

# Effect of Prenatal and Infancy Home Visitation by Nurses on Pregnancy Outcomes, Childhood Injuries, and Repeated Childbearing

## A Randomized Controlled Trial

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**Context.**—Interest in home-visitation services as a way of improving maternal and child outcomes has grown out of the favorable results of a trial in semirural New York. The findings have not been replicated in other populations.

**Objective.**—To test the effect of prenatal and infancy home visits by nurses on pregnancy-induced hypertension, preterm delivery, and low birth weight; on children's injuries, immunizations, mental development, and behavioral problems; and on maternal life course.

**Design.**—Randomized controlled trial.

**Setting.**—Public system of obstetric care in Memphis, Tenn.

**Participants.**—A total of 1139 primarily African-American women at less than 29 weeks' gestation, with no previous live births, and with at least 2 sociodemographic risk characteristics (unmarried, <12 years of education, unemployed).

**Intervention.**—Nurses made an average of 7 (range, 0-18) home visits during pregnancy and 26 (range, 0-71) visits from birth to the children's second birthdays.

**Main Outcome Measures.**—Pregnancy-induced hypertension, preterm delivery, low birth weight, children's injuries, ingestions, and immunizations abstracted from medical records; mothers' reports of children's behavioral problems; tests of children's mental development; mothers' reports of subsequent pregnancy, educational achievement, and labor-force participation; and use of welfare derived from state records.

**Main Results.**—In contrast to counterparts assigned to the comparison condition, fewer women visited by nurses during pregnancy had pregnancy-induced hypertension (13% vs 20%;  $P=.009$ ). During the first 2 years after delivery, women visited by nurses during pregnancy and the first 2 years of the child's life had fewer health care encounters for children in which injuries or ingestions were detected (0.43 vs 0.55;  $P=.05$ ); days that children were hospitalized with injuries or ingestions (0.03 vs 0.16;  $P<.001$ ); and second pregnancies (36% vs 47%;  $P=.006$ ). There were no program effects on preterm delivery or low birth weight; children's immunization rates, mental development, or behavioral problems; or mothers' education and employment.

**Conclusion.**—This program of home visitation by nurses can reduce pregnancy-induced hypertension, childhood injuries, and subsequent pregnancies among low-income women with no previous live births.

WITHIN the past 8 years, home-visitation services have been promoted as a way to improve the outcomes of pregnancy,<sup>1</sup> to reduce the rates of child abuse and neglect,<sup>2</sup> and, now that welfare has been given to the states in the form of block grants, to help families become economically self-sufficient. While some home-visitation programs have produced some positive effects,<sup>3,4</sup> most have failed to affect important aspects of maternal and child health and family functioning.<sup>5,6</sup>

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See also pp 637 and 680.

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Some of this recent interest in home visitation has grown out of the results of a trial of nurse home visitation with white women who had no previous live births and who lived in a semirural area in and around Elmira, NY.<sup>7-10</sup> Women visited by nurses during pregnancy reduced the number of cigarettes smoked, improved the quality of their diets during the course of pregnancy, and exhibited lower rates of pyelonephritis. In contrast to a comparison group, nurse-visited women who smoked cigarettes at the beginning of pregnancy had 75% fewer preterm deliveries, and nurse-visited young adolescents delivered newborns with higher birth weights.<sup>7</sup> Three percent of the nurse-visited women exhibited pregnancy-induced hypertension (PIH) compared with 9% in the comparison group, a nonsignificant difference.<sup>7</sup>

Home visitation during pregnancy and the first 2 years of the child's life in the Elmira program reduced the rates of state-verified cases of child abuse and neglect among children born to unmarried adolescents from low socioeconomic-status households through age 2 years.<sup>8</sup> While the program's effect on child abuse and neglect was attenuated during the

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2-year period after the program ended,<sup>11</sup> this was probably because of increased surveillance for child abuse and neglect among the nurse-visited families.<sup>12</sup> Children's health care encounters in which injuries were detected were reduced from 1 through 4 years of age, ie, for up to 2 years after the program ended.<sup>8,11</sup> Moreover, during the first 4 years after delivery of their first child, the nurse-visited mothers who were unmarried and from low socioeconomic-status households at registration had fewer subsequent pregnancies and greater participation in the labor force than did their counterparts randomly assigned to comparison services.<sup>9</sup> This produced substantial savings to government.<sup>10</sup>

Despite limited similarity with the program tested, many different types of home-visitation programs for pregnant women and parents of young children have been promoted on the basis of results from the Elmira trial.<sup>12</sup> We have maintained, however, that the program model studied in Elmira should not be disseminated until its findings are replicated in a major urban area with a minority population.<sup>13</sup>

The current trial was undertaken to determine the extent to which findings from the Elmira study would be replicated with an African-American sample of primarily low-income, unmarried women living in a major urban area (Memphis, Tenn), and when the program was administered through a public health department.

We hypothesized that the program would produce outcomes similar to those in the original trial. Pilot work and preliminary analyses disclosed, however, that some outcomes from the original study occurred too infrequently to be viable outcomes or moderating variables in the Memphis trial, including pyelonephritis (1%), prenatal cigarette smoking (9%), and state-verified reports of child abuse and neglect (3%-4%). The beneficial effects of the Elmira program on child maltreatment and injuries in the original trial were concentrated on children born to mothers with little sense of control over their life circumstances.<sup>8</sup> We hypothesized in the current trial that effects of the program on maternal caregiving and childhood injuries would be greater for women with few psychological resources, where psychological resources were defined in terms of women's intellectual functioning and mental health, in addition to their sense of control.

## SUBJECTS AND METHODS

The numbers of eligible subjects invited to participate, randomized, and assessed at various stages of the research are summarized in Table 1. As this table indicates, we achieved high rates of participation and

Table 1.—Profile of the Trial: Sample Composition Over Time by Treatment\*

	Treatment Group				Total
	1	2	3	4	
No. allocated to treatment	166	515	230	228	1139
No. of postrandomization drops†	1	4	4	4	13
No. of completed prenatal home visits (range)	...	...	7 (0-18)	7 (0-18)	...
No. of completed postnatal home visits (range)	...	...	...	26 (0-71)	...
No. of miscarriages	6	19	6	8	39
No. of stillbirths	0	5	3	2	10
No. of infant deaths‡	2	7	2	1	12
No. of preterm deliveries <28 wk	1	0	2	1	4
No. of completed 28-wk interviews	157	485	210	211	1063
No. of preterm deliveries <36 wk	7	42	20	11	80
No. of completed 36-wk interviews	137	411	179	189	916
No. of obstetrical records abstracted	163	511	228	228	1130
No. of labor and delivery records abstracted	162	509	228	227	1126
No. of newborn records abstracted	157	486	220	219	1082
No. of UT perinatal database records abstracted	140	427	191	191	949
No. of completed 6-mo assessments	Not followed up	469	Not followed up	203	672
12-mo assessments	Not followed up	Not followed up	Not followed up	Not followed up	Not followed up
No. of home assessments completed		471		211	682
No. of office assessments completed		470		211	681
24-mo assessments	Not followed up	Not followed up	Not followed up	Not followed up	Not followed up
No. of home assessments completed		467		208	675
No. of office assessments completed		465		206	671
Pediatric records completed	Not followed up	Not followed up	Not followed up	Not followed up	Not followed up
No. of well-child and illness records		467		204	671
No. of immunization records		470		210	680
No. of ED and hospitalization records		481		216	697
No. of AFDC records reviewed	Not followed up	455	Not followed up	201	656

\*A total of 1290 eligible subjects were invited to participate; 151 refused, and 1139 were randomized. Unless otherwise specified, the difference between the number of cases randomized and assessed is the result of missed assessments. UT indicates University of Tennessee; ED, emergency department; and AFDC, Aid to Families With Dependent Children.

†Ten of the 12 drops consisted of cases where the mother refused further participation after randomization. One woman (assigned to treatment 2) was dropped from the study when it was learned that she was registered and randomized a second time after an earlier registration and miscarriage; a second woman (assigned to treatment 1) was not followed up because of clerical error after a staff member identified her as not meeting the inclusion criteria.

‡One infant death occurred between 6 and 12 months of age.

retention. Office-based assessments were completed at 24 months post partum, for example, on 96% of the cases in which there was no fetal or child death.

## Participants

From June 1, 1990, through August 31, 1991, 1290 consecutive women from the obstetrical clinic at the Regional Medical Center in Memphis were invited to participate in the study. Women less than 29 weeks pregnant were recruited if they had no previous live births, no specific chronic illnesses thought to contribute to fetal growth retardation or preterm delivery (eg, chronic hypertensive disorders requiring medical treatment, severe cardiac disease, large uterine fibroids), and at least 2 of the following sociodemographic risk conditions: unmarried, less than 12 years of education, and unemployed. Eighty-eight percent (1139/1290) of the women completed informed consent and were randomized to 1 of 4 treatment conditions described below. Ninety-two percent of the women enrolled were African American, 98% were unmarried, 64% were aged 18 years or younger at registration, and 85% came from households with incomes at or below the federal pov-

erty guidelines. Compared with women who refused, those who agreed to participate were more likely to be African American than non-African American (89% vs 74%;  $P<.001$ ); younger (average age, 18 vs 19 years;  $P=.001$ ); and non-high school graduates (89% vs 84%;  $P=.01$ ).

## Statistical Power and Assignment Ratios

Sample size was established from a series of power calculations. For all calculations, we set  $\alpha=.05$  and  $\beta=.20$  and specified 2-tailed tests. We established sample size so that it would be sufficiently large (after attrition) to detect program effects that were limited to one half of the total sample defined as being at higher risk according to characteristics such as mothers' having few psychological resources. These calculations led to a sample of 1468 for the prenatal phase and 734 for the postnatal phase of the study. It was possible to enroll fewer women in the postnatal phase because, in the Elmira study, treatment effects (in SD units) were larger for postnatal outcomes than for prenatal outcomes. These analyses also indicated that we could assign women disproportionately

to the relatively expensive nurse-visited condition, with fewer in the comparison condition, with minimal loss of statistical power. Competition for subjects with other studies limited the final sample size for the prenatal phase of the study.

Given the sample actually enrolled, we show herein the estimate of smallest detectable treatment main effect for key outcomes: (1) mean increase in birth weight, 96 g, where  $SD=596$  g; (2) mean reduction in children's health care encounters in which injuries were detected, 0.58 to 0.36, where  $SD=1.06$ ; and (3) reduction in proportion of second pregnancies, 45% to 32%.

Slightly different assignment ratios and treatment allocation schemes were used during 3 time frames during the 15-month period of sample recruitment. This procedure was used to accommodate shifting expectations about completed sample size (because of the competition with other studies that sampled the same population), and to manage a relatively large number of women enrolled during the first 2 months of the study when only 10 of the 12 project nurses had been hired. Consequently, treatment 1 was added to the design during the second and third allocation periods to reduce the number of families assigned to the nurse-visited conditions (treatments 3 and 4) and to reduce workload stress among the nurses.

### Randomization

After completion of baseline interviews, identifying information on the participants was sent to the University of Rochester, Rochester, NY, where it was entered into a computer program that randomized individual women to treatment conditions by methods that are extensions of ones given by Soares and Wu.<sup>14</sup> This procedure concealed the randomization from individuals directly involved with the participants in Memphis. The randomization was conducted within strata from a model with 5 classification factors: maternal race (African American vs non-African American), maternal age (<17, 17-18, and  $\geq 19$  years), gestational age at enrollment (<20 vs  $\geq 20$  weeks), employment status of head of household (employed vs unemployed), and geographic region of residence (4 regions). Women assigned to the home-visitation groups subsequently were assigned at random to a nurse home visitor.

### Treatment Conditions

Women in treatment 1 ( $n=166$ ) were provided free round-trip taxicab transportation for scheduled prenatal care appointments; they did not receive any postpartum services or assessments. Women in treatment 2 ( $n=515$ ) were provided the free transportation for sched-

uled prenatal care plus developmental screening and referral services for the child at 6, 12, and 24 months of age. Those in treatment 3 ( $n=230$ ) were provided the free transportation and screening offered in treatment 2 plus intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home. Women in treatment 4 ( $n=228$ ) were provided the same services as those in treatment 3; in addition, they continued to be visited by nurses through the child's second birthday.

For the evaluation of the prenatal phase of the program, treatments 1 and 2 were combined to form a single comparison group and then contrasted with treatments 3 and 4, a group that was visited by nurses during pregnancy. For the postnatal phase of the study, treatment 2 was contrasted with treatment 4.

### Program Plan and Implementation

The experimental home-visitation program was carried out by the Memphis/Shelby County Health Department. The nurses completed an average of 7 home visits (range, 0-18) during pregnancy and 26 home visits (range, 0-71) during the first 2 years post partum. They followed a detailed visit-by-visit protocol to guide their efforts to help women improve their health-related behaviors; care of their children; and life-course development (pregnancy planning, educational achievement, and participation in the workforce).

To improve the outcomes of pregnancy, the nurses helped women complete 24-hour diet histories on a regular basis and plot weight gains at every visit; they assessed the women's cigarette smoking and use of alcohol and illegal drugs and facilitated a reduction in the use of these substances through behavioral analysis.<sup>15</sup> They also taught women to identify the signs and symptoms of pregnancy complications, encouraged women to inform the office-based staff about those conditions, and facilitated compliance with treatment. They gave particular attention to urinary tract infections, sexually transmitted diseases, and hypertensive disorders. They coordinated care with office-based staff and measured blood pressure when needed.

After delivery, the nurses helped mothers and other caregivers improve the physical and emotional care of their children. The nurses taught parents to observe the signs of illness, to take temperatures, and to communicate with office staff about their children's illnesses before seeking care for an illness or injury. Specific curricula were integrated into the program to promote parent-child interaction by facilitating parents' understanding of their infants' and toddlers'

communicative signals,<sup>16,17</sup> enhancing interest in playing with their children in ways that promote emotional and cognitive development,<sup>18</sup> and creating households that are safer for children.<sup>19</sup>

The nurses also helped women clarify their goals and solve problems that may have interfered with completing their educations, finding work, and planning future pregnancies. The program promoted work, education, and family planning, but it did so in the context of helping women set goals for themselves at a crucial stage in their own personal development.

The program protocols were based on theories of human ecology, human attachment, and self-efficacy.<sup>20</sup> The nurses helped families make use of needed health and human services and attempted to involve other family members and friends in the pregnancy, birth, and early care of the child. They established trusting relationships with parents and helped mothers set small, achievable behavioral objectives between visits that, when met, would increase mothers' confidence in their ability to manage greater challenges.

### Masking

Interviews and abstractions of medical and social service records were conducted 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. Clinical assessments recorded in the medical records were made by health care providers who had access to the women's treatment assignment. Although the principal investigators and statisticians also had access to the subjects' treatment assignments, all decisions about the coding of interview responses and conditions in the medical record and about the construction of variables were made explicitly without this information.

### Assessments and Definitions of Variables

Participating women were interviewed by research staff members at the time of registration (before their assignment to treatments), at the 28th and 36th weeks of pregnancy, and at the sixth, 12th, and 24th months of the child's life. Medical and social service records were abstracted.

At registration, women were interviewed to determine standard socioeconomic conditions, their mental health,<sup>21</sup> personality characteristics,<sup>22</sup> obstetrical histories, health-related behaviors (cigarette smoking, alcohol and illegal drug use), and social support. Women also completed brief tests to estimate their levels of intellectual functioning.<sup>23</sup> Women's prepregnancy weights and heights were also determined by self-report. The

last weights recorded in the prenatal record before delivery were used to calculate pregnancy weight gains.

Household per annum discretionary income was calculated by means of subsistence standards for determining Medicaid eligibility in Tennessee, the number of individuals in the household, and reported household income. In addition, each participant was assigned a value that represented the percentage of poverty households in the census tract in which she resided.<sup>24</sup>

A variable was created to index women's psychological resources measured at registration. It was based on the summed *z* scores of their intelligence,<sup>23</sup> mental health,<sup>21</sup> and sense of mastery/self-efficacy.<sup>15,22</sup> Self-efficacy was assessed with a measure developed for the current study to determine mothers' confidence in their ability to behave in accordance with the major behavioral objectives of the program. Each of the 3 dimensions was standardized to a mean of 100 and SD of 10, summed, and then restandardized to a mean of 100 and SD of 10. The psychological resource variable was dichotomized at values less than 100 vs 100 or more.

Women were interviewed at 28 weeks' gestation by telephone to assess their health-related behaviors, social support, use of community services, and participation in school and work. Identical interviews were conducted again at 36 weeks. At 36 weeks' gestation, women also were assessed to ascertain their mental health symptoms (with a focus on anxiety and depression)<sup>21</sup> and their sense of mastery.<sup>22</sup>

Obstetrical and newborn records were abstracted directly and verified against an on-line perinatal database from the University of Tennessee. Discrepancies between the perinatal database and our independent abstraction were resolved on a case-by-case basis. In addition, a subset of 41 records (every 25th record) was abstracted by 2 different coders. The reliability of abstraction was good, with correlations of 1.00 for birth weight and 5-minute Apgar score and 0.98 for gestational age.

Urine screens for marijuana and cocaine were performed on 511 women who registered for prenatal care at the Regional Medical Center as part of their clinical assessment during the time that this trial was conducted. The results of these screens (conducted before randomization) were abstracted from the perinatal database.

Urinary tract infections were recorded if a culture produced a colony count of more than 100 000/mL of clean-catch voided urine for a single uropathogen. Diagnoses of pyelonephritis were recorded from the medical record. (Urinary tract infections and pyelonephritis occurred too infre-

quently [5% and 1%, respectively] to serve as viable outcomes and so are not reported herein.) Cultures for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* were obtained at the first prenatal visit and were coded from the prenatal record; *Trichomonas vaginalis* was ascertained by diagnoses from the record. A sexually transmitted disease variable was created that consisted of the number of any 1 of these 3 types of infections. Syphilis was coded separately because of the severity of its effects on the fetus. Diagnoses of *Gardnerella vaginalis* and yeast infections were abstracted from the prenatal record. Infections separated by more than 21 days were treated as separate infections. Diagnoses were separated according to whether they occurred before or after randomization. Pregnancy-induced hypertension was coded when preeclampsia, eclampsia, toxemia, or PIH was coded in the intrapartum or postpartum record.<sup>25</sup>

Birth weight (in grams) was recorded from the hospital record. Intrauterine growth restriction was defined as birth weight less than the 10th percentile for gestational age.<sup>26</sup> Gestational age (in days) was estimated from reported last menstrual period (LMP) and ultrasound scans obtained before 26 weeks' gestation. (Ultrasound was performed on all subjects at registration for prenatal care.) If LMP and ultrasound converged within 14 days, then LMP was used for estimating gestational age. When LMP and ultrasound differed by more than 14 days, ultrasound was used as the estimate. When ultrasound was not done before 26 weeks' gestation, or LMP was unknown, the record was reviewed by 2 clinicians, independently and unaware of treatment condition, to determine the most reliable estimate of gestational age. Preterm birth was divided into 2 categories: (1) spontaneous preterm birth after preterm labor, with or without premature rupture of the membranes, or (2) indicated preterm birth performed for maternal or fetal complications.

At 6 months post partum, mothers and children were assessed in the study offices. Mothers completed interviews that assessed whether or not they attempted to breast-feed, their duration of breast-feeding, and their beliefs about children associated with child abuse and neglect (belief in physical punishment, unrealistic expectations, lack of empathy, and role reversal).<sup>27</sup> Mothers and children were observed while the mothers taught their children a developmentally challenging task by means of the Nursing Child Assessment Satellite Training procedure.<sup>28</sup> The mothers' behaviors were coded and summarized to characterize their sensitivity, responsiveness, and quality of teaching. The infants' behaviors were coded and aggregated to characterize

their responsiveness and clarity of communication toward their mothers.

At 12 and 24 months post partum, in their homes and in the office, the mothers completed the standardized interviews given at 6 months. The interviews included information on the number and outcomes of subsequent pregnancies, mothers' educational achievements, and number of months mothers participated in the workforce. They and their children were observed again by means of the teaching-interaction procedure. During the home visits, the educational and socioemotional properties of the home environment were assessed, by means of the Home Observation for Measurement of the Environment.<sup>29</sup> At the 24-month office visit, the children were tested with the Bayley scales of infant development, and their mothers completed the Achenbach Child Behavior Checklist.<sup>30</sup>

The children's medical records were reviewed with a focus on hospitalizations, emergency department visits, and outpatient encounters in which injuries and ingestions were detected. A summary variable was created to count the total number of health care encounters of all types (outpatient, emergency, and hospital admissions) in which injuries or ingestions were detected. We calculated the number of days that children were hospitalized and in which injuries or ingestions were noted.

The dates and types of children's immunizations were recorded. Whether children were completely immunized by their 24th month of life was determined. Children needed to have 4 or more diphtheria, pertussis, and tetanus vaccines, 3 or more oral poliovirus vaccines, and 1 or more *Haemophilus influenzae* type b and measles, mumps, and rubella vaccines to be considered completely immunized.

Data also were abstracted from Tennessee Department of Human Services records to ascertain women's and their firstborn children's use of Aid to Families With Dependent Children (AFDC) during the period from the child's birth through second birthday. Cases were matched on mother's name, Social Security number, and birthday. A variable was constructed to reflect whether mother and/or child received AFDC for each month of the child's life from birth through 24 months. Summary variables were constructed to indicate the total number of months that either mother or child used welfare (AFDC) for the 1- to 12-month and 13- to 24-month periods.

### Statistical Models and Methods of Analysis

Data analyses were conducted and reported on all cases with an "intention-to-treat" approach.

Table 2.—Background Characteristics of Sample at Randomization by Treatment Condition

Dependent Variables	Treatment Group			
	1	2	3	4
	%	%	%	%
White	4	8	7	11
Married	1	2	3	1
Head of household employed	58	57	57	50
Consumed alcohol (last 2 wk)	4	4	4	5
Smoked cigarettes (last 3 d)	10	10	7	11
Used marijuana (last 2 wk)	1	1	2	1
Used cocaine (last 2 wk)	1	0	0	0
Positive drug screen	3	5	2	4
Sexually transmitted diseases*	36	32	31	37
Syphilis (prerandomization)	7	4	7	6
<i>Gardnerella</i> infection	7	8	11	11
Urinary tract infection	7	10	14	11
Yeast infection	6	9	8	6
Previous abortion	17	18	17	18
Low body mass index	28	30	32	22
	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Age, y	18.0±3.3†	18.1±3.2	17.9±2.8	18.1±3.3
Education, y	10.1±2.0	10.3±1.9	10.3±2.0	10.1±2.0
Income, \$†	1089.6±6677.0	1671.1±6890.5	2324.6±7340.7	98.8±6611.4
% Census tract below poverty	39.2±20.6	34.5±21.3	36.1±21.3	35.8±20.5
Housing density	0.9±0.5	0.9±0.5	1.0±0.5	1.0±0.6
IQ	97.3±10.0	96.3±10.1	95.7±10.8	96.5±10.5
Mental health§	100.3±9.4	100.2±10.1	100.2±9.6	99.2±10.5
Maternal self-efficacy§	99.5±10.0	100.1±9.9	100.4±10.0	99.7±10.2
Mastery§	100.6±9.6	100.1±10.3	99.9±9.7	99.4±9.9
Maternal psychological resources§	100.6±9.6	100.1±10.0	100.0±9.6	99.3±10.7
Grandmother support§	99.9±10.1	99.9±9.8	99.3±10.9	101.0±9.3
Husband/boyfriend support§	99.2±9.8	100.2±10.0	99.8±10.0	100.3±10.1
Child abuse beliefs§	99.5±10.1	99.7±9.6	100.2±10.0	100.9±10.7
Height, cm	164.2±6.7	164.7±7.3	164.1±7.0	164.0±6.5
Prepregnant weight, kg	62.3±15.1	62.1±14.7	61.0±12.9	62.7±13.9
Gestational age, wk	16.4±6.0	16.4±5.8	16.3±5.5	16.5±5.6

\*Diagnosis of *Chlamydia trachomatis*, *Trichomonas vaginalis*, or *Neisseria gonorrhoeae* in current pregnancy before randomization.

†Mean±SD.

‡Annual household discretionary income based on income subsistence standards for Medicaid eligibility, reported household income, and number of individuals in household at registration.

§Standardized to sample mean=100, SD=10.

||Locally developed scale that assesses degree to which individual provides emotional and material support to mother.

Dependent variables for which a normal distribution was assumed were analyzed in the general linear model; dichotomous outcomes, such as PIH, in the logistic-linear model (assuming a binomial distribution); and low-frequency count data, such as the number of health care encounters in which injuries were detected, in the log-linear model (assuming a Poisson distribution). Estimates and tests were adjusted for all covariates, classification factors, and interactions. Homogeneity of regressions was tested for all covariates on the contrasts of interest.<sup>31</sup> In the generalized case, the analysis was carried out and estimates obtained in terms of the linearized form of the model—the logits (or log of the odds) in the logistic models, and logs of the incidence in the log-linear models. We use the term *incidence* in referring to the actual count or mean of counts over specific periods of measurement.

For both prenatal and postnatal outcomes, to rule out the potential interaction of treatments with the 3 periods that had different treatment allocation schemes, analyses also were carried out in models that included a 3-level factor for allocation period and its interaction with other effects in the model. No significant differences for time or its interaction with treatments were found, so it was possible to drop this variable from further consideration.

The final models derived for the reported results differed, depending on whether the outcomes were from the prenatal or the postnatal phase of the study because outcomes in each phase had different sets of predictors and different hypothesized moderators of treatment effects. In both phases, we tested hypotheses regarding the moderating influence of specific variables found to condition program effects in the Elmira trial.

**Pregnancy Models.**—The models analyzed in the evaluation of program effects for birth weight and gestational age outcomes focused on the classification effect for treatments (groups 1 and 2 vs 3 and 4), maternal age (<17 vs ≥17 years at registration), and sex of the child. Covariates included women's prepregnancy weight, height, and number of cigarettes smoked at registration. The models for social and behavioral intervening outcomes (such as social support, psychological distress, and use of services) included treatments, a classification factor specifying whether the woman was in school at registration, and covariates for the intake measurement of the behavior or condition under examination (when these intake variables were available). The model for PIH and end-of-pregnancy blood pressures included treatments and a covariate for mean arterial blood pressure derived from the mothers' initial prenatal visit. The model for rates of genitourinary tract infections included treatments and a covariate for the number of corresponding types of infections diagnosed before randomization. A repeated-measures model was used for the analysis of maternal weight gain; the focus of the analysis was on testing the treatment difference in change between the prepregnancy and end-of-pregnancy time points.

**Models for Postnatal Outcomes.**—The primary statistical model for postnatal outcomes focused on classification effects for treatments (2 vs 4) and maternal psychological resources (high vs low), plus 2 covariates (household income and census-tract poverty level). For outcomes measured at more than 1 point in time or under more than 1 situation (eg, home and office), we carried out repeated-measures analyses, adding to the basic model fixed factors for time and measurement location and a random factor for individuals. The focus of interpretation was on those levels of functioning assessed at the end of the program, 24 months post partum.

## RESULTS

### Preintervention Equivalence of Treatment Conditions

As shown in Table 2, the treatment groups were equivalent on background characteristics, with a few exceptions: Women in treatment 4 lived in households in which the head of the household was more likely to be unemployed, and in which there was less discretionary income than did women in treatment 2. There were no additional intervention-comparison differences for subgroups defined on the basis of the women's age, psychological resources, gestational age at enrollment, or randomization period. Similarly, there were no additional

treatment differences on prerandomization background characteristics after removing those cases for which follow-up data were not available.

## Birth Outcomes

Table 3 shows that there were no treatment main effects for birth weight, length of gestation, low birth weight, spontaneous preterm delivery, indicated preterm delivery, or Apgar scores.

## Prenatal Intervening Variables

Table 4 shows that by the 36th week of pregnancy, nurse-visited women were more likely to use other community services than were women in the control group ( $P=.01$ ). They also were more likely to be working ( $P=.06$ ), an effect that was particularly strong among women who were not in school when they were randomized (14% vs 8% [ $P=.05$ ] and 8% vs 2% [ $P=.01$ ] for the 28th and 36th weeks, respectively; data not shown).

There were no program effects on women's use of standard prenatal care or obstetrical emergency services after registration in the study, but nurse-visited women who were in school at registration had twice as many predelivery hospitalizations as did their counterparts in the comparison condition (0.18 vs 0.09;  $P=.003$ ; data not shown). These differences were not explained by any coherent pattern of diagnoses associated with those hospitalizations.

Table 4 also shows that, in contrast to women in the comparison group, nurse-visited women had fewer yeast infections after randomization and fewer instances of PIH ( $P=.05$  and  $P=.009$ , respectively). Among women with PIH, in contrast to those in the comparison group, those who received a nurse home visitor had mean arterial blood pressures during labor that were 4.6 points lower ( $P=.006$ ), although there were no treatment differences in birth weight, length of gestation, or Apgar scores for those with PIH (data not shown).

## Childhood Injuries and Ingestions

During the first 2 years of their lives, nurse-visited children had fewer health care encounters in which injuries and ingestions were detected than did children in the comparison condition ( $P=.05$ ), an effect that was accounted for primarily by a reduction in outpatient encounters ( $P=.02$ ) (Table 5). Nurse-visited children also were hospitalized for fewer days with injuries and/or ingestions than were children in the comparison condition ( $P<.001$ ). These program effects on both total health care encounters and number of days hospitalized with injuries and ingestions were greater for children born to women with few psycho-

Table 3.—Adjusted Birth Weight, Length of Gestation, and Apgar Outcomes by Treatment Condition\*

Dependent Variables	Comparison Groups, Mean	Nurse-Visited Groups, Mean	Mean Difference†	95% Confidence Interval
Birth weight, g	3050.4	3032.2	18.2	−62.4 to 98.7
Gestational age, wk	39.0	39.0	0.0	−0.4 to 0.4
5-min Apgar	8.7	8.6	0.1	−0.1 to 0.3

  

			Odds Ratio‡	95% Confidence Interval
Low birth weight (<2500 g), %	14	15	1.1	0.8 to 1.6
IUGR, %	9	9	1.0	0.6 to 1.5
Preterm (<37 wk), %	13	11	0.8	0.6 to 1.2
Indicated preterm delivery, %	3	3	1.0	0.5 to 2.4
Spontaneous preterm delivery, %	9	8	0.8	0.5 to 1.3

\*Estimates adjusted for maternal age, number of cigarettes smoked, sex of child, maternal prepregnancy weight, and maternal height. Comparison groups were treatment groups 1 and 2; nurse-visited groups, treatment groups 3 and 4.

†Difference = (comparison mean) − (nurse-visited mean).

‡Odds =  $p/(1-p)$ ; odds ratio = nurse-visited odds/comparison odds.

§Intrauterine growth restriction; cases with birth weights less than 10th percentile for gestational age.

Table 4.—Adjusted Variables for Use of Health and Community Services, School, Work, and Obstetric Problems Identified After Randomization by Treatment Condition\*

Dependent Variables	Comparison Groups, Mean	Nurse-Visited Groups, Mean	Mean Difference†	95% Confidence Interval
Gestational weight gain, kg	14.9	14.6	0.3	−0.6 to 1.3
Systolic blood pressure (labor admission), mm Hg	112.6	111.7	0.9	−0.7 to 2.5
Diastolic blood pressure (labor admission), mm Hg	67.5	66.8	0.6	−0.8 to 2.1
No. of prenatal visits (total)	6.5	6.2	0.3	−0.1 to 0.7
No. of visits for obstetrical evaluation (total)	2.8	2.8	−0.1	−0.3 to 0.2

  

	Incidence‡ (Log-Incidence)	Incidence‡ (Log-Incidence)	Log-Incidence Difference§	95% Confidence Interval
No. of hospitalizations during pregnancy	0.13 (−2.11)	0.15 (−1.93)	−0.19	−0.52 to 0.14
No. of <i>Gardnerella</i> infections	0.07 (−2.63)	0.06 (−2.75)	0.12	−0.34 to 0.58
No. of yeast infections	0.19 (−1.65)	0.14 (−1.94)	0.29	−0.00 to 0.58
No. of sexually transmitted diseases	0.21 (−1.58)	0.22 (−1.51)	−0.07	−0.32 to 0.18

  

	%	%	Odds Ratio¶	95% Confidence Interval
Used other community services	20	29	1.8#	1.2 to 2.7
In school	41	44	1.2	0.8 to 1.8
Employed	3	6	2.0**	1.0 to 4.0
Pregnancy-induced hypertension	20	13	0.6#	0.5 to 0.9

\*Use of health and community services and school and work estimates adjusted for whether women were in school at registration. Infections adjusted for number of prerandomization infections that correspond to those counted after randomization. Pregnancy-induced hypertension adjusted for mean arterial blood pressure measured at first antepartum visit. Comparison groups were treatment groups 1 and 2; nurse-visited groups, treatment groups 3 and 4.

†Difference = (comparison mean) − (nurse-visited mean).

‡Incidence = mean number of infrequently occurring events within stated time period. Individual cases may have values greater than 1, although the range is small.

§Difference = (comparison log-incidence) − (nurse-visited log-incidence).

|| $P<.05$ .

¶Odds =  $p/(1-p)$ ; odds ratio = nurse-visited odds/comparison odds.

# $P<.01$ .

\*\* $P<.10$ .

logical resources (0.41 vs 0.67 [ $P=.003$ ] and 0.02 vs 0.26 [ $P<.001$ ], respectively).

Table 6 shows that the nurse-visited children were hospitalized at older ages and for substantially less serious reasons. The 3 nurse-visited children who were hospitalized with injuries and ingestions were admitted when they were more than 12 months of age (and thus mobile), while 6 (46%) of the 13 comparison children were hospitalized when they were less than 6 months of age (and thus immobile). Seven (54%) of the comparison-group children were hospitalized with either fractures and/or head trauma, while

none of the nurse-visited children were. Two of the 3 nurse-visited children were hospitalized with ingestions.

## Qualities of Caregiving, Immunization Rates, Mental Development, and Behavioral Problems

As indicated in Table 7, nurse-visited mothers reported that they attempted breast-feeding more frequently than did women in the comparison group ( $P=.006$ ), although there were no differences in duration of breast-feeding (duration data not shown). By the 24th



Table 5.—Adjusted Incidence of Child Health Care Encounters in Which Injuries and Ingestions Were Detected During Children's First 2 Years of Life, by Treatment Condition\*

Dependent Variables	Comparison Group, Incidence† (Log-Incidence)	Nurse-Visited Group, Incidence† (Log-Incidence)	Log-Incidence Difference‡	95% Confidence Interval
Total No. of health care encounters— injuries/ingestions	0.56 (−0.59)	0.43 (−0.84)	0.25§	−0.00 to 0.50
No. of outpatient visits— injuries/ingestions	0.20 (−1.62)	0.11 (−2.19)	0.57§	0.10 to 1.04
No. of emergency department visits— injuries/ingestions	0.34 (−1.10)	0.33 (−1.12)	0.02	−0.27 to 0.31
No. of hospitalizations— injuries/ingestions	0.03 (−3.63)	0.01 (−4.31)	0.68	−0.66 to 2.02
No. of days hospitalized— injuries/ingestions	0.18 (−1.84)	0.04 (−3.47)	1.64	0.78 to 2.50

\*Estimates adjusted for maternal psychological resources, discretionary household income, and poverty level of census tract. Comparison group was treatment group 2; nurse-visited group, treatment group 4.

†Incidence = mean number of infrequently occurring events within stated time period. Individual cases may have values greater than 1, although the range is small.

‡Difference = (comparison log-incidence) − (nurse-visited log-incidence).

§ $P \leq .05$ .

|| $P < .01$ .

Table 6.—Diagnoses for Hospitalizations in Which Injuries and Ingestions Were Detected, by Treatment Condition

Diagnosis	Age, mo	Sex	Length of Stay, d
<b>Nurse-Visited (Treatment Group 4)</b>			
Burns (1st and 2nd degree to face)	12.0	M	2
Coin ingestion	12.1	M	1
Ingestion of iron medication	20.4	F	4
<b>Comparison (Treatment Group 2)</b>			
Head trauma	2.4	M	1
Fractured fibula/congenital syphilis	2.4	M	12
Strangulated hernia with delay in seeking care/burns (1st degree to lips)	3.5	M	15
Bilateral subdural hematoma*	4.9	F	19
Fractured skull	5.2	F	5
Bilateral subdural hematoma (unresolved)/ aseptic meningitis—2nd hospitalization*	5.3	F	4
Fractured skull	7.8	F	3
Coin ingestion	10.9	M	2
Child abuse/neglect suspected	14.6	M	2
Fractured tibia	14.8	M	2
Burns (2nd degree to face/neck)	15.1	M	5
Burns (2nd and 3rd degree to bilateral leg)†	19.6	M	4
Gastroenteritis/head trauma	20.0	F	3
Burns (splinting/grafting)—2nd hospitalization†	20.1	M	6
Finger injury/osteomyelitis	23.0	M	6

\*One child was hospitalized twice with a single bilateral subdural hematoma.

†One child was hospitalized twice for burns resulting from a single incident.

month of the child's life, in contrast to comparison-group counterparts, nurse-visited women held fewer beliefs about child-rearing associated with child abuse and neglect—lack of empathy, belief in physical punishment, unrealistic expectations for infants ( $P = .003$ ). Moreover, the homes of nurse-visited women were rated as more conducive to children's development by means of the Home Observation for Measurement of the Environment scale ( $P = .003$ ). There was no program effect on maternal teaching behavior, but children born to nurse-visited mothers with low psychological resources were observed to be more communicative and responsive toward their mothers than were children born to low-resource mothers in the comparison group (17.9 vs 17.2;  $P = .03$ ; data not shown). There were no program effects

on the children's use of well-child care, immunization status, mental development, or reported behavioral problems.

### Maternal Life Course

By the 24th month post partum (Table 8), nurse-visited women reported having fewer second pregnancies and fewer subsequent live births than did women in the comparison group ( $P = .006$  and  $P = .01$ , respectively). The program-control difference in subsequent live births was limited to women with high levels of psychological resources, for whom the rates were 14% vs 31%, respectively ( $P < .001$ ). Although there was some indication that nurse-visited women may have used AFDC slightly less during the second year of the child's life ( $P = .07$ ), there were no program effects on reported educational achieve-

ment or length of employment. By the 24th month, nurse-visited women reported higher levels of perceived mastery ( $P = .005$ ).

### COMMENT

For the prenatal phase of the trial, there were no treatment differences in length of gestation or birth weight, but there were differences in PIH. For the postnatal phase of the trial, children born to women visited by nurses during pregnancy and infancy had fewer health care encounters in which injuries and ingestions were detected and fewer hospitalization days in which injuries and ingestions were detected than did children in the comparison group (a difference accounted for by more severe and complex diagnoses for comparison children). In addition, nurse-visited women had fewer subsequent pregnancies and live births than did comparison group women.

The pattern of results for the prenatal phase of the study is different from that obtained in the Elmira trial and may be accounted for by different types of risks exhibited by African-American and white women enrolled in the 2 trials. Only 9% of the participants in the current trial smoked 1 or more cigarettes per day at registration, in contrast to 55% in the Elmira trial. Moreover, even in the current study, 6% of the African Americans vs 53% of the whites reported smoking cigarettes. The rates of sexually transmitted diseases, on the other hand, were higher in the current trial among African Americans (47%) than whites (16%). These differences in putative risks for adverse pregnancy outcome may help explain the difference in impact of the prenatal phase of the program in Elmira vs Memphis.

Although a reduction in PIH was hypothesized on the basis of results from the Elmira trial,<sup>7</sup> the information in the medical record did not allow us to make a reliable distinction between preeclampsia or gestational hypertension (nonproteinuric hypertension). Given the nurses' heightened awareness of hypertensive disorders, their monitoring of blood pressure, and their urging the women to communicate with office staff when problems were emerging, it is reasonable to assume that less serious manifestations of PIH were detected in the nurse-visited group. This may help to explain the lower mean arterial blood pressure measured at admission for labor and delivery in the nurse-visited women with PIH. The nurses' promotion of women's eating well-balanced diets, rest, and exercise may explain the reduction in PIH, given that calcium has been shown to reduce the rates of preeclampsia<sup>32,33</sup> and that exercise has been associated with a reduction in both preeclampsia and gestational hypertension.<sup>34</sup>

Additional findings from the current trial are consistent with other studies designed to reduce preterm delivery by increasing the monitoring of pregnant women.<sup>35</sup> We found a higher rate of predelivery hospitalization among the nurse-visited women who were in school at registration. The combination of nurses' attention to obstetric complications and a corresponding heightened awareness of these pregnant adolescents' health problems by school officials may have led to greater detection of emerging obstetrical complications and created increased pressure to hospitalize. The lower rate of yeast infections diagnosed after randomization in the nurse-visited groups is probably a reflection of the highly detectable symptoms of yeast infections and the nurses' urging women to comply with treatment.

Findings from the postnatal phase of the current trial, including the reduction in injuries and ingestions noted in the medical record, are more consistent with the Elmira study.<sup>8,11</sup> It is likely that some portion of the reduction in health care encounters in which injuries and ingestions were detected resulted from the nurses having taught women to observe their children's behavior for signs of illness, to take temperatures, and to call the office staff for guidance when problems arose. In theory, this should have led to a reduction in unnecessary health care encounters and an increase in problems that required more thorough evaluation. The reduction in outpatient encounters where injuries and ingestions were detected may be explained, at least in part, by this feature of the program.

A review of the diagnoses associated with children's hospitalizations, on the other hand, suggests that some portion of the treatment difference in number of days that children were hospitalized with injuries and ingestions resulted from the prevention of deficient caregiving and, in some cases, the prevention of child abuse and neglect. Our interpretation that these treatment differences are indicative of a reduction in deficient caregiving is supported by independent measures of the mothers' childrearing behaviors.

Nurse-visited women attempted breast-feeding more frequently; they provided home environments that were more conducive to children's intellectual and socioemotional development; and they expressed greater empathy, fewer unrealistic expectations, and diminished belief in the value of physical punishment for infants than did comparison-group mothers. While we cannot rule out the possibility that nurse-visited women simply provided more socially desirable responses, some of the beneficial effects of

Table 7.—Adjusted Outcomes on Qualities of Caregiving and Children's Use of Well-Child Care, Immunization Rates, Mental Development, and Behavioral Problems, by Treatment Condition\*

Dependent Variables	Comparison Group, %	Nurse-Visited Group, %	Odds Ratio†	95% Confidence Interval
Breastfeeding (attempted)	16	26	1.9‡	1.2 to 2.9
Immunizations up to date at 2 y	68	70	1.1	0.7 to 1.5
	Mean	Mean	Mean Difference§	95% Confidence Interval
No. of well-child visits (0-24 mo)	4.8	4.6	0.2	-0.1 to 0.6
Beliefs associated with child abuse, Bavolet total score	100.5	98.7	1.9‡	0.6 to 3.1
Emotional/cognitive stimulation, HOME total score	30.9	32.3	-1.3‡	-2.2 to -0.4
Maternal teaching, NCAST maternal total score	36.5	36.7	-0.2	-0.9 to 0.5
Child responsiveness, NCAST child total score	17.4	17.7	-0.3	-0.7 to 0.1
Bayley mental development score	94.3	94.5	-0.2	-2.4 to 2.0
Behavior problems total score	49.2	46.0	3.2	-0.6 to 7.0

\*Estimates adjusted for maternal psychological resources, discretionary household income, and poverty level of census tract. Comparison group was treatment group 2; nurse-visited group, treatment group 4. HOME indicates Home Observation for Measurement of the Environment; NCAST, Nursing Child Assessment Satellite Training.

†Odds =  $p/(1-p)$ ; odds ratio = nurse-visited odds/comparison odds.

‡ $P < .01$ .

§Difference = (comparison mean) - (nurse-visited mean).

Table 8.—Adjusted Maternal Life Course Outcomes During First 2 Years Post Partum, by Treatment Condition\*

Dependent Variables	Comparison Group, %	Nurse-Visited Group, %	Odds Ratio†	95% Confidence Interval
Subsequent pregnancy, 0-24 mo	47	36	0.6‡	0.4 to 0.9
Spontaneous abortion, 0-24 mo	3	5	1.5	0.7 to 3.4
Therapeutic abortion, 0-24 mo	4	2	0.5	0.2 to 1.4
Subsequent live birth, 0-24 mo	31	22	0.6‡	0.4 to 0.9
	Mean	Mean	Mean Difference	95% Confidence Interval
No. of months worked, 0-12 mo	1.7	2.2	-0.5	-1.0 to 0.0
No. of months worked, 13-24 mo	3.4	3.4	0.0	-0.7 to 0.7
No. of months on AFDC, 0-12 mo	7.6	7.3	0.3	-0.4 to 1.1
No. of months on AFDC, 13-24 mo	8.4	7.8	0.7	-0.0 to 1.4
Anxiety, 24 mo¶	100.3	99.1	1.2	-0.4 to 2.7
Depression, 24 mo¶	100.1	99.5	0.6	-1.0 to 2.2
Mastery, 24 mo¶	99.4	101.6	-2.2‡	-3.8 to -0.7

\*Estimates adjusted for psychological resources, discretionary household income, and poverty level of census tract. Comparison group was treatment group 2; nurse-visited group, treatment group 4. AFDC indicates Aid to Families With Dependent Children.

†Odds =  $p/(1-p)$ ; odds ratio = nurse-visited odds/comparison odds.

‡ $P < .01$ .

§Difference = comparison mean - nurse-visited mean.

|| $P < .10$ .

¶Standardized to sample mean=100; SD=10.

the program are based on data derived from reviews of medical records.

Many of the effects of the program on health care encounters in which injuries and ingestions were detected and on qualities of childrearing were greater for mothers with low psychological resources. For example, in contrast to counterparts in the comparison group, the children of nurse-visited mothers who had few psychological resources were observed to be more responsive and communicative toward their mothers. Infant-attachment research suggests that toddlers' behavior toward their mothers reveals the extent to which their mothers are sensitive and responsive rather than hostile, intrusive, or neglectful toward them, with toddlers' behavior being a better indication of the quality of the parent-child

relationship over time than currently observed behaviors of parents.<sup>36,37</sup>

It is important to note, in this regard, that the program was designed to decrease risks posed by limited intellectual functioning, mental health, and mastery on the part of caregivers.<sup>20</sup> The program provided a detailed educational protocol designed to help parents understand and respond appropriately to their children's unique temperament and communicative style by means of educational materials adapted to the intellectual levels of the mothers. Given that limited knowledge and capacity to anticipate children's needs can compromise parents' ability to care for their children, it is reasonable that this program would reduce risks imparted by limited intellectual functioning, even in the absence of an effect on maternal intellectual functioning.



While the program produced no effect on mothers' mental health, it may have reduced psychological distress related to parents' care of their children, which is affected by parents' depression and sense of competence.<sup>38,39</sup> Moreover, by the end of the program at the children's second birthday, there were significant treatment effects on women's sense of mastery. Mastery is a general psychological attribute that affects parents' ability to cope effectively with a wide range of challenges, and a deficit in mastery has been associated with child abuse and neglect.<sup>40</sup> Thus, the program diminished risks posed by limited intellectual functioning, psychological distress, and impaired sense of mastery.

Although there also was a trend for the nurse-visited women to use AFDC about 0.7 month less during the child's second year of life than did women in the comparison group, there were no treatment-comparison differences in educational achievement or labor-force participation after delivery, despite nurse-visited women being in the labor force to a greater degree at the end of preg-

nancy. The discrepancy between the findings for these 2 phases of the study will be examined in future reports. In the Elmira trial, the influence of the program on workforce participation did not emerge until the 2-year period after the program ended, and the influence of the program on promoting women's economic self-sufficiency was preceded by a reduction in the rate of subsequent pregnancy.<sup>9</sup> A 15-year follow-up of the Elmira sample now indicates that these early alterations of maternal life course portend substantial improvements in major maternal life outcomes.<sup>41</sup> It will be important to determine whether a corresponding pattern of results emerges in Memphis after the program ends.

Although one might consider dropping the prenatal phase of the program from the intervention in light of its failure to produce substantial prenatal and newborn effects in the current trial, this would be injudicious. We have only limited insight into the extent to which the salutary postnatal effects are dependent on the prenatal initiation of the service. This issue deserves careful examination

as the program is studied with new populations and in new contexts.

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