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Outcomes of a Universal Shared Reading Intervention by 2 Years of Age: The Let's Read Trial

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KEY WORDS

preliteracy, child language, communication and vocabulary, socioeconomic factors, randomized controlled trial

ABBREVIATIONS

LGA—local government area
MCH—maternal and child health

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WHAT'S KNOWN ON THIS SUBJECT: Literacy acquisition is an important developmental milestone and key to educational success. Interest in early literacy promotion has led to trials with some success in improving language and literacy activities; these trials have yet to demonstrate improved literacy outcomes.

WHAT THIS STUDY ADDS: This first population-based cluster randomized trial demonstrates how the key messages and corresponding activities of an early literacy-promotion program relate to the number of literacy activities in the home and infants' communication and language development at age 2 years.

abstract

BACKGROUND: Early shared reading and literacy promotion benefits have stimulated international interest in the development of early-years literacy-promotion programs despite limited evidence of effectiveness at a broader population level.

OBJECTIVE: To determine whether a population-based primary care literacy promotion intervention during the first 2 years of life improves early markers of subsequent literacy by 2 years of age.

DESIGN AND METHODS: This cluster randomized controlled trial took place in 5 relatively disadvantaged areas in Melbourne, Australia. Infants attending their maternal and child health centers were recruited at age 1–2 months. The intervention (4–8, 12, and 18 months) comprised maternal and child health nurses modelling shared reading activities to parents, supported by parent information and free books. Outcomes (at 2 years) included expressive vocabulary (MacArthur Bates Communicative Development Inventory), communication (Communication and Symbolic Behavior Scales), and home literacy environment (StimQ-Toddler). We analyzed the outcomes using random-effects (linear regression) models allowing for clustering.

RESULTS: A total of 552 families (87.6%; 324 intervention and 228 control families) of 630 recruited families (66.5% response) were retained to outcome. A total of 97.3% of intervention parents received some (93.7% to all) of the intervention. At 2 years, the trial arms had similar vocabulary (adjusted mean difference: −2.0 [95% confidence interval: −6.2 to 2.2]; $P = .36$), communication (adjusted mean difference: 0.2 [95% confidence interval: −2.3 to 2.7]; $P = .87$), and home literacy (adjusted mean difference: −0.4 [95% confidence interval: −1.0 to 0.2]; $P = .21$).

CONCLUSIONS: This universal literacy-promotion program was not beneficial in relatively disadvantaged communities by the age of 2 years and may be ineffective. Alternative interpretations may relate to program intensity, reach and/or sleeper effects. Definitive outcomes at 4 years are awaited. *Pediatrics* 2011;127:445–453

Literacy acquisition is 1 of the most important developmental milestones for young children and is the key to success within the educational system. Poor literacy is linked to dropping out of school, decreased work productivity, lower earnings, higher unemployment, and welfare dependency.[1]

Reading failure disproportionately affects children from lower socioeconomic status backgrounds.[2] Children from poorer families lose significant ground in relation to literacy acquisition throughout their early years, even before first grade, and the differences seem to widen as they progress through school.[3,4] Combined with the neuroscience findings supporting the importance of early brain development,[5] these outcomes provide a persuasive rationale for targeting preventive literacy interventions to the early years (birth to age 5 years) and to more disadvantaged populations.[6]

Recent reviews[7,8] support parental attitudes to reading and frequency of shared reading as both plausible and probable pathways for early literacy promotion. This is informed by 3 key areas of research: (1) research supporting the benefit of frequent shared reading[9,10]; (2) emergent literacy skills as measurable precursors of children's reading outcomes[11,12]; and (3) the importance of literacy-promoting environments (eg, books in the home).[13,14]

Internationally, literacy promotion programs built on this knowledge seem to be divided into 2 main approaches: clinic-based literacy promotion programs[15] aimed at disadvantaged and at-risk individuals[16–18] and programs that distribute free books to all children in participating communities[19]. Demonstrating positive literacy outcomes from either type of existing program remains a challenge.

Regarding the former, in the most recent review of trials using the US clinic–based literacy promotion program, Reach Out and Read,[7] almost all of the included studies demonstrated improvements in the frequency of parents reading to their children and in parental attitudes to shared reading. Three studies demonstrated receptive and expressive language benefits in disadvantaged young children (aged >18 months old), including those from ethnic minority groups.[15,16,20] However, these studies were limited by nonrandomized designs[15,21] and/or small clinic samples (n = 122–205) with short follow-up times (~12 months).[16] None of these studies demonstrated a longer-term literacy benefit (emergent or school based).

The largest and best known of the more general population–wide book distribution programs is the United Kingdom's national program, Bookstart, which is on the basis of a series of small longitudinal comparison studies that suggested a sustained benefit on early primary educational outcomes.[19,22] A subsequent before-and-after impact evaluation of the national program showed no effect on reading frequency at a population level. Although "low-reading" families (a few times a week or less) increased their literacy activities (daily reading increased by 30%), no significance levels were provided, numbers were small (n = 56), and children's language and literacy outcomes were not measured.[23] In Australia, there is a range of state and local community–wide literacy promotion programs, but none have undergone rigorous testing.[24]

Although no trials have conclusively demonstrated that community-wide literacy promotion programs result in better literacy or preliteracy skills, lower-intensity community-wide literacy promotion programs have been widely implemented. Bookstart alone now has a number of international affiliate programs (eg, Europe, Korea, Thailand, New Zealand, Nigeria, Uganda, Columbia, and the Falkland Islands).[25] It is concerning that this rapid multinational uptake has occurred in the absence of evidence because, even if they do no harm, population-based interventions that yield no benefit incur a significant cost and resource investment. For example, the government of Victoria, Australia, has budgeted $2.1 million AUD over 4 years to give free books to every child at birth (through libraries) and at the 2-year well-child checks.[26]

Designed specifically to address these issues, Let's Read is a cluster randomized controlled trial of an Australian preliteracy promotion program targeting all children living in relatively disadvantaged neighborhoods. It aims to determine whether a universal clinic-based literacy-promotion program improves language and emergent literacy outcomes by 4 years of age. This article presents interim outcomes at 2 years of age and hypothesizes that the intervention might already have led to relative gains in language and literacy interactive activities.

METHODS

Sampling and Participants

Based in Melbourne (population 3.9 million in 2008),[27] Australia, the Let's Read trial used a 2-stage random-sampling process. In the first stage, we ranked Melbourne's local government areas (LGAs) (31 in total) according to mean scores on the Socioeconomic Indexes of Areas Index of Disadvantage, which were derived from the 2001 Australian Census data.[28] From those in the bottom tertile (ie, areas of greatest disadvantage), we selected a convenience sample of 5 LGAs interested in participating and with a birth rate of over 1000 births per annum.

Parents were recruited, and the Let's Read program was delivered via ma-

ternal and child health (MCH) centers in these 5 LGAs. Throughout the state of Victoria, well-child care (10 visits up to the age of 5 years) is delivered by publicly funded maternal and child health nurses through centers local to the family. In the 5 LGAs, all MCH nurses were asked to approach all parents of infants attending their 4- to 8-week well-child care visit for a 3-month staggered recruitment period between March and August 2006 (>95% of all Victorian infants attend these visits).[5,29] Parents were excluded only if they did not speak or understand English. Contact details for interested parents were forwarded to the research team who then called each parent to assess eligibility and finalize recruitment and enrollment.

The Royal Children's Hospital Human Research Ethics Committee approved the trial, and all parents provided written informed consent. The trial is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement modified for cluster trials[30] and registered with an international clinical trials registry.

Randomization

Cluster randomization occurred after recruitment, just before children were 3 to 4 months of age, within each LGA, with the MCH centers as the units of randomization stratified by LGA. All 74 MCH centers in the study LGAs participated in the study. Because some nurses work in more than 1 MCH center, some centers were combined before randomization to avoid the situation where nurses might work in both a control and an intervention MCH center. MCH nurses were unaware of site assignment throughout the recruitment and enrollment period in each LGA. Within each LGA, the resulting 65 MCH clusters were ranked in descending order according to the number of families estimated to be eligible on the basis of expected preliminary recruitment numbers then randomized with a fixed block size of 2 to minimize imbalance in the number of families recruited to each trial arm. The randomizing statistician was unaware of the identities of the MCH units, thus ensuring allocation concealment.

Intervention: the Let's Read Program

Figure 1 outlines the methodology of the Let's Read program. Only intervention nurses were trained in intervention delivery postrandomization and again before the children turned 12 months of age (and subsequently before the 3.5-year visit). Each 2-hour group-training session was delivered by the same research coordinator and timed to precede an intervention delivery by ~4 to 6 weeks. Training consisted of adult educational strategies (role play, feedback, and modeling practice), and nurses were provided with Let's Read nurse tip sheets and a desk mat that acted as quick pneumonic reference guide and study reminder.

The intervention was delivered when children were 4 to 8, 12, and 18 months of age (a fourth session will be delivered at age 3.5 years). At the usual well-child visit, the nurse was asked to spend ~5 additional minutes delivering, modeling, and discussing the Let's Read intervention messages, and Let's Read take-home packs containing a free, age-appropriate picture book from the Let's Read book list (included in the pack) and guidance messages (plus a DVD at the first session only) were distributed. Guidance materials were evidence based and designed to promote shared reading and included messages known to enhance literacy acquisition, such as determining reading style, promoting parental verbal responsiveness, and encouraging appropriate book selection.[31,32] Control group nurses delivered their usual care, which comprises the brief, standardized-language promotion printed tip sheet handed out to parents at each key developmental visit.

Measures

Questionnaires for when children were 2 years old included general sociodemographic questions and measures of language and communication, the home literacy environment, literacy activities, and parental mental health. Questionnaires were written at no more than a sixth-grade reading level, and completion by telephone interview was available.

Outcome measures at 2 years of age were expressive vocabulary, communication skills, and home-based literacy environment. The vocabulary subscale of the Sure Start version of the MacArthur Bates Communicative Development Inventory[33] was used to assess vocabulary production, with potential raw scores ranging from 0 to 100. The Communication and Symbolic Behavior Scale Infant-Toddler Checklist[34] provided a standardized total score (normative mean = 100 and SD = 15) as well as composite scores for the domains of social, speech, and symbolic skills (normative means = 10 and SD = 3). These domains broadly relate to children's prelinguistic, linguistic, and cognitive abilities, each of which relates to later expressive-language development.[17,34,35]

The home-based literacy environment was measured by the StimQ-Toddler.[36,37] Initially designed as a home observation tool, it has age-appropriate versions and has been used in at least 2 other literacy-promotion trials.[15,36] In addition to a total score ranging from 0 to 39, the 3 StimQ-Toddler subdomains have possible scores of 0 to 4 (parental verbal pesponsivity), 0 to 18 (reading), and 0 to 10 (parental involvement in developmental advance). The Availability of

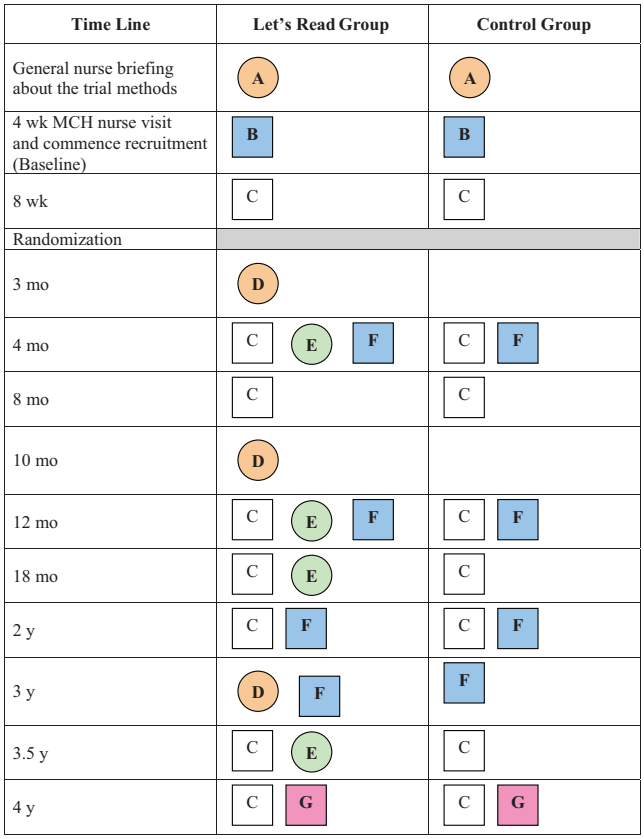

FIGURE 1
Graphical depiction of the components of the Let's Read trial.

Learning materials were not used. For this study, the StimQ-Toddler was completed by parent report for both groups.

Potential confounders included parental mental health, measured using the Short-Form 12 short-form health survey[38] at 3 to 4 months. The Short-Form 12 provides a standardized total score (normative mean = 50 and SD = 10) as well as subscale scores on the physical component summary and mental component summary. Other potential confounders were the child's gender, whether English was the main language spoken at home, the primary carer's (usually mother's) level of education (did not complete, completed school, or university degree), health care card status (pension-like status), no parent in paid employment, and the LGA.

Sample Size

The sample size was based on detecting a mean difference between intervention and control children of 0.35 SDs with 90% power at the 5% level of significance on standardized scores for the language outcome measure for 4-year-olds. We assumed an intracluster (intra-MCH cluster) correlation coefficient for language and literacy outcomes of 0.04 (on the basis of the upper bound of the 95% confidence interval for the intracluster correlation coefficient of the vocabulary section of the Communicative Development Inventory Words and Sentences Inventory administered to 2-year-old children in a previous population-based study[39]) and that each MCH cluster would recruit 16 infants. In addition, allowing for up to a 20% drop-out rate, we calculated that 352 participants and 22 MCH clusters were required in each trial arm.

Statistical Analysis

The trial arms were analyzed as randomly assigned, applying the intention-to-treat principle as far as possible given missing data, in both unadjusted analyses and analyses adjusted for the potential confounders listed above. Comparisons were implemented using random-effects (linear regression) models estimated using maximum likelihood to allow for the correlation between outcomes of participants from the same MCH cluster. Tests of interaction were used to assess whether the impact of the intervention on vocabulary and communication scores differed between the categories of carers' levels of education. All analyses were implemented using Stata 10.1 software.[40]

TABLE 1 Sample Characteristics At Baseline

	Control Arm, $n = 265$[a]	Intervention Arm, $n = 365$[a]
Child's characteristics		
Child's age, mean (SD), wk	8.1 (3.9)	9.6 (4.5)
Male, %	47.4	55.8
Term gestation, %	94.9	93.2
Primary care giver		
Age, mean (SD), y	32.1 (5.9)	31.6 (4.9)
Relationship status, %		
Married	74.2	77.2
De Facto	21.6	18.4
Divorce or separated	1.1	1.4
Single, never married	3.0	3.0
Born in Australia, %	70.0	75.7
Aboriginal or TSI, %	0.4	0.8
Completed year 12 of education, %	79.6	76.5
Short-Form 12 physical health, mean (SD)	52.6 (7.0)	51.9 (7.2)
Short-Form 12 mental health, mean (SD)	52.4 (8.0)	52.0 (7.2)
Secondary care giver		
Age, mean (SD), y	34.9 (5.9)	34.4 (5.3)
Born in Australia, %	70.7	75.7
Aboriginal/TSI, %	0.4	0
English main language spoken at home, %	85.9	88.3
Completed year 12 of education, %	68.0	64.9
Family health care card, %[b]	19.8%	20.1%

TSI indicates Torres Strait Islander.

[a] Sample size ranges from 217 to 265 in the control arm and 305 to 365 in the intervention arm.

[b] In Australia, families with low incomes ($798 combined weekly income for a couple with children) are eligible to receive a health care card. This gives them access to government cost-supplemented prescription medications, health care, and concessions for house amenities, transport, and education costs.

RESULTS

A total of 630 families (66.5% of 948 expressing interest and assessed for eligibility) were recruited from 65 participating MCH clusters. This represents 28% of the total administrative birth figures for the 5 LGAs for a 3-month time period.[41] In comparison with the general community demographics of the selected LGAs, our sample had a slightly higher proportion of primary caregivers who had completed high school (79.6% vs 75.5%), were born in Australia (70.7% vs 63.3%), and had homes where English was spoken as the main language (87.1% vs 68.3%).[42]

Thirty-three MCH clusters were randomly assigned to the control arm (265 families) and 32 to the intervention arm (365 families). The trial arm sizes differ markedly with respect to the numbers of families because the number of families estimated to be eligible within clusters before the trial was sometimes highly inaccurate. Baseline sample characteristics are summarized in Table 1. The children in the intervention arm had a higher average age on recruitment and a higher percentage of male subjects and Australian-born parents. Figure 2 (the CONSORT diagram) shows the participant flow. At 2 years of age, there were data for 552 children (87.6% of the original sample).

Table 2 shows the adjusted mean outcome differences for the intervention and control groups. There was little evidence of differences in vocabulary production (mean number of words as measured by the Communicative Development Inventory), communication (Communication and Symbolic Behavior Scale total or any of its 3 subscale scores), and total StimQ-Toddler scores or its 3 subscales (not shown). Of those in the intervention arm, 355 (97.3%) actually received the intervention, with 342 (93.7%) receiving the intervention at all 3 time points (4–8 months, 12 months, and 18 months). The majority (74.2%) of nurses spent 2 to 4 minutes delivering the intervention.

In tests of interaction, there was evidence that the effect of the intervention on the Communicative Development Inventory score was modified by the primary carer's education level (adjusted $P = .004$). Among mothers educated to at least school completion, intervention children knew on average 1.1 more words (adjusted mean difference: 1.1 [95% confidence interval: −3.6 to 5.7]), but for mothers who did not complete school, intervention children knew 15 fewer words (adjusted mean difference: 15.0 [95% confidence interval: 4.7–25.2]).

Intervention participants also were asked to evaluate the intervention. Overall, families enjoyed and used the resources. A total of 77% of participants felt that the intervention changed their own shared reading practices.

DISCUSSION

These analyses of 2-year-olds for the Let's Read trial do not suggest benefits to children's vocabulary production and communication or to parents' literacy activities, despite a very high rate of retention, reported parent satisfaction, and intervention group exposure. Although these are not the trial's final outcomes, some preliminary differences in literacy activities and language were expected by the age of 2 years. This absence of effect could reflect program issues (eg, insufficient intensity or dose of intervention), sample issues (eg, although the communities are relatively disadvantaged, we did not encounter extreme deprivation and our families already may have had access to the resources promoted by the trial), or sleeper effects that will emerge by the final assessments at 4 years of age.

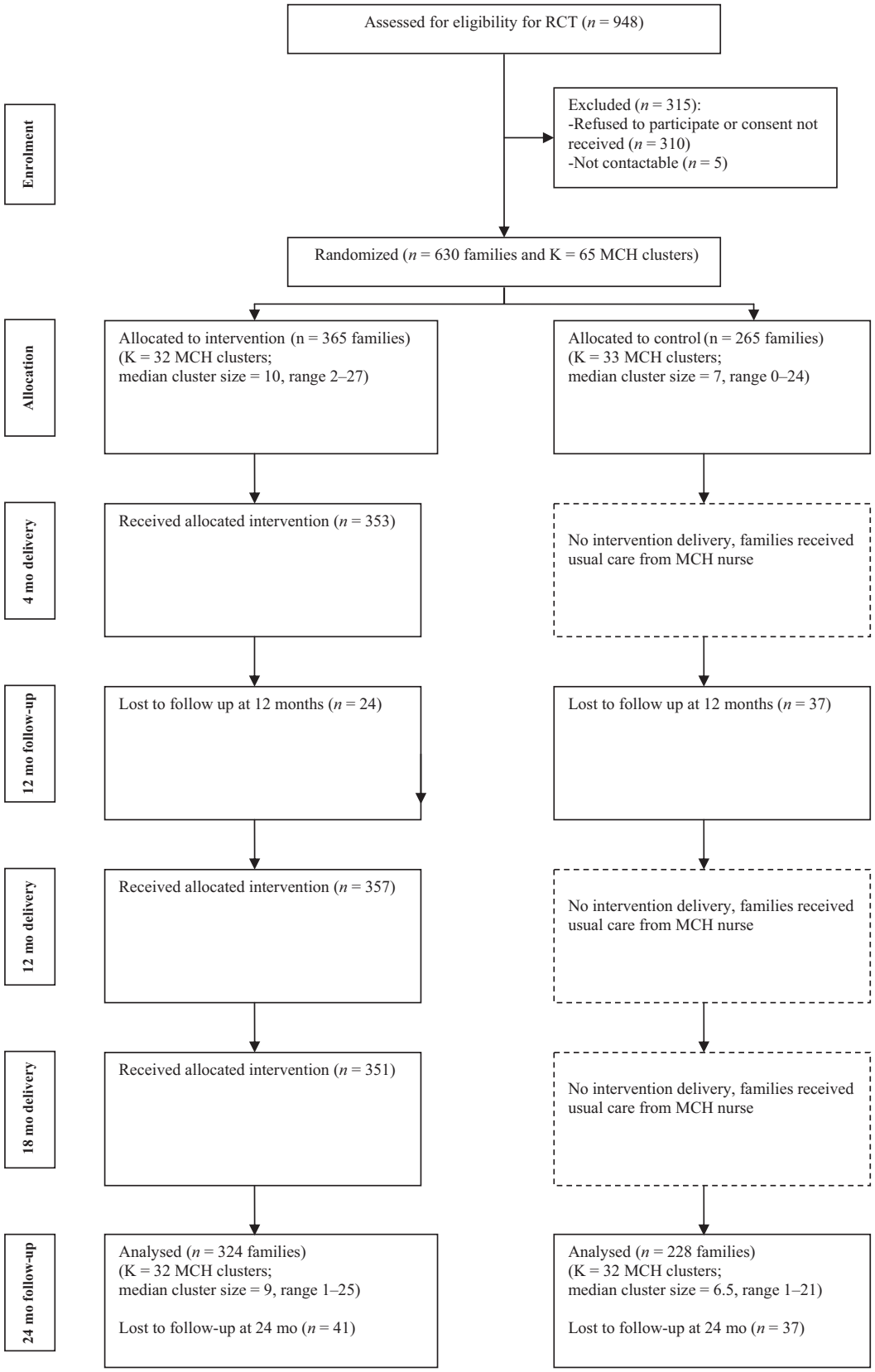

FIGURE 2
Participant flow—CONSORT (Consolidated Standards of Reporting Trials) diagram. RCT indicates randomized controlled trial; K indicates the number of clusters.

TABLE 2 Comparison of Outcomes Between Trial Arms At the 2-Year Follow-Up

Outcome	Intervention Arm, Mean (SD)[a]	Control Arm, Mean (SD)[a]	Unadjusted Difference (ICC), Mean Difference	Adjusted Difference (ICC)[b]			
				Mean Difference	95% Confidence Interval	*P*	ICC
Communicative Development Inventory vocabulary	51.1 (24.8)	53.9 (24.7)	−2.7	−2.0	−6.2 to 2.2	.36	0
Communication and Symbolic Behavior Scale, total	103.6 (14.5)	104.5 (14.4)	−0.7	0.2	−2.3 to 2.7	.87	0
Communication and Symbolic Behavior Scale, social	10.0 (3.6)	10.2 (3.6)	−0.1	0.05	−0.7 to 0.8	.90	0.024
Communication and Symbolic Behavior Scale, speech	12.7 (4.4)	12.6 (4.3)	0.1	0.2	−0.5 to 1.0	.58	0
Communication and Symbolic Behavior Scale, symbolic	12.5 (4.1)	12.6 (4.0)	−0.1	0.1	−0.6 to 0.8	.77	0
StimQ-Toddle, total	24.8 (3.5)	25.1 (3.8)	−0.3	−0.4	−1.0 to 0.2	.21	0

[a] Sample size ranges from 212 to 228 in the control arm and 294 to 324 in the intervention arm for the unadjusted analyses and from 199 to 214 in the control arm and 268 to 297 in the intervention arm for the adjusted analyses. ICC indicates intracluster (intra-MCH cluster) correlation coefficient.

[b] Adjusted for the potential confounders listed under Methods.

It was somewhat surprising to find that children of intervention mothers with poorer education knew, on average, 15 fewer words than those of the control mothers, when we might expect that children of more poorly educated families would differentially benefit from this type of literacy-promotion program. Although statistically significant, the observed differences may be a chance finding. Bias seems an unlikely mechanism, given the large sample size, randomized group allocation, and low attrition. However, there are other possible and plausible conclusions. The intervention might have differentially adverse effects for children of less-educated mothers, as was reported in the initial evaluation of the British Sure Start program.[43] Alternatively, more educated parents may, because of the program, become more stringent reporters of language, differentially reporting poorer skills.

This trial has some important methodologic strengths. These strengths include the randomized design, the strong uptake by families and MCH nurses throughout the targeted disadvantaged regions, and an extremely high retention rate. Enrollment of families before randomization prevented bias in baseline characteristics while still maintaining the full benefits of cluster randomization in terms of minimizing contamination. The intervention materials were evidence based, simple and easy to deliver, and well understood. Victoria's well-established universal primary care system had the capacity to deliver the intervention right throughout early childhood from babyhood, close to the child's home, by a trusted and well-supported health care provider (not unlike the US-based ROR [Reach Out and Read] research[20]). The confidence intervals were sufficiently narrow to exclude clinically meaningful advantages for the intervention at 2 years.

The trial also had some limitations. First, Let's Read was a low-intensity intervention that was delivered by the nurse health care provider 3 times in the first 2 years; we cannot determine if a universal home literacy program delivered with greater intensity and/or a different provider would be more effective. Second, although implemented as a universal intervention within less-advantaged communities, differential recruitment of the relatively more affluent within our selected areas may have occurred. This, however, may well reflect the program's reach even if delivered outside a research trial. Third, we excluded parents who were not able to speak English, limiting generalizability to these parents. Fourth, although our 2-year-old measures were parent reported, they were chosen because they have shown strong and expected associations in many published studies[44] and have great practical merit. At 4 years, the definitive trial outcomes will be assessed using objective face-to-face measurements. Finally, as with any effectiveness trial of a population health intervention, there was implementation variability, with a limited number of families receiving the intervention message over the phone, varying responses to the additional workload by the nurses, and movement by some nurses out of the area.

Despite these limitations, the robust methodology would seem sufficient to suggest that a relatively low-intensity literacy-promotion intervention delivered through primary care services at a population level has limited impacts on early childhood vocabulary, communication skills, or home-based literacy activities. These interim null[45] results are surprising and would seem contrary to the results of other studies,[7,23] although we note the different intensity, targeting, and distribution of other programs. Becauase these are interim results, the potential for language, literacy, social, and emotional benefits at 4 years old remains an important consideration.

CONCLUSIONS

There is considerable enthusiasm for literacy promotion, especially through the distribution of free books and brief messaging. The outcomes from this trial suggest that a population-wide primary care ap-

proach (even when targeted to relatively disadvantaged areas) might not deliver the anticipated benefits to language and communication or to enhanced uptake of literacy activities. Examination of effects of the intervention at 4 years will be an important next step.

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SELECTIVE REPORTING OF CLINICAL TRIALS: *Recently, I was reviewing an article for possible publication in a medical journal. When I flipped to the back pages, the bibliography struck me as too short. Entering a few search terms in Pub Med, however, confirmed the existence of a multitude of articles, some even randomized trials, on the same topic but not referenced by the authors of the particular manuscript I was reviewing. Evidently, I am not the only person to note this phenomenon. As reported in* The New York Times *(January 17, 2011: Health), published papers on clinical trials in medicine infrequently cite previous clinical trials addressing the same question. Researchers reviewed meta-analyses published in 2004 that combined four or more trials. Within each meta-analysis, they examined the extent to which each trial report cited the trials that preceded it by more than one year. In total, 1523 clinical trials published from 1963 to 2004 were reviewed. Amazingly, regardless of how many previous randomized clinical trials had been published, in 23 percent no prior clinical trials were reported and in another 23 percent, only a single one was cited. Reasons for the omissions are a bit mysterious. It may be that authors do not know how to search, opt not to search, or think their material is more unique than it really is. Regardless, serious complications can arise from selective reporting. Subjects can be harmed by researchers not aware of previously reported complications of a particular intervention. Moreover, failure to review all the relevant published data can critically affect hypothesis, study design and conclusions. For example, failure to discuss previously failed interventions may skew interpretation of a single positive result. As a reviewer, I cannot influence the trial design. However, while reviewing a manuscript, I can do my own literature search. If my search turns up far more clinical trials than reported by authors, I view that manuscript very warily.*

Noted by WVR, MD

Outcomes of a Universal Shared Reading Intervention by 2 Years of Age: The Let's Read Trial

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