Weight Control Program and Gestational Weight Gain in Disadvantaged Women with Overweight or Obesity: A Randomized Clinical Trial

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Objective: This study aimed to evaluate the efficacy of a home-based lifestyle intervention delivered through Parents as Teachers (PAT) to reduce excessive gestational weight gain (GWG).

Methods: This was a single-blinded randomized controlled trial conducted as part of the LIFE-Moms consortium at a single university-based tertiary care institution from October 2012 to March 2016. There were 267 socioeconomically disadvantaged (SED) African American women with overweight or obesity (BMI 25.0-45.0 kg/m²) before pregnancy. Participants were randomized to therapy with standard PAT alone (n = 134) or PAT plus a lifestyle intervention program embedded within the standard PAT program (PAT+) (n = 133). Both interventions were delivered in 10 biweekly home visits during pregnancy. The primary outcome was the percentage of women whose GWG exceeded the Institute of Medicine guidelines, and secondary outcomes included both weekly and total GWG.

Results: Compared with the standard PAT group in the intent-to-treat analysis, the PAT+ group gained less weekly (0.4 kg vs. 0.5 kg/week; P = 0.04) and total (8.0 kg vs. 9.6 kg; P = 0.02) weight during gestation. Fewer participants in the PAT+ group had excessive total GWG (36.1% vs. 45.9%), but the difference between groups was not statistically significant (P = 0.11).

Conclusions: PAT+ reduced the weekly and total GWG in SED African American women with overweight or obesity at the start of pregnancy.

Obesity (2018) 26, 485-491. doi:10.1002/oby.22070

Introduction

More than 50% of women who are pregnant in the United States have overweight or obesity, and approximately half of these women exceed the recommended guidelines for gestational weight gain (GWG) (1). Excess body weight and excessive GWG during pregnancy are associated with adverse pregnancy outcomes, including increased rates of preeclampsia, gestational diabetes, fetal growth disorders, stillbirth, preterm, cesarean delivery, and postpartum weight retention (2). Overweight and obesity disproportionately affect African American, socioeconomically disadvantaged (SED) women (3). Moreover, this population is at an increased risk for adverse pregnancy outcomes, which are further exacerbated by excessive GWG (4).
A series of randomized controlled trials have evaluated the efficacy of lifestyle interventions (diet and physical activity) during pregnancy on GWG. The results from the most recent meta-analyses of randomized controlled trials found lifestyle intervention decreased GWG and lowered the odds of cesarean section, but it did not affect neonatal outcomes (5). However, few randomized trials have evaluated the effect of lifestyle interventions for SED African American pregnant women, despite their increased disease burden and risk for adverse maternal, fetal, and infant outcomes (6,7). These women often face multiple barriers, such as time constraints associated with low-income jobs with minimal flexibility, parenting responsibilities, lack of transportation, and related social stressors, which prevent engagement in interventions that promote healthy lifestyle behaviors (8). Most GWG interventions require repeated visits to clinics or other locations, which can increase attrition and decrease treatment efficacy (9). Interventions that are sensitive to individual educational needs, are readily accessible, and offer strategies to reduce participant burden facilitate engagement and the ability to comply with therapeutic recommendations. Partnering with community organizations that reach women at home can enhance the convenience, accessibility, and availability of lifestyle interventions for SED African American women (10).

The purpose of the present randomized controlled trial was to evaluate whether an optimized, home-based, lifestyle weight management program could affect GWG and improve maternal and neonatal outcomes in SED African American pregnant women with overweight or obesity at the beginning of pregnancy. We collaborated with Parents as Teachers (PAT), a national home visiting organization that provides an evidence-based curriculum to promote positive child development and school readiness; this curriculum is delivered by parent educators through multiple home visits free of charge to SED pregnant women (11). The lifestyle intervention program was embedded within the existing standard PAT curriculum provided during the prenatal home visits.

Methods

Study participants

A total of 267 women participated in this study. Written informed consent was obtained from all participants before they participated in this study, which was approved by the Washington University Institutional Review Board. Eligibility criteria included (1) African American ancestry, (2) age 18 to 45 years, (3) body mass index (BMI) of 25.0 to 45.0 kg/m² measured at the initial visit during the first trimester, (4) singleton viable gestation at or before 15 0/7 weeks (established by ultrasound dating or by ultrasound itself), and (5) disadvantaged socioeconomic status (Medicaid recipient or home zip code associated ultrasound dating or by ultrasound itself), and (5) disadvantaged socioeconomic status (Medicaid recipient or home zip code associated
to March 2016. This trial was part of the Lifestyle Interventions for Expectant Moms (LIFE-Moms) consortium consortium (https://lifemoms.bsc.gwu.edu/), a collaborative group evaluating the effect of lifestyle therapies on maternal GWG and maternal, fetal, and infant health in pregnant women with overweight or obesity (13).

Participants were randomly assigned in a 1:1 allocation to treatment with the standard PAT education curriculum or PAT education curriculum plus lifestyle (diet and activity) weight management counseling (PAT+). The randomization sequence was determined by using a random number generator and a fixed allocation block strategy; investigators and study staff were blind to group assignment.

Participants in both groups were seen by the parent educators in 1-hour home visits every other week during pregnancy. Participants assigned to the standard PAT curriculum had home visits focused on development-centered parenting support and education and parent-child interaction using a family strength-based approach. Participants assigned to PAT+ received the standard PAT curriculum plus a lifestyle curriculum based on cognitive behavior change theory, which included participant goals for achieving appropriate GWG, regular self-assessment of weight, education and reinforcement of positive eating and physical activity behaviors, observational learning through role-play, and environmental changes in the home. The lifestyle intervention was developed in partnership with PAT to assure consistency with the organizational mission, format, practice, and funding requirements, and we addressed barriers and facilitators for healthy GWG identified by African American women during the development of the program. Specific topics embedded within each home visit are outlined in Supporting Information Table S2. To ensure the home intervention was delivered as designed, parent educators audiotaped the visits and completed lesson plan checklists documenting the delivery of content, which were reviewed by study staff. Study staff also randomly observed two home visits each year for each parent educator, an approach consistent with PAT standards of practice.

Participants were seen in the Washington University Clinical Research Unit at 15 weeks and 35 weeks of gestation to determine body weight, body composition (fat mass and fat-free mass were assessed by using air displacement plethysmography; BOD POD, Life Measurements Inc., Concord, California), plasma glucose, insulin and lipid concentrations, and the plasma glucose and insulin response to an oral glucose load (blood samples obtained before and at 30, 60, 90, and 120 minutes after ingesting a 75-g glucose drink). Infant plasma glucose and insulin concentrations were assessed from cord blood obtained at the time of delivery, and infant length, weight, and body composition (fat mass and fat-free mass were assessed by using air displacement plethysmography; PEA POD, Life Measurements Inc.) were determined after delivery, before hospital discharge. All research and clinical visits were conducted by staff who were blinded as to the participants’ treatment assignment.

Study outcomes

The primary study outcome was the percentage of participants with GWG who exceeded the goal range set by the Institute of Medicine (IOM) for women with overweight or obesity (1). Maternal secondary outcomes were weekly GWG and changes from 15 weeks to 35 weeks in (1) total GWG, (2) body fat and fat-free masses, (3) indices of glycemic control (fasting plasma glucose and insulin concentrations, homeostasis model assessment of insulin resistance [HOMA-IR], oral glucose insulin sensitivity, and both glucose and insulin areas under the curve [AUC]) during the oral glucose tolerance test.
test (OGTT), (4) plasma lipid profile (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides), and (5) systolic and diastolic blood pressures. Obstetric secondary outcomes included the following complications: (1) gestational diabetes (diagnosed at 24 - 28 weeks, based on a fasting plasma glucose ≥ 92 mg/dL or plasma glucose ≥ 180 mg/dL or ≥ 153 mg/dL 1 and 2 hours after ingesting a 75-g glucose drink, respectively), (2) hypertensive disease of pregnancy (14), (3) preterm birth (delivery before 37 0/7 weeks), (4) cesarean delivery, and (5) fetal death (after 20 0/7 weeks). Neonatal secondary outcomes included (1) birth weight and length, (2) body composition (fat-free mass and percent body fat), (3) percent who were large for gestational age, (4) percent who were small for gestational age, (5) umbilical cord plasma glucose and insulin concentrations, and (6) medical complications (neonatal intensive care unit admission within 24 hours of life, respiratory distress syndrome, hypoglycemia [plasma glucose < 30 mg/dL, at any time], and neonatal death within the first 28 days of life).

Calculations and analyses
Plasma glucose concentration was determined by using an automated glucose analyzer (Yellow Springs Instruments, Yellow Springs, Ohio). Plasma insulin concentration was determined by using a chemiluminescent immunometric method (Immulite; Siemens, Los Angeles, California). HOMA-IR was calculated by dividing the product of the plasma glucose (millimoles/liter) and plasma insulin (milliunits/liter) concentrations by 22.5 (15), glucose and insulin AUC during the OGTT was calculated by the trapezoidal rule, and oral glucose insulin sensitivity was calculated as described previously (16).

Statistical analyses
Preliminary data obtained from our clinic records demonstrated that 69.2% and 75.8% of SED African American women with overweight or obesity, respectively, gained more weight during pregnancy than that recommended by the IOM. Assuming a 10% attrition rate by delivery, we estimated 133 women in each group would be needed to detect a 30% reduction in GWG that exceeded the IOM recommendations, with a power of 0.9 and an alpha value of 0.05.

Primary analyses were performed according to the intention-to-treat (ITT) principle by using the last recorded maternal weight. A modified ITT (mITT) analysis was also performed that excluded participants with fetal deaths, miscarriages, absence of maternal weight measured between 33 and 37 weeks, and those who were lost to follow-up. Continuous variables were compared by using the Student’s t test or Mann Whitney U test, as appropriate. Normality was tested with the Kolmogorov-Smirnov test. Categorical variables were compared by using the χ² or Fisher’s exact test, as appropriate. No interim analyses were planned or performed. A P < 0.05 was considered statistically significant.

Results
Participant flow
A total of 3,994 women were screened for participation in this study, and 3,535 (88.5%) were deemed ineligible (Figure 1). The two most common reasons for ineligibility were gestational age ≥ 16 weeks and an out-of-range BMI. Of the 459 eligible women, 267 (58.2%) consented to participate and were randomized and included in the ITT analysis; 133 were assigned to the PAT + group, and 134 were assigned to the standard PAT group. The modified ITT analysis included 240 participants: 119 in the PAT + group and 121 in the standard PAT group (14 from the PAT + and 13 from the standard PAT groups were excluded). Baseline characteristics between participants included in the modified ITT analysis compared with those who were excluded were similar (Supporting Information Table S3). Participants in the PAT + group had more home visits than did standard PAT participants (PAT+: 9 visits [7-10] vs. standard PAT: 8 visits [5-10]; P = 0.04). Participants in the PAT + group also had longer visits than did standard PAT participants (PAT+: 53 min [44-60] vs. standard PAT: 32 min [21-49]; P < 0.01). The increased duration of home visits in the PAT + group was expected because of the increased content delivered during these visits.

Participant characteristics
Advanced maternal age, BMI, body weight, fat-free mass, percent body fat, insulin carrier, maternal education, household income level, gravidity, and parity were not different between treatment groups (Table 1). Mean age was about 1 year younger, and a history of previous cesarean delivery was more common in the PAT + group than the standard PAT group. Fifty-one percent of the participants changed their address once during the ~20-week prenatal intervention, and 12% moved two or more times.

Maternal body weight and composition
In both the ITT and mITT analyses, total GWG was 1.6 to 1.7 kg less in the PAT + group than in the standard PAT group (ITT P < 0.02; mITT P = 0.01) (Table 2; Supporting Information Figure S1). Fewer participants in the PAT + group than in the standard PAT group had total GWG that exceeded the recommended IOM guidelines, but the difference between groups was not statistically significant (ITT: 36.1% vs. 45.9%; P = 0.11; mITT: 36.1% vs. 47.9%; P = 0.06). In both the ITT and mITT analyses, the PAT + group gained 0.08 kg/wk less than the standard PAT group (P = 0.04 and P = 0.01, respectively). Fewer participants in the PAT + group than in the standard PAT group had weekly GWG that exceeded the recommended IOM guidelines (ITT: 62.4% vs. 77.4%; P = 0.01; mITT: 60.5% vs. 78.5%; P < 0.01). In addition, the PAT + group gained less body fat than did the standard PAT group (ITT: 0.25 ± 2.2 kg vs. 2.18 ± 5.8 kg; P < 0.01; mITT: 0.16 ± 5.1 kg vs. 2.18 ± 5.8 kg; P < 0.01) (Table 2).

Maternal outcomes
Cardiometabolic outcomes. Advancing gestation from 15 to 35 weeks was associated with expected increases in fasting insulin, HOMA-IR, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglyceride concentrations that occur during pregnancy, but did not differ between groups (Table 3; Supporting Information Table S4). Changes in insulin AUC during the OGTT and systolic blood pressure between 15 and 35 weeks gestation were significantly different between groups. The relative increase in insulin AUC was greater in the standard PAT group than in the PAT + group (ITT: 25.1% vs. 8.8% increase; P = 0.01; mITT: 28.3% vs. 8.9%; P = 0.01), and the relative increase in systolic blood pressure was greater in the standard PAT group than in the PAT + group (ITT: 1.6% vs. −1.7%; P = 0.02; mITT: 1.6% vs. −1.6%; P = 0.03).

Obstetric outcomes. There were no significant differences between the treatment group in obstetric complications, including the
development of gestational diabetes or hypertensive disorders, preterm birth, or cesarean delivery (Table 4; Supporting Information Table S5).

**Neonatal outcomes**
There were no significant differences in birth weight, birth length, body fat mass, large for gestational age, small for gestational age, hypoglycemia, cord blood glucose, cord blood insulin, respiratory distress, neonatal intensive care unit admissions, or neonatal deaths between the two treatment groups (Table 4; Supporting Information Table S6).

**Discussion**
This randomized controlled trial was conducted to evaluate the effect of PAT+, a home-based GWG lifestyle intervention embedded within an existing national parent education program (PAT) and delivered to SED African American women with overweight or obesity at the start of their pregnancy. Our data demonstrated that women who received PAT+ gained less weekly and total weight during pregnancy than those who received standard PAT home visits without the GWG intervention. In addition, fewer women in the PAT+ group than in the standard PAT group exceeded the IOM guidelines for weekly weight gain, but the difference between groups was not statistically significant. These data demonstrated the potential of a home-based lifestyle intervention in modulating GWG in an underserved SED population with extensive barriers to treatment engagement. Moreover, the use of the existing infrastructure of a national home visiting program allows for widespread dissemination of this therapeutic intervention at minimal additional cost.

It is likely that our PAT+ participants would have shown even greater efficacy in reducing GWG if the comparator group received
### TABLE 1 Baseline characteristics of standard PAT and PAT + groups

|                          | Standard PAT  | PAT+       | P value |
|--------------------------|---------------|------------|---------|
|                          | (n = 134), n (%) | (n = 133), n (%) |         |
| Maternal age (y)\(^a\)   | 26.0 ± 4.9    | 24.7 ± 4.9 | 0.04    |
| Advanced maternal age    | 9 (6.7)       | 7 (5.3)    | 0.62    |
| BMI at randomization (kg/m\(^2\))\(^a\) | 31.9 ± 4.9    | 32.8 ± 5.1 | 0.16    |
| Body weight (kg)\(^a\)   | 86.1 ± 15.2   | 87.3 ± 16.1| 0.52    |
| Fat-free mass (kg)\(^a\) | 57.4 ± 8.1    | 56.8 ± 7.7 | 0.55    |
| Body fat (%)\(^a\)       | 66.7 ± 5.2    | 65.6 ± 5.4 | 0.08    |
| Overweight               | 52 (38.8)     | 42 (31.6)  | 0.22    |
| Obesity                  | 82 (61.2)     | 90 (67.7)  | 0.27    |
| Medicaid                 | 119 (92.2)    | 119 (90.8) | 0.42    |
| Maternal education       |               |            | 0.47    |
| Less than high school    | 25 (18.7)     | 29 (21.8)  |         |
| High school graduate     | 51 (38.1)     | 59 (44.4)  |         |
| Some college             | 47 (35.1)     | 36 (27.1)  |         |
| College graduate         | 11 (8.2)      | 9 (6.8)    |         |
| Household income level   |               |            | 0.69    |
| < $25,000                | 120 (89.5)    | 121 (91.0) |         |
| ≥ $25,000                | 14 (10.4)     | 12 (9.0)   |         |
| Marital status           |               |            | 0.59    |
| Married                  | 18 (13.4)     | 11 (8.3)   |         |
| Not married and living with significant other | 42 (31.4) | 43 (32.3) |         |
| Separated/widowed/divorced | 4 (3.0)     | 5 (3.8)   |         |
| Not married              | 70 (52.2)     | 74 (55.6)  |         |
| Gravidity\(^b\)         | 2.0 (1.0-3.0) | 1.0 (0.0-3.0) | 0.16 |
| Nulliparous              | 25 (18.7)     | 38 (28.6)  | 0.06    |
| Prior cesarean           | 25 (50.0)     | 38 (69.1)  | 0.04    |
| Gravidity\(^b\)         |               |            | 0.16    |

\(^a\)Data are means ± SD.
\(^b\)Data are median (interquartile range).

### TABLE 2 Gestational weight gain and body composition in standard PAT and PAT + groups at 35 weeks gestation

|                          | Standard PAT  | PAT+        | P value |
|--------------------------|---------------|-------------|---------|
|                          | n = 134       | n = 133     |         |
| ITT analysis             |               |             |         |
| Total GWG (kg)\(^a\)     | 9.64 ± 5.4    | 8.05 ± 5.6  | 0.02    |
| Total GWG above IOM guidelines, n (%) | 61 (45.9)    | 48 (36.1)   | 0.11    |
| Weekly GWG (kg/wk)\(^a\) | 0.48 ± 0.3    | 0.40 ± 0.3  | 0.04    |
| Weekly GWG above IOM guidelines, n (%) | 103 (77.4) | 83 (62.4)   | 0.01    |
| Increase in fat mass (kg)\(^a\) | 2.18 ± 5.8    | 0.25 ± 5.2  | 0.01    |
| Increase in fat-free mass (kg)\(^a\) | 7.83 ± 4.6    | 7.52 ± 4.4  | 0.61    |
| Modified ITT analysis    | n = 121       | n = 119     |         |
| Total GWG (kg)\(^a\)     | 9.93 ± 5.3    | 8.11 ± 5.6  | 0.01    |
| Total GWG above IOM guidelines, n (%) | 58 (47.9)    | 43 (36.1)   | 0.06    |
| Weekly GWG (kg/wk)\(^a\) | 0.46 ± 0.2    | 0.38 ± 0.3  | 0.01    |
| Weekly GWG above IOM guidelines, n (%) | 95 (78.5)    | 72 (60.5)   | <0.01   |
| Increase in fat mass (kg)\(^a\) | 2.18 ± 5.8    | 0.16 ± 5.1  | <0.01   |
| Change in fat-free mass (kg)\(^a\) | 7.83 ± 4.6    | 7.54 ± 4.5  | 0.64    |

\(^a\)Data are means ± SD.
usual care rather than standard PAT. Standard PAT involves intensive parent support through regular home visits and is not representative of usual prenatal clinical care. GWG in the standard PAT group was approximately 40% less than what we have previously observed in a similar patient population in our obstetric clinic (data obtained from clinic records from March 2008 to February 2010), in which 76% of our SED African American patients with obesity and 69% with overweight gained more total weight than that.

### TABLE 3 Maternal cardiometabolic outcomes in standard PAT and PAT + groups, ITT analysis

|                      | Standard PAT (n = 134), median (IQR) | PAT+ (n = 133), median (IQR) |
|----------------------|-------------------------------------|-----------------------------|
|                      | ~15 Weeks                           | ~35 Weeks                   |
|                      |                                    |                             |
| Fasting glucose (mg/dL) | 80.7 (76.7-85.1)                   | 81.1 (76.0-85.3)            |
| Fasting insulin (µU/mL) | 9.6 (6.6-14.8)                     | 10.7 (7.0-17.0)             |
| OGIS                 | 406.5 ± 68.2                        | 390.9 ± 73.9                |
| Glucose AUC (mg/dL × 120 min) | 15,047 (13,667-16,295)           | 14,946 (13,918-16,269)      |
| Insulin AUC (µU/mL × 120 min) | 10,733 (8,212-15,503)          | 13,109 (9,333-19,339)       |
| HOMA-IR              | 2.0 (1.3-3.0)                       | 2.1 (1.5-3.4)               |
| Total cholesterol (mg/dL) | 158 (142.0-178.0)                 | 160 (140.0-186.0)           |
| LDL cholesterol (mg/dL) | 81.0 ± 23.6                       | 83.34 ± 25.63               |
| HDL cholesterol (mg/dL) | 63.0 ± 13.7                       | 63.1 ± 14.0                 |
| Triglycerides (mg/dL)  | 75.0 (60.0-97.0)                   | 76.0 (60.0-98.0)            |
| SBP (mmHg)            | 109.0 (104.0-119.0)                | 112.0 (105.7-120.0)         |
| DBP (mmHg)            | 67.0 ± 8.0                         | 67.2 ± 8.7                  |

*Data are means ± SD.

Change in value during pregnancy significantly different from standard PAT group: *P = 0.01, **P = 0.02.

SI conversion factors: to convert glucose from mg/dL to mmol/L, multiply by 0.0555; for insulin from µU/mL to pmol/L, multiply by 6.945; for cholesterol from mg/dL to mmol/L, multiply by 0.0259; for triglycerides from mg/dL to mmol/L, multiply value by 0.0113.

OGIS, oral glucose insulin sensitivity; AUC, area under the curve; HOMA-IR, homeostasis model assessment of insulin resistance; LDL, low-density lipoprotein; HDL, high-density lipoprotein; SBP, systolic blood pressure; DBP, diastolic blood pressure; IQR, interquartile range.

### TABLE 4 Obstetric and infant complications in standard PAT and PAT + groups, ITT analysis

|                      | Standard PAT, n (%) | PAT+, n (%) | P value |
|----------------------|---------------------|-------------|---------|
| Obstetrics complications | n = 134            | n = 133     |         |
| Gestational diabetes  | 12 (9.0)            | 11 (8.3)    | 0.83    |
| Hypertensive disorder | 27 (21.1)           | 32 (24.8)   | 0.48    |
| Preterm birth         | 12 (9.5)            | 18 (14.1)   | 0.26    |
| Cesarean delivery     | 47 (36.7)           | 53 (41.1)   | 0.47    |
| Infant complications  | n = 133             | n = 133     |         |
| Birth weight (g)      | 3,130 (2,810-3,463) | 3,155 (2,875-3,540) | 0.77    |
| Birth length (cm)     | 50.0 (48.3-51.5)    | 50.0 (48.20-51.50) | 0.86    |
| Body fat mass (%)     | 12.2 ± 4.3          | 12.5 ± 3.8  | 0.57    |
| LGA                   | 6 (4.8)             | 11 (8.6)    | 0.22    |
| SGA                   | 13 (10.3)           | 13 (10.2)   | 0.97    |
| Hypoglycemia          | 2 (1.6)             | 3 (2.3)     | >0.99   |
| Cord blood glucose (mg/dL) | 86.0 (76.0-95.0)   | 86.0 (76.0-96.5) | 0.72    |
| Cord blood insulin (µU/mL) | 5.7 (3.3-10.0)     | 6.0 (4.0-12.0) | 0.19    |
| Respiratory distress  | 11 (8.2)            | 16 (12.0)   | 0.30    |
| NICU admission        | 19 (14.3)           | 25 (18.8)   | 0.32    |
| Neonatal death        | 0 (0.0)             | 1 (0.8)     | >0.99   |

*Data are median (interquartile range).

*Data are means ± SD.

SI conversion factors: to convert glucose from mg/dL to mmol/L, multiply by 0.0555; for insulin from µU/mL to pmol/L, multiply by 6.945.

LGA, large for gestational age; SGA, small for gestational age; NICU, neonatal intensive care unit.
recommended by the IOM guidelines. This observation suggests the social support and contact provided by standard PAT alone helped prevent excessive GWG, which decreased our ability to detect the therapeutic effect of PAT+.

Although our PAT+ intervention had a significant effect on GWG, the clinical importance of this effect was modest. PAT+ resulted in a lower maternal systolic blood pressure, less of an increase in plasma insulin during the OGTT, and less gestational gain in body fat. However, there was no difference in other maternal cardiometabolic outcomes, pregnancy complications, neonatal birth weight and body composition, or neonatal complications.

We are aware of two previous randomized controlled trials that evaluated the effect of lifestyle intervention on GWG in SED African American women (6,7). The results from one study conducted in 66 African American women who had overweight or obesity found that a lifestyle intervention delivered through text messaging and health coach telephone calls was able to decrease GWG, demonstrating the importance of using interventions that are convenient to help patients overcome barriers to participation (6). The other randomized trial was conducted in 59 women (~ two-thirds of the participants had overweight or obesity) and used PAT to deliver a lifestyle (diet and physical activity) weight management curriculum through monthly home visits beginning in the early second trimester of pregnancy (7). The percentage of women who had excessive GWG in the group treated with PAT+ was not different than the group who were treated with PAT alone. However, the attrition rate was much higher in participants randomized to PAT+ than PAT, possibly because of the long, 90-minute duration of each home visit, which could have influenced weight outcomes. In contrast, in our study, attrition was lower in participants treated with PAT+ compared with those treated with standard PAT, possibly because we embedded the lifestyle content within more frequent, biweekly home visits and made sure home visits were completed within 60 minutes.

Lifestyle weight management interventions that are effective in clinical trials frequently fail in real-world patient care programs because of challenges related to acceptability and financial costs (9). Our previous work with PAT in African American parents of infants (17), rural parents of young children (18), and teen mothers (19) laid the groundwork for the current intervention by demonstrating that PAT has an effective organizational structure for reaching, delivering, and scaling-up interventions that can be successfully used to modify lifestyle behaviors. Moreover, the PAT organization reaches a large number of high-risk, SED women as part of routine home visiting practice, facilitating PAT+ delivery to those who are often unable to participate in multisite, clinic-based therapies. The PAT program has considerable reach across the United States, providing the infrastructure for the scale-up of PAT+ across the country. In 2015 and 2016, PAT trained 4,999 parent educators located in 1,183 community-based sites in all 50 states, who conducted 1,188,585 home visits involving 116,054 families and 140,740 children, including 20,889 pregnant women (11). Efforts to evaluate the impact of the widespread dissemination of PAT+ as part of routine PAT practice in pregnant women deserves further study.

In conclusion, we found that PAT+, a home-based lifestyle intervention for SED African American women with overweight and obesity at the start of pregnancy, resulted in reduced weekly and total GWG. However, the beneficial effect in limiting GWG did not translate into important clinical benefits for pregnancy or infant outcomes. Additional studies with a longer duration of follow-up are needed to assess subsequent maternal weight change and child health and development. Nonetheless, our data demonstrated the effectiveness of using a national home visiting program to deliver a lifestyle intervention that reduces GWG in a complex, high-risk population with very limited resources. Moreover, embedding the lifestyle intervention within an existing national infrastructure makes it possible to readily disseminate this approach throughout the United States at minimal cost.

Acknowledgments

We thank the LIFE-Moms consortium members for their contributions to the development and oversight of the common measures and procedures shared across the trials.

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References

1. Institute of Medicine; National Research Council; Rasmussen KM, Yaktine AL, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington, DC: National Academies Press; 2009.

2. Doherty DA, Magann EF, Francis J, Morrison JC, Newnham JP. Pre-pregnancy body mass index and pregnancy outcomes. Int J Gynecol Obstet 2006;95:242-247.

3. Davis EM, Stange KC, Horwitz RI. Childbearing, stress and obesity disparities in women: a public health perspective. Matern Child Health J 2012;16:109-118.

4. Kiel DW, Dodson EA, Artal R, Boehmer TK, Leet TL. Gestational weight gain and pregnancy outcomes in obese women: how much is enough? Obstet Gynecol 2007;110:752-758.

5. International Weight Management in Pregnancy (i-WIP) Collaborative Group. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. BMJ 2017;358:j3119. doi:10.1136/bmj.j3119

6. Herring SJ, Cruise JF, Bennett GG, Rose MZ, Davey A, Foster GD. Preventing excessive gestational weight gain among African American women: a randomized clinical trial. Obesity (Silver Spring) 2016;24:30-36.

7. Thomson J, Tussing-Humphreys L, Goodman M, Oleneder S. Gestational weight gain: results from the delta healthy sprouts comparative impact trial. J Pregnancy 2016;2016:5703607. doi:10.1155/2016/5703607.

8. Anderson CK, Walch TJ, Lindberg SM, Smith AM, Lindheim SR, Whigham LD. Excess gestational weight gain in low-income overweight and obese women: a qualitative study. J Nutrition Educ Behav 2015;47:404-411.e1.

9. Yeo S, Samuel-Hodge CD, Smith R, Leeman J, Ferraro AM, Asafa-Adjei JK. Challenges of integrating an evidence-based intervention in health departments to prevent excessive gestational weight gain among low-income women. Public Health Nurs 2016;33:224-231.

10. Kumanyiska SK, Whitt-Glover MC, Haire-Joshu D. What works for obesity prevention and treatment in black Americans? Research directions. Obes Rev 2014;15 (suppl 4):204-212.

11. Parents as Teachers National Center: PAT Quality Assurance Guidelines. St. Louis: Parents as Teachers National Center; 2016.

12. ACOG Committee Obstetric Practice. ACOG Committee opinion. Number 267, January 2002: exercise during pregnancy and the postpartum period. Obstet Gynecol 2002;99:171-173.

13. Clifton RG, Evans M, Cahill AG, et al. Design of lifestyle intervention trials to prevent excessive gestational weight gain in women with overweight or obesity. Obesity (Silver Spring) 2016;24:305-313.

14. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 125: chronic hypertension in pregnancy. Obstet Gynecol 2012;119:396-407.

15. Matthews DR, Hosker JP, Rudenski AS, Naylor BA, Treacher DF, Turner RC. Homeostasis model assessment: insulin resistance and beta-cell function from fasting plasma glucose and insulin concentrations in man. Diabetologia 1985;28:412-419.

16. Mari A, Tura A, Gastaldelli A, Ferrannini E. Assessing insulin secretion by modeling control of insulin secretion. Diabetologia 2002;45:1641. doi:10.1007/s00125-002-0673-y

17. Haire-Joshu D, Brownson RC, Nanney MS, et al. Improving dietary behavior in African Americans: the Parents As Teachers High 5, Low Fat Program. Prev Med 2003;36:684-691.

18. Haire-Joshu D, Elliott MB, Caito NM, et al. High 5 for Kids: the impact of a home visiting program on fruit and vegetable intake of parents and their preschool children. Prev Med 2008;47:77-82.

19. Haire-Joshu DL, Schwarz CD, Paskoe SB, Budd EL, Brownson RC, Joshu CE. A group randomized controlled trial integrating obesity prevention and control for postpartum adolescents in a home visiting program. Int J Behav Nutr Phys Act 2015;12:88-97.