$).

The mean observed summary scores with 95% CI for ADHD-RS, PSOC-efficacy, FSI, PsS, and PhS for both treatment arms at T1, T2, and T3 are provided in Table S3 (available online). In addition, the observed mean scores for each CHQ subdomain at all time points are presented in Table S4 (available online).

Mediators of Treatment-Related Improvements in HRQoL

The mediation analyses are illustrated in Figure 3A–C. The ADHD-RS score at T2 (Figure 3A) did not have a statistically significantly indirect effect (IE) on the increase in PsS at T3 (IE = 1.00, BC 95% CI [−0.08, 2.55]). However, there was a statistically significant IE of both PSOC-efficacy (IE = 0.94, BC 95% CI [0.17, 2.22]) and FSI (IE = 1.17, BC 95% CI [0.26, 2.52]) on the increase in PsS at T3 (Figure 3B, C). This means that a higher score at T2 on the PSOC-efficacy measure mediated a higher PsS score at T3, whereas a lower score on the FSI measure at T2 mediated a higher PsS score at T3. We adjusted for baseline scores of the mediator being interpreted, meaning that the posttreatment values of X at T2 was the difference in score between two children, one

TABLE 1 Baseline Characteristics of Children in the Study Sample and Their Parents

Characteristics	Study Sample (N = 160)
Child	
Age group	
3–5 years	91 (56.90%)
6–7 years	69 (43.10%)
Gender	
Girls	44 (27.50%)
Boys	116 (72.50%)
ADHD-RS, mean (SD)	34.42 (9.49)
Comorbid psychiatric diagnoses (*ICD-10*)	
Conduct disorder (F91.x; F92.x)	13 (8.10%)
Emotional disorder (F93)	7 (4.40%)
Disorder of social functioning (F94.x)	6 (3.80%)
Other behavioral and emotional disorder (F98.x)	6 (3.80%)
Borderline intellectual functioning (R41.83: IQ = 70–84)	11 (6.90%)
Tics disorder (F95)	4 (2.50%)
Specific developmental disorder (F80–F89 [excluding F84])	46 (28.80%)
Parents	
Mother's age, y, mean (SD)	35.20 (5.50)
Father's age, y, mean (SD)	37.40 (5.80)
Living arrangement	
Single parent	30%
Both parents	66%
Foster or unknown	4%
Mother's highest education level	
Elementary school	14%
High school level	47%
Bachelor's degree and above	32%
Father's highest education level	
Elementary school	10%
High school level	40%
Bachelor's degree and above	19%
Mother employed	74%
Father employed	65%
Mother ever received a psychiatric diagnosis	27%
Father ever received a psychiatric diagnosis	16%

Note: *ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale;* ICD-10 = International Classification of Diseases, Tenth Revision.

receiving TAU and one receiving NFPP, who had the same baseline measurement value of X at T1.

DISCUSSION

To the best of our knowledge, this is the first study to explore HRQoL in preschool children with ADHD using HRQoL as an outcome in a nonpharmacological treatment trial. Our results showed that children with ADHD in this age group had substantially lower parent-reported HRQoL compared with age-matched children from the general population before receiving treatment. This effect was seen most strongly in the psychosocial domains. When the NFPP and TAU were considered together, treatment was shown to significantly increase the children's psychosocial HRQoL post treatment (T2), an increase that was still present at the 36-week follow-up (T3). Specialized PT in the NFPP seemed to have a better outcome than TAU, but against our hypothesis we found no difference between the changes over time in the two treatment arms with the current sample size. Adjusting for baseline values of the mediator, both PSOC-efficacy and FSI had a statistically mediating effect on PsS at T3, while ADHD-RS at T2 did not.

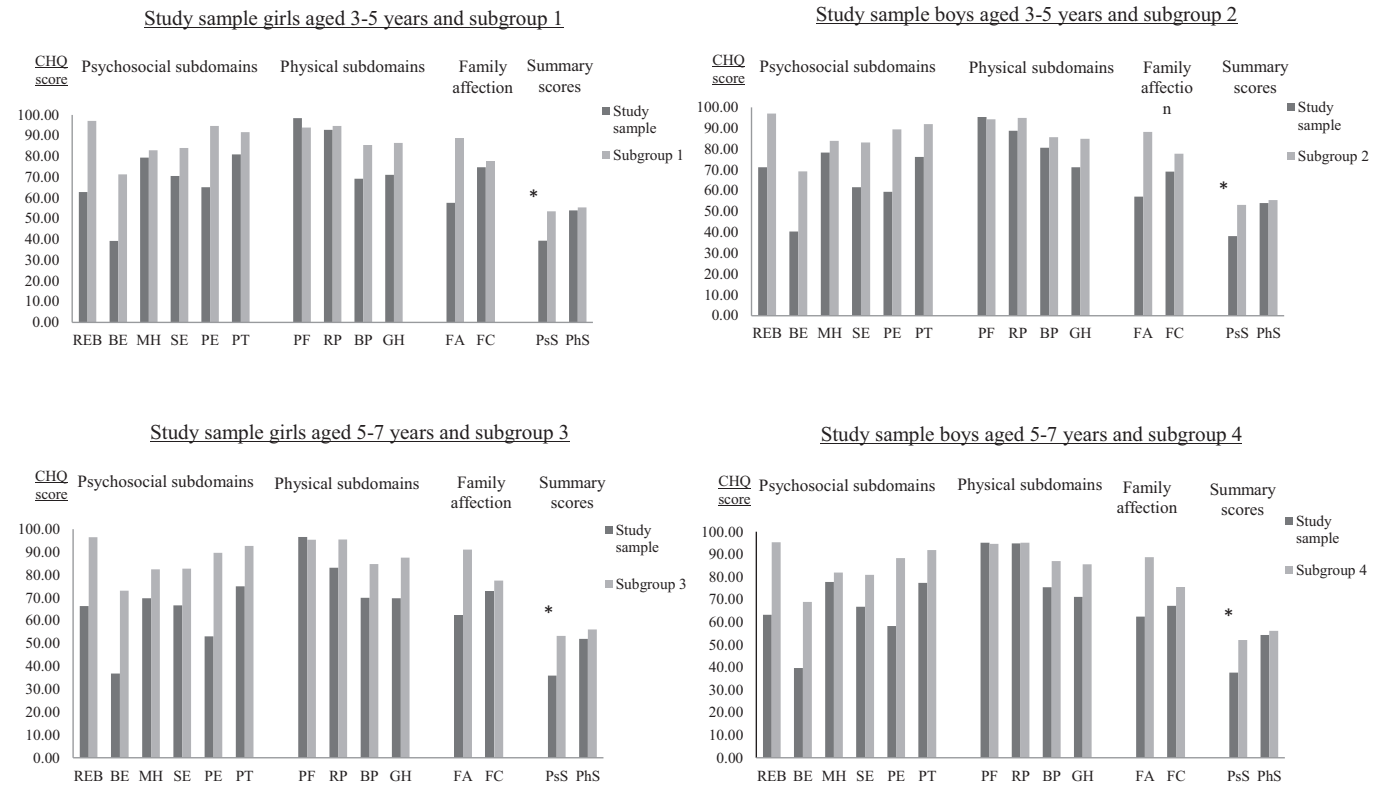
HRQoL in Preschool Children With ADHD

The children with ADHD had a lower score across almost all subdomains of the HRQoL measure, CHQ, compared with children in the reference groups drawn from general populations. This pattern was similar across age and gender and was comparable to prior studies using different HRQoL instruments in older children with ADHD.[14,20–22,36] A meta-analysis on HRQoL found a correlation between increasing age and reduced HRQoL in children and adolescents with ADHD.[14] However, compared with other studies examining HRQoL with the CHQ-PF28 in older children with ADHD,[7,27,37–39] our preschool sample seemed to score the same, or even a bit lower in some subdomains (eg, the behavioral subdomain). Further studies examining potential differences in subdomains as well as overall HRQoL between preschool and older children with ADHD are needed.

HRQoL After Treatment

Treatment was associated with HRQoL improvements for both treatment arms, although HRQoL levels were still lower (around 1 SD in the mean PsS score) compared with the two general population-based reference groups after treatment. This has also been seen in pharmacological treatment studies,[22] indicating that even with effective treatment ADHD remains impairing. Interestingly, even

FIGURE 2 Mean Subdomains Child Health Questionnaire Scores for Study Sample and Reference Group 1, Divided Into Subgroups



Note: *Subgroup 1 = girls age 4–5 years old (n = 1,249); subgroup 2 = boys age 4–5 years old (n = 1,355); subgroup 3 = girls age 6–7 years old (n = 1,295); subgroup 4 = boys age 6–7 years old (n = 1,313). BE = behavior; BP = bodily pain; CHQ = Child Health Questionnaire; FA = family activity; FC = family cohesion; GH = general health; MH = mental health; PE = parent impact: emotional; PF = physical function; PhS = Physical Summary Scale; PsS = Psychosocial Summary Scale; PT = parent impact: time; REB = role/social emotional behavior; RP = role/social: physical; SE = self-esteem.*

**Difference in score is significant calculated from z-score, p < .001.*

though there was no statistical significance between the treatment arms, the improvement in the PsS score was significant only in the NFPP group. This might be due to the way the two treatments are delivered and focused. Both treatments aim at giving the parents a better understanding of their child's disorder and how to manage the child's difficulties. However, an important difference may be that the NFPP adapts the treatment specifically for each child and family in individual sessions.[26] This might explain why the largest improvements for NFPP in the present study were observed in the subdomains relating to behavior, mental health, self-esteem, and family activities (see Table S4, available online). However, in both the NFPP and TAU, parents are asked to praise their child for positive behavior, which could help to improve the child's overall self-esteem and have a positive effect on the family's time together. For TAU, there were improvements in the same subdomains, but not to the same extent.

Mediators of Treatment-Related Improvements in HRQoL

We wanted to examine if improvements in HRQoL were due to the beneficial effects of treatment on ADHD and/or on parents' perception of themselves and their child. We found no evidence that increases in HRQoL were mediated by reduced ADHD symptoms. However, the BC 95% CI for the indirect effect of ADHD-RS at T2 (IE = 1.00, BC 95% CI [−0.08; 2.55]) had a lower boundary very close to zero, which indicates that low ADHD-RS at T2 most likely had a positive effect on HRQoL at T3. It has been shown that reductions in core ADHD symptoms are associated with improved social skills and a greater academic outcome,[2] which is likely to affect overall HRQoL positively. Earlier trials examining the effect of medication (atomoxetine and methylphenidate) have reported that a reduction in ADHD symptoms after end of treatment was associated with improved HRQoL.[20,21,36] However, HRQoL might not be as sensitive an outcome as ADHD

TABLE 2 Adjusted Mean Changes and Cohen's *d* Effect Sizes After Treatment and at Follow-up for the Whole Sample and Separately for the Treatment Arms: New Forest Parenting Programme and Treatment as Usual

	Change From T1 to T2						Change From T1 to T3					
	Whole Sample		NFPP		TAU		Whole Sample		NFPP		TAU	
ADHD-RS Change (95% CI)	−3.08	(−4.15, −2.01)	−4.32	(−5.72, −2.91)	−1.45	(−3.05, 0.13)	−3.55	(−4.62, −2.47)	−4.59	(−6.01, −3.16)	−2.23	(−3.81, −0.64)
PsS Change (95% CI)	2.28	(0.78, 3.77)	3.42	(1.42, 5.42)	0.86	(−1.37, 3.08)	2.05	(0.56, 3.54)	3.22	(1.22, 5.20)	0.60	(−1.62, 2.82)
PhS Change (95% CI)	−0.13	(−1.63, 1.38)	−1.01	(−3.03, 1.01)	0.94	(−1.30, 3.18)	−0.34	(−1.84, 1.17)	−1.09	(−3.11, 0.92)	0.55	(−1.68, 2.79)
Cohen's *d* for PsS (95% CI)	−0.18	(−0.41, 0.05)	−0.29	(−0.59, 0.02)	−0.04	(−0.37, 0.30)	−0.19	(−0.42, 0.03)	−0.31	(−0.61, 0.00)	−0.05	(−0.39, 0.28)
PSOC-efficacy Change (95% CI)	0.90	(0.28, 1.53)	1.76	(0.94, 2.57)	−0.15	(−1.09, 0.80)	1.45	(0.83, 2.08)	2.08	(1.27, 2.89)	0.67	(−0.28, 1.61)
FSI Change (95% CI)	−0.85	(−1.44, −0.25)	−1.52	(−2.31, −0.72)	−0.03	(−0.90, 0.85)	−0.69	(−1.29, −0.10)	−1.43	(−2.21, −0.64)	0.23	(−0.65, 1.10)

Note: Adjusted for gender and age using a mixed model with a random level for each child. ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale; FSI = Family Strain Index; NFPP = New Forest Parenting Programme; PhS = Physical Summary Scale; PSOC-efficacy = Parenting Sense of Competence efficacy subscore; PsS = Psychosocial Summary Scale; TAU = treatment as usual; T1 = baseline; T2 = posttreatment; T3 = 36-week follow-up.

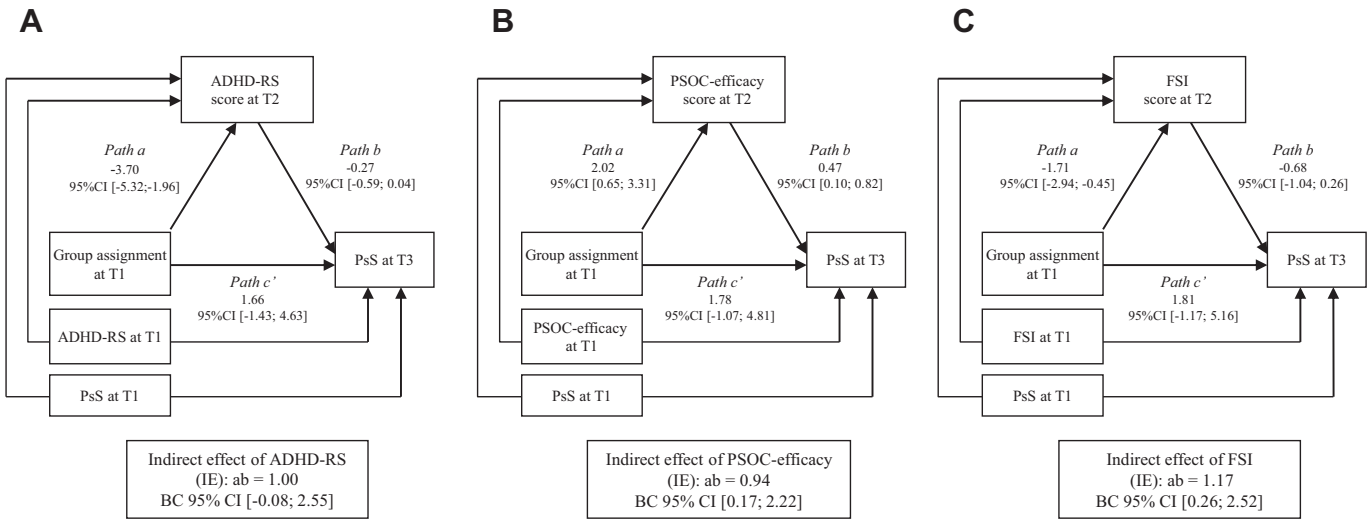
symptoms in the current trial with relatively short follow-up, and improvements in HRQoL may lag behind changes in ADHD. Medication trials in school-age children with ADHD report that improvements in ADHD symptoms and HRQoL are maintained up until 24 months after end of treatment.[20,40] In the current study, the positive outcome on HRQoL in the overall sample was also maintained at 36 weeks (ie, 9 months) of follow-up, which could indicate a lasting effect. Future studies with larger study populations and longer follow-up are needed to further explore whether a decrease in ADHD core symptoms mediates long-lasting improvements in HRQoL.

Better parental efficacy and lower overall stress and conflicts in the family appear to impact the child's HRQoL positively, as reflected in the statistically significant indirect effect of both an improved PSOC-efficacy score and a reduced FSI score at T2. This corroborates findings from a previous study showing that reduction of negative parenting behaviors by PT mediates a reduction in the child's oppositional behaviors.[41] As mentioned, the NFPP was more focused on the individual family than TAU, and the family receiving the NFPP intervention scored higher in the PSOC-efficacy after treatment (Table 2). This effect was also reflected in the mediation analysis in the direct effect of treatment assignment (Figure 3C, path a).

With the significant mediating effect of PSOC-efficacy and FSI and the nonsignificant mediating effect of ADHD-RS, it is difficult to say whether the improved HRQoL is caused by real changes in the child's HRQoL or the parents' perception of the child's HRQoL. PT may improve the HRQoL from the parents' point of view because it reduces stress and increases their sense of efficacy. It could also be that the intervention provides the parents with strategies to manage the child's behavior as well as advice and strategies on how to look after themselves. As HRQoL is a subjective measure, and the children in the current study were too young to rate HRQoL themselves, we were not able to explore whether the impact of the NFPP on HRQoL is a real effect or rather a change in the parents' appraisal of their situation.

This study has several strengths. It is the first study to examine HRQoL in a large sample of preschool children with ADHD and compare them with children from general populations. The children in the current study have previously been described to be representative of Danish children in the same age group diagnosed with ADHD,[25] and the results are therefore likely to be generalizable to other developed countries. To measure HRQoL, we used a widely used, validated questionnaire, making comparison of results with studies of school-age children with ADHD possible.[11,37] Also, our results were compared with two separate general population reference groups from two different countries. Furthermore, it

FIGURE 3 Mediation Model of the Attention-Deficit/Hyperactivity Disorder Rating Scale, Parenting Sense of Competence Scale, efficacy subscale, and Family Strain Index Scores at Posttreatment Effect on Psychosocial Summary Scale



Note: Path a is the effect of treatment assignment (New Forest Parenting Programme versus treatment as usual) on the specific variable, controlled for the baseline values of ADHD-RS (A), PSOC-efficacy (B) and FSI (C) score and PsS score (negative estimates correspond to reduced attention-deficit/hyperactivity disorder symptoms/FSI score, and positive estimates correspond to improved PSOC-efficacy score). Path b is the effect of a unit change in the intervening variable (ADHD-RS/PSOC-efficacy/FSI) on the outcome (PsS), controlled for treatment assignment and the baseline values of ADHD-RS/PSOC-efficacy/FSI score and PsS score (positive estimates correspond to an improvement). Path c' is the direct effect of treatment assignment on the outcome, controlled for the baseline values of ADHD-RS/PSOC-efficacy/FSI score and PsS score (positive estimates correspond to an improvement). ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale; BC = bias-corrected; FSI = Family Strain Index; IE = indirect effect; PSOC-efficacy = Parenting Sense of Competence efficacy subscore; PsS = Psychosocial Summary Scale; T1 = baseline; T2 = posttreatment; T3 = 36-week follow-up.

was the first study to examine HRQoL in a large rigorous randomized controlled trial of nonpharmacological treatment. We found there was an increase in PsS after end of treatment but not in PhS, which strengthens the internal validity. We examined both treatment-induced reductions in symptoms and changed parent efficacy and family stress as mediating factors to the improved HRQoL.

However, there were some limitations to be acknowledged. First, the absence of Danish norm data for the CHQ led to comparison with reference groups from other countries, ie, The Netherlands and the United States. However, it may be argued that especially The Netherlands is likely to be similar to Denmark with regard to most of these parameters.[42,43] Second, the CHQ was originally developed for children age 5–18 years, and our study sample included children as young as 3 years old. Nonetheless, one of our reference groups included 4-year-olds, and the questionnaire has previously been successfully applied by others for children as young as 4 years old.[34,44] Also, our sensitivity analysis excluding the 3-year-olds did not change the results. Third, in the current study with children as young as 3 years old, it was not possible to use self-report questionnaires. Some studies of older children with ADHD have shown that parents often rate their children as having a lower HRQoL than the children do themselves,[11] while other studies have found no discrepancy between child and parent ratings.[14] Fourth, comorbid physical conditions and other psychiatric conditions, such as anxiety and oppositional defiant disorder, could also have an effect on HRQoL, but we did not have the data to examine this. Fifth, as this study was a secondary analysis, the original study was not designed to ensure power to examine whether the NFPP was superior to TAU in increasing children's HRQoL.

In summary, the findings in the present study support the view that ADHD has a negative impact on preschool HRQoL especially within psychosocial domains. The impact on preschool children seems to be at least as serious as that observed in school-age children with ADHD. Overall, early intervention with nonpharmacological treatment seems to have the potential to improve not only the child's core symptoms of ADHD but also HRQoL. However, the effect was not significantly greater in the NFPP or TAU. The improvement in HRQoL did not seem to be driven by reductions in ADHD symptoms, while changes in parent efficacy and family stress had a positive effect. Future research could explore which treatment elements in PT programs might be most efficacious and compare the effect of nonpharmacological treatment with pharmacological treatment. Finally, long-term effects of improved HRQoL and how this may translate into daily functioning and social

educational outcome need to be studied in more detail for children diagnosed with ADHD at an early age.

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Writing — review and editing: Daley, Lange, Sonuga-Barke, Thomsen, Rask

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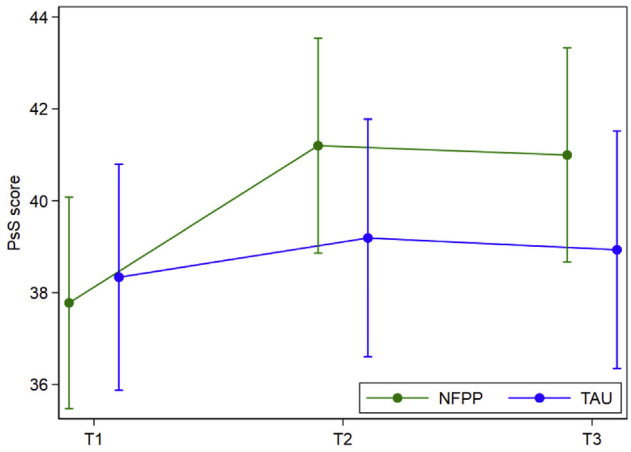
SUPPLEMENTAL MATERIALS

FIGURE S1 Adjusted Mean Psychosocial Summary Score According to the Two Treatment Arms



Note: Adjusted mean Psychosocial Summary Score for preschool children with attention-deficit/hyperactivity disorder who received the New Forest Parenting Programme and treatment as usual (TAU). NFPP = New Forest Parenting Programme; PsS = Psychosocial Summary Score; TAU = treatment as usual; T1 = baseline; T2 = posttreatment; T3 = 36-week follow-up.

TABLE S1 Subdomains in the Child Health Questionnaire

Scale Name	No. of Items	Questionnaire Section
Role/Social Emotional Behavior (REB)	1	Child's limitation due to emotional difficulties
Behavior (BE)	4	Child's behavior
Mental Health (MH)	3	Child's well-being
Self-Esteem (SE)	3	Child's self-esteem
Parent Impact: Emotional (PE)	3	Parent's emotional worry
Parent Impact: Time (PT)	2	Parent's limitation in their own time
Physical Function (PF)	3	Child's physical activities
Role/Social Physical (RP)	1	Child's limitation due to physical difficulties
Bodily Pain (BP)	1	Child's bodily pain and discomfort
General Health (GH)	4	Child's general health
Family Activity (FA)	2	Limitations in family activities
Family Cohesion (FC)	1	Family's ability to get along
Change in Health (CH)[a]	1	Child's health now compared with 1 year ago
Psychosocial Summary Scale (PsS)		Summary score for psychosocial items
Physical Summary Scale (PhS)		Summary score for physical items

Note: [a]This subdomain was not used in the current study.

TABLE S2 Mean Child Health Questionnaire Subdomain Scores for Children Age 5–7 Years in Study Sample and Two Reference Groups

	Study Sample (Age 5–7 Years), n = 125, Mean (SD) Score		Reference Group 1 (Age 6–7 Years), n = 1,117, Mean (SD) Score		Reference Group 2 (Age 6–7 Years), n = 1,117, Mean (SD) Score	
REB	65.36	(35.31)	95.68	(0.48)	94.50	(17.60)
BE	39.90	(17.06)	70.05	(1.78)	71.50	(14.90)
MH	76.93	(16.33)	82.10	(0.17)	80.30	(15.10)
SE	65.73	(22.26)	81.43	(0.74)	87.30	(13.70)
PE	59.20	(18.59)	88.71	(0.52)	81.20	(18.90)
PT	78.27	(17.35)	92.08	(0.31)	88.80	(20.20)
PF	95.56	(11.89)	94.85	(0.26)	96.70	(16.70)
RP	89.78	(24.86)	95.25	(0.09)	93.20	(22.20)
BP	73.44	(24.47)	86.41	(1.00)	84.40	(16.70)
GH	70.07	(24.16)	86.08	(0.83)	96.30	(21.40)
FA	60.20	(29.16)	89.63	(0.96)	89.20	(22.20)
FC	70.20	(25.15)	76.09	(0.83)	76.90	(21.40)
PsS	38.07	(10.72)	52.41*	(0.52)	52.10*	(7.90)
PhS	53.18	(8.79)	56.17	(0.04)	53.70	(10.90)

Note: Baseline mean Child Health Questionnaire scores (domain and summary scores with SD) for children age 5–7 years with attention-deficit/hyperactivity disorder and reference group 1, the Dutch general population sample (children age 6–7 years), and reference group 2, the American general population sample (children age 5–7 years). BE = Behavior; BP = Bodily Pain; FA = Family Activity; FC = Family Cohesion; GH = General Health; MH = Mental Health; PE = Parent Impact: Emotional; PF = Physical Function; PhS = Physical Summary Scale; PsS = Psychosocial Summary Scale; PT = Parent Impact: Time; REB = Role/Social Emotional Behavior; RP = Role/Social Physical; SE = Self-Esteem.
*$^{*}p < .001$.

TABLE S3 Observed Treatment Outcome of Parent-Reported Child Attention-Deficit/Hyperactivity Disorder Symptoms, Parental Sense of Competence, Family Strain Index, and Health-Related Quality of Life for the Whole Sample and Separately for the Treatment Arms: New Forest Parenting Programme and Treatment as Usual

	Whole Study Sample						NFPP						TAU					
	T1 (n = 160)		T2 (n = 143)		T3 (n = 144)		T1 (n = 85)		T2 (n = 80)		T3 (n = 81)		T1 (n = 75)		T2 (n = 63)		T3 (n = 63)	
ADHD-RS, Mean Score (95% CI)	34.42	(32.94, 35.90)	31.31	(29.78, 32.83)	30.58	(28.93, 32.22)	33.44	(36.28, 39.74)	29.18	(27.23, 31.13)	28.73	(26.52, 30.94)	35.37	(33.35, 37.39)	33.98	(31.82, 36.15)	32.91	(30.63, 35.18)
PsS, Mean Score (95% CI)	38.01	(36.27, 39.75)	39.96	(38.23, 41.68)	40.19	(38.31, 42.07)	37.69	(35.13, 40.25)	40.91	(38.62, 43.19)	41.1	(38.83, 43.55)	38.38	(36.07, 40.68)	38.75	(36.15, 41.35)	38.90	(35.90, 41.91)
PhS, Mean Score (95% CI)	53.93	(52.64, 55.22)	53.86	(52.42, 55.30)	53.57	(52.01, 55.13)	54.53	(52.68, 56.38)	53.32	(51.13, 55.51)	53.26	(51.29, 55.24)	53.25	(51.48, 55.01)	54.55	(52.88, 56.22)	53.96	(51.46, 56.47)
PSOC-efficacy, Mean Score (95% CI)	30.40	(29.50, 31.29)	31.03	(30.03, 32.02)	31.78	(30.90, 32.67)	30.58	(29.40, 31.77)	32.20	(30.95, 33.47)	32.54	(31.50, 33.58)	30.19	(28.80, 31.57)	29.54	(28.00, 31.07)	30.81	(29.30, 32.32)
FSI, Mean Score (95% CI)	10.39	(9.60, 11.17)	9.74	(8.91, 10.57)	9.60	(8.76, 10.43)	10.39	(9.23, 11.55)	9.16	(8.09, 10.24)	8.88	(7.83, 9.92)	10.39	(9.34, 11.49)	10.48	(9.17, 11.78)	10.52	(9.16, 11.84)

Note: Mean scores and 95% CI at T1, T2, and T3. ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale; FSI = Family Strain Index; NFPP= New Forest Parenting Programme; PhS = Physical Summary Scale; PsS = Psychosocial Summary Scale; PSOC-efficacy = Parenting Sense of Competence efficacy subscore; TAU = treatment as usual; T1 = baseline; T2= posttreatment; T3 = 36-week follow-up.

TABLE S4 Observed Mean Score for Child Health Questionnaire Subdomains After Treatment and at Follow-up for Whole Sample and for New Forest Parenting Programme and Treatment as Usual

	Whole Sample						NFPP						TAU					
	T1, Mean (95% CI)		T2, Mean (95% CI)		T3, Mean (95% CI)		T1, Mean (95% CI)		T2, Mean (95% CI)		T3, Mean (95% CI)		T1, Mean (95% CI)		T2, Mean (95% CI)		T3, Mean (95% CI)	
REB	66.65	(61.09, 72.21)	70.18	(64.54, 75.83)	67.13	(61.26, 73.00)	64.88	(56.96, 72.81)	68.91	(61.36, 76.47)	67.22	(59.66, 74.78)	68.65	(60.73, 76.58)	71.75	(63.17, 80.32)	67.53	(58.14, 76.93)
BE	39.62	(36.82, 42.41)	43.61	(40.75, 46.47)	45.89	(42.94, 48.83)	40.53	(36.82, 44.24)	47.45	(43.97, 50.94)	47.59	(43.72, 51.46)	38.58	(34.27, 42.89)	39.01	(34.42, 43.60)	43.61	(39.09, 48.14)
MH	77.50	(74.99, 80.01)	78.50	(75.89, 81.10)	78.36	(75.57, 81.14)	75.39	(71.69, 79.09)	79.01	(75.47, 82.56)	80.66	(77.16, 84.15)	79.89	(76.57, 83.21)	78.04	(74.16, 81.93	75.78	(71.27, 80.29)
SE	65.44	(61.93, 68.96)	70.98	(67.63, 74.33)	67.71	(63.98, 71.43)	65.10	(60.44, 69.76)	72.22	(67.71, 76.74)	69.96	(65.70, 74.22)	65.83	(60.39, 71.27)	69.71	(64.63, 74.78)	65.23	(58.69, 71.78)
PE	59.45	(56.49, 62.41)	63.02	(59.98, 66.07)	65.80	(62.42, 69.18)	62.06	(57.93, 66.19)	64.20	(60.06, 68.34)	65.43	(60.88, 69.98)	56.50	(52.26, 60.74)	61.90	(57.33, 66.48)	66.60	(61.44, 71.76)
PT	77.29	(74.50, 80.08)	74.24	(71.11, 77.37)	77.78	(74.40, 81.15)	77.45	(73.54, 81.36)	76.13	(71.85, 80.41)	78.19	(73.65, 82.73)	77.11	(73.04, 81.19)	72.22	(67.57, 76.87)	77.34	(72.24, 82.45)
PF	95.97	(94.17, 97.77)	95.14	(93.00, 97.28)	94.33	(91.83, 96.83)	96.86	(94.75, 98.97)	94.24	(90.94, 97.54)	95.20	(92.32, 98.08)	94.96	(91.92, 98.00)	96.30	(93.78, 98.81)	93.23	(88.82, 97.64)
RP	90.96	(87.36, 94.56)	94.85	(92.06, 97.65)	92.54	(89.59, 95.48)	91.69	(86.85, 96.54)	93.36	(88.91, 97.80)	93.32	(89.52, 97.12)	90.13	(84.65, 95.62)	96.78	(93.84, 99.72)	91.55	(86.81, 96.28)
BP	75.86	(72.20, 79.55)	75.69	(71.62, 79.77)	75.86	(71.92, 79.81)	76.94	(71.98, 81.90)	75.56	(70.71, 80.40)	73.83	(68.12, 79.54)	74.67	(69.09, 80.24)	75.87	(68.80, 82.95)	78.44	(73.07, 83.80)
GH	71.09	(67.42, 74.77)	72.14	(68.53, 75.76)	72.95	(68.87, 76.04)	70.78	(65.39, 76.17)	73.54	(68.44, 78.64)	72.22	(67.16, 77.29)	71.44	(66.39, 76.50)	70.37	(65.21, 75.54)	72.75	(67.61, 77.89)
FA	59.53	(54.99, 64.07)	65.03	(60.49, 69.58)	63.54	(59.16, 67.92)	60.88	(54.67, 67.09)	67.44	(61.60, 73.28)	65.43	(60.11, 70.75)	58.00	(51.22, 64.78)	62.30	(55.07, 69.53)	60.94	(53.61, 68.27)
FC	69.91	(66.05, 73.76)	68.88	(64.51, 73.25)	70.21	(66.09, 74.33)	70.47	(65.12, 75.82)	73.70	(68.21, 79.20)	72.96	(67.60, 78.33)	69.27	(63.58, 74.95)	63.17	(56.25, 70.10)	66.95	(60.57, 73.34)

Note: *BE = Behavior; BP = Bodily Pain; FA = Family Activity; FC = Family Cohesion; GH = General Health; MH = Mental Health; NFPP = New Forest Parenting Programme; PE = Parent Impact: Emotional; PF = Physical Function; PhS = Physical Summary Scale; PsS = Psychosocial Summary Scale; PT = Parent Impact: Time; REB = Role/Social Emotional Behavior; RP = Role/Social Physical; SE = Self-Esteem; TAU = treatment as usual; T1 = baseline; T2 = posttreatment; T3 = 36-week follow-up.*