

Effect of Pediatric Physical Therapy on Deformational Plagiocephaly in Children With Positional Preference

A Randomized Controlled Trial

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Objective: To study the effect of pediatric physical therapy on positional preference and deformational plagiocephaly.

Design: Randomized controlled trial.

Setting: Bernhoven Hospital, Veghel, the Netherlands.

Participants: Of 380 infants referred to the examiners at age 7 weeks, 68 (17.9%) met criteria for positional preference, and 65 (17.1%) were enrolled and followed up at ages 6 and 12 months.

Intervention: Infants with positional preference were randomly assigned to receive either physical therapy (n=33) or usual care (n=32).

Main Outcome Measures: The primary outcome was severe deformational plagiocephaly assessed by plagiocephalometry. The secondary outcomes were positional preference, motor development, and cervical passive range of motion.

Results: Both groups were comparable at baseline. In

the intervention group, the risk for severe deformational plagiocephaly was reduced by 46% at age 6 months (relative risk, 0.54; 95% confidence interval, 0.30-0.98) and 57% at age 12 months (0.43; 0.22-0.85). The numbers of infants with positional preference needed to treat were 3.85 and 3.13 at ages 6 and 12 months, respectively. No infant demonstrated positional preference at follow-up. Motor development was not significantly different between the intervention and usual care groups. Cervical passive range of motion was within the normal range at baseline and at follow-up. When infants were aged 6 months, parents in the intervention group demonstrated significantly more symmetry and less left orientation in nursing, positioning, and handling.

Conclusion: A 4-month standardized pediatric physical therapy program to treat positional preference significantly reduced the prevalence of severe deformational plagiocephaly compared with usual care.

Clinical Trial Registration: isrctn.org Identifier: ISRCTN84132771.

Arch Pediatr Adolesc Med. 2008;162(8):712-718

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IN AN INFANT WITH DEFORMATIONAL plagiocephaly (DP), the head and possibly the face are deformed as a result of prenatal and/or postnatal external molding pressure to the malleable and growing cranium.¹⁻⁴ The prevalence of DP varies between 6.1% to 13.0% at birth,^{5,6} 16.0% to 22.1% at age 6 to 7 weeks,^{5,7} 19.7% at age 4 months, 9.2% at age 8 months, and 6.8% at age 12 months.⁷ The causes of DP include a restrictive intrauterine environment, premature birth, assisted vaginal delivery, prolonged labor, unusual birth position, multiple birth, and primiparity.^{5,6,8-10} Of interest, DP at birth is not a predictor for DP at age 7 weeks.⁵ In 9 of 23 infants with DP at birth, DP was

still present at follow-up, whereas in 75 of 357 infants without DP at birth, DP developed between birth and age 7 weeks.⁵ Male sex, nonvarying nursing habits, nonvarying head position when awake or asleep, supine sleeping position, positional preference, developmental delay, and lower activity level have been described as risk factors for developing DP,^{5,7,11,12} whereas earlier achievement of motor milestones⁵ and prone positioning when awake for at least 5 minutes^{7,13} more than 3 times⁵ per day appear to be protective factors.

Many clinicians consider DP to be a minor and purely cosmetic condition.¹⁴ Although an association has been found between DP and auditory processing

disorders,¹⁵ mandibular asymmetry,¹⁶ and visual field defects,¹⁷ causality has never been established.^{12,14,18-21} However, this head-molding deformation does have the potential to induce negative physical and psychosocial effects.²² Parents fear that unattractive facial characteristics will lead to adverse effects such as teasing and poor self-perception.^{14,18}

Epidemiological studies have shown that prone and side sleeping are major risk factors for sudden infant death syndrome.^{23,24} Concurrent with the increase in supine sleeping, consistent with the American Academy of Pediatrics' recommendation that healthy term infants should be positioned on their sides or backs to sleep,²⁵⁻²⁸ a rise in the prevalence of positional preference and DP has been observed.^{6,7,29-32} In one study, positional preference was identified in infants who exhibited head rotation to either the right or the left side when in the supine position for approximately three quarters of the time of observation, without active rotation of the head over the full range of 180 degrees (minimal time of observation, 15 minutes).²⁹ In 1995 and 2005 in the Netherlands, positional preference prevalences of 8.2% and 12.2%, respectively, were reported in infants younger than 6 months.^{29,30} van Vlimmeren et al⁵ established that a positional preference prevalence of 17.9% at age 7 weeks was associated with DP (odds ratio [OR], 9.5; 95% confidence interval [CI], 5.30-17.01). This strong association is evidence of a causal relationship between supine sleeping and the development of positional preference and DP.^{4,5,10,33-35}

Conservative strategies to prevent or treat positional preference and DP are parental counseling, counterpositioning,^{12,19,29,33,36} physical therapy,³⁷ and orthotic devices.^{1,2,4,11,38-44} Studies on the effectiveness of these interventions are of moderate to poor methodological quality, and no randomized controlled trials were found.^{13,14,18,22,37}

We hypothesized that a standardized pediatric physical therapy program to treat children with positional preference starting at age 7 weeks is effective in reducing the prevalence of positional preference and of severe DP at ages 6 and 12 months, compared with the usual care.

METHODS

DESIGN, SETTING, AND PARTICIPANTS

The prospective cohort included 380 healthy term neonates (of 400 consecutive births of healthy term neonates) who were seen at the Bernhoven Hospital between December 1, 2004, and September 25, 2005. Children with congenital muscular torticollis (defined as preferential posture of the head and asymmetrical cervical movements caused by a unilateral contracture of the sternocleidomastoid muscle³⁵), dysmorphisms, or syndromes were excluded from this study.³⁷ At 7 weeks' postgestational age, 68 of 380 infants (17.9%) in this follow-up study were found to have positional preference (42 [61.8%] of them male) and were classified according to Boere-Boonekamp and van der Linden-Kuiper.²⁹ Of those with positional preference, the parents of 3 children refused to participate, and 65 infants were eligible for allocation to either the experimental or control group. Written informed consent was obtained from all parents, and the medical ethics committees of the Wilhelmina Chil-

dren's Hospital and the Bernhoven Hospital at Veghel approved the study.

ASSESSMENTS

Assessments were performed at study entry (age 7 weeks), at the end of the intervention (age 6 months), and at a follow-up visit (age 12 months) by 1 of 12 pediatric physical therapists blinded to group allocation. Training (outlined in the next section) was attained with regular instructions and control by 2 of us (L.A.V. and R.H.H.E.). The following characteristics were assessed:

- Specific nursing and positioning habits and parental opinions regarding the shape of their infant's head, assessed with a written questionnaire
- The infant's posture and active movements, with special attention paid to positional preference, and asymmetries of the trunk and extremities
- Qualitative motor development, assessed using the Alberta Infant Motor Scale (AIMS),^{45,46} and quantitative motor development, assessed using the Bayley Scales of Infant Development, second edition (BSID-II)⁴⁷
 - Passive range of motion of the cervical spine⁴⁸
 - Head circumference (in centimeters) measured in a standardized way
 - The transversal shape of the skull, measured using plagioccephalometry⁴⁹ (**Figure 1**)

The last 2 characteristics were measured by one of us (L.A.V.) and another examiner blinded to group allocation. During assessments, environmental characteristics (eg, temperature, light, or positioning) were the same for all infants.

RANDOMIZATION AND INTERVENTION

A computer-generated randomization table, stratified by sex, was constructed for this study by an independent employee of the information technology department of the Julius Center for Health Sciences and Primary Care, Department of Clinical Epidemiology, University Medical Center Utrecht. If an infant was eligible to participate, an independent therapist entered his or her characteristics and reported the allocated treatment to one of us (L.A.V.).

A standardized pediatric physical therapy intervention program was designed by 2 of us (L.A.V. and R.H.H.E.) based on the best evidence in the literature. We trained a group of 6 experienced pediatric physical therapists to use this program. These pediatric physical therapists were neither influenced nor informed by the group of pediatric physical therapists who assessed the infants. In the intervention group, infants received a maximum of 8 sessions of pediatric physical therapy between ages 7 weeks and 6 months. In the first month, these sessions were weekly and in the second and third months, they occurred every 2 or 3 weeks. The second and fifth sessions were always conducted at the infant's home. The pediatric physical therapy program consisted of exercises to reduce positional preference and to stimulate motor development and offered parental counseling about counterpositioning, handling, nursing, and the causes of positional preference. Parents also received a leaflet describing basic preventive measures. Earlier, more frequent, and longer playing time in the prone position when awake (ie, "tummy time") was encouraged. Pediatric physical therapy was stopped when positional preference no longer occurred during awake or asleep time, when the parents were shown to have incorporated advice about handling, and when there were no indications of motor developmental delay or asymmetries.

In the control group, parents received the leaflet describing basic preventive measures with no further education or in-

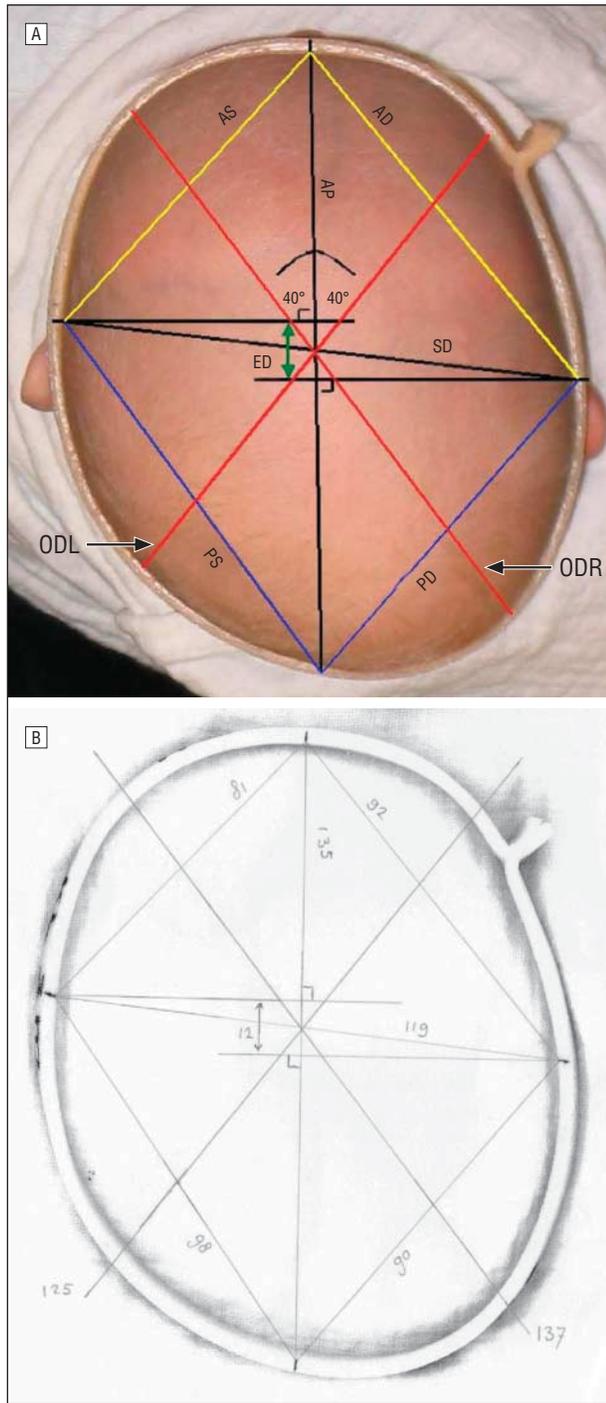


Figure 1. Plagiocephalometric measurements⁴⁹ in a 4-month-old boy with asymmetrical deformational plagiocephaly and left occipital flattening of the skull. A, Photograph of the infant with the thermoplastic measuring ring and digitally drawn lines indicating which measurements were taken. B, Illustration of the same thermoplastic ring with plagiocephalometric values (ODDI score, 109.6%; CPI score, 88.1%; ODL, 125 mm; ODR, 137 mm; ED, 12 mm; PD – PS, 8 mm). AD indicates anterior dextra; AP, anterioposterior; AS, anterior sinistra; CPI, Cranioproportional Index (calculated as SD divided by AP times 100%); ED, ear deviation; ODDI, Oblique Diameter Difference Index (calculated as longest oblique diameter divided by shortest oblique diameter times 100%); ODL, oblique diameter left; ODR, oblique diameter right; PD, posterior dextra; PS, posterior sinistra; SD, sinistra.

structions to intervene. As with every child in the Netherlands, both groups also received advice from health care providers at well-child care clinics (ie, usual care).

MAIN OUTCOME MEASURES AND SAMPLE SIZE

The primary outcome measure was severe DP, operationalized as an Oblique Diameter Difference Index (ODDI) score of 104% or more.⁴⁹ The ODDI score is calculated as the longest oblique diameter divided by the shortest oblique diameter multiplied by 100% (Figure 1). From clinical experience and psychometric analysis, we defined an ODDI score of 104% or more as clinically relevant asymmetry of the skull.⁴⁹ The secondary outcome measures were symmetry in posture and active movements, motor development, and passive range of motion of the cervical spine.

Based on the literature, we estimated the prevalence of DP in the control group to be 60%; from pilot data, we estimated that treatment with pediatric physical therapy would reduce the prevalence of DP to approximately 25%. Assuming a power of 80% and an α of .05, a sample size of at least 27 in each group was needed.⁵¹

Handling, positioning, and movement therapy affect active and passive symmetry in posture and movements, especially as part of a home treatment program.^{19,37} Preventive counseling for parents about positioning, handling, and nursing were expected to minimize the risk of positional preference and to correct DP.^{12,16,29,33,36} Also, encouraging parents to place infants regularly in the prone position when awake and being supervised (ie, “tummy time”) was expected to stimulate quantitative and qualitative motor development.^{5,12,19,33,34,52}

STATISTICAL ANALYSIS

All data were recorded using SPSS statistical software, version 12.0 (SPSS Inc, Chicago, Illinois). Analysis was undertaken on an intention-to-treat basis. Summary descriptive statistics, including frequencies (percentages), means, and SDs, were computed for the baseline and main outcome variables. In our analysis of interest, we compared the prevalence of severe DP in the intervention and control groups. Relative risks (RRs) and 95% confidence intervals (CIs), absolute risk reductions, and numbers needed to treat (ie, reciprocal of the absolute risk difference) were calculated. The AIMS raw score was transferred into a standardized z score (the individual score minus the average score divided by the SD).⁴⁶ Scaled scores of the BSID-II were transformed into the Psychomotor Development Index (mean [SD], 100 [16]; range, 50-150).⁴⁷

RESULTS

Of 380 healthy neonates assessed at age 7 weeks, 68 (17.9%) demonstrated positional preference, and 65 (17.1%) were randomized, stratified by sex; 33 were allocated to the intervention group and 32 to the control group. The intervention and control groups were similar on all baseline measures (**Table 1**). There were no missing data.

PRIMARY OUTCOME

In the intervention group, the number of infants with severe DP decreased significantly from 18 of 33 (55%) at age 7 weeks to 10 (30%) at age 6 months vs a decrease from 20 (63%) to 18 (56%) of 32 infants in the control group (RR, 0.54; 95% CI, 0.30-0.98) (**Table 2**). At age 12 months, the number of infants with severe DP decreased further to 8 (24%) in the intervention group and remained at 18 (56%) in the control group (RR, 0.43; 95% CI, 0.22-0.85) (Table 2).

Table 1. Clinical Characteristics at Baseline (Mean Age, 7 Weeks)^a

Characteristics	Intervention Group (n = 33)	Control Group (n = 32)
Male sex	20 (61)	20 (63)
Mother's first pregnancy	16 (48)	14 (44)
First-born child for mother	17 (52)	16 (50)
Unusual presentation at birth (eg, breech, occipitoposterior, sincipital)	6 (18)	4 (13)
Delivery		
Cesarean section	6 (18)	9 (28)
Vacuum assisted	4 (12)	4 (13)
Vaginal	23 (70)	19 (59)
Gestation, mean (SD), wk	39.7 (1.5)	39.5 (1.4)
Length of second-stage labor, mean (SD), h	0.62 (0.59)	0.65 (0.61)
Birth weight, mean (SD), kg	3.52 (0.44)	3.46 (0.45)
Sociodemographic		
Parents' age, mean (SD), y		
Mother	30.2 (3.3)	31.4 (3.9)
Father	33.7 (5.0)	33.6 (5.0)
Mother's educational level ^b		
Low	8 (24)	6 (19)
Medium	18 (55)	18 (56)
High	7 (21)	8 (25)
Father's educational level ^b		
Low	11 (33)	5 (16)
Medium	15 (45)	16 (50)
High	7 (21)	11 (34)
Anthropometric, mean (SD)		
Head circumference, cm	38.8 (1.2)	38.4 (1.0)
Cranioproportional Index score, %	81.0 (5.0)	82.5 (5.3)
ODDI score, %	104.8 (2.9)	104.6 (2.6)
ODDI score \geq 104%	18 (55)	20 (63)
Motor development, mean (SD)		
AIMS z score	-0.36 (0.65)	-0.50 (0.90)
BSID-II-PDI score	99.3 (12.1)	99.9 (12.8)
Sleeping		
Always supine after age 2 wk	27 (82)	28 (88)
Head always turned to the same side	12 (36)	17 (53)
Head always turned to the same side on changing table	10 (30)	15 (47)
Feeding		
Only bottle-fed	7 (21)	10 (31)
Always bottle-fed on the same arm of the caregiver	11 (33)	16 (50)
Tummy time ^e		
First at 3 wk or older	11 (33)	8 (25)
<3 Times per day	28 (85)	31 (97)
<5 Min per session	26 (79)	24 (75)

Abbreviations: AIMS, Alberta Infant Motor Scale⁴⁵; BSID-II, Bayley Scales of Infant Development, second edition⁴⁷; ODDI, Oblique Diameter Difference Index; PDI, Psychomotor Development Index.

^aData are given as the number (percentage) of participants unless otherwise indicated. Percentages may not total 100 because of rounding.

^bEducational levels were defined as low, lower technical and vocational training and lower general secondary education; medium, intermediate vocational training and advanced secondary education; and high, higher vocational education (college education) and university.

^cCalculated as left-to-right lengths divided by anthropometric lengths multiplied by 100%.

^dCalculated as longest oblique diameter divided by shortest oblique diameter multiplied by 100%.

^eTummy time defined as when the infant is placed in the prone position when awake and under supervision.

The numbers of infants with positional preference needed to treat were 3.85 and 3.13 at ages 6 and 12 months, respectively. This indicates that 3 to 4 children with posi-

tional preference must be treated according to the pediatric physical therapy protocol to avoid 1 child having severe DP between age 7 weeks and 6 or 12 months.

SECONDARY OUTCOMES

No infants demonstrated positional preference at ages 6 or 12 months. Motor development was not significantly different between both groups at both assessments (Table 2). Passive range of motion of the cervical spine was within the normal range and symmetrical in all infants at baseline and at ages 6 and 12 months.

In the intervention group, parental infant care at age 6 months demonstrated more symmetry and less left orientation in nursing, positioning, and handling: positioning infant symmetrically on the changing table (61% [intervention group] vs 28% [control group]; RR, 0.5; 95% CI, 0.34-0.88), positioning infant on the changing table with head to the left (12% vs 38%; 0.3; 0.12-0.90), and always bottle-feeding on the left arm (29% vs 50%; 0.6; 0.28-1.22). There was no difference in the type of feeding between the groups. Parents in the intervention group placed their infants in prone positions for longer when awake (tummy time for at least 15 minutes each time: 21% [intervention group] vs 9% [control group]; RR, 0.8; 95% CI, 0.69-1.09) and less frequently in a side-lying position (at least once a day in a side-lying position: 18% vs 44%; 0.4; 0.18-0.95). At age 12 months, results were similar; for example, infants in the intervention group were still positioned more symmetrically (nursing with head to the left, 13% [intervention group] vs 29% [control group]; RR, 0.6; 95% CI, 0.21-1.47). In the intervention group, the median number of pediatric physical therapy sessions was 5 (interquartile range, 4-6). Treatment began at the median age of 9 weeks (interquartile range, age 8-10 weeks), and the median follow-up was 5 weeks (4-11 weeks).

In the intervention group, the parents of 2 infants preferred manual therapy rather than pediatric physical therapy. In the usual care group, 1 infant showed increasing nonsynostotic skull deformation by age 4 months, and the parents decided not to continue with nonintervention. This infant received pediatric physical therapy until age 6 months followed by helmet treatment until age 12 months. When contacted by telephone, the parents of the 2 infants who received manual therapy indicated that they were very satisfied with the shape of their child's head at age 12 months (ODDI score, 102% at age 6 months for both), and they were not compliant with follow-up assessments. The helmet-treated child had an ODDI score of 116% at age 6 months; without helmet treatment, the score would not have decreased below 104%. For this reason, we carried the data obtained from study dropouts at age 6 months forward to age 12 months in our analysis (**Figure 2**).⁵⁰

COMMENT

To our knowledge, this is the first randomized controlled trial of a pediatric physical therapy program to treat infants with positional preference that focuses on parental

Table 2. Primary and Secondary Outcomes at End of the Intervention (Age 6 Months) and Follow-up (Age 12 Months)

	Intervention Group (n = 33)		Control Group (n = 32)	
	Age 6 mo	Age 12 mo	Age 6 mo	Age 12 mo
Primary outcome				
Severe deformational plagiocephaly, No. (%)	10 (30)	8 (24)	18 (56) ^a	18 (56) ^a
Risk and No. needed to treat calculation				
RR (95% CI)	0.54 (0.30-0.98)	0.43 (0.22-0.85)	NA	NA
Absolute risk reduction, %	26	32	NA	NA
Number needed to treat	3.85	3.13	NA	NA
Secondary outcomes				
Asymmetry in posture and movements, No. (%)				
Positional preference	0	0	0	0
Asymmetrical trunk alignment and movements	0	1 (3)	3 (9)	1 (3)
Motor development, mean (SD)				
AIMS z score	-0.95 (0.89)	-1.11 (1.38)	-0.77 (0.99)	-1.25 (1.90)
BSID-II-PDI score	81.1 (10.1)	80.1 (17.8)	85.8 (11.6)	82.2 (17.2)

Abbreviations: AIMS, Alberta Infant Motor Scale⁴⁶; BSID-II, Bayley Scales of Infant Development, second edition⁴⁷; CI, confidence interval; NA, not applicable; PDI, Psychomotor Development Index; RR, relative risk.

^a $P < .05$.

participation and extensive advice regarding infant feeding, positioning, and handling. As hypothesized, a standardized pediatric physical therapy intervention program to treat children with positional preference significantly reduced the prevalence of severe DP compared with usual care. In the intervention group, parents fed, positioned, and handled their infants more symmetrically. They placed their infants in prone positions for longer and in a side-lying position less frequently.

The infants who were enrolled in this randomized controlled trial were part of a cohort of 400 healthy neonates consecutively born at term in a district hospital. Only 3 eligible infants with positional preference did not participate in this randomized controlled trial, and 3 participants were not assessed at age 12 months. Although the sample size of 65 infants is small, the subjects are representative and the results are generalizable because the initial cohort of neonates was consecutively recruited.

For most participants, the intervention period was shorter than expected at the start of the study. Positional preference, the most significant cause of DP, was absent at age 6 months in all infants. However, although DP is the result of positional preference during the first months of life, it is not diminished by the absence of positional preference at age 6 months.

In the control group, parents received only the leaflet with basic preventive advice and no further education or instructions to intervene, but they may have begun paying more attention to positional preference.⁵⁰ This may have diminished the difference between the intervention and control groups regarding severe DP. However, a single demonstration on what to do, as represented by merely giving a leaflet to parents in the usual care group, has proved to be insufficient.⁵

There are few empirically tested mechanisms to account for the association of DP with developmental problems or of interventions to treat DP.^{5,14} Some studies support the hypothesis that nursing and all feeding habits as well as motor development and positional preference

are primarily associated with DP.^{5,7} In addition, earlier achievement of motor milestones was assumed to be protective against DP.⁵ Other studies of DP and motor development did not include a control group or studied only a few variables.⁵³⁻⁵⁷ In this study, motor development, measured by the AIMS z score, demonstrated an inverse, protective effect on DP at age 7 weeks (adjusted odds ratio, 0.6; 95% CI, 0.43-0.93). However, stimulating motor development in the intervention group did not result in a further increase in motor developmental scores. The AIMS and BSID-II might not be sensitive enough tests of the motor skills responsible for a decrease in DP (ie, more prone positioning and less side-lying positioning).

There is evidence that prone positioning while awake is positively correlated with AIMS scores.⁵⁴ This study supports the hypothesis that DP is associated with positional preference, asymmetrical positioning, and feeding habits^{5,7} and provides evidence of an etiological pathway linking DP with neurodevelopment.¹⁴ Prone positioning also seems to be important in reducing DP, and motivating parents to carry out a structured program to prevent positional preference reduces the risk of severe DP. In this study, the numbers of infants with positional preference needed to treat were 3.85 and 3.13 at ages 6 and 12 months, respectively, which shows the importance of pediatric physical therapy in preventing and diminishing DP. Side-lying positioning also may reduce DP, but may have the opposite effect if not used correctly, which may have occurred in the control group. Infants placed on their sides can roll partially onto their backs, resulting in a slight rotation toward the already flattening lateral occipital side of the head. In the intervention group, parents were extensively informed about the possible variances in motor development caused by DP. These parents also received hands-on instruction in nursing, handling, and feeding. Infants in the intervention group who were encouraged to play in a prone position as early, as frequently, and for as long as possible were likely to have less severe DP. In the control group,

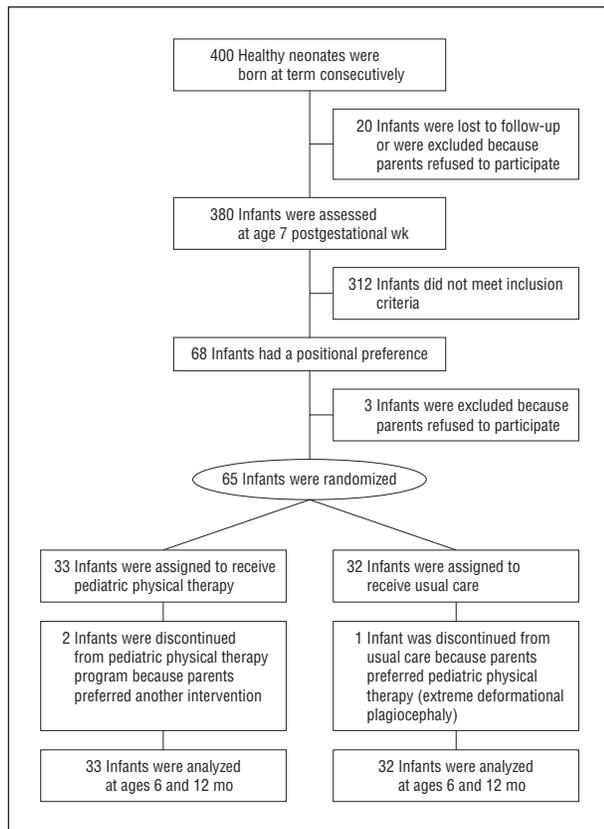


Figure 2. The CONSORT flowchart.⁵⁰

parents may have interpreted the recommendations on preventing sudden infant death syndrome to include avoiding prone positioning during the day, as has been suggested in previous studies.^{5,14}

Nurses at well-child care clinics and parents should be aware of the possible rapid progression of skull deformation in the first months of life and should be provided with adequate information about the causes of DP and its likely consequences.^{7,54,55} In addition, parents should be taught to recognize signals of positional preference, so they can intervene as early as possible or seek professional help. Parents should also be instructed to alternate positions during nursing and bottle-feeding and when positioning the infant on the changing table when the first signs of DP are observed. Infant characteristics, such as temperament and activity level, may influence this process as well,⁷ which may require parents to think creatively about how to stimulate their infant.

In this study, a pediatric physical therapy program to treat infants with positional preference prevented DP in 26% of infants at age 6 months and 32% at age 12 months. Based on evidence provided in this study, pediatric health care and physical therapy centers should begin implementing treatment to prevent and diminish DP.

Future studies should focus on the role of motor development in DP. In addition, the first follow-up assessment in studies of DP should be performed before age 6 months to discern possible differences between intervention and control groups regarding positional preference prevalence and motor development.

Early diagnosis of positional preference and identification of 1-sided infant care are essential for beginning early intervention with pediatric physical therapy, varying the infant's position when awake and under supervision (ie, prone positioning and side-lying positioning), and varying the infant's head position when sleeping in the supine position.

We conclude that a 4-month standardized pediatric physical therapy intervention program to treat children with positional preference significantly reduced the prevalence of severe DP compared with usual care.

Submitted for Publication: September 29, 2007.

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Author Contributions: Drs van Vlimmeren and Engelbert had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: van Vlimmeren, van der Graaf, Helders, and Engelbert. Acquisition of data: van Vlimmeren and Engelbert. Analysis and interpretation of data: van Vlimmeren, van der Graaf, and Engelbert. Drafting of the manuscript: van Vlimmeren, van der Graaf, Helders, and Engelbert. Critical revision of the manuscript for important intellectual content: van der Graaf, Boere-Boonekamp, L'Hoir, and Helders. Statistical analysis: van Vlimmeren, van der Graaf, and Engelbert. Obtained funding: van Vlimmeren. Administrative, technical, or material support: van Vlimmeren and Helders. Study supervision: van Vlimmeren, van der Graaf, Helders, and Engelbert.

Financial Disclosure: None reported.

Additional Contributions: Femke van Gastel, PT, PCS, BSc, Eveline Kolk, PT, PCS, BSc, Lineke Kleinlugtenbelt, PT, PCS, BSc, Vivienne Schellekens, PT, PCS, BSc, Miranda Lahuis, PT, PCS, BSc, Meike de Ruiter, PT, PCS, BSc, Nynke de Zee, PT, PCS, BSc, Nicole Fontijn, PT, PCS, BSc, Aletta Pomper, PT, PCS, BSc, Marijke Verstappen, PT, PCS, BSc, Wendy Verdult, PT, PCS, BSc, Christel Ebes, PT, PCS, BSc, and Marjolein van Velsen, PT, PCS, MSc, helped with data acquisition. Annette Roelands provided logistical support, and Lotte van Vlimmeren provided extensive help with data entry. We thank all parents and infants who participated in the study. None of the persons named received compensation for their contributions.

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