Home Visiting by Paraprofessionals and by Nurses: A Randomized, Controlled Trial

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ABSTRACT. *Objective.* **To examine the effectiveness of home visiting by paraprofessionals and by nurses as separate means of improving maternal and child health when both types of visitors are trained in a program model that has demonstrated effectiveness when delivered by nurses.**

Methods. **A randomized, controlled trial was conducted in public- and private-care settings in Denver, Colorado. One thousand one hundred seventy-eight consecutive pregnant women with no previous live births who were eligible for Medicaid or who had no private health insurance were invited to participate. Seven hundred thirty-five women were randomized to control, paraprofessional, or nurse conditions.**

Nurses completed an average of 6.5 home visits during pregnancy and 21 visits from birth to the children's second birthdays. Paraprofessionals completed an average of 6.3 home visits during pregnancy and 16 visits from birth to the children's second birthdays.

The main outcomes consisted of changes in women's urine cotinine over the course of pregnancy; women's use of ancillary services during pregnancy; subsequent pregnancies and births, educational achievement, workforce participation, and use of welfare; mother-infant responsive interaction; families' home environments; infants' emotional vulnerability in response to fear stimuli and low emotional vitality in response to joy and anger stimuli; and children's language and mental development, temperament, and behavioral problems.

Results. **Paraprofessional-visited mother-child pairs in which the mother had low psychological resources interacted with one another more responsively than their control-group counterparts (99.45 vs 97.54 standard score points). There were no other statistically significant paraprofessional effects.**

In contrast to their control-group counterparts, nurse-visited smokers had greater reductions in cotinine levels from intake to the end of pregnancy (259.0 vs 12.32 ng/mL); by the study child's second birthday, women visited by nurses had fewer subsequent pregnancies (29% vs 41%) and births (12% vs 19%); they delayed subsequent pregnancies for longer intervals; and during the second year after the birth of their first child, they worked more than women in the control group (6.83 vs 5.65 months).

Nurse-visited mother-child pairs interacted with one another more responsively than those in the control group (100.31 vs 98.99 standard score points). At 6 months of age, nurse-visited infants, in contrast to their control-group counterparts, were less likely to exhibit emotional vulnerability in response to fear stimuli (16% vs 25%) and nurse-visited infants born to women with low psychological resources were less likely to exhibit low emotional vitality in response to joy and anger stimuli (24% vs 40% and 13% vs 33%). At 21 months, nurse-visited children born to women with low psychological resources were less likely to exhibit language delays (7% vs 18%); and at 24 months, they exhibited superior mental development (90.18 vs 86.20 Mental Development Index scores) than their control-group counterparts. There were no statistically significant program effects for the nurses on women's use of ancillary prenatal services, educational achievement, use of welfare, or their children's temperament or behavior problems.

For most outcomes on which either visitor produced significant effects, the paraprofessionals typically had effects that were about half the size of those produced by nurses.

Conclusions. **When trained in a model program of prenatal and infancy home visiting, paraprofessionals produced small effects that rarely achieved statistical or clinical significance; the absence of statistical significance for some outcomes is probably attributable to limited statistical power to detect small effects. Nurses produced significant effects on a wide range of maternal and child outcomes.** *Pediatrics* **2002;110:486–496;** ***home visits, paraprofessionals, nurses, pregnancy, development.***

ABBREVIATIONS. SD, standard deviation; MDI, Mental Development Index.

Home visiting has been promoted by the American Academy of Pediatrics as an important complement to office-based practice.[1] It has been advocated as a way to improve the outcomes of pregnancy,[2] to reduce the rates of child abuse and neglect,[3] and to help low-income families become economically self-sufficient.[4] The background of visitors, however, seems to affect program success.[5–8] When examined in randomized trials, paraprofessional home visitors (those with no formal training in the helping professions) have produced small effects that rarely are statistically significant.[5–8] Is the absence of their effect attributable to lack of professional training or underdevelopment of the program models they delivered?

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We addressed this question in a 3-armed randomized trial (control, paraprofessional home visits, and nurse home visits) in which the paraprofessionals and nurses were provided well-structured home visit guidelines, training, and supportive supervision in a program model found to be effective when delivered by nurses in earlier trials.[9–18] If paraprofessionals could produce significant effects in the current trial, it would mean that they have the potential to achieve important effects on maternal and child health if they are trained to deliver proven models. If the paraprofessionals produced minimal impact, it would indicate that their lack of professional training in some way impedes their effectiveness.

The nurse arm was included for 2 reasons. First, it served as a positive control. It would be easier to interpret the success or lack of success of the paraprofessionals in light of the nurses' accomplishments in the same study. Second, the nurse arm provided a third trial of the program, allowing additional examination of the generalizability of positive effects for nurses.

We hypothesized that the nurse-visitors would produce results similar to those in the previous trials. Given weak results from previous trials of paraprofessional home-visitor programs,[5–8] we expected the paraprofessional-control differences to be somewhat smaller. The impact of the nurse home-visitor program on caregiving and child outcomes was greater in the earlier trials for cases where mothers had low psychological resources (limited intellectual functioning, mental health, and sense of control over their life circumstances),[10,17,19] so we hypothesized corresponding effects in the current trial for both types of visitors.

Although paraprofessionals can have a range of formal preparation for their roles, we chose to examine paraprofessional visitors who share many of the social characteristics of the families they serve, as many believe that shared social characteristics increase visitors' ability to empathize with their clients who, in turn, are more likely to trust those who are similar to them.[20,21] This segment of the paraprofessional population is important to test as the use of community health workers with limited educational backgrounds is a common service delivery strategy in many home visiting programs,[22,23] and it is estimated that 60% of home visiting programs for children do not require visitors to have bachelors' degrees.[24]

METHODS

The numbers of eligible women invited to participate, randomized, and assessed at various stages of research are summarized in Table 1.

Participants

From March 29, 1994, through June 15, 1995, 1178 consecutive women from 21 antepartum clinics serving low-income women in the Denver metropolitan area were invited to participate in the study. Women were recruited if they had no previous live births and either qualified for Medicaid or had no private health insurance. Women were allowed to enroll at any time before delivery. All participants completed informed consent procedures approved by the Colorado Multiple Institutional Review Board.

Given the large number of clinics in which recruitment was conducted, it was not possible to provide face-to-face explanations of the study to all prospective participants. Women thus could actively refuse participation or passively refuse (not respond before they delivered). Compared with active refusals ($n = 244$) and passive refusals ($n = 199$), those who accepted were more likely to be Hispanic (45% accepted vs 37% active refusals and 39% passive refusals), and less likely to smoke cigarettes (27% accepted vs 44% active refusals and 32% passive refusals). These groups were similar on other major sociodemographic characteristics, such as maternal age, language preference (English vs Spanish), and marital status.

Statistical Power and Assignment Ratios

Sample size was based on 80% power when using $\alpha = 0.05$ for 2-tailed tests and assuming effects in the range of 0.30 standard deviations (SD) between each treatment and control. This resulted in 600 subjects divided evenly among the 3 treatment groups. Allowing for a 20% attrition rate, an initial projected sample size of 750 was chosen, and we enrolled 735. We also were interested in detecting effects that were limited to half of the total sample that would be at higher risk (such as mothers with low psychological

TABLE 1. Sample Composition Over Time by Treatment Through Age 24 Months

Eligible invited to participate	1178
Active refusals	244
Passive refusals	199
Randomized	735

Treatment Group	Control	Paraprofessional	Nurse	Total
Allocated to treatment	255	245	235	735
Research refusals	5	13	10	28
Fetal demises	9	7	10	26
Preterm deliveries <36 wks	20	15	14	49
Completed 36-wk interviews	182	171	162	515
Infant deaths	2	1	1	4
Adoptions	2	1	1	4
Completed 6-mo interviews	220	201	184	605
Completed 6-mo child assessments	197	180	166	543
Completed 12-mo interviews	219	206	187	612
Completed 12-mo child assessments	210	193	178	581
Completed 15-mo interviews	209	175	176	560
Completed 15-mo child assessments	188	156	149	493
Completed 21-mo interviews	225	215	202	642
Completed 21-mo child assessments	216	204	190	610
Completed 24-mo interviews	223	213	194	630
Completed 24-mo child assessments	204	188	168	560

resources). For these comparisons, we had power to detect differences in the 0.42 SD range.

Because of constraints of sample size and cost, the study was not designed to make direct comparisons between paraprofessionals and nurses. We nevertheless conducted secondary analyses that compared their effect sizes.

Randomization

After completion of baseline interviews, identifying information on the participants was sent to the data operations office (located separately from interviewers' offices), where an individual who knew nothing about the participants entered their data into a computer program that randomized individual women to treatment conditions.[25] The randomization was conducted within strata from a model with 3 classification factors: maternal race/ethnicity (Hispanic, white non-Hispanic, African American, American Indian, or Asian), maternal gestational age at enrollment (<32 vs 32+ weeks), and geographic region of residence (4 regions). Women assigned to 1 of the 2 home-visitation groups subsequently were assigned at random to home visitors responsible for their geographic region.

Treatment Conditions

Women in the control group (n = 255) were provided developmental screening and referral services for their children at 6, 12, 15, 21, and 24 months old. Women assigned to the paraprofessional group (n = 245) were provided the screening and referral services plus paraprofessional home visitation during pregnancy and infancy (the first 2 years of the child's life). Women in the nurse group (n = 235) were provided screening and referral plus nurse home visitation during pregnancy and infancy.

Design and Implementation of Home-Visitation Programs

The home-visitation program delivered by both nurses and paraprofessionals was based on one tested previously[19] and has 3 broad goals: 1) to improve maternal and fetal health during pregnancy by helping women improve their health-related behaviors; 2) to improve the health and development of the child by helping parents provide more competent caregiving; and 3) to enhance parents' personal development by helping them plan future pregnancies, continue their education, and find work. Visit-by-visit guidelines and detailed objectives provided direction to the visits. Visitors adapted the program to the needs and interests of families.

Nurses were required to have BSN degrees and experience in community or maternal and child health nursing. Paraprofessionals were required to have a high school education but were excluded if they had college preparation in the helping professions or a bachelor's degree in any discipline. Both groups were required to have strong "people skills." Preference in hiring was given to paraprofessionals who had worked in human service agencies.[26,27]

Extensive efforts were made to ensure that the paraprofessionals were well suited for this work. Paraprofessional home visitor programs in Denver were invited to send their best home visitors to serve in this experimental program. The visitors were paid an average starting wage of $8.45 per hour, with full benefits, which was more than most paraprofessional visitors then earned in Denver. Program protocols were adapted to accommodate nonnurses by altering such things as the way maternal and child health problems were addressed. Both visitor types received 1 month of extensive training before their working with families in the study.

Each visitor managed caseloads of ~25 families. Paraprofessionals had twice the level of supervision (2 supervisors to 10 visitors) as nurses.[27] Nurses had greater staff retention: all 10 nurses stayed with the program for its duration whereas 7 paraprofessionals did; replacements were hired for paraprofessionals who left.[26]

Paraprofessionals completed an average of 6.3 (range: 0–21) home visits during pregnancy and 16 (range: 0–78) visits during infancy. Nurses completed an average of 6.5 (range: 0–17) home visits during pregnancy and 21 (range: 0–71) visits during infancy. The paraprofessional-nurse difference in completed infancy home visits was significant ($P < .001$). Overall, paraprofessionals had a higher average number of scheduled visits in which the families were not at home or did not answer the door (8 vs 5, $P < .001$). By the end of the program, 48% of the paraprofessional-visited families had discontinued the program versus 38% of those visited by nurses ($P = .04$).[26]

In 2002, the average inflation-adjusted per-family total cost of the 2.5-year program is $9140 for nurses and $6162 for paraprofessionals.

Masking and Assessment Procedures

Data were gathered by staff members who were unaware of the women's treatment assignment, except for a few cases in which the participants inadvertently revealed their treatment status to the interviewers. The maternal interviews were translated into Spanish for monolingual Spanish speakers.

Assessments and Definitions of Variables

To the extent possible, the outcomes examined here were selected to correspond to those in the earlier trials. The multiplicity of settings in which participants obtained health care in Denver and low rates of state-verified cases of child abuse and neglect in the target population made it impossible to use medical and child-protective-service records to assess obstetric, newborn, childhood-injury, and child maltreatment outcomes in the current trial. We therefore focused greater attention on measurement of infants' early emotional development,[28] as infants' emotional communications are connected to their being abused, neglected, and reared by depressed mothers.[29,30]

Baseline Assessments and Variables

At registration, interviews were conducted with participating women to determine their socioeconomic conditions, mental health,[31] personality characteristics,[32] obstetric histories, psychoactive drug use, conflict with partners, conflict with their own mothers, and experience of domestic violence.[33] Highly sensitive questions were administered by tape recorder with earphones to increase response accuracy. Women completed brief tests to measure their intellectual functioning[34] and supplied urine samples that were assayed with gas chromatography/mass spectrometry for cotinine (the major nicotine metabolite) and creatinine, tetrahydrocannabinol, and cocaine metabolites. Cocaine, marijuana, and alcohol use were too infrequently occurring to serve as valid outcomes to assess changes in women's substance use (Table 2). Individuals with creatinine-adjusted cotinine values ≥80 ng/mL at intake were designated as smokers.[35,36]

A variable was created to index women's psychological resources measured at registration and based on the averaged z scores of their: 1) mental health,[31] 2) sense of mastery,[32] and 3) intelligence.[34] It was dichotomized at raw score values that corresponded to the 50th percentile of these 3 variables used to construct a corresponding variable in an earlier trial.[17] This procedure split the Denver sample into low (40% of the sample) and higher (60%) functioning groups.

End-of-Pregnancy Assessments and Variables

Women were interviewed at 36 weeks of gestation in the study office to assess their health-related behaviors, including use of psychoactive substances and use of ancillary preventive services (eg, childbirth education and mental health) and emergency services (emergency housing and food banks). Urine was collected to assess biochemical markers for nicotine, marijuana, and cocaine. Change in tobacco use from intake to 36 weeks was measured by change in creatinine-adjusted cotinine among those designated as smokers at intake.

Maternal Life Course

Women were interviewed at 12, 15, 21, and 24 months' postpartum to assess their number and timing of subsequent pregnancies; and at 24 months to assess educational achievement, participation in the workforce, and use of welfare. Variables were constructed to reflect years of education completed and number of months women were in the workforce and used welfare during the 1- to 12-month and 13- to 24-month periods.

TABLE 2. Background Characteristics of Sample at Intake

Background Variable	Whole Sample			Low Psychological Resource Sample		
	Control $n = 255$ %	Paraprof $N = 245$ %	Nurse $n = 235$ %	Control $n = 82$ %	Paraprofessional $n = 115$ %	Nurse $n = 97$ %
Married	15	13	14	15	10	9
African American	16	17	16	16	20	22
Caucasians (non-Hispanics)	35	35	37	27	29	28
Hispanic (nearly all Mexican American)	46	45	44	56	47	47
Monolingual Spanish	4	4	3	4	2	2
Cigarette smoker*	25	21	24	23	24	27
Marijuana user†	15	15	16	16	19	16
Alcohol user‡	6	6	7	6	7	8
Cocaine user†	2	3	1	1	6	1
Registered after 28 wks of gestation	15	10	11	16	10	16
Any domestic violence in last 6 mo	16	18	16	18	30	27
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Maternal mental health inventory§	99.93 (9.83)	99.96 (9.87)	100.12 (10.36)	92.39 (9.49)	93.81 (8.86)	92.76 (9.82)
Maternal mastery§	100.79 (9.83)	99.53 (9.71)	99.63 (10.47)	92.00 (8.38)	93.38 (7.72)	91.41 (7.21)
Maternal intellectual functioning (Shipley)§	100.93 (9.27)	98.76 (10.14)	100.28 (10.52)	93.49 (8.76)	94.56 (10.88)	94.12 (10.34)
Maternal psychological resources§¶	100.80 (10.03)	99.16 (9.25)	100.01 (10.67)	89.29 (6.60)	91.17 (5.32)	89.50 (6.32)
Maternal education (y)	11.22 (1.88)	11.00 (1.83)	11.24 (2.04)	10.70 (1.73)	10.54 (1.82)	10.62 (2.10)
Maternal age (y)	19.70 (4.13)	19.44 (3.69)	20.24 (4.17)	19.71 (4.43)	19.04 (3.90)	19.74 (4.27)
Household annual income (dollars)	12 701 (11 295)	13 241 (13 612)	13 126 (11 966)	10 322 (11 127)	11 814 (13 328)	9517 (9973)
% Census tract below poverty	19.65 (13.98)	20.72 (13.37)	20.18 (15.07)	22.04 (15.27)	21.74 (13.90)	21.81 (14.37)
Housing density	0.83 (0.50)	0.95 (0.54)	0.83 (0.47)	0.88 (0.54)	1.01 (0.59)	0.86 (0.49)
Conflict with partner	1.66 (2.59)	1.29 (2.12)	1.41 (2.38)	1.99 (2.95)	1.68 (2.63)	1.75 (2.92)
Conflict with own mother	1.30 (2.24)	1.01 (1.93)	1.22 (2.09)	2.16 (2.80)	1.36 (2.34)	1.42 (2.29)
Gestational age (wk) at randomization	18.48 (7.48)	18.67 (7.17)	18.60 (7.04)	18.32 (7.92)	17.81 (6.88)	18.79 (7.55)

* Urine assay (adjusted cotinine ≥80 ng/mL).
† Either self-report or urine assay.
‡ Self-report.
§ Scales standardized to mean of 100 and SD of 10.
¶ Scale consists of averaged *z* scores of mental health inventory, mastery, and intellectual functioning.

Mother-Infant Interaction and Quality of the Home Environment

Mother-infant interaction was videotaped either in the laboratory or at home at all postpartum assessments using 2 validated procedures.[37,38] Factor analysis of subscale scores for maternal and infant behaviors identified a single internally consistent principal component, responsive interaction, that was standardized at each assessment to a mean of 100 and a standard deviation of 10. Infants' home environments were rated at 12 and 21 months.[39]

Child Emotional, Mental, and Behavioral Development

At 6 months of age in the laboratory, infants' emotional reactivity (latency to react and intensity of facial, body, and vocal cues) and looking at mother were videotaped and coded separately for their responses to stimuli designed to elicit fear, joy, and anger.[28] The reactivity and looking-at-mother dimensions were dichotomized at the mean and cross-classified. Emotional vulnerability was defined as high distress reactions to fear stimuli coinciding with limited efforts by the infants to look at or seek assistance or comfort from their mothers. Emotional vitality was defined as the lively expression of joyful and angry affect that was shared with others.[28] In an earlier report from this study, 6-month-old infants classified as "vulnerable" in response to fear stimuli (high reactivity and low looking at mother) and "low vitality" in response to joy and anger stimuli (low reactivity and low looking at mother) exhibited poorer language and cognitive development at 21 and 24 months than infants exhibiting high vitality (high reactivity and frequent looking at mother), supporting the predictive validity of these measures.[28]

Children's language development was tested at 21 months in their homes.[40] Their mental development (Mental Development Index [MDI]) was tested at 24 months in the laboratory.[41] Language and MDI were analyzed as both continuous and dichotomous outcomes. Children with language scores <85 were classified as delayed.[40] Children with MDI scores <77 (>1.5 SD below the population mean of 100) were classified as developmentally delayed as this is a typical threshold for referring children for developmental services. Although these variables are not independent of one another, each provides different information about the outcome. Mothers reported on their children's irritability at 6 months[42] and behavior problems at 24 months.[43]

Statistical Models and Methods of Analysis

Data analyses were conducted on all cases for which outcome data were available, irrespective of the degree to which families participated in the programs. The tables show trends ($P < .10$), but we report in the text only findings at $P \leq .05$ (2-tailed tests).

The primary statistical model consisted of treatments (3 levels), maternal psychological resources (high vs low), and the interaction between these 2 classification factors. In addition, 5 covariates were included to control for nonequivalence among the treatment groups at intake (ie, where the probability for any treatment contrast was <.10): maternal age, housing density, whether the mother registered in the study after 28 weeks of gestation, maternal conflict with her partner, and maternal conflict with her mother. All covariates were examined for homogeneity of regressions.[44] The results reported below are virtually identical for models both with and without covariates. Results are shown for the

models with covariates. Planned contrasts focused on the test of nurse versus control and paraprofessional versus control. For mother-child interaction, home environment, and child outcomes, treatment group contrasts are reported for the low psychological resources group as well as the whole sample.

Maternal age moderated the effect of the nurse program on duration of maternal employment, a conditional effect consistent with earlier findings.[13] Therefore, when maternal employment outcomes were analyzed, maternal age as a classification factor (<19 years vs ≥19 years) and its interaction with other classification factors were added to the primary model, and the maternal age covariate was removed.

Continuous dependent variables were analyzed in the general linear model and dichotomous outcomes in the logistic model.

The analysis of change in cotinine during pregnancy was limited to women identified as smokers at intake. Examination of residuals for the reduction in cotinine revealed atypical values in both positive and negative directions in all 3 treatment groups. A transformation to ranks was used to deal with this problem. To report estimates and confidence intervals in the original scale, we also analyzed the original data after replacing values beyond the inner fence of a box and whisker plot with the value at the inner fence. The *P* values from this truncated data analysis were virtually identical to the analysis of ranks, so the results are reported from the truncated analysis.

For variables assessed at >1 point in time (observations of maternal-child interaction and home environment), we conducted repeated-measures analyses, adding to the basic model a fixed factor for time and random factor for individuals. These analyses focused on treatment differences averaging across all time periods.

The timing of subsequent pregnancy was examined with proportional hazards analysis[45] using the primary model specified above, with tests performed on the planned treatment contrasts.

Finally, secondary analyses examined whether the performance of the paraprofessionals was attributable to their completing fewer home visits and higher rate of disrupted relationships with families.[26] We analyzed those dependent variables shown below in Figs 2 and 3, first in the primary models described above (but including only women in the 2 home-visited groups) and then after adding to that model covariates for number of completed home visits and whether the mother's relationship with her home visitor was continuous, including their interactions with psychological resources.

RESULTS

Comparison of Treatment Groups on Background Characteristics

With the few exceptions described above, the treatment groups were similar at baseline—both for the sample overall as well as for women with low psychological resources (Table 2). These patterns held for those who participated in subsequent assessments.

Nurse-visited women had lower rates of completed assessments than did women in the control group at each postpartum assessment period (Table 1). The pattern of baseline differences between nurse-visited and control-group women on whom assessments were not conducted by child age 2 indicated that these nurse-visited women were higher functioning than their counterparts in the control group. For example, compared with counterparts in the control group, nurse-visited women with missing post-baseline data were 2 years older at registration, and as a trend, had less conflict with their own mothers. This suggests that whatever bias did occur worked against the detection of beneficial nurse effects.

Impact of Paraprofessional Program

Tables 3 and 4 summarize the results. Paraprofessional-visited mother-child pairs in which the mother had low psychological resources interacted with one another more responsively than their con-

TABLE 3. Estimates of Program Effects on Maternal Outcomes

		Treatment Group Estimates			Treatment Comparisons and 95% CIs	
	Sample	Control	Paraprofessional	Nurse	Paraprofessional Versus Control	Nurse Versus Control
Prenatal use of tobacco and other services		LS Mean	LS Mean	LS Mean	Mean Difference (95% CI)	Mean Difference (95% CI)
Cotinine reduction (ng/mL)	Smokers	12.32	88.51	259.00	−76.19 (−302.21–149.82)	−246.68 (−466.19–−27.16)§
Use of preventive services*	Whole	0.69	0.67	0.80	−0.02 (−0.19–0.15)	0.11 (−0.07–0.28)
		%	%	%	OR (95% CI)	OR (95% CI)
Use of emergency services†	Whole	9	9	6	1.01 (0.51–2.00)	0.64 (0.29–1.39)
Subsequent fertility						
Subsequent pregnancy (24 mo)	Whole	41	33	29	0.70 (0.46–1.06)‡	0.60 (0.39–0.93)§
Subsequent birth (24 mo)	Whole	19	13	12	0.63 (0.37–1.07)‡	0.58 (0.33–1.01)§
Maternal education, employment, and welfare		LS Mean	LS Mean	LS Mean	Mean Difference (95% CI)	Mean Difference (95% CI)
Education achievement (21 mo)	Whole	11.51	11.62	11.51	0.11 (−0.17–0.39)	0.00 (−0.28–0.28)
No. of months						
Employed (1-12 mo)	Whole	3.97	4.21	4.35	0.23 (−0.67–1.14)	0.38 (−0.55–1.31)
Employed (13-24 mo)	Whole	5.73	6.14	6.87	0.42 (−0.55–1.38)	1.14 (0.15–2.13)§
On Aid to Families With Dependent Children (1-12 mo)	Whole	2.35	2.60	2.31	0.25 (−0.59–1.09)	−0.04 (−0.89–0.82)
On Aid to Families With Dependent Children (13-24 mo)	Whole	1.92	2.31	1.95	0.39 (−0.41–1.18)	0.03 (−0.79–0.84)

LS indicates least squares; OR, odds ratio; CI, confidence interval.
* Preventive services = mental health + legal aid + drug/alcohol treatment + child birth classes + rent and utility assistance + education and employment.
† Emergency services = emergency housing + emergency food banks.
‡ $P < .10$.
§ $P \leq .05$.

TABLE 4. Estimates of Program Effects on Mother-Child Interaction, Home Environment, and Child Outcomes

		Treatment Group Estimates			Treatment Comparisons and 95% Confidence Intervals	
	Sample	Control	Paraprofessional	Nurse	Paraprofessional Versus Control	Nurse Versus Control
Mother-infant interaction and home score		LS Mean	LS Mean	LS Mean	Mean Difference (95% CI)	Mean Difference (95% CI)
Mother-infant responsive interaction	Whole	98.99	100.15	100.31	1.16 (−0.11–2.42)*	1.32 (0.03–2.60)†
	Low resource	97.54	99.45	99.50	1.91 (−0.03–3.85)†	1.97 (−0.09–4.02)*
Home environment	Whole	37.10	37.40	37.79	0.30 (−0.49–1.10)	0.69 (−0.12–1.50)*
	Low resource	35.93	36.92	37.12	1.00 (−0.23–2.23)	1.20 (−0.11–2.50)*
Infant emotional vitality and vulnerability, language, and mental delay		%	%	%	OR (95% CI)	OR (95% CI)
Vulnerable: fear stimuli (6 mo)	Whole	25	18	16	0.67 (0.40–1.13)	0.57 (0.32–1.00)†
	Low resource	21	17	12	0.77 (0.34–1.72)	0.51 (0.20–1.31)
Low vitality: joy stimuli (6 mo)	Whole	34	31	26	0.88 (0.57–1.38)	0.68 (0.42–1.09)
	Low resource	40	30	24	0.64 (0.33–1.24)	0.46 (0.22–0.98)†
Low vitality: anger stimuli (6 mo)	Whole	28	26	19	0.89 (0.55–1.43)	0.62 (0.37–1.05)*
	Low resource	32	22	13	0.63 (0.31–1.29)	0.33 (0.14–0.79)†
Language delay (21 mo)	Whole	12	11	6	0.90 (0.48–1.66)	0.48 (0.23–1.01)†
	Low resource	18	13	7	0.66 (0.28–1.58)	0.32 (0.11–0.97)†
Mental development delay (24 mo)	Whole	13	14	11	1.07 (0.59–1.94)	0.83 (0.44–1.57)
	Low resource	19	19	10	0.97 (0.44–2.13)	0.48 (0.18–1.24)
Child cognitive and behavioral development		LS Mean	LS Mean	LS Mean	Mean Difference (95% CI)	Mean Difference (95% CI)
Language development (21 mo)	Whole	99.49	99.89	101.22	0.40 (−1.94–2.74)	1.73 (−0.64–4.11)
	Low resource	96.85	97.83	101.52	0.98 (−2.65–4.62)	4.67 (0.85–8.49)†
MDI (24 mo)	Whole	89.38	89.45	90.13	0.07 (−2.39–2.53)	0.75 (−1.77–3.28)
	Low resource	86.20	88.54	90.18	2.33 (−1.46–6.12)	3.98 (−0.07–8.02)†
Irritable temperament (6 mo)	Whole	2.84	2.83	2.80	−0.01 (−0.17–0.15)	−0.04 (−0.21–0.12)
	Low resource	2.92	2.95	2.88	0.02 (−0.22–0.27)	−0.04 (−0.30–0.22)
Behavior problems score (24 mo)	Whole	45.26	45.49	43.71	0.23 (−3.58–4.03)	−1.56 (−5.45–2.33)
	Low resource	49.25	48.79	48.13	−0.46 (−6.37–5.45)	−1.12 (−7.39–5.14)

LS indicates least squares; CI, confidence interval; OR, odds ratio.
* $P < .10$.
† $P \leq .05$.

trol-group counterparts (99.45 vs 97.54, $P = .05$). There were no other statistically significant effects for the paraprofessionals, although there were trends ($P < .10$) for them to reduce subsequent pregnancies and births (Table 3) and to delay subsequent pregnancies (Fig 1).

Impact of Nurse Program

Maternal Outcomes

Table 3 shows that, in contrast to their control-group counterparts, nurse-visited smokers had greater reductions in cotinine levels from intake to the end of pregnancy (259.00 vs 12.32 ng/mL, $P = .03$). By 24 months after delivery of their first child, nurse-visited women, in contrast to those in the control group, were less likely to have had a subsequent pregnancy (29% vs 41%, $P = .02$) and birth (12% vs 19%, $P = .05$). Figure 1 shows that in contrast to women in the control group, nurse-visited women had longer intervals until the next conception ($P = .02$). Women visited by nurses were employed longer during the second year after the birth of their first child than were controls (6.83 vs 5.65 months, $P = .02$), an effect that was greater for older women (≥19 at intake—data not shown).

Caregiving and Child Outcomes

Table 4 shows that nurse visited mother-infant dyads interacted with one another more responsively than control pairs (100.31 vs 98.99 standard score points, $P = .05$). At 6 months of age, nurse-visited infants, in contrast to control-group counterparts, were less likely to exhibit emotional vulnerability in response to fear stimuli (16% vs 25%, $P = .05$) and those born to women with low psychological resources were less likely to display low emotional vitality in response to joy and anger stimuli (24% vs 40%, $P = .04$ and 13% vs 32%, $P = .01$, respectively). At 21 months, nurse-visited children were less likely to exhibit language delays than children in the control group (6% vs 12%, $P = .05$), an effect concentrated among children born to mothers with low psychological resources (7% vs 18%, $P = .04$). Nurse-visited children born to women with low psychological resources also had superior average language and mental development in contrast to control-group counterparts (101.52 vs 96.85, $P = .02$; and 90.18 vs 86.20, $P = .05$, respectively).

There were no significant nurse effects on women's use of ancillary services during pregnancy, educational achievement, use of welfare, or their children's temperament or behavior problems.

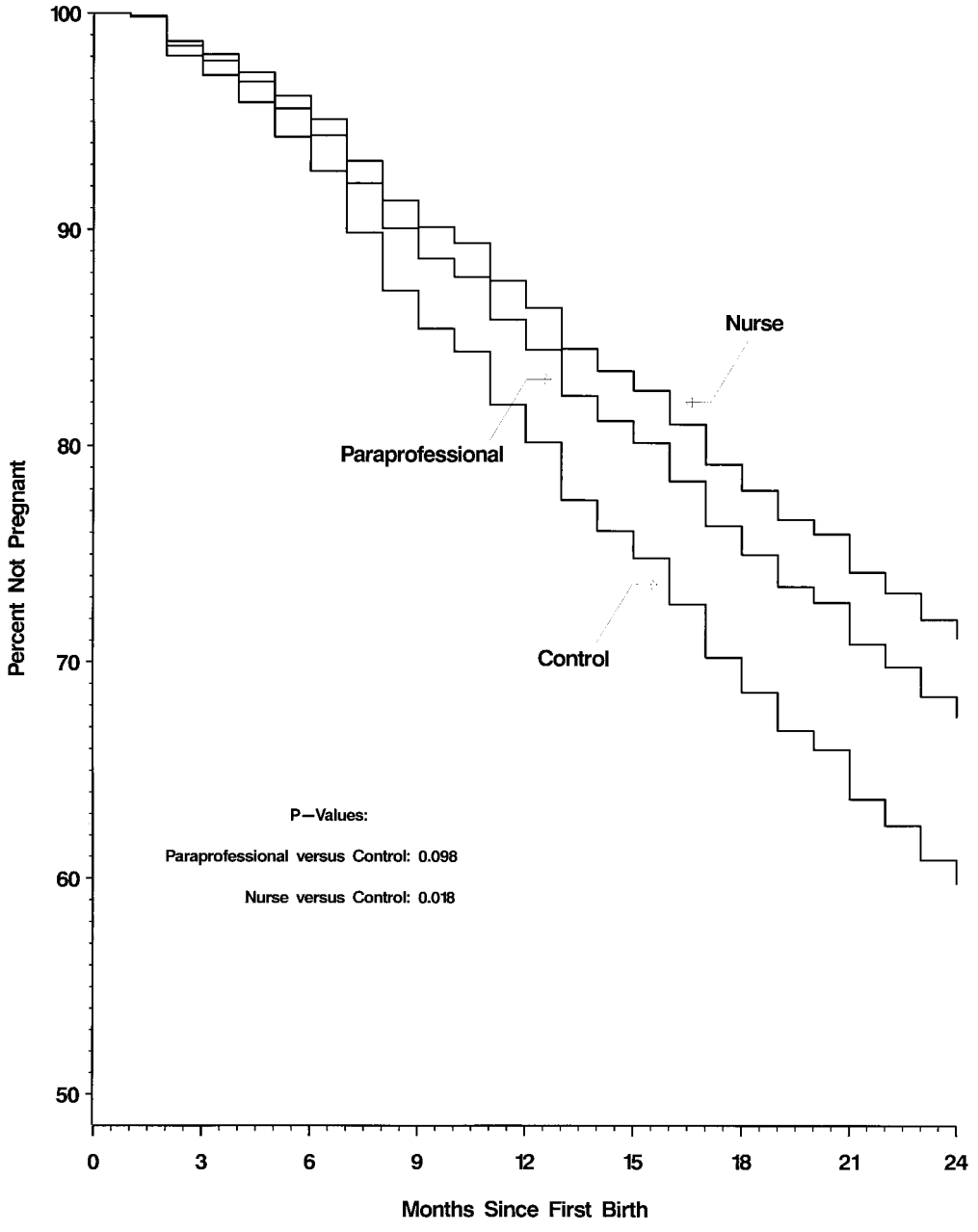

Fig 1. Curves from proportional hazard model of time to first subsequent pregnancy by treatment group.

Estimates of Nurse Versus Paraprofessional Effects

The effects of paraprofessionals and nurses on those outcomes for which there was a significant effect or trend for either visitor are summarized in Figs 2 and 3 for continuous and dichotomous outcomes, respectively. Figure 2 shows effects in standard deviation units (effect sizes) as well as original units, and both figures show estimates with standard errors. These figures show that for most outcomes paraprofessional effects were approximately half the size of those produced by nurses. Aside from significantly superior language development for the nurse-visited versus paraprofessional-visited children born to mothers with low psychological resources, none of these differences was statistically significant.

Does Controlling for Program Implementation Differences Improve Performance of the Paraprofessionals?

Table 5 shows the estimated effects for the nurse versus paraprofessional contrasts for those outcomes displayed in Figs 2 and 3 before and after adding to the statistical model the number of completed visits and whether the mother had a continuous relationship with her visitor. This table shows that after adjustment for these differences in program implementation, the nurse-paraprofessional differences sometimes decreased, sometimes increased, and often stayed essentially the same, indicating that the performance of the paraprofessional group was not because of fewer completed home visits or disruption in the visitor relationship.

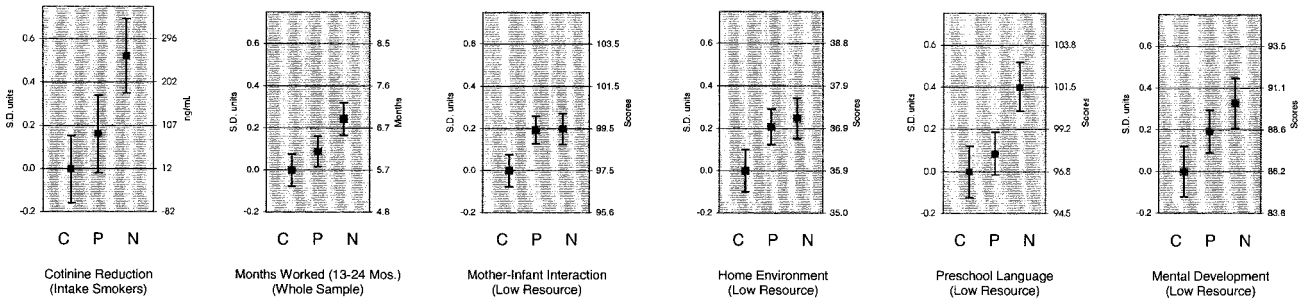

Fig 2. Effect sizes (in standard deviation units) and means ± standard errors for continuous outcomes that correspond to those in Tables 3 and 4 where there were significant effects or trends for any treatment contrast. Mother-infant interaction, home environment, and child outcomes are shown for children born to women with low psychological resources. C indicates control; P, paraprofessional; and N, nurse.

DISCUSSION

This study was designed to determine whether paraprofessional home visitors could produce important effects on maternal and child health if given structured guidelines, excellent training, and supportive supervision in a model that had been effective when delivered by nurses. We did not design it to determine whether nurses are better than paraprofessionals, as the more important question was whether we could enhance paraprofessionals' performance, given their sobering results in previous trials.[5–8]

In this study, paraprofessionals improved mother-child interaction in those dyads in which mothers had low psychological resources, and there were trends for them to reduce the rates of subsequent pregnancies and births, effects that were clinically significant. None of the other paraprofessional effects approached statistical significance. Although some of these other effects might have achieved statistical significance with a much larger sample, their clinical significance may be questioned.

Nurses produced significant and important effects on women's prenatal use of tobacco, timing and likelihood of subsequent pregnancies, subsequent births, and participation in the workforce; mother-child responsive interaction; and the emotional, language and mental development of children born to mothers with low psychological resources. For most outcomes on which the nurses produced beneficial effects, the paraprofessionals' effects were approximately half the size.

It is reasonable to ask whether this trial provided a fair test of the paraprofessional concept, given the paraprofessionals' implementation challenges and that they were expected to follow a program model developed originally for nurses. The literature is replete with descriptions of paraprofessional home-visiting programs that have experienced implementation challenges at least as severe as those encountered here,[7,46,47] suggesting that such challenges may be inherent in paraprofessional programs. Although other paraprofessional program models might perform better than the one tested here, the absence of clinically or statistically significant effects for most paraprofessional models tested in randomized trials makes this unlikely.

One also might ask whether the nurse-paraprofessional performance discrepancies are explained by differences in their understanding of the study outcomes. Both groups had equal access to the goals and objectives of the program through the visit-by-visit guidelines and paraprofessionals were provided twice the level of supervision as nurses to help them use these guidelines effectively, so differential access to the information is not the cause. Some paraprofessionals had difficulty making good use of the visit guidelines and their supervision,[27] however, so part of the discrepancy may be explained by differences in motivation and clinical skill.

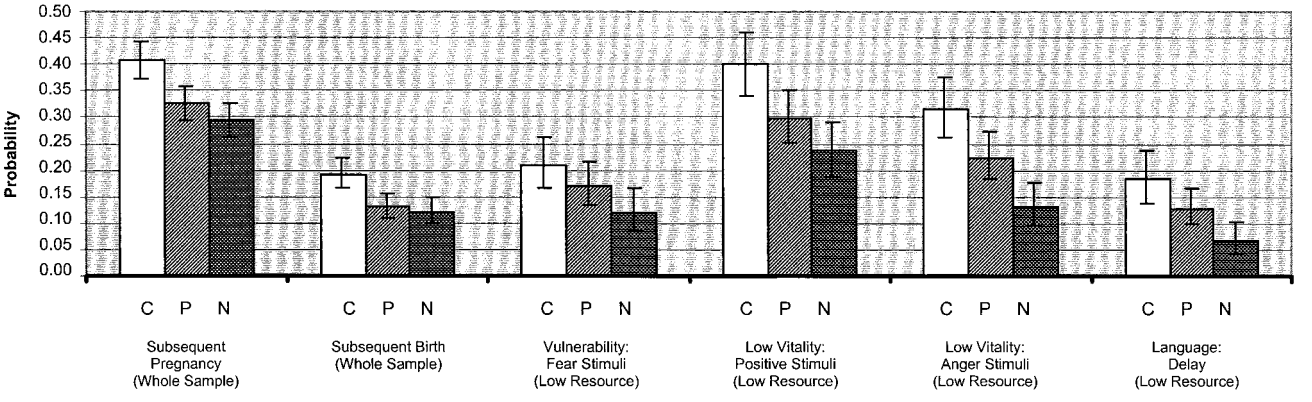

Fig 3. Probabilities ± standard errors that correspond to estimates for dichotomous outcomes presented in Tables 3 and 4 where there were significant effects or trends for any treatment contrast. Child outcomes are shown for children born to women with low psychological resources. C indicates control; P, paraprofessional; and N, nurse.

TABLE 5. Nurse-Paraprofessional Effect Sizes After Standard Model Adjustments and After Adjustment for Number of Visits Completed and Whether the Mothers Had Continuous Relationships With Their Visitors

		Adjustment	
		Standard Model*	Standard Model + Process Covariates†
Dependent Variables	Sample	LS Mean Difference (95% CI)	LS Mean Difference (95% CI)
Cotinine reduction	Intake smokers	189.16 (−51.38–429.69)	266.75 (−3.34–536.84)
Months worked 13–24 mo	Whole sample	0.71 (−0.28–1.69)	0.62 (−0.44–1.68)
Mother-infant interaction	Low resource	0.06 (−1.87–1.98)	0.08 (−1.99–2.16)
Home environment	Low resource	0.26 (−0.95–1.47)	−0.05 (−1.35–1.24)
Preschool language	Low resource	3.63 (0.11–7.16)	4.59 (0.82–8.36)
Mental development	Low resource	1.26 (−2.52–5.03)	1.33 (−2.71–5.37)
		OR (95% CI)	OR (95% CI)
Subsequent pregnancy	Whole sample	0.88 (0.57–1.36)	0.82 (0.51–1.31)
Subsequent birth	Whole sample	0.99 (0.54–1.79)	1.10 (0.57–2.13)
Vulnerability: fear stimuli	Low resource	0.70 (0.27–1.77)	0.84 (0.31–2.30)
Low vitality joy stimuli	Low resource	0.76 (0.37–1.59)	0.92 (0.42–2.01)
Low vitality anger stimuli	Low resource	0.53 (0.22–1.28)	0.57 (0.23–1.42)
Language disorders	Low resource	0.53 (0.18–1.59)	0.37 (0.12–1.16)

LS indicates least squares; OR, odds ratio; CI, confidence interval.
* Estimates are based on model with the following terms: maternal psychological resources and its interaction with treatments, plus 5 covariates (maternal age, housing density, registration after 28 weeks of pregnancy, conflict with partner, and conflict with own mother). Estimates of cotinine changes for smokers are based on a model that includes maternal psychological resources as a continuous covariate in addition to the 5 core covariates listed above.
† Number of home visits completed and continuous relationship with home visitor (yes or no) and their interactions with psychological resources.

Importantly, the performance of the paraprofessional program tested here was not explained by the paraprofessionals simply delivering less of the program or their having higher rates of disrupted relationships with their families compared with nurses. As explanations for the small effects produced by paraprofessionals are narrowed, it is reasonable to ask whether paraprofessionals have legitimacy in the eyes of families during pregnancy and infancy. Nurses are likely to have engagement and persuasive power with pregnant women and parents of young children because pregnant women have natural concerns about complications of pregnancy, labor and delivery, and care of newborns with which nurses are viewed as authorities.[8] Paraprofessionals probably lack this natural legitimacy. Moreover, nurses are rated by the public as having the highest honesty and ethics standards of all professionals.[48] This gives nurses significant power to engage parents and bring about adaptive behavior change and probably accounts for their lower number of attempted visits in which women were not at home compared with paraprofessionals.[26]

The concentration of beneficial nurse effects on the emotional, language, and mental development of children born to mothers with low psychological resources in the current trial is consistent with corresponding nurse effects on child abuse, neglect, and injuries among children born to low-resource mothers in earlier trials of this program.[10,17,19] The vulnerable and low-vitality emotion classifications are relevant to child maltreatment. Children who have been abused and neglected have distorted emotional expressions and patterns of communication with their mothers, including lack of social responsiveness, affective withdrawal, lack of pleasure, and heightened negative affect.[29]

The effect of the nurses and paraprofessionals on responsive mother-child interaction indicates that the program was operating as intended in helping parents provide more sensitive and responsive care for their children, which is thought to promote secure attachment and healthy emotional and behavioral development.[49] The reductions in subsequent pregnancies and increases in interpregnancy intervals are particularly important as short interpregnancy intervals increase the risk of child maltreatment (including infant homicide among teen parents)[50] and compromise families' economic self-sufficiency.[51]

While the cost of the nurse visitation program (now known as the Nurse Family Partnership) is not insignificant, it has been developed in over 270 counties in the United States outside of research contexts since 1996. Public officials have invested in the nurse visitor program in light of replicated evidence of its effectiveness from randomized trials.[52] Economic analyses have been conducted in the first trial of this program, where its cost to government was recovered with dividends when focused on higher risk families,[14,53] and this undoubtedly has influenced public investment. Corresponding economic analyses are being conducted in the current trial, but results will not be available for some time. Paraprofessional programs can cost more than nurse programs when paraprofessionals' caseloads are smaller.

We need to address the limitations of these findings. First, given the higher rate of refusal to participate in the study among women who smoked cigarettes, this trial has limited generalizability to the entire population of smokers and probably users of other substances. Substance users may respond better to paraprofessional visitors than to nurses, but the nurses' success in helping women reduce prenatal tobacco use and the paraprofessionals' lack of effect is not consistent with this hypothesis.

Second, there was higher study attrition among nurse-visited women. Although the risk profiles of

nurse-visited women who dropped out indicate that they were at lower risk than control group dropouts (biasing the study against the nurses), the nurse-visited drops may have unmeasured characteristics that place them at greater risk, which would bias the study in favor of the nurses.

Third, women visited by nurses and paraprofessionals may have altered their interview responses and behavior during the observations to coincide with what they thought was expected of them. Some of the strongest effects for the nurse-visited group, however, were on outcomes that do not depend on maternal report or behavioral observation (eg, cotinine markers for tobacco use, observations of infant emotional expressions, tests of child language development), suggesting that differences observed in other domains are valid as well.

Fourth, given the large number of dependent variables, some findings may be spurious. All of the significant effects and trends, however, are in favor of the 2 visited groups. Moreover, the nurse home visitor program has now produced effects in 3 separate trials on the outcome domains examined in this study and the current sample includes a large portion of Hispanics (compared with whites and blacks in previous trials), extending the validity and generalizability of beneficial nurse effects.

Finally, several of the outcome measures (such as subsequent pregnancies and births, language development and language delay) are not independent of one another. They are included to provide a more complete description of program effects on clinically important outcomes.

It is likely that professionals other than nurses can serve as effective home visitors for low-income parents of infants if they are given the right program resources,[8,54] and effective paraprofessional models eventually may be developed. But until there is consistent evidence from well-conducted randomized trials to support paraprofessional home visiting with any program model, the small effects observed here and elsewhere sound a cautionary note for the many maternal and child health and early intervention programs that purport to promote the health and development of pregnant women and infants with visitors who have limited professional training.

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One repays a teacher badly if one always remains a pupil.

—Friedrica Nietzche