Title: 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

Running title: Quality of life in preschool children with ADHD

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**Abstract**

**Objective**: School-aged children with attention-deficit/hyperactivity disorder (ADHD) have reduced health-related quality of life (HRQoL) but it is unclear whether this also applies to 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 are mediated by improvements in ADHD, parent efficacy (PE) and family stress (FS).

**Method:** Parents of 164 children, aged 3-7 years diagnosed with ADHD, participated in a randomized controlled trial, comparing the New Forest Parenting Programme (NFPP) and Treatment As Usual (TAU). Measures of HRQoL, ADHD, PE and FS were completed at baseline (T1), post treatment (T2) and 36 weeks follow-up (T3). 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. NFPP, but not TAU, was associated with improvement in the psychosocial HRQoL at T2 (2.28, 95% CI [0.78; 3.77]) and at T3 (2.05, 95% CI [0.56; 3.54). This difference between treatment arms was not statistically significant. PE and FS scores at T2 significantly mediated improvements in HRQoL at T3. ADHD scores at T2 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.

**Keywords: attention-deficit/hyperactivity disorder, health-related quality of life, preschool children, parent training.**

**Lay Summary**

We examined health related quality of life (HRQoL), parents feeling of efficacy (PE) and family stress (FS) in preschool children with ADHD from a large randomized controlled treatment study. Compared with two reference groups the children with ADHD had a lower HRQoL. Mediated by improvements in PE and FS, the HRQoL improved significantly after specialized treatment.

**Facebook:**

With data from the big randomized controlled DSNAPP trial this study found that preschool children with ADHD have lower health related quality of life (HRQoL) compared to their peers. Specialized parent training with the New Forest Parenting programme have proved to significantly improve the parent's sense of efficacy and lower the family stress. These improvements have a positive effect on the child's HRQoL and mediate an improvement in the child's HRQoL.

**Twitter:**

Study @JAACAP finds preschool children with ADHD to have lower health related quality of life (HRQoL) compared to their peers. Parent training significantly improves parent sense of efficacy and lower the family stress, which mediates an improvement in the child's HRQoL. #ADHD

## Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a common childhood neurodevelopmental disorder. Onset usually occurs in early childhood and often persists into adolescence[1] 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 present 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 comorbidity 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) is well documented in school-aged children with ADHD compared to children without the disorder [13,14] whereas the literature on preschool ADHD is minimal[18]. HRQoL is a multidimensional concept representing an *"individual's subjective perception of the impact of his/hers health status of disease and treatment, on physical, psychological and social function"* [15]. 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-aged children [16,17]. Furthermore, school entry might also impact HRQoL in children with ADHD due to new relations and demands.

The focus of ADHD treatment trials has increasingly been on everyday functional outcomes in addition to ADHD symptom reduction [13,18]. HRQoL indexes clinical improvements by providing a global evaluation of the impact treatment has on several domains such as every day functioning,

relations with peers, and overall well-being [19]. Pharmacological treatments for ADHD such as atomoxetine and methylphenidate have been shown to improve HRQoL in school-aged children with ADHD [20-23]. International clinical guidelines recommend non-pharmacological interventions, including parent training (PT), as first line treatment for preschool ADHD, and to the best of our knowledge, no studies have examined whether non-pharmacological treatments, including PT, improves HRQoL.

We recently reported the initial results from a large multicenter randomized controlled trial (RCT) [24,25] comparing a specialist PT program for preschool ADHD, the New Forest Parenting Programme (NFPP) [26] and non-pharmacological Treatment As Usual (TAU) in the treatment of preschool children with ADHD referred to specialist ADHD hospital-based services in Denmark (The D'SNAPP study) [25]. NFPP was shown to be superior to TAU with regard to the primary outcome, i.e. ADHD-symptoms [25] (effect size d=0.30, 95% confidence interval (CI) [-0.54; -0.08]) but also to increased levels of parenting efficacy (Parenting Sense of Competence Scale – Efficacy (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 paper we report a secondary re-analysis of the D'SNAPP data [25]. Our aims were to (i) compare the children's baseline HRQoL with HRQoL in children from two different age-matched general population reference groups; (ii) 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; (iii) test if potential HRQoL improvements are mediated by improvements in ADHD, parent efficacy and family stress, respectively. Based on the existing literature and the fact that both NFPP and TAU in the current study had significant active treatment components, we predicted that (i) preschool children with ADHD would have significantly reduced HRQoL compared to normal

populations, (ii) non-pharmacological treatment in general would show positive effects on HRQoL, i.e. both NFPP and TAU, but that this effect would be stronger in NFPP, and (iii) 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]. In brief, children were recruited from three different ADHD preschool clinics (3-7 years old) in the Danish Child and Adolescent Mental Health Services (CAMHS). Exclusion criteria were intellectual disabilities (IQ < 70), autism spectrum disorder diagnosis, already receiving pharmacological and/or psychological treatment for ADHD, severe parental psychiatric disorder (i.e., untreated psychosis, bipolar or severe depressive disorder), and severe social adversity in the home (i.e., active child protection involvement). In the D'SNAPP study a total of 164 children and their parents were randomized 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), post treatment (T2, week 12,) and at 36 weeks 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* [27] (CHQ-PF28) – a generic parent-reported HRQoL measure for children and adolescents. It is validated for children

aged 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 scales items (for example "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, PsS (Psychosocial summary Scale) and PhS (Physical summary Scale), using means and standard deviations from the combined general U.S. population available in the instructions manual. To simplify scoring, the PsS and PhS scores are standardized using a linear T-score transformation (mean of 50 and a standard deviation (SD) of 10). We calculated z-scores for the PsS and PhS to compare with scores in the reference group.
Internal consistency of the scales in the current study was adequate, i.e. at baseline Cronbachs alpha for the two summary scales was 0.83 for PsS and 0.77 for PhS, respectively.

**Child ADHD symptoms:** Parents completed the *ADHD Rating Scale (ADHD-RS)-IV preschool version* [28, 29]. The scale includes 18 items, each rated by one of the parents on a 4-point Likert-type scale varying 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 high [28].

**Parent efficacy:** The Parenting Sense of Competence Scale (PSOC) [31] was used to measure parental self-efficacy. The scale includes 17 items, each rated on a 6-point Likert scale from 1 ("Strongly Disagree") to 6 ("Strongly Agree"). The scale generates two dimensions, 'satisfaction' and 'efficacy', where 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 Family Strain Index (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**

*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; 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 nursery 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 3-4 group sessions of 2-3 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, how ADHD impacts play, 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 one consisted of 10,651 children aged 4-11 years participating in a Dutch general population study by Houben-van Herten et al from 2015 [34]. Permission to use the data was granted

from the first author (mail correspondence with Houben-van Herten). These data were categorized according to gender and age where only data on the subgroups of children aged 4-5 years (n=2584) and 6-7 years (n=2608), respectively, 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, n=1249), subgroup II (boys 4-5 years, n=1355), subgroup III (girls 6-7 years, n=1295) and subgroup IV (boys 6-7 years, n=1313).

Reference group two consisted of American children aged 5-18 years, drawn from the general population, in order to obtain normative data. The data were available for comparison in the Child Health Questionnaire manual [27]. To achieve the most relevant comparison, we only used data on children aged 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 aim (i) we compared HRQoL (i.e. 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. Since 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 aim (ii) 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 non-pharmacological treatment in general improved the children's HRQoL. 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 aim (iii) following the method proposed in Preacher and Hayes, 2004 [35], we used Stata's -sureg- command to explore if the effect of treatment on HRQoL, measured at T3, was mediated by ADHD-RS, the PSOC-efficacy and FSI scores, respectively, at T2. To perform the analysis we conducted the following steps: First, the proposed intervening variable was regressed on treatment assignment (path a). Second, the outcome, HRQoL (we only examined PsS) measured at T3 was regressed on treatment assignment (path c') and on the proposed intervening variable (path b, See Figure 3). To make a causal interpretation more plausible, we adjusted for baseline values of the mediator being examined (i.e. ADHD-RS, PSOC-efficacy or FSI) and the dependent variable HRQoL in both regressions. A non-parametric bootstrap analysis, using 5000 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.

## Results

### Attrition

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

### Baseline characteristics

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

### HRQoL of preschool children with ADHD

Mean CHQ-PF28 scores for preschool children with ADHD and the subgroups from reference group one (the Dutch population study) are displayed in Figure 2, divided in four groups after age and gender according to reference group one. 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 on 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-values<0.01). 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-values>0.05).

Sensitivity analyses excluding the 3-year-olds (the age which was not represented in the reference group) did not change the results. The comparison with reference group 2 had the same outcomes,

i.e. children with ADHD scored significantly lower on the psychosocial domains (mean PsS for the study sample children aged 5-7 years vs. reference group two: 38.07 (SD 10.72) vs. 52.10 (SD 7.90), p<0.001 (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 (see Table 2). As shown previously in the primary analysis on the D'SNAPP study, a significant decrease was observed for the ADHD-RS, FSI and an increase for PSOC-efficacy from T1-T2 and T1-T3 (see 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 (see Table 2). For the PhS 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 are 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 types, NFPP vs. TAU: 2.57, 95% CI [-5.56; 0.42] p=0.09, or from T1 to T3: 2.64 [-5.62; 0.35], p=0.08.

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 illustrated in Table S3 (available online).

In addition the observed mean score for each CHQ subdomain at all time points are illustrated in Table S4 (available online).

**Mediators of treatment-related improvements in HRQoL**

The mediation analyses are illustrated in Figure 3 (figures 3i, 3ii and 3iii). The score of ADHD-RS

at T2 (figure 3i) did not have a statistically significantly indirect effect on the increase in PsS at T3 (indirect effect, IE=1.00, BC 95% CI [-0.08; 2,55]). However, there was a statistically significant indirect effect 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 (see Figure 3, 3ii and 3iii). This means that a higher score at T2 on the PSOC-efficacy measure mediated a higher PsS score at T3 whereas as 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 post-treatment values of X at T2 was the difference in score between two children, one 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 non-pharmacological treatment trial. Our results showed that children with ADHD in this age group had substantially lower parent-reported HRQoL compared to age-matched children from the general population prior to 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 36 weeks follow-up (T3). Specialized PT as 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 to 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 to 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 (e.g. the behavioral subdomain BE). 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 to 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 though there was no statistical significance between the arms, the improvement in the PsS score was only significant 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 sub-domains relating to behavior, mental health, self-esteem, and family activities (BE, MH, SE and FA, see Table S4, available online). However, in both 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 was mediated by ADHD symptom reductions. 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 the 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 an improved HRQoL [20,21,36]. However, HRQoL might not be as sensitive an outcome as ADHD symptoms in the current trial with relatively short follow up and improvements in HRQoL may lag behind changes in ADHD. Medication trials on 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 (i.e. 9 months) 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, NFPP was more focused on the individual family than TAU, and the family receiving NFPP scored higher in the PSOC-efficacy post

treatment (Table 2). The effect was also reflected in the mediation analysis in the direct effect of treatment assignment (Figure 3iii, path a).

With the significant mediating effect of PSOC-efficacy and FSI, and the non-significant 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 child behavior, but also advice and strategies on how to look after themselves. As HRQoL is a subjective measure, and the children in the current study was too young to rate HRQoL themselves, we were not able to explore whether the impact of 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 on 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 was the first study to examine HRQoL in a large rigorous RCT study of non-pharmacological treatment. We found there was an increase in PsS after end of treatment but not in PhS, which strengthen the internal validity. We examined both treatment-induced reductions in symptoms, changed parent efficacy and family stress as mediating factors to the improved HRQoL.

There were however some limitations to be acknowledged. First, the absence of Danish norm data

for the CHQ led to comparison with reference groups from other countries, i.e. the Netherlands and USA. 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 has originally been developed for children aged 5-18 years, and our study sample included children down to the age of 3 years. Nonetheless, one of our reference groups included 4-year-olds, and the questionnaire has previously been successfully applied by others for children down to the age of 4 years [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, 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 and other psychiatric conditions like anxiety and ODD 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 NFPP was superior to TAU in increasing the children's HRQoL.

**Summary**

The findings in the 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-aged children with ADHD. Overall, early intervention with non-pharmacological treatment seems to have the potential to improve not only the child's core symptoms of ADHD but also the 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 non-pharmacological treatment to 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.

**Ethics**

The D'NSAPP study was approved by the ethics committee for the Central Denmark Region (number 1-10-72-140-12) and by the Danish Data Protection Agency (number 1-16-02-611- 15). Written informed consent was obtained from parents to all participating children [25].

Clinical trial registration information for the D'SNAPP study: http://clinicaltrial.gov/; NCT01684644.

**Figures and tables**

**Figure 1. Flowchart of study sample**

Note: Flowchart of study sample. 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 = after treatment; T3 = 36 weeks follow-up.

**Figure 2. Mean subdomains Child Health Questionnaire scores for study sample and reference group one, divided into subgroups.**

Note: Subgroup 1 = girls aged 4-5 years old (n = 1249), subgroup 2 = boys aged 4-5 years old (n = 1355), subgroups 3 = girls aged 6-7 years old (n = 1295), subgroup 4 = boys aged 6-7 years old (n = 1313).

BE = Behavior, BP = Bodily Pain, FA = Family Activity, FC = Family Cohesion, GH = General Health, MH = Mental Health, PE = Parental impact – Emotional, PF = Physical Function, PhS = Physical summary scale, PsS = Psychosocial summary scale, PT = Parental impact – Time, REB = Role/social Emotional Behavior, RP = Role/social – Physical, SE = Self Esteem.

* = Difference in score is significantly different calculated from a z-score $p<0.001$

**Figure 3. Mediation model of the Attention Deficit Hyperactivity Disorder – Rating Scale, Parent Sense Of Competence-efficacy and Family Strain Index scores at T2's effect on Psychosocial summary Scale.**

Note: Path *a* is the effect of treatment assignment (NFPP vs. TAU) on the specific variable, controlled for the baseline values of ADHD-RS (3i)/PSOC-efficacy (3ii)/FSI (3iii) score and PsS

score (negative estimates correspond to reduced ADHD symptoms/FSI score, 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, FSI = Family Strain Index, PSOC-efficacy = Parent Sense of Competence Scale – efficacy subscore, PsS = Psychosocial summary scale,

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**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[a])** | |
| **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 and above** | 32% |
| **Father's highest education level** | |
| **Elementary school** | 10% |
| **High school level** | 40% |
| **Bachelor and above** | 19% |
| **Mother employed** | |
| **Yes** | 74% |
| **Father employed** | |
| **Yes** | 65% |
| **Mother ever received a psychiatric diagnosis** | |
| **Yes** | 27% |
| **Father ever received a psychiatric diagnosis** | |
| **Yes** | 16% |

ADHD-RS=Attention-Deficit/Hyperactivity Disorder Rating Scale.
[a] International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) WHO Version, 2016: Mental and behavioral disorders.

**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: the New Forest Parenting Programme (NFPP) and Treatment as Usual (TAU)**

| | Change from T1 to T2 | | | Change from T1 to T3 | | |
|---|---|---|---|---|---|---|
| | Whole study sample | NFPP | TAU | Whole study sample | NFPP | TAU |
| ADHD-RS | -3.08 | -4.32 | -1.45 | -3.55 | -4.59 | -2.23 |
| Change (95% CI) | (-4.15; -2.01) | (-5,72; -2.91) | (-3.05; 0.13) | (-4.62; -2.47) | (-6.01; -3.16) | (-3.81; -0.64) |
| PsS | 2.28 | 3.42 | 0.86 | 2.05 | 3.22 | 0.60 |
| Change (95% CI) | (0.78; 3.77) | (1,42; 5.42) | (-1.37; 3.08) | (0.56; 3.54) | (1.22; 5.20) | (-1.62; 2.82) |
| PhS | -0.13 | -1.01 | 0.94 | -0.34 | -1.09 | 0.55 |
| Change (95% CI) | (-1.63; 1.38) | (-3.03; 1.01) | (-1.30; 3.18) | (-1.84; 1.17) | (-3.11; 0.92) | (-1.68; 2.79) |
| Cohen's d for PsS | -0.18 | -0.29 | -0.04 | -0.19 | -0.31 | -0.05 |
| (95% CI) | (-0.41; 0.05) | (-0.59; 0.02) | (-0.37; 0.30) | (-0.42; 0.03) | (-0.61; 0.00) | (-0.39; 0.28) |
| PSOC-efficacy | 0.90 | 1.76 | -0.15 | 1.45 | 2.08 | 0.67 |
| Change (95% CI) | (0.28; 1.53) | (0.94; 2.57) | (-1.09; 0.80) | (0.83; 2.08) | (1.27; 2.89) | (-0.28; 1.61) |
| FSI | -0.85 | -1.52 | -0.03 | -0.69 | -1.43 | 0.23 |
| Change (95% CI) | (-1.44; -0.25) | (-2.31; -0.72) | (-0.90; 0.85) | (-1.29; -0.10) | (-2.21; -0.64) | (-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, PsS = Psychosocial summary Scale, PSOC-efficacy = Parent Sense of Competence efficacy subscore, TAU = Treatment As Usual, T1 = baseline, T2 = after treatment, T3 = 36 weeks follow-up