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# The Frankfurt early intervention program FFIP for preschool aged children with autism spectrum disorder: a pilot study

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**Abstract** Different early intervention programs, developed predominantly in the US, for preschool aged children with autism spectrum disorders (ASD) have been published. Several systematic review articles including a German Health Technology Assessment on behavioural and skill-based early interventions in children with ASD reported insufficient evidence and a substantial problem of generalisability to the German context. In Germany, approx. 2–5 h early intervention is supported by social services. Here, we report the results of a 1 year pre–post pilot study on a developmentally based social pragmatic approach, the Frankfurt Early Intervention program FFIP. In FFIP, individual 2:1, behaviourally and developmentally based therapy with the child is combined with parent training and training of kindergarten teachers. Treatment frequency is 2 h/week. Outcome measures were the Vineland Adaptive Behaviour Scales II (VABS), mental age and the ADOS severity score. Improvements after 1 year were observed for the VABS socialisation scale and the mental age quotient/IQ (medium effect sizes). Results are comparable with several other studies with a similar or slightly higher therapeutic intensity implementing comparable or different early intervention methods or programs. Compared to most high-intensity programs (30–40 h/week), lower cognitive gains were observed. Results have to be replicated and assessed by a randomized-controlled study before any final conclusions can be drawn.

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## Introduction

Different early intervention programs, developed predominantly in the US, for preschool aged children with autism spectrum disorders (ASD) have been published (Freitag 2010). A recent extensive review including meta-analyses summarized a multitude of behavioural and developmental interventions for ASD (Ospina et al. 2008). Interventions were sorted along a continuum, from a strong focus on behaviour approaches and highly structured therapies guided by a therapist to a more developmentally based social pragmatic approach where teaching follows the child's interests and is embedded in naturally occurring situations. Most early intervention studies were performed on high intensity (25–40 h/week) discrete trial training respective Lovaas based applied behavioural therapy approaches. These programs implement a 1:1 highly structured behaviourial training program with the child using discrete trial training including prompts, and operant conditioning techniques like shaping, chaining, discrimination training and contingency management. Meta-analysis resulted in improved outcome of these classical applied behavioural therapy approaches over special education settings with regard to overall intellectual functioning, adaptive behaviour, communication and interaction, as well as language expression and comprehension. Compared to a developmentally based autism-specific approach; however, no differences with regard to the improvement of communication skills were observed. Another systematic review reported improvements of IQ by intensive early behaviourally based intervention on a group, but not necessarily on

the individual level (Howlin et al. 2009), showing that some but not all children will show IQ gains with this kind of intervention. A recent German Health Technology Assessment on behavioural and skill-based early interventions in children with autism spectrum disorders stated, that "there are only a few studies with high methodology evaluating early interventions in children with autism" and that "based on the available studies, there is no sufficient evidence for any of the evaluated behavioural early intervention programmes". In addition, it found a "substantial problem of generalisability into the German context" (Weinmann et al. 2009), referring to the legal and financial framework of early intervention in Germany.

The most recent randomised controlled study on early intervention (The Early Start Denver Model, ESDM) in 48 toddlers with autism implemented a comprehensive developmental behavioural intervention that integrates applied behaviour analysis (ABA) with developmental and relationship-based approaches, and compared this to community intervention (Dawson et al. 2010). Therapy intensity in the ESDM group was on average 15 h/week therapist delivered intervention plus additional 16 h/week training with parents who used ESDM strategies. In addition, 5 h/week of other individual therapies was provided for the child. The control children from the community setting spent on average 9 h/week of individual therapy, and additional 9 h/week of group-based intervention. The community control group received heterogeneous interventions, including speech and language, occupational, and ABA-based therapy as well as special education settings. After 1 and 2 years of therapy, the ESDM group made better gains in non-verbal IQ, and also improved with regard to receptive language. Expressive language and adaptive behaviour improved over the course of 2 years only.

Another recent large scale randomised, controlled multicenter study implemented a parent–child interaction training to improve the child's communication and social interaction abilities (Green et al. 2010). Therapy intensity was much lower than in the ESDM trial (2 h every 2 weeks; daily home practice of 30 min/day). Thus, the reported lack of effect of the Parent-mediated communication-focused treatment in children with autism (PACT) on core autism symptoms after 1 year might be due not only to the different therapeutic approach or the autism diagnostic observation schedule-generic as outcome measure, but also to the lower intensity of the intervention. Similarly to PACT, the focus parent training for toddlers, a low-intensity parent training program, did not result in improved language and social communication skills compared with community treatment (Oosterling et al. 2010). On the other hand, a low-intensity discrete trial training ($\sim$6.5 h/week) supplementing preschool services for 3–6-year-old children with ASD and intellectual disability lead to improved cognitive and adaptive skills in the matched, but not randomized, treatment group (Peters-Scheffer et al. 2010).

In Germany, no study to date has evaluated the effect and clinical feasibility of early intervention programs for children with ASD. Dependent on the location of the family home, between 2 and 5 h of non-specific early intervention are provided for by social services, which results in a far lower therapy intensity compared to early intervention programs in the US. In Frankfurt am Main, Germany, we therefore set out to develop a developmentally based social pragmatic approach (FFIP) involving the child, the parents and the child's kindergarten into the therapeutic efforts within the restricted time frame of 2 h early intervention/week. In FFIP, the low intervention frequency is counterbalanced by intensive involvement of parents, nursery and kindergarten teachers into the therapeutic efforts. In addition, some children receive speech and language therapy. The program is currently manualized. The program focuses on pre-school children with ASD, aged 2–6 years old, but due to its individualized approach, older children also can be treated within the program. In FFIP, individual child therapy is combined with parent and teacher training, based on the above reported study results that parent training alone was of insufficient effectivity (Green et al. 2010; Oosterling et al. 2010).

At the beginning of the treatment, a detailed interview with the parents is carried out to get an overview of the child's preferences, resources and difficulties in everyday life. In addition, the results of the autism diagnostic observation schedule (ADOS), the IQ/developmental test, the Vineland Adaptive Behavior Scales II (VABS) and other questionnaires on additional behavioural problems, as e.g., hyperactive or oppositional behaviour, are used to define the starting point for intervention. Based on this information, psycho-education for the parents is provided, and a structured behavioural analysis of specific situations is carried out and discussed with the parents. A set of specific therapeutic targets and the corresponding therapeutic methods with respect to three settings: the therapeutic session with the child, parent-mediated training at home, and teacher-mediated training at nursery/kindergarten is established. After six individual therapy sessions with the child, the established targets are discussed in a second parent session, and—if necessary—are adapted to the child's current progress. Therapeutic targets focus on increasing social interaction, receptive and expressive language skills, non-verbal and verbal communication, and on reducing aberrant behaviours. Also, if necessary, daily living and academic skills are targeted. A first meeting at the nursery/kindergarten takes place after approx. 8–10

therapy sessions, where general ASD specific psychoeducation is provided, and the specific current targets are discussed. Also, specific therapeutic methods to support the child's progress are taught. As a rule, individual therapy sessions take place 2×/week, and parents are expected to take part in the therapy. Parent only sessions to reflect about the child's progress and to gradually adapt the therapeutic targets are scheduled every 6–8 weeks. Meetings with nursery/kindergarten teachers take place 3×/year, the first around 4–6 weeks, the second around 3–4 months, and the third around 7–9 months after start of the therapy within the first year. Achievement of therapeutic targets is continuously documented and discussed, and new targets are individually adapted throughout the duration of FFIP.

Child therapeutic sessions are regularly structured as follows. First, the two therapists visually introduce the structure of the following therapy session to the child. Then they start working with the child, repeating the latest trained behaviours, language or play abilities, and also in turn introducing new aspects. Intermittently, unstructured play is allowed to enhance the child's own initiative. One of the therapists is in front of the child, constantly interacting with her/him, and the second therapist supports the child with prompting etc. When the child has grasped the respective target ability and shows it by her/himself without prompting, the parents change with the interacting therapist, and learn to elicit the target behaviour from the child. When the child shows stable behaviour, the parents practice at least a third of the session. Parents are regularly given specific "homework" to practice the child's abilities at least for 1 h a day at home. In addition, parents are trained in naturally employing social reinforcement strategies in every day situations. In the second and third year of therapy, when the child starts to actively get involved with other children and is able to verbally communicate, 2–3 ASD children are included into a small group-based therapy 1×/week (with reduction of individual therapy to 1×/week with one therapist), to especially target social interaction and communication abilities with peers.

The Frankfurt early intervention program FFIP implements empirically based techniques which especially support receptive and expressive language abilities, improve social interaction and the child's motivation, and reduce stereotyped and repetitive behaviours and interests. The specific therapeutic methods, which are implemented in FFIP, are predominantly based on classical behavioural therapeutic approaches (Matson et al. 1996), with a strong emphasis on positive reinforcement and on methods to increase the child's motivation. At the start of therapy, predominantly the discrete trial format is used to help the children engage in learning (Freitag 2008; Peters-Scheffer et al. 2010). Whenever possible, elements of natural learning are implemented to increase the child's own initiative, motivation, and independence from therapeutic support. It has been shown that language acquisition is more successfully achieved by natural learning than by discrete trial training (Delprato 2001). Incidental teaching methods are used to create opportunities to elicit the use of social behaviour, and to support language acquisition. Social learning with parents and therapists as models is another important aspect of FFIP. Also, joint attention training is implemented into the program from the beginning. Several studies have shown an improvement of expressive language skills with joint attention training in children with ASD (Charman 2003; Kasari et al. 2008), and response to joint attention predicted language abilities during early and middle childhood in children with ASD (Siller and Sigman 2008). Intensive training of imitation abilities aims to promote (social) learning and language acquisition. Impaired imitation abilities have been replicated in ASD, and some studies discussed a correlation of impaired imitation and language abilities (Rogers et al. 2003). One small scale study reported improved language use after behaviourally based object and gesture imitation training (Ingersoll 2010). If children do not gain sufficient language by, first, training these non-verbal communication abilities, and second, incidental teaching and positive reinforcement of non-verbal and verbal communication attempts, sign language gestures and picture cards are also used to improve non-verbal communication abilities. The setting is highly structured by visual cues, visually based time schedules, and implementation of routines (greeting, saying good by, etc.), but also promotes functional play initiated by the child (Kasari et al. 2008). The therapy is implemented by psychotherapists extensively trained in behavioural therapy methods and approaches.

The aim of this pilot study was to assess the 1-year outcome of FFIP on mental age and adaptive behaviour in a pre-/post-study. We expected improvements with regard to mental age and the VABS socialisation scale. In addition, changes of the ADOS severity score (Gotham et al. 2009) and moderating factors on therapeutic effect were explored. As the present study lacks a control group, the results of FFIP training are first compared with the (younger) community control group of the ESDM training, who showed a similar age standardized early learning composite score of mean = 59 (SD = 9) but slightly better adaptive behaviour (VABS total scores = 70, SD 7) than our group at start of therapy. This is a conservative comparison, as better therapeutic gains would be expected in the younger ESDM comparison group, but not in the older treatment group of the current study. Second, the control sample of a Norwegian study (Eikeseth et al. 2002), who showed similar age (65 months, SD 11), IQ (65, SD 15) and VABS total scores (60, SD 13) distribution at start of the intervention, but included only children with IQ > 50, was

compared. This control group received a mean of 29 h/week of eclectic treatment, which comprised TEACCH-based approaches, sensory motor integration therapy and ABA approaches. None of the other recent controlled studies which assessed the children after approx. 1 year of therapy and used the VABS as outcome measure (Howard et al. 2005; Salt et al. 2002) showed comparable age standardized mental age as well as VABS total scores to our group at the start of therapy.

## Methods

### Sample

Ten male and three female children with ASD (T0 diagnosis autism $N = 10$, atypical autism $N = 2$, asperger syndrome $N = 1$) diagnosed according to ICD-10, and by ADI-R (Lord et al. 1994; Poustka et al. 1996) and ADOS (Bolte and Poustka 2004; Lord et al. 2000) took part in the study. Two children received neuroleptic medication during the course of the study (Aripiprazol 2.5 mg/day, Risperidon 1.5 mg/day). The study design was approved by the local ethical committee of the Medical Faculty at JW Goethe University Frankfurt.

Children were successively included into the study after having received an ASD diagnosis. Start of the therapy depended on the available capacity. Children with IQ $< 30$ or with a mental age below 18 months were excluded from the study. Other exclusion criteria were sensory impairments, cerebral palsy, epileptic seizures not treatable by antiepileptic therapy, other chronic neurological and motor disorder, severe psychosocial deprivation, insufficient care by parents, attachment disorder, and institutional upbringing.

### Clinical measures

Diagnosis (T0) was made according to ICD-10 by obtaining a detailed clinical history, by the autism diagnostic interview-revised (ADI-R) with the parents, and direct observation of the child by the ADOS module 1 or module 2, using WPS algorithms, as well as clinical judgement by an experienced clinician. Baseline assessment (T1) was done within 4 weeks prior to the start of therapy, and the follow-up assessment (T2) took place after 1 year (mean 12.2 months, min 9.7, max 14.0 months; Table 1). The assessments were done by researchers not involved in therapy.

The following measures were obtained at T1 and T2: mental age was measured either by the cognitive scale of the Bayley Scales II (Reuner et al. 2008) in children with a mental age below 30 or by the Snijders-Oomen non-verbal Intelligence Test 2½–7 (SON) (Tellegen et al. 2007). A mental age quotient was calculated by dividing mental age (months)/chronological age (months) multiplied by 100. Repeated IQ measures could only be obtained in children who were capable of passing the SON at T1 ($N = 10$). The correlation of the mental age quotient and the SON-IQ in this sample was $\rho = 0.97$ (T1) and $\rho = 0.96$ (T2), respectively. Due to the floor effect of the SON, two children with a SON-IQ $= 50$ showed a lower mental age quotient of 39 and 43, respectively, at the beginning of therapy (Table 2). Adaptive behaviour was assessed by the Vineland Adaptive Behaviour Scale II (VABS; parent rating) (Sparrow et al. 2005), using published US-American norms. In addition, the ADOS module 1 or module 2 was performed. To compare the results of the ADOS across modules, the standardized ADOS severity scores were calculated (Gotham et al. 2009), based on the revised ADOS algorithm, which combines two domains, i.e., "Social Affect" and "Restricted, Repetitive Behaviours" (Gotham et al. 2007).

### Statistics

For the outcome measures of interest, difference scores of T2−T1 measures were calculated. All difference scores were (approximately) normally distributed. $T$ tests were done as follows: for standardised measures, as the SON, the mental age quotient or the Vineland subscales, and the ADOS severity score the expected value was set to H0: $\mu = 0$, i.e., no change. In addition, for mental age, the expected value was set to H0: $\mu = 7.46$, as the children prior to start of the therapy had made a cognitive progress of on average 7.46 months/year [i.e., mental age (months)/chronological age (months) $\times$ 12] prior to therapy. To explore the influence of the length of the time interval between T1 and T2, the T2−T1 difference measure was additionally corrected for the time interval between the two measurements $X$ (months) as follows: T2−T1/$X \times 12$. Calculations were done on the uncorrected and the corrected difference value. In the tables, the results on the uncorrected difference (T2−T1) are shown; in the text, additionally the results of the corrected difference (T2−T1-corr) are reported. To compare the results of our study to two control groups (Dawson et al. 2010; Eikeseth et al. 2002), additionally the 1-year progress of these control groups with regard to the Mullen Scales of Early Learning composite score, which is a developmental quotient with a mean value =100 and SD = 15 (Dawson et al. 2010), or IQ measures obtained by different Wechsler or the revised Bayley Scales (Eikeseth et al. 2002), the VABS, and the ADOS severity score were used as comparison measures.

**Table 1** Descriptive data of the sample

| | Male *N* (%) | Female *N* (%) | Total *N* |
|---|---|---|---|
| Gender | 10 (77) | 3 (23) | 13 |
| Autism | 8 (80/males) | 2 (67/females) | 10 |
| Asperger syndrome | 1 (10/males) | 1 (33/females) | 2 |
| Atypical autism | 1 (10/males) | – | 1 |

| Full sample | Mean (SD) | Min | Max |
|---|---|---|---|
| At diagnosis (T0) | | | |
| Age at diagnosis (months) | 52.3 (13.8) | 27.9 | 76.4 |
| ADI-R social interaction (A) | 19.8 (4.5) | 15 | 28 |
| ADI-R non-verbal communication (B) | 9.6 (3.4) | 4 | 14 |
| ADI-R stereotyped behaviour (C) | 4.7 (2.7) | 1 | 11 |
| ADI-R onset criteria (D) | 4.0 (1.2) | 2 | 5 |
| ADOS M1 communication[a] ($N = 11$) | 5.5 (1.8) | 3 | 8 |
| ADOS M1 social interaction[a] ($N = 11$) | 10.6 (2.6) | 6 | 14 |
| ADOS M1 combined[a] ($N = 11$) | 16.2 (4.1) | 9 | 21 |
| ADOS M2 communication[a] ($N = 2$) | 7.0 (0) | 7 | 7 |
| ADOS M2 social interaction[a] ($N = 2$) | 10.5 (2.1) | 9 | 12 |
| ADOS M2 combined[a] ($N = 2$) | 17.5 (2.1) | 16 | 19 |
| ADOS M1 + M2 repetitive behaviour[a] ($N = 13$) | 2.6 (1.6) | 0 | 5 |
| ADOS severity score[b] ($N = 13$) | 6.8 (1.3) | 4 | 9 |
| At start of intervention (T1) | | | |
| Age at start of intervention (months) | 69.3 (15.2) | 47.5 | 91.6 |
| Mental age at start of intervention (months) | 40.9 (14.3) | 25 | 69 |
| quotient mental age/chronological age at start of intervention (*100) | 62.2 (23.9) | 35.4 | 107.7 |
| ADOS M1 communication[a] ($N = 9$) | 5.0 (1.7) | 2 | 7 |
| ADOS M1 social interaction[a] ($N = 9$) | 10.0 (1.4) | 8 | 12 |
| ADOS M1 combined[a] ($N = 9$) | 15.0 (2.2) | 11 | 19 |
| ADOS M2 communication[a] ($N = 4$) | 7.0 (1.8) | 5 | 9 |
| ADOS M2 social interaction[a] ($N = 4$) | 9.3 (2.2) | 7 | 12 |
| ADOS M2 combined[a] ($N = 4$) | 16.3 (3.4) | 13 | 21 |
| ADOS M1 + M2 repetitive behaviour[a] ($N = 13$) | 2.4 (1.2) | 0 | 4 |
| ADOS severity score[b] ($N = 13$) | 6.8 (0.8) | 6 | 8 |
| T2−T1 (months) | 12.2 (1.3) | 9.7 | 14.0 |

[a] WPS algorithm scores: separate algorithms for ADOS module 1 and ADOS module 2. The repetitive behaviour score is based on similar items in the ADOS module 1 and module 2

[b] Calculation of the severity score from Modules 1 and 2 was done according to Gotham et al. (2009), based on the revised ADOS algorithm, combining "Social Affect" and "Restricted Repetitive Behaviors" into one score (Gotham et al. 2007)

To explore possible moderating factors on therapy response, age at beginning of therapy, the mental age quotient at the beginning of therapy, the ADOS severity score and the ADOS WPS repetitive behaviour score (Items D1, D2, D4) at T1 were assessed as independent variables for their influence on the respective outcome measures of interest (change in mental age quotient, Vineland Scales, and ADOS severity score) by linear regression.

No adjustment for multiple testing was done, as the present study is a pilot study. Statistics were calculated by SAS 9.2 (SAS Institute Inc., Cary, NC, USA).

## Results

Descriptive data on the sample are shown in Table 1, individual data on each child are shown in Table 2. Children were diagnosed on average at age 4.4 (SD 1.2) years old and started therapy at a mean age of 5.8 (SD 1.3) years old. At start of the therapy (T1), 12 children met the criteria for autism, and one child met criteria for autism spectrum in the ADOS (WPS algorithm). The ADOS severity score (Gotham et al. 2009) was $\geq 6$, i.e., in the range of autism, in all children at T1. At T2, one child had moved to an ADOS

**Table 2** Children's individual data

| Child | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| T0 age (years) | 6.4 | 3.6 | 3.9 | 5.1 | 5.4 | 3.4 | 5.3 | 5.8 | 4.0 | 4.8 | 2.3 | 5.0 | 4.8 |
| T0 ADOS severity score | 7 | 7 | 9 | 4 | 8 | 6 | 8 | 6 | 6 | 8 | 6 | 8 | 6 |
| T1 age (years) | 7.2 | 4.0 | 4.4 | 6.4 | 6.4 | 4.0 | 7.6 | 6.7 | 5.2 | 7.0 | 4.4 | 5.8 | 5.4 |
| T1 ADOS severity scores | 8 | 8 | 7 | 6 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 8 | 6 |
| T1 mental age (months) | 67 | 37 | 25 | 43 | 46 | 50 | 36 | 40 | 25 | 29 | 36 | 29 | 69 |
| T1 mental age quotient | 78 | 77 | 47 | 56 | 60 | 106 | 39 | 50 | 41 | 35 | 67 | 43 | 108 |
| T1 SON-IQ | 77 | 73 | – | 50 | 57 | 107 | 50 | 50 | – | – | 58 | 50 | 108 |
| T1 VABS communication | 86 | 47 | 54 | 57 | 38 | 67 | 50 | 59 | 54 | 52 | 79 | 59 | 95 |
| T1 VABS socialisation | 76 | 57 | 65 | 59 | 48 | 53 | 50 | 70 | 57 | 63 | 85 | 57 | 55 |
| T1 VABS daily living | 103 | 58 | 71 | 60 | 46 | 60 | 66 | 77 | 64 | 66 | 89 | 60 | 101 |
| T1 VABS total score | 86 | 55 | 60 | 55 | 51 | 60 | 56 | 63 | 59 | 57 | 80 | 57 | 82 |
| T2 age (years) | 8.3 | 5.0 | 5.4 | 7.6 | 7.6 | 5.1 | 8.6 | 7.6 | 6.1 | 8.1 | 5.5 | 6.6 | 6.4 |
| T2 ADOS severity score | 7 | 8 | 9 | 6 | 7 | 8 | 6 | 7 | 6 | 7 | 4 | 10 | 7 |
| T2 mental age (months) | 74 | 58 | 34 | 53 | 68 | 67 | 47 | 40 | 35 | 32 | 56 | 23 | 83 |
| T2 mental age quotient | 76 | 95 | 52 | 58 | 76 | 111 | 45 | 43 | 48 | 33 | 86 | 43 | 108 |
| T2 SON-IQ | 82 | 95 | 50 | 54 | 79 | 112 | 50 | 50 | 50 | – | 87 | 50 | 108 |
| T2 VABS communication | 77 | 47 | 72 | 65 | 54 | 74 | 48 | 56 | 52 | 56 | 76 | 65 | 93 |
| T2 VABS socialisation | 85 | 53 | 63 | 62 | 62 | 59 | 51 | 73 | 63 | 53 | 95 | 70 | 61 |
| T2 VABS daily living | 100 | 51 | 66 | 73 | 55 | 75 | 62 | 66 | 69 | 66 | 100 | 58 | 93 |
| T2 VABS total score | 85 | 52 | 64 | 66 | 58 | 69 | 54 | 65 | 60 | 59 | 88 | 61 | 76 |

severity score in the Autism Spectrum (severity score = 4; see Table 2).

With regard to cognitive abilities (Table 3), an improvement of the mental age quotient (5 points) was observed, which relates to a medium effect (H0: $\mu = 0$, T2−T1 $p$ value 0.049, T2−T1-corr $p$ value 0.044). Mental age showed a mean increase of 11.4 months (H0: $\mu = 7.46$; T2−T1 $p$ value 0.062, T2−T1-corr $p$ value 0.094); however, large differences between no change in cognitive abilities (0 months) and increase of 22 months in mental age were observed. The SON-IQ, which at T1 could only be obtained in $N = 10$ children with a mental age $\geq$29 months at start of the therapy, also showed improvement (H0: $\mu = 0$; T2−T1 $p$ value 0.036, T2−T1-corr $p$ value 0.038; medium effect). Compared to the much younger control group of the ESDM study (Dawson et al. 2010), who were aged 23.1 (SD 3.9) months old at study entry and showed an IQ-increase of 4.4 IQ points in the first year, no difference was observed to the increase of the mental age quotient ($N = 13$, H0: $\mu = 4.4$, T2−T1 $p$ value 0.803, T2–T1-corr $p$ value 0.806) or of the SON IQ ($N = 10$, H0: $\mu = 4.4$, T2−T1 $p$ value 0.253, T2−T1-corr $p$ value 0.278). Compared to control group of the Norwegian study (Eikeseth et al. 2002), who showed an IQ-increase of 4.33 IQ points after 1 year, again, no difference was observed (mental age quotient: $N = 13$, H0: $\mu = 4.33$; T2−T1 $p$ value 0.780, T2−T1-corr $p$ value 0.812; SON IQ: $N = 10$, H0: $\mu = 4.33$, T2−T1 $p$ value 0.246, T2−T1-corr $p$ value 0.270).

With regard to adaptive behaviour (Table 3), FFIP increased socialisation abilities of the children (H0: $\mu = 0$, T2−T1 $p$ value 0.045, T2−T1-corr $p$ value 0.046; medium effect). A trend was observed also for the adaptive behaviour composite score (H0: $\mu = 0$, T2−T1 $p$ value 0.072, T2−T1-corr $p$ value 0.058; medium effect). Only small changes were seen with regard to the VABS communication scale (H0: $\mu = 0$, T2−T1 $p$ value 0.206, T2–T1-corr $p$ value 0.170; small effect), and no change in daily living skills was achieved (H0: $\mu = 0$, T2−T1 $p$ value 0.684, T2−T1-corr $p$ value 0.600). Compared to the younger control group of the ESDM study (Dawson et al. 2010), who partly showed a decline in abilities over 1 year of therapy, strong differences were observed (VABS socialisation scale H0: $\mu = -3.5$, T2−T1 $p$ value 0.002, T2−T1-corr $p$ value 0.002; VABS daily living skills H0: $\mu = -7.4$, T2−T1 $p$ value 0.004, T2−T1-corr $p$ value 0.005; VABS adaptive behaviour composite H0: $\mu = -6.3$, T2−T1 $p$ value $< 0.0001$, T2−T1-corr $p$ value $< 0.0001$). No effect was found for the VABS communication abilities, which were higher in the ESDM control sample than in the FFIP sample at start of therapy (H0: $\mu = 1.2$, T2−T1 $p$ value 0.446, T2−T1-corr $p$ value 0.349). Compared to the control group of the Norwegian study (Eikeseth et al. 2002), a trend for better communication and total adaptive

**Table 3** Child outcome after 1 year of therapy

| | T1<br>mean (SD)<br>min–max | T2<br>mean (SD)<br>min–max | T2-T1<br>mean (SD)<br>min–max | *t*-test<br>*p*-value | Effect size | ESDM[a]<br>control<br>group<br>*t* test<br>*p*-value | Norwegian<br>control<br>group<br>*t* test<br>*p*-value |
|---|---|---|---|---|---|---|---|
| Mental age ($N = 13$) | 40.9 (14.3) | 52.4 (17.0) | 11.4 (7.0) | H0: $\mu = 7.46$ | $d = 0.56$ | | |
| | 25–39 | 32–83 | 0–22 | $p = 0.062$ | | | |
| Quotient mental age/ chronological age ($N = 13$) | 62.2 (23.9) | 67.2 (26.3) | 5.0 (8.2) | H0: $\mu = 0$ | $d = 0.61$ | MSEL | IQ[b] |
| | 35.4–107.7 | 33.2–110.8 | −7.8–18.5 | $p = 0.049$ | | H0: $\mu = 4.4$ | H0: $\mu = 4.33$ |
| | | | | | | $p = 0.803$ | $p = 0.780$ |
| SON 2½–5 IQ ($N = 10$)[c] | 68.0 (23.0) | 76.7 (24.4) | 8.7 (11.1) | H0: $\mu = 0$ | $d = 0.78$ | MSEL | IQ[b] |
| | 50–108 | 50–112 | 0–29 | $p = 0.036$ | | H0: $\mu = 4.4$ | H0: $\mu = 4.33$ |
| | | | | | | $p = 0.254$ | $p = 0.246$ |
| VABS II communication ($N = 13$) | 61.3 (16.3) | 64.2 (13.7) | 2.9 (7.9) | H0: $\mu = 0$ | $d = 0.37$ | H0: $\mu = 1.2$ | H0: $\mu = -1.58$ |
| | 38–95 | 47–93 | −9–18 | $p = 0.206$ | | $p = 0.446$ | $p = 0.062$ |
| VABS II socialisation ($N = 13$) | 61.2 (10.6) | 65.4 (12.7) | 4.2 (6.8) | H0: $\mu = 0$ | $d = 0.62$ | H0: $\mu = -3.5$ | H0: $\mu = 8.5$ |
| | 48–85 | 51–95 | −10–14 | $p = 0.045$ | | $p = 0.002$ | $p = 0.044$ |
| VABS II daily living skills ($N = 13$) | 70.8 (17.2) | 71.8 (16.2) | 1.0 (8.6) | H0: $\mu = 0$ | d = 0.12 | H0: $\mu = -7.4$ | H0: $\mu = 5.5$ |
| | 46–103 | 51–100 | −11–15 | $p = 0.684$ | | $p = 0.004$ | $p = 0.085$ |
| VABS II total score ($N = 13$) | 63.2 (11.6) | 65.9 (11.1) | 2.8 (5.1) | H0: $\mu = 0$ | $d = 0.55$ | H0: $\mu = -6.3$ | H0: $\mu = 0.17$ |
| | 51–86 | 52–88 | −6–11 | $p = 0.072$ | | $p < 0.0001$ | $p = 0.088$ |
| ADOS severity score ($N = 13$) | 6.8 (0.8) | 7.1 (1.5) | 0.23 (1.4) | H0: $\mu = 0$ | $d = 0.17$ | H0: $\mu = 0.4$ | |
| | 6–8 | 4–10 | −3–2 | $p = 0.553$ | | $p = 0.663$ | |

*ADOS* autism diagnostic observation schedule, *max* maximum value obtained, *min* minimum value obtained, *MSEL* Mullen scales of early learning, *SD* standard deviation, *VABS* Vineland Adaptive Behavior Scales

[a] ESDM control group data for the 1 year of therapy obtained from Dawson et al. 2010. The children in the ESDM study were aged 23.1 (SD 3.9) months old at the beginning of therapy, and were matched with regard to quotient mental age/chronological age (=MSEL) and VABS II total score

[b] IQ (Norwegian sample) obtained by the Wechsler preschool scales-revised (WPPSI-R), the Wechsler scale for children-revised (WISC-R) or the Bayley Scales—revised

[c] The SON 2½–5 could only be obtained in children with a mental age >30 and an IQ measure of ≥50 (floor effect). The quotient mental age/chronological age is not affected by floor effects

behaviour by FFIP was observed (VABS communication scale H0: $\mu = -1.58$, T2−T1 $p$ value 0.062, T2−T1-corr $p$ value 0.058; VABS adaptive behaviour composite H0: $\mu = 0.17$; T2−T1 $p$ value 0.088, T2−T1-corr $p$ value 0.071), whereas a trend for less achievement in socialisation skills by FFIP was found (VABS socialisation scale H0: $\mu = 8.5$, T2−T1 $p$ value 0.044, T2−T1-corr $p$ value 0.088; VABS daily living skills H0: $\mu = 5.5$, T2−T1 $p$ value 0.085, T2−T1-corr $p$-value 0.124).

No change of the ADOS severity score by therapy was observed (H0: $\mu = 0$, T2−T1 $p$-value 0.553, T2−T1-corr $p$-value 0.500). When compared to the younger ESDM control children, who showed a slight increase in ADOS severity, again, no difference was present (H0: $\mu = 0.4$, T2−T1 $p$-value 0.663, T2−T1-corr $p$-value 0.727).

Lower age at the beginning of FFIP was predictive of more gains in the mental age quotient ($\beta = -0.48$, SE 0.16, $p = 0.014$, $N = 13$) and IQ ($\beta = -0.78$, SE 0.17, $p = 0.006$, $N = 10$). More repetitive behaviour at T1 predicted better gains in the mental age quotient ($\beta = 5.2$, SE 1.9, $p = 0.028$, $N = 13$) and IQ ($\beta = 8.1$, SE 1.8, $p = 0.006$, $N = 10$), but less improvement of the ADOS severity score ($\beta = -0.96$, SE 0.36, $p = 0.029$). None of the independent variables predicted gains in the VABS scales. The mental age quotient/IQ did not influence outcome, and no correlation of the mental age quotient and the VABS socialisation skills at T1 and T2 was found ($\rho < |0.09|$).

## Discussion

This pre–post pilot study of the FFIP shows that a relatively low frequent, but highly structured individual therapy with the child which essentially involves parents and also educates kindergarten teachers, and which emphasizes an autism-specific approach by focussing on joint attention, imitation and rule-based social learning as well as nonverbal and verbal communication abilities can improve socialisation skills as measured by the VABS in older preschool children with autism. Also, some cognitive gains were observed in this sample. Similar to previous reports (Howlin et al. 2009), variability in outcome was large.

Several previous studies on different methods and techniques of early intervention in preschool aged children with ASD have also implemented the VABS (first or second version) as outcome measure (Cohen et al. 2006; Dawson et al. 2010; Eikeseth et al. 2002; Eldevik et al. 2006, 2010; Fernell et al. 2011; Hayward et al. 2009; Howard et al. 2005; Magiati et al. 2007; Salt et al. 2002; Smith et al. 1997, 2000; Tsang et al. 2007; Valenti et al. 2010). Most of these studies showed a longer time interval of follow-up than 1 year (most often 2 years), and most therapy and control groups were not matched to our group with regard to age, IQ and VABS at start of therapy. The reported VABS changes are very heterogeneous from almost no effect in any of the VABS domain standard scores after 1 or 2 years of therapy (Fernell et al. 2011; Magiati et al. 2007) to medium to large effect sizes with regard to VABS communication (Eikeseth et al. 2002; Hayward et al. 2009; Howard et al. 2005; Smith et al. 2000; Tsang et al. 2007), socialisation (Eikeseth et al. 2002; Howard et al. 2005; Tsang et al. 2007), daily living skills (Eikeseth et al. 2002; Tsang et al. 2007) and the VABS total score (Eikeseth et al. 2002; Hayward et al. 2009; Howard et al. 2005). These different outcomes are likely due to the different characteristics of the included children with regard to age, mental abilities and adaptive behaviour at start of the intervention. In addition, different therapeutic techniques and a different application of comparable programs may have led to these different findings. With the exception of two studies (Dawson et al. 2010; Smith et al. 2000), none of the controlled studies was randomised. In addition, changes in the control groups also varied strongly from medium decreases in the standard scores to small improvements in the VABS domain standard scores.

The medium gains in the VABS socialisation standard score by FFIP are in line with the following studies, predominantly performed in younger children with ASD: a 1-year follow-up study implementing a relatively low frequency therapy of 8 h/2 weeks using comparable therapeutic techniques combined with a parent training (Salt et al. 2002); a 4-year follow-up study on intensive (25 h/week) classical applied behavioural therapy in children with IQ < 75 at intake (Smith et al. 2000); an intensive (36 h/week) classical applied behavioural therapy after 12 months (Hayward et al. 2009), and a naturalistic pre–post study on a community-based intervention (Valenti et al. 2010). Compared to the more intensive ESDM (Dawson et al. 2010), where the far younger treatment group showed a reduction of −3.8 in VABS socialisation skills, the effect of FFIP on the VABS socialisation standard score was significantly stronger. No difference to the Norwegian control group (Eikeseth et al. 2002) was observed. The inclusion criteria into that study differed from ours by including only children with an IQ ≥ 50 at start of therapy. Interestingly, in our study, the children with a mental age quotient ≥50 at start of therapy ($N = 8$) showed a higher VABS socialisation score increase of 6.1 points (T1−T2 difference corrected; SD 6.0) than the full sample ($N = 13$) value of 4.6 (T1−T2 difference corrected; SD 7.5). Therapeutic studies which reported a stronger increase in the VABS socialisation standard score of 8–10 points after 1 year of therapy as a rule implemented a far more intensive therapy of >30 h/week 1:1 training (Eikeseth et al. 2002; Howard et al. 2005; Tsang

et al. 2007). However, one study implementing such intensive classical applied behavioural therapy of 36 h/week achieved a similar increase in the treatment group with regard to the VABS socialisation standard score (5 points) as our study (Hayward et al. 2009).

In our pre–post pilot study, only a small effect on VABS communication standard score was observed. However, this effect was slightly stronger than in the age, IQ, and VABS matched Norwegian comparison group (Eikeseth et al. 2002). Also, compared to the Scottish Centre Program (Salt et al. 2002) which shows a comparable treatment intensity, gains by FFIP were stronger (Scottish Centre −5 points). Better gains with regard to the VABS communication standard score with a broad range of 5–19 points increase again were achieved with far more intensive classical applied behavioural therapy (Eikeseth et al. 2002; Hayward et al. 2009; Howard et al. 2005; Smith et al. 2000), ESDM (Dawson et al. 2010) or TEACCH-based approaches (Tsang et al. 2007).

No gains in VABS daily living skills were observed in our study. This specific profile (gains in socialisation, no gains in daily living skills) likely is due to the specific focus of FFIP on social interaction. In addition, daily living skills at intake were higher than communication and socialisation abilities in our sample. Still, compared to the younger ESDM therapy and control groups, who showed a decline of −5 and −7, respectively, in daily living skills, significant differences were observed (Dawson et al. 2010). The results of the more intensive classical applied behavioural therapy studies are very heterogeneous with higher gains (Eikeseth et al. 2002; Howard et al. 2005), no effect (Hayward et al. 2009) or even decline (Eldevik et al. 2006; Smith et al. 2000) of daily living skills.

A medium effect on the VABS adaptive behaviour composite also was achieved by FFIP, which was slightly higher than in the younger ESDM therapy and control sample (Dawson et al. 2010), and the Norwegian control sample (Eikeseth et al. 2002). Higher gains of 6–11 points increase in the adaptive behaviour composite were only found for highly intensive classical applied behavioural therapy programs (Eikeseth et al. 2002; Hayward et al. 2009; Howard et al. 2005). Other studies on highly intensive programs, however, did not report an increase in the adaptive behaviour composite after 1–5 years of therapy (Dawson et al. 2010; Fernell et al. 2011; Smith et al. 2000).

A limitation of implementing the VABS in this study is the lack of current German norms of this instrument. As the study was a pre–post study; however, this should have not influenced the results of the study, as the target measure was a difference measure.

Gains in the mental age quotient and IQ in our study (medium effect size) are comparable with other studies implementing either 12 h/week classical applied behavioural therapy in children with IQ < 80 (Eldevik et al. 2006) or a high frequency eclectic therapy (Howard et al. 2005). Stronger IQ gains in our study were achieved when compared to an intensive community-based early intervention, which resulted in a decline of 4.6 points, and a nursery program (no changes) after 2 years (Magiati et al. 2007). Still, the highly intensive classical applied behavioural therapy approaches reported far stronger gains in IQ measures of ≥15 IQ points (Eikeseth et al. 2002; Hayward et al. 2009; Howard et al. 2005; Smith et al. 2000), similar to the highly intensive ESDM (Dawson et al. 2010). This may reflect the strong focus of these programs on cognitive abilities. Taken together, it seems to be likely that larger IQ gains of ASD children by early intervention require a higher therapeutic frequency than the frequency of the FFIP. Longitudinally, IQ before age 5 years was predictive of better social interaction and communication abilities in adults with ASD (Billstedt et al. 2007; Howlin et al. 2004). Thus, early intervention programs in ASD should aim at increasing social interaction, communication and cognitive abilities in these children.

The use of IQ measures as a central outcome measure for the effect of early intervention in children with ASD has been questioned (Magiati and Howlin 2001) due to the following reasons: In small children with ASD, IQ measures are confounded by behavioural difficulties and receptive language problems. Also, the different developmental or IQ tests employed do not necessarily measure the same construct or the same cognitive abilities. Often, studies have used the Bayley Scales for the first assessment, and then a different IQ test during the second assessment, as we also had to do in our study due to the lack of a non-verbal developmental test with German norms for children aged below 30 months of age. Still, a majority of the children in our study received the same IQ measure at pre- and post-test, therefore, our findings are unlikely to be confounded by different measurement instruments. An advantage of using IQ tests as outcome measure when performed by blinded observers is their independence of rater effects.

In our study we also assessed the ADOS severity score obtained by blinded observers, which showed no effect on autism severity as obtained by this measure. The only other early intervention study using the ADOS-G as outcome measure showed some improvement on the ADOS-G algorithm score in the treatment group, but this did not differ from their control group (Green et al. 2010). This replicates findings from previous studies that by early intervention in ASD, especially adaptive behaviour and IQ can be improved but not necessarily autism-specific symptoms (Ospina et al. 2008). In addition, the ADOS is a diagnostic instrument, which was developed to diagnose ASD, but not to monitor treatment response.

Lower age at the beginning of therapy was predictive of more gains in mental age and IQ in the present study. This also might explain different study results with regard to IQ improvement of our and previous studies, as many studies have included children far below 36 months of age at start of the therapy (Dawson et al. 2010; Hayward et al. 2009; Howard et al. 2005). The youngest child in our study in contrast was 47.5 months old. This is a limitation of this study compared to other recently published early intervention studies. A study on treatment effects of FFIP in younger children is currently under way. From previous studies, higher cognitive abilities at the beginning of the study were described as predicting better cognitive gains and adaptive behaviour (Fernell et al. 2011; Gabriels et al. 2001; Magiati et al. 2007). This finding was not observed in our study, possibly to the very heterogeneous and small sample.

The strongest limitation of this study is the small sample size and the inclusion of a heterogeneous ASD sample with regard to age, autism severity, cognitive and language abilities at start of the intervention. Many of these aspects are due to the implementation of the FFIP within the framework of publicly funded clinical services, and the relatively late age at diagnosis of ASD at start of the program. Still, studies like this pilot study are a necessary step in developing empirically based early intervention programs which fit into the legal and financial framework of early intervention in Germany. In addition, the lack of a matched control group is a strong limitation of the study. The comparison to published control groups with comparable cognitive and adaptive skills tried to overcome this lack of a control group. However, the ESDM control group was younger, and the Norwegian control group showed higher IQ inclusion criteria than our study, so these groups are not well matched to our sample for these aspects. In addition, the study was performed as an exploratory study only and thus results can be regarded as hypothesis generating but not as generalizable for all children with ASD.

In conclusion, this pilot study on a low-intensity FFIP implementing a developmentally based social pragmatic approach, adapted to the German context, resulted in medium gains in socialisation, adaptive behaviour, and the mental age quotient/IQ, which were also reported by other developmentally based programs with even higher weekly therapeutic intensity. Compared to highly intensive classical applied behavioural therapy programs, results were partly comparable with regard to the VABS socialisation standard score, but gains in the VABS communication standard score and IQ were smaller by FFIP. A randomized-controlled trial needs to be performed to proof its effectivity compared to community-based early interventions programs in Germany.

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