Feasibility of a Preventive Parenting Intervention for Very Preterm Children at 18 Months Corrected Age: A Randomized Pilot Trial

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Objective To evaluate the feasibility and potential efficacy of an age-appropriate additional parenting intervention for very preterm born toddlers.

Study design In a randomized controlled pilot study, 60 of 94 eligible very preterm born children who had received a responsive parenting intervention in their first year were randomized to usual care or the additional intervention, consisting of 4-6 home visits between 18 and 22 months' corrected gestational age (CA). Parents were supported to responsively interact during increasingly complex daily activities and play. Parental satisfaction with the intervention was evaluated with a questionnaire. At baseline and 24 months CA, parents completed the Infant Toddler Social and Emotional Assessment, the Ages and Stages Questionnaire, and the Dutch Schlichting Lexilist for receptive language. At 24 months CA, motor, and cognitive development was measured by the Bayley Scales of Infant and Toddler Development, Third Edition Dutch version, and parent-child interaction was evaluated by the Emotional Availability Scales.

Results Parental compliance and satisfaction with the intervention was high. Effect sizes (after correction for baseline variables) were small for internalizing and competence behavior, receptive language, and problem solving; medium for cognitive development and parent-child interaction; and large for externalizing and dysregulation behavior and motor development.

Conclusion After a postdischarge intervention during the first year, an additional responsive parenting support at toddler-age is feasible and associated with positive outcomes in a broad array of parental and child outcome measures. *(J Pediatr 2016;176:79-85)*.

Trial registration www.toetsingonline.nl: NL40208.018.12.

Very preterm birth (<32 weeks of gestation) and very low birth weight (<1500 g) are strongly associated with developmental and behavioral problems.[1-4] In response, various postdischarge intervention programs have been developed. The magnitude of the effects, however, has been modest, and the challenge for future programs is to design and test resources and intervention strategies that improve the preterm child's development and participation later in life.[5-8]

The Infant Behavioral Assessment and Intervention Program (IBAIP)[9] is a postdischarge preventive neurobehavioral intervention programs that yields long-term benefits for the very preterm child's development. The program consists of 6-8 home visits from discharge until 6 months' corrected gestational age (CA) and has been evaluated extensively with follow-up studies until 5.5 years' CA in the Netherlands. Better cognitive, motor, and behavioral outcomes were found at 6 months' CA, and better motor outcome at 12 and 24 months' CA.[10,11] At 5.5 years' CA, the intervention group had better visual-motor outcomes, better verbal IQ, and lower frequency of a performance IQ less than 85.[12,13]

Aiming to further boost the results of the IBAIP intervention, an early intervention program providing transmural developmental support for preterm infants and their parents (ToP program) was developed and implemented as a standard of care in the Netherlands in 2010. The ToP program is available for children born with a gestational age <32 weeks and/or birth weight <1500 g. It consists of 12 home visits from discharge until 12 months (CA) and is carried out by specially trained pediatric physical therapists. The focus of the ToP program is to strengthen the parent's well-being and sensitive-responsive parenting, to enhance the infant's self-regulatory competence and exploratory participation, and to diminish stress, because these aspects play a central role for a favorable development of young infant's brain.[5,14]

Recent literature has emphasized the importance of consistent parental responsiveness across both infancy and the toddler-preschool period for behavioral and cognitive development in term infants and even more in preterm infants.[15,16] In addition, if

ASQ-3	Ages and Stages Questionnaire, Third Edition
BSID-III-NL	Bayley Scales of Infant and Toddler Development, Third Edition, Dutch Version
CA	Corrected gestational age
EAS	Emotional Availability Scales
IBAIP	Infant Behavioral Assessment and Intervention Program
ITSEA	Infant Toddler Social and Emotional Assessment
ToP	Transmural developmental support for preterm children and their parents

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the intervention coincides with the sensitive periods for these developmental domains they might improve optimally.[17-20] If so, this may require parental understanding of children's changing developmental needs over time. Consequently, we wanted to evaluate a staged curriculum that begins with the ToP intervention during the first year of life, followed by an additive responsive parenting program (the ToP+ program) during the age of 18-22 months.

The primary aim of this pilot study was to examine the feasibility of the additional ToP+ intervention. In addition, we wanted to explore whether the additional intervention was favorable for cognitive, motor, and behavioral development of the child and the parent-child interaction.

Methods

Families were eligible for the study if they had received the ToP program during the first year; the child had not been diagnosed previously with cerebral palsy, Down syndrome, or participated in another intervention program; the parents were sufficiently able to understand the Dutch or English language; and the child lived within a reasonable travel distance from the therapist's working area.

For the purpose of the ToP+ program, 5 ToP physical therapists received additional training on age-specific aspects of behavioral expressions, self-regulation, and the different developmental domains, with a special focus on preverbal communication, play, and the use of scaffolding techniques (www.toetsingonline.nl: NL40208.018.12). The ToP+ program involved a minimum of 4 in-home sessions (60-90 minutes each session) when the infant was between the age of 18 and 22 months' CA. In addition, 1 or 2 in-home sessions could be used if the physical therapists felt that more contact to optimize the intervention was needed.

The ToP+ program uses a process and strength-based approach to support well-tuned and matched parent-child interactions. Parents are encouraged to follow their child's interest to positively engage in daily activities, such as eating and dressing, and age-specific activities with their child, including free play or shared book reading. The therapist provides the parent with short comments about the child's expressions of positive engagement, self-regulatory strategies, or efforts. Accordingly, the therapist may give suggestions how the parent can give information in a scaffolding way (physical or verbal support, or by structuring the ask), or how the parent can co-regulate and support the child's feeling of comfort and safety. After each session, a written report is made for the parents, including strength-based recommendations with supporting photos. The same therapist who delivered the ToP program and who was familiar to the family was assigned, when possible.

To maintain the consistency of the intervention, written parent reports were regularly reviewed and supervised by the trainer. Monthly meetings with the 5 therapists were scheduled to share experiences and discuss aspects of the intervention.

Eligible families received an information folder and invitation to participate in the study. After written informed consent was obtained by the ToP physical therapists, the children were assigned randomly to the ToP+ intervention group or the control group. A computer-generated block randomization was performed, stratified for therapist. Children from multiple births were assigned to the same group because of the nature of the intervention. Perinatal variables were abstracted from medical records. Socioeconomic data were obtained by parent interview. Three questionnaires were completed by the parents at baseline (18 months' CA) and at the follow-up assessment (24 months' CA). At that time, the Bayley Scales of Infant and Toddler Development, Third Edition, Dutch Version (BSID-III-NL)[21] was conducted by independent specialized psychologists blinded to group assignment. The BSID-III-NL is part of the standard follow-up protocol at 24 months and was conducted in either the Academic Medical Center or Free University Medical Center in Amsterdam.

A video-recording to evaluate the parent-child interaction with the Emotional Availability Scales (EAS, Fourth Edition)[22] at 24 months CA was done by a researcher in a free play situation at the home of the children. Scoring was done by an EAS-certified psychologist blinded to group assignment. Parents who received the additional ToP$^+$ intervention filled out a questionnaire to evaluate their satisfaction with the intervention. Because this was a pilot study, no sample size calculations were performed; however, we aimed to include 30 children per group to capture the diversity of this group. The study was approved by the Medical Ethics Committee of the AMC, the Netherlands.

The Infant Toddler Social and Emotional Assessment (ITSEA) is a parent-report questionnaire developed to assess social-emotional problems and competencies in 12- to 36-month-old children.[23] It consists of 166 items that measure 17 syndrome scales and 4 domains via a 3-point Likert rating scale (0 = not true/rarely, 1 = somewhat true/sometimes, 2 = very true/often, "No opportunity" available for some items). On the basis of these ratings, age- and sex-specific *t* scores (mean = 50, SD = 10, range 25-80) were calculated for the 4 domains: social-emotional competence; externalizing behavior problems; internalizing behavior problems; and dysregulation. The ITSEA has good test-retest reliability, good criterion validity, and a well-supported factor structure.[23]

The Ages and Stages Questionnaire, Third Edition (ASQ-3) is a screening questionnaire to detect developmental delays in children.[24] For this study, we used the ASQ-3 at 18 and 24 months. The questionnaire consists of 30 developmental items to assess 5 domains of child development; communication, gross motor, fine motor, problem solving, and personal-social. For each item, the parents indicate "yes" (10 points), "sometimes" (5 points), or "not yet" (0 points) to represent their child's ability to perform a task. A greater score indicates better development. Scores for each domain and an overall score can be calculated. The presence of any domain <2 SD below the mean was considered a positive screen for "at risk" for developmental delay. Because there was no standardization for Dutch children at the time of the study, normative

values from the US were used. Reliability and specificity are high, and sensitivity ranges from 51% to 90%.[24]

The Dutch Schlichting Lexi-list for receptive language was used at both 18 and 24 months' CA.[25] This parent-reported list consists of 225 words and small sentences that children between 15 and 25 months can understand. Dutch age norms for each month are available. The test score was converted into a standard score (Lexi-list Perceptive language quotient), with age norms for each month (mean = 100, SD = 15). The Schlichting Lexi-list is a valid and reliable measure.[25] Parents who were included in the ToP+ program evaluated the usefulness and duration of the intervention with a questionnaire that addressed 4 aspects (practicability, knowledge transfer, collaboration, and amount of sessions) of the intervention. The questionnaire consisted of 13 multiple-choice, 3 open questions, and 1 question to grade the usefulness of the intervention.

The BSID-III-NL and US norms were used to assess the cognitive and motor development at the CA of 24 months.[21,26] The BSID-III-NL is normative, value-referenced assessment. The composite scores for the cognitive and motor scales are age standardized with means of 100 and SDs of 15. The Fine Motor and Gross Motor subscales scores are age-standardized with a mean (SD) score of 10.[3] The BSID-III-NL was found to be a reliable and valid instrument with good psychometric characteristics for Dutch children and high reliability on the subtests.

The EAS is a measure of the overall quality of the observed emotional availability in parent-child interactions.[27,28] The EAS consists of 6 dimensions: 4 dimensions of parental behavior (sensitivity, structuring, nonintrusiveness, and nonhostility) and 2 dimensions of child behavior (responsiveness and involvement).

Statistical Analyses

Data were analyzed with the Statistical Package for the Social Sciences version 20.0. (SPSS Inc, Chicago, Illinois). Differences in sociodemographic and perinatal characteristics were analyzed with the independent-samples t test or χ^2 tests. ANOVA was used to analyze group differences on the ITSEA, Lexi-list, and ASQ-3 at 18 and 24 months and the BSID-III-NL and EAS at 24 months. In addition, ANOVA corrected for prerandomization baseline differences (gestational age) and known influential factors (small-for-gestational age, sex, maternal education) was performed for the BSID-III-NL and EAS. Effect sizes were expressed in Cohen d, which is interpreted as follows, >0.2 small, >0.5 medium, and >0.08 large effect.[29] The domain and total scores of the ASQ-3 at 24 months CA were analyzed with ANOVA and the frequency of "at risk" for developmental delay with logistic regression analyses, both performed with the ASQ-3 at 18 months as covariate. For the ITSEA and Lexi-list, repeated-measures ANOVA was performed with and without covariates.

Results

Enrollment for the study began in March 2013 and the study was completed in August 2014. Ninety-four very preterm infants who completed the ToP intervention and reached the adjusted age of 18 months were assessed for eligibility. Fourteen families could not be traced, and 20 families decided not to participate (**Figure**; available at www.jpeds.com). After informed consent, infants were assigned randomly to the intervention group (n = 30) or control group (n = 30).

The nonparticipating group did not differ from the participating group in gestational age (P = .23) and birth weight (P = .60) or length of stay at the hospital (P = .78). Mothers of the participating group had a significantly greater mean age (32 years) compared with the nonparticipating mothers (30 years) (P = .04).

All 30 infants of the intervention group received the planned 4-6 home sessions and written reports; 22 children (73%) were seen by their familiar ToP physical therapist. Twenty (80%) caregivers filled in the evaluation form after the intervention was completed. For twins, only 1 evaluation form was provided. Overall, parents were very satisfied with the intervention. All parents (100%) evaluated the number of sessions as adequate, the interventionist knowledgeable (95%), and the recommendations of the interventionist's valuable (95%). Parents gave the additional intervention a mean satisfaction rating 8.9 on a scale of 0-10, with a greater score indicating more satisfaction.

Despite randomization, infants in the intervention group had a lower mean gestational age than children in the control group (29.0 vs 30.9 weeks, P = .01). In addition, the infants in the intervention group had greater rates of ventilation support (P = .02) and oxygen support >28 days (P = .03). The intervention group had fewer male subjects and small for gestational age infants than the control group, but these differences were not significant (**Table I**).

At baseline, there were no significant differences in scores at baseline (18 months' CA) between the intervention and control group on the ITSEA, Lexi-list, and the ASQ-3 developmental domains and total score. The control group scored slightly greater on the ASQ-3 domain communication (P = .05).

At 24 months, we observed a significant improvement over time in the intervention group on the ITSEA for externalizing behavior (P = .00) and dysregulation behavior (P = .01). After adjustment for baseline variables, the effect size was large for externalizing behavior and medium for dysregulation behavior. On the Lexi-list, a nonsignificant effect for the time by group interaction was found (P = .22; **Table II**). At 24 months, the control group had a mean Lexi-list Perceptive language quotient of 90.4, indicating a small delay in receptive language. Only small, nonsignificant effects were observed on the ASQ domains between the intervention and control group at 24 months. On the personal-social domain, a significant difference was found in favor of the intervention group (P = .03). This difference remained significant after adjustment for gestational age, small for gestational age, maternal education, and sex (P = .04) with a medium effect size (**Table II**).

At 24 months CA, the intervention group had a significantly greater score on the motor composite score (P = .04). After adjustment, the scores for both the cognitive (P = .02)

Table I. Perinatal and social background characteristics

Characteristics	Intervention group, n = 30	Control group, n = 30	*P* value
Perinatal factors			
GA, wk, mean (SD)	29.0 (17.5)	30.9 (17.9)	.01*
GA <28 wk, (%)	10 (33)	6 (20)	.24
Birth weight, g, mean (SD)	1182 (430)	1353 (372)	.10
SGA, (%)	7 (23)	13 (43)	.20
Sex, male/female	12/18 (40%/60%)	18/12 (60%/40%)	.12
Twins, (%)	10 (33)	6 (20)	.24
Apgar score at 5 min, mean (SD)	7.7 (1.5)	7.7 (1.7)	.93
Ventilation (%)	19 (63)	10 (33)	.02*
Oxygen therapy >28 d, n, (%)	15 (50)	7 (23)	.03*
Oxygen therapy >GA 36 wk, n (%)	7 (23)	3 (10)	.17
Surfactant use, n (%)	15 (50)	8 (27)	.06
Dexamethasone use, n (%)	2 (7)	2 (7)	1.0
Indocin/ibuprofen use, n (%)	4 (13)	3 (10)	.70
Necrotizing enterocolitis, b (%)	1 (3.3)	0 (0.0)	.31
Septic periods before discharge, n (%)	16 (53)	10 (33)	.12
IVH grade I + II/III-IV (%)	4/1 (13/3)	3/0 (10/0)	.54
PVL	0	0	
At discharge			
LOS, days, mean (SD)	65.0 (29.8)	51.8 (32.7)	.11
Postmenstrual age at d/c, wk, mean (SD)	38.3 (2.6)	38.0 (2.9)	.97
Breast milk at discharge, n (%)	22 (73)	20 (69)	.71
Oxygen supply at discharge, n (%)	0 (0)	2 (7)	.15
Monitor at discharge, n (%)	0 (0)	1 (3.3)	.31
Social factors			
Firstborn child, n (%)	12 (40)	16 (53)	.30
Family status of 2 parents, n (%)	28 (93)	27 (90)	.64
Mother born in the Netherlands, n (%)	23 (77)	22 (73)	.76
Father born in the Netherlands, (%), n = 57	22 (76)	15 (54)	.08
Maternal education, (%)*			
Low	3 (10)	3 (10)	.60
Middle	7 (23)	4 (13)	
High	20 (67)	23 (77)	
Paternal education, n (%), n = 57			
Low	6 (21)	6 (21)	.99
Middle	7 (24)	7 (25)	
High	16 (55)	15 (54)	
Language spoken at home, n (%)			
Dutch language	22 (73)	19 (63)	.39
Dutch and other language	4 (13)	5 (17)	
Exclusively other language	4 (13)	6 (20)	

d/c, discharge; *GA*, gestational age; *IVH*, intraventricular hemorrhage; *LOS*, length of stay; *PVL*, periventricular leukomalacia; *SGA*, small for gestational age.
*Low level education refers to primary school, prevocational secondary school (<12 y); middle educational level refers to senior general education, preuniversity education of secondary vocational education (13-16 y); and high educational level refers to greater professional education of university (>16 y).

and motor domain ($P = .01$) were significantly greater in the intervention group (Table III). Effect sizes were large for the motor domain and gross motor subtest. A medium effect size was found for the cognitive domain.

There were no significant differences between the groups on the 6 domains of the EAS measured at 24 months CA. After adjustment, the parents in the intervention group had significantly greater (better) scores on 2 maternal scales (sensitivity [$P = .01$] and structuring [$P = .02$]), and on 1 dimension of child behavior (child involvement [$P = .02$]). Medium-to-large effect sizes were found on the different EAS domains, except for nonhostility (small effect) (Table III).

Discussion

In the Netherlands, a responsive parenting intervention (the ToP program) is implemented to support very preterm born children and their parents during 12 home visits throughout the first year after hospital discharge. The current pilot study was designed to explore the feasibility of an additional preventive intervention for very preterm born toddlers.

The additive intervention appears feasible because parents were willing to participate (response rate 64%), all participating parents completed the intervention, and the program was well received. In addition, the medium-to-large intervention effect sizes support our hypothesis that an additional preventive intervention improves responsive parenting and developmental and behavioral outcomes. We observed better quality of the emotional availability of the parent-child interactions in the intervention group. On the EAS, large effect sizes were found for the domains sensitivity, structuring, and child involvement. This additional intervention seems to induce a better understanding of the toddler's behavior, potentially helping parents to match the information and support to the individual developmental opportunities and needs of their child.

Table II. Comparison of the outcomes of the intervention group and control group on the ITSEA, ASQ-3, and Lexi-list

Outcomes	18 mo intervention	18 mo control	24 mo intervention	24 mo control	*P* value	*P* value adjusted*	Cohens d† (95% CI)
ITSEA (mean, SD)							
Internalizing‡	45.3 (12.0)	43.5 (7.6)	44.6 (12.5)	44.5 (8.9)	.54	.24	0.35 (−0.22; 0.92)
Externalizing‡	47.3 (6.1)	46.0 (11.3)	44.2 (6.4)	48.8 (9.7)	.00*	.01	0.91 (0.26; 1.56)
Dysregulation‡	50.0 (10.3)	48.0 (10.7)	47.3 (10.9)	50.0 (8.7)	.01	.05	0.63 (0.04; 1.22)
Competence§	50.6 (11.3)	50.1 (10.6)	53.2 (9.2)	50.3 (10.7)	.22	.59	0.17 (−0.39; 0.73)
ASQ-3							
Communication	32.4 (14.1)	25.5 (11.0)	50.6 (13.3)	44.6 (14.0)	.72	.63	0.14 (−0.42; 0.70)
Gross motor	47.7 (13.8)	46.4 (16.4)	48.9 (14.3)	48.9 (9.4)	.87	.39	0.29 (−0.27; 0.85)
Fine motor	50.9 (6.9)	47.9 (9.7)	50.7 (6.3)	50.4 (7.0)	.78	.38	0.29 (−0.27; 0.85)
Problem solving	40.6 (14.5)	37.9 (13.2)	47.7 (7.6)	45.8 (9.0)	.51	.38	0.29 (−0.29; 0.87)
Personal social	40.5 (8.2)	43.9 (7.9)	49.1 (8.9)	43.6 (9.9)	.03*	.04	0.67 (0.09; 1.25)
ASQ-3 total score	179.6 (28.1)	176.0 (25.0)	247.0 (35.5)	233.6 (35.1)	.42	.59	0.17 (−0.39; 0.73)
ASQ-3 <−2 SD, n (%)	10 (36)	8 (31)	2 (9)	5 (20)	.63	.46	N/A
Lexi-list							
LBQ	96.2 (15.6)	92.1 (16.7)	99.6 (19.3)	90.4 (21.7)	.45	.22	0.35 (−0.23; 0.93)

LBQ, Lexi-list Perceptive language quotient; *N/A*, not applicable.
*>0.2 small effect, >0.5 medium effect, >0.8 large effect.
†Adjusted for GA, SGA, sex, and maternal education.
‡Greater scores indicate more problem behavior.
§Lower scores indicate less optimal behavior.

Sansavini et al[30] described the relationship between mother-infant co-regulation patterns and motor development. Better motor outcomes were found if the interaction between parents and premature born children was mutual with a shared, symmetric focus of attention. In line with Sansavini et al, we found a large intervention effect on motor

Table III. Outcomes on the BSID-III-NL and the EAS at 2 years (CA)

Domain score (mean, SD)*	T2 at 24 mo (CA) (mean, SD)	*P* value	Difference, mean (95% CI)	Adjusted *P* value	Adjusted mean diff/SE§	Cohen d† (95% CI)
Cognitive		.17	4.5 (−11.1 to 2.0)	.02*	8.4 (3.5)	0.66 (0.12-1.20)
Intervention	101.7 (11.5)					
Control	97.2 (12.7)					
Motor		.04*	6.6 (−12.8 to −0.5)	.01*	9.3 (3.4)	0.85 (0.28-1.42)
Intervention	103.6 (11.0)					
Control	96.9 (10.9)					
Gross motor subtest		.01*	1.1 (−2.0 to 1.1)	.01*	1.9 (0.64)	0.95 (0.37-1.53)
Intervention	9.1 (1.7)					
Control	8.1 (2.0)					
Fine motor subtest		.10	1.1 (−2.7 to 0.4)	.20	1.1 (0.83)	0.55 (−0.01 to 1.11)
Intervention	12.0 (3.0)					
Control	11.0 (2.0)					

EAS (total scores)‡	T2 at 24 mo (CA) (mean, SD)	*P* value	Mean difference	Adjusted *P* value	Adjusted mean diff/SE§	Cohen d† (95% CI)
Sensitivity		.16	1.5	.01*	3.0 (1.1)	0.88 (0.24-1.52)
Intervention	25.7 (3.3)					
Control	24.3 (3.4)					
Structuring		.38	0.8	.02*	2.5 (1.0)	0.71 (0.08-1.34)
Intervention	25.9 (3.2)					
Control	25.1 (3.5)					
Nonintrusiveness		.72	1.0	.09	2.7 (1.6)	0.64 (0.01; 1.27)
Intervention	25.2 (4.4)					
Control	24.2 (4.2)					
Nonhostility		.35	0.2	.48	0.5 (.60)	0.29 (−0.33; 0.91)
Intervention	27.7 (1.5)					
Control	27.6 (1.7)					
Child responsiveness		.66	0.2	.05	2.2 (1.1)	0.57 (−0.05; 1.19)
Intervention	26.2 (3.3)					
Control	26.0 (3.8)					
Child Involvement		.54	0.5	.01*	2.8 (1.1)	0.77 (0.14; 1.40)
Intervention	26.4 (3.3)					
Control	25.9 (3.6)					

T2, second assessment; *EA*, Emotional Availability.
*Scores on the BSID-III-NL are all corrected for prematurity.
†>0.2 small effect, >0.5 medium effect, >0.8 large effect.
‡Emotional Availability Scores ranging from 7 to 17 are considered to be nonoptimally EA, 18 to 25 inconsistently EA, and 26 to 29 optimally EA.
§Adjusted for GA, SGA, sex, and maternal education.

development and a medium effect on cognitive development. Comparable early intervention programs do not report beneficial effects for cognitive development at 24 months of age.[5,14] In our previous studies on the effect of the IBAIP, positive effects on motor development were found at 24 months, whereas cognitive improvements were only found at 6 months and age 5 years.[10,12,13] Our additive intervention may have boost the consistency of responsive interactions during the sensitive period of cognitive development. Our outcomes are in agreement with the findings from Landry et al,[17] reporting that following intervention components that worked in infancy with a second dose of age-specific intervention strategies at toddler age achieves a better result.

In addition to the developmental improvements we found, parents in the intervention group reported fewer behavioral problems. Positive results on parental ratings of behavioral problems at 24 months (CA) also were reported in the Victorian Infant Brain Studies and Modified Mother-Infant Transaction Program study[5,14] but not in combination with enhanced developmental outcomes. Our outcomes may be more comparable with the study of Treyvaud et al,[31,32] who demonstrated that a more optimal home environment with engagement in shared activities and communication was associated with better cognitive development in preterm infants at age 2 years, including fewer externalizing and internalizing behaviors, and more regulated behavior and emotions. The developmental improvements as reported by parents on the ASQ-3 were only seen in the personal-social domain. The large improvements on the BSID-III-NL are not reflected in the parental perception of development in similar domains. In studies of the concurrent validity of the ASQ-3,[33-35] only a modest association between the ASQ-3 and the BSID-III-NL has been found. Furthermore, Steenis et al[35] concluded that although the labels of the developmental domains are similar between the ASQ-3 and the BSID-III-NL, they do not seem to measure the same constructs. In addition, parental observation of developmental activities at home may differ from activities performed in a standardized test situation, causing differences between the scores of the ASQ-3 and the BSID-III-NL.

Only a small effect size for receptive language was found on the Lexi-list. This may point at the need for objective and more extensive instruments to measure communicative and language development to detect effects and to explore which intervention elements may be successful. Unfortunately, the BSID-III-NL, receptive communication subtest, was not available in Dutch at the time of the design of the study.

The results of this pilot study are promising, but outcomes should be interpreted with care. Our study group was small and not sufficiently powered to detect small differences between the groups. In addition, our study groups were not well balanced, requiring correction of our results by multivariate data analyses. Larger and more balanced study groups are necessary to confirm our moderate and large effect sizes. Thirty-four eligible families did not want to participate, and there was not enough background information on them to evaluate for possible inclusion bias. Nevertheless, we succeeded in including participants from a range of perinatal and sociodemographic backgrounds and various ethnic groups, consistent with the Amsterdam population. Completing the questionnaires was difficult for some families, and therefore we were not able to collect all outcome measures in all families (**Figure**). The BSID-III-NL and EAS were performed only at 24 months (CA) to minimize the additional appointments for the families. Therefore, we measured differences between the groups but not the changes over time. Future studies should include objective measures at baseline. We only measured outcomes 2 months after the intervention was completed and suggest that future trials should include a longer follow-up interval to evaluate for sustained intervention effects. Another limitation of this study was the use of questionnaires that are developed to detect developmental delay, rather than direct measurement of behavioral development. The questionnaires reflect parental perception of child development and child behavior and parents were not blinded for treatment allocation, although investigators assessing outcomes were.

The positive results of this pilot study suggest that an additional preventive intervention at toddler age is feasible and potentially useful. The findings underscore recent insights that interactive dyadic processes with mutual adjustments support children's neurodevelopmental outcomes. This study adds that staged, age-appropriate interventions may boost the consistency of these responsive interactions and may further improve outcomes for preterm children. These promising results warrant further evaluation with a larger group to replicate the findings, confirm causality, assess intervention elements effecting change, and measure the long-term duration of intervention effects. ■

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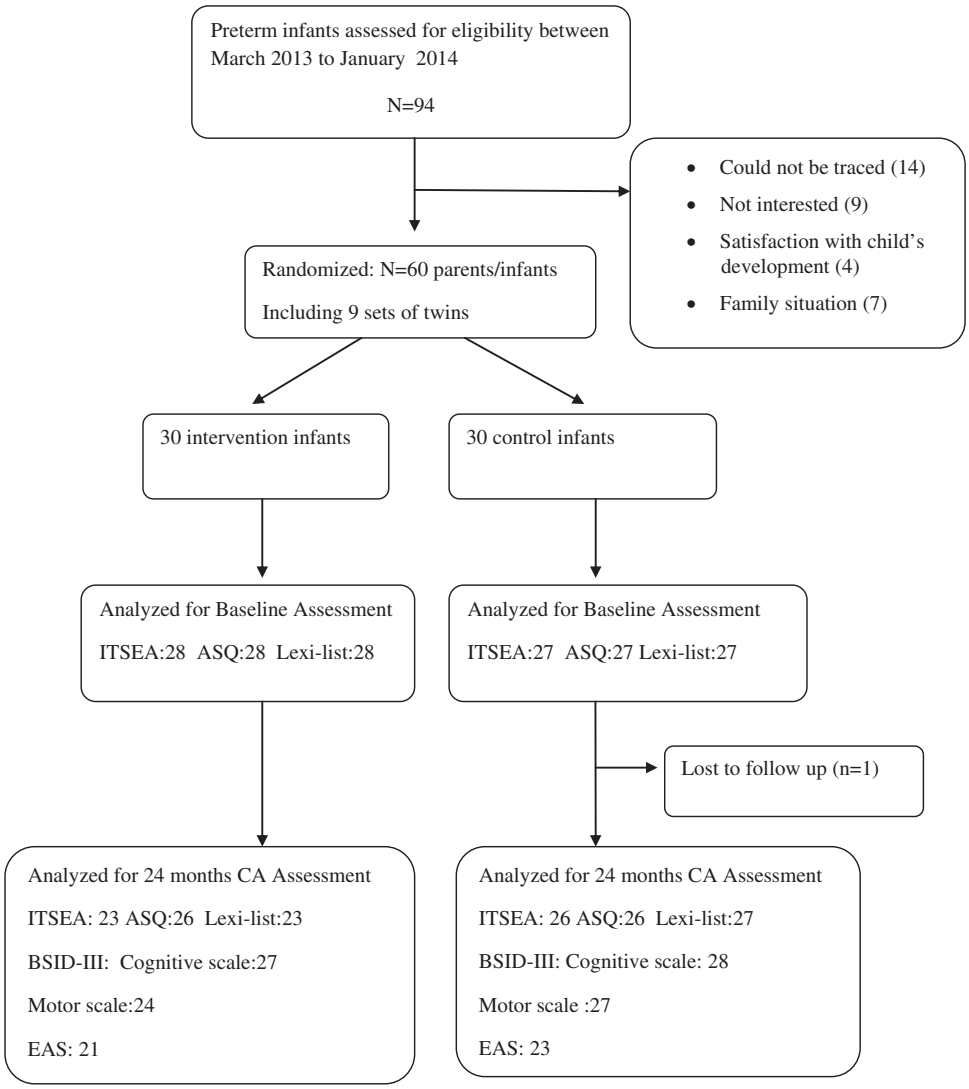

Figure. Flow chart of participants.