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A pilot randomised control trial of a parent training intervention for pre-school children with autism

Preliminary findings and methodological challenges

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■ **Abstract** Few attempts have been made to conduct randomised control trials (RCTs) of interventions for pre-school children with autism. We report findings of a pilot RCT for a parent training intervention with a focus on the development of joint attention skills and joint action routines. Twenty-four children meeting ICD-10 criteria for childhood autism (mean age = 23 months) were identified using the CHAT screen and randomised to the parent training group or to local services only. A follow-up was conducted 12 months later (mean age = 35 months). There was some evidence that the parent training group made more progress in language development than the local services group. However, the present pilot study was compromised by

several factors: a reliance on parental report to measure language, non-matching of the groups on initial IQ, and a lack of systematic checking regarding the implementation of the parent training intervention. Furthermore, three parents in the local services group commenced intensive, home-based behavioural intervention during the course of the study. The difficulties encountered in the conduct of RCTs for pre-school children with autism are discussed. Methodological challenges and strategies for future well-designed RCTs for autism interventions are highlighted.

■ **Key words** autism – early intervention – parent training – language – randomised control trial (RCT)

Introduction

Progress has recently been made in the earlier identification of children with autism [4, 14] and many children are now first identified in the pre-school period [8, 19]. Given that impairments in social and communication abilities characterise children with autism [2, 37], it is imperative to identify forms of early intervention that are effective in promoting increased social and communication competence in pre-school children with autism.

There have been relatively few empirical evaluations of intervention programmes for children with autism, in

particular for pre-schoolers [12, 20, 27, 30]. Findings from studies of both behavioural [25, 33] and education-based approaches [28] have demonstrated positive outcomes in terms of IQ gains and reductions in symptom severity. Intervention approaches that have placed an emphasis on the development of non-verbal social-communicative skills have also provided promising data [31]. Few studies have utilised the randomised control trial (RCT) design necessary to demonstrate that treatment effects are due to the intervention and not to other uncontrolled factors.

There is an emerging consensus that joint attention abilities and other non-verbal social communication skills are an important target for intervention in autism

and that increased facility in joint attention behaviour is likely to lead to greater language and communicative competence [7]. The present paper reports preliminary findings from a pilot RCT study of a parent training intervention programme for pre-school children with autism that adopted a psycholinguistic and social-pragmatic approach to language development [15, 29]. The training emphasised the development of joint attention skills and joint action routines, as well as delivering advice about behavioural management in particular promoting compliance. It was predicted that the intervention would have a specific, beneficial effect on the development of language abilities.

The CHAT (Checklist for Autism in Toddlers) screening tool [3, 5] was used to identify the participants. The sample is the youngest ever recruited into an intervention programme for children with autism. The effects of the parent training programme for a small group of children (N = 12) were compared in an RCT design to that for children receiving locally available services only (N = 12).

Method

■ Procedure

A shortened version of the Checklist for Autism in Toddlers (CHAT) including the key screening items only was employed to identify children at high risk for autism below two years of age. The shortened version included only the five key items for the high-risk threshold employed previously [3, 5], i. e. parental (A7) and Health Visitor (Biv) report of a lack of pointing for interest, parental (A5) and Health Visitor (Biii) report of a lack of pretend play and Health Visitor report of a failure to monitor gaze (Bii). In addition, the parent report item A6 "Does your child ever use his/her index finger to point to ask for something?" was included, as in the original study parents found it hard to discriminate between pointing for interest and for requesting [4]. In order to minimise screen false positives, Health Visitors were asked to refer children who failed all six items and about whom there was also concern about possible autism, and to exclude children with severe general development delay (for whom the parent training programme would not have been developmentally appropriate).

On receipt of a referral the CHAT was re-administered by a member of the research team over the telephone. If the child was still failing all six items the family was invited to bring the child for a full diagnostic assessment. This was conducted, as soon as possible afterwards, at the hospital clinic in which the project was based. The assessment employed standardised measures that were also baseline pre-intervention measures. Of 51 children referred to the study, five failed to meet risk cri-

teria on retest by telephone. Forty-six children were seen for a full clinical assessment. The clinical assessment consisted of a structured clinical interview including administration of the Autism Diagnostic Interview-Revised (ADI-R) [23], and a structured child-adult interaction assessment to elicit examples of social interaction, reciprocity, non-verbal social communication abilities (e.g. joint attention, requests, imitation, turn-taking) and affective responsivity. ICD-10 [37] diagnoses of childhood autism were achieved using all available clinical, historical and psychometric information. A consensus clinical judgement was reached by two clinicians highly experienced in the diagnosis of autism and related PPDs (GB, AC). The ADI-R was not taken as the sole arbiter of diagnosis, since the instrument has been shown to have only moderate specificity for children with mental ages below two years of age [11]. All subjects fell above the ADI-R cut-off on the reciprocal social interaction dimension and all but one also fell above the cut-off on the nonverbal communication dimension (one subject was one point below the cut-off). Seven children failed to reach the cut-off of the repetitive and stereotyped behaviours dimension but all but one scored only one point below the cut-off, as has been found previously for children younger than 24 months of age [11]. Previously it has been demonstrated using the same diagnostic assessment that a diagnosis of childhood autism can be reliably made by an expert team at the age of 20 months [11]. Of the 46 children assessed, 31 had childhood autism, 5 atypical autism or pervasive developmental disorder – unspecified, 6 a receptive-expressive language disorder, 2 global developmental delay, and 1 child had attention deficit hyperactivity disorder (ADHD). Only one child appeared clinically normal.

If the child met entry criteria the parents' consent to enter the RCT was sought. Random allocation was explained and parents were told that their child would be referred for local service support whether or not they agreed to join the research. Allocation to the Parent training or Local services only groups was made from a random numbers table. Thirty-one eligible children were identified by the screening process. Seven parents declined to enter the study and were not followed-up further as part of the study. Twenty-four parents agreed to participate and were randomised into either the Parent training group (N = 12; 11 boys, 1 girl) or to the Local services only group (N = 12; 8 boys, 4 girls).

■ Measures

The following measures were administered at baseline and follow-up by the research team. *Language comprehension and production*: MacArthur Communicative Development Inventory (CDI) [13]. The majority of chil-

dren had insufficient language at both assessments to conduct a direct, formal language test. At the initial assessment 22 from 24 children were non-verbal (fewer than 5 words), and 13 remained so at follow-up. *Non-verbal IQ*: D and E subscales of the Griffiths Scale of Infant Development [16]. *Symptom severity*: Autism Diagnostic Interview-Revised (ADI-R) [23]. *Parental stress*: Parental Stress Inventory (PSI) [1]. Some questionnaire data were missing. The CDI was completed at both timepoints by 12 parents in the Parent training group and 10 parents in the Local services group. The PSI was completed at both timepoints by 10 parents in each group.

The children were seen for an initial assessment at a mean age of 22.5 (SD = 3.4) months. The interim follow-up assessments reported here were conducted an average of 12.3 (SD = 1.6) months after the initial assessments, at a mean age of 34.8 (SD = 3.8) months.

In order to measure input from other health and education services (e.g. speech and language therapy sessions, part-time placement in a nursery) for both groups, an activity checklist was completed every 3 months by parents. The type and amount of provision their child had received during the previous 3 months was recorded. Across the 12 month period between the initial and the follow-up assessments 14 parents returned 4 activity checklists, 6 returned 3 and 4 returned 2. Following diagnosis 3 parents in the local services only group opted to enrol in intensive, home-based behavioural programmes (in all cases the programme started within 3 months of the initial assessment). The hours of therapist and parent 1-to-1 intervention were also monitored in the activity checklists.

■ Content and aims of the social-pragmatic joint attention focused parent training programme.

The parent training programme had several features:

- Parents were given advice about behavioural management and promoting compliance. This included the principles of reinforcement, interrupting unwanted behaviours and positively teaching alternative behaviours by keeping the child occupied in joint action routines.
- The programme focused on the development of early precursors to social and communicative competence. It aimed to promote joint action routines, the explicit teaching of joint attention behaviours such as index finger pointing and gaze switching, and the use of visual supports for spoken language. Target behaviours included commenting or declarative acts such as pointing, showing and holding objects out to adults (when combined with eye contact these are called “joint attention” acts). It also included an emphasis on non-verbal requests, object-function play, imitating actions and turn-taking games.
- Specific activities included mirror games (diadic joint attention and imitation, moving on to mirror play with objects), index finger pointing in joint picture book “reading” (insisting on an adult-led pace, scaffolding and prompting index finger pointing to elicit adult naming), games to teach the child to follow adult index finger pointing (e.g. “Look!” to things the child likes), gaze switching eye contact game with balloons and bubbles, and adult-led “table games” e.g. posting, lotto, sorting.
- There was an initial emphasis on teaching the child to be eager for more and for parents to acquire behavioural management strategies to elicit compliance and mutual enjoyment, as well as learning to watch and wait, look and listen and do as asked. Simple enactive and representational gestures including actions songs and Makaton nursery rhymes, holding up arms to be picked up and waving bye-bye were also scaffolded in repeated to-and-fro games. The programme aimed to ensure that shared meaning was established in joint action routines, and that the developmental sequence of responding to, maintaining and then initiating joint attention bids was followed [6].
- It also aimed to support wholistic learning of language by exaggerated prosody and analytic learning by repetitive paraphrasing to maximise the likelihood that the child would become able to understand the meaning of key referent words in different sentence contexts [9].
- The programme was integrated into everyday routines, such as mealtimes, tidying up, and independence skills such as dressing, washing and bedtime. This allowed opportunities for generalisation of skills learnt in specific intervention task activities (mirror play routines, turn taking games etc.) into all social contacts that the child experienced with their parents [35]. Parent training interventions are designed to maximise the ecological validity of interventions and have previously been shown to be effective for children with language delays [24] and children with autism [18].
- The parent training programme adopted a consultant model with parents acting as the everyday “therapists”. Parents were visited at home by a speech and language therapist (AD, VS) every 6 weeks for a 3-hour session. Throughout the course of intervention the therapists described and demonstrated the principles of behavioural management, the social pragmatic approach taken to the development of joint attention, non-verbal social communication and language skills, and monitored and provided feedback on the parents’ implementation of the programme. The activities and the aims for each 6-week period were set by the therapist in collaboration with the parent and were determined by the cognitive and communicative

level the child had reached and the child's individual learning style. The recommended activities were designed to be used both in "set aside" time for activities (e. g. joint play times) and also to be incorporated into everyday routines. Initially 2–3 minutes were recommended for each activity, gradually increasing to 5 minutes per activity. Table games were gradually increased to 15–20 minutes daily. Activities were designed to take between 30 and 60 minutes "set aside" time. However, as they became incorporated into everyday activities it was anticipated that some parents (for all children fathers as well as mothers attended some sessions) would spend considerably more time than this utilising the social pragmatic approach when interacting with their child.

The therapists were available for telephone support and advice to the parents throughout the intervention period. In addition to the Parent training programme, parents were encouraged to take up the offer of whatever therapy or pre-school services were available to them locally. The use of a consultant model allowed daily input to be provided for the child at a very much lower cost than models where professionals deliver daily treatment to the child (though see the Discussion for comment on the parents' need for support).

■ Description of input to the Local services group

The children in the Local services group received a mixture of services including speech and language therapy sessions, portage home worker input and other paramedical therapy services (e. g. occupational therapy, physiotherapy) (see Results for details). As described, three children commenced home-based, 1-to-1 treatment based on behavioural, discrete-trial principles with ongoing supervision being provided by one of the recognised Lovaas/ABA groups in the UK. In some families parents themselves acted as part of the team of therapists (under supervision) while in others outside therapists delivered all of the treatment. The mean number of hours of 1-to-1 intervention for these three children was 32.9 per week across the 12 month period. In order to protect the RCT design an 'intention-to-treat' approach was taken, with the two groups of $N=12$ randomised children compared to each other at the initial and follow-up assessments.

Results

■ Statistical analysis

Analysis of variance was used to examine group differences at the initial assessment. Analysis of covariance was used to examine group differences at follow-up,

with initial scores on each variable being entered as a covariate.

■ Initial and follow-up group comparisons

Group mean and standard deviation (SD) scores for all variables at the initial and follow-up assessments are shown in Table 1. At the pre-intervention initial assessments the Parent training group and the Local services group were matched for age. However, the Parent training group had a higher NVIQ than the Local services group ($F[1, 23]=14.8, p<0.001$). The groups did not differ in language ability (number of words understood, number of words used, number of gestures produced) as measured by the CDI. In terms of overall level of language use as rated on the ADI-R, 11 of 12 children in both groups were nonverbal (fewer than 5 words). There were no differences in symptom severity as measured by the Reciprocal Social Interaction, Nonverbal communication and Repetitive and stereotyped behaviours domain scores of the ADI-R. Neither did the groups differ in terms of parental stress as measured by the PSI.

At follow-up there were no group differences in age or NVIQ. The Parent training group had marginally higher language comprehension as measured by the CDI total words understood although this missed statistical significance ($F[1,20]=3.1, p=0.09$ two-tailed). There were significant covariate effects (i. e. across both groups time 1 scores were associated with time 2 scores) for initial words understood ($F[1,20]=6.6, p<0.05$), gestures produced ($F[1,20]=7.9, p<0.05$) and parental stress ($F[1,16]=8.7, p<0.01$). There were no group differences on words produced or gestures produced. In terms of overall level of language use as rated on the ADI-R, three of the children in the Parent training group had spontaneous use of three-word phrases, five had single word speech and four had fewer than five words. In the Local services group no children had spontaneous use of three word phrases, three had single word speech and nine had fewer than five words. From the initial to follow-up assessment significantly more children in the Parent training group moved from being nonverbal to having single word or phrase speech ($N=7$) than in the Local services group ($N=2$ and one child went from single words to fewer than five words from the initial to the follow-up assessment) (Fisher exact test, $p<0.05$). There were no differences in symptom severity as measured by the domain scores of the ADI-R at follow-up, nor any difference in parent self-report of stress.

■ Data from activity checklists

Summary data averaged across the whole year from the parent-completed activity checklists indicated the ave-

Table 1 Group mean (SD) scores at initial and interim follow-up assessments

Group	Parent training N = 12		Local services N = 12	
	Initial	Follow-up	Initial	Follow-up
Age (months)	21.4 (2.7)	33.5 (2.5)	23.6 (3.8)	36.2 (4.5)
NVIQ ^a	88.1 (11.2)	77.9 (14.8)	66.0 (16.5)	66.1 (17.1)
Words understood ^b	52.0 (60.5)	176.1 (121.9)	53.0 (63.7) ^e	100.3 (80.2)
Words said ^b	6.8 (20.9)	96.6 (118.8)	6.6 (13.7) ^e	44.0 (50.2)
Total gestures produced ^b	20.9 (7.0)	38.6 (12.5)	20.9 (14.4) ^e	29.1 (18.4)
ADI – RSI ^c	19.6 (3.0)	18.3 (4.9)	20.3 (4.5)	20.1 (4.3)
ADI – NVC ^c	12.8 (1.6)	11.0 (2.8)	12.0 (2.4)	11.9 (1.8)
ADI – RSB ^c	3.2 (1.1)	3.9 (1.8)	3.7 (1.6)	4.2 (2.0)
ADI – Overall language rating				
Nonverbal (< 5 words)	11	4	11	9
Single words	1	5	1	3
Phrase speech	0	3	0	0
PSI ^d	113.8 (21.7) ^f	104.3 (20.0) ^f	110.0 (28.6)	112.1 (20.1) ^f

^a NVIQ non-verbal IQ from D and E scales of Griffiths Scale of Mental Development (NVIQ NVMA/age).

^b MacArthur Communicative Development Inventory.

^c Autism Diagnostic Interview-Revised domains: RSI Reciprocal Social Interaction; NVC Nonverbal Communication; RSB Repetitive and stereotyped behaviour.

^d Parental Stress Inventory total score.

^e N = 11

^f N = 10

rage number of hours per week that children spent in playgroup or nursery (Parent training group mean (SD) = 6.3 (10.7); Local services group = 3.5 (3.6)) and the number of hours of speech and language therapy per month (excluding the parent training consultations) (Parent training group mean (SD) = 0.3 (0.3); Local services group = 0.6 (1.1)). The groups did not differ on these measures. The Local services group were in receipt of more other intervention (which for three cases included the intensive, home-based ABA therapy) than the Parent training group although this trend did not quite reach statistical significance (Hours per week: Parent training group mean (SD) = 0.3 (0.1); Local services group = 8.4 (14.9); $F[1, 23] = 3.6, p = 0.07$). There were no group differences in the time parents spent in 1-to-1 structured activities with their child (Hours per day: Parent training group mean (SD) = 1.0 (0.7); Local services group = 1.6 (1.1)). None of the measures of playgroup, speech and language therapy, other intervention or parent time spent in 1-to-1 activities was significantly associated with NVIQ, language measures, symptom severity or parental stress at follow-up.

Discussion

This pilot study was an attempt to conduct a RCT of a parent training intervention for pre-school children with autism, identified before their second birthday using the CHAT screening instrument. Findings were in line with our prediction that the parent training intervention focusing on joint attention and joint engagement routines would specifically enhance communica-

tion skills. At follow-up the Parent training group understood marginally more words than the Local services group. In addition, according to the parent report on the ADI-R interview more children in the Parent training group than the Local services group moved from being nonverbal to having single words or phrase speech.

These findings are consistent with the theoretical and empirical basis of the Parent training programme. A social pragmatic approach to developing non-verbal communication competence should lead to increased language competence [9, 15, 22, 26, 34, 36]. This replicates findings for children with specific language impairment [10, 15]. Note, however, that the language ability of the children in both groups remained severely compromised at follow-up. At age 34 months the Parent training group of patients were at the language age equivalent of approximately 16 months for words understood and in terms of words used they were only slightly above the 16 month ceiling on the Words and Gestures form of the CDI [13]. Furthermore, there was considerable variability in progress within each group. For example, in the Parent training group the range of increase in words used from the initial to the follow-up assessment ranged from 0 to 365. The small numbers of children within each group do not allow us to identify the initial characteristics of those children who made most progress in each intervention stream. Such an analysis is required with larger groups in subsequent studies to identify which interventions may be best suited to which children, or 'what works for whom'.

The groups did not differ at follow-up in NVIQ, symptom severity or parental self-report of stress. None of these were specific goals of the parent training pro-

gramme but comprehensive intervention approaches should target these important areas of child and family function. There may be clear ceilings on the improvements to be expected in these core symptom domains following a one-year intervention period.

This pilot study had several limitations and has highlighted significant challenges for future studies. Parents of three children allocated to the Local services group opted to start home-based behavioural programmes. However, such parental choice reflects the real-life clinical situation. The analysis was conducted according to an 'intention to treat' design in order to uphold the fidelity of the RCT design. Further, the two groups were not matched at the initial assessment in terms of NVIQ. Thus, it is not possible to rule out that the marginally significant finding of greater language gains in the Parent training group was due to this difference in initial characteristics. This reflects the small sample size of this pilot RCT. Future RCT studies should be of sufficient sample size to avoid such biases and to increase statistical power to detect differences between groups.

Another limitation is the lack of data on the implementation of the parent training approach. Although an attempt was made to collect data on playgroup, therapist and parent activities in terms of hours of input at three monthly intervals, no data on the treatment itself were available. The need to identify effective elements within treatment programmes for pre-school children with autism and to document the consistency of application of the treatment protocols is an important goal for future work. Related to this, systematic assessment of parent-child interaction was not conducted. An attempt to collect such data was made by the therapist at the initial and final home visits but this was not successful, partly because of conflicting parental roles and expectations and partly due to time constraints. Given the particular nature of the intervention tasks in the joint attention parent training programme, the lack of such data prevents determination of whether the groups differed in a critical treatment variable before or after treatment. Another limitation is that many of the outcome measures relied on parental report (ADI-R, CDI, PSI). In part, this reflects the difficulty of conducting direct assessments of young pre-school children with autism. Direct measures of language competence were only completed on six children at follow-up as the majority of children at follow-up were below the basal of direct language measures (not reported). However, direct measures of behaviour and competence need to be included in future studies in order to demonstrate objective and generalisable gains in skills.

The present study employed a low-cost and widely applicable professional-as-consultant, parent-as-therapist model. Note, however, that the investment of therapist time was not insignificant as the sessions lasted three hours and arrangements were made to avoid the breaks that occur in vacations etc. in many clinic-based programmes. It is also important to note that many parents (mothers and fathers) found it difficult to implement and maintain the recommended activities as assiduously as they wished, often because of the competing demands of other children, work, family life etc. The frequency of therapist visits was dictated by the resources available to the research project and is not considered the optimum level of support for families on such programmes. There is also evidence that parents value the opportunity to share ideas about management and treatment strategies with other parents [32]; however this important additional element was not built into the parent training model at this initial stage.

Appropriate research strategies to evaluate treatments can take a variety of different forms [17]. Although no design other than a randomised control trial can avoid bias resulting from unmeasured confounding factors, other research designs are also important and data from all available sources are required in order to make judgements about which treatments are best for patients. Single case, or small group designs are also needed in order to determine the types of intervention that are appropriate for more costly, larger scale randomised trials (e.g. [21]). The present study has highlighted the significant practical and methodological difficulties in undertaking a RCT of an intervention for pre-school children with autism. Notwithstanding these difficulties, the modest findings of improved language competence point to the need for further work on parent training approaches. This should include RCTs of sufficient size and methodological rigour to confirm and extend these tentative findings and more clearly demonstrate whether parent training approaches focused on joint attention and joint engagement have a specific beneficial effect on the communicative competence of pre-school children with autism.

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