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Feasibility of a Dutch post-discharge parenting intervention (TOP program) for moderate preterm born infants

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ABSTRACT

Background and aim: Moderate preterm (MP) birth is associated with an increased risk of developmental problems. However, post-discharge support for this group is scarce. The aim of this study was to evaluate the feasibility of a post-discharge parenting program (TOP program) for MP infants. Three feasibility dimensions were evaluated (1) recruitment capability and compliance, (2) intervention acceptability, and (3) limited efficacy testing.

Methods: A group of MP infants with a gestational age (GA) between $32^{0/7}$-$34^{6/7}$ weeks and their parents received six home visits by a TOP interventionist until 6 months corrected age (CA). A pre-posttest intervention design with quantitative and qualitative measures was used.

Recruitment capability and compliance, acceptability, and satisfaction with the intervention were evaluated using a questionnaire, checklists, interviews, and a focus group. Infant socio-emotional development, parental distress, self-efficacy, and reflective functioning were measured with questionnaires. Observation measurements were used for infant motor development and parental sensitivity.

Results: Thirty-two families completed the six home visits. The satisfaction rate (scale 0–10) was remarkably high (Mean 9.4, range: 8–10). Parents reported that the program was suitable, enhanced their understanding of their infants' developmental needs, and increased their self-efficacy. The infants showed age-appropriate motor and socio-emotional development post-intervention. Parental self-efficacy, reflective functioning, and sensitivity improved from pre to post intervention, with small to large effect sizes.

Conclusion: The study demonstrated high compliance, acceptability, and satisfaction with the TOP program for MP infants with promising infant and parent outcomes. This study contributes to the preparatory work prior to a larger scale evaluation and dissemination.

1. Introduction

Preterm birth can adversely affect the developmental outcomes and quality of life of the child. Although the risk of severe infant morbidity, such as developmental disabilities, declines with increasing gestational age (GA) [1,2], children born with a GA between 32 and 37 weeks, defined as moderate and late preterm (MLPT), have more hospital re-admissions than full term (FT) infants in the first thirty days after

Abbreviations: EOP, Expertise Centrum Ontwikkelingsondersteuning Prematuren; TOP program, Transmural developmental support for preterm children and their parents; PPT, pediatric physical therapist; CA, Corrected age; GA, Gestational age; SGA, Small for gestational age; FT, Full term born infants (>37 weeks of gestational age); VP, Very preterm born infants (<32 weeks of gestational age); MP, Moderate preterm born infants ($32^{0/7}$–$34^{6/7}$ weeks of gestational age); MLPT, Moderate and late preterm born infants ($32^{0/7}$–$36^{6/7}$ weeks of gestational age); IC, Informed Consent; ADS, The Massie-Campbell Attachment during Stress Scale; PRFQ, Parental Reflective Functioning Questionnaire; PRF, Parental Reflective Functioning; SENR, Maternal Self-efficacy in the Nurturing Role; DT-P, Distress Thermometer for Parents; ASQ-SE2-NL, Ages and Stage Questionnaire Socio-Emotional Dutch version, 2nd edition.

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discharge for e.g. jaundice, respiratory distress, crying, and vomiting [3]. They also have a higher risk of feeding problems [4], language problems [5], impaired neuro-psychological functioning, emotional and behavioral problems [6,7] and poorer academic performances than FT infants [8,9]. In later life, MLPT birth even increases the risk for mental health disorders, obesity, and coronary artery disease [10,11].

MLPT birth can also negatively impact parents, as demonstrated by increased parental stress [12,13], lower confidence [14], and increased risk for post-partum depression [15]. This can in turn negatively affect parent-infant co-regulation and parenting behavior [16]. The quality of caregiving is central to the child's developing resilience in the face of adversity, however, parenting a preterm infant can be challenging as preterm born infants show more diffuse behavioral signs, less approach behavior and more regulation difficulties [17]. Being able to understand the behavioral signs, interpretation of the infant's needs and being able to co-regulate are connected to parental self-efficacy and reflective functioning and have emerged as an important clinical target for interventions. Parental self-efficacy, first described in 1977 as parents' belief in their ability to successfully parent their child [18], is considered to be important for the health and well-being of parents and influences infant regulation and parents' perception of their infant's temperament [19,20]. Parental reflective functioning (PRF), described as the ability of parents to mentalize and adjust to the mental needs of their infant, is also considered to affect infant development, and is especially important for preterm infants given the challenges they face [12].

Early intervention incorporating multiple strategies, active parental participation, and focus on the infant, parents or parent-child interaction could reduce the risk of adverse outcomes and enhance infants' development [21,22]. Despite increased risks of adverse outcomes for MLPT infants, they do not routinely enroll in specialized medical follow up or early intervention programs [23].

Low health literacy (LHL) is associated with poorer health outcomes, including higher rates of hospitalization and suboptimal use of preventive services. For parents of preterm infants, this can translate to difficulties in managing the infant's health needs, potentially leading to worse developmental outcomes [24]. We aimed to include a relatively high number of parents with a low educational level in this study to learn whether the transfer of information during the home-visits or the additional e-TOP app was suitable form them.

In the Netherlands, the evidence-based TOP program for very preterm (VP) children (GA <32 weeks and/or birth weight <1500 g), carried out by pediatric physical therapists (TOP interventionists), is implemented as usual care [25]. The TOP program contains seven strategies to strengthen parental responsiveness, improve parents' knowledge and understanding of their child's developmental needs, and decrease parental stress (Fig. 1). We hypothesized that the strategies of the TOP program are also suitable to address the challenges MP infants and their parents face after being discharged home and can improve developmental outcomes.

To determine whether an intervention can be expanded to a different population, feasibility studies are recommended before efficacy testing or implementation [26,27]. We were aiming to answer the research questions; (1) recruitment capability and compliance. Will MP parents be identified by hospital staff. Will MP parents participate and complete the intervention? (2) intervention acceptability. Do parents perceive the adapted TOP program as appropriate, and does it accommodate their needs? (3) limited-efficacy testing. Are the measures appropriate and sensitive to evaluate change, is there preliminary evidence for positive changes. The aim of this study is to evaluate if the modified TOP program is feasible for MP infants and their parents.

2. Methods

2.1. Setting and procedure

The study was conducted by the research team, consisting of researchers and educators from the Dutch Expertise Centrum Ontwikkelings ondersteuning Prematuren (EOP), affiliated with the Amsterdam Medical Center, and the Centre of Expertise, Faculty of Health, Amsterdam University of Applied Sciences The EOP is responsible for

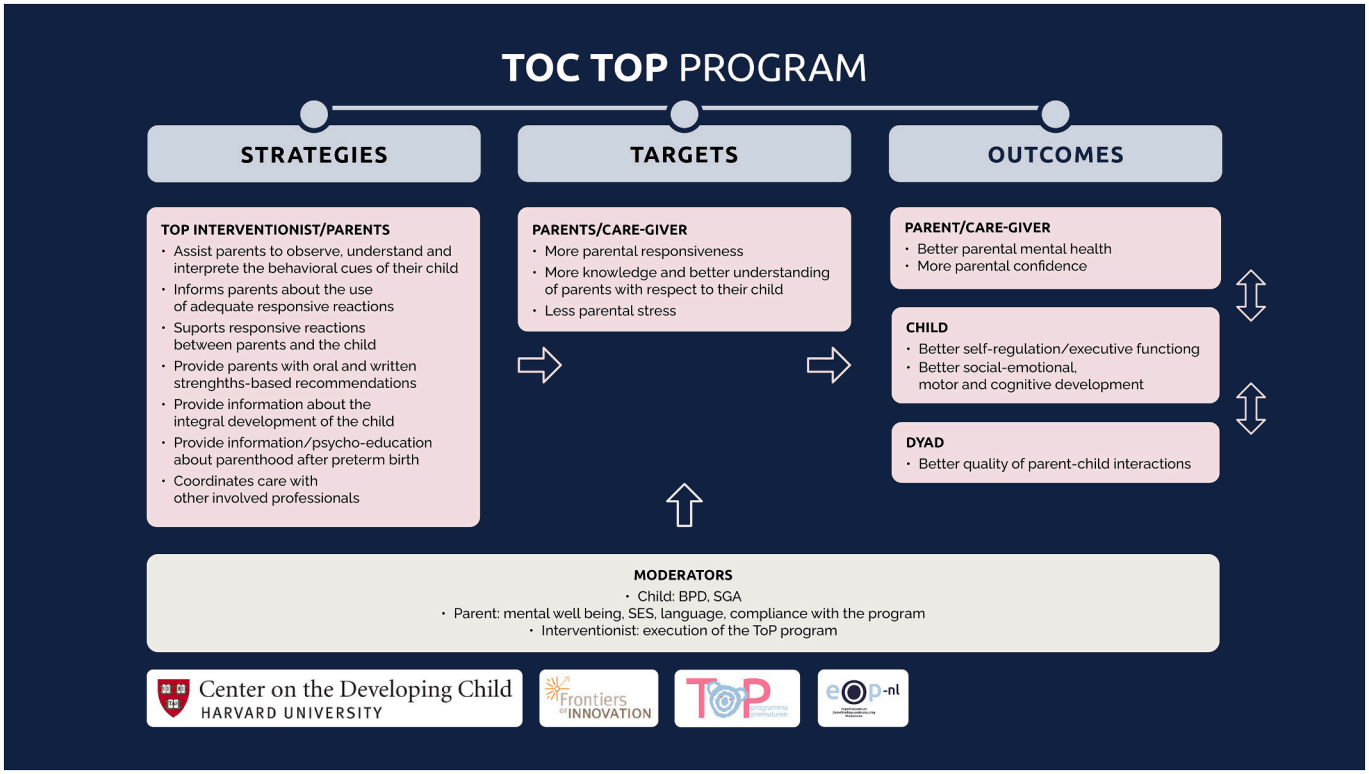

Fig. 1. Theory of change of the TOP program.

coordination and implementation of the existing TOP program for very preterm born infants. Prior to the enrollment of participants, the research team recruited fifteen affiliated and experienced TOP-interventionists, from different geographic and socio-economic regions. The TOP-interventionists all had a working relationship with the hospital staff and provided the hospitals with information about this feasibility study.

The feasibility of the adapted TOP program was assessed in a group of MP infants and their parents, using pre and post intervention measures. Enrollment for the study was from November 2022 till March 2023. Eligible participants were approached by the hospital staff (pediatrician or pediatric physical therapists) of the participating secondary-care level hospitals. When interested, participants received an information letter including a QR code referring to a short video-clip about the study The TOP-interventionist in that region was informed by the hospital staff. The TOP-interventionist was the primary contact for the parents and scheduled the pre-intervention home visit and also informed the study center. During the pre-intervention home visit, the TOP-interventionist obtained written informed consent (IC). Additional written consent was asked for filming of the parent-child interaction. When provided, this interaction was filmed during the same home visit. All participants that provided consent received the adapted TOP-program in addition to care as usual. Non-participants received care as usual, which was not provided by TOP-interventionists. In case of non-participation after the pre-home visit, the first author collected additional information by making a phone call to TOP interventionists to elucidate the parents' concerns.

After the study center received the signed IC, both parents received an e-mail with the invitation to complete online questionnaires at baseline (T0). One reminder was sent to the families via e-mail or WhatsApp. Perinatal variables (GA, sex, multiple birth, birth weight, APGAR score, length of hospital stay, and morbidities) were extracted from the medical record by the referring hospital staff and send to the TOP-interventionist. The TOP interventionist transferred this data to the study center using a system for securely sending data.

During the last home visit, parent-child interaction was videotaped again. After completion of the intervention, parents again received an intervention to complete a set of online questionnaires. The first author also interviewed several parents about their experiences with the intervention. After completion of all home visits, TOP interventionists participated in a focus group on their experiences with the execution of the intervention and participating in the study.

The study protocol was approved by the medical Ethical Committee of the Amsterdam UMC (NL78996.018.21).

2.2. Intervention development and training

The intervention protocol for MP infants was based on the existing evidence-based TOP program. This post-discharge intervention for VP infants consists of 12 home visits by a TOP interventionist in the first year. In co-creation with parents, TOP interventionists, pediatric physical therapists (PPT), and pediatricians, adaptations to the TOP protocol were established. An important adaptation was to shorten the TOP program for MP infants to six home intervention sessions until the corrected age (CA) of 6 months. Each home visit had a duration between 45 and 60 min. The use of the seven key strategies including the parent-report with individualized strength-based recommendations were indicated as essential and remained unchanged (Fig. 1) [30]. To strengthen two key strategies (providing information about the integral development of the child, parenthood after preterm birth), an information app (e-TOP) for parents was designed. The e-TOP app was developed in co-creation with parents, TOP interventionists, and experts in the field of prematurity with special knowledge of e.g. nutrition, sleep, long-term consequences of prematurity. Usability of this app will be evaluated separately and is outside the scope of this feasibility study.

For this study, fifteen certified and experienced TOP interventionists received a 1-day training. The training was conducted by senior TOP-educators and members of the research team (MF, EM, MJ). The training contained substantive information about the target group, the use of the e-TOP app, the research protocol, including the measurements and Informed Consent procedure.

2.3. Participants

Infants were eligible to participate if (a) they were born with a GA between 32 0/7–34 6/7 and a birth weight $>$ 1500 g (as MP infants with a birth weight $<$ 1500 g can already participate in the regular TOP program); (b) parents were able to understand and read the Dutch language or an interpreter could be arranged; (c) lived within acceptable traveling distance from a participating TOP-interventionist (approximately 20 min). Infants were excluded if (a) the infant had congenital abnormalities; (b) participated in another parent-child intervention program. For multiple birth, only one infant was included in the study. A sample size of 40 infants was chosen to capture the social and medical heterogeneity in the study group, aiming at 15 families with a lower educational background defined as completed primary school, vocational education, lower or middle general secondary education.

2.4. Measures

2.4.1. Compliance and execution of the intervention (T1)

The TOP interventionist completed checklists after each home-visit, including registration of caregiver attendance during the home visit (fathers/mothers). The content of intervention-execution was assessed by the key strategies, questions, issues and topics that were addressed during each home visit.

2.4.2. Intervention acceptability (T1)

Parents completed a questionnaire containing questions about perceived appropriateness of the intervention and indicated how satisfied they were with the intervention on a scale of 1 (lowest) to 10 (highest).

Following completion of the intervention, eight parents were interviewed by the first author (MF) to gain more in-depth information about their experience with the TOP program. Interviews (video or phone call) were offered at a time convenient for the parents. For the post-intervention interview we used the following five questions: (1) How is [name infant] doing? How are you, as parents, doing after the first months at home?; (2) Can you tell me how you experienced the TOP program and TOP interventionist?; (3) Could you tell if and how the intervention helped you with taking care of your preterm infant?; (4) Did you make use of other services or health care professionals during the intervention period?; and (5) Could you give us any suggestions or advice for improvements to the intervention?

Following completion of the study, interventionists were asked to participate in a focus group meeting to share their experiences with the execution of the intervention and participating in the study. The following themes and questions were discussed: (1) Overall thoughts about participating in the study and execution of the intervention; (2) Timing, frequency, duration of the TOP program for MP infants; (3) Used intervention tools (part of the intervention protocol); (4) Suitability of the TOP training to carry out the MP intervention; (5) The use, feasibility, and content of the app. The evaluation of the fifth theme was not the focus of the current study and will be described separately.

2.4.3. Limited-efficacy testing

2.4.3.1. Child outcomes (T1). Infant motor development was assessed at T1 with the Alberta Infant Motor Scale (AIMS) [28]. The total score of the items of the four gross motor positions was used and translated to a percentile ranking compared to a normative age-matched sample of

infants. A score below the 5th percentile, based on the Canadian norms, was used to define delayed motor functioning. The AIMS is a reliable and validated observational tool [29].

Parent report of infant social-emotional development at T1 was assessed with the Ages and Stage Questionnaire Socio-Emotional 6-month Dutch version, 2nd edition (SED: ASQ-SE2-NL). The parent-report screening instrument consists of 26 items related to developmentally appropriate behavior. Parents indicate whether the child shows the described behavior 'most of the time' (0 points), 'sometimes' (5 points), or 'rarely/never' (10 points). Additionally, 5 points were given if parents indicated being worried about the described behavior. Scores range from 0 to 145, with higher scores representing a worse socio-emotional development. The cut-off score of 30 points was used to define infants at risk for socio-emotional difficulties [30]. The ASQ-SE-2-NL has good psychometric properties and clinical utility in screening for delay or problems [31,32].

2.4.3.2. Parent outcomes (T0). Parents completed the Distress Thermometer for Parents (DT-P) at T0. The DT-P measures overall distress using a thermometer score ranging from 0 to 10, with a score of 4 or higher indicating clinically elevated distress. It also evaluates everyday problems across six domains: practical (seven items), social (four items), emotional (nine items), physical (seven items), cognitive (two items), and parenting (five items). Scores for each domain are calculated by summing the items marked as problems (yes = 1, no = 0). The DT-P is a widely used tool in clinical practice and has shown good psychometric properties [33,34].

2.4.3.3. Parent outcomes (T0-T1). Parenting self-efficacy was assessed at T0 and T1 with the Dutch version of the Maternal Self-efficacy in the Nurturing Role (SENR) [35]. The total score of the 16 items, each rated on a 7-point Likert scale from 1 (Not at all representative) to 7 (Strongly representative) was used. Higher scores reflect greater feelings of competence in parenting. Previous studies have shown moderate to high test-retest reliability and good internal consistency [36,37].

Parental reflective functioning with regard to their child was measured at T0 and T1 with the Parental Reflective Functioning Questionnaire (PRFQ). The PRFQ (18 items) assesses three domains: Certainty about mental states (ability to recognize the opacity of mental states), Interest and Curiosity in mental states (genuine parental interest in and curiosity about infant mental states), Pre-mentalizing (a parent's tendency to make negative attributions about their child's behavior) rated on a 7-point Likert scale ranging from disagree to agree. In this study all three domain scores were used. The PRFQ has good psychometric properties [38,39].

Parental sensitivity was assessed with the parent scale of the Attachment During Stress scale (ADS) at T0 and T1 [40]. The ADS can be used in mildly stressful situations, such as a doctor's visit, but also in daily situations such as bathing, dressing, and free play. The ADS can distinguish sensitive from less sensitive mothers. In this study, two structured parent-infant interaction tasks (diaper change and free play) were video-recorded by the TOP interventionists. For the diaper change, parents were instructed to undress their child, change the diaper, and then redress the child. The undressing and dressing were filmed, but recording was paused during the actual diaper change for privacy. For free play, parents played or interacted with their child for 3 min, starting the recording after receiving instructions and stopping it after 3 min. Coding was conducted by two master students in pedagogy, trained by two researchers (EM, MJ). The ADS has seven parental sensitivity items (gazing, vocalizing, touching, holding, affect, proximity) rated on a 5-point scale, with scores of 1–2 suggest avoiding contact, 3–4 reflecting sensitive behavior, and 5 reflecting over-anxious interaction. A total score for parental sensitivity per task was calculated based on the frequencies of the sensitive scores (scores 3 and 4) obtained for each of the behaviors displayed. The scores for parental holding were not used, as this behavior did not occur frequently enough. Thus, a score between 0 and 6 for parental sensitivity was possible, with 0 indicating the absence of any sensitive behavior, and 6 indicating all the behaviors displayed were sensitive. To determine interobserver reliability, 19 % of the videos were double coded. Mean interobserver reliability (intraclass correlations; ICC) was 0.96 (range 0.93–1.00) for diaper change and 0.98 (0.89–1.00) for free play. The final scores for the double coded data were obtained by randomly selecting the scores of one of the observers.

2.5. Analysis

2.5.1. Quantitative data

Data were exported from the Castor database (Electronic Data Capture, Ciwit BV, Amsterdam, the Netherlands, 2021) to the Statistical Package for the Social Sciences version 28 (SPSS Inc. Chicago, Illinois). Baseline infant and parent characteristics, intervention data, child outcome measures (ASQ-SE-NL and AIMS) were summarized by descriptive statistics using the mean, standard deviation, frequencies, percentiles, or percentages. The median and interquartile range (IQR) was used when the data were non-normally distributed. The change scores for the SENR and PRFQ were calculated at an individual level, using the Reliable Change Index (RCI). The RCI reflects the absolute change in scores pre- and post-intervention that are required to be confident that the observed change was not due to random variations over time. The ADS results were analyzed using Paired Sample *t*-tests. For the parametric tests, the effect sizes were calculated and interpreted according to the Cohens' d criteria (0.20 = small, 0.50 = medium and 0.80 = large) [41]. Significance testing was not appropriate for this feasibility study due to the set-up and sample size [42].

2.5.2. Qualitative data

Qualitative data (audio recordings) from the interviews with parents and the focus group meeting with interventionists were evaluated by the first author (MF). This data was used to gain more insights about the usability and suitability of the intervention and to verify if findings correspond with the findings on the satisfaction questionnaire. Content related questions were used to identity points for improvement.

3. Results

3.1. Recruitment capability and compliance

Ultimately, ten interventionists were able to include MP families. The most common reasons for interventionists not including families were an unexpected smaller number of discharged MP infants during the inclusion period as reported by the hospitals. All of the collaborating hospitals were interested in the study and were in close contact with the TOP-interventionist.

A total of 38 families were identified by hospital staff and were interested in the study. Thirty-three families were eligible and agreed to participate and gave informed consent. One family withdrew after signing IC, but before the first intervention home visit. Thirty families gave additional consent for filming the parent-child interaction (Fig. 2).

The pre-intervention visit was on average 13 days after discharge, the first home visit (intervention) a month after discharge. All 32 families completed the intervention program and received the six home visits. Mothers were present almost all six home visits (80 %). Fathers were present more than half of the home visits. Additional information about the actual execution of the intervention is provided in Table 2.

3.2. Perinatal and socio-demographic characteristics

Infant were born on average at a GA of 33.6 ± 0.7 weeks. Six children were small for gestational age. One infant was diagnosed with bronchopulmonary dysplasia. Within the study group, no severe complications such as necrotizing enterocolitis, IVH grade III/IV, PVL grade

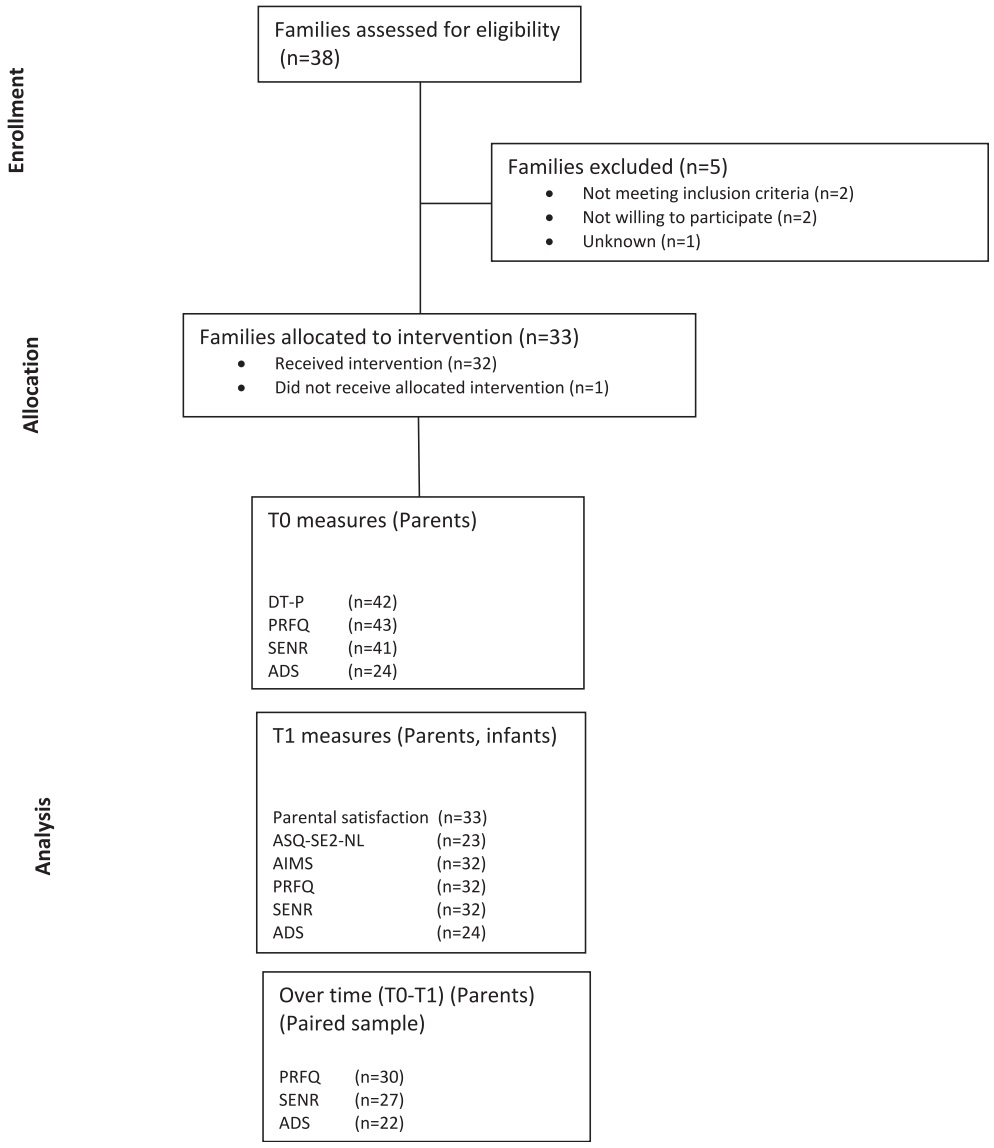

Fig. 2. Flow of participants.

> 1 were reported in the medical history.

Length of hospital stay (LOS) was almost 3 weeks, and infants were on average discharged at $36^{5/7}$ weeks GA. Despite the efforts to include families with lower educational backgrounds, parents were mostly well educated, employed and had a family status of 2 parents. Parents reported an elevated level of distress at T0. The mean (SD) DT-P thermometer score was 3.68 (2.6) with the highest problem scores on the emotional, physical, and practical domains. Half of the parents scored within the clinical range of the DT-P (score $\geq$ 4). Mothers scored more often within the clinical range than fathers (62 % vs 25 %) (Table 1).

3.3. Intervention acceptability

Parents were very satisfied with the amount of home visits (6) and were very satisfied with the intervention (mean satisfaction rate of 9.4 on a scale of 0–10). Two parents indicated the need for prolongation of the intervention due to their infant's delayed development. In general, parents stated that the intervention was helpful to learn to understand the behavioral needs of their infant, they gained confidence in their caregiving, and valued the strength-based parent report (Table 3).

Ten families were approached to participate in the interview after the intervention by first author (MF). Two families did not respond to the mail invitation and two families did not want to participate due to their busy schedules. Ultimately, six families participated, including six mothers and two fathers. All eight parents emphasized their need for appropriate support after discharge, they felt unprepared and insecure. All parents emphasized the importance of receiving support promptly, preferably within the first few days after discharge. They expressed that the intervention fitted their needs and described it as most suitable care. Participating in the intervention provided them with the care they needed, and they hoped this intervention would become available for other parents. Parents valued the interventionists for their expertise and knowledge on the impact of prematurity, their accessibility, and practical guidance. Parents indicated again that the amount of six home visits was sufficient and valued the individualized parent report after the home visit. They assigned their enhanced self-efficacy and understanding of their infant's needs to the intervention (Table 3).

Ten TOP interventionists evaluated the MP intervention during a focus group meeting. They all agreed that in general six home visits were sufficient, but also indicated the need for flexibility to schedule additional visits if necessary for the infant or family. They emphasized the need for a rapid start of the intervention, preferably within the first week after discharge. They reported that the implementation of the TOP program strategies within this target group was well applicable and that

Table 1
Baseline clinical and demographic characteristics of the families.

Infant characteristics	
Gestational age (GA), week, mean (SD)	33.6 (0.7)
Birth weight (BW), g, mean (SD)	2201 (379)
Small for gestational age (SGA), n (%)	6 (19)
Sex, male/female, n (%)	17/15 (53 %/47 %)
Number of twins, n (%)	5 (15.6 %)
Apgar score at 5 min, mean (SD)	8.5 (0.3)
Bronchopulmonary dysplasia, n (%)	1 (3.1 %)
Necrotizing entercolitis n (%) IVH	0 (0 %)
grade III/IV n (%)	0 (0 %)
PVL grade > 1 n (%)	0 (0 %)

Parental characteristics		
	Mothers ($n = 29$)	Fathers ($n = 14$)
Age, years, mean (SD)	30.9 (4.3)	33.4 (4.8)
Firstborn child, n (%)	19 (65.5 %)	7 (50 %)
Family status of 2 parents, n (%)	29 (100 %)	14 (100 %)
Country of birth, n (%)		
Netherlands	28 (96.6 %)	14 (100 %)
Turkey	1 (3.4 %)	
Dutch language spoken at home, n (%)	29 (100 %)	14 (100 %)
Education, n (%)		
Lower	1 (3.4 %)	1 (7.1 %)
Intermediate	13 (44.8 %)	5 (35.7 %)
High	15 (51.7 %)	8 (57.2 %)
Job n (%)		
Fulltime	15 (51.7 %)	12 (85.7 %)
Part time	14 (48.3 %)	2 (14.3 %)
DT-P		
Mean (SD)	4.00 (8)	1.5 (7)
>Clinical cutoff (%)	61.5 %	25 %

At discharge	
Length of hospital stay (LOS), days, median, (Q1–Q3)	19.5 (15.3–28.5)
Postmenstrual age at d/c, days, mean (SD)	257.3 (7.5)
Time between d/c and 1 pre-visit (days), median (Q1–Q3)	13.0 (9.0–23.3)
Time between d/c and 1 intervention	31.0 (24.3–48.8)
Median (days), median (Q1–Q3)	

SGA was defined as <P10 with the reference data from https://www.perined.nl/onderwerpen/geboortegewichtcurven
Bronchopulmonary dysplasia (BPD) was defined as oxygen dependent after GA 36 weeks.
Necrotizing enterocolitis was defined as stage ≥2 according to Bell's clinical staging.
Periventricular Leukomalacia (PVL) was defined when ≥1 Intraventricular hemorrhage (IVH) was defined when >3.
Highest educational level completed: Lower-level education refers to primary school, vocational education, lower of middle general secondary education. Intermediate: refers to higher secondary general education, pre-university education. High: Higher vocational education or university. This classification is based on the 'Standaard Onderwijsindeling 2021' [25].
DT-P: Distress Thermometer for Parents, with a scale from 0 to 10.

their extensive expertise with VP infants was easily transferable to the new target group. They also indicated that specifically parents with a lower educational background found the Informed Consent procedure, videotaping during the pre-home visit and the extensive data collection somewhat threatening.

3.4. Limited efficacy testing

3.4.1. Child outcomes

For motor development, infants' mean AIMS score at T1 was 24.8 (SD 6.1). Three infants (9 %) scored below the cut-off score of P5. Regarding socio-emotional development, the median score on the ASQ-SE2-NL was 20.0 (IQR 13.8, 26.3). Two infants (6 %) were identified as

Table 2
Dosage and execution of intervention delivery.

Parental attendance at home visits (range 0–6 home visits)	Mean (SD) or %
Mothers	
Attendance at home visits	5.75 (0.51)
Attendance of >3 home visits	100 %
Attendance of 6 home visits	79.9 %
Fathers	
Attendance at home visits	2.56 (2.08)
Attendance of >3 home visits	31.2 %
Attendance of 6 home visits	12.5 %

Topics[a]	Mean (SD)
Behavioral cues and responsive reaction	5.60 (0.81)
Sleep	5.16 (1.04)
Feeding	5.32 (1.35)
Motor development	5.51 (0.62)
Correcting for infant age	4.45 (1.68)
Transition to parenthood	3.29 (1.68)
Long term consequences of prematurity	1.51 (1.28)
Return to work	3.16 (1.71)
Health related questions	1.39 (1.22)
Follow up/care after intervention	1.42 (1.52)

[a] Topics; Per home-visit (0–6) registered focus of treatment.

Table 3
Parental satisfaction with the TOP program ($n = 33$).

Questions	Mean (range) or yes (n) no (n)	Comments of parents
How would you rate the intervention you received (1–10)	9.39 (8–10)	*The TOP program was very valuable for us.*
		The best guidance we received.
		Home visits were wonderful.
1. Was the number of home-visits sufficient?	Yes (31) No (2)	*I am still insecure about my baby's development, would have liked more home visits.* *Six months is a good period for the intervention. I do feel that everything is going as it should be right now.*
2. Did the intervention help to understand behavior and needs of my child?	Yes (32) No (1)	*I do not think I would have become such a sensitive parent without the guidance in how to read my baby's signals.*
		I do know better when he's ready to make contact and when he needs some rest.
3. Did the intervention help to gain confidence in caregiving?	Yes (29) No (1) Unknown (3)	*My insecurities about does he have pain, can he be on his tummy, what is good for him would be discussed during the home visits.*
		She helped me understand and gave support and trust in myself.
4. Did you find the parent report of additional value?	Yes (32) No (1)	*Good to receive specific information about my child and be able to see the progression.*
		Gives possibility to read all the information given in the home visit.
		Pictures give insights and show my baby's change.

Table 4
Descriptive statistics and effect sizes for infant and parent outcome measures.

Measure	M (SD), n		Percentage above/below cut-off[a]
	T0	T1	
AIMS raw score			9.4
Mean (SD)		24.1 (5.5) n = 32	
Prone		9.7 (3.1)	
Supine		8.2 (1.3)	
Sitting		4.9 (2.2)	
Standing		2.1 (.82)	
ASQ-SE-NL Median (IQR)		20.0 (13.8–26.30) n = 32	6.7

	T0 M(SD), n	T1 M(SD), n	Cohen's d	Improvement T0-T1 (no., %)[c]
SENR	90.60 (11.9) n = 41	94.80 (9.7) n = 32	0.35 n = 27	7/27 (26)
PRFQ-PM[b]	1.64 (0.64) n = 43	1.55 (0.52) n = 32	0.59 n = 30	9/30 (30)
PRFQ-CMS	4.11 (0.84)	4.55 (0.77)	0.81	12/30 (40)
PRFQ-IC	5.34 (0.91)	5.39 (0.89)	0.56	1/30 (3)
ADS				
Diaper change	5.64 (0.70)	5.88 (0.33)	0.400.38 .	
Free play	5.2 (1.20) n = 24	5.6 (0.57) n = 24	n = 22	

[a] Used Cut off score: AIMS < P5, ASQ-SE2-NL > 30 pt.
[b] PRFQ-PM refers to domain: Pre-mentalizing, PRFQ-CMS refers to domain Certainty about mental States PRFQ-IC refers to domain Interest Mental states.
[c] Used RCI index: SENR 10.57. PRFQ-PM 0.81, PRFQ-CMS1.19, PRFQ IC 0.97.

at risk for delay (Table 4).

3.4.2. Parental outcomes

Parental sensitivity, as measured with the ADS at T0, was high for both tasks, diaper change (M 5.64, SD 0.70) and free play (M 5.17, SD 1.20) and improved over time (Cohens' d 0.40 and 0.38 respectively).

Parents' perception of their competence in caring for their infant as measured with the SENR showed a high initial score at T0 (M 90.6, SD 11.9) and increased 4.2 points (M 94.8, SD 9.7). The effect size was small (Cohens' d = 0.35) and 26 % of the parents reported a clinically relevant improvement in their confidence in parenting skills (RCI > 10.57). Parents' reflective functioning as measured with the PRFQ (three dimensions) improved over time. Certainty about mental states improved from T0-T1 with a large effect size (Cohens' d 0.81), 40 % of the parents showed a clinically relevant improvement (RCI > 1.19). For the domains Interest and Curiosity and Pre-mentalizing medium effect sizes were found (Cohens' d 0.56 versus 0.59). The RCI indices for the PRFQ interest and Curiosity, showed only for 1 participant a clinically relevant positive change (RCI > 0.97). For the PRFQ domain Pre-mentalizing, 30 % of the participants showed clinical important progression (RCI > 0.81) (Table 4).

4. Discussion

The ability to enroll and retain families and the positive results of this study fully support the feasibility of the TOP program for the new target population of MP infants and their parents. The three feasibility dimensions; recruitment capability/compliance, acceptability, and limited efficacy testing will be discussed separately.

4.1. Recruitment capability and compliance

The willingness of the clinical staff at the participating hospitals to inform parents, and parents wanting to participate in this intervention confirmed the observed need for support after discharge in studies from Davis-Strauss (2020) and Adama (2016) [43,44]. Taking into consideration that the TOP program is offered preventively, our enrollment feasibility rate and the compliance with the intervention was remarkably high compared to other parenting intervention studies [45,46].

Non-participating families (6) of 38 interested families wanted to receive the TOP program, however participating in the study was too much to ask. They found the Informed Consent letter difficult to understand, and despite the fact the video recording of the ADS before the intervention was not mandatory, parents perceived it as an assessment for their parenting skills. These unintended consequences of participating in a study could have led to less already disadvantaged participants. A postponed informed consent procedure, availability of translated documents, support to complete questionnaires, and text to speech features might be useful to explore in future intervention research.

For feasibility research, findings about compliance with the data collection is also important. Via questionnaires, parents cited reasons for not completing assessments at T0 and/or T1, including returning to work, feeling overwhelmed by life stressors such as moving, and the amount of self-reported measures for both fathers and mothers. These findings advocate for brief self-reported measures to reduce respondent burden and facilitate involvement of fathers.

4.2. Intervention acceptability

All families adhered to and engaged in the intervention. De-briefing post-intervention interviews showed acceptability and suitability of the strategies on improving parent-child interaction. Another important aspect parents appreciated was the collaborative relationship with the TOP-interventionist. The importance of promoting parent-infant interaction and trust between parent and the interventionist for successful participation, is confirmed by Oberg (2023) in a qualitative systematic synthesis [21].

The timing of the first intervention session, in our study one month after discharge, requires adjustment. Both parents and TOP interventionists expressed the need for support to start earlier, ideally within the first two weeks post-discharge. Starting the TOP intervention immediately after hospital discharge would assist parents in managing their insecurities and enhancing practical skills during the transition from hospital to home. In this feasibility study, informed consent and reflection time to consider participation delayed the first home visit. Including families already during hospital admission may decrease this time.

4.3. Limited efficacy testing

4.3.1. Child outcomes

The post-intervention level of motor development at 6 months CA surpassed our expectations (Mean AIMS score of 24.1). Recently, Suir et al. (2022) found lower mean scores [18.5–22.4] in a general Dutch population than in our sample [47]. The execution of the responsive strategies containing holding, positioning, and stimulating mobility activities for the infants could have improved the motor development in our sample, especially in the age-related supine and prone position. To learn if the positive motor development persists with achieving new motor milestones, we would recommend monitoring the gross motor trajectory over a longer period of time. After all, research showed low predictive values of the AIMS (4 months: 40 %; 8 months: 66 %) due to intra-individual variability [48,49].

Another consideration regarding the high AIMS scores is that TOP interventionists, who are experienced pediatric physical therapists

skilled in scoring motor development using the AIMS, were directly involved in the intervention, and not blinded. For future studies, we recommend video-recording the motor development assessment, allowing independent, blinded researchers to conduct the scoring.

Parents reported a positive socio-emotional development of their MP infants. All aspects of the measured socio-emotional development (i.e., behavior regulation, feeding, sleeping, and interaction) were addressed during the home visits, in the customized parent reports, and additional information was provided via the e-TOP app. These deployed intervention strategies could have contributed to the positive impact on the parent-reported socio-emotional development of their child. Although the ASQ-SE2-NL was useful to open the conversation with parents as a guidance for intervention strategies, we need to be careful to draw conclusions based on these outcomes. Low sensitivity indices and low predictive value at the age of 6 months was reported by de Wolff (2013) and Krijnen (2021) and we therefore recommend longer follow up to evaluate if these short-term results perpetuate [31,32].

4.3.2. Parent outcomes

We found improvements on all parental measures (SENR, PRFQ, ADS) with small to large effect sizes. We speculate that the intervention strategies have contributed to the positive outcomes in parents' feelings of self-efficacy, reflective functioning, and parental sensitivity. During the home visits, the primary focus was on observing and understanding the infant's behavioral cues across various developmental domains, such as interaction, sleeping, and feeding. Subsequently, the appropriate parental responsive reaction, to meet the infant's emotional and developmental needs, were identified and practiced with the parents. Although our results were very promising, the effect of time and assessing efficacy of the intervention on the parental outcomes cannot be determined with the single group design and would require a control group.

The pre-intervention scores on parental self-efficacy were unexpectedly high compared to the baseline high distress scores on corresponding DT-P domains (1) emotional problems containing questions about self-confidence, feelings of depression, and (2) parenting problems in caring, feeding, and development of the child. Our findings subscribe the view of de Moor (2023) that in addition to measuring distress, assessing parenting self-efficacy during an intervention can help to understand parents' appraisal of one's ability to parent [37].

This feasibility study confirmed the need for post-discharge intervention for MP infants and the TOP program positively affected the infants and their parents. By pairing our surveys and checklists with qualitative data we gained valuable information about suitability and the impact of the used TOP-strategies. The use of qualitative measures (interviews, ability to comment in the questionnaires, focus group) added to the understanding of modifiable factors influencing the recruitment outcomes, and compliance with data collection.

4.3.3. Limitations

The present study is the first step to explore if moderate preterm born infants and their parents benefit from the modified TOP intervention. There are several limitations to the present study.

This feasibility study was conducted with a small sample size and was not set up to compare between groups, limiting our analyses of potential efficacy. We need to advance to a larger, randomized controlled trial design to be able to confirm the positive study results, and to be able to better identify mechanisms of change and interrelationship between outcomes. The used measures relied partially on subjective self-report measures, which may be biased by social desirability. The use of direct measures, such as the ADS, AIMS and the qualitative data however endorse the found positive findings.

Both fathers and mothers were invited to participate in the study and all signed informed consent. Fathers participated on average in 2.5 (out of six) home-visits, and only a limited number of fathers completed the questionnaires, and we could only compare the pre-post data of seven fathers, which is insufficient to draw conclusions. Dutch fathers have limited parental leave and were less present during the home visits which may have also impacted the compliance with the data-collection. We would recommend more flexibility in work-schedules of the interventionists to promote paternal attendance.

Although the level of parents' education differed, almost all participants received higher secondary general education and were all employed. The inclusion criteria such as language, the strict research protocol including the informed consent procedure, and the number of digital questionnaires might have led to underrepresentation of families with different backgrounds and lower educational levels. During the initial phase of developing the MP intervention and the e-TOP information app, partnership with low literacy end-users has been successful. To make studies and implementation trials more accessible and meaningful for participants, we would recommend involving parents or parent representatives throughout the entire research cycle, including design and choice of measures [50].

Additional findings from the interviews and a focus group contained valuable information and were very much in favor of the feasibility of the intervention. It confirmed the high parental satisfactory rates and need for support. However, the re-listening of the audiotapes, summarizing the transcripts and the evaluation of the focus group results were all executed by the first author and discussed with the research team. To limit biases in data analyses, we recommend having double coders for the qualitative data in future research.

5. Conclusion

The Dutch post-discharge parenting intervention (TOP program) is feasible to use with moderate preterm born children and their parents. The findings of this study indicate that the modified TOP program meets the needs of MP infants and their parents, resulting in a high intervention adherence and acceptability, promising child outcomes and positive changes in caregiver sensitiveness, self-efficacy, and reflective functioning. This study contributes to the preparatory work prior to a larger scale evaluation and dissemination.

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CRediT authorship contribution statement

Monique Flierman: Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Eline L. Möller:** Writing – review & editing, Visualization, Methodology, Formal analysis. **Raoul H.H. Engelbert:** Writing – review & editing, Supervision, Funding acquisition. **Anton H. van Kaam:** Writing – review & editing, Supervision. **Daniël Bossen:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition. **Martine Jeukens-Visser:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition, Formal analysis.

Declaration of competing interest

The authors have no conflict of interests.

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