



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 Lexillist 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

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