European Child & Adolescent Psychiatry (2019) 28:165–175
https://doi.org/10.1007/s00787-018-1144-x

ORIGINAL CONTRIBUTION

Efficacy of individualized social competence training for children with oppositional defiant disorders/conduct disorders: a randomized controlled trial with an active control group

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Received: 16 August 2017 / Accepted: 9 March 2018 / Published online: 28 March 2018

Abstract

Patient-focused cognitive-behavioral therapy in children with aggressive behavior, which uses group-based social skills training, has resulted in significant reductions in behavioral problems, with effect sizes in the small-to-medium range. However, effects of individually delivered treatments and effects on aggressive behavior and comorbid conditions rated from different perspectives, child functional impairment, child quality of life, parent–child relationship, and parental psychopathology have rarely been assessed. In a randomized controlled trial, 91 boys aged 6–12 years with a diagnosis of oppositional defiant disorder/conduct disorder and peer-related aggression were randomized to receive individually delivered social competence training (Treatment Program for Children with Aggressive Behavior, THAV) or to an active control involving group play that included techniques to activate resources and the opportunity to train prosocial interactions in groups (PLAY). Outcome measures were rated by parents, teachers, or clinicians. Mostly moderate treatment effects for THAV compared to PLAY were found in parent ratings and/or clinician ratings on aggressive behavior, comorbid symptoms, psychosocial impairment, quality of life, parental stress, and negative expressed emotions. In teacher ratings, significant effects were found for ADHD symptoms and prosocial behavior only. THAV is a specifically effective intervention for boys aged 6–12 years with oppositional defiant disorder/conduct disorder and peer-related aggressive behavior as rated by parents and clinicians.

Keywords Social skills training · Oppositional defiant disorder · Conduct disorder · RCT design

Introduction

Parent training has been shown to be effective in the treatment of children with Oppositional Defiant Disorder or Conduct Disorder (ODD/CD), with marked effects on parent-rated child aggressive behavior mainly in the home [1]. However, effects on child social skills regarding their interactions with peers have only been found using child-based interventions [2]. Research indicates that different factors contribute to the development and maintenance of aggressive behavior; these factors include anger and aggression-provoking cognitions, irritability or affective dysregulation, deficits in social skills or problem solving, callous-unemotional traits, and interactions that reinforce aggressive behavior [3, 4]. The main drawbacks of group-based interventions for children with aggressive behavior are that they are not individually tailored to address problem-maintaining factors specific to each child. A group treatment makes it difficult to tailor the intervention individually

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00787-018-1144-x) contains supplementary material, which is available to authorized users.

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to the problem situations in which aggressive behavior is observed and the problem-maintaining factors that are specific to each child. This very time-consuming tailoring procedure is hard to implement in a group setting. Group formats usually, therefore, use a combination of interventions that address different problem-maintaining factors to help children to cope with problem behavior in standard problem situations. However, this approach may limit the effects of the intervention, especially in terms of their generalizability to behavioral problems in natural settings. Fossum et al. [5] showed in their meta-analysis of long-term treatment effects that individual treatments resulted in larger changes in aggressive behavior as compared to group treatments. Moreover, some studies show potential negative effects of group-based interventions in homogeneous groups of adolescents with aggressive behavior problems, which are interpreted as results of "deviancy training" [e.g., 6, 7]. Ang and Hughes [8] found in their meta-analysis that skills training interventions delivered in the context of groups consisting of only antisocial peers produced smaller benefits than did skills training interventions that avoided aggregating antisocial peers (i.e., groups comprised prosocial and antisocial youth or individual treatment). However, in nother meta-analysis, Weisz et al. [9] found no deviancy training effects overall. Moreover, in clinical practice, it is hard to arrange group treatment for children of similar ages and with similar behavioral problems.

Most of the treatment packages available and analyzed in previous studies [10, 11] focus primarily on improving child social skills using a combination of multiple cognitive-behavioral intervention techniques involving 16 sessions on average, which are mostly group-based. Only 7% of the studies analyzed in a meta-analysis by McCart et al. delivered individual sessions [12].

While the modest effects of child-based interventions compared to waiting-list controls are well established, only a minority of studies compared the intervention with an active control condition, with effect sizes for parent-rated aggressive behavior ranging from $d = -0.12$, favoring the control group, to $d = 0.69$, favoring the intervention group [13]. Several trials have found that combining patient-focused interventions with parent- or teacher-focused interventions may have clinically significant beneficial effects [2, 14, 15]. Therefore, the inclusion of parent interventions in child-focused treatments may enhance the effects of treatment.

Only a small number of studies have analyzed the effect of child-based CBT on measures of child functional impairment, child quality of life, parent–child relationships, or parental psychopathology. Kazdin et al. [15] found significantly stronger reductions in parental stress, depression, and overall psychopathology with a combination of child-based treatment and parent management training than with either intervention alone.

The present study investigates the efficacy of a social competence training program developed in Germany—the Treatment Program for Children with Aggressive Behavior (THAV) [16] in comparison to group play (PLAY) as an active control condition in boys, because the majority of patients with (peer-related) overt aggressive behavior are boys while girls more often use relational aggression [17]. Goertz-Dorten et al. [18] reported the results of a within-subject analysis, using a sample that overlaps with the sample of the current study, comparing the course during a waiting phase (with pre1 and pre2 assessment before and after waiting phase) and a subsequent treatment phase (with post-assessment) in 60 boys aged 6–12 years with ODD/CD and peer-related aggressive behavior. The authors found the training program to have marked effects on peer-related aggressive behavior, ODD symptoms, CD symptoms, problem-maintaining factors, and prosocial behavior as rated by parents, together with patient-rated disturbances in social interactions. This within-subject analysis demonstrated the effects of THAV in comparison with a no-treatment condition. The primary aim of the current analysis is to assess the efficacy of THAV in comparison to an active control condition on multiple outcome measures starting with pre2 assessment. Supplement 5 reports all data points for the primary outcome.

Methods

Ethical considerations

The protocol of the study conducted at the University of Cologne (Clinical trials.gov Identifier: NCT01406067) was approved by the ethics committee of the University Hospital, Cologne. The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All participants provided written informed consent.

Inclusion criteria, participant flow, and study design

Figure 1 describes the participant flow and the overall study design of the current RCT analysis and the within-subject analysis already published [18].

A total of 181 patients consecutively referred to the outpatient unit of the clinic and their parents were assessed for eligibility by research personnel according to the inclusion and exclusion criteria between January 2011 and January 2013 at Pre1/Pre2 assessment. Children were eligible for inclusion if they were boys aged 6–12 years with an IQ ≥ 80 (in the Culture Fair Intelligence Test) and an ICD-10 diagnosis of CD (F91), mixed disorder of conduct and emotions (F92), or hyperkinetic conduct disorder (F90.1) using the

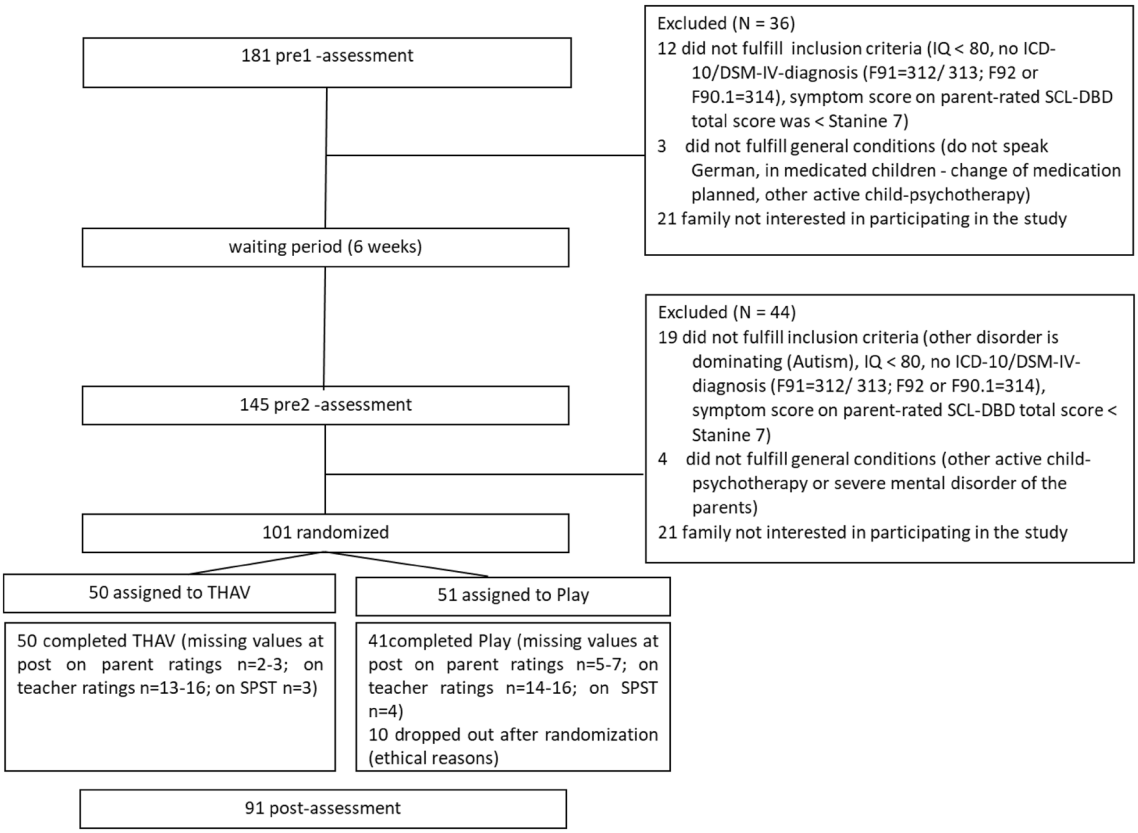

Fig. 1 Flow diagram of treatment study

semi-structured interview for Disruptive Behavior Disorders (ODD, CD) (DCL-DBD) of the German Diagnostic System for Children and Adolescents (DISYPS-II) [19]. Moreover, peer-related aggressive behavior had to cause persistent impairments in relationships with other children (clinical rating in the semi-structured interview) and the child had to have a high symptom score (Stanine score ≥ 7) on the German Symptom Checklist for Disruptive Behavior Disorder (SCL-DBD) total score of the DISYPS-II [19] at the pre-assessment. Exclusion criteria were the presence of a primary comorbid disorder (e.g., autism) according to the judgment of the clinician, a planned change in medication in a child receiving psychotropic medication, other child psychotherapy, and parents who do not speak German.

Thirty-six patients were excluded and 145 patients underwent a 6-week waiting period, after which Pre2 assessment was conducted (see Fig. 1). A further 44 patients were excluded because they did not fulfill the eligibility criteria at that assessment point. A total of 101 patients were randomized (50 THAV; 51 PLAY; block randomization with a block size of 4 and random selections from all 6 permutations). Ten patients dropped out from the PLAY condition after randomization due to ethical objections of the therapists (i.e., that active THAV treatment was necessary because of a risk of exclusion of the child from school due to behavioral problems). We decided to exclude these patients from further analysis in this RCT study because an imputation of missing values in this control group (e.g., with last observation carried forward) would have favored the treatment group (the ten patients who dropped out were included in the within-subject analysis with a total of 60 patients [18]). These ten patients which are excluded from PLAY did not differ statistically on the German Symptom Checklist for Disruptive Behavior Disorder (SCL-DBD) symptom score ($t = 1{,}20$, $df = 49$, $p = 0.237$) at pre-2. Besides these 10 patients, all other randomized patients completed the THAV and PLAY conditions.

In the current RCT analysis, we analyze 50 children in the THAV condition, who were also part of the within-subject analysis [18] of 60 children which analyzed their course during THAV treatment in comparison to a preceding waiting phase. In the present study, the data of Pre2 and Post are analyzed.

Interventions

In the current study, the treatment and control interventions were carried out by 13 experienced child therapists

or therapists in training. The same therapists administered the treatment and control interventions. The therapists received weekly group supervision by a senior child therapist (A.G-D).

THAV is a CBT intervention for children aged 6–12 years with peer-related overt aggressive behavior. It provides individualized treatment for problem-maintaining factors in specific daily life situations, which each respective child has experienced in previous weeks. Depending on the problem-maintaining factors specific to each individual, THAV aims to modify social-cognitive information processing, impulse control, social problem solving, social skills, and social interactions in these situations. It combines patient-, parent-, teacher-, and peer-focused interventions. Patient-focused interventions are the main component, and parent-, teacher-, or peer-focused interventions are added according to the individual needs of the patient. Treatment with THAV comprises 24 weekly child sessions (lasting 45 min each) and additional sessions or shorter contacts with parents. For a more detailed description of THAV, see electronic supplement 1.

The active control condition (PLAY) comprised educational group play, with 3–5 children in each group. Each group received 12 fortnightly sessions (lasting 90 min each) over 24 weeks. Techniques to activate resources and the opportunity to practice prosocial interactions in groups were utilized. During the group sessions, social play interactions and projects were offered that aimed to develop cooperative interaction (e.g., making a movie together, constructing game materials together and playing with them afterwards) or to provide the opportunity to practice socially competent ways of solving conflicts (e.g., sharing, negotiating). Children were supported to solve conflicts and to develop cooperative interactions, and were also praised for socially competent behavior and for their own general competencies (e.g., being good at sports). No specific problem-solving techniques (e.g., development of alternative solutions, evaluation of solutions) or other cognitive interventions (e.g., identification of anger thought) were implemented. Moreover, no skills training with role playing and rehearsal or interventions to support transfer to real life (e.g., therapeutic homework assignments) were provided. Parents attended two parent group sessions (90 min each), during which they received psychoeducation on appropriate general parenting strategies. However, these general parenting strategies were not tailored to the specific problems of the child and the parents were not trained to implement these techniques in their daily parenting behavior.

Assessments

For a detailed description of the assessment tools including their psychometric quality, see supplement 2. The semi-structured interview for Disruptive Behavior Disorders (including ODD and CD) (DCL-DBD) of the German Diagnostic System for Children and Adolescents (DISYPS-II) [19] rated by child therapists was used to assess all ODD and CD symptoms according to ICD-10 and DSM-IV criteria and to establish a diagnosis of conduct disorder.

For all subscale scores and scale scores of the following assessment instruments, mean standardized scores [(sum of item scores)/(number of items)] were calculated. Thus, the range of the scale scores is identical to the range of the item scores.

The Questionnaire for Aggressive Behavior of Children (FAVK) [20] was rated by parents and teachers to assess several maintaining factors of peer- and adult-related aggression: (1) disturbance of social-cognitive information processing (FAVK-Soc-Inf; e.g., thinks that many children do not like him and have hostile attitudes against him.); (2) disturbance of social skills (FAVK-Skills; e.g., beats or yells at other children, if somebody takes something away from him, because he does not know, what else to do.); (3) disturbance of impulse control (FAVK-Impulse; e.g., Knows alternative options to solve a conflict with other children instead of beating or offending, but is in the conflict situation not able to take control of it.); and (4) disturbance of social interaction (FAVK-Interact; e.g., often receives what he wants in disputes with other children.). The primary outcome of this study was the parent-rated peer-related aggression—total score consisting of 25 Items (FAVK-total (peer)).

The parent- and teacher-rated DISYPS-II Symptom Checklist for Disruptive Behavior Disorders (SCL-DBD) [14] was used to assess all ODD and CD symptoms according to ICD-10 and DSM-IV criteria as well as prosocial behavior. The Child Behavior Checklist for Ages 4–18 (CBCL 4–18) [21] and the Teacher Report Form for Ages 6–18 (TRF 6–18) [22] were used for the assessment of a broad spectrum of child behavioral and emotional problems as perceived by parents and teachers, respectively. Further rating scales were the DISYPS-II parent- and teacher-rated Symptom Checklist for attention deficit hyperactivity disorder (SCL-ADHD) [19] and the parent-rated Inventory of Callous-Unemotional Traits (ICU) [23], a modified version of the Weiss Functional Impairment Rating Parent Report (WFIRS-P-M) [24, 25], which is a German parent questionnaire for measuring health-related quality of life in children and adolescents (KINDL-P) [26].

The Depression Anxiety Stress Scale (DASS) [27, 28 German Version] is a self-report instrument for parents, which assesses symptoms of depression, anxiety, and stress on separate subscales. A Social Problem-Solving Test (SPST; Döpfner et al., 2013 unpublished manuscript, University of Cologne) assesses role-played socially competent and aggressive behavior as well as self-efficacy expectations and outcome

expectations of competent solutions and aggressive solutions in five specific conflict situations.

A modified version of the Five-Minute Speech Sample (FMSS-M) assesses expressed emotion as a measure of family emotional climate and requires family members to talk about their thoughts and feelings about the patient and their relationship for five uninterrupted minutes. The speech is recorded and later coded for the overall level of expressed emotion [29, 30].

Treatment integrity was rated by the therapist after each unit of THAV therapy using a newly developed integrity questionnaire that assessed the percentage of time spent on specific interventions of the THAV treatment program and the percentage of the THAV materials proposed for this specific unit that were used during treatment sessions. Moreover, the implementation of specific treatment components was rated by the therapist. Adherence of patients and parents to the intervention was rated separately by therapists after each session on five items assessing the degree of cooperation during sessions and compliance with therapeutic homework assignments.

Statistical analyses

The study sample size ($n = 100$; 50 in the THAV group, 50 in the PLAY group) was determined based on power calculations to detect a moderate effect size ($f \geq 0.25$) with 80% power using a two-tailed t test with type I error rate set to 0.05.

Missing values were identified for some outcome measures (e.g., some parents/teachers did not answer some questions/questionnaires). The ranges of missing values post-treatment for parent ratings, teacher ratings, or SPST in both groups are listed in Fig. 1. Missing values were imputed using the expectation maximization procedure, assuming a missing at random pattern. Intervention effects were estimated based on analysis of covariance (ANCOVA) with pre-treatment assessment as covariate. Specifically, we fitted linear mixed models accounting for nesting (PLAY condition: 3–5 patients in a group and participants within therapists) and heteroscedasticity [31]. Corresponding effect size estimates with 95% confidence intervals were derived from marginal means and standard errors, thus taking into account the baseline value and the hierarchical structure of the model [32]. Calculations were performed with SPSS Statistics 24 (IBM Corp.) [33]. Jacobson's Reliable Change Index was used to indicate clinically significant change.

Results

Patients in the THAV group ($n = 50$; mean age 8.88 years, SD 1.95) had the following distribution of ICD-10 diagnoses: 3.4% CD ($F_{91.1}$; $F_{91.2}$), 80% ODD ($F_{91.3}$), 1.7% mixed disorders of conduct and emotions ($F_{92.8}$), and 15% hyperkinetic conduct disorder ($F_{90.1}$). Patients in the PLAY group ($n = 41$; mean age 8.63 years, SD 1.74) had the following distribution of ICD-10 diagnoses: 2.5% CD (F91.1), 73.1% ODD ($F_{91.3}$), 2.5% mixed disorders of conduct and emotions ($F_{92.8}$), and 21.9% hyperkinetic conduct disorder ($F_{90.1}$). 12% of children in the THAV condition and 17% of children in the PLAY condition received psychotropic medication, which doesn`t change during the treatment period.

With regard to treatment integrity and treatment adherence, therapists indicated that they spent 88% of the total treatment time on specific modules of the THAV treatment program (detailed information see supplement 3). For the PLAY condition, only the general outlines of the intervention were given, indicating which interventions were/were not allowed. Therapists were supervised regularly and treatment integrity was rated globally as good to excellent by the supervisor.

Patient outcomes

Results of the ANCOVA including means and SDs as well as effect sizes are detailed in Table 1 (parent ratings), Table 2 (teacher ratings), and Table 3 (clinician ratings) for the main scales of each assessment tool. Results on the subscale level are reported in electronic supplement 4. Statistically significant effects favoring THAV were found on the reduction of peer-related aggression as rated by parents (primary outcome) and on most other scales assessing parental ratings of aggressive behavior and rule-breaking behavior, including callous-unemotional traits, social competencies, quality of life, parental psychopathology for the subscale stress (Table 1, supplement 4) as well as for child problem solving and parental negative expressed emotion (Table 3). Teacher-rated aggressive behavior was reduced in both treatment conditions, with a non-significant stronger reduction in THAV. Significantly stronger effects for THAV were found in the improvement of teacher-rated prosocial behavior and comorbid ADHD symptoms.

Clinical significance

According to the study inclusion criteria, all patients had high symptom scores (Stanine scores ≥ 7) prior to treatment on the parent-rated SCL-DBD total score. At post-assessment, 66% of patients in the THAV condition and 26% of patients in the PLAY condition had dropped below this cutoff (indicating normalization).

Jacobson's Reliable Change Index (RCI) was used to assess individual variations following treatment. It was found that 2.0% of patients in the THAV condition deteriorated, 32% did not change reliably, and 66.0% improved,

Table 1 Patient outcomes (parent ratings) on main scales; means and standard deviations for the outcome measures at the two assessment points, Cohen's *d* effect sizes and the results of the analysis of covariance (ANCOVA)

Scale[n]	Group	Descriptive statistics			Analysis of covariance (ANCOVA)			95% CI
		Mean (SD)[b] pre2	Mean (SD)[b] post	$d_{(pre2-post)}$	*F*	*p*	$d_{(THAV/PLAY)}$	
FAVK-total (peer)[25,a]	THAV	1.72 (0.42)	0.93 (0.40)	−1.49	2.17	0.043	−0.46	−0.2;−0.90
	PLAY	1.55 (0.44)	1.14 (0.51)	−0.81				
FAVK-total (adult)[25]	THAV	1.08 (0.39)	0.66 (0.40)	−1.01	1.42	0.171	−0.30	0.14;−0.74
	PLAY	1.13 (0.45)	0.82 (0.49)	−0.84				
SCL-DBD (ODD)[9]	THAV	1.95 (0.41)	1.04 (0.54)	−1.42	3.70	0.015	−0.61	−0.15;−1.08
	PLAY	1.92 (0.48)	1.49 (0.63)	−0.86				
SCL-DBD (CD)[16]	THAV	0.36 (0.18)	0.18(0.15)	−0.90	1.29	0.207	−0.27	0.16;−0.70
	PLAY	0.40 (0.35)	0.23(0.18)	−0.58				
SCL-DBD (prosocial behavior)[12]	THAV	1.60 (0.43)	1.91 (0.41)	0.83	2.01	0.048	0.42	0.84;0.00
	PLAY	1.57 (0.34)	1.73 (0.52)	0.37				
SCL-ADHD (total)[20]	THAV	1.27 (0.60)	0.95 (0.58)	−0.69	0.82	0.422	−0.17	0.26; −0.61
	PLAY	1.43 (0.58)	1.12 (0.56)	−0.58				
CBCL (total)[118]	THAV	0.45 (0.15)	0.27 (0.14)	−1.24	3.26	0.034	−0.57	−0.06; −1.09
	PLAY	0.45 (0.18)	0.35 (0.17)	−0.80				
CBCL (internalizing problems)[31]	THAV	0.40 (0.21)	0.22 (0.18)	−0.88	3.06	0.303	−0.28	0.52;−1.07
	PLAY	0.33 (0.22)	0.29 (0.23)	−0.20				
CBCL (externalizing problems)[33]	THAV	0.75 (0.24)	0.44 (0.22)	−1.25	2.91	0.030	−0.54	−0.06;−1.01
	PLAY	0.79 (0.29)	0.59 (0.28)	−0.88				
ICU (total)[24]	THAV	1.21 (0.33)	0.97 (0.34)	−0.86	2.24	0.029	−0.47	−0.05;−0.89
	PLAY	1.22 (0.31)	1.10(0.27)	−0.40				
WFIRS-P-M (total)[31]	THAV	1.11 (0.37)	0.58(0.40)	−1.18	2.14	0.040	−0.45	−0.02;−0.88
	PLAY	1.15 (0.47)	0.78 (0.42)	−0.89				
DASS (total)[42]	THAV	1.66 (0.42)	1.43 (0.33)	−0.53	1.83	0.077	−0.39	0.55;−0.82
	PLAY	1.75 (0.49)	1.59 (0.35)	−0.33				
KINDL-P (total)[24]	THAV	2.65 (0.41)	2.96 (0.45)	0.62	2.09	0.040	0.44	0.86;0.02
	PLAY	2.74 (0.40)	2.83 (0.41)	0.25				

DBD Disruptive Behavior Disorder, *CBCL* Child Behavior Checklist, *CD* Conduct Disorder, *DASS* Depression Anxiety Stress Scale, *FAVK* Questionnaire for Aggressive Behavior, ICU Inventory of Callous-Unemotional Traits, *KINDL-P* German parent questionnaire for measuring health-related quality of life in children and adolescents, *ODD* Oppositional Defiant Disorder, *PLAY* group play control ($n=41$), *SCL-ADHD* Symptom Checklist for Attention Deficit Hyperactivity Disorder, *SCL-DBD* Symptom Checklist For Disruptive Behavior Disorder, *THAV* Treatment Program for Children With Aggressive Behavior ($n=50$), *WFIRS-P* Weiss Functional Impairment Rating Parent Report

$d_{(pre2-post)}$ = effect sizes of pre2 − post changes in each group

$d_{(THAV/PLAY)}$ = effect size of THAV in comparison to PLAY

[n]Number of items

[a]Primary outcome measure

[b]Mean standardized scores = (sum of item scores)/(number of items); to calculate mean raw scores (and SD of mean raw scores), multiply mean standardized scores (SD of mean standardized scores) by number of items

while 0.0% of patients in the PLAY condition deteriorated, 70.7% did not change reliably and 29.3% improved. A Chi square test of the distribution of deteriorated or unchanged patients compared to improved patients showed a statistically higher percentage of improved patients in the THAV condition ($chi^2(1) = 12.16$, $p < 0.001$).

Discussion

The present study evaluated the efficacy of an individualized treatment program in boys aged 6–12 years with peer-related aggressive behavior and a diagnosis of ODD/CD. The THAV intervention was individually tailored to

Table 2 Patient outcomes(teacher ratings) on main scales; means and standard deviations for the outcome measures at the two assessment points, Cohen's *d* effect sizes and the results of the analysis of covariance (ANCOVA)

Scale[n]	Group	Descriptive statistics			Analysis of covariance(ANCOVA)			95% CI
		Pre2 Mean (SD)[a]	Post Mean (SD)[a]	$d_{(pre2–post)}$	*F*	*p*	*d*	
FAVK-total (peer)[25]	THAV	1.72 (0.52)	1.08 (0.50)	−1.16	1.21	0.209	−0.24	0.22;−0.69
	PLAY	1.62 (0.48)	1.22 (0.69)	−0.51				
FAVK-total (adult)[25]	THAV	1.01 (0.51)	0.62 (0.45)	−0.86	1.61	0.127	−0.34	0.11;−0.78
	PLAY	0.84 (0.46)	0.72 (0.50)	−0.21				
SCL-DBD (ODD)[9]	THAV	1.95 (0.52)	1.17 (0.58)	−1.55	1.92	0.134	−0.34	0.12;−0.79
	PLAY	1.78 (0.53)	1.33 (0.74)	−0.65				
SCL-DBD (CD)[16]	THAV	0.35(0.20)	0.15 (0.10)	−0.99	1.71	0.109	−0.36	0.09;−0.81
	PLAY	0.41 (0.36)	0.23 (0.17)	−0.52				
SCL-DBD (prosocial behavior)[12]	THAV	1.33 (0.37)	1.74 (0.40)	1.02	2.46	0.048	0.42	0.84;0.00
	PLAY	1.23 (0.41)	1.49 (0.38)	0.57				
SCL-ADHD (total)[20]	THAV	1.27 (0.61)	0.89 (0.50)	−0.81	2.45	0.027	−0.52	−0.07;−0.96
	PLAY	1.33 (0.58)	1.22 (0.57)	−0.18				
TRF (total)[117]	THAV	0.56 (0.21)	0.38 (0.18)	−1.17	0.81	0.429	−0.17	0.28;−0.62
	PLAY	0.55 (0.23)	0.41 (0.18)	−0.61				
TRF (internalized problems)[35]	THAV	0.30 (0.24)	0.22 (0.17)	−0.41	0.62	0.544	0.13	0.57;−0.31
	PLAY	0.29 (0.18)	0.19(0.14)	−0.48				
TRF (externalized problems)[34]	THAV	0.92 (0.30)	0.61 (0.27)	−1.08	1.11	0.282	−0.23	0.21;−0.68
	PLAY	0.91 (0.36)	0.68 (0.32)	−0.67				

DBD Disruptive Behavior Disorder, *CBCL* Child Behavior Checklist, *CD* Conduct Disorder, *DASS* Depression Anxiety Stress Scale, *FAVK* Questionnaire for Aggressive Behavior, *ICU* Inventory Of Callous-Unemotional Traits, *KINDL-P* German parent questionnaire for measuring health-related quality of life in children and adolescents, *ODD* Oppositional Defiant Disorder, *PLAY* group play control ($n=41$), *SCL-ADHD* Symptom Checklist for Attention Deficit Hyperactivity Disorder, *SCL-DBD* Symptom Checklist for Disruptive Behavior Disorder, *THAV* Treatment Program for Children with Aggressive Behavior ($n=50$), *WFIRS-P-M* Weiss Functional Impairment Rating Parent Report Modified

$d_{(pre2\text{-}post)}$ = effect sizes of pre2-post changes in each group

$d_{(THAV/PLAY)}$ = effect size of THAV in comparison to PLAY

[n]Number of items

[a]Mean standardized scores = (sum of item scores)/(number of items); to calculate mean raw scores (and SD of mean raw scores), multiply mean standardized scores (SD of mean standardized scores) by number of items

address problem-maintaining factors and the social situations in which the problem behavior occurred, which were specific to each participating child. In a randomized controlled trial, we assessed the effects of combined child- and parent-focused THAV treatment (consisting of 24 child treatment sessions and a mean of 8 parent sessions/contacts) in comparison to an active control group involving group play, which included techniques to activate resources and the opportunity to train prosocial interactions in groups.

The results show that THAV is specifically effective in the modification of aggressive and prosocial behavior compared to a group play intervention in terms of (1) reducing peer-related aggression as rated by parents (primary outcome) and (2) improving parent-rated child aggressive and rule-breaking behavior and prosocial behavior. Moreover, specific effects of THAV were found on aggressive and socially competent behavior and on socially competent solutions in a social problem-solving test. Similar to Kazdin et al. [34], we mostly found moderate effect sizes of this predominantly child-centered individually delivered intervention on aggressive behavior problems rated by parents compared to an active treatment control. By contrast, group-based interventions found either no or only small effects in comparison to active treatment controls or effects favoring the control treatment (ranging from $d=-0.38$ favoring the intervention group to $d=0.37$ favoring the control group) [35–39]. Overall, these results give hints that individualized treatment may be more intensive and, therefore, possibly more effective than group-based interventions in children with aggressive behavior problems as rated by parents.

The effects of THAV compared to PLAY on callous-unemotional traits are in line with those found by Kolko et al. [40] and Lochman et al. [41] for group-based interventions.

Table 3 Patient outcomes (clinician ratings) on main scales; means and standard deviations for the outcome measures at the two assessment points, Cohen's *d* effect sizes and the results of the analysis of covariance (ANCOVA)

Scale[n]	Group	Descriptive statistics			Analysis of covariance (ANCOVA)			95% CI
		Mean (SD)[a] Pre2	Mean (SD)[a] Post	$d_{(pre2-post)}$	*F*	*p*	*d*	
SPST								
Socially competent behavior[5]	THAV	4.80 (2.71)	6.38 (2.59)	0.52	3.42	0.021	0.66	1.18;0.13
	PLAY	5.15 (2.62)	4.78 (2.14)	−0.09				
Aggressive behavior[5]	THAV	5.60 (4.75)	3.49 (3.60)	−0.51	2.30	0.025	−0.50	−0.07;−0.94
	PLAY	4.46 (3.35)	4.68 (3.75)	0.04				
PECS[10]	THAV	1.29 (0.42)	1.49 (0.29)	0.62	2.22	0.031	0.53	1.02;0.05
	PLAY	1.33 (0.32)	1.35 (0.34)	0.12				
PEAS[10]	THAV	1.02 (0.43)	0.82 (0.48)	−0.28	1.30	0.202	−0.34	−0.19;−0.86
	PLAY	0.91 (0.40)	0.99 (0.44)	0.15				
FMSS-M								
Expressed emotion score[7]	THAV	1.12 (0.40)	0.76 (0.49)	−0.78	2.30	0.046	−0.51	−0.01;−1.04
	PLAY	1.03 (0.41)	1.00 (0.39)	−0.08				

FMSS-M Five-Minute Speech Sample-Modified, *SPST* Social Problem-Solving Test, *THAV* Treatment Program for Children with Aggressive Behavior ($n=50$), *PEAS* Positive Expectations of an Aggressive Solution, *PECS* Positive Expectations of a Competent Solution, *PLAY* group play control ($n=41$)

$d_{(pre2\text{-}post)}$ = effect sizes of pre2-post changes in each group

$d_{(THAV/PLAY)}$ = effect size of THAV in comparison to PLAY

[n]Number of items

[a]Mean standardized scores = (sum of item scores)/(number of items); to calculate mean raw scores (and SD of mean raw scores), multiply mean standardized scores (SD of mean standardized scores) by number of items

Despite the fact that children with ODD/CD also experience psychosocial impairment [42], the effects of treatment on psychosocial impairment have rarely been assessed. This study provides evidence that THAV has a specific effect on child psychosocial impairment as rated by parents, and extends the results of Kazdin et al. [15], who found an improvement in parent-rated social competence and teacher-rated adaptive functioning during combined parent management and social skills training in children with antisocial behavior. Moreover, Kazdin and Wassell [43] found changes in family functioning during the course of treatment of children with oppositional, aggressive and antisocial behavior.

In contrast to the findings of Kazdin et al. [33], we did not find that individualized therapy with THAV reduced internalizing problems as rated by parents. Moreover, parental stress was specifically reduced in the THAV group compared with the PLAY group, which extends the findings of Kazdin et al. [15], who reported a reduction in parental depression and stress during combined parent management and social skills training for children with antisocial behavior. Similar results were reported by Kazdin and Wassell [43].

Parental negative expressed emotion may play an important role in the development of ODD/CD in children [44, 45], and the modification of negative expressed emotion may be an important mediator of child-focused and parent-focused interventions. However, we identified only one previous study examining this factor, which found no convincing effects of treatment on negative expressed emotion [46]. The present study found that parental negative expressed emotions were specifically reduced by THAV.

Besides the effects on aggressive behavior as rated by parents, we also found THAV to have effects on role-play behavior and on a measure of social-cognitive problem solving, as also reported by Van Manen et al. [36]. Contrary to our expectations, increased problem solving had no mediating effect on aggressive behavior (Katzmann et al., submitted).

The results also show that THAV is specifically effective in modifying prosocial behavior as rated by teachers compared to a group play intervention. We also found a reduction of teacher-rated aggressive behavior during THAV, although this did not differ statistically significantly from the reduction during PLAY. Previous studies found no to large effects on teacher-rated aggressive behavior in comparison to active treatment controls, or favored the control treatment (effect sizes ranging from $d=-0.88$ favoring the intervention group to $d=0.55$ favoring the control group) [34–37, 47–50]. However, the results of the studies which found effects were of questionable validity, because patients were recruited via teachers

in schools, the treatments were conducted in schools, or the medication regimen or treatment setting were changed during the intervention.

Limitations This study has several strengths and limitations. One of the strengths is that the same therapists administered the treatment and control interventions which reduces error variance (i.e., therapist effect) and which is rarely controlled in treatment studies. Another strength is that we used linear mixed models accounting for nesting in the PLAY condition (groups of patients) and in the THAV condition (therapists). The effects in the analyses without nesting were stronger. Therefore, comparisons with previous studies should take this into account. Despite further advantages of having an active control group and the multimethod outcome design, several limitations have to be mentioned. First, the results are restricted to boys—the group with the highest prevalence rate of ODD/CD symptoms. Further research should also focus on girls. Second, a common limitation of intervention studies is the lack of blinded outcome assessment, which may cause expectancy effects. Parents could not be fully blinded because they took an active part in the intervention. However, parents were blinded to the specific hypotheses of the study and many of the parents in the PLAY condition actually believed that this was the intervention that was expected to be more effective. A third limitation lies in the lack of follow-up data, which are currently being collected. Fourth, ten patients dropped out from the PLAY condition after randomization because of ethical objections by the therapists. For these patients, the more effective treatment according to the hypotheses of the trial was strictly indicated according to the regulations of the ethics committee, which required that the patients must not be put at a disadvantage due to their participation in the trial. We decided to exclude these patients from further analysis because the alternative—an imputation of missing values in this control group (e.g., with last observation carried forward)—would have favored the treatment group and thus the research hypotheses.

Fifth, only the therapists monitored the adherence to the treatment protocol on a session-by-session basis in the THAV condition, and therapist self-ratings were not compared to a gold standard (for example videotaped and coded by an expert).

Finally, most outcome measures were parent ratings, which may be biased by expectancies of the parents. However, parents were not aware of the research hypotheses (i.e., which treatment was expected to be superior), and therefore, differences between the two active treatment conditions cannot be reduced to a bias. Moreover, effects were also found for blinded clinical ratings on social problem solving and expressed emotions measures as well as some teacher ratings.

Conclusion

Overall, the study found that an individually tailored treatment in boys with peer-related aggressive behavior that addresses specific problem-maintaining factors and the specific social situations in which the problem behavior occurs is effective in comparison to an active control condition in reducing parent-rated peer-related aggression, overall aggressive, rule-breaking behavior, callous-unemotional traits, comorbid symptoms and teacher-rated ADHD symptoms of the child, and in improving parent- and teacher-rated prosocial behavior as well as social skills and social-cognitive problem solving in a role-play test. Moreover, psychosocial impairment and quality of life were improved and parental stress and negative expressed emotions were reduced.

Acknowledgements The study received financial support from the School of Child and Adolescent Behavior Therapy at the University Hospital Cologne. The authors wish to thank all families that participated in this study.

Compliance with ethical standards

Conflict of interest AG.-D. and M.D. receive royalties from publishing companies as authors of books and treatment manuals on child behavioral therapy, and of assessment manuals, including the treatment manual for THAV, which is evaluated in this trial. Other authors have no potential conflicts of interest.

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