Does Additional Prenatal Care in the Home Improve Birth Outcomes for Women with a Prior Preterm Delivery? A Randomized Clinical Trial

Melanie Lutenbacher · Patricia Temple Gabbe · Sharon M. Karp · Mary S. Dietrich · Deborah Narrigan · Lavenia Carpenter · William Walsh

Abstract   Women with a history of a prior preterm birth (PTB) have a high probability of a recurrent preterm birth. Some risk factors and health behaviors that contribute to PTB may be amenable to intervention. Home visitation is a promising method to deliver evidence based interventions. We evaluated a system of care designed to reduce preterm births and hospital length of stay in a sample of pregnant women with a history of a PTB. Single site randomized clinical trial. Eligibility: >18 years with prior live birth ≥20– <37 weeks gestation; <24 weeks gestation at enrollment; spoke and read English; received care at regional medical center. All participants (N = 211) received standard prenatal care. Intervention participants (N = 109) also received home visits by certified nurse-midwives guided by protocols for specific risk factors (e.g., depressive symptoms, abuse, smoking). Data was collected via multiple methods and sources including intervention fidelity assessments. Average age 27.8 years; mean gestational age at enrollment was 15 weeks. Racial breakdown mirrored local demographics. Most had a partner, high school education, and 62 % had Medicaid. No statistically significant group differences were found in gestational age at birth. Intervention participants had a shorter intrapartum length of stay. Enhanced prenatal care by nurse-midwife home visits may limit some risk factors and shorten intrapartum length of stay for women with a prior PTB. This study contributes to knowledge about evidence-based home visit interventions directed at risk factors associated with PTB.

Keywords   Preterm birth · Home visitation · Prenatal care · System of care

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Introduction

Preterm birth (PTB) has garnered persistent and energetic attention over the past 50 years. In spite of these efforts, the problem persists and can, in part, be explained from what has been discovered along the way. Approximately three-fourths of preterm births result from spontaneous onset of labor or premature rupture of membranes prior to 37 weeks gestation [1]. The pathologic process that initiates early, spontaneous birth is only partially understood. For women having one spontaneous preterm birth, the probability of another PTB rises to 30 %, with the risk rising to almost 70 % if the woman has more than one PTB [2, 3], suggesting the influence of genetic factors. In addition, recurrent preterm births tend to occur at an earlier gestational age than the first PTB [4]. While clinicians must await answers to root causes of spontaneous preterm

birth, studies examining the role of short cervical length and specific genetic markers for premature labor appear promising [5–7].

For most women with a prior preterm birth, prevention of recurrence remains elusive, although intramuscular injections of 17-alpha hydroxy progesterone caproate (17-P) started at 16–20 weeks and continued through 36 weeks gestation can reduce the risk of spontaneous recurrent preterm births in some women [8, 9]. Otherwise, decreasing the impact of deleterious maternal health behaviors and harmful exposures associated with preterm birth, and assisting in risk reduction is key to reducing its recurrence. A variety of predisposing factors examined include short cervical length [5], AA race [10, 11], low pre-pregnancy weight [12, 13], low or high gestational weight gain [13], smoking [14, 15], misuse or abuse of illicit substances [16], mental illness [17, 18], lack of or delayed prenatal care [16], experiencing a short interval between pregnancies [19, 20], exposure to socio-environmental stressors such as poverty, food insecurity, or violence [21–25], experiencing infections during pregnancy [26, 27], multiple gestation [28], and the presence of a chronic disease such as diabetes or hypertension [29].

Most studies that have investigated interventions designed to decrease the impact of predisposing factors have offered the interventions in the outpatient setting [30] and often have focused on a single risk such as smoking. On the other hand, home visiting programs aimed at a wide range of health problems have recently garnered significant national interest with the Affordable Care Act (2011) directing over $1.5 billion into the Maternal, Infant, and Early Childhood Home Visiting Program. Home visitation programs could be an effective modality for improving maternal health during and following pregnancy, although only limited empiric evidence supports their effectiveness for pregnant women at risk. Mixed and modest results from studies examining their effects may point to the tenuous nature of home visiting while the potential benefits underscore the importance of further examination of this modality [31–33].

Several clinical trials of home visitation programs for childbearing families have targeted young primigravidas living in poverty with the goal of improving pregnancy, and maternal and child health (e.g., [31–33]). These studies are often considered the best evidence of the effectiveness of home visitation to improve maternal and child health indicators. In a recent report [34], several home visitation programs demonstrate evidence of improving maternal and child health (e.g., [35, 36]). This report and others [37] note, however, that the positive effects of the intervention obtained in initial studies may be weaker or disappear entirely when the home visitation programs are implemented in community practice. Fidelity to intervention is often raised as a critical component of effective implementation but often not considered when evaluating program outcomes. In addition, few studies have focused on other populations of pregnant women, particularly at risk multigravidas.

Results from a study conducted by Brooten and colleagues indicated that home visitation by an advanced practice nurse to high risk pregnant women may be a viable strategy that improves birth outcomes and maternal–infant health [38, 39]. Although an important and encouraging finding, the sample size in their study was small. Prior studies have demonstrated that the risk factors listed earlier may show some improvement with specific interventions. These studies also underscore the importance of developing a therapeutic helping relationship between the provider and the study participant. This relationship facilitates identifying specific risks and personal concerns, and calls on participant strengths to support goal setting and behavioral change [40–43]. Our study builds on Brooten's study, the seminal work of Olds and his colleagues and gaps identified in the literature [34].

This report presents findings from a randomized clinical trial that tested a system of care for pregnant women at high risk of giving birth to a preterm infant due to their history of a prior preterm birth. Our hypothesis was that the study's system of care would result in participants giving birth at a later gestation than the gestational age of the prior preterm birth and in turn, the later gestation would decrease hospital length of stay associated with preterm births when compared to participants receiving standard prenatal care. Standard prenatal care was augmented with protocol driven home visits by nurse midwives during pregnancy. Primary outcomes of interest were participant infants' gestational age at birth, change in gestational age from the prior preterm birth, and maternal length of hospital stay at delivery. We report on the first portion of the study, from enrollment through discharge after delivery.

Methods

This single site randomized clinical trial was approved by the institutional review board of a university in the Southeastern part of the United States (# 070684) and registered at www.clinicaltrials.gov.

Sample

The sample consisted of 217 pregnant women receiving prenatal care with a physician or nurse-midwife at a large regional medical center in the Southeastern US from April, 2007 through January, 2010. Criteria for study eligibility included a confirmed pregnancy with gestation less than 24 weeks at enrollment; a prior preterm birth (i.e., live birth

≥20 weeks and <37 weeks gestation); the ability to speak and read English; living within 90 miles of Vanderbilt University Medical Center; acceptance of nurse home visits; and willingness for random study group assignment. Trained staff determined eligibility by review of medical records for documented history of a prior preterm birth and dating of the current pregnancy (as calculated per Department of Obstetrics protocol). From the 217 women, 104 were randomized to the control group and 113 to the intervention group. We analyzed data for participants who remained in the study for at least 4 weeks following enrollment. The final sample totaled 211 women: 109 intervention and 102 controls. See Consort Flow Diagram, Fig. 1.

Procedure

Recruitment began upon receiving IRB approval for the study protocol. Potentially eligible patients were identified from the daily roster of prenatal patient appointments and invited to participate if deemed eligible. All women agreeing to participate completed a written informed consent process with a trained research assistant in a private area of the clinic per IRB approved protocol. Upon completion of the consent process, the research assistant opened a sealed envelope that contained the group assignment for the participant. Assignments were generated via a series of computerized random identification numbers to either the control or the intervention group conducted by the project statistician. The participant was informed of her group assignment. Once this process was completed, research staff conducted a structured baseline interview. A nurse-midwife was notified within 12 h of women assigned to the intervention group so that an initial home visit could be scheduled. The study goal was for intervention group participants to receive a minimum of five prenatal home visits. The nurse-midwife used study protocols in determining need for additional home visits.

Intervention group participants also had cellular phone access to their assigned nurse-midwife. In contrast, control group participants received only conventional prenatal

Fig. 1 Consort flow diagram
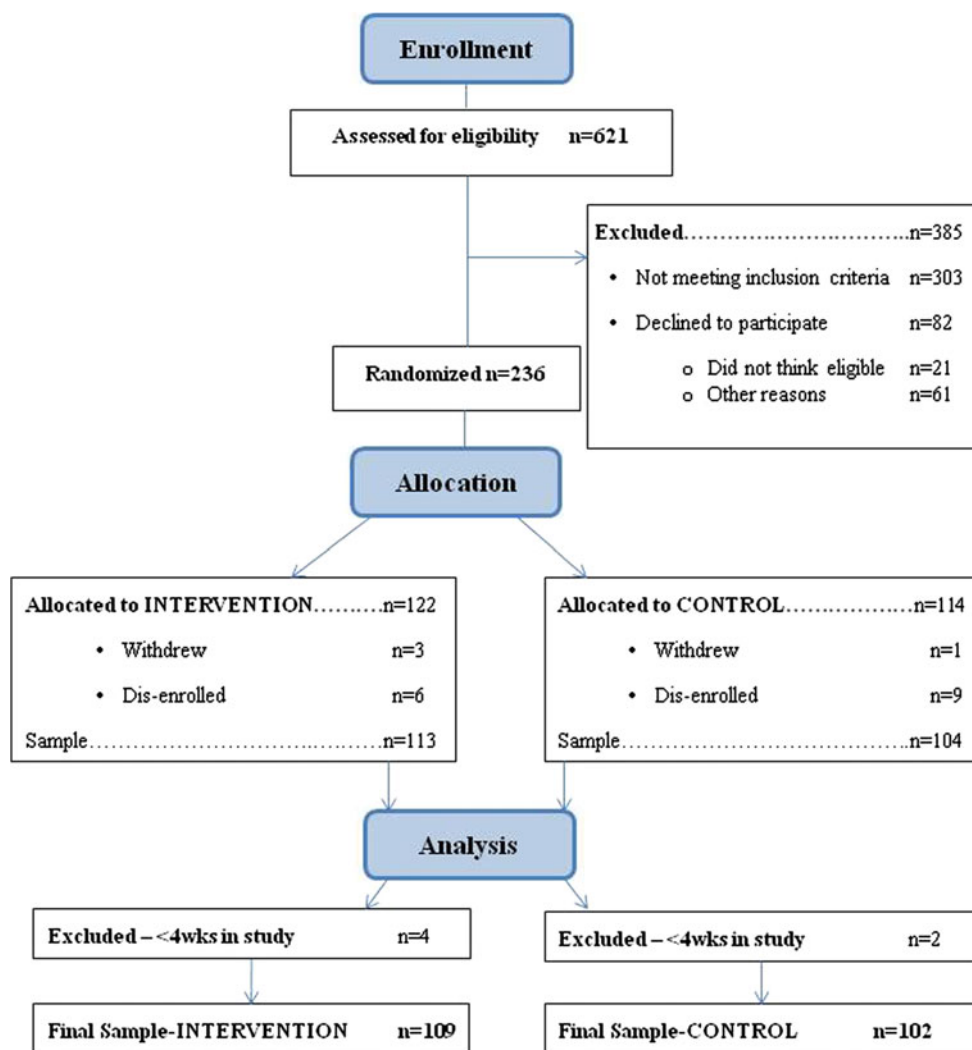
care. During the course of the study, additional resources were added to the prenatal clinic that included a psychiatrist, and a second full time social worker. Both the intervention and control groups experienced this change.

Multiple sources were used to collect behavioral, cost, and outcome data. After the baseline interview at enrollment, all participants had five structured interviews that lasted 30–45 min at approximately 23, 26, 30 and 34 weeks gestation and 48 h postpartum. Baseline interviews at enrollment for all participants were conducted by trained research assistants. For subsequent data collection, control group participants were interviewed by phone while intervention participants had data collection by the nurse-midwife during home visits. This method was intentional as the measures selected for the study were included for their psychometric properties and clinical usefulness. Nurse-midwifes were specifically trained to collect data prior to intervention. Participants were compensated with a gift card to a national retail chain on completion of the 48 h postpartum interview.

Additional data was abstracted from maternal and infant medical and hospital records via a standardized research protocol by trained research assistants. Data for both study groups presented in this manuscript were collected by trained research assistants.

Intervention: System of Care

Specific protocols to decrease malleable risk factors associated with preterm birth guided the home visit intervention. We based our protocols on current evidence for effective screening and interventions (e.g., [44–46]) and recommendations from national agencies such as the National Women's Health Information Center, National Institute of Mental Health, Centers for Disease Control, Nurses for Tobacco Control Coalition and the Agency for Healthcare Research and Quality. Individual protocol topics included: developing a therapeutic relationship, perinatal depressive symptoms, stress, substance use and abuse, smoking, reproductive life planning, dental health, alcohol use, breastfeeding, domestic violence, nutrition, appropriate use of 17-P, and maternal infections. Each protocol guided assessment, determination of risk level, and interventions to decrease the identified risk. Interventions included one of two parallel sets of standard health education information specific to baseline health literacy level, referral sources when appropriate, follow up actions for the participant and the nurse-midwife (e.g., plan for an additional visit), and documentation of this visit process.

The nurse-midwives accessed the medical center's electronic medical record system (EMR) via laptop computer to communicate regularly with the participant's obstetrical provider, document home visits, exchange messages with clinic nurses, and review test results, prenatal clinic visits, and other relevant reports.

Fidelity to Intervention

Prior to beginning in her role as home visitor each nurse-midwife reviewed all relevant study materials and participated in a structured training session to learn visit procedures, data collection, documentation, and the specific application of the protocols. We then used two methods to foster the nurse-midwife's fidelity to the study processes.

First, the study team met regularly twice a month to review selected participant files to clarify or reinforce the nurses' understanding of and application of the intervention process, and to discuss clinical challenges and successes. Prior to each meeting, approximately 10 % of active participants were randomly selected by the project coordinator. The nurse-midwives assigned to these cases presented a structured status report.

Second, we used direct observation of home visits. Each month the project coordinator or one of two investigators observed approximately 10 % of the home visits using a structured observation tool to evaluate several features of the visit, including communication and problem- solving, and application of the protocol interventions. Observation was very helpful in learning more about the real life challenges faced by the nurse-midwife, identifying intervention drift early, and then using the clinical review meetings to bolster or clarify specific clinical protocols.

Other strategies to help nurse-midwives maintain fidelity included providing them with laminated note cards with key points from each protocol for easy reference, a notebook with a complete set of all protocols, and clinical forms to document the assessment interventions, and plans. In addition they had telephone access to study staff or the obstetrical clinical staff for clinical and/or study back up.

Measures

Primary Outcomes

Primary study outcomes were determined from medical record abstraction and hospital billing records. Detailed obstetrical histories were also abstracted using a standardized form. A minimum of 10 % of all completed abstractions were reviewed by senior study staff for completeness of documentation. Using these data, we determined gestational age of "*the index preterm birth*" defined as the most recently occurring preterm birth that qualified the participant to be included in the study and served as the comparison gestational age for the current study. *Infant gestational age* was determined by the weeks and days gestation documented in the maternal delivery record.

Infant nursery/NICU records were used to document *highest level of care* received by infants and the *final status of the infants* (i.e., discharged home, neonatal death, discharged with safety plan).

Hospital billing records were utilized to calculate the number of clinic and hospital encounters, including maternal length of stay for the delivery. Inpatient and outpatient encounters at the medical center that occurred during the prenatal period and for two-weeks postpartum were collected. In addition, nursery billing records for the infants were used to determine infant length of stay.

Other Measures

A combination of single item and standardized measures were used to collect socio- demographic data, pre-pregnancy body mass index (BMI) data, and information on planning for the current pregnancy, current smoking practices, experiences of domestic violence during the pregnancy, past pregnancy experiences, prenatal hassles, functional social support and depressive symptoms. All questions and measures presented in this paper were administered at baseline by a trained research assistant. We report here only on measures used to assess group similarities and differences at baseline (see Table 1).

Statistical Analysis and Sample Size

Statistical analyses were conducted using SPSS (Version 20). An alpha of 0.05 was used for determining statistical significance (i.e., $p < 0.05$). Frequency distributions summarize the nominal and ordinal data. Distributions of the continuous data were assessed graphically and with the Fisher Test of Skewness. Normally distributed data were summarized using means and standard deviations, skewed data using median and 25th–75th inter-quartile range (IQR). Tests of differences between the study groups in baseline characteristics, type of delivery, prenatal health encounters, and length of hospital stay at birth were conducted using Likelihood Chi Square statistic (nominal and ordinal data), independent t tests (normally distributed continuous data), and Mann–Whitney tests (skewed distributions). The intent-to-treat analyses of the primary study outcomes were tested using generalized linear modeling. The binary logistic link function was used in models testing for differences in rates of preterm birth ($\leq$37 weeks gestation); the gamma with log link function was used for the skewed gestational age distributions. General linear regression was used for the continuous outcome variables of current birth gestational age and change in gestational age from the index gestation. To diminish the bias of extreme values on the standard errors of the regression estimates, these gestational age outcome variables were square root transformed prior to conducting these analyses.

The original proposed sample size for this study was 300 (N = 150 in each study group). This sample size was based on previously published research (39) that indicated that a reduction of 15 % in the rate of preterm birth in the nurse home visit intervention group compared to that in the control group could be justified and would be detectable with groups of 150. Because of concerns with systemic changes in the study's health care delivery environment, an interim analysis was conducted after 200 women had delivered. As a result of that analysis a decision was made to stop recruitment.

Continuous as Treated Analyses

Control group participants were contacted via phone by study staff up to 4 times during the prenatal period (after baseline assessment) for completion of study measures. As a result, the control group did receive exposure to a form of intervention (i.e. the process of verbally completing measures having to do with health concerns). Conversely, intervention group participants did not necessarily receive the full "dose" of the intervention of 5 prenatal home visits. For the "as treated" analyses, each contact with study staff for data collection was weighted as a single

Table 1 Standardized baseline measures

Measure	Number of items	Range of scores	Interpretation of Scores	Reliability coefficient
Modified prenatal psychosocial profile [47]	18	18–47	Higher scores indicate more reported stressors during pregnancy	α = 0.79
Neighborhood/block conditions [48]	14	14–42	Higher scores indicate higher levels of perceived problems in the neighborhood	α = 0.93
Duke-UNC Family Functional support Questionnaire [49]	8	1–5	Higher scores indicate higher functional support	α = 0.97
Center for epidemiologic studies-depression (CES-D) [50]	20	0–60	Higher scores indicate more depressive symptoms	α = 0.85

Cronbach's Alpha

Table 2 Sample Characteristics

	Total N = 211 N (%)	Control N = 102 N (%)	Intervention N = 109 N (%)	p value
Race (N = 209)				0.517
African American	75 (35.9)	34 (33.7)	41 (38.0)	
Caucasian	134 (64.1)	67 (66.3)	67 (62.0)	
Literacy level* (N = 210)				0.022
<9th Grade reading level	15 (7.1)	3 (2.9)	12 (11.1)	
≥9th Grade reading level	195 (92.9)	99 (97.1)	96 (88.9)	
Marital status				0.279
Married or partnered	153 (72.5)	75 (73.5)	78 (71.6)	
Divorced or separated	12 (5.7)	8 (7.8)	4 (3.7)	
Never married	46 (21.8)	19 (18.6)	27 (24.8)	
People living in home				0.863
≤4	57 (27.0)	27 (26.5)	30 (27.5)	
>4	154 (73.0)	75 (73.5)	79 (72.5)	
Employment status (N = 210)				0.428
Full-time	80 (38.1)	37 (36.6)	43 (39.4)	
Part-time	17 (8.1)	6 (5.9)	11 (10.1)	
Unemployed	113 (53.8)	58 (57.4)	55 (50.5)	
Annual Income				0.615
<$25,000	110 (52.1)	55 (53.9)	55 (50.5)	
≥$25,000	101 (47.9)	47 (46.1)	54 (49.5)	
Type of insurance (N = 209)				0.165
TennCare/Medicaid	126 (60.3)	62 (61.4)	64 (59.3)	
Private/Champus/TriStar	80 (38.3)	36 (35.6)	44 (40.7)	
None/self pay	3 (1.4)	3 (3.0)	0 (0.0)	
Planned current pregnancy				0.304
No	129 (61.1)	66 (64.7)	63 (57.8)	
Yes	82 (38.9)	36 (35.3)	46 (42.2)	
Timing of pregnancy (N = 209)				0.322
Too soon/late	85 (40.7)	45 (44.1)	40 (37.4)	
Right time/did not care	124 (59.3)	57 (55.9)	67 (62.6)	
	Mean (SD)	Mean (SD)	Mean (SD)	
Age at enrollment (years)	27.6 (5.3)	27.8 (5.2)	27.4 (5.5)	0.582
Education (years)	13.3 (2.6)	13.4 (2.6)	13.2 (2.5)	0.748
Gestational age at enrollment (weeks^{days})	15^3 (4^4)	15^2 (4^4)	15^3 (4^4)	0.888

* As measured by rapid estimate of adult literacy in medicine-short form (REALM-SF) [57]

"dose" of the study. For example, if the participant completed three prenatal data collection assessments, the "as treated" data value was '3'. For participants in the intervention group, a nurse-midwife home visit was weighted double the dose of data collection in the control group (data collection + targeted intervention). Therefore a participant receiving three prenatal nurse-midwife home visits would be given an "as treated" data value of '6'. This "as treated" continuous variable (instead of the intent-to-treat dichotomous study group variable) was then entered into logistic regression analysis for the categorical outcome variable of "term" or "preterm" birth. Note that the "term" group included one infant with a gestational age of 42 weeks and 1 day.

Results

Demographic and current pregnancy characteristics of women in the control and intervention groups at entry into the study were very similar (See Table 2). For the entire sample mean age was 27.6 years (SD = 5.3); mean education slightly more than 13 years; 36 % were African American, 73 % were married or partnered, and approximately 40 % were

employed full-time. The average gestational age at study enrollment was 15 weeks, 3 days. While there was no statistically significant difference between the groups in terms of education, a slightly higher percentage of the control group than the intervention group demonstrated a high-school level of health literacy (97 vs. 90 %, $p = 0.022$).

Distributions of Factors Assessed at Entry

Summaries of prior pregnancy experiences, psychosocial, behavioral and environmental risk factors assessed at entry into the study are depicted in Table 3. Approximately 40 % of the women had experienced more than one prior preterm birth and almost 62 % had experienced a prior spontaneous loss more than 15 weeks in gestation (see Table 3). The levels of reported perinatal stress, depressive symptoms

and neighborhood problems were generally low while perceived functional social support was relatively high. With the exception of reports of 'abuse since being pregnant' (control: 1 %, intervention: ~ 8 %, $p = 0.023$), there were no other statistically significantly differences between groups.

Primary Outcomes

Disposition of Live Births and Gestational Age

All but one (intervention group) of the pregnancies resulted in a live birth. Table 4 presents summaries of the disposition of live births (N = 210). Approximately 20 % were admitted directly to the NICU and an additional 5 % were admitted to the NICU at some time prior to discharge.

Table 3 Summaries of risk factors at study entry

	Total N = 211 N (%)	Control N = 102 N (%)	Intervention N = 109 N (%)	p value
BMI				0.125
Underweight (<18.5)	7 (3.3)	5 (4.9)	2 (1.8)	
Normal (18.5–24.9)	88 (41.7)	39 (38.2)	49 (45.0)	
Overweight (25.0–29.9)	49 (23.2)	21 (20.6)	28 (25.7)	
Obese (30.0–39.9)	51 (24.2)	25 (24.5)	26 (23.9)	
Morbidly obese (≥40.0)	16 (7.6)	12 (11.8)	4 (3.7)	
Planned current pregnancy				0.304
No	129 (61.1)	66 (64.7)	63 (57.8)	
Yes	82 (38.9)	36 (35.3)	46 (42.2)	
Currently smoking (N = 210)				0. 773
No	173 (82.4)	84 (83.2)	89 (81.7)	
Yes	37 (17.6)	17 (16.8)	20 (18.3)	
Domestic violence since being pregnant (N = 202)				0.023
No	193 (95.5)	96 (99.0)	97 (92.4)	
Yes	9 (4.5)	1 (1.0)	8 (7.6)	
Prior preterm births				0.248
1	122 (57.8)	54 (52.9)	68 (62.4)	
2	65 (30.8)	37 (36.3)	28 (25.7)	
≥3	24 (11.4)	11 (10.8)	13 (11.9)	
Prior loss >15 weeks gestation				0.580
0	81 (38.4)	40 (39.2)	41 (37.6)	
1	100 (47.4)	46 (45.1)	54 (49.5)	
≥2	30 (14.2)	16 (15.7)	14 (12.8)	
	Median (N, IQR)	Median (N, IQR)	Median (N, IQR)	
Prenatal Hassles	22.0 (211, 20–28)	23.0 (102, 20–28)	22.0 (109, 20–28)	0.793
Neighborhood block conditions	1.1 (204, 1.0–1.3)	1.1 (99, 1.1–1.3)	1.1 (105, 1.0–1.3)	0.258
Duke UNC functional support	4.6 (210, 3.3–5.0)	4.6 (101, 3.0–5.0)	4.5 (109, 3.6–5.0)	0.615
CES-D	10.0 (211, 5.0–17)	10.0 (102, 5.0–17.3)	10.0 (109, 5.0–16.0)	0.687

IQR: 25th–75th interquartile range

Approximately 98 % were discharged home with mother. No statistically differences were observed in these rates between the two study groups (see Table 4).

Change in Gestational Age from Index Preterm Birth

There was no statistically significant difference between the groups in the ages of the index preterm birth (i.e., the birth used for eligibility in the study). The index births were primarily between 30 and 36 weeks with a median of 34 weeks, 3 days (see Table 4). For all births there was a statistically significant increase in gestational age from that of the index preterm birth ($p < 0.001$). The median increase was 4 weeks from the index birth. As illustrated in Fig. 2, there was a very strong inverse association between the gestational age of the index birth and the study birth gestational age (earlier loss in the index birth was associated with greater change in birth age of the study infant ($r_s = -0.65$, $p < 0.001$). There were, however, no statistically significant differences between the groups in this gestational age increase ($p = 0.364$), nor in terms of the study infant's gestational age ($p = 0.643$) or prevalence of a current preterm birth ($p = 0.822$).

Subset of Women Eligible for Use of IM 17-P

Given the clinical implications of the use of 17-P, we conducted a separate analysis of the subset of women eligible for 17-P (N = 130; Control = 62, Intervention = 68). No statistically significant difference between the groups was observed in the proportion who received at least one dose of 17-P (control 25.8 %; intervention 33.8 %, $p = 0.319$). There was a statistically significant inverse association of the use of 17-P in the study pregnancy with gestational age of the index birth (r = −0.38, $p < 0.001$). In other words, fewer women tended to receive 17-P as the gestational age of the index prior preterm birth approached term (i.e., 37 weeks). As summarized in Table 5, similar findings to those observed in the overall sample of women were observed in this subset of women.

Clinical and Hospital Encounters, Length of Stay at Delivery

Of the 211 participants, data on length of stay at delivery, as well as clinic and hospital encounters during the prenatal and first 2 months postpartum were available for 194

Table 4 Summary of disposition of live births and gestational age

Disposition of live births	Total N (%)	Control N (%)	Intervention N (%)	p value
Immediate disposition	N = 208	N = 101	N = 107	0.751
NICU	41 (19.7)	19 (18.8)	22 (20.6)	
Normal nursery	167 (80.3)	82 (81.2)	85 (79.4)	
Highest level of care	N = 206	N = 99	N = 107	0.746
NICU	52 (25.2)	26 (26.3)	26 (24.3)	
Normal nursery	154 (74.8)	73 (73.7)	81 (75.7)	
Final status	N = 201	N = 97	N = 104	0.150
Discharged with mother	196 (97.5)	93 (95.9)	103 (99.0)	
Other[a]	5 (2.5)	4 (4.1)	1 (1.0)	
	Median (IQR) (N = 210[b])	Median (IQR) (N = 102)	Median (IQR) (N = 108)	
Gestational change from index preterm infant (weeks^{days})	4^0 ($1^5,6^1$)	3^4 ($1^4,5^6$)	4^2 ($1^6,6^1$)	0.364
≥ 1 week increase N (%)	174 (82.5)	86 (84.3)	88 (80.7)	0.494
Index birth gestational age (weeks^{days})	34^3 ($31^1,36^0$)	34^6 ($31^6,36^0$)	34^1 ($30^5,36^0$)	0.978
BBO birth gestational age (weeks^{days})	38^1 ($36^4,39^2$)	38^1 ($36^2,39^1$)	38^1 ($36^4,39^2$)	0.643
	N (%)	N (%)	N (%)	
Gestational age groups				0.822
<34^0	26 (12.3)	14 (13.7)	12 (11.0)	
34^0–36^6	41 (19.4)	19 (18.6)	22 (20.2)	
≥37^0	144 (68.2)	69 (67.6)	75 (68.8)	

[a] Other included died before discharge, adoption, discharged home with DCS safety plan

[b] Birth gestational age could not be obtained for one participant

women. The most common reason for the lack of this information was that the birth did not take place at the study's medical center. No statistically significant differences between the groups were observed in prenatal inpatient or outpatient encounters (see Table 6). On the other hand, intervention group participants' length of hospital stay at delivery was shorter (median of 1 day) than that for control group participants ($p = 0.048$). While not statistically significant, there was a lower percentage of C-Section deliveries compared to vaginal deliveries in the intervention group than in the control group (39.8 vs. 50.5 %, $p = 0.121$). These differences in type of delivery however,

Fig. 2 Change in gestational age from index preterm birth

accounted for a statistically significant component of the difference in length of stay ($\eta^2 = 0.16$, $p < 0.001$). No statistically significant differences emerged between groups for infant length of stay at delivery ($p = 0.406$). As noted in Table 6, both groups had a median of one outpatient encounter with the healthcare system between delivery through 60 days postpartum. Nevertheless, 10 % of the control group had more than 2 encounters during that period while 15 % of the intervention group had the higher number ($p = 0.038$) (see Table 6). Limited information was available about the encounters. Aside from visits associated with routine postpartum follow up, very few principle diagnoses were provided. Those mentioned included such issues as cellulitis (N = 1), edema (N = 1), cough (N = 1), complications with kidneys (N = 1), and tubal ligation (N = 4).
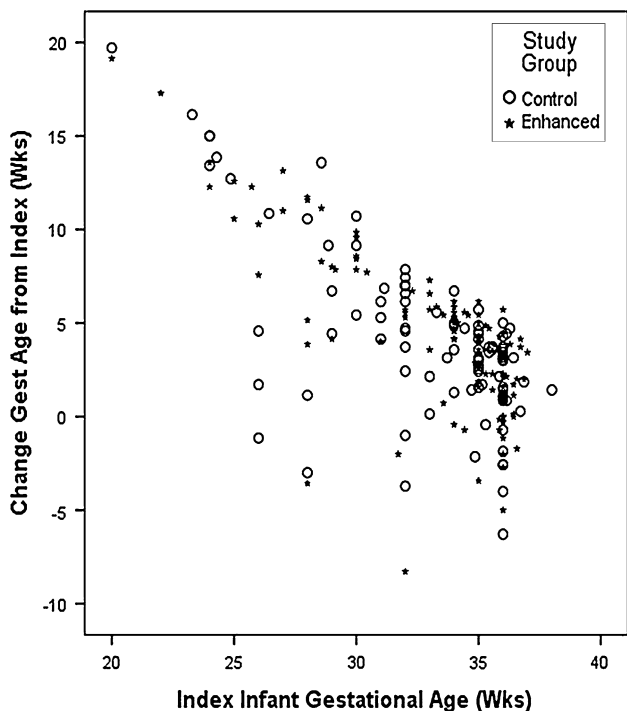
Continuous as Treated Analyses

Within the control group, a median of 3 data collection contacts occurred (min = 0, max = 4, 25th–75th IQR: 0.7–4.00); the intervention group received a median of 8 home visit contacts (min = 0, max = 20, 25th–75th IQR: 7.0–9.5). While not statistically significant, each increase in the number of study contact increased the likelihood of a term birth by two-fold after controlling for the index birth gestational age (OR 2.04, 95 % CI 0.97–4.28, $p = 0.060$). Using the more detailed outcome variable of change in gestational age from the index birth, each increase in contact resulted in a statistically significant increase in gestational age from the index birth ($\beta = 0.13$, $p = 0.025$). The adjusted effect translated into an increase of 1.2 gestational days on average (95 % CI 0.4–2.0 days). In the subset of women eligible for IM 17-P, there was a statistically significant increase in the likelihood of a term birth with increase in contact. This increase persisted after

Table 5 Summary of birth outcomes for participants with prior spontaneous loss >15 weeks

Cases Eligible for 17-P[a]		Total N 130 Median (IQR)	Control N = 62 Median (IQR)	Intervention N = 68 Median (IQR)	p value
Gestational change from index preterm infant (weeks[days])		4^1 $(1^4,6^1)$	3^4 $(1^3,5^2)$	4^3 $(1^4,7^4)$	0.179
≥1 week increase N (%)		106 (81.5)	51 (82.3)	55 (80.9)	0.241
Index birth gestational age (weeks[days])		34^0 $(30^0,35^4)$	34^1 $(30^0,35^6)$	34^0 $(30^0,35^4)$	0.948
BBO birth gestational age (weeks[days])		38^1 $(35^5,39^2)$	37^6 $(35^1,39^1)$	38^1 $(36^4,39^2)$	0.314
	N (%)	N (%)		N (%)	
Gestational age groups					0.361
$<34^0$	21 (16.2)		13 (21.0)	8 (11.8)	
34^0–36^6	24 (18.5)		11 (17.7)	13 (19.1)	
$\geq37^0$	85 (65.4)		38 (61.3)	47 (69.1)	

[a] Cases with gestational age data available

Table 6 Summaries of maternal health encounters, maternal and infant delivery length of stay

	Total N = 194	Control N = 93	Intervention N = 101	p value
Maternal				
Prenatal outpatient encounters				
Median	11	10	11	0.485
Min, Max	1, 35	1, 35	2, 33	
In-patient Encounters (Prenatal, not including delivery) N (%)				
0 Encounters	167 (86.1)	80 (86.0)	87 (86.1)	0.762
1 Encounter	19 (9.8)	9 (9.7)	10 (9.9)	
2 Encounters	7 (3.6)	3 (3.2)	4 (4.0)	
3 Encounters	1 (1.1)	0 (0.0)	1 (0.5)	
Delivery LOS				
Median	3	3	2	0.048
Min, Max	0, 40	0, 40	1, 12	
Outpatient encounters (Delivery through 60 days postpartum)				
Median	1	1	1	0.038
Min, Max	0, 11	0, 6	0, 11	
In-patient Encounters (Delivery through 60 days postpartum) N (%)				
0 Encounters	191 (98.5)	92 (98.9)	92 (98.9)	0.610
1 Encounter	3 (1.5)	1 (1.1)	2 (2.0)	
	Total N = 190	Control N = 91	Intervention N = 99	p value
Infant				
Delivery LOS				
Median	2	2	2	0.406
Min, Max	0,229	0, 64	1, 229	

controlling both for the index birth gestational age and the use of IM 17-P (OR 1.32, 95 % CI 1.03–1.68, $p = 0.025$). As with the overall sample, an increase in the intervention was associated with a statistically significant increase in the change in gestational age from the index gestation again after adjusting for that index gestational age and the use of IM 17-P ($\beta = 0.16$, $p = 0.015$).

Discussion

Our findings add to the growing body of literature related to home visitation and prevention of preterm births. This study is one of the only home visitation studies to prospectively evaluate a system of care for pregnant women at high risk of recurrence of preterm birth. We hypothesized that participants randomized to the study's system of care (i.e., home visitation arm) would give birth at a later gestation than the gestational age of the prior preterm birth and in turn, the later gestation would decrease the hospital length of stay when compared to women receiving standard prenatal care. Our hypotheses were partially supported. Using an intent to treat analytic approach, no significant differences for rate of preterm birth, gestational age, change in gestational age from the index (i.e., prior) preterm infant, or immediate disposition of infants to the NICU between groups were found including the subsample analysis of women eligible for 17-P. We did find a difference between groups in length of intrapartum hospital stay. Women in the intervention group had a shorter length of stay compared to women in the control group. Upon closer examination of the type of deliveries, although not statistically significant, women in the intervention group had fewer cesarean sections than women in the control group. It is plausible that prenatal visits by a nurse-midwife may have contributed to this difference, although a causal relationship cannot be assumed. A closer examination of actions and the therapeutic relationship occurring during home visits may help clarify any true relationship.

Translating evidence into a comprehensive programmatic intervention delivered in the home is a complicated

process. Capturing the specific elements of a system of care involving home visitation that improve outcomes is difficult. Few clinical research studies have undertaken this, yet developing and evaluating models such as ours is critical to developing replicable models of service delivery. The national interest in interventions in the home environment remains high despite the complex nature of such interventions [51]. How to balance an integrated, comprehensive, individualized approach with a standardized intervention remains challenging. Our study intervention was driven by standardized protocols that were adaptive in nature [52]. Decision rules were embedded in protocols to determine the specific intervention required. This delivery model approximates clinical practice. For example, all women in the intervention group were screened at each home visit for the presence or absence of domestic violence. The nurse-midwife's responses derived directly from the study protocol. Her intervention could have ranged from commendations for continued healthy relationships to calling for emergency services. Methodological work is needed to develop analytic techniques that can delineate what portions of an intervention, particularly those delivered in the home, make a difference (positively or negatively) in outcomes.

Prior works [53–55] have often focused on linking the structure of the home visitation program (e.g., number of visits or length of a visit) with outcomes rather than the content and interactions of the visit. There is a critical need to assess individual components of the often vast set of interventions included in a single home visit with health outcomes as we attempt to advance the science in this area. Horn and colleagues [56] developed the Clinical Practice Improvement methodology which is a comprehensive analysis of patient, process and outcome variables. It facilitates analysis of the content and timing of the individual components of interventions in order to determine linkages with desired patient outcomes. Although the method has been primarily used in hospital settings, it may be applicable to opening the 'black box' of home visitation as we attempt to identify the linkages among client profiles, needs, intervention components and health outcomes.

When we looked more closely at our groups from an 'as treated' analytic approach we found a significant increase in gestational age from the index birth with each increase in the number of study contacts (the dose). While the adjusted effect translated into what seems a small increase (i.e., 1.2 days of gestational age on average), even small increases in gestational age can improve infant outcomes and reduce related health care costs. More work also is needed to develop analytic techniques that delineate the effect of the interaction between intervention components and duration of intervention.

Our study has both strengths and limitations. One significant limitation was our use of a prospective randomized clinical trial (RCT). Although considered a gold standard, it may not be the best approach when trying to evaluate focused behavioral interventions. These types of interventions tend to have varying effects across participants and may interact with other variables. Also, prior reports evaluating home visitation often show small and inconsistent effect sizes; large samples are often required to determine an effect. Our initial power analysis yielded a target sample of 300 women (150 in each group). As the study progressed, however, and we used our own data to benchmark progress for our first 200 participants, it became clear a much larger sample (i.e., over 900) would be required to demonstrate differences between our study groups. Reaching this target number of participants was not feasible. Future studies should consider using designs other than the randomized clinical trial. Another limitation was that we did not have a 'true' control group because we interacted with these participants to collect data and unexpected enhancements of prenatal clinical services occurred during the study period. Most notably, there was the addition of a psychiatrist. While this improved care for all study participants, it made detecting a small difference between groups more difficult.

Strengths included our collecting detailed home visit information that will allow examination of the specific effects of our system of care and we will also be able to use analytic techniques such as cluster analysis to identify subgroups of risks and women who may have benefited most from the intervention. Developing and using intervention fidelity checks was another strength of our study. The regular clinical meetings and direct home visit observations allowed us to identify drift from intervention protocols and difficulties in translating the system of care in the real world and in maintaining the integrity of the system of care.

With the national impetus to expand home visitation programs, this study is an important contribution. Very few studies have focused on home visitation targeting pregnant women with a prior preterm birth. Nurse-midwife home visits or contact may limit some risk factors and shorten length of stay at delivery. Extension and refinement of our system of care to examine the effectiveness of interventions that use one or more other modalities such as texting, cellular phone applications, and group interactions is warranted. More broadly, investigation is needed to understand the nature of home visits per se and their linkage with specific health outcomes.

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