
Reducing Low Birth Weight Through Home Visitation

A Randomized Controlled Trial

Eunju Lee, PhD, Susan D. Mitchell-Herzfeld, MA, Ann A. Lowenfels, MPH, Rose Greene, MA, Vajeera Dorabawila, PhD, Kimberly A. DuMont, PhD

- Background:** Poor birth outcomes increase the risk of infant mortality and morbidity, developmental delays, and child maltreatment. This study assessed the effectiveness of a prenatal home-visitation program in reducing adverse birth outcomes among socially disadvantaged pregnant women and adolescents.
- Design:** As part of a larger RCT, this study examined the effects of home-visitation services on low birth weight (LBW) deliveries.
- Setting/ participants:** Pregnant women and adolescents eligible for Healthy Families New York (HFNY) were recruited in three communities. Eligibility was based on socioeconomic factors such as poverty, teen pregnancy, and the risk of child maltreatment. Two thirds of the participants were black or Hispanic, and 90% were unmarried.
- Intervention:** Pregnant women and adolescents were randomized to either an intervention group that received bi-weekly home-visitation services ($n=236$) or to a control group ($n=265$). Home visitors encouraged healthy prenatal behavior, offered social support, and provided a linkage to medical and other community services. Services were tailored to individual needs.
- Main outcome measure:** An LBW of <2500 grams on birth certificate files. Baseline and birth interviews were conducted from 2000 to 2002, and birth records were collected in 2007. Analyses were done from 2007 to 2008.
- Results:** The risk of delivering an LBW baby was significantly lower for the HFNY group (5.1%) than for the control group (9.8%; AOR=0.43; 95% CI=0.21, 0.89). The risk was further reduced for mothers who were exposed to HFNY at a gestational age of ≤ 24 weeks (AOR=0.32; 95% CI=0.14, 0.74).
- Conclusions:** A prenatal home-visitation program with focus on social support, health education, and access to services holds promise for reducing LBW deliveries among at-risk women and adolescents.
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Introduction

Poor birth outcomes can have negative consequences for children's health and development and have been associated with increased risk for maltreatment. Preterm and low birth weight (LBW) babies face an elevated chance of early mortality,^{1,2} health problems, and developmental delays.^{3,4} LBW infants are twice as likely as their normal-weight peers to be placed in foster care⁵ and to be maltreated over their early years of life.⁶ In response, *Healthy People*

2010, the national health agenda, established a goal to reduce the prevalence of LBW to 5.0%.⁷

Pregnant women who are young, black, poor, or a combination thereof face a substantially higher risk of delivering LBW babies than other mothers.^{8–13} The disparities persist¹⁴ despite the proliferation of programs designed to address socioeconomic disadvantages during pregnancy.^{15–25} The persistence of elevated LBW numbers among disadvantaged women and adolescents highlights the need for further rigorous research to identify approaches that are effective in serving these populations.

Home visitation is a service-delivery strategy that holds promise for improving birth outcomes for pregnant women and adolescents who may lack strong social support networks and be reluctant or unable to seek assistance outside the home.^{16,22–24,26,27} From services for the poor at the turn of the century to preven-

From the Center for Human Services Research, School of Social Welfare, University at Albany, State University of New York (Lee, Lowenfels, Greene); and the Bureau of Evaluation and Research, New York State Office of Children and Family Services (Mitchell-Herzfeld, Dorabawila, DuMont), Albany, New York

Address correspondence and reprint requests to: Eunju Lee, PhD, Center for Human Services Research, School of Social Welfare, University at Albany, 135 Western Avenue, Albany NY 12222. E-mail: elee@uamail.albany.edu.

tion programs for disadvantaged expectant and new mothers today, home visitation brings services directly to those most in need.^{28–33} Recommendations from national advisory boards^{34–36} have spurred the implementation of home-visitation models varying in scope, content, target population, service intensity, and staff qualifications,^{27,33,37,38} with the increasing use of state and local funds.³⁹

Despite the widespread use of home visitation in prevention programs,^{16–20,22–27,40–43} only two RCTs found a program that affected LBW.^{17,26} One program offering a targeted social support intervention for pregnant black women achieved reductions in LBW for initial births.¹⁷ The other program, which used a broad-based approach to provide social support, education, and care coordination to expectant mothers of varying racial/ethnic groups, reduced the rate of LBW for subsequent births.²⁶

The current study used an RCT to evaluate the effects on LBW of Healthy Families New York (HFNY),⁴⁴ a program based on a widely implemented national home-visitation model, Healthy Families America (HFA).^{45–49} Targeting disadvantaged women and adolescents who are pregnant or have recently given birth, HFNY is designed to enhance child health and development, promote positive parenting, and prevent child abuse and neglect.^{44,50} The present study, capitalizing on the HFNY RCT's inclusion of a large number of women and adolescents randomized prenatally,⁴⁹ examined LBW outcomes among the prenatal subsample.

Methods

Study Design

This study is part of a larger trial in which expectant and new mothers eligible for HFNY at three sites were randomly assigned to an intervention condition or a control group.^{49,50} The intervention group was offered HFNY home-visitation services, while the control group was given information and referrals to services other than home visitation. The current study is based on a subset of pregnant women and adolescents who were part of the larger trial's sample. Baseline interviews were conducted with all women and adolescents participating in the trial and, for the pregnant cohort, brief follow-up interviews were conducted shortly after the child's birth. The protocol was approved by the IRB of the University at Albany–State University of New York. Baseline and birth interviews were conducted between 2000 and 2002, and birth certificate records were obtained in 2007. Analyses were done in 2007 and 2008.

Recruitment and the Prenatal Sample

The target population for HFNY consists of pregnant women and adolescents at any gestational age and new mothers with an infant aged <3 months who live in communities that have high rates of teen pregnancy, LBW babies, infant mortality, Medicaid births, and mothers with late or no prenatal care. Slightly more than half of the participants enroll in HFNY

while pregnant, and are therefore eligible to receive prenatal home-visitation services.

Through a network of community service agencies, prospective participants are screened for socioeconomic risk factors such as poverty, teen pregnancy, and not being married. Women and adolescents who screen positive are referred to a local HFNY program, where, through the use of the family stress checklist, they are further assessed for the risk of engaging in child abuse and neglect.⁵¹ Eligibility for HFNY is limited to those who have a score indicating a high risk of child maltreatment and who live under or at 200% of the federal poverty guidelines.

The trial was conducted at three established program sites chosen for their capacity to recruit a sufficient sample size and to provide geographic and demographic diversity. Site A was associated with a prenatal/perinatal service organization and drew its clientele from predominantly black and Hispanic neighborhoods within a large upstate city. Site B was affiliated with a local hospital and served primarily white clients. Site C, nested within a family health center, had primarily white clients but also had substantial Hispanic representation. Site A provided half the sample, while Sites B and C each provided one quarter.

Over the 18-month sample-selection period, 1297 women and adolescents agreed to participate in the trial and were randomized (Figure 1). Baseline interviews were completed in the home for 1173 participants (HFNY, *n*=579; control, *n*=594) by independent research staff, some of whom were bilingual. At baseline, approximately half of the participants were pregnant. The pregnant cohort completed follow-up interviews about their pregnancy and birth experiences following the target child's birth.

To verify maternal reports of birth outcomes, birth certificate data were obtained from the New York State Department

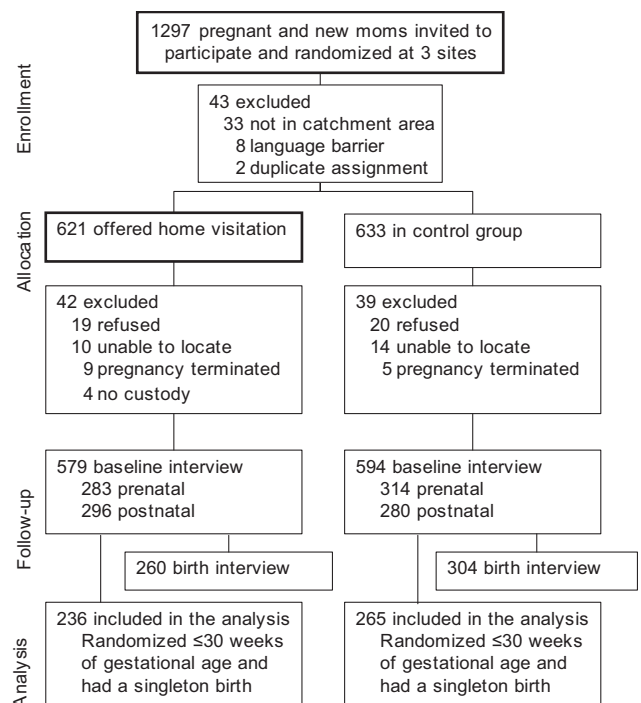


Figure 1. Randomization of trial participants and selection of the prenatal subsample

of Health (NYSDOH) for mothers who were randomly assigned prenatally and provided informed consent to a review of the target child's birth records. The match was performed using the names and dates of birth of the child and the mother and resulted in finding birth certificate data for 99% of the cases.

The analysis sample for the current study comprised mothers who had a single birth and were randomized at a gestational age of ≤ 30 weeks to allow sufficient time prior to birth to benefit from prenatal home-visitation services. The gestational age at randomization was calculated using the study's random assignment date and the date of the first day of the last menstrual period (LMP) obtained from NYSDOH birth records. This information was available for 501 (HFNY, $n=236$; control, $n=265$) of the 545 mothers who had birth weight data.

The LMP, birth weight, and other data from NYSDOH's birth file have shown a high degree of accuracy when compared to obstetricians' medical records and are a reliable data source for examining birth outcomes.⁵² In addition, researchers recommend estimating gestational age at birth based on the LMP rather than relying on neonatal estimates of gestational age, which tend to be less precise although clinically relevant.^{53,54} The selection of the subsample based on gestational age is consistent with methods used in other evaluations of prenatal prevention programs.^{15-17,23,24,26}

Interventions

Once an expectant mother agreed to participate in HFNY, she was assigned to a home visitor who initiated contact and scheduled home visits. The home visitor, indigenous to the community, shared the same language and cultural background as the program participants. Home visitors varied in age (median=38 years) and typically had experience working with infants and young children; approximately half had some college education but did not have nursing or professional degrees. All home visitors received intensive training by certified HFA trainers and received weekly supervision. During the prenatal period, home visitors were expected to make bi-weekly visits lasting an average of 1 hour. Visits generally took place at home, but home visitors could accompany participants to other services, if needed. The goal was to assist expectant mothers in attaining an optimal pregnancy experience.

To this end, prenatal home visits focused on three related activities: improving the mother's social support, providing prenatal education, and linking the mother to other services in the community. First, home visitors worked with participants to establish a trusting relationship, discuss their psychological preparedness for motherhood, and develop strategies to decrease stress that included problem solving and seeking support from family members. Second, home visitors assisted participants in developing healthy prenatal behaviors by providing information about fetal development; promoting healthy habits such as eating nutritious foods; discouraging risky behaviors such as smoking, drinking, and using illicit drugs or unnecessary medications; and encouraging compliance with prenatal appointments and medical advice. Finally, home visitors helped the expectant mother establish a consistent healthcare provider and facilitated access to other needed services such as food stamps and the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

Measurements

Covariates and independent variables. Group assignment was the primary independent variable. Age and racial/ethnic group were included in the analysis as covariates. If the respondent reported being of Hispanic origin, she was coded as Hispanic regardless of any other racial/ethnic identification. Non-Hispanic respondents were coded as black (ref) or white. The three program sites were coded as dummy variables, with the largest site serving as the referent. This site was exclusively urban; the two other sites consisted of both urban and rural areas. All respondents were asked whether they or someone in their household received cash assistance through temporary assistance for needy families (TANF) at baseline. TANF receipt was used as a proxy for abject poverty. The number of previous pregnancies recorded in the birth certificate data served as a measure of maternal reproductive history.

As smoking is consistently and significantly associated with adverse birth outcomes,^{55,56} it was included as a covariate. The prenatal smoking data on birth certificate records were incomplete, so the study used data collected from the interviews. Expectant mothers were asked about current and past smoking habits, including the date they quit. Based on this information, a variable was created to indicate whether the respondent ever smoked while pregnant.

Low birth weight. The primary outcome measure was a delivery weight of <2500 grams, calculated from the birth weight recorded on birth certificates. Given the psychosocial focus of the HFNY intervention and previous research suggesting that programs with a psychosocial emphasis have little impact on prematurity, the study did not expect HFNY to affect levels of preterm birth.^{17,26,57,58} However, because preterm birth is a major contributing factor to LBW, its association to LBW was examined in the study. Preterm birth was coded as <37 weeks of gestational age, based on the first day of the LMP.

Analyses

All women and adolescents in the prenatal sample who were assigned to the HFNY group were included in the analyses regardless of their level of participation in the program. This approach was intended to preserve the equivalence of the groups achieved through randomization. Demographic risk factors and outcome variables were examined for differences between the intervention and control groups using *t*-test and chi-square statistics. Binary logistic regressions were used to examine the effects of HFNY on the prevalence of LBW, and a goodness-of-fit test was conducted to assess the overall fit of the model.⁵⁹

Analyses were run for the full prenatal sample: 501 women and adolescents who were randomized at a gestational age of ≤ 30 weeks. In order to explore whether better outcomes were associated with earlier enrollment, subsequent analyses were then limited to participants randomized at a gestational age of either ≤ 24 weeks or ≤ 16 weeks. Because the sample was pulled from three sites and consisted of mothers of varying racial/ethnic groups, analyses were done for each site and for different racial/ethnic groups to further understand program effects. All logistic models included the covariates described earlier. AORs and 95% CIs were calculated for the prevalence of LBW.

To understand the possible mechanisms underlying reductions in LBW, the study first examined changes in the percentage of women and adolescents having a primary care

provider from pregnancy to birth for both groups. In addition, the study examined program data from the HFNY administrative database for those who enrolled in HFNY. A particular focus was on program dosage and the linkages to social and health services arranged by home visitors.

To test the association of preterm births to LBW, the study compared the prevalence of prematurity for LBW babies to healthy-weight babies. Then it explored whether HFNY was associated with fetal weight gain regardless of whether the mother carried the baby to term. Relying on national birth weight percentiles for gestational age by racial/ethnic group,⁶⁰ the incidence of small-for-gestational-age (SGA) births was calculated, and the mean weights were compared by group and gestational age. SAS and SPSS software were used for all statistical analyses.

Results

Study Participant Characteristics

Table 1 summarizes the demographic characteristics and risk factors for the prenatal sample, showing that the intervention and control groups were largely equivalent. Due to site variation in prenatal enrollment, Site B made up less than the expected 25% of the prenatal sample. Otherwise, the prenatal sample resembled the overall population in the trial (not presented).⁴⁹ The prenatal sample included a sizable number of women and adolescents known to be at increased risk for poor birth outcomes: young, unmarried, and receiving welfare. Black respondents made up close to half of the sample, and Hispanics approximately one fourth.

Reduction in Prevalence of LBW

As shown in **Table 2**, the mothers in the HFNY group were significantly less likely to have LBW babies than the mothers in the control group (5.1% vs 9.8%, respectively). These effects remained even after adjusting for covariates (AOR=0.43). Further, earlier enrollment in the program was associated with a larger reduction in LBW. Odds for LBW (AOR=0.32) were further reduced for mothers randomized at a gestational age of ≤ 24 weeks—a group that had the potential to receive prenatal home-visitation services for at least 3 months—and even lower for mothers randomized at a gestational age of ≤ 16 weeks (AOR=0.13).

To assess the potential for missing data to influence findings, the study re-analyzed LBW after substituting clinical estimates of gestational age for the 44 mothers who were missing the date of the LMP.⁵³ This

substitution increased the size of the prenatal sample to 545. The results were consistent with those from the sample using only the LMP for gestational age, indicating reduced odds of LBW across the three gestational age groups that were examined (AOR=0.56, 0.47, and 0.16, respectively; data not shown).

Post-hoc analyses were conducted to examine whether the outcomes varied by racial/ethnic group, given the differential risks for LBW. Black mothers assigned to the HFNY group at ≤ 30 weeks' gestation were significantly less likely than black mothers in the control group to deliver LBW babies (3.1% vs 10.2%, respectively). Although not significant, levels of LBW were noticeably lower for Hispanics in the HFNY group than for those in the control group. There was little difference in LBW among white mothers in the HFNY and control groups.

Program effects were also estimated within each of the three sites to test the robustness of the results. At Site B, LBW levels were similar for the HFNY and the control-group mothers, but were markedly lower for HFNY mothers compared to control-group mothers at Site A and Site C.

Potential Mechanisms

Home visits. Among the mothers assigned to the HFNY group, 7.6% did not receive any prenatal home visits. These mothers either did not enroll in time to receive the visits or did not enroll in HFNY at all. Those who did enroll received a median of seven prenatal visits (range: 1–28 visits), and 95% of these visits addressed prenatal health issues including stress, medical appointments, nutrition, or risk behaviors. Moreover, there were differences in the number of home visits depending on when the mothers were offered the program. The participants who were randomized at a gestational age of ≤ 16 weeks received a median of nine visits, while those who were

Table 1. Characteristics and risk indicators of the prenatal subsample, Healthy Families New York (HFNY) RCT

	HFNY n (%)	Control n (%)	All n (%)	p-value
Maternal racial/ethnic group				
Black	98 (41.5)	127 (47.9)	225 (44.9)	0.626
Hispanic	58 (24.6)	54 (20.4)	112 (22.4)	0.283
White	74 (31.4)	77 (29.1)	151 (30.1)	0.626
Aged <18 years	58 (24.6)	51 (19.2)	109 (21.8)	0.159
Currently married	25 (10.6)	25 (9.4)	50 (10.0)	0.766
Receiving TANF	64 (27.2)	52 (19.7)	116 (23.2)	0.056
Smoked while pregnant	69 (29.2)	66 (24.9)	135 (26.9)	0.313
First-time mother	131 (55.5)	151 (57.0)	282 (56.3)	0.787
M of previous pregnancies	1.6	1.4	1.5	0.352
Site A	124 (52.5)	133 (50.2)	257 (51.3)	0.654
Site B	40 (16.9)	51 (19.2)	91 (18.2)	0.562
Site C	72 (30.5)	81 (30.6)	153 (30.5)	1.000
n	236 (47.1)	265 (52.9)	501 (100.0)	

TANF, Temporary Assistance for Needy Families

Table 2. Prevalence of low birth weight in HFNY and control groups by program exposure, racial/ethnic group, and site

Program exposure ^a	HFNY n (%)	Control n (%)	AOR (95% CI)	Sig.	n
Randomized at ≤30 weeks pregnant	12 (5.1)	26 (9.8)	0.43 (0.21, 0.89)	0.022	501
Randomized at ≤24 weeks pregnant	9 (5.1)	22 (11.3)	0.32 (0.14, 0.74)	0.008	371
Randomized at ≤16 weeks pregnant	3 (3.6)	12 (14.1)	0.13 (0.03, 0.59)	0.008	169
Racial/ethnic group^b					
Black	3 (3.1)	13 (10.2)	0.21 (0.06, 0.80)	0.022	225
Hispanic	3 (5.2)	5 (9.3)	0.43 (0.09, 2.04)	0.285	112
White	6 (8.1)	7 (9.1)	0.85 (0.20, 1.67)	0.785	151
Site^c					
A: Urban	7 (5.6)	16 (12.0)	0.38 (0.15, 0.99)	0.048	257
B: Urban and rural	3 (5.9)	3 (7.3)	0.66 (0.18, 5.61)	0.672	91
C: Urban and rural	3 (4.2)	7 (8.6)	0.30 (0.06, 1.47)	0.138	153

^aAORs are adjusted for prenatal smoking, TANF receipt, aged <18 years, number of previous pregnancies, racial/ethnic group, and site.

^bAORs are adjusted for prenatal smoking, TANF receipt, aged <18 years, number of previous pregnancies, and racial/ethnic group.

^cAORs are adjusted for prenatal smoking, TANF receipt, aged <18 years, number of previous pregnancies, and site.

HFNY, Healthy Families New York; Sig., significance; TANF, Temporary Assistance for Needy Families

offered the program at a gestational age of ≤24 weeks received a median of eight visits.

To understand the relationship between the intensity of home visits and LBW, the HFNY group was divided into two strata: one with zero to six visits and the other with seven or more visits (median=7). The prevalence of LBW was lower for the group of HFNY mothers with seven or more visits than for those with zero to six visits (2.7% vs 7.2%; OR=0.30; $p=0.079$).

Linkage to medical and community services. As indicated in Figure 2, home visitors improved expectant mothers' linkage to primary care providers between baseline and birth, whereas there was no change in the percentage of control-group mothers with a primary care provider. No group differences were found in maternal reports of the frequency of prenatal care visits during the third trimester, despite the fact that home visitors provided assistance with transportation and emphasized the need to keep medical appointments.

Program data showed that home visitors helped expectant mothers to access community services. The

most common referrals were to WIC, food-stamps services, and food pantries or nutritional counseling. Other mothers were assisted with finding better housing and securing clothing and furniture. However, because comparable data on service referrals were not collected for the control group, it is not possible to assess the potential contribution of increased access to community services to reductions in LBW among HFNY mothers.

Birth Weight, Preterm Birth, and SGA

Finally, the study examined whether the reduction in LBW was associated with a decrease in preterm births. As expected, no significant differences were found in preterm births between the HFNY group and the control group. There was, however, a significant relationship between LBW and preterm birth. While 60.5% of the LBW babies were born preterm, only 8.9% of the normal-weight babies were premature.

Although the results were not significant, HFNY mothers delivered fewer SGA babies than control-group mothers. Among the full-term births, 18 HFNY babies (8.8%) were SGA compared to 27 control-group babies (11.6%), and HFNY babies weighed 41 grams more, on average, than control-group babies. A similar pattern was observed for babies born between 20 and 36 weeks' gestation. One baby (3.2%) in the HFNY group was SGA compared to four infants (12.5%) in the control group, while the mean weight of HFNY babies was 79 grams heavier than that of control-group babies.

Discussion

The current study found that home-visited mothers were approximately half as likely as mothers assigned to the control group to deliver LBW babies. Indeed, the percentage of LBW for the home-visited mothers met *Healthy*

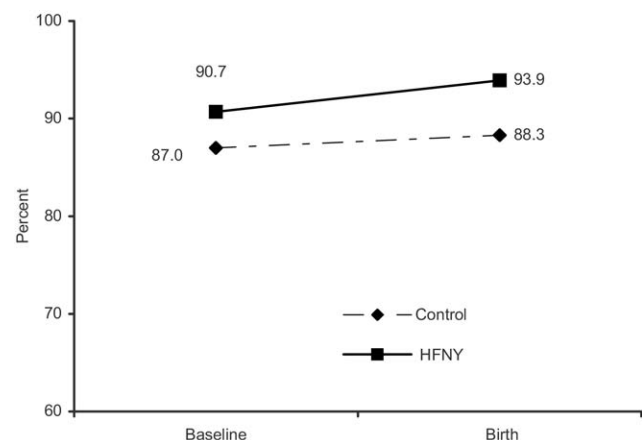


Figure 2. Changes in mothers with primary care providers in Healthy Families New York (HFNY) and control group ($n=461$)

People 2010's goal of reducing the prevalence of LBW to 5.0%. Further, mothers offered home-visitation services earlier in their pregnancies experienced even greater reductions in LBW, suggesting a benefit of engaging vulnerable participants early in pregnancy. Black and Hispanic mothers in the HFNY group had lower rates of LBW than their counterparts in the control group, whereas no difference was observed among white mothers. The reduction in LBW was particularly pronounced for black mothers in the HFNY group.

Unfortunately, the study's ability to pinpoint the exact mechanisms through which the program exerted its effects was compromised by the larger RCT's broader objectives. For example, while program data indicated that home visitors helped mothers to access resources such as nutrition programs or better housing, the lack of comparable data on the services received by the control group prevented the analysis of the role of such services in explaining the reductions in LBW. Similarly, the study did not measure the home visitors' role in reducing mothers' stress or in increasing social support.

This study does, however, provide some insight about how the home visitor may assist the expectant mother to achieve an optimal pregnancy experience: providing psychosocial support, improving linkages to medical providers as well as to nutrition and social services, and encouraging healthy prenatal behaviors. Studies have shown that access to services and case management for teenage or low-income mothers resulted in better birth outcomes.^{15,16,18–20,23,24,26,47,61} Research also has indicated that the rate of LBW for black mothers is associated with aspects of the social environment that are amenable to change, including social support and neighborhood characteristics.^{13,17,62,63} Thus, social and tangible support by a home visitor may have contributed to a healthier and less stressful pregnancy and may have lowered the likelihood of LBW, especially among black mothers.^{17,62}

The study suggests that HFNY prenatal home visitation is associated with reduced LBW deliveries. It adds to a growing body of research evaluating the benefits of prenatal prevention programs targeting vulnerable populations with enhanced, multifaceted services.

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