Parent training for preschool ADHD in routine, specialist care: A randomized controlled trial

Authors

Anne-Mette Lange*, David Daley, Morten Frydenberg, Tine Houman, Lene Juel Kristensen, Charlotte Rask, Edmund Sonuga-Barke, Signe Søndergaard-Baden, Aparna Udupi, Per Hove Thomsen

Affiliations

Ms Lange, Drs Frydenberg, Udupi, Rask & Thomsen, and Mss Juel Kristensen and Søndergaard Baden are with Aarhus University, Denmark. Dr Thomsen is also with University of Trondheim. Dr Daley is with University of Nottingham, UK. Dr Houman is with Copenhagen University, Denmark. Dr Sonuga-Barke is with Kings College, London, UK, Aarhus University, Denmark, and Ghent University, Belgium.

Corresponding author

Anne-Mette Lange*. MSc (ClinPsyc).

Aarhus University Hospital, Research Department, Center for Child and Adolescent Psychiatry.

Skovagervej 2

8240 Risskov

Denmark

E: annelang@rm.dk

T: 0045 28771566.

Presentation information

This study was presented at the American Academy of Child and Adolescent Psychiatry's 63rd Annual Meeting, New York, October 24-29, 2016.

Key words

Attention Deficit Hyperactivity Disorder; Treatment; Preschool; Psychosocial; Randomized Controlled Trial.

Abstract

Objective: Parent training (PT) is recommended for attention-deficit/hyperactivity disorder (ADHD) in preschool children. Evidence-based interventions are important, but only if they produce better outcomes than usual care.

Method: We conducted a multi-center, two-arm parallel group randomized controlled trial in routine, specialist ADHD clinics in Danish Child and Adolescent Mental Health Services (CAMHS). Children (N=164, age 3-7) with ADHD received either a well-established PT programme (New Forest Parenting Programme (NFPP)) (n=88) or treatment as usual (TAU) (n=76). The primary outcome was parent ratings of child ADHD symptoms. Secondary outcomes included teacher ratings and direct observations of ADHD symptoms. Outcomes were measured at baseline (T1) and post-treatment (T2) and at follow-up (T3: 36 weeks after T2). Representativeness of participants was evaluated against the total national cohort of children (n=1378) diagnosed with ADHD during the same time period, using the Danish Civil Registration System. Statistical analysis employed a repeated measure model.

Results: By T2, NFPP was superior to TAU on parent-rated ADHD symptoms (p=0.009; ES d.=0.30), and on parenting self-efficacy and family strain. Effects persisted to T3. There were no effects on teacher ratings or direct observations of ADHD or on ratings of conduct problems or parenting. Our clinical sample was similar to the national cohort of young children with ADHD.

Conclusions: Evidence-based PT has value as an intervention for preschool ADHD in routine clinical settings. As in previous trials effects were restricted to parent-reported outcomes. Surprisingly, there were no effects on child conduct problems.

ClinicalTrial.gov identity no: NCT01684644. A Controlled Study of Parent Training in the Treatment of ADHD in Young Children (D'SNAPP)

Introduction

Behavioral parent training (PT) is recommended as the first-line treatment for pre-school ADHD[1] and is often favored by parents over medication [2]. Medication appears less effective in the treatment of preschool ADHD, compared to the effects of medication for school-aged children with ADHD, and is associated with more adverse effects[2]. A recent systematic review supported the classification of behavioural PT as a well-established treatment for preschool children with ADHD[3].

Different behavioral PT approaches have been manualized and trialed with preschoolers [4,5] [6,7], and produce a reduction in ADHD symptoms following treatment[8]. In general, the positive effects of behavioral parenting interventions are not mirrored on blinded outcomes[9,10]. Although PT can reduce ADHD symptoms and conduct problems as reported by parents, access to evidence-based PT remains limited [11-13]. Also, we do not know whether PT programs improve outcomes for preschoolers in routine settings, as trials have rarely been run in this context[14]. This is problematic as one cannot necessarily generalize the findings of most trials to treatments implemented in everyday practice in real world clinics [15].

The purpose of this study was to evaluate evidence-based PT for preschool ADHD in routine specialist clinics in public Child and Adolescent Mental Health Services (CAMHS), where most children receive their care, and where PT had not previously been available. The New Forest Parenting Programme[16] (NFPP) was selected as a suitable evidenced-based PT intervention for

implementation in CAMHS as it offers individual sessions to parents with the child present for some sessions. The individualized mode of delivery is compatible with the objectives of personalized treatment for young children with ADHD [17], and with the mission of the Danish public health service[18].

NFPP has been implemented and trialed in different countries [19]. Trials have mainly been implemented as community interventions delivered in family homes[6,7,16,20]. However, it is not known whether NFPP can improve outcomes for children seen in routine specialist settings. In this study, we conducted a multicenter RCT to assess the effect of NFPP versus treatment as usual (TAU) in three routine CAMHS settings in Denmark. The trial was pragmatic in orientation[21], although exclusion criteria and fidelity checks were applied unlike in routine care.

We predicted that NFPP would be superior to TAU and lead to significantly larger reductions in parents' ratings of children's symptoms of ADHD and conduct problems and improve parenting sense of competence and family wellbeing. We assessed the effect of NFPP on children's ADHD symptoms using parents' and teachers'ratings and with direct laboratory observation; and on parent and teacher ratings of conduct problems, parenting sense of competence, levels of family strain and parent-child interaction. We also tested whether previously identified moderating factors (single parenthood[22,23], parental ADHD[24], child conduct[25] and gender[26,27]). To determine whether our participants were representative we compared them to all other Danish children diagnosed with ADHD in routine CAMHS during the same period on key child and parent demographics, including socioeconomic status.

Methods

The study was approved by the Ethics Committee for Central Danish Region (No: 1-10-72-140-12), and by the Danish Data Protection Agency (No. 1-16-02-611-15). A detailed research protocol has been published [28].

Study design, participants and setting

The study was a multi-center, randomized, controlled trial comparing the effectiveness of NFPP and TAU in the treatment of ADHD for young children. Children and their parents were recruited between May 2012 and November 2015 from 3 different specialist ADHD clinics (Risskov, Herning and Glostrup) for preschool children (ages 3-7) in Danish CAMHS.

Eligibility Criteria

Inclusion criteria were: age between 3-7 years; clinical ADHD diagnosis supported by the Development and Well-Being Assessment (DAWBA)[29]; Danish as a first language spoken at home. Exclusion criteria were: Intellectual disabilities (IQ < 70); autism spectrum disorder diagnosis; in receipt of pharmacological or psychosocial treatment for ADHD. Severe parental psychiatric disorder (i.e. untreated psychosis, bipolar or severe depressive disorder); severe social adversity in the home (i.e. active child protection involvement).

Procedure

The trial was imbedded in everyday clinical practice. Parents of eligible referrals completed the online DAWBA[29] and received standard clinical, multidisciplinary assessment, medical examination, evaluation of intelligence quotient (IQ) based on the Wechsler Intelligence Scales, and when indicated, supplementary neuropsychological assessment and Autism Diagnostic Observation Schedule[23]. ADHD diagnosis was made by specialist child and adolescent psychiatrists based on

results from all clinical assessments and DAWBA profiles, conducted by trained raters [30]. Diagnostic agreements between DAWBA expert diagnoses and clinical diagnoses have been found to be fair to moderate and comparable to other structured diagnostic interviews[31]. Research team members met parents of eligible children at the end of a routine diagnostic feedback session, and provided verbal and written information about the content of the study and its treatment arms. Written, informed consent was obtained. Research assistants administered all outcome measures and saw children and parent/s for baseline assessments (T1), follow-up at T2 (12 weeks post T1), and T3 (36 weeks post T2). Assessment measures were implemented electronically in Trialpartner [32] by the Data Management Unit in The Central Denmark Region and administered to parents and teachers/day-care staff for online completion.

Randomization and masking

Participants were randomly assigned (1:1) to NFPP and TAU following T1 assessment. Randomization was conducted in blocks of four or six and in 12 strata defined by center, gender and age (3-5 and 6-7 year) using a web-based and logged randomization service within Trialpartner [32]. Research assistants were masked to treatment allocation and located separately to avoid contamination; trial participants could not be masked. Parents were asked not to reveal treatment status of their children to teachers. Videotaped observations were rated by trained assessors blind to treatment allocation. Treatment fidelity was rated by qualified psychologists without access to outcome information, but aware of study goals. All data was stored by the independent Data Management Unit and released one month after the last participant completed T3. Treatments between T1-T3 were limited to NFPP and TAU. Access to interventions outside CAMHS was beyond the control of the trial.

Treatment

NFPP includes 5 elements[20]: 1) Psychoeducation about the nature of preschool ADHD to enhance parents' understanding of child's behavior; 2) Scaffolding to help parents work from the child's level of development; 3) Promoting proactive parenting and enhancing parent-child interaction to support child development and reduce parental stress; 4) Improving child's ADHD symptoms and related neuropsychological deficits through play and games that target attention, impulsivity and self-regulation; 5) Guiding parents in the use of behavioral strategies to improve behavior and ADHD symptoms. Therapists provide weekly homework assignments tailored to child and parent needs, including videotaped practice of specific tasks. The original NFPP manual [16] consists of eight sessions delivered individually to parents in the child's home, with the child present during 3 sessions. This delivery mode was changed in the present study to enhance the acceptability and feasibility of the NFPP to Danish CAMHS with six sessions delivered in the clinic and two in the home. The content of the NFPP manual was otherwise unchanged (see protocol[28]). Four therapists from each CAMHS sites were recruited and trained to deliver NFPP, and placed in buildings separate from the clinical teams to avoid treatment contamination. Therapists had different professional backgrounds (clinical psychologists (2); nurse specialist (1); nursery teacher (1)). All had extensive clinical experience of preschool ADHD (5-15 years), but no experience of delivering manualized treatments or of practicing behavioral methods. They received weekly 2-hour clinical supervision sessions in groups of two delivered by the main investigator, who in turn received fortnightly supervision by the original NFPP developers.

TAU typically consisted of a standard package of psycho-education delivered to groups of individual parents by specialized staff. The majority of parents were offered between 3-4 group

sessions each lasting between 2-3 hours, and some were offered individual sessions in addition to or instead of group intervention. TAU included information about a) ADHD as a developmental disorder; b) How ADHD symptoms obstruct normal play and the development of preschool skills, and c) how ADHD and executive dysfunctions interrupt daily routines. Parents were also offered practical advice on how to support young children through psychosocial management, e.g. visual aids and daily structure. TAU was not homogenous between or within the 3 sites, reflecting different clinical practices in everyday CAMHS. At all sites TAU was carried out by mental health professionals with different backgrounds (clinical psychologists (n=3); specialist nurses (n=3) with extensive clinical experience of preschool ADHD (5-15 years).

Fidelity

Fidelity was assessed in a random selection of videotapes from 20 cases (5 per therapist). An 80-item check list where each item was rated 'completed'; 'not completed' or 'not relevant' to yield a total fidelity score (range 0-80 was used).

Measures

Measures were chosen to enhance comparability to previous trials of PT for ADHD. To enhance methodological rigor, blinded and observed measures were also used. Internal consistency of all measures in this sample was good (see Appendix A, table S8).

Primary outcome: Parent ratings (total score) on the ADHD Rating Scale-IV–Preschool Danish Version [33] measured change in ADHD symptom severity.

Secondary outcomes

Child: Teacher ADHD RS-IV ratings. Directly observed ADHD behaviors during solo play 'index of attention/engagement' using the Child Solo Play instrument [16]. Conduct problems - parent and teacher ratings on the conduct scale of the Strengths and Difficulties Questionnaire (SDQ)[34].

Parent: The Parenting Sense of Competence Scale (PSOC) [35] assessed parental self-efficacy and satisfaction. The Family Strain Index (FSI) [36] measured levels of stress in the context of living with a child with ADHD. The Adult ADHD Self-Report Scale (ASRS-v1.1) measured levels of parental ADHD[37]. The direct observation schedule *The Global Impressions of Parent-Child Interactions* (GIPCI-R)[38] evaluated parent and child interaction. The General Health Questionnaire (GHQ12) data on maternal mental wellbeing was collected but was unavailable for analysis due to errors in the electronic set-up.

Sample size calculation

The primary endpoint was parent ADHD ratings at T2. It was estimated that a total sample of 126 would be sufficient to demonstrate statistically significant difference between NFPP and TAU with 80 percent power and effect size of .50 (Cohen's d) and expected drop-out of 10% [39] - the minimum effect size and power generally recommended when calculating sample size in clinical trials[40,41]. The study was powered to detect difference between NFPP and TAU arms, not to conduct moderator effects.

Statistical analysis

All outcomes were analyzed with a repeated measure model in STATA (version 14.1)[42]. Covariates included: randomization arm, center, gender, age (above or below 5 year) and year of randomization. We estimated the intervention effect at T2 (Intervention –TAU) in terms of the change from T1 to T2 and T1 to T3. We considered four potential moderators of the primary

outcome, gender, living with single parent, parental self-reported ADHD symptoms and parent reported levels of child conduct at T1. We repeated all analyses excluding observation with residuals exceeding 2.5* standard deviations (SD). The repeated measure model is relatively robust to data missing at random, but we supplemented all the analyzes with sensitivity analyses representing four missing not at random scenarios. Missing outcome were substituted with the models-based-prediction adding or subtracting 0.2*SD in the intervention or the TAU arm. All analyzes were based on intention to treat. P-values below 5% were considered statistically significant.

Sample representativeness

We assessed the representativeness of participants against data from the Danish Civil Registration System (CRS) [43]. The CRS contains detailed data on all Danish citizens, including a personal identification number that enables accurate linkage between and within the numerous nationwide registers (e.g., linking parents with children). Data was obtained through and linked by Statistics Denmark (DST) and the Danish National Health Board (DNHB)[44]. Background and socio-demographic data for all other children diagnosed in Danish CAMHS, aged 3-7, who were diagnosed with ADHD (ICD-10 diagnoses: F90.x & F98.8) between 2012 and 2015 was used.

Results

Representativeness

The study sample (N=164) were somewhat older, parents were slightly less educated, family income was somewhat lower, and more parents were single compared to the comparison group of children (N=1378) of similar age, who received a diagnosis of ADHD in the same time period (Table 1).

TABLE 1

Allocation, drop out and fidelity

In total,164 participants were randomized (Fig 1). Outcome measures were completed by mothers (n=139), fathers (n=15) and foster parents/other (n=9). Eighty-eight families were randomized to NFPP, and 83 completed all 8 sessions. (mean no. of hours/family = 12.07). Sessions were attended by both parents (58.8%), mother (29.5%), father (4.5%) (see Table S10, available online). Content fidelity was 95.3% (range: 83-100%). Seventy-six families were randomized to TAU (mean no. hours/family=8.8 hours). Patient records showed that 20 of these families did not receive any treatment between T1 & T3. Forty-six families attended parent groups and 32 families attended individual sessions instead of or in addition to group intervention across the three sites.

FIG 1.

Background and clinical characteristics, including diagnosed comorbid disorders, of the sample at baseline were well balanced across arms (see tables S1 and S9, available online) Response rates at all time-points on the primary outcome were satisfactory, although somewhat lower for TAU (Table 2).

TABLE 2

NFPP versus TAU

Table 2 reports raw scores for the primary and secondary outcomes across assessment points. At T2, 2%, and 15% of primary outcome data were missing for NFPP and TAU, respectively. Table 3 reports the adjusted change scores and the group difference between the adjusted change scores. Although a decrease was observed between T1 and T2 on parents' reports of ADHD symptoms for both arms (NFPP: 4.31 95% CI (2.90; 5.71) and TAU: 1.46 (-0.13;3.05)), NFPP was statistically superior to TAU (p=0.009). The effect persisted to T3 (p=0.031). There were also significant benefits of NFPP over TAU measured on the Family Strain Index (p= 0.017; p= 0.010), and Parenting Efficacy (T2: p=0.004 and T3: p=0.028) at both time-points. The effect for parenting sense of satisfaction at T2 bordered significance (p= 0.051). All other outcomes were non-significant. All exploratory moderation analyses were non-significant (see Table S2, available online). Outlier and sensitivity analyses showed similar results (see tables S3-S7, available online). For effect sizes see table S11, available online. The results are illustrated in figure SF1, available online.

TABLE 3

Discussion

Our clinical sample was representative of a national cohort of children of similar ages diagnosed with ADHD during the same time period. NFPP delivered in CAMHS was superior to TAU in terms of reducing parent-rated ADHD symptoms. The effect size of d.=0.30 seems to be somewhat smaller than that found in the previous four published NFPP trials (0.34-1.26)[45 6,7,16]. This may be explained by the fact that previous NFPP trials were conducted in community settings, with control conditions involving minimal[7] or no intervention or a wait-list condition[6,16]. The smaller effect size

may also be related to the effectiveness oriented trial design where effect sizes are commonly smaller for trials delivered in real life clinical settings[46].

Effects did not generalize to teacher ratings or to direct observations. This finding is consistent with results from a meta-analysis of behavioral interventions for ADHD (nearly all of which involved PT), and with a meta-analysis involving PT for preschoolers with ADHD[9,10,14]. Taken together, these findings have important implications and there is considerable debate about the clinical importance of parent-rated changes in ADHD following PT when they are not corroborated by informants blind to treatment allocation[3,14,20,47]. Firstly, it may be unrealistic to expect correspondence between parent and teacher and parent and observer ratings of ADHD symptoms, as the effects of PT in the home may not be observable in other contexts with different demands and contingencies[3]. Secondly, teacher or blinded observer ratings are limited by the narrow context in which symptoms are rated, i.e. nursery school or the laboratory[48]. Thirdly, parents may rate behavior over a period of time while observations are snapshots. Finally, teacher ratings may lack reliability as studies, to the best of our knowledge, do not standardize teacher ratings at different time-points. To optimize improvements in ADHD symptoms across domains, combined PT and teacher training interventions for young children with ADHD have been proposed, but trials have so far shown nonsignificant results on core ADHD symptoms[49,50]. Parents are important informants when evaluating treatments for children[3], but further research is needed understand the significance of parent ratings and the value of PT in improving the lives of young children with ADHD.

There were no significant effects of NFPP on child conduct problems reported by either rater. The findings from previous NFPP trials are somewhat inconsistent with regards to impact on conduct problems. While previous trials have reported large effects[7], two recent trials reported smaller effect sizes around 0.3[6,20] . A meta-analysis of PT for preschool ADHD found small to

moderate effect on parent-reported conduct problems but no effect on probably blinded measures[10]. Levels of conduct problems were fairly low in this sample (see Table S9, available online) in line with the reported lower prevalence of conduct problems in the Scandinavian countries [51], which may explain the lack of effect. It may also be that the Danish version of the five-item conduct SDQ subscale was not sufficiently sensitive to change in the present study?

NFPP had positive effects on indicators of parent and family wellbeing. Family strain was reduced compared to TAU and parenting self-efficacy and satisfaction increased. This is consistent with previous trial results[47] and highlights the wider benefits of NFPP. Some of these effects persisted to T3. Against expectations – there was no improvement in parenting behaviors directed towards the child during direct observation. Two recent ADHD trials of NFPP[6,20] also failed to detect changes in parenting practices using these same observation schedules. This may suggest that the schedule lacks external validity as a measure of ADHD related parenting. Alternatively, it may be that parenting does not improve as a function of intervention which would be at odds with a meta-analysis that found that behavioral interventions, which mostly included PT, improved self – reports and also blinded observations of parenting measures[47].

Finally, exploratory moderator analysis indicated that intervention effects were not influenced by child gender, family SES or composition, parental ADHD or child conduct problems. Levels of treatment adherence (95,3%) and outcomes were encouraging [21,42] suggesting that therapists from different cultures working in different settings can be trained to deliver NFPP effectively. However, it should be noted that adding fidelity checks may have increased clinical engagement in the active trial and so may have reduced the generalizability of the results to normal clinical setting where such checks are less common.

This study had several strengths. It was conducted in specialized CAMHS where the majority of young children with ADHD are already offered psycho-education and support. Treatment in both arms was carried out by general therapists already in position within participating CAMHS. The study demonstrated sample representativeness by accessing data on a variety of sociodemographic data on the entire population of young children with ADHD from th Danish registers. The trial had an adequate sample, high retention and strong fidelity. The trial was independent, conducted in collaboration with NFPP researchers, but without their involvement in the collection and processing of data. It was the first NFPP trial in a non-English speaking context, where therapist supervision was independent of the original NFPP developers.

However, several limitations have to be recognized. Diagnostic assessment relied on routine clinical procedures, and the utility of the DAWBA in trials with preschoolers has not been established. Also, no data was available on the diagnostic status of the children after treatment. Engagement in treatments outside the clinical system was not recorded, although this could have impacted equally on both arms. Results may have been influenced by expectation bias. Given the finding from previous studies that parents of children with ADHD prefer individualized over group based PT[52], parents may have expected a more positive outcome from NFPP than TAU.There was a narrow assessment of conduct problems, and no corroboration via direct observation of oppositional behavior. Technical errors prevented an exploration of the impact of intervention on parents' mental wellbeing. The trial was powered for effects on ADHD at T2, and was not powered to study moderator effects. The effects of clustering of therapists and treatment groups as recommended by CONSORT[53] could not be fully analyzed due to data protection laws preventing access to patient files. It should be recognized that applied exclusion criteria may have reduced the trial's external validity as an effectiveness trial . Finally, treatment dosage and engagement was higher in NFPP,

as 20 participants did not take up the offer of TAU. Further research is needed to determine the barriers to engagement in clinical services in order to improve patient outcome and increase service efficiency.

Summary

Effective treatments are needed for young children with ADHD. Our findings showed that NFPP was superior to TAU in reducing ADHD symptoms, as rated by parents, increasing parenting satisfaction and efficacy, and reducing strain within the family. Consistent with prior PT trials [9], these effects did not generalize to teacher ratings and direct observations. There was no effect on children's conduct problems. Further research is needed to understand the significance of parent ratings in the evaluation of PT. Access to evidence based PT in routine CAMHS may contribute towards improved outcomes for young children with ADHD and their parents.

Table 1. Characteristics of randomized children and all Danish children with ADHD at time of diagnosis

Characteristics	Randomized (N=164)	All children (N=1378)
Year of diagnosis		
2012	16%	24%
2013	35%	34%
2014	49%	42%
Age group		
3-5yrs	57%	34%
6-7yrs	43%	66%
Sex		
Girls	27%	26%
Boys	73%	74%
Living arrangement		
Single parent	32%	40%
Both parents	65%	52%
Foster or unknown	4%	8%
Registered mother[a]		
Biological mother	99%	99%
Registered father[a]		
Biological father	100%	98%
Mother's highest education level[a]		
Elementary school	15%	26%
High School level	51%	43%
Bachelor and above	33%	28%
Father's highest education level[a]		
Elementary school	15%	24%
High School level	56%	49%
Bachelor and above	26%	25%
Mother employed[a]		
Yes	79%	72%
Father employed[a]		
Yes	68%	92%
Family gross income (1000 €)[b]		
<=50	20%	24%
50-75	12%	19%
75-100	34%	24%
>100	25%	22%
Mother ever received psychiatric diagnosis[a]		
Yes	23%	32%
Father ever received psychiatric diagnosis[a]		
Yes	16%	17%
Mother's age, mean (SD)[a]	35.4 (5.4)	35.5 (5.4)
Father's age, mean (SD)[a]	38.5 (5.6)	38.9 (6.0)

*values are for parents living with the child

**of the child's family

Table 2: Observed outcome for New Forest Parenting Programme (NFPP) and Treatment as Usual (TAU) (N: mean (SD)

	NFPP			TAU		
	T1	**T2**	**T3**	**T1**	**T2**	**T3**
Primary outcome						
ADHD-RS-Parent						
Total	86: 33.44 (9.97)	84: 29.18 (9.08)	81: 28.73 (10.13)	75: 35.37 (8.90)	64: 33.98 (8.82)	64: 32.91 (9.26)
Secondary outcome						
ADHD-RS-Teacher						
Total	86: 33.35 (10.37)	80: 31.27 (9.97)	74: 32.02 (10.14)	69: 34.64 (12.52)	67: 32.94 (12.01)	55: 30.69 (13.72)
SDQ-Parent						
Conduct	86: 4.78 (2.44)	84: 4.04 (2.37)	81: 3.99 (2.36)	75: 5.27 (2.50)	64: 4.92 (2.13)	64: 4.77 (2.52)
SDQ-Teacher						
Conduct	86: 5.02 (3.14)	80: 4.25 (2.96)	74: 4.46 (3.11)	69: 5.30 (2.86)	66: 4.89 (3.04)	55: 4.44 (3.01)
GIPCI-Parent						
Average item score	83: 3.38 (0.32)	81: 3.45 (0.32)	78: 3.45 (0.28)	75: 3.35 (0.27)	62: 3.39 (0.37)	58: 3.39 (0.33)
GIPCI-Child						
Average item score	83: 3.88 (0.36)	81: 3.88 (0.29)	78: 3.92 (0.28)	75: 3.92 (0.29)	62: 3.88 (0.35)	58: 3.98 (0.28)
PSOC						
Efficacy	86: 30.54 (5.46)	81: 32.21 (5.67)	81: 32.54 (4.71)	75: 30.19 (6.03)	64: 29.52 (6.05)	64: 30.83 (5.96)
Satisfaction	86: 38.06 (7.01)	81: 39.59 (6.06)	81: 39.45 (6.63)	75: 37.20 (7.11)	64: 36.81 (7.00)	64: 38.05 (7.91)
FSI						
Total	86: 10.37 (5.34)	81: 9.12 (4.82)	81: 8.88 (4.72)	75: 10.39 (4.56)	64: 10.42 (5.16)	64: 10.47 (5.39)
Child solo play						
Switches[a]	86: 7.0 (1.0; 15.0)	80: 6.0 (0.0; 17.0)	79: 7.0 (1.0; 17.0)	74: 6.0 (0.0; 15.0)	60: 6.0 (0.0; 22.5)	60: 6.0 (0.0; 16.5)

ADHD-RS: ADHD Rating Scale; SDQ: Strength and Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of Competence; FSI: Family Strain Index

[a] N: Median (10th percentile; 90th percentile)

Table 3: Adjusted[a] mean changes for New Forest Parenting Programme (NFPP) and Treatment as Usual (TAU)

	Change from T1 to T2				Change from T1 to T3			
	NFPP	TAU	NFPP vs TAU		NFPP	TAU	NFPP vs TAU	
	Adjusted mean (95% CI)			p-value	Adjusted mean (95% CI)			p-value
Primary outcome								
ADHD-RS-Parent								
Total	-4.31 (-5.71; -2.90)	-1.46 (-3.05; 0.13)	-2.84 (-4.96; -0.73)	0.009	-4.57 (-5.99; -3.15)	-2.23 (-3.81; -0.64)	-2.35 (-4.48; -0.21)	0.031
Secondary outcome								
ADHD-RS-Teacher								
Total	-2.22 (-4.30; -0.15)	-1.05 (-3.34; 1.25)	-1.18 (-4.27; 1.92)	0.457	-1.85 (-3.99; 0.28)	-2.57 (-5.05; -0.09)	0.71 (-2.56; 3.98)	0.669
SDQ-Parent								
Conduct	-0.75 (-1.13; -0.37)	-0.38 (-0.81; 0.04)	-0.36 (-0.94; 0.21)	0.212	-0.77 (-1.16; -0.39)	-0.45 (-0.87; -0.02)	-0.33 (-0.90; 0.25)	0.264
SDQ-Teacher								
Conduct	-0.72 (-1.25; -0.19)	-0.22 (-0.81; 0.37)	-0.50 (-1.29; 0.30)	0.219	-0.58 (-1.13; -0.04)	-0.61 (-1.24; 0.03)	0.03 (-0.81; 0.86)	0.951
GIPCI-Parent								
Average per item	0.07 (0.01; 0.14)	0.04 (-0.03; 0.11)	0.03 (-0.07; 0.13)	0.517	0.07 (0.00; 0.13)	0.04 (-0.04; 0.11)	0.03 (-0.07; 0.13)	0.586
GIPCI-Child								
Average per item	0.00 (-0.07; 0.08)	-0.04 (-0.13; 0.04)	0.05 (-0.07; 0.16)	0.420	0.04 (-0.03; 0.12)	0.05 (-0.04; 0.13)	-0.00 (-0.12; 0.11)	0.954
PSOC								
Efficacy	1.66 (0.83; 2.48)	-0.17 (-1.08; 0.75)	1.82 (0.59; 3.06)	0.004	2.04 (1.21; 2.86)	0.66 (-0.26; 1.57)	1.38 (0.15; 2.61)	0.028
Satisfaction	1.50 (0.23; 2.76)	-0.39 (-1.80; 1.02)	1.88 (-0.01; 3.78)	0.051	1.28 (0.01; 2.54)	0.56 (-0.84; 1.97)	0.71 (-1.18; 2.61)	0.459
FSI								
Total	-1.44 (-2.23; -0.66)	-0.02 (-0.89; 0.86)	-1.43 (-2.60; -0.26)	0.017	-1.35 (-2.13; -0.56)	0.19 (-0.68; 1.07)	-1.54 (-2.71; -0.37)	0.010
Child solo play								
Switches	-0.02 (-1.81; 1.76)	1.63 (-0.39; 3.64)	-1.65 (-4.34; 1.04)	0.230	0.32 (-1.47; 2.11)	0.37 (-1.64; 2.38)	-0.05 (-2.74; 2.65)	0.972

CI: Confidence Interval; ADHD-RS: ADHD Rating Scale; SDQ: Strength and Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of Competence; FSI: Family Strain Index

[a]Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child.

Figures

Fig 1. CONsolidated Standards of Reporting Trials (CONSORT) diagram

Supplemental figures

Supplementary figure 1: Changes in parent-rated mean scores for New Forest Parenting Programme (NFPP) and Treatment as Usual (TAU)

Supplemental tables:

Table S1: Characteristics at time of ADHD diagnosis among 86 children randomized to New Forest Parenting Programme and 76 children randomized to Treatment as Usual (TAU)

Table S2: Results of moderator analyses on the primary outcome (ADHD-RS-parent rated)

Table S3: Adjusted[a] mean changes among 86 children randomized to New Forest Parenting Programme and 76 children randomized to Treatment as Usual (TAU)

Table S4: Adjusted[a] mean changes among 86 children randomized to New Forest Parenting Programme (NFPP) and 76 children randomized to Treatment as Usual (TAU)

Table S5: Adjusted[a] mean changes among 86 children randomized to New Forest Parenting Programme (NFPP) and 76 children randomized to Treatment as Usual (TAU)

Table S6: Adjusted[a] mean changes among 86 children randomized to New Forest Parenting Programme (NFPP) and 76 children randomized to Treatment as Usual (TAU)

Table S7: Adjusted[a] mean changes among 86 children randomized to New Forest Parenting Programme (NFPP) and 76 children randomized to Treatment as Usual (TAU)

Table S8: Schedule of measures together with internal consistency coefficients of the scales used

Table S9: Comorbid diagnoses (ICD-10*) at baseline for both groups

Lay summary

This study investigated whether parent training (PT) added value in the treatment of ADHD in young children referred to three routine, specialized Child and Adolescent Mental Health Services (CAMHS) in Denmark. We found that PT was superior to treatment as usual in CAMHS because it reduced parent-rated ADHD symptoms (ES: 0.30). There were no effects on teacher or observer rated ADHD outcomes. The significance of parent ratings and the clinical value of PT in improving outcomes for young children require further exploration.

References

1. Wolraich M, Brown L, Brown RT, et al. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics.* 2011;128(5):1007-1022.
2. Davis DW, Williams PG. Attention deficit/hyperactivity disorder in preschool-age children: issues and concerns. *Clinical pediatrics.* 2011;50(2):144-152.
3. Evans SW, Owens JS, Wymbs BT, Ray AR. Evidence-Based Psychosocial Treatments for Children and Adolescents With Attention Deficit/Hyperactivity Disorder. *Journal of Clinical Child & Adolescent Psychology.* 2018;47(2):157-198.
4. Webster-Stratton CH, Reid MJ, Beauchaine T. Combining parent and child training for young children with ADHD. *J Clin Child Adolesc Psychol.* 2011;40(2):191-203.
5. Bor W, Sanders MR, Markie-Dadds C. The effects of the Triple P-Positive Parenting Program on preschool children with co-occurring disruptive behavior and attentional/hyperactive difficulties. *Journal of abnormal child psychology.* 2002;30(6):571-587.
6. Abikoff HB, Thompson M, Laver-Bradbury C, et al. Parent training for preschool ADHD: a randomized controlled trial of specialized and generic programs. *Journal of Child Psychology and Psychiatry.* 2015;56(6):618-631.
7. Thompson MJ, Laver-Bradbury C, Ayres M, et al. A small-scale randomized controlled trial of the revised new forest parenting programme for preschoolers with attention deficit hyperactivity disorder. *European child & adolescent psychiatry.* 2009;18(10):605-616.
8. Mulqueen JM, Bartley CA, Bloch MH. Meta-Analysis:Parental Interventions for Preschool ADHD. *Journal of Attention Disorders.* 2015;19(2):118-124.
9. Sonuga-Barke EJS, Brandeis D, Cortese S, et al. Nonpharmacological interventions for ADHD: Systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. *American Journal of Psychiatry.* 2013;170(3):275-289.
10. Rimestad ML, Lambek R, Zacher Christiansen H, Hougaard E. Short- and Long-Term Effects of Parent Training for Preschool Children With or at Risk of ADHD: A Systematic Review and Meta-Analysis. *J Atten Disord.* 2016;0(0):1087054716648775.
11. Fiks AG, Ross ME, Mayne SL, et al. Preschool ADHD diagnosis and stimulant use before and after the 2011 AAP Practice Guideline. *Pediatrics.* 2016:e20162025.
12. Wolraich ML. It Takes a Full-Service Village to Treat Children With ADHD. *Pediatrics.* 2016:e20162928.
13. Visser SN. Vital signs: National and state-specific patterns of attention deficit/hyperactivity disorder treatment among insured children aged 2–5 years—United States, 2008–2014. *MMWR Morbidity and mortality weekly report.* 2016;65.
14. Daley D, Van Der Oord S, Ferrin M, et al. Practitioner Review: Current best practice in the use of parent training and other behavioural interventions in the treatment of children and adolescents with attention deficit hyperactivity disorder. *Journal of child psychology and psychiatry, and allied disciplines.* 2017:Epub ahead of print.
15. Santucci LC, Thomassin K, Petrovic L, Weisz JR. Building Evidence-Based Interventions for the Youth, Providers, and Contexts of Real-World Mental-Health Care. *Child Dev Perspect.* 2015;9(2):67-73.
16. Sonuga-Barke EJ, Daley D, Thompson M, Laver-Bradbury C, Weeks A. Parent-based therapies for preschool attention-deficit/hyperactivity disorder: a randomized, controlled trial with a community sample. *J Am Acad Child Adolesc Psychiatry.* 2001;40(4):402-408.

17. March JS. The preschool ADHD treatment study (PATS) as the culmination of twenty years of clinical trials in pediatric psychopharmacology. *Journal of the American Academy of Child & Adolescent Psychiatry.* 2011;50(5):427-430.
18. Health DMo. Personalised medicine for the benefit of patients: Clear diagnosis, targeted treatment, strengthened research. National Strategy for Personalised Medicine 2017-2020. In: Health DMo, ed. Copenhagen: Danish Ministry of Health; 2016.
19. Thompson MJJ, Au A, Laver-Bradbury C, et al. Adapting an attention-deficit hyperactivity disorder parent training intervention to different cultural contexts: The experience of implementing the New Forest Parenting Programme in China, Denmark, Hong Kong, Japan, and the United Kingdom. *PsyCh Journal.* 2017;6(1):83-97.
20. Sonuga-Barke EJ, Barton J, Daley D, et al. A comparison of the clinical effectiveness and cost of specialised individually delivered parent training for preschool attention-deficit/hyperactivity disorder and a generic, group-based programme: a multi-centre, randomised controlled trial of the New Forest Parenting Programme versus Incredible Years. *European child & adolescent psychiatry.* 2017:1-13.
21. Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *The BMJ.* 2008;337:a2390.
22. Chacko A, Wymbs BT, Wymbs FA, et al. Enhancing Traditional Behavioral Parent Training for Single Mothers of Children with ADHD. *Journal of Clinical Child & Adolescent Psychology.* 2009;38(2):206-218.
23. Lord C, Rutter M, DiLavore PC, Risi S, Gotham K, Bishop SL. *Autism diagnostic observation schedule (ADOS): Manual.* WPS; 2001.
24. Sonuga-Barke EJ, Daley D, Thompson M. Does maternal adhd reduce the effectiveness of parent training for preschool children's adhd. *Journal of the American Academy of Child and Adolescent Psychiatry.* 2002;41:696-702.
25. Forehand R, Parent J, Sonuga-Barke E, Peisch VD, Long N, Abikoff HB. Which type of parent training works best for preschoolers with comorbid ADHD and ODD? A secondary analysis of a randomized controlled trial comparing generic and specialized programs. *Journal of abnormal child psychology.* 2016;44(8):1503-1513.
26. Hinshaw SP. Moderators and Mediators of Treatment Outcome for Youth With ADHD: Understanding for Whom and How Interventions Work. *Journal of Pediatric Psychology.* 2007;32(6):664-675.
27. Rucklidge JJ. Gender differences in ADHD: implications for psychosocial treatments. *Expert Review of Neurotherapeutics.* 2008;8(4):643-655.
28. Lange A-M, Daley D, Frydenberg M, Rask CU, Sonuga-Barke E, Thomsen PH. The effectiveness of parent training as a treatment for preschool attention-deficit/hyperactivity disorder: Study protocol for a randomized controlled, multicenter trial of the New Forest Parenting Program in everyday clinical practice. *JMIR Research Protocols.* 2016;5(2):e51.
29. Goodman R, Ford T, Richards H, Gatward R, Meltzer H. The Development and Well-Being Assessment: description and initial validation of an integrated assessment of child and adolescent psychopathology. *Journal of child psychology and psychiatry, and allied disciplines.* 2000;41(5):645-655.
30. Foreman D, Morton S, Ford T. Exploring the clinical utility of the Development And Well-Being Assessment (DAWBA) in the detection of hyperkinetic disorders and associated diagnoses in clinical practice. *Journal of Child Psychology and Psychiatry.* 2009;50(4):460-470.

31. Aebi M, Kuhn C, Metzke CW, Stringaris A, Goodman R, Steinhausen H-C. The use of the development and well-being assessment (DAWBA) in clinical practice: a randomized trial. *European child & adolescent psychiatry.* 2012;21(10):559-567.
32. Datamanagement Unit CDR. Trialpartner.dk. [Online datamanagement software].
33. McGoey KE, DuPaul GJ, Haley E, Shelton TL. Parent and teacher ratings of Attention-Deficit/Hyperactivity disorder in preschool: The ADHD rating Scale-IV preschool version. *J Psychopathol Behav.* 2007;29(4):269-276.
34. Goodman A, Goodman R. Strengths and difficulties questionnaire as a dimensional measure of child mental health. *Journal of the American Academy of Child and Adolescent Psychiatry.* 2009;48(4):400-403.
35. Johnston C, Mash EJ. A Measure of Parenting Satisfaction and Efficacy. *J Clin Child Psychol.* 1989;18(2):167-175.
36. Riley AW, Lyman LM, Spiel G, et al. The Family Strain Index (FSI). Reliability, validity, and factor structure of a brief questionnaire for families of children with ADHD. *European child & adolescent psychiatry.* 2006;15 Suppl 1(1):I72-78.
37. Kessler RC, Adler L, Ames M, et al. The World Health Organization adult ADHD self-report scale (ASRS): a short screening scale for use in the general population. *Psychol Med.* 2005;35(2):245-256.
38. Brotman LM, Gouley KK, Chesir-Teran D, Dennis T, Klein RG, Shrout P. Prevention for preschoolers at high risk for conduct problems: Immediate outcomes on parenting practices and child social competence. *Journal of Clinical Child and Adolescent Psychology.* 2005;34(4):724-734.
39. Van Den Hoofdakker BJ, Van Der Veen-Mulders L, Sytema S, Emmelkamp PMG, Minderaa RB, Nauta MH. Effectiveness of behavioral parent training for children with ADHD in routine clinical practice: A randomized controlled study. *Journal of the American Academy of Child and Adolescent Psychiatry.* 2007;46(10):1263-1271.
40. Sedgwick P. Effect sizes. *BMJ : British Medical Journal.* 2012;345.
41. Sedgwick P. The importance of statistical power. *BMJ.* 2013;347:f6282.
42. *Stata Statistical Software* [computer program]. College Station, TX: StataCorp LP; 2015.
43. Schmidt M, Pedersen L, Sørensen HT. The Danish Civil Registration System as a tool in epidemiology. *European Journal of Epidemiology.* 2014;29(8):541-549.
44. Mors O, Perto GP, Mortensen PB. The Danish psychiatric central research register. *Scandinavian Journal of Public Health.* 2011;39(7):54-57.
45. Sonuga-Barke EJS, Thompson M, Daley D, LaverBradbury C. Parent training for Attention Deficit/Hyperactivity Disorder: Is it as effective when delivered as routine rather than as specialist care? *British Journal of Clinical Psychology.* 2004;43(4):449-457.
46. Weisz JR, Kuppens S, Eckshtain D, Ugueto AM, Hawley KM, Jensen-Doss A. Performance of evidence-based youth psychotherapies compared with usual clinical care a multilevelmeta-analysis. *JAMA Psychiatry.* 2013;70(7):750-761.
47. Daley D, van der Oord S, Ferrin M, et al. Behavioral interventions in attention-deficit/hyperactivity disorder: a meta-analysis of randomized controlled trials across multiple outcome domains. *J Am Acad Child Adolesc Psychiatry.* 2014;53(8):835-847, 847 e831-835.
48. Matza LS, Margolis MK, Deal LS, Farrand KF, Erder MH. Challenges of Developing an Observable Parent-Reported Measure: A Qualitative Study of Functional Impact of ADHD in Children. *Value in Health.* 2017;20(6):828-833.

49. McGoey KE, DuPaul GJ, Eckert TL, Volpe RJ, Brakle JV. Outcomes of a Multi-Component Intervention for Preschool Children At-Risk for Attention-Deficit/Hyperactivity Disorder. *Child & Family Behavior Therapy.* 2005;27(1):33-56.
50. Rimestad ML, Trillingsgaard T, O'Toole MS, Hougaard E. Combining Parent and Teacher Training for Early ADHD: A Randomized Study of Effectiveness. *Journal of Child and Family Studies.* 2018;27(5):1567-1578.
51. Rescorla L, Achenbach T, Ivanova MY, et al. Behavioral and emotional problems reported by parents of children ages 6 to 16 in 31 societies. *Journal of Emotional and behavioral Disorders.* 2007;15(3):130-142.
52. Wymbs FA, Chen Y, Rimas HM, Deal K, Waschbusch DA, Pelham WE. Examining Parents' Preferences for Group Parent Training for ADHD When Individual Parent Training is Unavailable. *Journal of Child and Family Studies.* 2016:1-17.
53. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, for the CG. Extending the consort statement to randomized trials of nonpharmacologic treatment: Explanation and elaboration. *Annals of Internal Medicine.* 2008;148(4):295-309.

Appendix A: Supplementary data (Tables S1-S11, and SF1)

Table S1: Schedule of measures together with internal consistency coefficients of the scales used				
Assessment measures	**Timeline (weeks)**			**Cronbach's α (reliability coefficient)**
	Baseline (T1)	**12 (T2)**	**36 (T3)**	
Primary Outcome Measure	x	x	x	
ADHD symptoms				
Preschool ADHD-RS (parent rated)	x	x	x	0.90
Secondary Outcome Measures				
ADHD symptoms				
Preschool ADHD-RS (teacher rated)	x	x	x	0.93
Child solo play – observation measure	x	x	x	NA
Behavioral symptoms				
SDQ P2-4 & P4-16 – (parent rated)				
Conduct subscale	x	x	x	0.73
SDQ T2-4 & T4-16 – (teacher rated)				
Conduct subscale	x	x	x	0.81
Parent ADHD				
The Adult ADHD self-report scale (ASRS-V1.1)	x			
Perceived parenting				
Parenting Sense of Competence Scale (PSOC)				
Efficacy	x	x	x	0.78
Competence	x	x	x	0.77
Family Strain Index (FSI)	x	x	x	0.86
Positive and constructive parenting				
Global Impressions of Parent-Child Interactions (GIPCI: (Jigsaw/Tidy up/Freeplay)) observation measure	x	x	x	NA
Note: ADHD-RS: ADHD Rating Scale; SDQ: Strength and Difficulties Questionnaire.				

Table S2: Proportion of adult/s attending New Forest Parenting (NFPP) sessions

Participant	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Both biological parents[a]	58 %	62.5 %	63.6 %	65.9 %	54.5 %	58 %
Biological mother[b]	30.6 %	28.4 %	28.4 %	22.7 %	32.9 %	28.4 %
Biological father only	5.7 %	3.4 %	2.3 %	4.5 %	5.7 %	4.5 %
Foster parents[c]	3.4 %	3.4 %	3.4 %	3.4 %	3.4 %	2.3 %
Attendants not registered	2.3 %	2.3 %	2.3 %	3.4 %	3.4 %	6.8 %

[a] includes both biological parents and other person (i.e. professional)
[b] includes biological mother and other person (e.g. stepfather, friend, grandparent)
[c] Includes foster mother only + foster parents and other person (e.g. professional)

Table S3: Characteristics at time of ADHD diagnosis among 88 children randomized to New Forest Parenting Pro children randomized to Treatment as Usual (TAU)

		NFPP
Year of diagnosis		
	2012	15
	2013	29
	2014	44
Site		
	1 (Risskov)	50
	2 (Herning)	9
	3 (Glostrup)	29
Child: Clinical ADHD diagnosis		
	F90	84
	F98.8	5
Age		
	3-5yrs	49
	6-7yrs	39
Sex		
	Girls	27
	Boys	61
Living arrangement		
	Single parent	>25
	Both parents	58
	Foster or Unknown	<5
Registered mother [a]		
	Biological mother	84
Registered father[a]		
	Biological father	59
Mother's highest education level[a]		
	Elementary school- first 10 years	12
	High School level - 10 to 13 years	41
	Bachelor or Higher	30
Father's highest education level[a]		
	Elementary school-first 10 years	10
	High School level - 10 to 13 years	33
	Bachelor or Higher	16
	Not applicable	29
Mother employed[a]		69
Father employed[a]		56
Family gross income (1000 €)[b]		
	<=50	19

50-75	11
75-100	29
>100	21
Mother ever recieved a psychiatric diagnosis[a]	19
Father ever recieved a psychiatric diagnosis[a]	12
Mother's[a] age mean (sd)	36.1 (5.5)
Father's[a] age mean (sd)	38.6 (4.9)
Parent ASRS-score. n:mean(sd)	84: 7.24 (5.45)
Child conduct (SDQ parent rated) n:mean(sd)	86: 4.78 (2.44)

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; ASRS: Adult Self Report Scale; SDQ: Strength and Questionnaire

[a]values are given for the parents living with the child

[b]of the child's family

Table S4: Comorbid diagnoses (ICD-10[a]) at baseline for both groups

Comorbid diagnoses (ICD-10[a])	
Oppositional defiant disorder/conduct disorder (F91.x; F92.x)	
Emotional disorders (F93)	
Disorders of social functioning (F94.x)	
Tic disorders (F95)	
Other behavioral and emotional disorders (F98.x)	
Specific developmental disorders (F80-F89 (excluding F84))	
Borderline intellectual functioning (R41.83: IQ =70-84)	

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual

[a]International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) WHO behavioural disorders.

Table S5: Results of moderator analyses on the primary outcome (ADHD-RS-parent rated)

		Change from T1 to T2		
	Number of children	NFPP vs TAU	NFPP vs TAU	
Moderator		**Adjusted mean (95% CI)[a]**	**p-value[b]**	
Gender				
Boy	117	-1.71 (-4.17; 0.75)	0.173	-
Girl	44	-5.70 (-9.82; -1.59)	0.007	-
Difference	161	-3.99 (-8.79; 0.80)	0.103	-
Single Parent				
Yes	49	-1.10 (-4.93; 2.74)	0.576	-
No	112	-3.57 (-6.08; -1.05)	0.006	-2
Difference	161	-2.47 (-7.06; 2.12)	0.291	-
ASRS-score of the parent				
Per unit	156	-0.10 (-0.49; 0.30)	0.633	(
SDQ Conduct-score (parent rated) at T1				
Per unit	161	0.10 (-0.74; 0.94)	0.818	(

Note: ADHD-RS: ADHD Rating Scale; NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; C
Self Report Scale; SDQ: Strength and Difficulties Questionnaire

[a] Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child

[b] Wald test, 1 df.

Table S6: Adjusted[a] mean changes among 88 children randomized to New Forest Parenting Programme as Usual (TAU)

	Outliers (2.5SD) exclude				
	Change from T1 to T2				
	NFPP	TAU	NFPP vs TAU	p-value	NFPP
Measure	Adjusted mean (95% CI)				Adju
Primary outcome					
ADHD-RS-Parent					
Total	-4.50 (-5.79; -3.22)	-1.45 (-2.89; -0.00)	-3.06 (-4.99; -1.13)	0.0019	-4.21 (-5.51; -2.90)
Secondary outcome					
ADHD-RS-Teacher					
Total	-2.23 (-4.11; -0.36)	-1.16 (-3.27; 0.94)	-1.07 (-3.89; 1.75)	0.4569	-1.88 (-3.81; 0.05)
SDQ-Parent					
Conduct	-0.85 (-1.22; -0.48)	-0.38 (-0.80; 0.03)	-0.46 (-1.02; 0.09)	0.1008	-0.86 (-1.23; -0.48)
SDQ-Teacher					
Conduct	-0.82 (-1.30; -0.34)	-0.21 (-0.74; 0.32)	-0.61 (-1.32; 0.11)	0.0955	-0.50 (-0.99; 0.00)
GIPCI-Parent					
Average per item	0.07 (0.01; 0.14)	0.04 (-0.03; 0.11)	0.03 (-0.06; 0.13)	0.5291	0.07 (0.00; 0.13)
GIPCI-Child					
Average per item	-0.03 (-0.10; 0.04)	-0.04 (-0.12; 0.04)	0.01 (-0.10; 0.11)	0.9029	0.02 (-0.05; 0.09)
PSOC					
Efficacy	1.63 (0.85; 2.40)	-0.48 (-1.35; 0.38)	2.11 (0.95; 3.27)	0.0004	1.88 (1.11; 2.65)
Satisfaction	1.44 (0.24; 2.64)	-0.40 (-1.72; 0.93)	1.84 (0.05; 3.63)	0.0436	1.14 (-0.06; 2.33)
FSI					
Total	-1.25 (-1.98; -0.53)	0.14 (-0.67; 0.95)	-1.39 (-2.48; -0.30)	0.0121	-1.33 (-2.06; -0.60)
Child solo play					
Switches	-0.10 (-1.53; 1.32)	0.48 (-1.13; 2.09)	-0.58 (-2.73; 1.57)	0.5958	0.57 (-0.86; 1.99)

Note: CI: Confidence Interval; NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; ADHD-RS Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of
[a] Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child
[b] Total number of observations in the analysis when outliers excluded.

Table S7: Adjusted[a] mean changes among 88 children randomized to New Forest Parenting Programme Treatment as Usual (TAU)

Sensitivity analysis 1	NFPP	0.2[a] sd added to predicted	TAU

	Change from T1 to T2				
	NFPP	TAU	NFPP vs TAU	p-value	NFPP
Measure	Adjusted mean (95% CI)				Adj
Primary outcome					
ADHD-RS-Parent					
Total	-4.29 (-5.59; -2.99)	-1.46 (-2.86; -0.06)	-2.83 (-4.74; -0.91)	0.0038	-4.53 (-5.83; -3.22)
Secondary outcome					
ADHD-RS-Teacher					
Total	-2.14 (-3.97; -0.32)	-1.05 (-3.01; 0.92)	-1.10 (-3.78; 1.58)	0.4218	-1.70 (-3.53; 0.12)
SDQ-Parent					
Conduct	-0.74 (-1.10; -0.39)	-0.38 (-0.76; -0.01)	-0.36 (-0.88; 0.16)	0.1733	-0.76 (-1.11; -0.41)
SDQ-Teacher					
Conduct	-0.70 (-1.17; -0.24)	-0.22 (-0.72; 0.28)	-0.48 (-1.16; 0.20)	0.1696	-0.54 (-1.01; -0.08)
GIPCI-Parent					
Average per item	0.07 (0.02; 0.13)	0.04 (-0.02; 0.10)	0.03 (-0.05; 0.12)	0.4469	0.07 (0.01; 0.13)
GIPCI-Child					
Average per item	0.00 (-0.07; 0.07)	-0.04 (-0.12; 0.03)	0.05 (-0.05; 0.15)	0.3509	0.05 (-0.02; 0.12)
PSOC					
Efficacy	1.68 (0.93; 2.43)	-0.17 (-0.97; 0.64)	1.85 (0.75; 2.95)	0.0010	2.06 (1.31; 2.81)
Satisfaction	1.53 (0.38; 2.69)	-0.39 (-1.63; 0.85)	1.92 (0.23; 3.62)	0.0263	1.32 (0.16; 2.47)
FSI					
Total	-1.42 (-2.13; -0.71)	-0.02 (-0.78; 0.75)	-1.40 (-2.45; -0.36)	0.0086	-1.32 (-2.03; -0.61)
Child solo play					
Switches	0.05 (-1.57; 1.67)	1.63 (-0.12; 3.37)	-1.57 (-3.95; 0.81)	0.1948	0.41 (-1.21; 2.03)

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; CI: Confidence Interval; ADHD-RS
Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of
[a] Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child
[b] Total number of observations including imputed values

Table S8: Adjusted[a] mean changes among 88 children randomized to New Forest Parenting Programme
Treatment as Usual (TAU)

Sensitivity analysis 2	NFPP	0.2[a] sd Subtracted from predicted	TAU

Measure	Change from T1 to T2				
	NFPP	TAU	NFPP vs TAU	p-value	NFPP
	Adjusted mean (95% CI)				Adju
Primary outcome					
ADHD-RS-Parent					
Total	-4.32 (-5.63; -3.02)	-1.46 (-2.86; -0.06)	-2.86 (-4.78; -0.95)	0.0034	-4.61 (-5.92; -3.31)
Secondary outcome					
ADHD-RS-Teacher					
Total	-2.30 (-4.12; -0.48)	-1.05 (-3.01; 0.91)	-1.25 (-3.93; 1.42)	0.3591	-2.01 (-3.83; -0.19)
SDQ-Parent					
Conduct	-0.75 (-1.11; -0.40)	-0.38 (-0.76; -0.01)	-0.37 (-0.89; 0.15)	0.1623	-0.79 (-1.14; -0.43)
SDQ-Teacher					
Conduct	-0.74 (-1.21; -0.28)	-0.22 (-0.72; 0.28)	-0.52 (-1.20; 0.17)	0.1375	-0.62 (-1.09; -0.16)
GIPCI-Parent					
Average per item	0.07 (0.01; 0.13)	0.04 (-0.02; 0.10)	0.03 (-0.05; 0.12)	0.4702	0.07 (0.01; 0.12)
GIPCI-Child					
Average per item	0.00 (-0.07; 0.07)	-0.04 (-0.12; 0.03)	0.05 (-0.06; 0.15)	0.3710	0.04 (-0.03; 0.11)
PSOC					
Efficacy	1.63 (0.88; 2.38)	-0.17 (-0.97; 0.64)	1.80 (0.70; 2.90)	0.0014	2.01 (1.26; 2.76)
Satisfaction	1.46 (0.30; 2.61)	-0.39 (-1.63; 0.85)	1.84 (0.15; 3.54)	0.0330	1.24 (0.08; 2.39)
FSI					
Total	-1.47 (-2.18; -0.75)	-0.02 (-0.78; 0.75)	-1.45 (-2.50; -0.40)	0.0066	-1.37 (-2.08; -0.66)
Child solo play					
Switches	-0.09 (-1.72; 1.53)	1.63 (-0.12; 3.37)	-1.72 (-4.10; 0.66)	0.1569	0.24 (-1.39; 1.86)

Note: New Forest Parenting Programme; TAU: Treatment as Usual; CI: Confidence Interval; ADHD-RS: ADH
Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of Competence
[a] Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child
[b] Total number of observations including imputed values

Table S9: Adjusted[a] mean changes among 88 children randomized to New Forest Parenting Programme
Treatment as Usual
(TAU)

Sensitivity analysis 3	NFPP	as predicted		TAU	

	Change from T1 to T2					
	NFPP	TAU	NFPP vs TAU	p-value	NFPP	
Measure	Adjusted mean (95% CI)				Adjus	
Primary outcome						
ADHD-RS-Parent						
Total	-4.31 (-5.61; -3.00)	-1.35 (-2.75; 0.05)	-2.96 (-4.87; -1.04)	0.0025	-4.57 (-5.87; -3.27)	
Secondary outcome						
ADHD-RS-Teacher						
Total	-2.22 (-4.04; -0.40)	-1.02 (-2.98; 0.94)	-1.21 (-3.88; 1.47)	0.3773	-1.85 (-3.68; -0.03)	
SDQ-Parent						
Conduct	-0.75 (-1.10; -0.40)	-0.35 (-0.73; 0.02)	-0.39 (-0.91; 0.12)	0.1352	-0.77 (-1.13; -0.42)	
SDQ-Teacher						
Conduct	-0.72 (-1.19; -0.26)	-0.21 (-0.71; 0.29)	-0.51 (-1.19; 0.17)	0.1440	-0.58 (-1.05; -0.12)	
GIPCI-Parent						
Average per item	0.07 (0.01; 0.13)	0.05 (-0.02; 0.11)	0.03 (-0.06; 0.11)	0.5499	0.07 (0.01; 0.13)	0
GIPCI-Child						
Average per item	0.00 (-0.07; 0.07)	-0.04 (-0.11; 0.04)	0.04 (-0.06; 0.14)	0.4447	0.04 (-0.03; 0.11)	0
PSOC						
Efficacy	1.66 (0.91; 2.41)	-0.10 (-0.91; 0.70)	1.76 (0.66; 2.86)	0.0017	2.04 (1.29; 2.79)	0
Satisfaction	1.50 (0.34; 2.65)	-0.29 (-1.53; 0.95)	1.78 (0.09; 3.48)	0.0394	1.28 (0.12; 2.43)	0
FSI						
Total	-1.44 (-2.16; -0.73)	0.05 (-0.72; 0.81)	-1.49 (-2.54; -0.44)	0.0053	-1.35 (-2.06; -0.63)	0
Child solo play						
Switches	-0.02 (-1.64; 1.60)	1.83 (0.08; 3.57)	-1.85 (-4.23; 0.54)	0.1290	0.32 (-1.30; 1.94)	0

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; CI: Confidence Interval; ADHD-RS
Difficulties Questionnaire; ; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense o
[a] Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child
[b] Total number of observations including imputed values

Table S10: Adjusted[a] mean changes among 88 children randomized to New Forest Parenting Programm Treatment as Usual (TAU)

Sensitivity analysis 4	NFPP as predicted			TAU	
	Change from T1 to T2				Cl
	NFPP	TAU	NFPP vs TAU		NFPP	
Measure	Adjusted mean (95% CI)			p-value	Adjuste	
Primary outcome						
ADHD-RS-Parent						
Total	-4.31 (-5.61; -3.00)	-1.57 (-2.98; -0.17)	-2.73 (-4.65; -0.82)	0.0052	-4.57 (-5.87; -3.27)	-2
Secondary outcome						
ADHD-RS-Teacher						
Total	-2.22 (-4.05; -0.40)	-1.08 (-3.04; 0.89)	-1.15 (-3.83; 1.54)	0.4024	-1.85 (-3.68; -0.03)	-2
SDQ-Parent						
Conduct	-0.75 (-1.10; -0.40)	-0.41 (-0.79; -0.04)	-0.33 (-0.85; 0.18)	0.2061	-0.77 (-1.13; -0.42)	-0
SDQ-Teacher						
Conduct	-0.72 (-1.19; -0.26)	-0.23 (-0.73; 0.27)	-0.49 (-1.17; 0.20)	0.1624	-0.58 (-1.05; -0.12)	-0
GIPCI-Parent						
Average per item	0.07 (0.01; 0.13)	0.03 (-0.03; 0.10)	0.04 (-0.05; 0.13)	0.3764	0.07 (0.01; 0.13)	0.0
GIPCI-Child						
Average per item	0.00 (-0.07; 0.07)	-0.05 (-0.13; 0.02)	0.06 (-0.05; 0.16)	0.2878	0.04 (-0.03; 0.11)	0.0
PSOC						
Efficacy	1.66 (0.91; 2.41)	-0.23 (-1.04; 0.58)	1.89 (0.79; 2.99)	0.0008	2.04 (1.29; 2.79)	0.5
Satisfaction	1.50 (0.34; 2.65)	-0.49 (-1.73; 0.75)	1.98 (0.29; 3.68)	0.0218	1.28 (0.12; 2.43)	0.4
FSI						
Total	-1.44 (-2.16; -0.73)	-0.08 (-0.84; 0.69)	-1.37 (-2.41; -0.32)	0.0106	-1.35 (-2.06; -0.63)	0.1
Child solo play						
Switches	-0.02 (-1.64; 1.60)	1.43 (-0.32; 3.17)	-1.45 (-3.83; 0.93)	0.2328	0.32 (-1.30; 1.94)	0.1

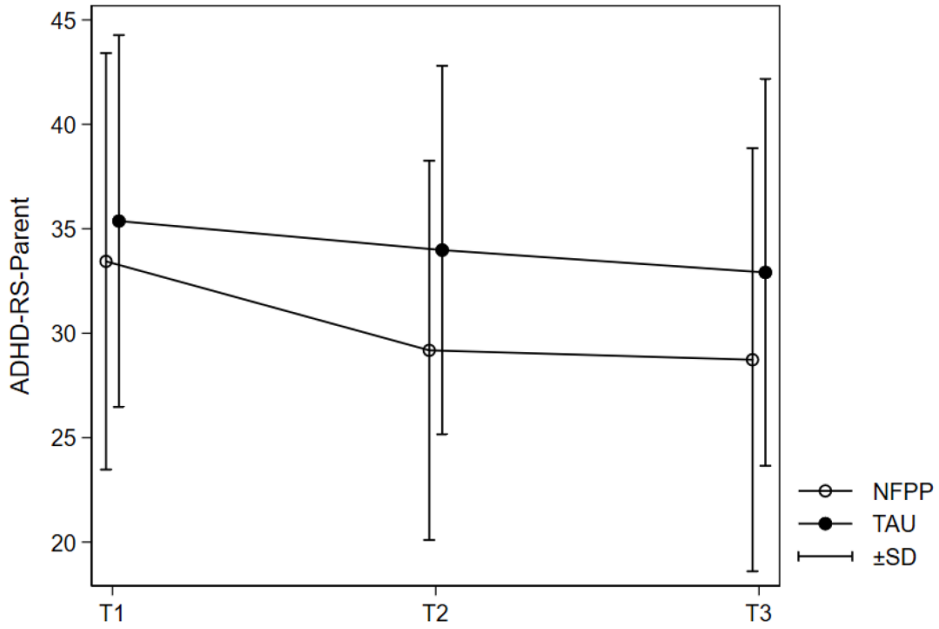
Tabel S11: Study effect sizes

			Adjusted estimates / Standard deviation at T1			
			Change from T1 to T2		Change from T1 to T3	
			NFPP vs TAU		NFPP vs TAU	
Primary outcome			**Mean (95% CI)**	**p-value**	**Mean (95% CI)**	**p-valu**
	ADHD-RS-Parent					
		Total	-0.30(-0.53; -0.08)	0.009	-0.25(-0.47; -0.02)	0.03
Secondary outcome						
	ADHD-RS-Teacher					
		Total	-0.10(-0.37; 0.17)	0.457	0.06(-0.22; 0.35)	0.66
	SDQ-Parent					
		Conduct	-0.15(-0.38; 0.09)	0.212	-0.13(-0.36; 0.10)	0.26
	SDQ-Teacher					
		Conduct	-0.17(-0.43; 0.10)	0.219	0.01(-0.27; 0.29)	0.95
	GIPCI-Parent					
		Average score per item	0.10(-0.24; 0.44)	0.517	0.10(-0.24; 0.44)	0.58
	GIPCI-Child					
		Average score per item	0.15(-0.22; 0.50)	0.420	0.00(-0.37; 0.34)	0.95
	PSOC					
		Efficacy	0.32(0.10; 0.53)	0.004	0.24(0.03; 0.45)	0.02
		Satisfaction	0.27(0.00; 0.54)	0.051	0.10(-0.17; 0.37)	0.45
	FSI					
		Total	-0.29(-0.53; -0.05)	0.017	-0.31(-0.55; -0.07)	0.01
	Child solo play					
		Switches	-0.30(-0.78; 0.19)	0.230	-0.01(-0.49; 0.47)	0.97

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; ADHD-RS: ADHD Rating Scale; SDQ: Strength and Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of Competence; FSI: Family Strain Index

Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual; CI: Confidence Interval; ADHD-RS Difficulties Questionnaire; GIPCI: Global Impressions of Parent-Child Interactions; PSOC: Parenting Sense of
[a]Adjusted for gender, center, age, and year of inclusion using a mixed model with a random level for each child imputed values

Supplementary figure 1: Changes in parent-rated mean scores for New Forest Parenting Programme (NFPP) and Treatment as Usual (TAU)



Note: NFPP: New Forest Parenting Programme; TAU: Treatment as Usual