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The Impact of a Lifestyle Intervention on Postpartum Cardiometabolic Risk Factors Among Hispanic Women With Abnormal Glucose Tolerance During Pregnancy: Secondary Analysis of a Randomized Trial

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Background: Women with abnormal glucose tolerance during pregnancy are at risk for cardiovascular disease (CVD), with higher rates among Hispanics. However, studies on the impact of lifestyle interventions on postpartum CVD profiles are sparse. ***Methods:*** This is a secondary analysis of a controlled trial among a subsample of Hispanic women with abnormal glucose tolerance participating in Estudió PARTO (Project Aiming to Reduce Type twO diabetes; mean age = 28.2 y, SD: 5.8) who were randomized to a culturally modified Lifestyle intervention (n = 45) or a comparison Health and Wellness intervention (n = 55). Primary endpoints were biomarkers of cardiovascular risk (lipids, C-reactive protein, fetuin-A, and albumin-to-creatinine ratio) and insulin resistance (fasting insulin, glucose, HbA_{1c}, homeostasis model assessment, leptin, tumor necrosis factor-alpha, and adiponectin) measured at baseline (6-wk postpartum) and 6 and 12 months. ***Results:*** In intent-to-treat analyses, there were no significant differences in changes in biomarkers of CVD risk or insulin resistance over the postpartum year. In prespecified sensitivity analyses, women adherent with the Lifestyle Intervention had more favorable improvements in insulin (intervention effect = −4.87, SE: 1.93, $P = .01$) and HOMA-IR (intervention effect = −1.15, SE: 0.53, $P = .03$) compared with the Health and Wellness arm. In pooled analyses, regardless of intervention arm, women with higher postpartum sports/exercise had greater increase in HDL-cholesterol (intervention effect = 6.99, SE: 1.72, $P = .0001$). ***Conclusions:*** In this randomized controlled trial among Hispanic women with abnormal glucose tolerance, we did not observe a significant effect on postpartum biomarkers of CVD risk or insulin resistance. Women adherent to the intervention had more favorable changes in insulin and HOMA-IR.

Keywords: exercise, gestational diabetes, GDM, HOMA-IR, metabolic parameters

Hispanic women are disproportionately affected by type 2 diabetes and cardiovascular disease (CVD), and CVD is the most common cause of mortality in Hispanic Americans.[1,2] Women with abnormal glucose tolerance during pregnancy are more likely to have an adverse postpartum cardiovascular risk and insulin resistance profile, as well as an increased risk of future type 2 diabetes (T2D) and CVD.[3] Indeed, 50% of Hispanic women with gestational diabetes mellitus (GDM) go on to develop T2D within 5 years of delivery.[4]

Puerto Ricans are the second largest US Hispanic subgroup with a population growth rate 3 times higher than the general US population.[5,6] Hispanics of Puerto Rican heritage have the highest prevalence of diabetes, obesity, and major cardiometabolic risk factors among Hispanic subgroups.[2,7,8] Compared with non-Hispanic White women, Hispanic women with a history of GDM are less aware of diabetes risk factors and prevention strategies, such as physical activity, dietary behaviors, and weight management.[9]

Increasing physical activity in the general population is known to have significant effects on cardiovascular and metabolic health through improvements in glucose tolerance, lipid profiles, inflammation, and vascular function[10] with further downstream positive effects in the prevention of CVD and T2D.[11] However, the impact of postpartum exercise interventions in modulating lipid and insulin resistance profile in the postpartum period has not been well studied.[12–17]

Such postpartum interventions may impact CVD risk and insulin resistance among postpartum women by reducing oxidative stress and inflammation, and improving endothelial function, hepatic glucose output, lipoprotein lipase activity, and parasympathetic nervous system activity.[18,19]

Prior studies on lifestyle interventions among women with GDM have had inconsistent findings; some studies found significant decreases in insulin resistance-related measures among the intervention group, while other studies found no effect of lifestyle intervention on glycemic outcomes.[20–22] However, among

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postpartum physical activity intervention studies, only one was conducted among a Hispanic population[12] and none in Hispanics of Puerto Rican heritage; only one was conducted among women with abnormal glucose tolerance in pregnancy,[13] and only one relied upon a theoretical model.[12] As noted in recent reviews, the majority of interventions to prevent T2D among women with history of GDM did not consider long-term sustainability, gendered issues in physical activity, or social norms for women.[20,21] Physical activity needs to be incorporated in the context of the daily lives of women and culturally modified to create meaningful health outcomes.[23]

Therefore, we evaluated the effect of a culturally modified, motivationally targeted, and individually tailored lifestyle intervention on biomarkers of CVD risk and insulin resistance in a subsample of participants in Estudió PARTO (Project Aiming to Reduce Type twO diabetes), a randomized trial among Hispanic women with a history of abnormal glucose tolerance in pregnancy. We used a pragmatic low-cost high-reach strategy such that findings could readily be translated into clinical practice among underserved at-risk minoritized populations. In prior studies in this cohort, we found that women in the Lifestyle intervention arm had a statistically significant 2.5-fold higher odds of weight reduction to at or below prepregnancy weight (95% confidence interval, 1.09–5.82)[24] and a significant increases in vigorous physical activity (mean change = 1.3 MET-h/wk, $P = .03$)[25] at 12-month postpartum compared with women in the Health and Wellness arm.

We hypothesized that participants randomized to the Lifestyle intervention arm would also experience beneficial changes in postpartum biomarkers of CVD risk and insulin resistance compared to the comparison Health and Wellness arm.

Methods

Participants

Study participants were enrolled in Estudió PARTO. Inclusion criteria were limited to pregnant Hispanic women who had abnormal results (ie, ≥135 mg/dL) on the routine GDM screening test at 24 to 28 weeks of gestation. Hispanic ethnicity was self-reported. Exclusion criteria included: (1) history of type 1 or T2D, heart disease, or chronic renal disease; (2) contraindications to intervention activities (ie, physical activity and diet modification) during the postpartum period; (3) unable to read English or Spanish at a sixth-grade level; or (4) under 18 years of age or over 45 years of age at the time of recruitment.

Study Design

Estudió PARTO was a randomized controlled trial conducted from January 2013 to December 2017 at Baystate Medical Center in Western Massachusetts to test the efficacy of a culturally and linguistically modified, individually tailored lifestyle intervention to reduce risk factors for T2D and CVD among Hispanic women with an abnormal glucose tolerance during pregnancy. All protocols were approved by the appropriate Baystate Health Institutional Review Board. Details of the study protocol and the Lifestyle Intervention and Health and Wellness interventions have been previously published[26] and this study is registered at www.clinicaltrials.gov NCT01679210.

Briefly, women were recruited by bilingual and bicultural health educators at the time of routine screening for GDM (24- to 28-wk gestation). Women were informed of the aims and procedures of the study and were asked to sign an approved written informed consent form. Following informed consent, women were randomly assigned 1:1 to either the Lifestyle intervention arm or the Health and Wellness arm (control arm). Randomization was stratified by the results of the diagnostic 100 g oral glucose tolerance test using thresholds for GDM defined by the American Diabetes Association: (1) no glucose values meeting or exceeding the American Diabetes Association thresholds or (2) ≥1 glucose values meeting or exceeding the American Diabetes Association thresholds.[27]

Trained bicultural/bilingual health interviewers, blinded to the intervention arm, conducted assessments at 6 weeks, 6 months, and 12 months of postpartum. The majority of these assessments took place in participants' homes. Of the randomized participants, a subsample of women (n = 100, 70% of those eligible) volunteered to provide a fasting blood sample immediately after these home visits which required additional travel to the laboratory. Travel vouchers were provided to reduce barriers to participation in this component.

In both arms, the intervention began with an introductory phase (~29 wk of gestation) followed by an active phase (6 wk to 6 mo of postpartum) and a maintenance phase (6–12 mo of postpartum). Both intervention arms received the same number of contacts/sessions: 4 face-to-face sessions and 13 total booster sessions, and participants received mailed print-based intervention materials. Intervention sessions and materials were offered in either English or Spanish, dependent on participant preference.

The Lifestyle intervention was an evidence-based approach utilizing culturally and linguistically modified, motivationally targeted, individually tailored intervention materials developed in previous randomized controlled trials in Hispanic populations[28–31] as well as theoretical concepts and strategies from Social Cognitive Theory[32] and the Transtheoretical Model.[33] The postpartum weight loss goal was 1 to 2 pounds per week via increasing physical activity by 10% per week, with trial goals of weight reduction to prepregnancy weight if prepregnancy body mass index (BMI) was normal, or a 5% reduction if prepregnancy BMI was overweight/obese. Corresponding calorie goals were based on the Diabetes Prevention Program[34] and accounted for breastfeeding status as recommended by the Institute of Medicine.[35]

Tailoring questionnaires administered at 6 weeks, 6 months, and 1 year of postpartum were used by study personnel to inform culturally and motivationally tailored feedback and to select targeted diet and physical activity goals for participants. Motivational interviewing strategies were used to identify and strengthen participants' motivations for change. Telephone booster sessions reviewed progress toward goals, problem-solving discussion, and setting new goals.

The Health and Wellness comparison arm received face-to-face visits, mailed health materials and telephone booster calls on the same schedule as the Lifestyle intervention participants. However, the self-help materials focused on nonexercise and nondietary topics, so the content remained distinct from that provided to the Lifestyle intervention arm.

Measures

Primary endpoints were biomarkers of cardiovascular risk and insulin resistance. Plasma lipids (total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides), insulin, glucose, albumin, and creatinine were measured using the Roche P Modular system.[36] High-sensitivity C-reactive protein was measured on the Roche P Modular system with an immunoturbidimetric assay with reagents and calibrators from

DiaSorin. Hemoglobin A1c (HbA_{1c}) determination on the Roche R Modular system was based on turbidimetric immunoinhibition using packed red cells. Fetuin-A was measured using an enzyme immunoassay (BioVendor). Leptin was measured using an ultra-sensitive ELISA assay, an enzymatically amplified "two-step" sandwich-type immunoassay (R&D Systems). Tumor necrosis factor (TNF)-alpha-receptor II, herein referred to as TNF-alpha, was measured using an ELISA assay from R&D Systems that employs the quantitative sandwich enzyme immunoassay technique. Adiponectin was measured using an ELISA method from ALPCO Diagnostics Inc. Homeostatic model assessment for insulin resistance (HOMA-IR) was calculated as (fasting insulin × fasting glucose)/22.5 on a scale of 1 (maximally sensitive) to 8 (maximally resistant).

Demographic and behavioral characteristics were collected at the time of recruitment via standardized questionnaires and included age, education, annual household income, marital status, living with a spouse or partner, number of adults and children living in the household, and generation in the continental United States. Acculturation was measured via the Psychological Acculturation Scale[37] and was categorized as low acculturation (scores of 1 to less than 3) or high acculturation (greater than 3). Postpartum depression was measured using the Edinburgh Postpartum Depression Scale, validated for Hispanics.[38,39] At the least, probable minor depression was defined as scoring 13 on the scale. Physical activity was assessed via the Pregnancy Physical Activity Questionnaire[40]; meeting American College of Obstetricians and Gynecologists guidelines was defined as obtaining at least 150 minutes of moderate to vigorous sports/exercise.[41]

Clinical characteristics of the current pregnancy were abstracted from the medical record and included prepregnancy BMI (in kilograms per square meter), parity, gestational weight gain, and glucose tolerance defined as isolated hyperglycemia, impaired glucose tolerance, or GDM.[42] Gestational weight gain was determined as the difference between maternal weight at delivery and prepregnancy weight and was categorized as below, within, or above the Institute of Medicine gestational weight gain guidelines.[43] Breastfeeding at 6-week postpartum was self-reported.

Statistical Analysis

To account for anticipated loss to follow-up between the pregnancy and postpartum time periods, we sought to over-enroll participants. A final sample of 100 women randomly assigned to 2 groups of n = 50 at 12 months of follow-up had 80% power to detect a "small medium" effect size with a .05 level of significance.[44]

Two-sample *t* tests and chi-square tests, or in the case of small sample size, Fisher exact tests, were used to evaluated differences in covariates between arms at baseline. An intent-to-treat analysis was conducted using a complete case analysis to evaluate differences in the changes in biomarkers between the intervention arms from 6-week postpartum (baseline) to 6- and 12-month postpartum. To compare difference in biomarkers within and between groups over time, Wilcoxon signed rank tests were used. Generalized linear mixed effect models (using intervention group as a fixed effect, subjects as a random effect, and an unstructured covariance matrix) were used to evaluate differences in the change in biomarkers over the course of postpartum follow-up time. A group by time interaction term was used to test whether change in biomarkers differed significantly with time. Because we did not observe a statistically significant difference in treatment effect by time for any of the biomarkers, with the exception of TNF-alpha, we present main effects models only.

Several sensitivity analyses were conducted. First, we evaluated whether participants who provided a blood sample differed from those who did not provide a blood sample according to any covariates. Second, we limited the analysis to women in the Lifestyle intervention arm who were adherent with the intervention defined as: (1) meeting American College of Obstetricians and Gynecologists exercise guidelines and (2) returning > 1 tailoring questionnaires. Third, the analysis was limited to women who had an overweight or obese prepregnancy BMI, as there is evidence that lifestyle interventions may be more effective among this group.[45] Lastly, to evaluate the association of actual physical activity with cardiovascular risk and insulin resistance biomarkers in the pooled sample regardless of assigned intervention arm, generalized linear models were used to assess the relationship between self-reported sports/exercise and these biomarkers. These models were adjusted for age and prepregnancy BMI.

Results

Baseline Participant Characteristics

A total of 100 of the eligible randomized women provided one or more blood samples: Lifestyle intervention (n = 45) and Health and Wellness intervention (n = 55). Of this group, 96 provided a sample at 6-week postpartum, 79 at 6-month postpartum, and 75 at 12-month postpartum. Rates of follow-up did not differ between intervention arms.

The majority of participants were born outside the continental United States (51.5%), had a family history of diabetes (71.6%), were overweight/obese (mean prepregnancy BMI 31.6 [8.3] kg/m^2), and exceeded Institute of Medicine gestational weight gain guidelines (55.7%) (Table 1). There were no statistically significant differences at baseline between participants in the Lifestyle intervention, and Health and Wellness arms according to sociodemographic, behavioral, and medical history factors, although participants in the Lifestyle intervention arm had lower rates of isolated hyperglycemia and higher rates of impaired glucose tolerance, but equivalent rates of GDM, compared with participants in the Health and Wellness arm (Table 1).

There were no statistically significant differences in baseline (6 wk) biomarker values between intervention arms (Table 2). On average, participants had desirable levels of total cholesterol, optimal or near/above optimal LDL cholesterol concentrations, and normal HDL cholesterol concentrations at baseline per National Cholesterol Education Program Adult Treatment Panel III criteria (Table 2).[46] Mean values for HbA_{1c} and fasting plasma glucose were normal.[47]

Changes in Biomarkers over Time

At 6-month follow-up, participants in the Lifestyle intervention arm experienced significant decreases in total cholesterol, LDL-cholesterol, triglycerides, and albumin-to-creatinine ratio but significant increases in HbA_{1c} concentrations and glucose (Table 3). The Health and Wellness arm also experienced significant decreases in total cholesterol and albumin-to-creatinine ratio, and additionally experienced significant increases in insulin, HOMA, and adiponectin. Findings were similar at 12-month follow-up, with the Lifestyle intervention arm additionally experiencing a significant decrease in fetuin A and leptin; while the Health and Wellness arm had a significant decrease in TNF-alpha, although concentrations remained above the recommended levels for both arms. Changes in adiponectin were no longer significant.

Table 1 Characteristics of Study Participants at Baseline According to Intervention Arm[a]; Estudió PARTO 2013–2016

	Total sample (N = 100)		Lifestyle intervention (n = 45)		Health and Wellness intervention (n = 55)		
Covariates	**N**	**% or mean (SD)**	**N**	**% or mean (SD)**	**N**	**% or mean (SD)**	***P***
Age							
16–19	4	4.0%	0	—	4	7.3%	.10
20–24	24	24.0%	7	15.6%	17	30.9%	
25–29	36	36.0%	19	42.2%	17	30.9%	
30–34	19	19.0%	11	24.4%	8	14.6%	
35–45	17	17.0%	8	17.8%	9	16.4%	
Education							
Less than high school	24	24.0%	9	20.0%	15	27.3%	.49
High school graduate or GED	28	28.0%	15	33.3%	13	23.6%	
Post high school	48	48.0%	21	46.7%	27	49.1%	
Annual household income							
≤$15,000	22	40.7%	7	31.8%	15	46.9%	.54
>$15,000–$30,000	13	24.1%	6	27.3%	7	21.9%	
>$30,000	19	34.2%	9	40.9%	10	31.3%	
Don't know/refused	46	—	23	—	23	—	
Marital status							
Single/separated/divorced/widowed	68	68.0%	28	62.2%	40	72.7%	.26
Married	32	32.0%	17	37.8%	15	27.3%	
Living with a spouse or partner							
Yes	72	72.7%	30	66.7%	42	77.8%	.22
No	27	27.3%	15	33.3%	12	22.2%	
Number of adults living in the household							
1	11	11.0%	7	15.6%	4	7.3%	.26
2	63	63.0%	29	64.4%	34	61.8%	
3 or more	26	26.0%	9	20.0%	17	30.9%	
Number of children living in the household							
0	18	18.0%	8	17.8%	10	18.2%	.68
1	43	43.0%	20	44.4%	23	41.8%	
2	21	21.0%	11	24.4%	10	18.2%	
3 or more	18	18.0%	6	13.3%	12	21.8%	
Generation in the United States							
Born outside continental United States	51	51.5%	28	63.6%	23	41.8%	.14
Parent born outside continental United States	30	30.3%	10	22.7%	20	36.4%	
Grandparent born outside continental United States	12	12.1%	5	11.4%	7	12.7%	
All grandparents born outside continental United States	6	6.1%	1	2.3%	5	9.1%	
Acculturation status							
Low acculturation (1 to < 3)	79	79.0%	39	86.7%	40	72.7%	.09
High acculturation (≥3)	21	21.0%	6	13.3%	15	27.3%	
At least probable minor depression							
Yes	5	5.4%	2	4.7%	3	6.1%	.99
No	87	94.6%	41	95.4%	46	93.9%	
Total sleep score, 6-wk postpartum	95	6.4 (3.6)	44	6.09 (3.61)	51	6.59 (3.67)	.51
Prepregnancy BMI, kg/m^2	100	31.6 (8.3)	45	32.80 (9.23)	55	30.67 (7.31)	.20
Family history of diabetes							
Yes	68	71.6%	31	73.8%	37	69.8%	.67
No	27	28.4%	11	26.2%	16	30.2%	

(continued)

Table 1 *(continued)*

Covariates	Total sample (N = 100)		Lifestyle intervention (n = 45)		Health and Wellness intervention (n = 55)		
	N	% or mean (SD)	N	% or mean (SD)	N	% or mean (SD)	*P*
Parity							
0	25	25.0%	12	26.7%	13	23.6%	.83
1 or 2	57	57.0%	26	57.8%	31	56.4%	
3 or more	18	18.0%	7	15.6%	11	20.0%	
Adherence to IOM gestational weight gain guidelines							
Below	21	21.7%	9	20.5%	12	22.6%	.96
Within	22	22.7%	10	22.7%	12	22.6%	
Above	54	55.7%	25	56.8%	29	54.7%	
Glucose tolerance							
Isolated hyperglycemia	41	41.0%	12	26.7%	29	52.7%	.0005
Impaired glucose tolerance	21	21.0%	17	37.8%	4	7.3%	
GDM	38	38.0%	16	35.6%	22	40.0%	
Feeding type, 6-wk postpartum							
Breastmilk	13	13.3%	8	18.2%	5	9.3%	.30
Formula	63	64.3%	25	56.8%	38	70.4%	
Both breastmilk and formula	22	22.5%	11	25.0%	11	20.4%	

Abbreviations: BMI, body mass index; GDM, gestational diabetes mellitus; GED, general educational development test; IOM, Institute of Medicine; PARTO, Project Aiming to Reduce Type twO diabetes.

Main Effects

In main effects models across postpartum follow-up time, we observed no significant differences in mean changes between the intervention arms for all cardiovascular risk and insulin resistance biomarkers with the exception of TNF-alpha (Table 3). Specifically, participants in the Lifestyle intervention arm had a significantly smaller decrease in TNF-alpha than those in the Health and Wellness arm (intervention effect = 207.9, SE: 94.2, $P_{group} = .03$), although all participants had values above the recommended reference range (<5.6 pg/mL).[48] Although not statistically significant, we did observe a greater decrease in total cholesterol, LDL cholesterol, triglycerides, leptin, and less of an increase in high-sensitivity C-reactive protein, albumin-to-creatinine ratio, and insulin in the Lifestyle intervention arm as compared with the Health and Wellness arm, but a greater increase in glucose and HbA_{1c}.

Sensitivity Analyses

Additionally, we evaluated whether baseline characteristics differed between participants who provided a blood sample versus those who did not, and found that the groups did not significantly differ according to any sociodemographic, behavioral, or clinical variable. We then limited the analysis to women who were adherent with the Lifestyle intervention defined as meeting guidelines for sports/exercise (55.6%). In this sensitivity analysis, participants in the Lifestyle intervention arm had a significantly smaller increase in insulin (intervention effect = –4.87, SE: 1.93, $P = .01$) and HOMA (intervention effect = –1.15, SE: 0.53, $P = .03$) compared with those in the Health and Wellness arm, however, the remainder of the findings remained virtually unchanged (Supplementary Table S1 [available online]).

Next, we conducted another sensitivity analysis limiting the analysis to women who were adherent with the intervention defined as returning the tailored questionnaires (93.3% and 94.6% in the Lifestyle and Health and Wellness arms, respectively). Findings were virtually unchanged (data not shown). We then limited the analysis to those women with an overweight or obese prepregnancy BMI (80% and 74.5% in the Lifestyle and Health and Wellness arms, respectively). In this analysis, findings for TNF-alpha were attenuated and no longer statistically significant, and we again observed a suggestion of a smaller increase in insulin among participants in the Lifestyle intervention arm as compared with the Health and Wellness arm (intervention effect = –4.02, SE: 2.08, $P = .06$).

Last, we pooled intervention arms to evaluate the overall association of self-reported sports/exercise at 6-week postpartum, regardless of randomization arm, with postpartum change in biomarkers. After adjusting for age and prepregnancy BMI, participation in high levels of sports/exercise activity was associated with a greater increase in total cholesterol (intervention effect = 13.69, SE: 4.96, $P = .007$), largely due to a greater increase in HDL cholesterol (intervention effect = 6.99, SE: 1.72, $P = .0001$), as compared with less active participants (Supplementary Table S2 [available online]).

Discussion

In this randomized controlled trial among postpartum Hispanic women with abnormal glucose tolerance during pregnancy, we found that a culturally modified, individually tailored lifestyle intervention did not lead to a significant difference in changes in biomarkers of CVD risk and insulin resistance over the postpartum year. Women adherent to the intervention had more favorable changes in insulin and HOMA-IR. In the pooled sample, we observed that women who participated in high levels of sports or exercise, regardless of their assigned intervention arm, had a greater increase in HDL cholesterol as compared with those with low levels.

Table 2 Cardiovascular and Insulin-Resistance Biomarkers According to Intervention Arm; Estudió PARTO 2013–2016

	6 wk			6 mo			12 mo		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Cardiovascular disease biomarkers									
Total cholesterol, mg/dL									
Lifestyle intervention	44	173.91	34.21	37	164.41	28.87	34	160.65	29.09
Health and Wellness intervention	52	171.75	25.87	42	162.12	31.02	41	165.29	38.19
LDL cholesterol, mg/dL									
Lifestyle intervention	44	106.66	30.56	37	100.61	24.87	34	98.33	22.53
Health and Wellness intervention	52	102.22	21.01	42	95.39	22.21	41	98.55	27.19
HDL cholesterol, mg/dL									
Lifestyle intervention	44	46.68	10.74	37	46.86	9.38	34	46.32	10.30
Health and Wellness intervention	52	46.11	13.48	42	45.77	14.02	41	47.44	16.47
Triglycerides, mg/dL									
Lifestyle intervention	44	109.84	63.07	37	91.22	43.07	34	92.76	39.79
Health and Wellness intervention	52	117.16	66.14	42	107.38	64.35	41	108.38	62.41
High-sensitivity C-reactive protein, mg/L									
Lifestyle intervention	44	5.12	4.62	37	5.20	4.87	33	5.71	6.48
Health and Wellness intervention	52	5.81	5.96	42	6.92	9.36	41	7.19	8.24
Fetuin-A, ng/mL									
Lifestyle intervention	44	670.03	150.89	37	672.36	123.05	34	634.07	122.04
Health and Wellness intervention	52	713.78	137.93	42	731.21	204.34	41	686.53	164.96
Albumin-to-creatinine ratio									
Lifestyle intervention	44	7.19	1.34	37	7.49	1.52	34	7.53	1.58
Health and Wellness intervention	52	6.77	1.03	42	7.01	0.93	41	7.18	0.99
Insulin resistance biomarkers									
Insulin, uIU/mL									
Lifestyle intervention	44	17.22	11.69	37	17.86	12.41	34	19.42	14.10
Health and Wellness intervention	52	15.46	9.07	42	19.50	9.30	41	23.40	21.21
Glucose, mg/dL									
Lifestyle intervention	44	92.14	15.60	37	96.19	15.35	33	102.45	32.85
Health and Wellness intervention	52	90.58	9.74	42	92.95	12.19	41	92.71	14.01
HbA_{1c}, %									
Lifestyle intervention	44	5.14	0.40	37	5.24	0.52	34	5.43	0.85
Health and Wellness intervention	52	5.05	0.37	40	5.15	0.35	41	5.21	0.37
HOMA									
Lifestyle intervention	44	4.10	3.14	37	4.45	3.65	33	5.41	5.30
Health and Wellness intervention	52	3.55	2.22	42	4.57	2.68	41	5.56	5.44
Leptin, pg/mL									
Lifestyle intervention	44	39.58	23.71	37	36.52	22.98	34	33.62	24.80
Health and Wellness intervention	52	36.69	18.85	42	38.19	19.96	41	34.42	18.31
TNF-a, pg/mL									
Lifestyle intervention	44	1908.38	474.93	37	1817.60	472.03	34	1877.91	502.68
Health and Wellness intervention	52	2062.30	467.86	42	2015.05	578.82	41	1930.38	486.58
Adiponectin, ng/mL									
Lifestyle intervention	44	3.92	1.92	37	4.02	2.00	34	3.75	1.84
Health and Wellness intervention	52	3.95	1.75	42	3.47	1.58	41	3.62	1.88

Abbreviation: PARTO, Project Aiming to Reduce Type twO diabetes.

Table 3 Change From Baseline in Cardiovascular and Insulin-Resistance Biomarkers at 6 and 12 Months According to Intervention Arm; Estudió PARTO 2013–2016

	Change from baseline at 6 mo				Change from baseline at 12 mo				Main effects model[a]		
	N	Mean	SD	*P*[b]	N	Mean	SD	*P*[b]	Intervention effect	SE	*P*
Cardiovascular disease biomarkers											
Total cholesterol, mg/dL											
Lifestyle intervention	37	−11.49	22.33	.02	33	−12.21	26.80	.01	−4.19	4.87	.39
Health and Wellness intervention	40	−10.83	22.77	.002	39	−5.05	31.96	.08			
LDL cholesterol, mg/dL											
Lifestyle intervention	37	−7.70	21.44	.08	33	−7.08	22.75	.08	−2.35	4.44	.60
Health and Wellness intervention	40	−7.89	21.72	.007	39	−4.02	25.81	.17			
HDL cholesterol, mg/dL											
Lifestyle intervention	37	0.24	7.44	.72	33	−0.06	8.01	.84	−1.13	1.81	.53
Health and Wellness intervention	40	−0.22	9.30	.78	39	2.31	11.51	.49			
Triglycerides, mg/dL											
Lifestyle intervention	37	−18.14	49.04	.04	33	−23.07	56.30	.02	−13.31	10.65	.21
Health and Wellness intervention	40	−10.94	54.75	.08	39	−5.20	58.89	.66			
High-sensitivity C-reactive protein, mg/L											
Lifestyle intervention	37	0.20	3.76	.80	32	0.50	6.40	.86	−0.41	1.10	.71
Health and Wellness intervention	40	0.79	7.26	.92	39	0.51	5.65	1.00			
Fetuin-A, ng/mL											
Lifestyle intervention	37	−0.18	109.20	.53	33	−51.28	138.10	.01	−27.92	26.99	.30
Health and Wellness intervention	40	12.87	147.50	.87	39	−15.11	164.70	.21			
Albumin-to-creatinine ratio											
Lifestyle intervention	37	0.39	0.99	.03	33	0.29	0.87	.10	−0.007	0.17	.97
Health and Wellness intervention	40	0.30	0.69	0.01	39	0.35	0.82	.02			
Insulin resistance biomarkers											
Insulin, uIU/mL											
Lifestyle intervention	37	0.67	8.45	.95	33	0.44	9.75	.52	−2.58	1.81	.16
Health and Wellness intervention	40	2.79	8.30	.008	39	7.37	19.00	.0005			
Glucose, mg/dL											
Lifestyle intervention	37	4.00	12.45	.05	32	8.69	22.26	.05	2.14	2.56	.41
Health and Wellness intervention	40	2.85	12.33	.14	39	2.90	13.50	.17			
HbA_{1c}, %											
Lifestyle intervention	37	0.10	0.34	.05	33	0.27	0.65	.04	0.001	0.07	.98
Health and Wellness intervention	38	0.10	0.28	.08	39	0.13	0.27	.005			
HOMA											
Lifestyle intervention	37	0.33	2.37	.63	32	0.77	3.60	.23	−0.53	0.51	.30
Health and Wellness intervention	40	0.79	2.38	.008	39	1.99	4.82	.0005			
Leptin, pg/mL											
Lifestyle intervention	37	−0.89	9.86	.42	33	−5.68	14.96	.03	−2.53	2.28	.27
Health and Wellness intervention	40	1.01	12.16	.51	39	−2.89	10.16	.33			
TNF-a, pg/mL											
Lifestyle intervention	37	−130.60	402.90	.09	33	26.72	403.40	.85	207.9[c]	94.24	.03
Health and Wellness intervention	40	−84.16	516.30	.10	39	−202.30	423.90	.002			
Adiponectin, ng/mL											
Lifestyle intervention	37	−0.05	0.98	.72	33	0.09	0.80	.58	0.23	0.20	.24
Health and Wellness intervention	40	−0.27	0.99	.04	39	−0.23	1.11	.12			

Abbreviation: PARTO, Project Aiming to Reduce Type twO diabetes.
[a]Generalized linear mixed effect models. [b]*P* value from Wilcoxon signed rank test. [c]For TNF alpha only, we observed a significant group × time effect; 6-month results were −38.62 (SE = 103.30); 12-month results are presented in the body of the table.

Despite their current diagnosis of abnormal glucose tolerance and their generally overweight/obese status, the subsample in this analysis was comprised of young women with on average normal postpartum biomarker levels. In general, both groups experienced improvements in biomarkers over the postpartum time period. Our findings are comparable to the majority of prior postpartum exercise trials conducted in the immediate postpartum period which largely observed either null findings or a favorable impact on some, but not all, biomarkers. In the most similar study to date performed among Hispanic women, Vega-López et al[12] randomized 44 Hispanic women with overweight and obesity at 6-week postpartum to weekly walking groups. Walkers had an 11% increase and nonwalkers a 7% decrease in HDL cholesterol from 6 to 12 months ($P = .0367$) without an effect on LDL cholesterol. There were no statistically significant differences between the arms with regards to insulin or glucose.[12]

Similar to our study, Zilberman-Kravits et al[13] was the only prior study to focus on women who had abnormal glucose tolerance (ie, GDM) during pregnancy, although women were not recruited until 3- to 4-month postpartum. A total of 180 women in Israel were randomized to individual and group counseling sessions and advised to increase their level of exercise to at least 150 minutes per week. At 1-year postpartum, the authors found a statistically significant decrease in insulin, glucose, and HOMA-IR levels in the intervention group compared with those in the control group, but no impact on lipid profile.[13] In a 16-week weight loss intervention among n = 40 women starting at 7- to 8-week postpartum that included supervised walking sessions 3 to 4 times/week, Davenport et al[16] observed significant reductions in fasting glucose and LDL cholesterol concentrations relative to a nonrandomized historical control group. The remaining postpartum exercise trials were of small size, and of short duration, and found no differences in changes in lipid profile nor insulin resistance biomarkers between exercise versus control groups.[14,15,17]

?A3B2 tlsb .005w?>Differences in findings are likely due to differences in study populations and the content of the exercise intervention. In prior studies in this cohort we found that the intervention led to increased physical activity[25] and weight reduction[24] compared with the comparison arm. It is possible that the magnitude of these physical activity and weight changes was of smaller magnitude than what would cause physiologically meaningful changes in lipid concentrations. This suggests that perhaps a higher dose of physical activity (frequency, intensity, and/or duration), greater dietary changes, or a long-term active period of intervention may be required to improve biomarkers in this high-risk group. Interestingly, a meta-analysis of physical activity interventions targeting minority adults documented that neither supervised exercise interventions nor behavioral interventions resulted in significant changes in lipid concentrations despite small effects on anthropometric measurements.[23] Behavioral interventions conducted in free-living conditions have had inconsistent effects on lipoproteins; specifically, while a linear dose–response relationship has been observed between activity levels and HDL cholesterol levels, more intense activity is required to elicit reductions in LDL cholesterol and triglyceride levels.[49]

It is well established that the pressures of caring for a new baby, including fatigue, work-related obstacles, and lack of time tend to dominate the early postpartum period and are major barriers to engagement.[50] Indeed, we found that adherence to the lifestyle intervention was 55.6% over the postpartum period, and in a sensitivity analysis among this group, observed a significantly smaller increase in insulin ($P_{group} = .01$) and HOMA ($P_{group} = .03$) compared with the Health and Wellness arm. In addition, our findings of a beneficial association of high levels of sports/exercise, regardless of intervention arm, with HDL suggests if the lifestyle intervention could attain this level, it would likely have a positive impact on risk.

These results are supported by a growing body of research that has observed positive associations between acute and chronic physical activity and anti-inflammatory exerkines, which have been identified for their potential as treatment of CVD and T2D.[51] Type and duration of exercise have been identified as important factors in the body's exerkine response, which may explain why our observations of improvements in select cardiometabolic biomarkers were limited to participants who were adherent to the Lifestyle intervention and/or performing high levels of sports/exercise activity.

One of the most important differences between the current study and the majority of prior trials is our use of a comparison Health and Wellness arm matched for contact time. Thus, both arms received enhanced social support which may have led to beneficial changes in lifestyle behaviors and therefore a similarly less atherogenic lipoprotein profile in both arms. Similarly, Vega-López et al,[12] found that the increase in healthy behaviors observed in both their intervention and control groups could partially be attributed to attention to the health messages mailed to both groups.

This study had several strengths. First, our study focused on Hispanic women of Puerto Rican heritage, a growing high-risk population who are consistently underrepresented in research. Second, our study utilized a prospective randomized control trial design, allowing us to isolate the effect of the lifestyle intervention on cardiometabolic biomarkers. Third, our sample size provided adequate power to observe even a small to moderate effect of the Lifestyle intervention. Other strengths included the culturally modified intervention, the use of bilingual and bicultural health educators, and the reliance upon a theoretical model and an evidence-based approach.

This study also faces several limitations. The subsample of participants who provided a blood sample (70%) did not represent a random sample. However, this group did not differ from those who did not provide a blood sample thus reducing concerns regarding bias.

We relied upon self-reported ethnicity in selecting women for inclusion into our study, which could have led to misclassification. However, medical record classification of ethnicity has only been found to have moderate sensitivity and positive predictive value for Latinas (64% and 68%, respectively).[52] In contrast, our use of self-report is consistent with the approach used by the US Census and our reliance on bilingual/bicultural interviewers further helped to minimize misclassification.

Similarly, several covariates including breastfeeding were also based on self-report. Self-reported breastfeeding was collected using the Infant Feeding Questionnaire, which inquired about the type of feeding method currently used and has previously demonstrated high validity when compared with interview responses.[53] In addition, it is important to note that participants randomized to the Lifestyle versus the Health and Wellness arms did not differ significantly on these factors.

Tailoring questionnaires also relied upon self-report and were used to inform feedback and to select targeted diet and physical activity goals for participants. The dietary tailoring questionnaire utilized in this study, the Latino Dietary Behaviors Questionnaire, demonstrates substantial validity via correlations with 24-hour dietary recall scores and food group servings.[54] These tools were

also administered by bilingual/bicultural health interviewers further helping to minimize social desirability bias.

Clinical characteristics were abstracted from the medical record. Medical record abstraction within Baystate Medical Center has been previously validated using International Statistical Classification of Diseases and Related Health Problems-9 codes.[55] Clinical characteristics could be misclassified; however, participants did not differ with regard to these factors across intervention arms.

Lastly, due to the cultural tailoring of the provided intervention and the restriction of the study population to include Hispanic women with abnormal glucose tolerance during pregnancy, the results of this study should be limited to other Hispanic postpartum women with similar risk status during pregnancy.

Conclusions

In summary, in this randomized controlled trial of a culturally tailored, individually modified lifestyle intervention among Hispanic women with abnormal glucose tolerance during pregnancy, we did not observe a significant effect on biomarkers of CVD and insulin resistance. These findings suggest that an unsupervised active lifestyle program among at-risk Hispanic women may not be sufficient to improve the lipoprotein profile and insulin resistance biomarkers of postpartum women beyond the physiological changes after childbirth. These results are consistent with prior literature suggesting minimal to no effect of lifestyle interventions on cardiometabolic biomarkers.[20,21] Whether a greater amount and higher intensity of exercise than that attained in the current and previous studies can provide additional benefits should be further investigated. Future studies should also address barriers to engagement in physical activity among this high-risk population, including stressors, low health literacy, and inequities in social and physical environmental conditions experienced by Hispanic women. Additionally, future studies should evaluate whether this association is moderated by a family history of diabetes which could potentially act as an indicator of intergenerational metabolic risk. Healthcare providers rarely incorporate exercise programs into postpartum care plans and could be engaged to facilitate compliance with implementing evidence-based exercise programs for postpartum women.

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