A Randomized Trial of Baby Triple P for Preterm Infants: Child Outcomes at 2 Years of Corrected Age

Paul B. Colditz, DPhil (Oxon)[1,2], Roslyn N. Boyd, PhD[3], Leanne Winter, PhD[1,4], Margo Pritchard, PhD[1,5,6], Peter H. Gray, MD[5,7], Koa Whittingham, PhD[3], Michael O'Callaghan, MSc[5], Luke Jardine, MClinEpid[5,7], Peter O'Rourke, PhD[8], Louise Marquart, PhD[8], Kylee Forrest, DClinPsych[1,7], Carmen Spry, PhD[4], and Matthew R. Sanders, PhD[4]

Objective To determine the efficacy of a hospital-based intervention that transitions into existing community support, in enhancing developmental outcomes at 2 years of corrected age in infants born at less than 32 weeks.

Study design In total, 323 families of 384 infants born <32 weeks were randomized to receive intervention or care-as-usual. The intervention teaches parents coping skills, partner support, and effective parenting strategies over 4 hospital-based and 4 home-phone sessions. At 2 years of corrected age maternally reported child behavior was assessed by the Infant and Toddler Social Emotional Adjustment Scale. Observed child behavior was coded with the Revised Family Observation Schedule. Cognitive, language, and motor skills were assessed with the Bayley Scales of Infant and Toddler Development III.

Results Mean gestational age of infants was 28.5 weeks (SD = 2.1), and mothers' mean age was 30.6 years (SD = 5.8). A total of 162 families (n = 196 infants) were allocated to intervention and 161 families (n = 188 infants) received care-as-usual. There was no significant adjusted difference between treatment groups on dysregulation (0.2; 95% CI −2.5 to 3.0, P = .9) externalizing (0.3; 95% CI −1.6 to 2.2, P = .8), internalizing (−1.5; 95% CI −4.3 to 1.3, P = .3), observed aversive (0.00; −0.04 to 0.04, P = .9), or nonaversive behavior (−0.01; 95% CI −0.05 to 0.03, P = .7). Intervention children scored significantly higher on cognition (3.5; 95% CI 0.2-6.8, P = .04) and motor skill (5.5; 95% CI 2.5-8.4, P < .001), and approached significance on language (3.8; 95% CI −0.3 to 7.9, P = .07).

Conclusions Baby Triple P for Preterm Infants increases cognitive and motor skills but does not impact behavior. The results are evidence that hospital-based interventions can improve some developmental outcomes for infants <32 weeks. *(J Pediatr 2019;■:1-7)*.

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See editorial, p •••

Children born very preterm (<32 weeks of gestation) are at increased risk of motor and cognitive abnormalities and language, behavioral, and emotional problems.[1-5] Systematic reviews of early interventions[6-8] suggest positive behavioral and cognitive effects, but improvements may not be sustained at school age. Furthermore, existing interventions are often high-cost postdischarge (home-visit) designs resulting in few very preterm infants receiving high quality intervention in clinical practice.

Parenting practices have a major impact on children's development.[9,10] Improving the parent-child relationship and enriching the home environment for preterm infants delivers positive outcomes.[11] Accordingly, early interventions that target parenting hold the greatest potential to create sustained effects on child development.[12,13]

Preterm birth is associated with parental depression and anxiety,[14,15] post-traumatic stress,[16] and lower levels of maternal coordination with infant cues.[17] Postpartum psychological distress in mothers is associated with poorer child outcomes[18,19] and in the preterm population has been linked with later child behavior problems[20] and poorer neurodevelopmental outcomes.[21]

Bayley-III	Bayley Scales of Infant and Toddler Development-Third Edition
CSBS DP	Communication and Symbolic Behavior Scales of Development Profile
GMFCS	Gross Motor Function Classification System
ITSEA	Infant and Toddler Social and Emotional Assessment
NICU	Neonatal intensive care unit
SCN	Special care nursery

From the [1]University of Queensland Center for Clinical Research, Faculty of Medicine, The University of Queensland, Brisbane, Australia; [2]Royal Brisbane and Women's Hospital, Brisbane, Australia; [3]Queensland Cerebral Palsy and Rehabilitation Research Center, UQ Child Health Research Center, Faculty of Medicine, The University of Queensland, Brisbane, Australia; [4]The Parenting and Family Support Center, School of Psychology, Faculty of Health and Behavioral Sciences, The University of Queensland, Brisbane, Australia; [5]Mater Mothers' Hospital, Brisbane, Australia; [6]Australian Catholic University, Brisbane, Australia; [7]Mater Research Institute-University of Queensland, Brisbane, Australia; and [8]QIMR Berghofer Medical Research Institute, Brisbane, Australia

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Interventions that target parental mental health have been shown to impact positively on child behavior at 2 years of age.[22] Parents of preterm infants identify a need for support and more information on supporting their infant's development.[23,24] Thus, initiation of an early intervention that focuses on sustained environmental enrichment through enhanced parenting practices and addresses sustainability of effect is desirable.

The Triple P-Positive Parenting Program is a multilevel system of intervention targeting parents of children from infancy to adolescence, implemented in Australia and over 28 other countries. Evaluations of this program demonstrate positive effects on child behavior and adjustment, parenting practices, and parental mental health.[25-27] Baby Triple P for Preterm Infants,[28] a tailored variant of Triple P, was developed using a focus group of parents of very preterm infants and is focused on normalization of preterm parenting, information about development, creating a safe environment, building a positive parent-infant relationship, strategies to manage behavioral issues, building adaptive coping skills, and a focus on "learning to parent together."[29] The intervention commences in the neonatal unit and allows for increased sustainability by continuing into an existing Triple P community-based parenting resource after discharge. The aim of this randomized controlled trial was to determine the efficacy of Baby Triple P for Preterm Infants in enhancing child development at 2 years of corrected age. It was hypothesized that children whose parents participated in the intervention would have lower levels of problematic behavior and higher cognitive, language, and motor skills than children in the care-as-usual group.

Methods

A detailed research protocol has been published.[29] Infants born very preterm (<32 weeks of gestational age), and their parents, admitted to the Royal Brisbane and Women's Hospital and Mater Mothers' Hospital, Brisbane, Australia, between February 2012 and April 2015 were eligible for the study. Families were excluded if the infant had major congenital anomalies associated with a poor neurodevelopmental outcome, the parents had insufficient English or stated they were unwilling to return for follow-up at 2 years of corrected age.

The design was a randomized controlled trial with 2 conditions (intervention, care-as-usual). Data were collected at the time of randomization (baseline), by parent questionnaire and from infant medical records, and at 2 years of corrected age by parent questionnaires, direct observation, and neurodevelopmental assessment. Ethics approval was granted from The University of Queensland and the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee. Families of medically stable infants were approached by recruitment nurses at each site. After consenting to participate, parents completed a baseline questionnaire. Family units were then randomly allocated, by research nurses, to either the intervention group (Baby Triple P for Preterm Infants plus routine care) or care-as-usual group (received routine care for preterm infants). The allocation sequence was generated by staff not associated with the study and comprised computer-generated random numbers in a block design. Allocations were concealed in opaque envelopes. Envelopes were stratified for site and for risk of brain injury on routine cranial ultrasound into normal or intraventricular hemorrhage grade I or II, or intraventricular hemorrhage grade III or IV or periventricular leukomalacia. The unit of randomization was the family and so multiple births were assigned to the same group.

Baby Triple P for Preterm Infants, a modified version of Baby Triple P[28] was developed for the present study and a comprehensive description is contained in the published protocol.[29] The intervention guides parents to enhance coping skills, increase their knowledge of effective partner support strategies, recognize their infant's needs, promote their infant's development through creating a safe, engaging, nurturing, and positive learning environment, teach their infant new skills, develop a positive relationship with their infant, using settling techniques and promoting good sleep habits. There were a total of 8 sessions: 4 × 2-hour group sessions conducted in the hospital while infants were still in either the neonatal intensive care unit (NICU) or special care nursery (SCN) followed by 4 × 30-minute home telephone consultations conducted weekly, postdischarge beginning at 2 weeks of corrected age. The telephone consultations aimed to tailor the program content to the individual needs of the family and assist parents to put the learned content into practice. The sessions were conducted by facilitators with psychology degrees. To maintain fidelity and reduce drift over time, facilitators participated in a standardized 3-day training, used a manual, attended supervision sessions, and completed postsession adherence checklists. The program was designed for flexible delivery. Families whose babies were back-transferred to regional hospitals or discharged prior to the completion of the 4 hospital sessions were given a DVD of remaining sessions to watch at home followed by a telephone consultation with their facilitator. In Queensland, Australia, it is common for nurses at community-based health centers to be accredited in Primary Care Triple P.[26] After the final session parents were provided with contact details for their nearest community-based Triple P support location and encouraged to access available services until their infant reached 2 years of corrected age. At 3 monthly intervals, beginning at 3 months of corrected age, families were sent Triple P tip-sheets providing developmentally appropriate parenting advice and received phone support. Parents were also sent a fortnightly text-message reiterating program content until 2 years of corrected age.

Care-as-Usual

Families in both intervention and care-as-usual groups received standard routine care provided at each site prior to discharge or back-transfer to a local or regional hospital.

In general, routine care consists of medical follow-up and surveillance, however, it is not uniform across NICUs or SCNs within Australia. There were no positive support programs on parenting provided by psychologists in any of the units during the study. Postdischarge follow-up care for very preterm infants also varies between hospitals. Families from both groups were likely to have accessed other services including general practitioner, pediatrician, lactation consultant, community health nurse, and possibly Primary Care Triple P support at community health centers or other parenting interventions between the time of discharge and study follow-up. Baby Triple P was not available in the community or in hospitals during the study. The services accessed were measured at 2 years of corrected age by parent recall.

Sample Descriptors

Demographic information was collected at baseline using the Family Background Questionnaire, adapted from the Western Australian Child Health Survey.[30] Medical risk factors were taken from the infants' case notes using the standardized Australian and New Zealand Neonatal network data definitions (eg, gestational age, birth weight).[31]

The Gross Motor Function Classification System (GMFCS)[32] was used to classify the functional motor abilities of children at 2 years of corrected age. The GMFCS is a classification system comprising 5 levels with higher levels indicating greater dysfunctionality.

Child Outcomes

The primary outcome was child behavioral and emotional problems at 2 years of corrected age. The Infant Toddler Social and Emotional Assessment (ITSEA)[33] was used to assess mother-reported behavioral dysregulation, externalizing, and internalizing behavior. Observed child behavior was measured via 15-minute mother-toddler video-recorded observations conducted in the hospital.[29] Observations were coded in 10-second intervals by trained research assistants, blind to condition, using a revised version of the Family Observation Schedule.[34] Dependent measures were "combined child aversive behavior," defined as the percentage of intervals where the child engaged in any of the aversive child codes (eg, noncompliance, complaint, physical negative) and "combined child nonaversive behavior," defined as the percentage of intervals where the child engaged in any of the nonaversive child codes (engaged activity, appropriate verbal, or affection). Interrater reliability (Kappa) was calculated on a random selection of 17% of the video recordings and substantial agreement was achieved (M κs = 0.65). During the observation, mothers completed the Communication and Symbolic Behavior Scales Developmental Profile (CSBS DP),[35] a 24-item screening tool for the early identification of children with, or developing, a communication impairment. It results in a total score and 3 composite scores: communication composite (use of communication, eye-gaze, gestures), expressive speech composite (sounds and words), and symbolic composite (understanding words and object use) with higher scores indicating greater competency. Scores 1.25 SDs below the normative value in a domain are classified as "of concern."[35]

Secondary outcomes were cognitive, language, and motor skills at 2 years of corrected age, assessed using the Bayley Scales of Infant and Toddler Development-Third Edition (Bayley-III),[36] administered by trained psychologists and physiotherapists blind to group allocation and normed for a mean of 100 and SD of 15.

Statistical Analyses

A clinically important difference in child behavioral and emotional problems is considered to be a standardized effect size of 0.33 on the ITSEA.[33] With a type-1 (alpha) level of 0.05 and 80% power, 140 participants per group (a total sample size of 280) were required. With anticipated retention of >85% a final sample size in excess of 320 was recruited. Although the unit of randomization was the family the outcome measures were child specific, and, therefore, all analyses were performed with the child as the experimental unit. χ^2 tests of independence were calculated to examine differences between treatment groups for parent-reported access to other services, CSBS DP categories of concern, and the GMFCS. Linear mixed models were used to examine the differences between treatment groups on continuous outcome measures with a random intercept for each family included to account for clustering of multiple births. Logistic mixed models were used to examine differences between groups for ITSEA dichotomous categories of concern. Adjustments were made for the potential influence of hospital site and gestational age (<28 weeks, ≥28 weeks). In accordance with intention-to-treat principles, all children of intervention group families who completed follow-up assessment were included in the analyses. Estimated marginal means, adjusted differences and 95% CIs are presented for the intervention effect of each outcome. ORs and CIs are also presented for the CSBS DP categories of concern. Statistical analyses were performed in SPSS Version 22 (SPSS Inc, Chicago, Illinois).

Results

In total, 323 families of 384 infants were randomized to either the intervention (n = 162 families, n = 196 infants) or care-as-usual groups (n = 161 families, n = 188 infants) (**Figure**; available at www.jpeds.com). The mean age of mothers was 30.6 years (SD = 5.8) and the mean gestational age was 28.5 weeks (SD = 2.1) (**Table I**). All 8 intervention sessions were completed by 108 families, and 14 families did not complete any sessions. Of those who completed the first 4 sessions (n = 129), 86 (67%) completed all face-to-face with the facilitator, 39 (30%) completed via a combination of face-to-face and DVD, and 4 (3%) watched the DVD only. On average, intervention families participated in 4.1 of 7 (SD = 1.8) tip sheet follow-up support phone calls. At 2 years of corrected age, 286 mothers (82%) completed the

Table I. Participant characteristics at baseline

Characteristics	Intervention n (%)	Care-as-usual n (%)
Infant*		
Female	80 (41)	78 (42)
Normal or IVH grade I or II	188 (96)	183 (97)
Mother*		
Infant/s born <28 wk of gestational age	67 (41)	51 (31)
No previous children	97 (60)	94 (60)
Speak only English at home	146 (90)	147 (91)
Planned pregnancy	115 (71)	113 (70)
Multiples birth (twins and triplets)	32 (20)	27 (17)
Relationship status		
Married or defacto	145 (90)	141 (88)
Not living with partner/single	17 (11)	20 (12)
Education†		
High school (part or complete)	38 (24)	47 (29)
Trade certificate	57 (35)	46 (29)
University degree/postgrad study	66 (41)	68 (42)
Current financial stress‡,§		
None	56 (35)	64 (40)
Moderate	85 (53)	79 (49)
High	19 (12)	17 (11)
Accessed mental health services in past 12 mo¶	49 (30)	36 (23)

IVH, intraventricular hemorrhage.
*For infants, n = 196 intervention, n = 188 care-as-usual; for mothers n = 162 intervention, n = 161 care-as-usual.
†n = 161 for intervention and n = 161 for care-as-usual (1 missing data).
‡n = 160 for intervention and n = 160 for care-as-usual (3 missing data).
§None: Enough money left over after essential household needs to comfortably purchase most things desired; Moderate: Enough money left over after essential household needs to purchase only some things desired; Low: Not enough money left over after essential household needs to purchase much of anything desired.
¶n = 161 for intervention and n = 160 for care-as-usual (2 missing data).

questionnaire on their access to other services after hospital discharge. More mothers in the intervention group reported accessing other Triple P services than did mothers in the care-as-usual group (17% vs 10%, $P = .046$), but the groups did not differ with respect to accessing general practitioners, community health nurses, pediatricians, lactation consultants, or other services. The classification of infants on GMFC was not significantly different between groups ($P = .11$) with 310 (96.6%) classified as level I (walks without aids), 4 (1.2%) level II (walks only with aid), 2 (0.6%) level III (sits alone and crawls for mobility), 1 (0.3%) level IV (sits with trunk support), and 4 (1.2%) level V (cannot sit). There was a selection of key baseline characteristics associated with those families not completing the ITSEA at 2 years of corrected age compared with those who did complete. These characteristics included younger age, the index pregnancy being unplanned, no formal education after high school, and financial distress.

Primary Outcome

The ITSEA was completed by 286 mothers for 334 children. There were no significant differences between the groups on dysregulation, externalizing, or internalizing behavior, either on mean adjusted differences or categories of concern (Table II). Observations were recorded for 284 mother-toddler dyads. The groups did not differ significantly on either aversive or non-aversive behavior (Table II). All standardized effect sizes were small (0.02-0.12 SD) and lower than expected for clinical significance.

Secondary Outcomes

The Bayley-III assessment was conducted for 275 (85.1%) families. Of the 48 families who did not return, 16 had withdrawn, 2 had infants who had died, 12 could not be contacted or had moved overseas, 7 declined to return, and 11 failed to arrive for appointments. Child noncompliance prevented some children from completing all 3 scales. Four children could not be assessed on any scale because of severe developmental delay and were assigned scores of <−3 SDs. Children in the intervention group scored significantly higher on the cognitive and motor scales than children in the care-as-usual group, and the groups did not differ significantly on the language scale (Table III). Standardized effect sizes were 0.23, 0.36, and 0.25 SD, respectively. Children in the

Table II. Child behavior outcomes at 24 months of corrected age adjusted for site and gestational age

Measures	Intervention (n = 171) mean (95% CI)	Care-as-usual (n = 163) mean (95% CI)	Adjusted difference (95% CI)	OR (95% CI)	*P* value
ITSEA*,†					
External	45.4 (44.1-46.8)	45.1 (43.7-46.5)	0.3 (−1.6 to 2.2)		.8
Internal	43.8 (41.8-45.7)	45.2 (43.2-47.3)	−1.5 (−4.3 to 1.3)		.3
Dysregulation	45.1 (43.2-47.1)	44.9 (42.9-46.9)	0.2 (−2.5 to 3.0)		.9
Categories of concern*,‡					
External, n (%)	9 (5.3)	2 (1.2)			
Internal, n (%)	10 (5.8)	15 (9.2)			
Dysregulation, n (%)	12 (7.0)	15 (9.2)			
Any of concern, n (%)	22 (12.9)	23 (14.1)		0.9 (0.4-1.68)	.7
Mother-toddler observation§					
Combined child aversive¶	0.24 (0.21-0.26)	0.23 (0.21-0.26)	0.00 (−0.04 to 0.04)		.9
Combined child nonaversive**	0.75 (0.73-0.78)	0.76 (0.73-0.79)	−0.01 (−0.05 to 0.03)		.7

*Due to the small percentage of children categorized to be "of concern" in each of the 3 domains, external, internal and dysregulation, the logistic mixed model failed to converge, therefore, no results are presented.
†Higher scores indicate more problematic behaviours.
‡Mean scores at, or above, the 90th percentile are considered at risk and may indicate deficient or deviant behavior.
§Data were available for 146 and 138 children in the intervention and care-as-usual groups, respectively.
¶Higher scores indicate more aversive behavior.
**Higher scores indicate more non-aversive behavior.

Table III. Child outcomes on Bayley-III and CSBS DP at 24 months corrected age adjusted for site and gestational age

	Intervention		Care-as-usual		Adjusted difference		
Domains	**n**	**Mean (95% CI)**	**n**	**Mean (95% CI)**	**Mean (95% CI)**	**OR (95 % CI)**	***P* value**
Bayley-III							
Cognition	160	98.5 (96.2-100.8)	155	95.0 (92.5-97.4)	3.5 (0.2-6.8)		.04
Language	156	96.0 (93.1-98.8)	148	92.2 (89.2-95.2)	3.8 (−0.3 to 7.9)		.07
Motor skill	150	99.6 (97.5-101.7)	148	94.1 (91.9-96.3)	5.5 (2.5-8.4)		<.001
CSBS DP	161		150				
Total score		47.1 (45.8-48.4)		45.7 (44.3-47.1)	1.4 (−0.5 to 3.2)		.16
Communication composite		20.6 (20.0-21.2)		20.3 (19.7-21.0)	0.3 (−0.6 to 1.2)		.50
Expressive speech composite		11.6 (11.1-12.1)		11.3 (10.8-11.2)	0.3 (−0.3 to 1.0)		.33
Symbolic composite		14.9 (14.4-15.3)		14.1 (13.7-14.6)	0.7 (0.1-1.4)		.03
Categories of concern, n (%)							
Total score		29 (18)		35 (23)		0.7 (0.4-1.4)	.36
Communication composite		33 (21)		41 (27)		0.7 (0.4-1.2)	.21
Expressive speech composite*		20 (12)		24 (16)			
Symbolic composite		21 (13)		33 (22)		0.5 (0.3-1.0)	.05

*The "of concern" expressive speech general linear mixed model failed to converge, therefore no results are presented.

intervention group scored significantly higher on the symbolic CSBS DP scale, with standardized effect size of 0.27 SD, and fewer intervention group children were categorized as "of concern" on this scale.

Discussion

Baby Triple P for Preterm Infants, delivered in hospital and continuing with existing Triple P support in the community resulted in better cognitive, motor, and symbolic communication skills at 2 years of corrected age for children in the intervention group, however, there were no condition differences for child behavior. The proportion of children in both groups identified as at risk on the ITSEA, was either lower than, or similar to that found in both the norm-referenced population[33] and term samples,[1] which may have resulted in floor effects limiting our ability to detect condition differences in behavior. Children in both conditions showed no evidence of significant behavior difficulties, and we are unable to determine whether this is a study effect or due to factors unrelated to intervention.

The motor skill effect of 0.36 SD on the Bayley-III is greater than the 0.10 SD reported in a recent Cochrane review of early developmental intervention programs to prevent motor and cognitive impairment of preterm infants[6]; the cognitive effect of 0.23 SD is smaller than the 0.32 reported. Why motor skill increased to such an extent is unclear, however, programs that promote an enriched home environment, enhance parent-infant interactions, and guide parents to teach their infant new skills, all key components of this intervention, have been shown to result in greater motor skill in infants with cerebral palsy.[37]

The parenting strategies likely to affect motor and cognitive performance are able to be employed by parents immediately. The strategies, which assist parents to manage and prevent behavior problems were not appropriate to be used until several months after discharge. This time lag may have contributed to parents either forgetting the strategies, or reducing their confidence in using them. This may have contributed to why the program did not result in group differences on child behavior.

Intervention families received Triple P tip sheets regularly over 2 years, but on average, each family participated in only 58% of the follow-up phone support offered. Intervention families reported engaging with Triple P community providers more than care-as-usual families but the nature of the assistance sought is unknown. For Baby Triple P for Preterm Infants to reduce child behavior problems at 2 years of corrected age, it may be necessary to design and implement strategies for busy parents to increase engagement with phone support. In addition, a refresher of age-appropriate content or a top-up intervention delivered at around 12 months of corrected age, when infants are transitioning to toddlerhood, such as Triple P Online,[38] may be effective and is a suggestion for future research. Although the analyses in this study are based on intention to treat, it is also possible that dosage, or the amount of intervention received by parents may impact outcomes. Improvements in outcomes might be increased with increasing participation rates and is a suggestion for future research. If the program became universally offered in NICUs and considered a routine service for all families with a clear expectation that parents participate, fewer retention problems might be expected than in a clinical trial where parents face many additional requirements.

A major strength of the study is the use of a hospital-based intervention that continues into existing Triple P community support. The results are evidence that a hospital-based intervention, which transitions into existing community support, can enrich the home environment and improve developmental outcomes for very preterm infants without the high costs typically associated with home-visit programs. Currently, there is a lack of published data on the cost-effectiveness of hospital-based interventions compared with home-visit-based interventions, and a direct comparison should be conducted. Flexible mode of delivery is another key strength. Infants admitted to, or born at tertiary referral hospitals, are often back-transferred quickly to secondary

hospitals meaning intervention programs have a limited time window in which to complete sessions. Of families who completed the first 4 "hospital"-based sessions in this study, 33% did so, at least in part, by watching the sessions on DVD. Without this flexibility, the rate of successful intervention completion would have been substantially lower. Another strength of the study is the inclusion of a parent-report measure of communication (CSBS-DP). The finding that intervention group children scored significantly higher on the symbolic composite score is consistent with the result for the Bayley-III language scale which approached significance. The difference in effect sizes between the measures may reflect the challenges of conducting a reliable Bayley-III language assessment of 2-year-olds in a clinical environment.

Generalizability is limited to very preterm infants, and future research should examine the efficacy of the intervention in moderate to late preterm infants. The difference in pre- and post-routine care at transfer hospitals was not able to be controlled, which may be considered a potential weakness of the study. This was a pragmatic trial to test the effectiveness of the intervention in the "real life" conditions of Queensland, Australia. The nature of routine care in Queensland is variable and back-transfers from the Royal Brisbane and Women's Hospital and Mater Mothers' Hospital to regional SCNs are a common occurrence. Access to other interventions was monitored at follow-up. The findings also only provide evidence of effects at 2 years of corrected age. It will be important to determine if this effect, together with the effects for cognition and communication, are sustained at school age and later. ■

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Reprint requests: Paul B. Colditz, DPhil (Oxon), UQ Center for Clinical Research, Building 71/918, Royal Brisbane and Women's Hospital, Herston, 4029, Brisbane, Queensland, Australia. E-mail: p.colditz@uq.edu.au

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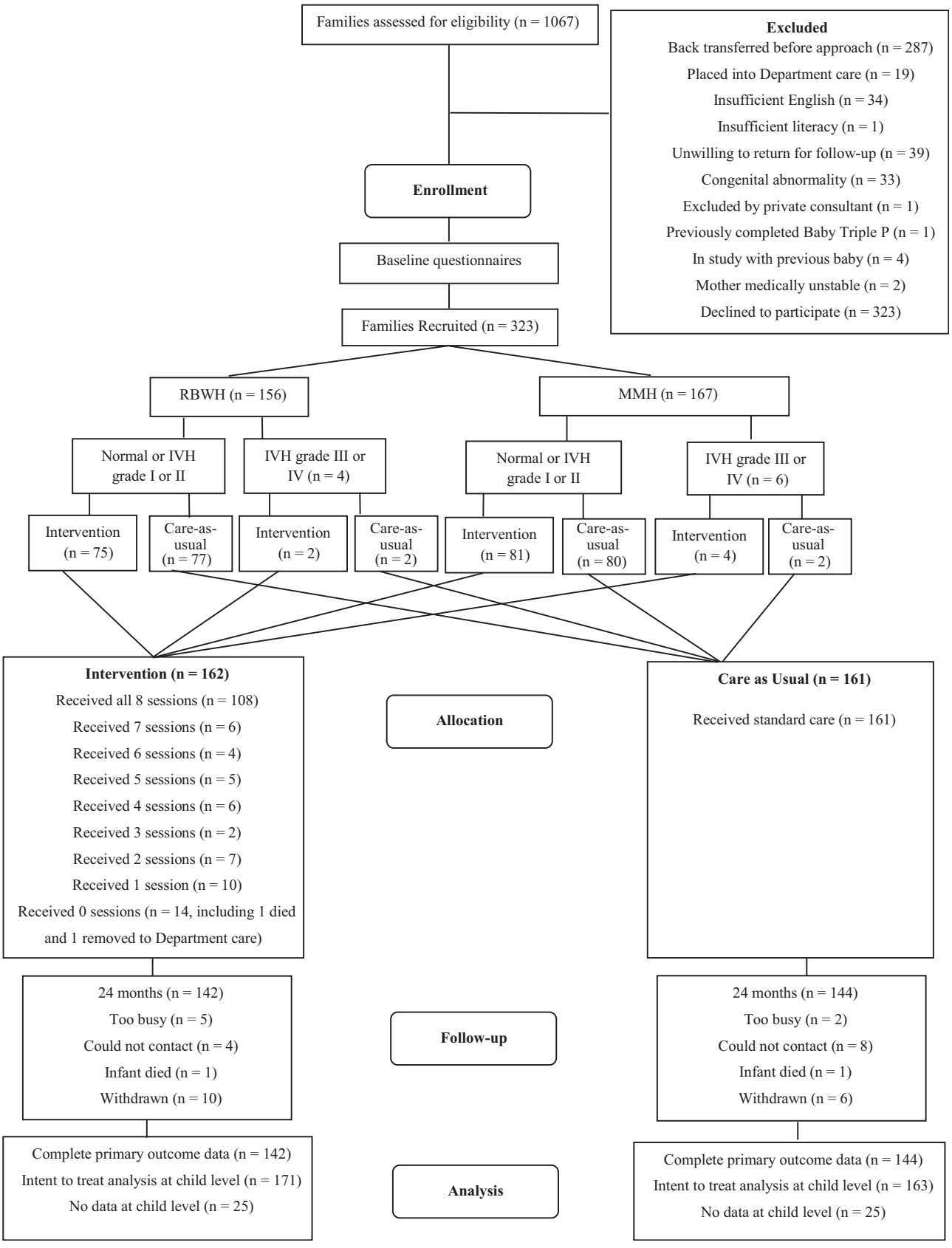

Figure. Participant flow. *IVH*, intraventricular hemorrhage; *MMH*, Mater Mothers' Hospital; *RBWH*, Royal Brisbane and Women's Hospital.