

Early Parent-Administered Physical Therapy for Preterm Infants: A Randomized Controlled Trial

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abstract

OBJECTIVE: To investigate the short-term effect of parent-administered physical therapy in the preterm period on motor performance in medically stable infants.

METHODS: This study was a pragmatic, multicenter, randomized controlled trial including 153 infants born at gestational age ≤ 32 weeks and randomized to an intervention ($n = 74$) or a control ($n = 79$) group. The intervention promoted postural control, head control, and midline orientation. Parents, supervised by a physical therapist, conducted the intervention 10 minutes twice a day for 3 weeks from 34 to 36 weeks' postmenstrual age (PMA). The control group received usual care. The Test of Infant Motor Performance Screening Items was used at baseline and the Test of Infant Motor Performance postintervention (week 37 PMA). Linear mixed models were used to assess change in motor performance between groups from 34 to 37 weeks' PMA by using z scores. Effect size was measured by using Cohen's *d*.

RESULTS: The mean baseline z score was 0.06 (95% confidence interval, -0.48 to 0.60). After the intervention, there was a significant group difference, indicating a change in motor performance from week 34 to 37 PMA favoring the intervention group. The estimated difference in z scores was 0.42 (95% confidence interval, 0.13 to 0.72 ; $P = .005$), and the effect size was 0.40.

CONCLUSIONS: Parent-administered physical therapy conducted before term-equivalent age improved motor performance at 37 weeks' PMA more than conventional care. All infants will be followed up until 2 years' corrected age to evaluate the long-term effects of this brief intervention.

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Mrs Ustad participated in planning the study, baseline and postintervention assessments, statistical analyses, and drafting of the manuscript; Dr Evensen was involved in supervision of statistical analyses and preparation of the manuscript; Drs Campbell and Girolami participated in planning the study, in preparation of the manuscript, and in proofreading; Dr Helbostad supervised the statistical analyses and preparation of the manuscript; Drs Kaaresen and Jørgensen participated in planning the study and in preparation of the manuscript; and Dr Øberg was responsible for design and planning the study and participated in postintervention assessments from video recordings, statistical analyses, and preparation of the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

WHAT'S KNOWN ON THIS SUBJECT: Studies on early intervention to improve motor function in preterm infants have failed to show large effects. Interventions involving parents seem to be more effective than when therapists conduct the intervention.

WHAT THIS STUDY ADDS: Three weeks of parent-administered physical therapy implemented before term-equivalent age in very preterm infants improved short-term motor performance more than in the control group. The intervention was feasible and well tolerated by the infants.

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Despite sparse documentation, early physical therapy (PT) is assumed to be beneficial in optimizing motor development in infants born preterm. Developmental impairments increase with decreasing gestational age (GA) at birth.¹ Impaired self-regulation, attention and behavioral state, and poor postural control and quality of movements are early signs of developmental concerns.^{2,3} Postural control is a prerequisite for the development of optimal movement strategies, and reduced postural control in infants born preterm is related to reduced balance at 6 years.^{4,5} In addition, a meta-analysis showed that prematurity is associated with motor impairments persisting throughout childhood.⁶

The brains of infants born preterm are particularly vulnerable to lesions because of rapid brain maturation in the last trimester.⁷ Motor development is dependent on experience and active participation, by which synaptic connections are refined and lead to changes in function and organization of the brain.^{8,9} Enriched environments and appropriately targeted training strategies affect brain and corticospinal development and are thereby likely to influence the brain's capacity to compensate for deficits after lesions.¹⁰⁻¹² The preterm period and first year postterm might be a sensitive period for motor development; as a result, interventions during this period could be beneficial to optimize motor development.¹³

A meta-analysis on effects of early interventions posthospital discharge concluded with a small significant difference in motor outcome at age 0 to 3 years favoring intervention groups.¹⁴ Interventions initiated while the infants were in the hospital showed a slightly larger impact than those implemented after discharge, and a study with parents actively involved in the intervention found favorable change in motor

performance in the treatment group compared with the control group.¹⁵

More research is needed to elucidate the optimal age and type of intervention for improving outcomes associated with motor development. The primary goal of our randomized controlled trial (NOPPI [Norwegian Physiotherapy Study in Preterm Infants])¹⁶ was to assess the effect of parent-administered PT in the preterm period on motor performance at 24 months' corrected age (CA) in infants born very preterm. The intervention group received daily individually tailored PT for 3 weeks from 34 through 36 weeks' postmenstrual age (PMA), and a control group received usual care.

The present article is the second in a series of articles planned as part of the NOPPI. The purpose of this article was to compare the effect of parent-administered PT from 34 through 36 weeks' PMA on motor performance at the conclusion of therapy. We hypothesized that infants who received PT would demonstrate greater improvements in motor performance from baseline to 37 weeks than infants in the control group.

METHODS

Design and Setting

The NOPPI is a pragmatic, parallel-group, multicenter, single-blinded randomized controlled trial.¹⁶ The 3 participating hospitals (the University Hospital of North Norway [hospital 1], Trondheim University Hospital [hospital 2], and Oslo University Hospital [hospital 3]) belong to the National Health Service. The study was conducted in conjunction with the NICUs. The NOPPI was approved by the Regional Committee for Medical and Health Research Ethics in Northern Norway (REC North: 2009/916-7) and registered at Clinical Trials.

gov. The protocol was described in a previously published methods article.

Participants

Infants with GA ≤ 32 weeks who tolerated handling at 34 weeks' PMA were eligible for inclusion. Parents were required to understand and speak Norwegian. Triplets and higher pluralities, infants with malformations or syndromes, and infants having undergone major surgery were excluded from participation. Subject recruitment was initiated in March 2010 in hospital 1, April 2010 in hospital 2, and March 2013 in hospital 3. Recruitment ended in October 2014.

Randomization and Blinding

We used a Web-based, computer-generated randomization system developed and administered by the Unit for Applied Clinical Research, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway. The infants were stratified according to GA at birth (<28 weeks and ≥ 28 weeks) with twins assigned to the same group. The nature of the intervention made it impossible to withhold group assignment from the parents and the physical therapists instructing the parents. If the physical therapist administering the postintervention assessment knew the group allocation, the test was video recorded and later scored by a second physical therapist unaware of the group assignment.

Assessment Instruments

The Test of Infant Motor Performance (TIMP)¹⁷ and its short version, the Test of Infant Motor Performance Screening Items (TIMPSI), were used to assess motor performance. The TIMP has been described as one of the best tools to discriminate between age-appropriate and delayed motor performance in preterm and term infants, and to predict later motor development.^{18,19}

It was developed to assess functional motor performance in infants between 34 weeks' PMA and 17 weeks' postterm CA. The test can also be used to evaluate the effect of interventions, but the minimum clinically important difference for the TIMP has not yet been identified.^{15,17,18,20–22} It consists of 13 dichotomous observed items to rate infants' spontaneous movements, and 29 elicited items scored on rating scales of 0 to 4–6 points, to assess the infants' responses to handling and to visual and auditory stimuli.¹⁷ The assessment takes ~30 minutes and may be stressful for fragile infants. For those infants, the TIMPSI (containing one-half of the items of the TIMP) was developed.^{17,23} Concurrent validity of the TIMPSI versus TIMP has been shown to be high ($r = 0.93$),²³ and test–retest reliability of the TIMPSI is also high (intraclass correlation coefficient, 0.99).²⁴

Assessment Procedure

Parents of eligible infants were verbally invited to participate and received written information when the infants were 33 weeks' PMA. After the parents gave their written consent, motor assessments were conducted before randomization. Two or 3 physical therapists at each hospital participated in the assessment of the infants either at baseline (34 weeks' PMA) or postintervention (37 weeks' PMA) and collected perinatal and social background data from the parents and the medical records. At baseline, the infants were assessed by using the TIMPSI.¹⁷ General movements assessment was performed at 34, 36, and 52 weeks' PMA.²⁵ Postintervention, all infants were assessed with the TIMP at 37 and 52 weeks' PMA. Longitudinal assessments of the general movements and of TIMP at 52 weeks' PMA will be reported elsewhere.

The physical therapists who administered the TIMP and the TIMPSI had all completed a 2-day training workshop on administration and scoring of the test.

Intervention

The intervention was based on the research of Girolami and Campbell²⁶ and described in detail in our earlier methods article.¹⁶ The main objectives were to improve postural control, head control, and midline orientation. The intervention was conducted 10 minutes twice a day for 3 weeks when the infants were 34 to 36 weeks' PMA. One parent in each family was taught to administer the intervention. On day 1, the physical therapist explained and demonstrated the activities, and the parent received a booklet containing photos and instructions of activities implemented in prone, supine, side-lying, supported sitting, or in transitions between positions. The intervention was individualized based on each infant's level of development and tolerance for movement. At least 1 activity in each of the 4 positions and 1 activity in transition between positions were selected. On day 2, the parent demonstrated the intervention to the physical therapist, and hand-over-hand guidance was provided if the parent was in doubt or had difficulties performing the intervention. After 1 week, each parent received a third consultation. Additional consultations were provided based on individual needs. Two physical therapists at each hospital were involved in teaching the intervention.

An important element of the intervention was to enhance parent–infant interactions.²⁷ Parents were taught to wait for the infant's responses and to modify the support according to the infant's reactions to handling to ensure that the infants were actively participating during the intervention. The parents chose

the time of day for performing the two 10-minute interventions based on their infants' availability to fully interact. If the infant showed signs of stress, the intervention was stopped to calm the infant or the session was terminated. The parents were asked to keep a daily log to record the time spent on the intervention and report any reasons for not performing or for terminating a session.¹⁶ In cases of early discharge from the hospital, the parents continued the intervention until the end of week 36 of PMA.

All 3 NICUs applied principles from the Newborn Individualized Developmental Care and Assessment Program²⁸ as standard medical and nursing care. None of the hospitals had routines of individualized PT before 37 weeks' PMA, and no additional PT was given to the parents of infants in the control group other than general information about positioning and handling.

Analysis

Sample size was calculated according to the primary outcome of the NOPPI Peabody Developmental Motor Scales–2²⁹ at 24 months' CA. A difference of 0.5 SD between the groups at this age was considered by the NOPPI group to be clinically significant. Sixty-three infants in each group were required to ensure an 80% chance of detecting this difference at a significance level of 0.05 (α) on a 2-sided test. We planned to recruit 150 infants to account for attrition and the impact of including twins.

Baseline data were summarized by using descriptive statistics, and group differences were assessed by using Pearson's χ^2 test, the Mann-Whitney U test, or independent sample t tests.

The TIMPSI and the TIMP raw scores were transformed into z scores for comparison of scores between the 2 time points.^{17,30} Normality of the z scores was visually inspected by using a Q–Q plot.

An intention-to-treat analysis was performed by using a linear mixed model to analyze differences in change in motor performance from 34 to 37 weeks' PMA between the 2 groups and adjusted for clustering effects of twin pairs and hospital. Fixed effects variables were baseline TIMPSI z score and GA. Dropouts were treated as missing at random, and P values $< .05$ were considered to be statistically significant. Because the assumption of this model is random missing values, we performed a complete case analysis for comparison. Effect size, Cohen's d , was estimated based on comparison of raw scores for the 2 groups postintervention. An effect size of 0.20 is regarded as small, 0.50 as moderate, and 0.80 as large.³⁰ Data were analyzed by using Stata version 13.1 (Stata Corp, College Station, TX).

RESULTS

A total of 153 (71%) of 217 invited parents consented to participate (Fig 1). After baseline assessment, the infants were randomized to the intervention ($n = 74$) or the control ($n = 79$) group. Eleven infants in the intervention group withdrew after randomization, leaving 63 infants to complete the intervention. Parents of 3 of the 11 infants wanted the baseline data to be excluded from all analyses, while 1 of them participated in the postintervention assessment; in the control group, 3 children withdrew. Furthermore, 3 infants from the intervention and 2 from the control group were not available for postintervention assessment, resulting in a total of 61 and 74 infants, respectively, with postintervention assessments.

Perinatal and social background factors in the 2 groups are presented in Table 1. There were no significant group differences at baseline. Raw scores for TIMPSI at baseline and TIMP postintervention are given in Table 2. Mean baseline TIMPSI

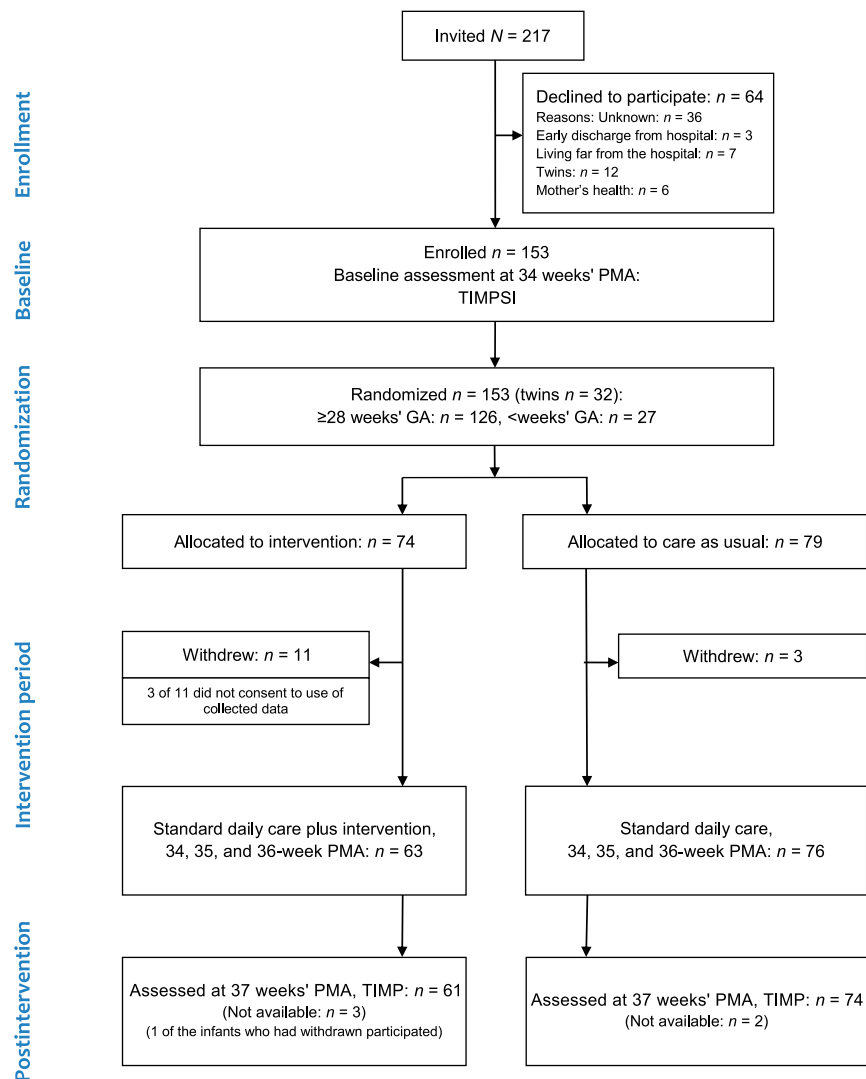


FIGURE 1 Participant flowchart from invitation through randomization, participation in intervention, and postintervention assessment.

z score in the study sample was 0.06 (95% confidence interval [CI], -0.48 to 0.60) (Fig 2), and z scores for each group are also shown in Table 2. There was no significant between-group difference in TIMPSI z scores at baseline. Postintervention, there was a significant group difference, indicating a change in motor performance from week 34 to 37 PMA, favoring the intervention group, with an estimated difference in TIMP z scores of 0.42 (95% CI, 0.13 to 0.72 ; $P = .005$). The effect size was 0.40. In the intervention group, the change in z score from baseline to 37 weeks' PMA was 0.26 (95% CI, 0.01 to 0.51 ;

$P = .04$), and in the control group, it was -0.16 (95% CI, -0.39 to 0.07 ; $P = .16$). Complete case analysis revealed similar results, with an estimated difference in z score of 0.42 (95% CI, 0.13 to 0.71 ; $P = .004$).

Parents of 56 infants maintained a written log. The median total number of sessions was 26.5 (interquartile range [IQR], 16.3 – 32.8), and the median number of sessions per day was 1.3 (IQR, 0.8 – 1.6). Median total intervention time was 229 minutes (IQR, 119.8 – 298.5 minutes), and median duration was 9.0 minutes per session (IQR, 7.5 – 9.6 minutes per

TABLE 1 Perinatal and Social Background Factors in the Intervention and the Control Groups

Perinatal Factor	Intervention Group (n = 71)		Control Group (n = 79)		P
	N	%	N	%	
GA <28 wk	10	14	17	22	.237
Males	36	51	44	55	.543
Twins	12	17	23	29	.078
No older siblings	41	57	54	68	.178
Intraventricular hemorrhage grades 1–2	4	6	8	10	.429
Intraventricular hemorrhage grades 3–4	2	3	2	2	.914
Periventricular leukomalacia	6	8	4	5	.393
Sepsis	7	10	12	15	.343
Bronchopulmonary dysplasia	6	8	8	10	.896
	Median	IQR	Median	IQR	
No. of other diagnoses	2	2–3	3	2–4	.059
Days of ventilation	0	0–1	0	0–1	.919
Days of CPAP	7	1–18	8	3–28	.365
Days with oxygen	1	0–9	1	0–11	.506
	Mean	SD	Mean	SD	
Birth weight, g	1417	417	1385	368	.622
Social background factors					
Mother's age, y	32.1	5.5	30.5	4.9	.065
Mother's education, y	15.6	2.7	14.9	2.8	.145
Father's education, y	14.5	3.0	14.6	2.7	.832

P value assessed by using Pearson's χ^2 test, the Mann-Whitney U test, or independent sample *t* tests. CPAP, continuous positive airway pressure.

TABLE 2 Motor Performance in the Intervention and the Control Groups at Baseline and Postintervention

Variable	Intervention Group (n = 71)		Control Group (n = 79)		Between-Group Differences		P	Effect Size
	Mean	95% CI	Mean	95% CI	Mean	95% CI		
Baseline								
TIMPSI raw score	27.3	24.8 to 29.8	26.0	24.1 to 27.9				
TIMPSI z score	0.07	−0.19 to 0.34	−0.07	−0.27 to 0.13	0.14 ^a	−0.46 to 0.18	.394	
Postintervention								
TIMP raw score ^b	53.7	51.4 to 56.0	50.1	47.9 to 52.2				0.40 ^c
TIMP z score	0.21	−0.02 to 0.45	−0.18	−0.42 to 0.06	0.42 ^d	0.13 to 0.72	.005	

^a Independent sample *t* tests.

^b Data missing for 10 infants in the intervention group and 5 in the control group.

^c Cohen's *d*.

^d Linear mixed model.

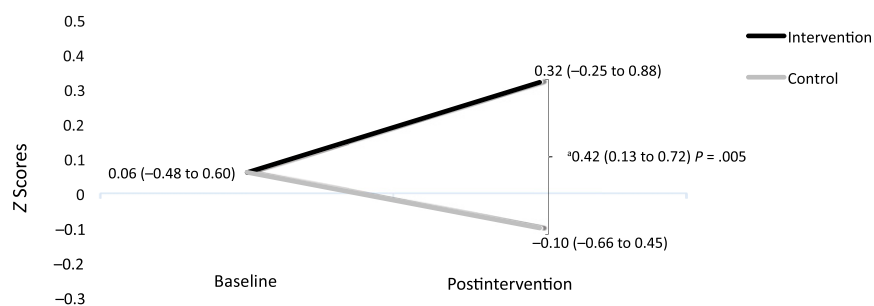
session). Association between change in z score and total intervention time was $r_s = 0.181$ ($P = .186$). Reasons for not performing the intervention or for spending less than intended time on intervention were largely related to the infants' behavioral state (being sleepy, tired, hungry, or unwell). No adverse events were reported.

DISCUSSION

To the best of our knowledge our study is the first pragmatic, randomized controlled study addressing the effect of parent-administered PT to improve motor performance conducted solely before 37 weeks' PMA. Assessment

of motor performance revealed that infants in the intervention group had significantly higher TIMP scores after the 3-week intervention compared with the control group.

Few studies have evaluated the effect of PT conducted before term-equivalent age in infants born preterm. One such study was that of Girolami and Campbell.²⁶

**FIGURE 2**

Motor performance reported by using z scores with 95% CIs of the TIMPSI at baseline and the TIMP postintervention. ^aEstimated between-group difference in change in z scores from baseline to postintervention between the intervention and the control groups.

In a cohort of 19 infants born preterm and randomly assigned to an intervention or a control group, the investigators found superior postintervention motor performance in the intervention infants compared with the control group infants. We based our intervention on activities from this study with the exception that in our study, the intervention was parent-administered. Involving parents as primary practitioners might help them to understand and respond more knowledgably to their infants' behavior, which can promote optimal development.³¹

In the systematic review from 2015 by Spittle et al¹⁴ that assessed early developmental intervention programs posthospital discharge, intervention studies performed both before and after discharge from the hospital were included. Types of interventions varied from teaching the parents about infant development and behavioral cues to performing stimulation programs. Primary outcomes of the included studies were cognitive development, motor development, or influence on parent–infant interactions. Treatment effect was reported as standardized mean difference, and the effect of intervention versus standard care on motor development in infancy was 0.10 (95% CI, 0.01 to 0.19). We found an effect size of 0.40, but the clinical importance of our results remains unknown.

The preterm period is considered to be a sensitive time frame for motor development involving changes in brain structure and function, including neuronal proliferation and migration, synapse formation, and development of corticospinal fiber connections with spinal motor neurons.^{7,9} Because function and organization of the brain are activity-dependent and experience plays a crucial role in motor development,^{8,9} we speculate that the PT optimized motor development in the intervention group.

Eighty-four percent of the families completed the intervention, but most parents reported that they performed the intervention fewer than twice a day. The median duration of each session was 9 minutes, close to the maximum intended duration. This dosage is similar to the intended dosage in another study of early PT by Cameron et al,³² included in the review of Spittle et al.¹⁴ Not many studies of early PT have included reports on compliance. In the aforementioned study, infants of parents with good compliance had higher percentile ranks on the Alberta Infant Motor Scale at 4 months compared with those with moderate or poor compliance (median 75th versus 46th percentile; $P = .05$). However, compliance was defined as remembering activities included in the intervention and not actual time spent on the intervention.³² In our study, we found no association between total time spent on the intervention and infant motor performance. Although the total number of sessions was less than intended, a significant difference was found in change in motor performance between the intervention and control groups between 34 and 37 weeks' PMA. We speculate that this finding might be due to the fact that the infants participated actively during the intervention, as was the criteria for doing the intervention. In addition, the fact that the parents learned to read their infant's signals could have resulted in transfer to other situations, and thereby led to increased time spent on the intervention other than reported in the logs. Intervention once a day seemed to be feasible for most parents and could be used as part of ordinary clinical practice in similar populations of infants born preterm. Principles to reduce stress (Newborn Individualized Developmental Care and Assessment

Program),²⁸ such as assuring restfulness, comfortable positions and timing, and slowed tempo of caregiving procedures, were applied for both groups. In hospitals in which these principles are not applied, the gains from early intervention similar to ours might be even greater.

Strengths of the present study were the study design with PT conducted as part of ordinary clinical practice and participation from 3 different hospitals. In addition, our sample size was large enough to ensure the power of the study. We used assessment tools rigorously evaluated and found to be valid and reliable,^{20,24,33} which systematic reviews have shown to be the most accepted.^{18,19} Weaknesses of the study were lack of blinding of the staff in the NICU and for some of the assessments at 37 weeks' PMA. These potential biases were minimized because the staff dealing with the infants was not directly involved in the intervention, and the therapist who scored the assessments from the video recordings was unaware of the group assignment. Another limitation is that the present article only reports on the short-term outcome immediately after intervention.

Until 3 months' CA, there is only a weak association between TIMP scores and motor development at 12 months,²¹ and the results of our intervention on long-term outcome might therefore change. The infants in our study will be assessed at regular intervals until 24 months' CA, with the Peabody Developmental Motor Scales–2 as the primary outcome. Based on our short-term results, one might speculate that the hypothesized group difference of 0.5 SD at 2 years' CA will not be obtained. An interim assessment of whether results are sustained after the end of the intervention will be made at

3 months' CA as well as at the study end point of 24 months' CA.

CONCLUSIONS

This study is the first to address the effect of parent-administered PT implemented before term-equivalent age. The results show that the intervention improved short-term motor performance more than conventional care. Implementing this type of intervention in NICUs seems to be feasible for medically stable preterm infants and their parents from week 34 PMA. Long-term effects of the intervention will be published after the infants have reached 2 years' CA.

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ABBREVIATIONS

CA: corrected age
CI: confidence interval
GA: gestational age
IQR: interquartile range
PMA: postmenstrual age
PT: physical therapy
TIMP: Test of Infant Motor Performance
TIMPSI: Test of Infant Motor Performance Screening Items

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