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## ORIGINAL ARTICLE

# Early psychomotor therapy in very preterm infants does not improve Bayley-III scales at 2 years

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## Abstract

**Aim:** To assess the efficacy of post-hospital psychomotor therapy in the development of very preterm infants at nine and 24 months.

**Methods:** We conducted a randomised controlled study at Toulouse Children's Hospital between 2008 and 2014 among preterm infants aged under 30 weeks. All infants in both groups could benefit from physiotherapy to prevent motor disorders. The intervention group received 20 early post-hospital psychomotor therapy sessions. The development was assessed by the Bayley Scale Infant Development at nine and 24 months.

**Results:** The intervention and control group contained 77 and 84 infants, respectively, with 57 infants in each group undergoing assessment at 24 months. Boys accounted for 56% of the population. Median gestational age was 28 weeks, range 25–29. The development scores at 24 months did not significantly differ between the randomisation groups. At 9 months, we observed improvements in global motricity (mean difference 0.9 point,  $p=0.04$ ) and fine motricity for the subgroup containing educationally underserved mothers (mean difference 1.6 point,  $p=0.008$ ). There was no significant difference in neuromotor functioning between the two groups.

**Conclusion:** The benefits of psychomotor therapy were short-lived and did not persist post-intervention. Our results and this organisational model encouraged us to persevere towards similar multi-professional care.

## KEYWORDS

development, early intervention, psychomotor therapy, very preterm infants

**Abbreviations:** BSID-III, Bayley Scale Infant Development—Third edition; IVH, intraventricular haemorrhage; SD, standard deviation; SE, standard error; VPT infants, very preterm infants.

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## 1 | INTRODUCTION

Very preterm (VPT) infants remain at high risk of neurodevelopmental disability over time.<sup>1</sup> In France, developmental and academic disorders occur in half of all cases.<sup>2,3</sup> Brain injuries do influence outcomes, but only account for a small proportion of disorders.<sup>4</sup> A number of other factors greatly influence brain plasticity such as immaturity, dystimulating and stressful hospital environments, parental socioeconomic<sup>5</sup> and psychological<sup>6,7</sup> conditions. The benefits of early intervention programmes implemented before hospital discharge are inconsistent in childhood<sup>8</sup> and quite unlikely to offset the consequences of preterm birth. It appears critical that care is continued after discharge.<sup>9</sup> A wide range of post-hospital programmes are conducted with substantial variations in terms of focus, nature, duration and follow-up, thereby limiting the ability to compare.<sup>10</sup> Cognitive and behavioural benefits are inconsistent in childhood, but the most effective programmes are aimed at both the parent-infant relationship and infant development.<sup>11-13</sup> Motor outcome benefits are less obvious,<sup>9,10</sup> and it remains a challenge for neonatologists to provide adapted early care.

For some years, the adverse influence of early disorders of sensory-motor processing on the long-term brain scaffolding is recognized<sup>14</sup> and early interventions are developing.

Certain physiotherapy, occupational and psychomotor therapy approaches may appear similar, because they all aim to support sensoriality, proprioception, posture and movement, and act on sensory-motor and perceptive integration. In France, psychomotor therapists play a specific role in supporting children's development. They are the only rehabilitation professionals who receive full initial education based on knowledge of the cognitive, motor and communication development of children. Psychomotor therapy is based on the concept of intentionality. This means the fact of acting according to an intention, that is a representation of a future action not yet realised. This applies to motor, relational or cognitive actions. This type of therapy focuses on the links between actions and bodily feeling, lived emotions and affects. In contrast, physiotherapists work on motor function rehabilitation, while occupational therapists concentrate on abilities and autonomy in daily activities as well as adjustment to the environment.

This study tested the hypothesis that early post-hospital psychomotor therapy would improve development in VPT infants at 24 months of corrected age.

## 2 | METHODS

### 2.1 | Study design

We conducted a prospective parallel-group open-label randomised controlled trial with inclusions from early October 2008 to late July 2012. The participating infants were randomly assigned before discharge to receive either the intervention or standard care at a 1:1 ratio. Randomisation was stratified by type of pregnancy, either

### Key notes

- Early post-hospital psychomotor therapy based on combined cognitive, motor and communication support for 9 months in very preterm infants did not result in higher development scores at 2 years of age compared to standard care.
- At 9 months, benefits were observed in global motricity and fine motricity for the subgroup with educationally underserved mothers.
- Despite short-lived benefits, this first trial encouraged us to persevere towards similar multi-professional care.

single or multiple, and by gestational age at birth as follows: <26, 26–27, 28–29 weeks of gestation. The infants were allocated to groups after their parents provided consent. Twins were allocated to the same group due to the nature of the intervention. Randomisation lists were created by an independent statistician who was not involved in the study. For each stratum, the sequence of randomisation was generated with the Stata 11 software (StataCorp), using permuted blocks of varying size, with a minimum block size of two.

### 2.2 | Eligibility criteria

The eligible subjects were all infants born between 24 and 29 completed weeks of gestation and hospitalised at Toulouse University Children's Hospital, the only neonatal intensive care unit tertiary centre in the area. They were included at 34 weeks if they were still alive. Some pathologies were excluded in order to obtain a more homogenous sample to demonstrate risk of developmental impairment. This concerned the infants with congenital malformation, genetic diseases, grade III–IV intraventricular haemorrhage (IVH), cystic periventricular leukomalacia and infants whose mothers had a documented psychotic illness. Infants from families that did not speak French were excluded for practical reasons. The parents were informed about the study by the coordinating research assistant approximately 2 weeks before inclusion and signed an informed consent form if they agreed to participate.

### 2.3 | Study description

Care procedures and developmental care strategies did not change over the course of the 3-year inclusion period. All infants received in-hospital developmental care previously implemented in line with the Neonatal Individualised Developmental Care Assessment Programme. The entire cohort of randomised infants was included and followed up in the regional professional network, which is highly organised and enable to conduct research programmes. The network paediatricians assessed the infants' neurodevelopment

every 3 months during the first year and at 18 and 24 months of age. Follow-up was standardised in accordance with the Amiel-Tison framework<sup>15</sup> and selected data on general movement.<sup>16</sup> We had previously implemented early physiotherapy for VPT infants as an integral part of developmental care based on sensory-motricity, self-regulation, body axis organisation and motor repertoire. The immaturity and deprivation of movement experiences associated with hospitalisation have an impact on the development and organisation of axial body tone.<sup>15</sup> These conditions favour the persistence of the earliest maturing extensor tone and leads to abnormal tone, posture and movement.<sup>17</sup> In our study, physiotherapy could be offered to infants in both randomisation groups from the first paediatrician visit at two, three months and throughout the study. Physiotherapy aims to prevent and take on the treatment of the entire continuum of motor disorders. It was delivered to infants with minor neuromotor disorders defined by abnormal movement, tone or posture. The intervention group received 20 1-h sessions of psychomotor therapy between 2 and 9 months following hospital discharge, once a week for 4 months and then every 15 days for the next 4 months. Psychomotor therapy was discontinued at 9 months of age except in cases where paediatricians suspected a severe developmental impairment. Care was administered nearest to home by one of the 20 participating psychomotor therapists. We developed a new analytical approach for dynamic development in vulnerable infants based on the specificities of psychomotor therapy. This approach took into account the cause-effect mechanisms of early developmental trajectories such as why an early atypical process can impact a later development stage. The psychomotor therapy focused on both parental support and the specific care axis for infants. The intervention encouraged parental sensitivity and confidence in their own skills to decode their baby's behaviours, involving active engagement with feedback from health care professionals. Specific care for infants was based on their skills and subtle early atypical developmental signs. Care focused on positive bodily and emotional experiences, feelings and dynamic developmental processes. Psychomotor therapists received 4 days of academic teaching and 4 days of practical experience followed by a 1-year experimental phase of care before starting the current study. A clinical analytical assessment and care framework was designed to help direct the care provided (Appendix S1). The framework was organised by categorising certain foundations of development including engagement and maintaining attention, visuo-spatial environment exploration, bodily exploration and interactional behaviours. In France, developmental and academic disorders account for half of all cases. Clinical observation focused on sensory-motor and perceptive integration, relational and exploratory behaviours, tonic-emotional self-regulation, motor organisation and coordination. The care included both primary and secondary prevention, encouraging infant and parental skills as well as identifying and treating subtle early atypical development. The control group received standard care. Parents and professionals were aware of how the groups were allocated and were instructed not to inform the outcome assessor. The sample size was calculated based on a minimal clinically meaningful effect defined as an absolute difference between groups of

0.6 standard deviation (SD) in the Bayley Scale Infant Development-third edition (BSID-III) at 24 months of age. With a significance level (type-I error) of 0.05, a sample size of 45 subjects per arm provided more than 80% power to detect such a difference. Taking into account a loss of 20% of infants by the time of follow-up at 24 months, we had to include 56 infants per group at the baseline before hospital discharge for a total of 112 infants.

## 2.4 | Assessment procedure and outcome measures

Baseline characteristics were recorded: gestational age at birth, gender, birth weight, small for gestational age, multiple pregnancy IVH grade 1–2, bronchopulmonary dysplasia, postnatal steroid use and duration in hospital. Small for gestational age was defined as birth weight less than the 10th percentile according to the French curves based on the Association of Users of Computerised Records in Paediatrics, Obstetrics and Gynaecology. Neonatal morbidity was defined as at least one among the following: IVH grade 1–2, oxygen supply at discharge or small for gestational age. Educationally underserved mothers, defined as those mothers with an education level of secondary school or lower, was considered as indicating maternal social vulnerability. Maternal psychological vulnerability included living alone and history of depression. Up to 2 years of age, the age of the infants was described as a corrected age, taking their prematurity into account. The neurological functioning of the infants was recorded at around 3 months, after examination by one of five paediatricians, in accordance with network follow-up standardisation. Neurological data included general spontaneous and directed motor skills and movement, limb, hand and axis fluidity and richness, posture and tone of body axis and limbs. They were classified as normal or abnormal. Abnormal functioning was defined by at least one abnormal item.

### 2.4.1 | Primary outcome

Development was evaluated using the BSID-III at 24 months of age by two psychomotor therapists, blinded for group assignment. Using the American norms, the BSID-III raw scores were converted into composite and scaled scores. To describe cognitive, motor and communication skills, composite scores were scaled to a 40–160 metric with a mean of 100 points and a SD of 15 points. Scaled scores separated receptive and expressive communication, and fine and gross motor skills, with a 1–19 range, an expected mean of 10 points and a SD of 3 points.

### 2.4.2 | Secondary outcomes

An intermediate BSID-III assessment was performed at 9 months of age. Neurological functioning was evaluated by paediatricians at 24 months of age, which included tone, posture and movement.<sup>15</sup> Abnormal functioning was defined by at least one abnormal item.

## 2.5 | Statistical analysis

The baseline characteristics of the final study sample, consisting of 114 infants evaluated at 24 months of age, were described for each randomisation group. Categorical variables were presented as numbers and percentages, while quantitative variables were presented as a mean ( $\pm$ SD). The primary and secondary outcomes were analysed using an intention-to-treat analysis. Patients were analysed according to their randomisation assignment. The BSID-III scaled and composite scores at 24 months of age and secondary outcomes were compared between randomisation groups using unadjusted linear regression models. The randomisation group was the unique independent variable. Multivariate models were then created. These models were adjusted for baseline characteristics, which were assumed to be associated with psychomotor development, if they were highly imbalanced between randomisation groups. Imbalance was deemed high if a difference of more than 10 points was observed between randomisation groups in the intention-to-treat sample of 114 infants evaluated at 24 months of age. Interactions between the randomisation group and each covariate were tested at a 1% level to determine whether a differential treatment effect was observed. Finally, a sensibility analysis of the primary outcome of BSID-III composite

scores was applied in a per-protocol perspective since there were some cases of noncompliance concerning randomisation assignment and protocol deviations. Patients who did not receive the treatment as allocated by randomisation or who did not complete the study according to the protocol were excluded from this sensibility analysis. Results were presented as marginal means. Mixed effect models were used to take into account the non-independence of observations due to multiple pregnancies. Analyses were developed using Stata 14.2 (StataCorp) using a significance level of 5%.

The Toulouse Research Ethics Committee approved the study, which was registered on the [ClinicalTrials.gov](https://clinicaltrials.gov) website under the number NCT03093337.

## 3 | RESULTS

The eligible sample comprised 161 infants, 77 in the intervention group and 84 in the control group. There were 148 infants followed up at 9 months and 122 at 24 months. In the intention-to-treat sample, complete data on the primary outcome was obtained for 114 infants, amounting to 57 in each randomised group (Figure 1). Of the 54 infants (33%) born from multiple births, 21 sets of twins survived at

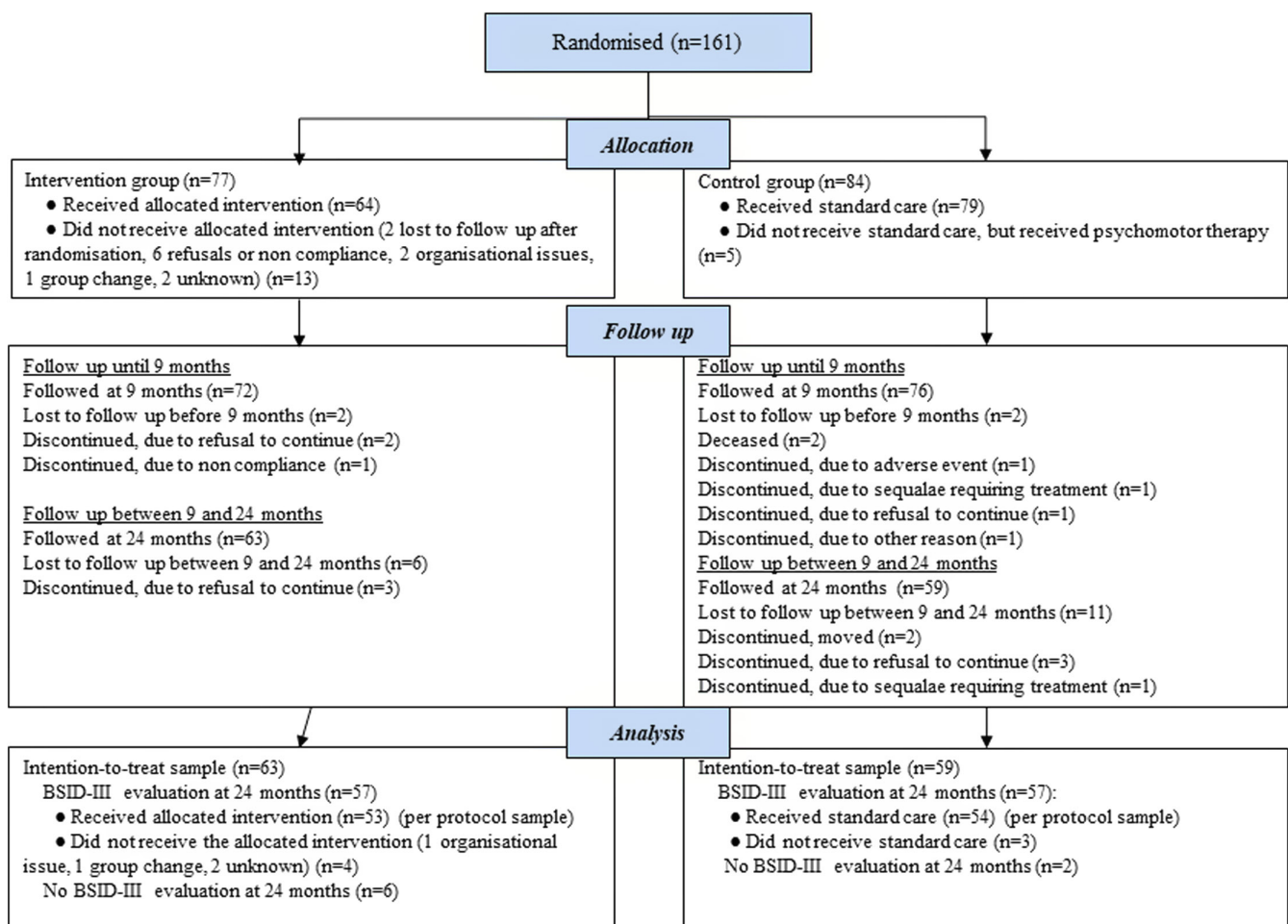


FIGURE 1 Patient flow and follow-up.

the time of discharge. When considering the intention-to-treat sample at 24 months of age, an imbalance in baseline data between the randomisation groups was observed (Table 1). Male sex, IVH grade 1–2, bronchopulmonary dysplasia and low maternal educational level were more frequent in the control group, while maternal depression history was more common in the intervention group. As a consequence, the multivariate linear regression models were adjusted for the following covariates: the child's sex, neonatal morbidity including IVH, maternal educational level and depression history. Infants excluded from the intention-to-treat analyses had been born to mothers who were living alone more frequently (17% of the cases) than in the intervention group (9%) and in the control group (4%). Their mothers had a lower educational level with a level of secondary school or less

in 64% of the cases compared to 27% in the intervention group and 38% in the control group. Their median gestational age at birth was 28.1 weeks. It was higher than in the intervention and control group, respectively, 27.6 and 27.4 weeks. Their gestational age at discharge was higher than 40 weeks in 19% of the cases compared to 4% in the intervention group and 11% in the control group. Table 2 shows the delivered care, either psychomotor therapy and/or physiotherapy, according to the randomisation group and for the infants excluded from the intention-to-treat analysis. Infants enrolled in the control group were supported by physiotherapy before 9 months more often than in the intervention group, respectively, 26% and 16%. When considering the total period between discharge and 24 months, the frequency of physiotherapy support was similar in both groups (50% vs. 46%).

TABLE 1 Infants' and mothers' characteristics at baseline according to randomisation group, among eligible infants ( $n = 161$ ).

Variable	Intervention ( $N = 57$ ) with BSID-III at 2 years (ITT analysis sample)	Control ( $N = 57$ ) with BSID-III at 2 years (ITT analysis sample)	Discontinued/lost to follow-up/ no BSID-II at 2 years ( $N = 47$ ) (excluded from the ITT analysis)
	$n/N$ (%)	$n/N$ (%)	$n/N$ (%)
<b>Birth and hospitalisation</b>			
Gestational age (WA) (mean $\pm$ SD)	27.6 $\pm$ 1.3	27.4 $\pm$ 1.4	28.0 $\pm$ 1.2
Birthweight (grams) (mean $\pm$ SD)	1056 ( $\pm$ 210)	1069 ( $\pm$ 234)	1057 ( $\pm$ 243)
Boys	29/57 (50.9)	35/57 (61.4)	20/47 (42.6)
Multiple pregnancy	20/57 (35.1)	19/57 (33.3)	15/47 (31.9)
Twin included in the study (surviving)	14/20 (70.0)	16/19 (84.2)	12/15 (80.0)
Small for gestational age (SGA) <sup>a</sup>	4/57 (7.0)	2/57 (3.5)	4/47 (8.5)
Intra ventricular haemorrhage grade 1–2	17/57 (29.8)	25/57 (43.9)	19/47 (40.4)
Broncho pulmonary dysplasia at 36 WA	20/57 (35.1)	25/57 (43.9)	14/47 (29.8)
Postnatal steroid use	0/48 (0.0)	2/53 (3.8)	1/41 (2.4)
Age at hospital discharge (WGA) (median, 25–75 perc)	37, 36–39	37, 36–39	37, 35–38
Age at hospital discharge >40 WGA	2/57 (3.5)	6/57 (10.5)	9/47 (19.1)
SGA around the term <sup>b</sup>	53/56 (94.6)	53/57 (93.0)	41/45 (91.1)
Oxygen supply at discharge	10/56 (17.9)	13/57 (22.8)	5/45 (11.1)
Neonatal morbidity <sup>c</sup>	26/57 (45.6)	31/57 (54.4)	25/47 (53.2)
<b>Infant development at starting intervention</b>			
Abnormal muscle tone <sup>d</sup>	3/52 (5.8)	6/51 (11.8)	7/40 (17.5)
Abnormal spontaneous motricity <sup>e</sup>	23/51 (45.1)	20/50 (40.0)	13/38 (34.2)
Abnormal motricity <sup>f</sup>	41/57 (71.9)	40/57 (70.2)	32/45 (71.1)
<b>Mother's social context and mental health</b>			
Mother living alone	5/56 (8.9)	2/57 (3.5)	7/41 (17.1)
Mother of low educational level <sup>g</sup>	15/56 (26.8)	20/53 (37.7)	27/42 (64.3)
Mother known depression history	17/57 (29.8)	6/57 (10.5)	8/47 (17.0)

Abbreviation: SD, Standard deviation.

<sup>a</sup>SGA: birth weight < 10th percentile (by sex and gestational age).

<sup>b</sup>SGA around the term (WGA): weight < -2 SD according to WHO curves for sex and age (in months).

<sup>c</sup>Known neonatal morbidity: at least one among the following: IVH grade 1–2, oxygen supply at discharge, SGA at birth.

<sup>d</sup>Abnormal muscle tone: abnormal body axis and/or abnormal arms muscle tone and/or abnormal legs muscle tone.

<sup>e</sup>Abnormal spontaneous motricity: of upper limbs and/or lower limbs.

<sup>f</sup>Abnormal motricity: at least one item of neurological functioning (spontaneous motricity, movement, posture or tone).

<sup>g</sup>Mother of low educational level: secondary school or lower.

**TABLE 2** Physiotherapy and/or psychomotor therapy before 9 months, and from birth until 24 months, by randomisation group, in the ITT population of the Early Psychomotor Therapy Intervention Programme.

	Intervention (N = 57) with BSID-III at 2 years	Control (N = 57) with BSID-III at 2 years	Discontinued/lost to follow-up/no BSID-II at 2 years (N = 47)
	n (%)	n (%)	n (%)
Physiotherapy and/or psychomotor therapy before 9 months			
None	3 (5.3)	41 (71.9)	18 (40.0)
Physiotherapy alone	1 (1.7)	13 (22.8)	13 (28.9)
Psychomotor therapy alone	44 (77.2)	1 (1.7)	6 (13.3)
Both	9 (15.8)	2 (3.5)	8 (17.8)
Missing data	n=0	n=0	n=2 <sup>a</sup>
Physiotherapy and/or psychomotor therapy before 24 months			
None	2 (3.6)	26 (48.1)	15 (35.7)
Physiotherapy alone	1 (1.8)	18 (33.3)	9 (21.4)
Psychomotor therapy alone	28 (50.0)	1 (1.9)	5 (11.9)
Both	25 (44.6)	9 (16.7)	13 (31.0)
Missing data	n=1	n=3	n=5 <sup>b</sup>

<sup>a</sup>One missing data, one deceased infant.

<sup>b</sup>Three missing data, two deceased infants.

At 24 months of age, the BSID-III mean composite scores across the entire studied population were  $92.8 \pm 8.7$ ,  $92.6 \pm 8.9$ ,  $88.9 \pm 11.1$  for cognitive, motor and language development, respectively. The composite scores did not significantly differ between the two groups (Table 3). When considering scaled subscales, fine motor skills were significantly lower in the intervention group (mean score 10.1 standard error (SE) 0.3) compared to the control group (mean score 9.4, SE 0.3,  $p=0.047$ ). After adjustment for covariates, the difference in fine motor skills remained in favour of the control group, but no longer to a significant extent. The per-protocol analysis consisted of 107 infants evaluated at 24 months of age and revealed no significant difference between the randomisation groups in the composite scores, both in the unadjusted model and the adjusted model.

The intervention had a significant benefit on motor composite BSID-III scores at 9 months of age (Table 3). There was a considerable difference between groups with higher scaled scores for gross motricity in the intervention group. A significant correlation was observed in terms of fine motricity between randomisation group and maternal educational level. A significant benefit of intervention was found for fine motor scaled scores in the subgroup with educationally underserved mothers. The marginal mean was 9.1 (SE=0.5) in the intervention group compared to 7.5 (SE=0.4) in the control group ( $p=0.008$ ). The mean cognitive and language-communication composite and scaled scores did not differ between the two groups.

The neurological outcome at 24 months of age was completed for 119 infants from the intention-to-treat analysis sample. No difference was found between randomisation groups. Neuromotor dysfunction affected 42% (25/60) of infants in the intervention group and 44% (28/59) of the control group.

## 4 | DISCUSSION

Our randomised study compared early post-discharge psychomotor therapy to standard care for VPT infants in an entire region in France. It failed to demonstrate any benefit on the BSID-III at 24 months compared to standard care. In the literature, intervention programmes have reported a cognitive benefit that dilutes by the time the child reaches school age.<sup>10</sup> The most effective interventions were aimed both at the parent-infant relationship and infant development.<sup>18-23</sup> Although motor benefits were less obvious,<sup>16,17</sup> the Infant Behavioural Assessment and Intervention Programme demonstrated improvement, particularly on visual-motor integration and coordination.<sup>22,23</sup> However, we included infants with a lower gestational age relative to other programmes, since prior studies involving VPT infants are rare. Previous interventions aimed at the parent-infant relationship reported a cognitive gain at infancy<sup>20,24,25</sup> but not at the age of five.<sup>24</sup> Occupational therapy showed a delayed cognitive improvement at the age of four.<sup>26</sup> Combined educational support from nurses and physiotherapy did not indicate any benefit during infancy.<sup>27</sup> Motor development did not improve.<sup>24,27</sup> By contrast, we observed a benefit in terms of global motricity at 9 months of age. For fine motricity, benefit was observed only in the subgroup with educationally underserved mothers. Some functional developmental specifications appear around 16 months of age. These are of increasing complexity and are essential for later optimal development. Some infants who develop normally in the early months may have difficulties from this time onwards. An assessment of development at this time may identify infants who are having difficulties and need continued care. This may be an argument for longer-term care. This may

TABLE 3 BSID-III assessment at 9 and 24 months—Raw and adjusted scaled scores by randomisation group, in the ITT population of the Early Post-Hospital Discharge Psychomotor Therapy Intervention Programme.

	9 months				24 months			
	Raw means		Marginal means		Raw means		Marginal means	
	Mean (SE)	p-value	Mean (SE)	p-value	Mean (SE)	p-value	Mean (SE)	p-value
Composite scores								
Cognitive	n=136	0.112	n=128	0.193	n=113	0.520	n=108	0.430
Control	92.4 (1.1)		92.71(1.2)		93.0 (1.2)		93.1 (1.3)	
Intervention	95.0 (1.1)		95.0 (1.2)		91.9 (1.2)		91.6 (1.3)	
Communication	n=135	0.916	n=128	0.739	n=113	0.911	n=108	0.995
Control	85.7 (1.3)		86.0 (1.4)		88.8 (1.6)		88.7 (1.7)	
Intervention	85.5 (1.3)		85.3 (1.4)		88.6 (1.6)		88.7 (1.6)	
Motricity	n=136	0.029	n=128	0.040	n=114	0.418	n=109	0.255
Control	82.4 (1.5)		82.6 (1.6)		93.3 (1.3)		93.6 (1.4)	
Intervention	87.0 (1.5)		87.2 (1.6)		91.8 (1.2)		91.4 (1.3)	
Scaled scores								
Cognitive	n=136	0.112	n=128	0.193	n=113	0.520	n=108	0.430
Control	8.5 (0.2)		8.5 (0.3)		8.6 (0.2)		8.6 (0.3)	
Intervention	9.0 (0.2)		9.0 (0.2)		8.4 (0.2)		8.3 (0.3)	
Receptive communication	n=136	0.919	n=128	0.920	n=114	0.737	n=109	0.980
Control	7.5 (0.3)		7.6 (0.3)		7.7 (0.3)		7.7 (0.3)	
Intervention	7.6 (0.3)		7.6 (0.3)		7.6 (0.3)		7.7 (0.3)	
Expressive communication	n=135	0.891	n=128	0.656	n=113	0.958	n=108	0.938
Control	7.5 (0.3)		7.5 (0.3)		8.4 (0.3)		8.5 (0.3)	
Intervention	7.4 (0.3)		7.3 (0.3)		8.5 (0.3)		8.4 (0.3)	
Fine motor	n=136	0.361	n=128	0.358 <sup>a</sup>	n=114	0.047	n=109	0.061
Control	8.3 (0.3)		8.2 (0.3)		10.1 (0.3)		10.1 (0.3)	
Intervention	8.6 (0.3)		8.6 (0.3)		9.4 (0.3)		9.3 (0.3)	
Gross motor	n=136	0.023	n=128	0.039	n=114	0.466	n=109	0.995
Control	5.9 (0.4)		6.0 (0.4)		7.6 (0.3)		7.8 (0.3)	
Intervention	7.0 (0.4)		7.1 (0.4)		7.9 (0.3)		7.8 (0.3)	

Note: Marginal mean: results from linear regression models adjusted for sex, neonatal morbidity (defined as at least one among: IVH grade 1–2, oxygen supply at discharge, SGA at birth), mother depression history, mother of low educational level (defined as secondary school or lower). Abbreviation: SE, standard error.

<sup>a</sup>A significant interaction term was observed between randomisation group and mother educational level. The intervention effect was not significant in the subgroup of children issued from mothers of high educational level (Marginal means: 8.8 (0.4) in the control group, 8.3 (0.3) in the intervention group  $p=0.374$ ); there was a significant intervention effect in the subgroup of children issued from mothers of low educational level (Marginal means: 7.5 (0.4) in the control group, 9.1 (0.5) in the control group,  $p=0.008$ ).

explain the lack of motor benefit at 24 months and the decrease in cognitive scores in the intervention group revealed after the intervention period, as reported by other authors.<sup>12,21,26,27</sup> Moreover, deprivation of positive experiences and stressful exposure go far beyond the absorptive capacities of VPT infants who struggle to understand the meaning of events<sup>28</sup> in terms of relation, body references and temporo-spatial integration. VPT infants also develop lasting sensory-motor aversive behaviours that are persistent, difficult and a lengthy process to mitigate. The Infant Health and Development Programme provided the longest programme, running up to the age of three, based on socio-educational support.

Long-term benefit was found for socially disadvantaged families and for low birth weight infants.<sup>18</sup> For very low birth weight infants, the benefit did not persist after the intervention, emphasising that early functional changes in the brain might require specific, sustained and targeted support.

The broadly outlined high rate of maternal distress of VPT infants is known to influence child development.<sup>29</sup> Our study aimed to support confidence among parents in their own skills and sensitivity with their baby. We also planned to measure the impact of the intervention on parental anxiety and depression, maternal post-traumatic stress and relationship adjustment with their infant. Due to the high



rate of missing data, we were unable to analyse the effect of parental distress throughout the study period or compare the subgroups with regard to parental psychological conditions. In addition to neonatal deprivation and intrusive experiences, the high rate of maternal depression and social disadvantage among mothers of VPT infants may play a role in low cognitive and communication scores. The higher frequency of socially disadvantaged families in the lost-to-follow-up group reflected well-known difficulties in adhering to care<sup>3</sup> and could have led to overestimation of the BSID-III results.

The context within which our study was conducted limited the assessment of psychomotor therapy effects. Early psychomotor therapy is a newly emerging concept. It is likely that the skills of the psychomotor therapists improved over the course of the study period and they are able to provide increasingly effective care. The numerous participating professionals induced a heterogeneous quality of care that could have limited our results. Sensorimotor physiotherapy had been previously implemented in the regional network and physiotherapists were more competent than psychomotor therapists when we conducted the study. In the control group, physiotherapy was more frequent during the first 9 months of life than in the intervention group. This could be due to a slightly higher rate of abnormal tone in the control group at the baseline, although no neurological functioning difference was found between the two randomised groups. Furthermore, due to the unblinded nature of the intervention, paediatricians potentially faced the dilemma of determining whether the control group had missed out on the benefits of psychomotor therapy. Consequently, they might have offered physiotherapy care more often to the control group. To improve motor functions, physiotherapy was based on sensory, proprioceptive and musculoskeletal body sensations. It could thus act on perceptual processes, whose underlying mechanisms may be common to both motor skills and cognition. Thus, although the aims of physiotherapy and psychomotor therapy were different, and although they did not act in the same way, their effects might have intersected. As a consequence, physiotherapy could have a contaminating positive effect on cognition and motricity.<sup>17</sup> However, we were unable to measure this potential impact of physiotherapy on our results. Indeed, we did not know whether it was delivered for empathic reasons or due to motor disability. We can assume that combined physiotherapy and psychomotor therapy were provided for the most disabled infants, but, due to the sample size of our study, we did not perform subgroups analyses based on infants with specific neonatal pathologies or neuromotor disorders.

The Infant Behavioural Assessment and Intervention Programme highlighted that the major issue for early care could be related to professional skills and experience. This programme was based on physiotherapy and rooted on a highly experienced model of Neonatal Individualised Developmental Care Assessment Programme. It focused both on strengthening parental sensitivity as well as child behaviours and self-regulation.<sup>22</sup> Our programme may have some common ground with the Infant Behavioural Assessment and Intervention Programme. Some characteristics of the developmental approach may differ since our intervention focused on

both primary prevention using the baby's skills, and on secondary prevention, through the identification and management of early signs of atypical development. The varied and closely intertwined developmental processes hint that early care should be defined by multifaceted targets and multi-professional care. Unfortunately, this remains challenging for cost-related reasons and an obvious lack of professional skills. Different targets of care provided by different categories of professionals might have convergent effects, since sensory-motor physiotherapy, psychomotor therapy or occupational therapy could act on perceptive integration. Studies reported that combined care by nurses and physiotherapists<sup>27</sup> or by psychologists and physiotherapists<sup>21</sup> decreased behavioural disorders and parental anxiety and depression<sup>21</sup> without benefit in VPT infant development. Further research is needed to better define the nature and axis of early care.

Thus, several of the limitations addressed above were highlighted in our study. The sample size was a major restricting factor in term of analysing the multiple determinants of development and subgroups of pathologies. The lack of professional skills when the study was conducted and heterogeneity of care might erase the effects of psychomotor therapy. The physiotherapy, might have a contaminating positive effect on motricity and cognition. Another issue and limitation when assessing the effect of early interventions is the measure of the development of the infants. The BSID-III could be irrelevant for picking up early subtle deficits and assessing specific skills<sup>30</sup> as well as the strategies that infants employ to reach them. In our study, infants were assessed with a non-validated French translation of the BSID-III USA version. However, we assume no impact on the results, given that the two groups of comparison were assessed using the same scale. The strengths of our study lie in the fact that we were able to conduct a randomised study with the required number of subjects in a large region. By conducting this study, our regional network created a model of local early health care for vulnerable infants and demonstrated the feasibility of early care implementation throughout a large area, rather than hospital-centred care. Our study changed our professional practices. Based upon this efficient organisational model, we created an important training programme for professionals. We also defined the nature of care with a multi-professional and multi-targeted approach, in line with infants' skills and early subtle signs of deviation.

In terms of the benefit of certain in-hospital programmes<sup>10</sup> on child development, further research is needed to assess full intervention programmes combining in-hospital and post-hospital programmes. These programmes could include primary and secondary prevention in a multi-targeted approach. A full intervention should be able to limit exposure to stressful environments and to treat the subtle signs of deviation observed from the in-hospital neonatal period. Our follow-up network for vulnerable infants provides continuous data on infant outcomes. So, further longitudinal analyses comparing infant outcomes year by year will help us to measure the impact over time of multi-targeted care associated with multi-professional skill improvement.

## 5 | CONCLUSION

Our randomised study provided early post-discharge psychomotor therapy for VPT infants. We demonstrated benefits for BSID-III gross motor skills and among infants with educationally underserved mothers for fine motor skills at the end of the intervention. No persisting benefit was found at the 24-month of age for BSID-III assessment. Considering the varied and closely intertwined processes involved in early development, further research would be necessary to assess full programmes. These programmes could include in-hospital and post-discharge periods and take into account multi-professional and multi-targeted interventions.

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### CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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