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A randomized, controlled evaluation of early intervention: the Born to Learn curriculum

D. Drotar,* J. Robinson,† L. Jeavons and H. Lester Kirchner‡

*Cincinnati Children's Hospital Medical Center, Cincinnati, OH
†National Jewish Hospital, Denver, CO, and
‡Center for Health Research, Geisinger Health System, Danville, PA, USA

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Correspondence:
Dennis Drotar, Division of Behavioral Medicine and Clinical Psychology, Cincinnati Children's Hospital Medical Center, 3333 Burnet Avenue, MLC 7039, Cincinnati, OH 45229-2029, USA
E-mail:
dennis.drotar@cchmc.org

Abstract

Background This study addressed the need for studies of the efficacy of the Born to Learn (BTL) curriculum.

Methods Based on random assignment, 227 families of infants received the BTL curriculum conducted in monthly home visits, and 237 families received general child development education only.

Results The BTL curriculum resulted in higher mastery motivation (task competence) at 36 months ($P < 0.05$) and greater effects for children from low ($P < 0.01$) versus high socio-economic status on mastery motivation and cognitive development at 24 months. No effects were found on a wide range of other developmental outcomes.

Conclusion Future studies should document the BTL curriculum effectiveness in diverse settings and samples.

Introduction

The first 3 years of life are recognized as a critical window of opportunity in which to influence the development of young children (Karoly *et al.* 1998; Ramey & Ramey 1998). There is a critical need to evaluate early intervention models that reach large numbers of young children and their families. The Parents as Teachers (PAT) organization has recently developed and implemented a new curriculum, Born to Learn (BTL), throughout the United States (McGilly *et al.* 2000). Preliminary research on BTL has yielded promising results: McGilly (2000) found that parents who received the BTL curriculum demonstrated improved child development knowledge compared with a control group and children showed decreased behavioural symptoms (McGilly 2000). However, these results were limited by several problems: (1) absence of random assignment to groups and possible selection bias; (2) high levels of sample attrition; and (3) use of parental reports rather than direct assessment as the primary measure of child developmental outcomes.

To address these limitations, this study conducted the first randomized, controlled trial of the efficacy of the BTL curriculum in a 3-year prospective study of young children (birth to 3 years) based on a comprehensive assessment of children's development in multiple domains. A second innovation, which was an important one given the prevalence and impact of economic disadvantage on young children worldwide (Duncan & Brooks-Gunn 1997), was to test the efficacy of the BTL curriculum in a diverse sample of high- and low-socio-economic status (SES) families.

Informed by theories that underscore the critical importance of stimulation for early brain development (Nelson 2000), the BTL curriculum was designed to impact child development by providing information and coaching to parents to enhance the quantity and quality of their stimulation and relationships with their infants (Smilkstein 2003). We hypothesized that children

whose parents received the BTL curriculum would demonstrate more competent cognitive and language development, security of attachment (SAT), mastery motivation (MM), academic readiness skills and social competence than children whose families received a general parent education programme. Based on research that has documented the efficacy of other early intervention programmes for children from lower-SES families (Ramey & Ramey 1998), we hypothesized that the BTL curriculum would have greater effects on the development of children from lower versus higher-SES families.

Methods

Study design

Two groups of children and parents were randomized to either: (1) the BTL curriculum; or (2) a comparison intervention involving general parent education programme that included educational handouts and access to various developmental activities.

Method of randomization

Randomization lists prepared by a biostatistician were placed in a series of sequentially numbered sealed coin envelopes, each containing the name of the study and the sequence number on the outside and a slip with the sequential number and randomized assignment inside. The randomization list consisted of blocks of varying sizes stratified by SES. Each block contained equal numbers in each treatment group to ensure that the numbers of families assigned to the groups were approximately balanced over the period of recruitment following randomization. Study staff who conducted the recruitment were then notified of the group assignment.

Selection criteria

Selection criteria were as follows: (1) birth and 9 months of age; (2) normal term and birthweight; (3) no medical or pre-existing developmental impairments (e.g. birth injury, congenital malformations); and (4) residence in Cleveland or its eastern suburbs.

Recruitment and randomization

The study was approved by the investigators' Institutional Review Board. Families were recruited by announcements in local papers and outreach in paediatric clinics, day care practices and health fairs. Dates of recruitment were: 1999–2001, and follow-up: 2001–2004.

Participants

A flow chart of study participation is shown in Fig. 1. Eligible families were randomized to either the BTL curriculum ($n = 256$) or the comparison group ($n = 271$) in a stratified manner based on the Hollingshead (1957) Two-Factor Scale (parental education level and current employment) to ensure a comparable distribution of SES. A number of families ($n = 29$) in the BTL group and ($n = 39$) in the comparison groups could not be contacted and hence did not receive intervention.

Demographic characteristics of the two groups who received intervention, which are shown in Table 1, were comparable with respect to sex, ethnicity and SES. Sample size was determined by a priori power calculations to detect a medium effect size at 0.90 power.

BTL programme group

The BTL curriculum, which included two home visits in the first month, and monthly visits and group meetings thereafter,

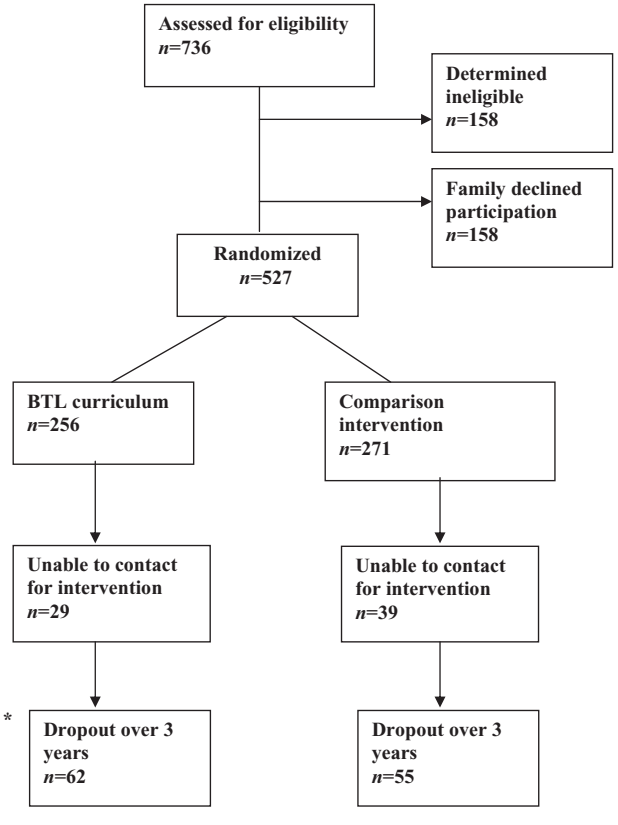

Figure 1. Flowchart of participants. *Mean dropout across various outcome measures.

Table 1. Demographic characteristics of control and intervention groups for baseline visit $N = 459$ (unless otherwise noted)

	BTL curriculum $n = 227$		Comparison $n = 232$	
Variable	**Freq**	**%**	**Freq**	**%**
Child gender				
Female	106	46.7	123	53.0
Male	121	53.3	109	47.0
Race				
African American		29.5	65	28.0
Caucasian	67	64.3	156	67.2
Other	14	6.2	11	4.7
Yes	204	89.9	205	88.4
Martial status				
Live together or married	183	80.6	182	78.4
Separated or single	44	19.4	50	21.6
Mother education				
High school or less	34	15.0	43	18.5
More than high school	193	85.0	189	81.5
Father education ($n = 450$)				
High school or less	45	19.8	51	22.0
More than high school	177	78.0	177	76.3
Income level				
≤30 000	66	29.1	68	29.3
>30 000	161	70.9	162	69.8
Socio-economic status (Hollingshead)				
Middle/high	163	49.5	166	50.5
Low	64	48.5	66	51.5

BTL, Born to Learn.

focused on age-specific experiences designed to facilitate children's development through detailed personal visit plans (McGilly 2000; McGilly *et al*. 2000; Smilkstein 2003). Each visit was delivered in the family home by a trained parent educator who provided handouts and videos that emphasized key developmental principles [e.g. the critical role of the child's environment in early brain development (McGilly *et al*. 2000)]. Parents also attended group meetings that emphasized the BTL curriculum. Parent educators were aware of group assignments.

Monitoring programme fidelity

To implement the BTL curriculum, which includes standardized manuals and handouts, parent educators were extensively trained by the PAT National Center staff during a week-long session. Programme implementation by parent educators was monitored based on the following PAT National Center standards: (1) home visit attendance; (2) coverage of curriculum material; and (3) performance (e.g. executing BTL curriculum activities, establishing rapport, etc.). The evaluation of staff's videotaped ratings by parent educators' visits documented that more than 90% of the curriculum objectives were met.

Comparison group

The comparison group received the following, none of which included any of the BTL curriculum content or structure: (1) handouts that described children's development at various ages; and (2) invitation to participate in the services such as parent discussion groups held separately from that of the BTL programme group.

Evaluation of primary outcomes

Children were seen for individual assessments at 12, 18 (SAT), 24 and 36 months of age for evaluations based on measures with demonstrated reliability and validity that covered key developmental outcomes. Assessments were conducted in a testing room designed for this purpose. Assessors were not apprised as to children's group status. The success of blinding was evaluated by asking the assessors what group they thought the child was in. Assessors achieved a chance performance in responding to this question. Assessment quality control included videotaping and review by project investigators.

Cognitive development

Cognitive development at 12 and 24 months was assessed by the Bayley Scale of Mental Development, Second Edition (BSMD), a well-standardized, reliable and valid measure (Bayley 1993). At 36 months, children were given the Kaufman Assessment Battery (KAB), which is a reliable and valid measure of intelligence (Kaufman & Kaufman 1983).

Adaptive behaviour

The Bayley Behavioural Rating Scale (BBRS) (Bayley 1993) assessed children's behaviour during testing (e.g. engagement and emotional regulation) at 12, 24 and 36 months. At 24 months, the Child Behaviour Rating Scale (CBRS) (Mahoney & Perales 2005) assessed the quality of children's behaviour (e.g. cooperation, positive and negative effect) with developmentally appropriate toys. Interrater reliability ranged from 0.80 to 0.91.

Security of attachment

The Q-Sort measure of SAT, which was rated by trained observers in the child's home setting at 18 months of age, has demonstrated validity with laboratory-based assessments of attachment and measures of competent socio-emotional

development (Vaughn & Waters 1990). Observers were trained to criterion (0.90 interrater reliability) by an experienced Q-Sort researcher (Posada *et al.* 2002).

Mastery motivation

Mastery motivation, defined as persistent problem solving with novel tasks, was assessed at 12, 24 and 36 months of age (McGrath *et al.* 1995). The assessors introduced various toys, evaluated children's persistence, pleasure and competence for up to 4 min (Morgan *et al.* 1992). Interrater reliability ranged from 0.78 to 0.91.

Language development

Language development at 36 months of age was assessed using a spontaneous language sample (Bornstein & Hayes, 1998) from a 10-min mother–child play interaction. Research assistants who were unaware of children's group status coded transcripts of language using the Systematic Analysis of Language Transcripts (SALT) (Miller & Chapman 1993). The following measures were derived: (1) total number of different word; (2) mean length of utterance (Bates & Carenvale 1993); and (3) total number of words. Interrater reliability ranged from 0.82 to 0.93.

Concept development

The Bracken Basic Concept Scale – Revised (Bracken 1998) was given at 36 months to assess the child's comprehension of relevant concept categories (e.g. Colours, Letters, Numbers/Shapes, etc.).

Pre-reading skills

Pre-reading skills were assessed at 36 months by the Test of Early Reading Ability-2 (TERA-2) (Reid *et al.* 1989), a reliable and valid measure in which children were asked to identify words and letters, and to point out capital and small letters, etc.

Social competence

Social competence was assessed at 36 months of age by the Social Skills Rating System (SSRS), a standardized instrument based on parent and teacher report with demonstrated validity (Gresham & Elliott 1990a,b).

Data analysis

Post-randomization dropout or attrition over 3 years was $n = 117$ (25.5%). Comparable numbers of dropouts accrued in the BTL curriculum ($n = 62$, 27.3%) and comparison group ($n = 55$, 23.7%; $P < 0.38$). Reasons for attrition, which did not differ across the two groups, included: no response/lost contact ($n = 55$), too busy ($n = 20$), moving out of the area ($n = 20$) and dissatisfaction with programme ($n = 8$).

Data reduction

To limit the number of statistical comparisons, total scores were used to analyse most measures. Because the SALT, MM and CBRS included multiple, intercorrelated measures, principal components factor analyses were conducted, and single factors based on this analysis were used to analyse group differences. The factors derived from MM included: (1) persistence; (2) task pleasure; and (3) task competence. One factor was derived from each of the SALT and CBRS measures.

Analyses of group differences

In an intention-to-treat analysis, a mixed linear model tested the effects of the BTL curriculum using restricted maximum likelihood estimation with an unstructured covariance matrix. This analysis controlled for SES, randomization blocking (low SES vs. middle/high SES), and included terms for group, age and the interaction between group and age. Each analysis was repeated by stratifying on SES, and including additional interactions between group, age and SES. To test for a differential intervention effect by SES status (low SES vs. high/middle SES), the interaction between the randomization group and SES status was tested at each follow-up time. Intervention effects were tested separately by SES level for significant interactions. All analyses were pre-specified.

All analyses were performed using SAS (SAS Institute Inc., Cary, NC, USA). Because some families missed interim visits or otherwise dropped out of the programme, sensitivity analyses were run using pattern mixture models to determine the impact of missing data on study findings. The results of these analyses were similar to the mixed linear model results.

Cognitive development

No group differences in cognitive development were found either at 12 and 24 months on the BSMD, or at 36 months on the KAB (see Table 2). However, at 24 months the Group X SES interaction was significant ($P < 0.003$). Within the low-SES subgroup, the effect of the BTL curriculum was significant ($P < 0.01$): children who received the BTL curriculum scored

Table 2. Cognitive development at 12–36 months' follow-up

	BTL curriculum			Comparison						
	n	Mean	Standard deviation	*n*	Mean	Standard deviation	95% CI intervention comparison	*t*	*P*	Effect size
Bayley MDI (12 months)	189	95.19	9.88	187	94.51	9.22	−1.15,2.76	0.81	0.42	0.08
Bayley MDI (24 months)	166	96.97	14.12	178	97.75	15.02	−3.63,2.32	−0.43	0.67	0.05
KABC (36 months)										
Sequential processing standard score	142	105.91	14.66	156	104.78	14.13	−2.39,4.03	0.50	0.62	0.06
Simultaneous processing standard score	161	107.77	15.33	170	109.29	14.99	−4.71,1.47	−1.03	0.30	0.11
Mental processing standard score	141	109.13	14.47	154	108.90	14.06	−3.33,2.91	−0.13	0.89	0.02

BTL, Born to Learn; CI, confidence interval; KABC, Kaufman Assessment Battery; MDI, Mental Development Index.

Table 3. Behaviour during testing at 12–36 months' follow-up

	BTL curriculum			Comparison						
	n	Mean	Standard deviation	*n*	Mean	Standard deviation	95% CI intervention comparison	*T*	*P*	Effect size
Behavioral rating scale (total)										
12 months	190	123.86	8.36	187	124.19	9.73	−1.95,1.64	−0.17	0.87	0.02
24 months	169	109.63	11.42	185	109.20	13.44	−1.72,3.15	0.58	0.56	0.06
36 months	165	111.84	12.15	177	113.48	10.81	−3.99,0.83	−1.29	0.20	0.14

BTL, Born to Learn; CI, confidence interval.

higher [mean (M) = 89.67, standard deviation (SD) = 16.20] than children in the comparison group (M = 82.16, SD = 17.24).

Security of attachment

At 18 months, SAT did not differ between BTL curriculum and comparison groups.

Adaptive behaviour

As shown in Table 3, no intervention effects were found for the BBRS scores at 12, 24 or 36 months, or for the CBRS factor scores.

Mastery motivation

As shown in Table 4, no group differences were identified on MM with one exception: the BTL curriculum group demonstrated higher scores on task competence (M = 847.98, SD = 32.54) than the comparison group (M = 841.74, SD = 34.91, $P < 0.05$) at 36 months. In addition, a significant group SES interaction was found for task competence at 24 months. The BTL curriculum was associated with higher scores (M = 584.49, SD = 37.97) than the comparison group for low-SES families (M = 556.21, SD = 57.18, $t = 2.27$, $P < 0.02$) but not for high-SES families [BTL programme (M = 618.36, SD = 58.2) and control group (M = 681.0, SD = 54.82, $t = 0.50$ NS)].

Language, conceptual development, school readiness and social skills

No differences were found between the BTL curriculum and comparison groups on language as assessed by the SALT, TERA-2 or SSRS (parent and teacher report) (see Table 5).

Discussion

To our knowledge, this study is the first randomized, controlled trial to test the efficacy of the BTL curriculum in a diverse sample stratified by SES based on a comprehensive, objective assessment of child development. Consistent with hypotheses, the BTL programme demonstrated beneficial effects on MM (e.g. task competence) at 36 months of age. The BTL curriculum may have achieved such effects by enhancing parents' abilities to provide an environment that enhanced the quality of their children's spontaneous problem solving and persistence on novel tasks (Morgan *et al.* 1992). Another hypothesized finding concerned the beneficial effects of the BTL curriculum on the cognitive development and MM of children from the low versus high SES at 24 months.

Table 4. Mastery motivation scores at 12–36 months' follow-up

Measure and age at assessment	BTL curriculum			Comparison			95% CI intervention comparison	*t*	*P*	Effect size
	n	Mean	Standard deviation	*n*	Mean	Standard deviation				
12 months										
Task persistence	100	4.48	4.10	99	5.11	4.64	–1.75,0.67	–0.88	0.38	0.12
Task pleasure	100	0.27	0.60	99	0.31	0.55	–0.20,0.12	–0.47	0.64	0.07
Task competence	100	150.71	25.72	99	154.24	31.56	–11.15,5.33	–0.69	0.48	0.10
24 months										
Task persistence	138	12.57	4.36	155	13.04	4.44	–1.45,0.56	–0.87	0.39	0.10
Task pleasure	138	0.30	0.46	155	0.26	0.49	–0.085,0.16	0.65	0.51	0.09
Task competence	138	610.75	56.09	155	604.85	60.70	–1.66,23.12	1.70	0.09	0.20
36 months										
Task persistence	152	17.30	3.79	166	16.49	4.39	–0.08,1.75	1.80	0.07	0.20
Task pleasure	152	0.51	0.60	167	0.52	0.74	–0.17,0.12	–0.37	0.71	0.03
Task competence	152	847.98	32.54	167	841.74	34.91	0.16,14.76	2.01	0.05	0.20

BTL, Born to Learn; CI, confidence interval.

Table 5. 36-month outcome: language, conceptual development, school readiness and social skills

Measure	BTL curriculum			Comparison			95% CI intervention comparison	*t*	*P*	Effect size
	n	Mean	Standard deviation	*n*	Mean	Standard deviation				
SALT	152	194.50	48.31	174	198.41	54.68	–14.32,6.77	–0.70	0.48	0.08
Bracken basic concept scale composite (scaled score)	160	113.47	17.79	176	112.23	19.04	–2.24,4.47	0.65	0.51	0.07
TERA-2	161	106.12	9.90	172	105.58	10.73	–1.70,2.47	0.51	0.72	0.04
SSRS: parent report (standard score)	162	103.07	14.82	174	100.37	15.27	–0.45,5.90	1.69	0.09	0.18
Teacher report of social skills (standard score)	64	102.30	17.26	73	100.23	13.15	–3.19,7.15	0.76	0.45	0.13

BTL, Born to Learn; CI, confidence interval; SALT, Systematic Analysis of Language Transcripts; SSRS, Social Skills Rating System; TERA-2, Test of Early Reading Ability-2.

On the other hand, contrary to hypotheses, the BTL curriculum had no overall effect on children's cognitive development, SAT, adaptive behaviour and a range of other outcomes, including conceptual skills, early reading readiness, expressive language, and parent and teacher ratings of social skills. What might account for these negative effects? Although the BTL curriculum was designed to enhance a wide range of child developmental outcomes, it is possible that it may have selective effects on specific domains of children's development. By controlling for extraneous influences, the study design may also have reduced effects (Sweet & Applebaum 2004).

However, alternative explanations of these findings should be considered: the sample included a disproportionate number of high-SES families who may have been providing their children with more stimulating environments than low-SES families (Bradley & Whiteside-Mansell 1998) and hence might have had less opportunity to benefit from the intervention.

Several study limitations should be considered: although the BTL curriculum was delivered by trained parent educators who followed programme content standards set by PAT, programme intensity as defined by frequency of visits was less than optimal, especially for the third year and for low-SES families. The level of attrition in the sample, especially among low-SES families, was relatively high, which may have limited the detection of effects.

Our findings have several important implications for future research and application of the BTL curriculum in a range of settings and populations. Our results suggest that the BTL curriculum may need to be modified to result in more powerful effects on a broader range of child development outcomes. Moreover, two critical questions raised by our findings that should be addressed in future research are: (1) for which families and children is the curriculum most effective? and (2) for which particular outcomes is the curriculum most effective? For this reason, it will be important to evaluate the effectiveness of the BTL curriculum in a range of settings and populations, including international samples. An important question for future research of the BTL curriculum is: what is the most

efficient and effective use of a less than optimal number of BTL curriculum visits for various populations? To address such questions, detailed evaluation of the effect sizes of the BTL curriculum in a range of settings and samples is a logical next step in the evolution of this programme.

Key messages

- An early intervention curriculum, Born to Learn, had positive effects on children's mastery motivation but not on general developmental outcomes.
- Findings suggest that the Born to Learn curriculum may need to be modified to result in more powerful effects on a broader range of developmental outcomes.
- The effectiveness of the Born to Learn curriculum in a range of settings and populations including interventional samples should be studied.

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