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Glucose Intolerance during Pregnancy:

Assessing the Feasibility of Lifestyle Intervention in an Under-Served Population

By

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Doctor of Philosophy

Graduate Division of Biological and Biomedical Science

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An abstract of
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Abstract

Glucose Intolerance during Pregnancy:
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By Jessica A. Marcinkevage

This dissertation investigates two important factors to consider in the realm of glucose metabolism in women of childbearing age. We first provide an analysis of the underlying disparities by race/ethnicity in glycemic status among U.S. non-pregnant women of childbearing age. We then describe the feasibility of implementing a lifestyle intervention during pregnancy – focused on improved diet and increased physical activity – for the prevention of gestational diabetes mellitus (GDM) in a high-risk, under-served urban population of Atlanta, GA. Our findings illuminate issues affecting these two very important populations, and can provide insight into the design and development of interventions to improve health outcomes not only for women today, but also for future generations.

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Tables and Figures

CHAPTER 1. INTRODUCTION

Gestational diabetes mellitus (GDM) is a common complication of pregnancy, affecting over 200,000 U.S. births each year. There are indications that prevalence of GDM has increased in recent years, following a similar trajectory as prevalence estimates for type 2 diabetes in the U.S. Also, much like type 2 diabetes, the burden of GDM seems to be greatest among minorities, as well as women who are overweight or obese. Although in many cases a woman with GDM returns to normal glycemic levels after delivery, the effects of GDM can be lasting for both mother and child. It is estimated that at least 50% of all women with GDM will go on to develop type 2 diabetes later in life. For this reason, many researchers believe that GDM should be viewed more as a marker for chronic disease, such as type 2 diabetes, that is unmasked by pregnancy.

Although there are known differences in risk of both type 2 diabetes and GDM by race/ethnicity, the underpinnings of these differences are not yet clear. What is more, risk of type 2 diabetes following GDM also shows disparities by race/ethnicity, with higher risk attributed to Blacks when compared with non-Hispanic Whites. Lifestyle interventions focused on healthy diet and increased physical activity have proven effective for controlling weight gain as well as preventing type 2 diabetes in non-pregnant men and women. These studies also show the benefit of lifestyle interventions for preventing type 2 diabetes in women with previous GDM. Lifestyle interventions have also been shown to be safe and effective during pregnancy; whether they can have the same effect on glucose metabolism in pregnancy as they do outside of pregnancy – specifically, by lowering risk of GDM – remains to be determined. Despite these

observations, few studies have focused on prevention of GDM, and even fewer have focused on lifestyle interventions for high-risk minorities.

This dissertation investigates two important factors to consider in the realm of glucose metabolism in women of childbearing age: 1) the underlying disparities by race/ethnicity in glycemic status among women of childbearing age; and 2) the feasibility of a lifestyle intervention for prevention of GDM in a high-risk, disadvantaged urban population. In the first two chapters, we summarize the literature on GDM and lifestyle interventions during pregnancy. We next highlight our findings from an analysis of national survey data investigating the burden of diabetes and impaired glucose metabolism in women of childbearing age, identifying potential contributors to the disparities in these conditions, to provide a larger context to understanding how these might play out during a woman's child-bearing years. We then describe in Chapter 5 our methodology for a mixed-methods pilot feasibility trial for a lifestyle intervention in low-income, overweight/obese minorities, and present our findings in Chapters 6, 7, and 8. We conclude with a summary and discussion of our findings and conclusions in Chapters 9 and 10, including some lessons learned and their implications for future research. Our research highlights the importance of investigating not only factors associated with disparity in glucose levels among women in their reproductive years, but also methods to improve glycemia among those who may need it most.

CHAPTER 2. REVIEW OF THE LITERATURE: GESTATIONAL DIABETES

Gestational diabetes mellitus (GDM) complicates hundreds of thousands of pregnancies in the United States each year. Once thought a transient condition, GDM proves to be of greater concern for both mother and child for its potential adverse effects not only during pregnancy but also in the postpartum period. This chapter discusses the important tenets of GDM including: the pathophysiology of the condition during the pregnant state; the various methods of screening and diagnoses used; the epidemiology of the condition in the United States; risk factors for the condition; health consequences of the condition, both during pregnancy and in the postpartum period, for mother and child; and the methods of treatment for the condition. It concludes with a discussion of the public health significance of GDM, considering the health and wellbeing of women of childbearing age today and future generations to come.

Pathophysiology

GDM is defined as any degree of glucose intolerance where the onset or first recognition occurs during pregnancy (1). In normal states, outside of pregnancy, insulin is secreted by pancreatic β-cells in response to increasing blood glucose supply (2). This circulating insulin acts in a multitude of functions, particularly to aid in the cellular uptake of circulating glucose, thus maintaining normal concentrations of plasma glucose within the body. Either inadequate insulin secretion or insulin resistance (i.e., when insulin acts less effectively in promoting glucose uptake) can result in elevated blood sugar levels, or hyperglycemia, indicating a state of glucose intolerance.

In the case of GDM, this hyperglycemia is due to pregnancy-induced insulin resistance, and the inability to overcome this resistance. Pregnancy is indicated as a

period of accelerated starvation and facilitated anabolism, both metabolic changes that are to benefit the developing fetus, to ensure an adequate supply of nutrients to the baby (3-5). In early pregnancy, it is estimated that glucose production in the liver (hepatic glucose production) is increased by as much as 30%, despite the associated increase in fasting plasma insulin (5). This indicates an inherent fall in hepatic insulin sensitivity, and therefore increased insulin resistance. Increasing insulin resistance in pregnancy, especially in the third trimester, helps meet increased nutrient requirements for fetal development and promotes fetal growth by increasing maternal glucose supply to the fetus (6). Several factors work together to lead to the increase of insulin resistance as pregnancy progresses. Increases in maternal adipose tissue stores, as well as the release of pregnancy hormones and cytokines such as human placental lactogen, progesterone, prolactin, cortisol, and TNF-alpha -- particularly during late pregnancy -- antagonize the effects of insulin (6, 7). These changes in the hormonal milieu, along with the manifestation of subclinical inflammation (8, 9), create a 'diabetogenic' environment in which insulin resistance can -- and does -- naturally result (7). By midpregnancy, maternal insulin requirements are elevated in order to overcome this observed increased insulin resistance, and insulin secretion is accelerated (10). When maternal insulin secretion is inadequate to meet the degree of insulin resistance present, hyperglycemia during pregnancy occurs. If a woman's body is completely exacerbated by this environment, hyperglycemia increases and manifests as a positive GDM diagnosis. Delivery of the infant in most pregnancies leads to a return to prepregnancy levels for both insulin and glucose. Since the majority of GDM cases also return back to normal glycemic levels after delivery (11), GDM has long been considered a 'transient

condition'. However, mounting evidence suggests that GDM should be viewed more as a marker for chronic disease, such as type 2 diabetes, that is unmasked by pregnancy, and might identify women with underlying deficiencies in β-cell function (12).

Screening and diagnosis

Although screening and diagnostic criteria have changed over the years (13), GDM diagnosis continues to be based on a clinically-administered oral glucose tolerance test (OGTT). Current practice from the American College of Obstetricians and Gynecologists (ACOG) recommend a two-step approach in which pregnant women are screened using a 1-hour, 50-g glucose challenge test (GCT) at 24-28 weeks gestation, or earlier if certain risk factors are present . These risk factors include a history of GDM, type 2 diabetes in a first-degree relative, advanced maternal age, non-white race or ethnicity, and overweight or obesity (body mass index (BMI) $\geq$25 kg/m^2) (12). Those women with abnormal values at 1-hour post-glucose load, as indicated in Table 2.1, proceed to the second step, a 3-hour, 100-g OGTT to confirm GDM (14-16). A GDM diagnosis results when a woman meets or exceeds two or more values during her 3-hour OGTT, as depicted in Table 2.1. In recent years, the American Diabetes Association (ADA) also approved the use of a 75-g, 2-hour OGTT in place of the 3-hour OGTT (15); diagnosis of GDM follows the criteria of the 3-hour test, omitting the 3-hour value. This practice for screening and diagnosing GDM has been met with criticism in recent years due to the time involved and the specificity of the GCT. Additionally, these diagnostic criteria for GDM are originally based on the woman's risk for type 2 diabetes later in life (12), and not on potential adverse pregnancy outcomes. In an effort to address this concern and change the course on GDM diagnosis, several researchers and institutions

around the globe collaborated to conduct the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (17). A large, multi-center trial, HAPO has shown using a 2-hour, 75-g OGTT, an increased risk of adverse fetal and maternal outcomes at lower levels of hyperglycemia in pregnancy than those currently in use for GDM diagnosis (17). Based on these findings, the International Association of Diabetes in Pregnancy Study Groups (IADPSG) has recommended a new set of criteria for GDM diagnosis (18). In practice, these criteria eliminate the 1-hour GCT and use a single 2-hour OGTT for GDM diagnosis at 24-28 weeks. Diagnosis for GDM is then based on one or more abnormal values, with slightly different cut-offs than those currently in practice, as depicted in Table 2.1. In January 2010, the ADA adopted the IADPSG recommendations for GDM diagnosis and include these new guidelines in their Standards of Medical Care (19); as a result, a handful of clinics and practices around the country have begun implementing this method in their prenatal care practices. To date, however, ACOG continues to support the use of the 2-step approach, and this remains the one most commonly seen in obstetric clinics across the nation.

Table 2. 1. Currently practiced criteria for the glucose challenge test (GCT), 3-hour oral glucose tolerance test (OGTT) and 2-hour OGTT.

	Glucose challenge test (GCT)	100-g oral glucose tolerance test (OGTT)*	75-g OGTT
Duration	1 hour	3 hours*	2 hours
Number of blood draws	1	4*	3
Fasting	---	≥95 mg/dL	≥92 mg/dL
1-hour	≥140 mg/dL	≥180 mg/dL	≥180 mg/dL
2-hour	---	≥155 mg/dL	≥153 mg/dL
3-hour	---	≥140 mg/dL	---
Number of values for diagnosis	1 (if abnormal, proceed to OGTT)	2	1

* 75-g OGTT may be used. In this case, test duration is 2 hours, and number of blood draws is 3; the 3-hour draw is eliminated.

Epidemiology

GDM is a significant public health concern, particularly in minorities and overweight or obese women. Approximately 7% of all pregnancies are complicated by GDM, resulting in more than 200,000 cases annually (19), though national prevalence rates are estimated between 1-14% depending on the population studied and the diagnostic test and criteria used (15). Recent studies also show that GDM rates have been increasing in recent years (20-24), with a 100% increase for some ethnic groups compared to 20 years ago (22). This could be a result of increased screening practices and methods of diagnosis, or a true reflection of the increase in the burden of the condition. Nevertheless, this observation mirrors the increasing rates of both diabetes (15) and obesity (25), particularly among women of childbearing age (25-27). GDM rates tend to mirror type 2 diabetes rates, and like type 2 diabetes, increased BMI and increased weight gain in adulthood are both risk factors for GDM (28, 29). Because there is no national surveillance for GDM, and because of the differing methods of screening and diagnosis, it is difficult to define specifically the burden of GDM in pregnant women within the U.S. Additionally, GDM prevalence estimates might incorporate women who have underlying diabetes that has not been detected prior to her starting prenatal care (12), a plausible concern considering that approximately one-third of the estimated 6% of U.S. women of childbearing age with diabetes are not aware they have the condition (30, 31).

It is estimated that adoption of the IADPSG criteria could lead to a 50% increase in diagnosed GDM cases both within the U.S. and worldwide (32, 33). In centers involved in the HAPO study, the prevalence of GDM measured 17.8%, with great center-

to-center variation. Within the U.S., these estimates ranged from 17.3% in Chicago, IL, to 25% in Cleveland, OH, and 25.5% in Bellflower, CA (34). Compared with current estimates of 1-14%, it is apparent the increase in GDM diagnosis that would result with the national adoption of the IADPSG criteria.

Known and potential risk factors for GDM

Identified risk factors: Age, BMI, race/ethnicity and diabetes history

Several known risk factors exist for GDM and are used for current screening practices. Maternal age has been directly associated with GDM (28, 35), as GDM risk increases with increasing maternal age. Women who are overweight or obese in the prepregnancy period consistently show higher rates of GDM when compared with normal weight women (28, 29, 36, 37). A recent systematic review of the literature (38) shows that overweight women (BMI 25-30 kg/m^2) are almost twice as likely and obese women (BMI > 30 kg/m^2) more than three times as likely to develop GDM compared with normal weight women. A report from the Nurses' Health Study (28) shows similar results. Results from women enrolled for services in Seattle and Tacoma, WA, hospitals show a direct relationship with increasing BMI and GDM risk (29). Two recent studies -- one using data from 7 states participating in a national survey of pregnancy, another utilizing data from linked Florida birth certificates and hospital discharge data – show that over 40% of GDM cases are attributable to prepregnancy overweight/obesity (39, 40).

Additionally, several studies have looked at not only BMI but also weight gain during a specified time and have found increased weight gain prior to pregnancy to be associated with increased GDM risk (28, 37, 41). An analysis from the Nurses' Health

Study II shows a 67% increased risk of self-reported GDM in women who gained 5.9-9.9 kg from age 18 to just before pregnancy when compared with women who maintained a stable weight (±4.9 kg). Among women gaining 10.0-19.9 kg, the risk of GDM increased 2.5-fold (28). Similarly, other research shows that weight gain of ≥10.0 kg during adulthood is associated with a 3-fold increased GDM risk (29). Thus, evidence of increased BMI – whether manifesting in overweight/obese status or simply as an indication of weight gain – and associated increased risk of GDM is strong.

As seen with type 2 diabetes, there are observed differences in GDM risk by race/ethnicity (21, 23), with higher prevalence seen in minorities, particularly among Latinas (23), women of Asian descent (35, 39, 42) and African Americans (21, 23) compared with non-Hispanic white women. This may also be a residual factor of disparities in overweight/obesity between these groups, as evidenced by more recent studies (39, 43, 44).

Recurrent GDM is also common. Women who have had GDM in one pregnancy have a higher risk of developing GDM in a subsequent pregnancy (45, 46). One systematic review of the literature (46) found that published rates of recurrent GDM vary between 30-84%, with higher rates (52-69%) among minority populations when compared with non-Hispanic white populations (30-37%). Other identified risk factors for recurrent GDM include increased BMI, large-for-gestational-age babies, and women who require insulin for control of their initial case of GDM (45). There is also evidence that family history of type 2 diabetes in a first-degree relative is associated with increased GDM risk (47). Women participating in the Nurses' Health Study II were almost twice

as likely to develop GDM if a first-degree relative had type 2 diabetes compared with women with no family history of diabetes (28).

Potential risk factors – lifestyle and GDM

Lifestyle factors – specifically, diet and exercise – have been researched for their role in the development of first-time and recurrent GDM, though results are difficult to interpret. Evidence suggests certain nutrients – including cholesterol (48), vitamin D (49) and heme-iron (50) – may be associated with GDM risk. Increased dietary fat intake has been implied as an independent risk factor for both hyperglycemia in pregnancy (51) and recurrent GDM (52), though not all studies support this (53). Glucose intolerance in pregnancy has also been associated specifically with decreased polyunsaturated fat and increased saturated fat intakes (51). Among the Nurses' Health Study II cohort, consumption of red and processed meat in particular was associated with increased risk of GDM (54), but this was not replicated among a cohort of Spanish women (48). However, the differences in study results may be due to different populations: the latter includes Spanish women whose diet follows strongly the Mediterranean diet, a dietary pattern particularly known for its role in preventing cardiovascular disease. Current research also supports that dietary patterns may play a role in GDM, with greater adherence to more healthful dietary patterns being protective of GDM (54, 55), whereas results from other research fail to show any association of any dietary factors with GDM (53). Since the majority of studies investigating the association between dietary factors and GDM risk are cross-sectional in nature with few cases of GDM, and rely upon self-report of diet (56, 57), it is difficult to draw any concrete conclusions as to the role of dietary factors in the development and manifestation of GDM.

Whether exercise and physical activity (PA) is protective of GDM, as observed with type 2 diabetes, is not yet established. Results may vary according to the timing of exercise in relation to pregnancy. Some evidence exists of a reduced risk of GDM with exercise in the prepregnancy period (58-62) compared with inactivity. However, evidence from trials are not clear on the association of exercise with GDM prevention (2). One study (59) shows reduced risk of GDM in women who participated in PA of any kind before pregnancy, but not among those who were sedentary before pregnancy but adopted PA during pregnancy, when comparing both groups to inactive women. The greatest risk reduction was among those women active both before and during pregnancy. Considering this, the current snapshot of exercise in pregnancy shows that fewer women are physically active in pregnancy than before pregnancy, and more than one-third of women are sedentary in pregnancy (63), with only 13-20% meeting PA guidelines (64, 65).

A recent meta-analysis involving eight studies (66) shows that total prepregnancy PA indicated 55% lower risk for GDM in women in the highest PA quantiles compared to those in the lowest quantiles (pooled OR: 0.45 [95% CI: 0.28-0.75]). Additionally, PA in early pregnancy results in a 24% lower risk of GDM for women with the highest level of activity compared with those with the lowest level of activity (OR: 0.76 [95% CI: 0.70-0.83]). Hours spent watching television have not been associated with GDM risk in two prospective studies (66). Though the association between PA and GDM is not conclusive, many studies on PA and GDM rely on self-report, recall of exercise habits, and/or small sample sizes, introducing possible areas for bias or unreliable results.

Treatment of GDM

Diet therapy is the common prescription for the control of GDM. Altering diet via individualized medical nutrition therapy (MNT) is the prescribed first-line of treatment to normalize blood glucose levels (15, 67, 68) and reduce the risk of adverse perinatal outcomes (69) in a woman diagnosed with GDM. In the event that these MNT is not able to control the woman's blood glucose levels, insulin is prescribed (15). It is estimated that 39% of GDM cases are unable to control glucose levels by diet alone and must receive insulin (70). Recent years have also seen the safe use of some oral diabetes agents, such as glyburide (71-73).

Because of the effects that exercise has on insulin resistance (70), it is endorsed by both the ADA and ACOG as a plausible additional therapy for glycemic control in GDM. However, as noted by a recent Cochrane review (74), the data from trials on the efficacy of PA as a GDM treatment are insufficient to discourage or promote exercise for the prevention of GDM-related adverse outcomes. Additionally, although pregnancy is often seen as an opportune time to introduce the lasting effects of lifestyle intervention (75), research indicates that in real life situations, diet modifications during an index pregnancy may have little effect on subsequent diet (52). Very often women with GDM who are given dietary and PA advice during their pregnancy do not follow these recommendations in the postpartum years (76).

Adverse health outcomes

During pregnancy: maternal and fetal outcomes

GDM and maternal hyperglycemia are associated with various adverse pregnancy and birth outcomes. During pregnancy, hyperglycemia is associated with increases in the

risk of intrauterine fetal death during the last weeks of gestation (15); the frequency of maternal hypertensive disorders, including preeclampsia (12, 77); the likelihood of fetal macrosomia (15, 69, 77, 78) and/or large-for-gestational-age babies (79), and subsequently, Caesarean section deliveries (15); and polyhydramnios (77). The baby of a mother with GDM is also at higher risk for shoulder dystocia and hypoglycemia upon birth (80). GDM has also been associated with both cardiac and non-cardiac birth defects, though this might be restricted to only overweight or obese women (81). The adverse effects of GDM are not limited to physical outcomes either. Recent research shows an association between GDM and depression during the perinatal period among low-income women in New Jersey (82). The researchers' results show that women with GDM – regardless of whether or not they take insulin – have almost twice of odds of having depression during the perinatal period, after adjustment for age, race, and other confounders.

Advanced hyperglycemia in pregnancy not resulting in a diagnosis of GDM is also associated with adverse outcomes (83, 84). Results from the HAPO study show that various degrees of maternal glucose intolerance less severe than in overt GDM are associated with adverse pregnancy outcomes, including birthweight greater than the 90th percentile, shoulder dystocia or birth injury, and preeclampsia (17). The researchers' findings support the hypothesis that risk for these adverse birth outcomes increases with increasing glucose values during the OGTT. These results highlight the potential adverse outcomes associated with hyperglycemia in general during pregnancy.

Post-delivery: maternal and infant outcomes

Adverse outcomes associated with GDM continue through pregnancy into the postpartum period, for both the mother and her child. Postpartum, a GDM mother is at increased risk for developing type 2 diabetes (20, 44, 85-88); an estimated 50% of women with a history of GDM will go on to develop type 2 diabetes within a decade of her GDM diagnosis (89). A recent meta-analysis (85) incorporating 20 studies published from 1960 through January 2009 and involving 675,455 women shows that the pooled estimated risk ratio (95% confidence interval [CI]) for type 2 diabetes in women with GDM was 7.4 (4.8-11.5). What is more, this risk might vary by race/ethnicity as well.

Women with a history of GDM also have a high prevalence of cardiovascular disease (CVD) risk factors postpartum; compared with women with no history of GDM, they are more likely to be obese, insulin resistant, symptomatic of the metabolic syndrome, and chronically hypertensive (90, 91). This is discussed in more detail in Appendix 1 (92). Additionally, as previously mentioned, women with a history of GDM are at increased risk of developing GDM in a subsequent pregnancy (1, 78, 93, 94). Her child is also at increased risk for developing type 2 diabetes in late adolescence or early adulthood (95) and for becoming obese later in life (87, 95). Also of note is the burden of GDM on the medical system. One recent study (96) estimates that the ~180,000 cases of GDM in 2007 increased national medical costs by $636 million, including $596 million for costs attributed to maternal care and $40 million for costs attributed to prenatal care. This averages to an extra $3,305 per pregnancy plus $209 for the newborn's first year of life. GDM therefore affects not only the woman's well-being but also that of her child and the nation's medical system.

Like the condition of GDM itself, adverse health outcomes following GDM might also show differences by race/ethnicity. A recent study (44) using data from a large U.S. health maintenance organization shows the prevalence of GDM in Black women as relatively low compared to that of other race/ethnicities. However, Black women with a history of GDM show the highest risk of any group of developing diabetes after GDM, independent of age, parity, education, comorbidity status, prepregnancy medical utilization, and BMI. For this group, the risk for developing type 2 diabetes is 52% higher than for non-Hispanic White women. These findings highlight that factors outside of BMI may be dictating increased risk among certain sub-groups, perhaps due to genetic, environmental or lifestyle factors, or, more likely, a mixture of these.

Public Health Significance

GDM is a serious complication of pregnancy that has often been discounted because of its once-thought "transient" nature. However, the lasting effects of GDM – both physical and psychosocial – are apparent, for both mother and child. With the increasing prevalence of obesity in the U.S., especially among women of childbearing age, and the potential adoption of new diagnostic criteria, GDM poses a large burden on the health care system at present and also for the future. In addition, GDM may play a crucial role in the increasing prevalence of diabetes and obesity for the next generation and adds to the burden of the nation's racial health disparities.

Conclusion

Each year, approximately 200,000 pregnancies in the U.S are affected by GDM. This is a conservative value, as estimates are likely to increase with better methods of screening and diagnosis. Women who develop GDM during pregnancy are at increased

risk for adverse health outcomes during that pregnancy, both for the mother and the fetus. Although once thought to "vanish" with delivery, the lasting effects of GDM are apparent, including increased risk of type 2 diabetes for both mother and child. It is apparent that differences exist by race/ethnicity, although the etiology of why is not yet clear. In particular, although Blacks may not be as likely to develop GDM as other minorities, those Black women with a history of GDM go on to develop type 2 diabetes at higher rates than seen in other racial/ethnic groups. Whether it is an indicator of future disease or simply associated with it, the need to investigate the prevention of GDM is apparent, not only for the health of the present generation, but also for the health of the future.

CHAPTER 3. REVIEW OF THE LITERATURE:

LIFESTYLE INTERVENTIONS DURING PREGNANCY

Lifestyle interventions focused on improving healthy dietary intakes and increasing time spent in physical activity (PA) have proven to be effective for reducing risk of chronic disease and controlling weight gain in a multitude of diverse populations. Such interventions have been tested in pregnancy for their safety and efficacy, and may be effective for reducing excessive gestational weight gain (GWG) and improving glucose metabolism. This chapter reviews the role of diet and exercise on glucose control outside of pregnancy, and discusses factors specific to the design of lifestyle interventions for implementation during pregnancy. We summarize findings of lifestyle interventions during pregnancy for the control GWG and GDM prevention, as well as highlight missing pieces within the current literature. We also review factors that may affect uptake and delivery of lifestyle interventions during pregnancy, particularly among underserved populations.

Lifestyle interventions as effective tools for glucose control outside of pregnancy

Research supports healthy diet and PA lifestyle interventions for controlling weight gain as well as preventing type 2 diabetes (97-99) . Several studies, including the Diabetes Prevention Program (DPP), show that lifestyle interventions are effective for preventing type 2 diabetes or normalizing blood glucose levels in non-pregnant women at risk for the disease (74, 98, 100, 101). These studies also show the benefit of lifestyle interventions for preventing type 2 diabetes in women with previous GDM (88). In normoglycemic conditions, PA is effective for improving blood glucose control, decreasing insulin resistance, and decreasing cardiovascular risk factors, in addition to

improving overall mood and well-being (102). Clinical studies support that exercise increases both insulin-independent glucose uptake in the muscle and insulin sensitivity (103). In this vein, exercise and insulin stimulate glucose utilization in synergy (104). However, recruitment of additional transporters of glucose to the muscle – particularly of the glucose transporter GLUT4 – is from a different pool for insulin vs. exercise, signifying a different etiology of effects for each system. Studies show that in type 2 diabetes, the stimulatory effects of exercise on glucose utilization are still effective, even though this is a state of insulin resistance. In fact, research also supports that exercise-induced glucose utilization may be greater in type 2 diabetes due to recruitment of GLUT4 transporters coupled to elevated circulating glucose levels (103). These findings highlight how exercise can be biologically effective for improving glucose clearance, particularly in T2DM.

In addition to exercise, lifestyle interventions also commonly focus on dietary factors, several of which have been implicated for their role in altering insulin resistance and potentially preventing diabetes (105, 106). Research supports diets high in whole grains (107) and fiber (108) for their ability to neutralize insulin resistance, especially for those individuals already in an insulin resistant state. Additionally, the type of carbohydrate eaten may play a role in lowering diabetes risk (109, 110) potentially because of their differing effects on insulin resistance. Lower intakes of both red meat (111) and the consumption of sugary beverages (112) have also been implicated for lower diabetes risk.

Developing lifestyle interventions for pregnancy

Whether modifying lifestyle factors during pregnancy will have the same effects on weight control and subsequently GDM is inconclusive (113, 114). Despite the racial differences in the burden of GDM outlined in the previous chapter, few studies have focused specifically on these issues among minorities. However, pregnancy provides an opportune time for a woman to make lasting changes to her lifestyle, and various studies have shown both the feasibility and safety of implementing lifestyle interventions during pregnancy (115-117). In order for these interventions to be successful, it is important to understand the dimension of factors that may affect their uptake and efficacy.

Overweight/ obesity in U.S. women of childbearing age

Recent reports using national data show that in the U.S., almost two-thirds of women of reproductive age are overweight or obese (BMI $\geq$ 25.0 kg/m^2); for non-Hispanic Black women, this measure is closer to 80% (25). Estimates vary by state, with the highest estimates seen in the South (118). This is cause for concern, since maternal overweight and obesity during pregnancy increases the risk for such complications as pregnancy-induced hypertension and preeclampsia (119-121), large for gestational age/macrosomia (119, 120, 122), birth defects (81, 123), cesarean delivery (119, 120, 124), and postpartum infection (120). A recent meta-analysis shows that overweight women are almost twice as likely and obese women more than three times as likely to develop GDM compared with normal weight women (38). As described in the previous chapter, women with GDM are at increased risk for several adverse maternal and fetal outcomes during pregnancy, as well post-delivery.

Institute of Medicine Guidelines for GWG

Excess weight gained in pregnancy and failure to lose pregnancy weight after delivery have both been shown to be strong factors contributing to the long-term development of overweight and obesity in women (125, 126). In the U.S., more than two-thirds of pregnant women gain more weight during their pregnancy than is recommended by leading medical institutions (127). Higher gestational weight gain (GWG) in excess of recommended goals has been associated with increased risk for cesarean delivery (128, 129), impaired glucose tolerance in pregnancy (130), pregnancy-induced hypertension and preeclampsia (128), and large for gestational age and macrosomia (129, 131-133). In 2009, after a review of several trials to optimize birth outcomes, the Institute of Medicine (IOM) released new recommendations for weight gain during pregnancy based on a woman's prepregnancy BMI (127), updating the previous 1990 version. These recommendations were novel in that they used BMI cut-offs based on the World Health Organization (WHO) (134) and for the first time included a specific range of GWG for obese women. A comparison of the 1990 and 2009 recommendations is shown in Table 3.1. Though these recommendations are the first to acknowledge a range of healthy GWG for obese women, the committee acknowledged that there was insufficient evidence to make specific recommendations for the different classes of obesity, i.e., classes II (BMI = 35-39.9 kg/m^2) and III (BMI $\geq$ 40 kg/m^2). Upon release of these guidelines, the committee also recommended providing support for conducting studies in large, diverse populations to understand how dietary intake, physical activity, and the social, cultural, and environmental context all work to affect GWG.

Table 3. 1. IOM recommendations for weight gain in pregnancy, 1990 and 2009.

	1990 Guidelines			***2009 Guidelines***		
Prepregnancy BMI category	***Insufficient***	***Sufficient***	***Excessive***	***Insufficient***	***Sufficient***	***Excessive***
Underweight (BMI < 18.5)*	< 28 lb	28-40 lb	>40 lb	< 28 lb	28-40 lb	>40 lb
Normal weight (18.5≤BMI< 25)	< 25 lb	25-35 lb	>35 lb	< 25 lb	25-35 lb	>35 lb
Overweight (25 ≤ BMI < 30)	< 15 lb	15-25 lb	>25 lb	< 15 lb	15-25 lb	>25 lb
Obese (BMI ≥ 30)		≥ 15 lb		< 11 lb	11-20 lb	>20 lb

BMI= Body mass index, in kg/m2; IOM=Institute of Medicine; lb=pound. *For 1990 recommendations, BMI categories were low (<19.8), normal (19.8-26.0), high (26.0-29.0), and obese (>29.0).

Disparities in GWG

There are several observations of racial health disparities related to obesity, weight gain and complications during pregnancy. Racial differences affect the complication rates in overweight and obese pregnant women, with minority women having higher rates of diabetes (30, 31, 135) and high blood pressure (136) before entering pregnancy. Additionally, minorities – particularly Black women and Latinas – are more likely to enter pregnancy overweight or obese (26). Knowing the adverse outcomes associated with obesity and pregnancy, efforts during pregnancy could prove to be effective for reducing the health disparities seen between minorities and Caucasian women.

Lifestyle interventions during pregnancy – previous findings

Several trials both within the U.S. and abroad have focused on improving maternal and fetal pregnancy outcomes by improving lifestyle measures; specifically, these have involved dietary and/or PA interventions and have largely focused on limiting

GWG to within recommended values (137-141). While several of these studies have shown the safety and efficacy of lifestyle interventions during pregnancy (141-143), their representation of high-risk groups – i.e., obese women and minorities – is limited. Most of the studies have been conducted primarily within Caucasian populations (142, 144-146) and in some instances excluded obese women (141). Additionally, while most of these previous studies have focused primarily on GWG, few have assessed the effects of interventions on glucose metabolism. Also, even though many studies have assessed the efficacy of lifestyle intervention for treating GDM (74, 115), few have looked conclusively at *preventing* GDM. Those studies that have looked at the effects of lifestyle intervention on glucose metabolism in pregnancy (144, 147, 148) have not included some of the groups at highest risk for developing the condition, including minorities. Because of the health disparities seen in excessive GWG and GDM and the known health implications of these factors for both mother and baby, the need for rigorous studies assessing the plausibility of *preventing* GDM through lifestyle changes is apparent.

Many systematic reviews of the literature and/or meta-analyses have been performed to assess the efficacy of lifestyle interventions to improve pregnancy outcomes. A general finding of these reviews is the need for more controlled trials to properly assess this association. A recent systematic review of the literature identified healthy lifestyle interventions that incorporated goal-setting strategies for the prevention of excessive GWG (149). The authors identified only five studies that met their qualifications for inclusion in their review. Of these five studies, only one was considered to be of high methodological quality and four were considered of moderate

quality. The heterogeneity of the studies included made it difficult to provide information on exactly what aspects of goal-setting might be most effective in affecting lifestyle change during pregnancy. Additionally, as highlighted by the authors, no studies included qualitative information on participant enthusiasm for the program.

One study conducted in the U.S. assessed the efficacy of a lifestyle intervention for achieving appropriate GWG in pregnant women enrolled in an obstetric clinic for low-income families (140). Findings from this study showed that in overweight women (BMI > 26.0), almost two-thirds of participants exceeded recommended levels of GWG at some point in their pregnancy, regardless of whether they received the intervention or not. Among normal weight women (BMI < 26.0), those in the intervention group were significantly less likely than those in the control group to gain above 1990 IOM recommendations; in overweight women, however, there was no significant effect of the intervention, and the trend was in the opposite direction. Participants in this study were largely non-Hispanic white, and ~60% were unemployed; for 47% of the population, this was their first pregnancy. Additionally, overweight and obese women were grouped and analyzed together. The authors acknowledged the difficulties in working with their specific population, and the many barriers affecting participation, including lack of social support, financial hardships, and practical issues such as unreliable transportation and disruption to phone service among their population. They also mentioned the need for intensive education and counseling due to the limited knowledge among study participants about nutrition and healthful eating.

Among programs aimed specifically at preventing GDM, a recent systematic review identified 19 studies rigorous enough to include for analysis (113). These studies

varied in their methodologies and type of intervention offered, with the majority implementing dietary interventions for GDM prevention, and only three incorporating exercise. Results were inconsistent, but the majority of studies did not see a significant difference in maternal fasting glucose levels between women receiving the intervention vs. those not receiving the intervention, and all showed no significant difference in risk for GDM between the two groups. The dietary interventions included showed no significant difference in maternal fasting glucose between those receiving intervention vs. regular care, but most did observe a small difference in GDM risk (risk difference: -0.05 (-0.1, -0.01)). However, the authors acknowledged that the evidence for most of the findings were of very low quality due to lack of blinding, small sample sizes and imprecision of results.

Safety and efficacy of lifestyle interventions during pregnancy

Pregnancy may provide an opportune time for a woman to make lasting changes to her lifestyle, particularly with regard to obesity and weight management. Many researchers and health professionals view pregnancy as a "teachable" period in a woman's life, when interventions to affect change in dietary habits and physical activity can have the greatest impact because of the frequency of prenatal care visits and woman's concern for not only her own health but also the health of her unborn child (75). If behavioral modifications aimed at preventing GDM and affecting GWG are made during pregnancy, it is hoped these changes will last through postpartum, preventing onset of GDM in subsequent pregnancies or type 2 diabetes later in life (76). Although there is valid concern regarding changes to lifestyle habits during pregnancy and the impact it could have on either the mother or baby or both, various study results show the safety of

intervening during this particular stage in a woman's life. In patients with GDM, a PA training program was not only able to be completed but also of low risk to the participant and offered health benefits by delaying the need for insulin treatment (115). Results from a feasibility study in Finland (117) showed that a lifestyle intervention aimed at controlling weight gain during pregnancy by increasing PA was well-received by both participants and the research interventionists, and that the intervention was safe and applicable for implementation within the country's health system (150). Specific to obese women, a study from Australia (143) also showed the safety and subsequent positive effects of restricting weight gain within this BMI level; women receiving intensive dietary counseling had significantly lower GWG and gestational weight retention at four weeks postpartum than women not receiving the intervention. A more intensive intervention (116) demonstrated that among women with GDM, an intervention involving caloric restriction and moderate PA reduced GWG, lowered rates of macrosomic babies and did not result in any adverse pregnancy outcomes. Though some researchers (151) highlight the paucity of available, conclusive evidence to assess the benefits or harms of lifestyle interventions during pregnancy, these and other findings (152) support the safety of PA during pregnancy for both mother and child.

Potential barriers to lifestyle changes in pregnancy

Although lifestyle interventions in pregnancy have been shown to be safe and could be effective for improving birth outcomes, several barriers exist that may affect the implementation of these efforts during pregnancy. Studies show that fewer women are physically active during pregnancy than before pregnancy, and more than one-third of women are sedentary in pregnancy (63), with only 13-20% meeting PA guidelines (64,

65, 153). While pregnancy may be an opportune time to intervene to improve a woman's health, there are several factors that may affect behavior changes, including nausea, discomfort, pain, and fatigue (154-156). A recent study showed that women who exercised during pregnancy were less likely to report nausea or vomiting midpregnancy, and reported fewer symptoms of back pain than women who did not exercise (154). Cravings have also been identified as a barrier to healthy eating in pregnancy (155). It is apparent the multitude of unique barriers that researchers encounter when implementing lifestyle changes during pregnancy, and how these could adversely affect program implementation and efficacy.

Barriers of pregnancy lifestyle interventions specific to underserved populations

Several factors in addition to the ones mentioned above affect changes to pregnancy behaviors in low-income populations. Qualitative data from focus groups conducted in both high- and low-income women in Ithaca, New York (156) showed great differences in what constituted "healthy" for women in the two income strata. Namely, high-income women focused on increasing specific nutrients, modifying exercise routines, switching to organic foods, and de-stressing activities (e.g., yoga, meditation), whereas low-income women were more focused on quitting or reducing smoking, drug use, and/or drinking during their pregnancy, and beginning to eat fruits and vegetables. Overall, diet and PA behaviors reported by low-income women were more likely to promote positive energy balance vs. those behaviors reported from high income women. The authors identified a "web of risk factors" affecting their low-income population, including depression and stress caused by custody issues, child care, partner relationships, lack of social support, unintended pregnancies, and poor home

environments. These women also reported more "emotional eating", with stress and depression more likely to negatively affect their eating habits. Many participants mentioned their belief in "eating for two" during pregnancy, and that weight was not included in their definition of health. The low-income participants also identified low self-efficacy for PA, and factors that kept them from being active included not only fatigue and discomfort, but also family burdens. Previous studies have shown that psychosocial factors such as stress and depression were more common among low-income (157), minority (158, 159) and obese (160, 161) women. Even more alarming, hardships that might potentially lead to stress and depression are highly prevalent in low-income women during pregnancy, with one estimate showing 14% of low-income women experiencing 4 or more hardships during pregnancy (162). These data highlight the importance of addressing these issues and normative beliefs when targeting low-income, underserved populations for lifestyle interventions during pregnancy.

Several studies on social factors and birth outcomes acknowledge that many disadvantaged women begin their pregnancies predisposed to factors yielding unfavorable pregnancy outcomes. These factors include high BMI, low socio-economic status, and participation in adverse health behaviors such as smoking and illicit drug use (156, 162-164). Such observations might help to explain the poor representation of these groups in the literature on lifestyle interventions for healthy pregnancies. However, these groups often are at the greatest risk and may therefore see the greatest benefit from such interventions.

Conclusion

Lifestyle interventions aimed at improving dietary intakes and increasing time spent in PA have been proven effective for decreasing risk of disease outside of pregnancy. Their effectiveness for decreasing such pregnancy outcomes as excessive GWG and GDM remains to be proven. Although several trials have explored the utility of lifestyle interventions during pregnancy and have shown the safety of such programs during pregnancy, there is a paucity of data exploring their impact on obese and/or low-income, underserved populations. These populations are worthy of attention, as they may be at greatest risk for adverse outcomes and may see the greatest benefit from lifestyle changes.

CHAPTER 4: REALIZING THE BURDEN OF DYSGLYCEMIA IN U.S. WOMEN OF CHILDBEARING AGE

Race/Ethnic Disparities in Dysglycemia among U.S. Women of Childbearing Age Found Mainly in the Non-overweight/obese

Running title: Dysglycemia in US Women of Childbearing Age

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Abstract

Objective. To describe the burden of dysglycemia – abnormal glucose metabolism indicative of diabetes or high risk for diabetes – among U.S. women of childbearing age, focusing on differences by race/ethnicity.

Research design and methods. Using U.S. National Health and Nutrition Examination Survey data (NHANES 1999-2008), we calculated the burden of dysglycemia (i.e., prediabetes or diabetes, from measures of fasting glucose, A1C, and self-report) in nonpregnant women of childbearing age (15-49) by race/ethnicity status. We estimated prevalence risk ratios (PRRs) for dysglycemia in subpopulations stratified by BMI (kg/m^2), using predicted marginal estimates and adjusting for age, waist circumference, C-reactive protein and socioeconomic factors.

Results. Based on data from 7,162 nonpregnant women, representing over 59,000,000 women nationwide, 19%(95% CI: 17.2-20.9) had some level of dysglycemia, with higher crude prevalence among non-Hispanic Blacks and Mexican Americans vs. non-Hispanic Whites (26.3%[22.3-30.8] and 23.8%[19.5-28.7] vs. 16.8%[14.4-19.6], respectively). In women with BMI<25, dysglycemia prevalence was roughly twice as high in both non-Hispanic Blacks and Mexican Americans vs. non-Hispanic Whites. This relative increase persisted in adjusted models (PRR_{adj}[95% CI]: 1.86[1.16,2.98] and 2.23[1.38,3.60] for non-Hispanic Blacks and Mexican Americans, respectively). For women with BMI 25-29.99, only non-Hispanic Blacks showed increased prevalence vs. non-Hispanic Whites (PRR_{adj}: 1.55[1.03,2.34] and 1.28[0.73,2.26], non-Hispanic Blacks and Mexican

Americans, respectively). In women with BMI>30, there was no significant increase in prevalence of dysglycemia by race/ethnicity category.

Conclusions. Our findings show that dysglycemia affects a significant portion of U.S. women of childbearing age, and that disparities by race/ethnicity are most prominent in the non-overweight/obese.

While national trends show that diabetes prevalence among all U.S. adults (men and women) has risen in recent years, seemingly concomitantly with rates of overweight and obesity, non-Hispanic Blacks and Mexican Americans continue to be disproportionately affected, with rates almost twice those of non-Hispanic whites [1,2]. This has also been the trend for impaired fasting glucose (IFG), a marker of future diabetes risk [1,2]. Previous research on racial disparities of diabetes prevalence has focused on disparities for common risk factors for the disease -- obesity and poverty, among others [3-5]. However, findings from these studies show that there appears to be a residual effect of race/ethnicity [5], while controlling for the effect of body mass index (BMI) and social factors, with no concrete explanation as to why this might be so.

Little attention has been paid specifically to investigating factors associated with disparity in glucose levels among women in their reproductive years. However, this proves an important population to target, not only because of the woman's health needs and subsequent risk for Type 2 diabetes [6,7], but also because of her role as a caregiver, and the potential adverse consequences for her offspring if exposed to gestational hyperglycemia [8-10]. We therefore conducted an analysis using U.S. national data to describe the burden of dysglycemia – diabetes, IFG or high risk for diabetes by A1C criteria -- among women of childbearing age, focusing specifically on differences by race/ethnicity. We also explored the extent to which measurements of obesity – measured by body mass index (BMI) and waist circumference – might modify these associations.

Research Design and Methods

Sample population and data source

The National Health and Nutrition Examination Survey (NHANES) is an ongoing national survey conducted by the National Center for Health Statistics (NCHS) [11]. It utilizes a complex multistage probability sample so as to represent the civilian, noninstitutionalized U.S. population. Participants of the survey complete in-home interviews followed by medical and laboratory examinations in mobile examination centers. Additionally, half of those who participate in the medical examination are asked to fast overnight for laboratory testing, comprising a nationally representative fasting subsample. Our study focuses on nonpregnant females 15-49 years of age who underwent the interview, medical and/or laboratory examinations of NHANES, combined from five survey cycles, from 1999-2008. Pregnancy status was by self-report, confirmed with a laboratory test. For fasting measures, we included women who were part of the morning fasting session, and excluded women from the fasting sub-sample if their fasting times were <8 hours. The NCHS Research Ethics Review Board (ERB) approved the surveys and documented consent was obtained from all participants. The interview, examination and lab procedures are detailed elsewhere [11] .

Study variables

Demographic variables

Demographic information was collected on the basis of self-report during the in-home interviews. Race/ethnicity was categorized according to NHANES guidelines for comparing across survey cycles, and included: ‘non-Hispanic White,’ ‘non-Hispanic

Black', 'Mexican American', and 'Other'. We chose not to present estimates from women in the 'Other' category, due to the small sample size for, and heterogeneity of, this group. We considered age as a continuous variable, and dichotomized education attainment as having completed less than high school, or having completed high school (or the equivalent) or more. We categorized civil status as single or married/cohabitating and the number of live births to women as 0, 1, 2, 3 or 4 or more. The poverty income ratio (PIR) – measuring the ratio of family income to the family's appropriate poverty threshold – was computed by the NCHS from the poverty threshold for the relevant calendar year, family income, and other family data provided by the respondents to measure income status [11]. We present PIR classified into 3 categories, as suggested by Healthy People 2010 [12]: PIR < 1 (poor), PIR ≥ 1 but < 2 (near poor), and PIR ≥ 2 (middle or high income).

Outcome variables

We defined dysglycemia as any abnormality in glucose metabolism, indicative of diabetes or high risk for diabetes (IFG or elevated A1C). Specifically, a participant was identified as having some measure of dysglycemia if she met any one of the following criteria: 1) during the in-home interview, she responded affirmatively to the question of whether, outside of pregnancy, a doctor or other health care professional had ever told her that she had diabetes; she reported taking insulin; or she reported taking diabetic medicines; 2) results from her clinical examination indicated diabetes by either a fasting plasma glucose value ≥126 mg/dl or hemoglobin A1C (A1C) ≥ 6.5% (48 mmol/mol) [13]; or 3) results from her clinical examinations indicated a high risk for diabetes by

either a fasting plasma glucose value between 100 mg/dL and 126 mg/dL, or A1C value of 5.7-6.4% (39-46 mmol/mol) [13].

Details about collection and processing of blood samples can be found in documentation on the NHANES website [11]. Briefly, fasting plasma glucose was measured using a hexokinase enzymatic method, with a coefficient of variation of 1.3-2.2%. To account for changes to the laboratory and equipment used for measurement of glucose in 2005-2008 vs. those used for 1999-2004, we converted values from 2005-2008 via a linear transformation to make them comparable to values from 1999-2004 [11]. A1C was measured using whole blood at a central laboratory by a high-performance liquid chromatographic assay and standardized according to the method of the Diabetes Control and Complications Trial [14], with a coefficient of variation of 1.0-1.7% [11]. We used only A1C values from 1999-2006 for this analysis, to avoid any bias that might be introduced by the inexplicable trending higher values from 2007-2008 [11].

Other cardiometabolic factors and covariates

Height and weight were measured in the mobile examination centers [11], and BMI was calculated by taking the weight in kilograms divided by the square of the height in meters (kg/m^2). We categorized BMI according to World Health Organization definitions [15], and grouped these into 3 categories: under or normal weight (BMI < 25.0 kg/m^2), overweight (BMI 25-29.99 kg/m^2) and obese or morbidly obese (BMI $\geq$ 30 kg/m^2). To consider the adverse metabolic effects and increased cardiovascular mortality resulting from greater abdominal adiposity [16,17], we assessed waist circumference as an independent risk factor. High central adiposity was considered as waist circumference

≥ 88 cm [18]. To account for low-grade inflammation, and its potential association with diabetes development [18], we categorized levels of C-reactive protein (CRP), a pro-inflammatory marker, with the cutpoint at 0.3 mg/dL or higher [18]. CRP concentrations were measured by latex-enhanced nephelometry on a Behring Nephelometer (Siemans Healthcare Diagnostics, Deerfield, IL, USA).

Statistical analysis

Women were considered eligible for the analysis if they attended the medical exam and had complete information for race/ethnicity status, pregnancy status, age, education attainment, and PIR. Statistical analyses were performed using SAS-callable SUDAAN version 9.2 (SAS Institute, Cary, NC). The five survey cycles (1999-2000, 2001-2002, 2003-2004, 2005-2006, and 2007-2008) were merged into one dataset, and 10-year sampling weights were calculated based on guidelines recommended by NCHS for analyses that combine two or more survey cycles [11]. All analyses incorporated the correct sample weights for the subsample and complex survey design. We calculated mean levels (95% confidence intervals [CIs]) for continuous variables and prevalence estimates (95% CIs) for categorical variables. Standard errors were estimated using the Taylor series linearization method. Estimates were considered reliable if degrees of freedom were ≥12 and the relative standard error (RSE) ≤30% [12]. We utilized fitted multiple logistic regression models to estimate crude and adjusted odds ratios (ORs) and prevalence risk ratios (PRRs) with accompanying 95% CIs for our outcome variable dysglycemia [19,20]. Our calculation of the PRR was performed as a function of the average marginal predictions from the fitted regression models [20]. We considered the following variables for confounding, based on previous literature: age, PIR, education,

number of live births, waist circumference, and CRP. We elected to keep the covariates stated above in the model if they changed the full model OR by ≥10%. Our final models therefore adjusted for age, education, PIR, waist circumference, and CRP. We assessed effect modification by using fully adjusted models containing all relevant two-way interaction terms; because the interaction between race/ethnicity and BMI was significant in our models ($p<0.05$), we present our findings stratified on BMI category.

Results

After exclusion of women with inadequate fasting times (n=421), our final sample totaled 7,162 women, with 2,950 eligible for the fasting analyses. Demographic characteristics of the study population are provided in Table 1. The mean age of our population was 33 years, with Mexican American women slightly younger than the total population and both non-Hispanic White and non-Hispanic Black women. Most women surveyed in the total population were married or cohabitating, with at least a high school education, and had had at least one live birth. Compared with non-Hispanic Whites, both non-Hispanic Blacks and Mexican Americans were more likely to be near poor or below the poverty line (55.4% and 65.9% vs. 30.2%, respectively), and less likely to have attained a high school degree or greater (71.0% and 50.7% vs. 84.6%, respectively, $p < 0.01$ for each comparison).

Over 50% of U.S. women of childbearing age were overweight, obese, or morbidly obese. Prevalence of obesity was significantly higher in non-Hispanic Black and Mexican American women compared with non-Hispanic White women [prevalence estimates (95% confidence intervals): 47.0% (44.6, 49.5), 36.3% (33.1, 39.6), and 28.0%

(25.8,30.3) for non-Hispanic Black, Mexican American, and non-Hispanic White women, respectively ($p<0.01$ for each comparison, Figure 1)]. Additionally, high central adiposity (waist circumference ≥ 88 cm) affected almost 50% of all women in this population, with proportions reaching 58% or greater for both non-Hispanic Blacks and Mexican Americans compared with 46% for non-Hispanic Whites (Table 1).

We observed higher fasting plasma glucose, A1C, and CRP levels among non-Hispanic Blacks and Mexican Americans compared with non-Hispanic Whites (Table 1). Almost 20% of all nonpregnant U.S. women of childbearing age had some measure of dysglycemia. Higher proportions of dysglycemia were seen among minority groups when compared with non-Hispanic whites: 26.3% (95% CI: 22.3, 30.8%) in non-Hispanic Blacks and 23.8% (95% CI: 19.5, 28.7%) in Mexican Americans vs. 16.8% (95% CI: 14.4, 19.6%) in non-Hispanic Whites.

In stratified analyses (Table 2 and Appendix Table 1), within normal–to-underweight women, we saw higher prevalence of dysglycemia among both non-Hispanic Black and Mexican American women when compared with non-Hispanic White women. For this BMI category, in our unadjusted models, prevalence of dysglycemia was twice as high in both non-Hispanic Blacks and Mexican Americans compared with non-Hispanic Whites. These observations held when models were adjusted for age, socioeconomic factors, waist circumference and CRP levels, though the estimates were slightly attenuated (PRR_{adj}: 1.86, 95% CI: 1.16,2.98 for non-Hispanic Blacks; PRR_{adj}: 2.23, 95% CI: 1.38,3.60 for Mexican Americans, Table 2). Lower education attainment was also significantly associated with higher prevalence of dysglycemia within this BMI category, as was having a waist circumference ≥ 88 cm. Among overweight women, we

observed that non-Hispanic Blacks had approximately 1.5 times the prevalence of dysglycemia compared with non-Hispanic Whites; this disparity persisted after adjusting for age, socioeconomic factors, waist circumference, and CRP (PRR_{adj}: 1.55, 95% CI: 1.03, 2.34), with the same effect for both lower education attainment and waist circumference observed as seen in the normal and underweight women. We found no significant differences in dysglycemia prevalence between overweight Mexican American women and overweight non-Hispanic White women. Additionally, among obese and morbidly obese women, we did not observe any differences in dysglycemia by race/ethnicity status, in either crude or adjusted models (Figure 2).

Conclusions

Using nationally representative data collected over 10 years and representing over 50 million women, we found that almost one in 5 U.S. women of childbearing age were affected by some form of dysglycemia. Additionally, over half of all U.S. women of childbearing age were overweight or obese, and nearly 50% had high central adiposity. We also observed the disproportionate burden of dysglycemia among racial and ethnic minorities compared with non-Hispanic Whites, with prevalence estimates in minorities approximately 1.5 those in non-Hispanic Whites. When stratified by BMI category, we continued to see disparities in dysglycemia prevalence by race/ethnicity status, though this was restricted to distinct BMI categories. Within the normal-to-underweight group, both non-Hispanic Blacks and Mexican Americans had almost twice the prevalence of dysglycemia vs. non-Hispanic Whites. In the overweight group, only non-Hispanic Blacks had increased prevalence, at almost 1.5 that of non-Hispanic Whites.

Hyperglycemia among women of childbearing age poses a risk not only to the woman as she progresses through various life stages [7], but also to her fetus if she becomes pregnant [8-10]. These effects could impact the long-term health of her child, including increased risk of obesity and type 2 diabetes later in life [21,22]. However, little attention has been paid to diabetes and measures of dysglycemia specifically among nonpregnant women of childbearing age. Most estimates from U.S. data for this particular population sub-group are derived from analyses using broad age-ranges, as well as pregnant and nonpregnant women. Previously reported prevalence estimates range between 3-7.5% for self-reported diabetes and 8-23% for clinical measures of IFG [1,2], with higher estimates for both measures in minority groups and higher age categories. Our results for overall dysglycemia (which includes diabetes and prediabetes measures, including IFG) are comparable to these estimates, despite our younger cohort. This is of note, since diabetes and dysglycemia in general increase with age [23], and highlights the importance of focusing interventions on this younger age group.

Research focusing specifically on nondiabetic women of childbearing age show disproportionate levels of obesity and other clinical characteristics of the metabolic syndrome, including impaired fasting glucose, among both non-Hispanic Blacks and Hispanics when compared with non-Hispanic Whites [24]. Since these data excluded diabetic women our study is the first to investigate diabetes and prediabetes measures specifically among women of childbearing age. Other findings from national data have shown variations in diabetes prevalence by BMI group. A recent study [25] looking at 30 years of NHANES data shows variation in racial/ethnic disparities of diabetes by BMI

group: in normal and overweight individuals, minority groups experience a greater increase in diabetes prevalence than Whites over the time period studied, but in obese and severely obese groups this disparity is less pronounced. Though this recent study includes a larger age group (20-74 years old) as well as men and women together, it corroborates some of our observations presented here.

Diabetes has been shown to be associated with obesity [26,27]. However, in our results, we see discordance in dysglycemia and obesity, with differences by race/ethnicity among women not considered obese by standard clinical measures. Others before us have noted differential effects of BMI on diabetes risk between Black and White Americans [5]. This highlights the fact that obesity, as measured by either BMI or waist circumference, does not explain the whole of disparities by race/ethnicity in impaired glucose metabolism, in a clinical setting or at a population level. One possible explanation for the disparity within non-obese subjects is a differential beta cell function between race/ethnicity groups. Results from clinical studies have shown decreased insulin sensitivity in African American women compared with European American women [28,29], with differential responses by race/ethnicity in insulin sensitivity and beta cell responsiveness according to level of body fat [30], and location of body fat depots [31,32]. Although obesity alone causes a state of insulin resistance, it is possible that the pancreatic response is different in the presence of adipose tissue within different race/ethnic groups, which may help to explain our observation by BMI category.

We focused our attention on variations within BMI categories. However, BMI has been criticized as a crude measure for obesity, since it does not discriminate between lean muscle and body fat and therefore might not account for those individuals with

normal weight obesity (i.e. normal BMI but high body fat). Clinical studies among women with a normal BMI showed that as body fat increased, so did prevalence of metabolic syndrome and dyslipidemia [33]. Furthermore, among those women with normal weight obesity, insulin sensitivity was significantly decreased. Additionally, the researchers found an increased risk of cardiovascular mortality among these women, suggesting that classifying a person as "normal" based on BMI alone might mask the effects of that person's body fat content. However, the body fat measures used in these clinical studies did not account for the distribution of fat – specifically, the location of the fat stores. Although visceral adipose has been linked to increased diabetes incidence [16], clinical studies have shown that African American women have less visceral adipose stores compared with European American women, even after periods of significant weight gain and loss [34,35]. We attempted to account for the increased risk posed by central adiposity by adjusting for waist circumference category using a clinically relevant measure, and still noticed differences in dysglycemia prevalence by race/ethnicity among women with a normal BMI. The use of these clinical indices alone may not identify some women at increased risk for impaired glucose tolerance.

Differences in dysglycemia by race/ethnicity may also be due to factors unrelated to glucose control, and could be a result of genetic or ancestral differences, particularly related to A1C variation. Several epidemiological studies have reported higher A1C values in African Americans vs. Whites, independent of fasting plasma glucose levels [36,37]. Results from the Diabetes Prevention Program show that among individuals with impaired glucose tolerance, both Blacks and Hispanics had higher A1C levels than Whites, even after adjusting for cofactors such as age, sex, education, BMI, blood

pressure, and insulin resistance [38]. Previous research estimates that genetic factors might explain >50% of variation in A1C [39] and support the exploration for a genetic loci unique to A1C. However, recent research from the Atherosclerosis Risk on Communities (ARIC) Study shows a small contribution of genetic ancestry relative to social and metabolic factors in explaining A1C variation among African Americans, indicating that ancestral genetic differences might not explain significantly the observed race/ethnicity differences in A1C [40]. More research is warranted to investigate the role of genetic factors in these specific associations.

While our analysis utilizes robust, nationally representative survey data, there are some limitations to our study. NHANES data is based on a cross-sectional survey; consequently, there is no way to assess causality. Also, because of possible disclosure risks, for the 2007-08 survey cycle only pregnancy status information for women aged 20-44 was available. We therefore may have missed some nonpregnant women aged 15-19 and 45-49 in the survey. We also restrict our analyses to only three race/ethnicity categories; small sample size and wide heterogeneity of a fourth category ('Other') did not allow for reliable comparison with the other defined categories for race/ethnicity. Additionally, fasting measures are based on one fasting plasma glucose value, and fasting state is based on the participants' self-report. For clinical diagnoses, it is recommended that the subject be retested in the presence of an abnormal result; we did not have this opportunity. Therefore, it is likely that some prevalence estimates from the use of fasting plasma glucose values might be overestimated. Also, diagnosed diabetes is by self-report; however, we are able to utilize laboratory values for diabetes measures to help eliminate any biases of self-report. Finally, we are missing values of A1C from the 2007-

2008 NHANES cycle. NCHS released a statement in March, 2012, noting an increase in the proportion of A1C values between 5.7-6.4% (39-48 mmol/mol) and subsequent shift to the right (increased values) of A1C distribution in NHANES 2007-2010 compared with 1999-2006. However, after extensive investigation, the specific source for this observation is currently unknown [11]. Since our analyses are focused on those persons with higher A1C – particularly, 5.7% (39 mmol/mol) and above – inclusion of these data from 2007-08 may have biased our results; therefore, we chose not to include these data in our analyses. Because of this, some individuals may have been misclassified on their status of dysglycemia. A breakdown of our outcome showed that 8.3% of our population were categorized as having dysglycemia by A1C criteria, 16.2% by fasting plasma glucose (FPG) criteria, and 2.7% by interview response (i.e. with diagnosed diabetes). Within the whole study sample, 3.0% were categorized as having dysglycemia by meeting both A1C and FPG criteria, 1.3% by A1C criteria alone, and 8.4% by FPG criteria alone. However, the fact that we were able to include both lab measures for glucose and A1C, as well as a self-report of doctor-diagnosed diabetes, adds to the robustness of our study.

In summary, we found that approximately one in 5 of the nation's nonpregnant women of childbearing age is affected by some form of dysglycemia. This corresponds to almost 9 million U.S. women between the ages of 15-49, with a greater burden among minorities when compared with non-Hispanic Whites. While our findings confirm the presence of disparities in dysglycemia prevalence by race/ethnicity, contrary to previous literature we find this difference is not explained by obesity, rather by differences within normal-to-underweight groups. These findings suggest that special attention should be

paid specifically to the disparities among non-obese individuals, both in clinical practices and in development of public health programs and interventions.

Author contributions

J.A.M. assisted with project conception, conducted the statistical analysis, reviewed the data and results, and wrote the manuscript. C.J.A. researched the data, led the statistical analysis, provided statistical consult, and reviewed/edited the manuscript. K.M.V.N. reviewed the results, contributed to the discussion, and reviewed/edited the manuscript. H.S.K. contributed to the data analysis, reviewed the results, contributed to the discussion and reviewed/edited the manuscript. J.R. researched the data, contributed to the discussion and reviewed/edited the manuscript. A.C. assisted with project conception, reviewed the results, contributed to the discussion, and reviewed/edited the manuscript.

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There are no conflicts of interest to disclose.

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A.C. is the guarantor of this work and had full access to the study data. As such he takes responsibility for the integrity of the data and the accuracy of the data analysis.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Tables and Figures

Table 4. 1. Population statistics for nonpregnant U.S. women of childbearing age, NHANES 1999-2008.

	n‡	Total population ($n_{weighted}$= 59,465,044)	Non-Hispanic White ($n_{weighted}$= 39,758,373)	Non-Hispanic Black ($n_{weighted}$= 7,853,867)	Mexican American ($n_{weighted}$= 5,109,137)
Social factors					
Age (y)†	7162	33.1 (32.7-33.4)	33.5 (33.1-34.9)	32.6 (32.1-33.2)[a]	31.3 (30.8-31.8)[b]
Education level	7162				
< High school	2711	21.2 (19.8-22.7)	15.4 (13.7-17.2)	29.0 (25.8-32.5)[b]	49. 4 (45.5-53.2)[b]
High school or greater	4451	78.8 (77.3-80.2)	84.6 (82.8-86.3)	71.0 (67.6-74.2)[b]	50.7 (46.8-54.5)[b]
Civil status	7069				
Married/cohabitating	3132	56.9 (55.1-58.6)	61.8 (59.8-63.8)	34.8 (32.0-37.7)[b]	61.1 (58.3-63.9)
Poverty Income Ratio (PIR)†	7162	2.8 (2.7-2.9)	3.1 (3.0-3.2)	2.1 (2.0-2.2)[b]	1.9 (1.8-2.0)[b]
PIR < 1 -- Below poverty line	1881	18.2 (16.7-19.8)	13.0 (11.1-15.1)	29.1 (25.7-32.7)[b]	33.0 (29.8-36.4)[b]
1 ≤ PIR < 2 -- Near poor	1797	20.7 (19.5-22.0)	17.2 (15.4-19.0)	26.3 (23.4-29.4)[b]	32.9 (30.3-35.6)[b]
PIR ≥ 2 -- Middle or high income	3484	61.1 (59.1-63.1)	69.8 (67.0-72.5)	44.6 (41.3-48.0)[b]	34.2 (31.2-37.0)[b]
Number of live births†	3822	2.1 (2.1-2.2)	2.0 (2.0-2.1)	2.3 (2.2-2.4)[b]	2.5 (2.4-2.6)[b]
0	245	6.5 (6.1-7.8)	6.6 (6.1-8.4)	7.7 (7.0-10.2)[*]	3.0 (2.5-4.7)[*,b]
1	1005	25.0 (23.3-26.8)	25.7 (23.2-28.3)	23.3 (20.8-25.9)	23.2 (19.9-26.8)
2	1211	36.0 (34.1-37.8)	37.9 (35.4-40.4)	32.7 (29.5-36.0)[a]	27.3 (23.9-31.1)[b]
3	854	22.3 (20.8-23.9)	22.2 (20.2-24.3)	20.8 (17.9-23.9)	27.5 (25.0-30.3)[b]
4 or more	507	10.2 (9.0-11.6)	7.6 (6.1-9.4)	15.6 (13.3-18.3)[b]	19.0 (16.1-22.2)[b]
Cardiometabolic factors					
BMI (kg/m^2)†	7027	27.6 (27.3-27.9)	27.0 (26.6-27.5)	30.7 (30.3-31.2)[b]	28.7 (28.2-29.1)[b]
BMI <25 (Under or normal weight)	3065	44.6 (42.5-46.7)	48.9 (45.9-52.0)	26.4 (24.3-28.7)[b]	32.8 (30.1-35.7)[b]
25 ≤ BMI <30 (Overweight)	1747	24.6 (23.2-26.2)	23.1 (21.3-24.9)	26.6 (24.3-29.0)	30.9 (28.7-33.2)[b]
BMI 30+ (Obese or morbidly obese)	2215	30.8 (29.1-32.6)	28.0 (25.8-30.3)	47.0 (44.6-49.5)[b]	36.3 (33.1-39.6)[b]
Waist Circumference (cm)†	6900	90.5 (89.8-91.2)	89.7 (88.7-90.7)	95.8 (94.8-96.7)[b]	92.7 (91.8-93.6)[b]

≥ 88 (High)	3331	48.8 (46.7,50.9)	46.1 (43.3,48.9)	62.4 (60.1,64.6)[b]	58.4 (55.0,61.8)[b]
C-reactive Protein (CRP; mg/dL)†	6696	0.4 (0.4-0.5)	0.4 (0.4-0.4)	0.6 (0.5-0.6)[b]	0.5 (0.5-0.6)[b]
> 0.3 (Elevated)	2435	37.1 (35.5-38.8)	35.4 (33.1-37.7)	44.6 (41.9-47.4)[b]	44.5 (41.1-47.9)[b]
Fasting Plasma Glucose (mg/dL)†	2950	93.3 (92.5-94.1)	92.1 (91.1-93.1)	95.2 (92.6-97.8)[a]	97.1 (94.8-99.5)[b]
Hemoglobin A1c (A1C; %)†	5764	5.2 (5.2-5.3)	5.2 (5.1-5.2)	5.5 (5.4-5.5)[b]	5.4 (5.3-5.4)[b]
Any level of dysglycemia present^	2954	19.0 (17.2-20.9)	16.8 (14.4-19.6)	26.3 (22.3-30.8)[b]	23.8 (19.5-28.7)[b]

All results are presented as percentage (95% CI), unless otherwise noted.

‡Unweighted n

†Mean (95% CI)

a: p-value <0.05, b: p-value <0.01, compared with non-Hispanic Whites

* Degrees of freedom < 12, and relative standard error (RSE) >30%; presenting adjusted CI [12]

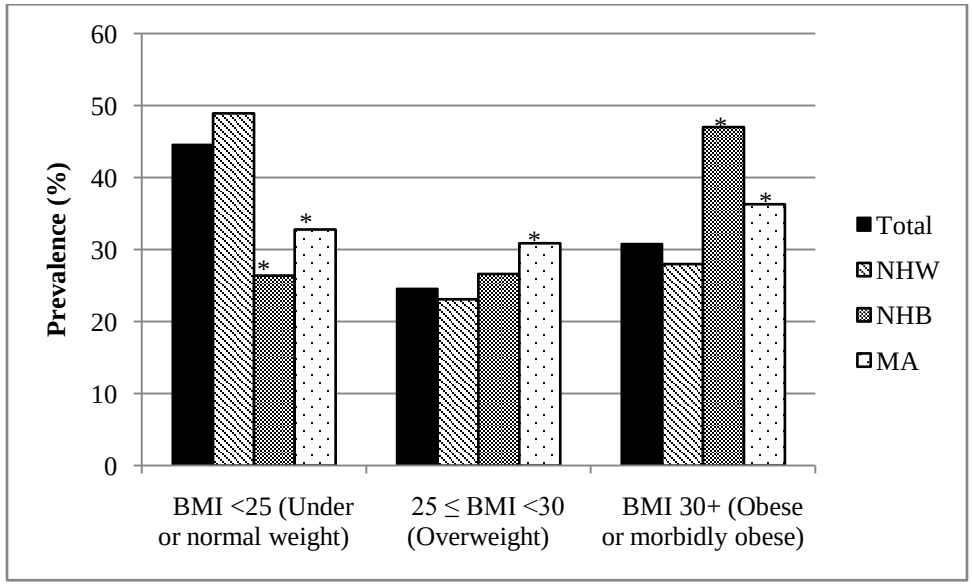
^ Self-report of diabetes or taking diabetic medicines from the interview, fasting plasma glucose ≥100 mg/dL or HbA1c >5.7% (39 mmol/mol) from laboratory measures.

Table 4. 2 Crude and adjusted[1] prevalence risk ratios (PRRs) and 95% confidence intervals (CIs), for dysglycemia in nonpregnant U.S. women of childbearing age (15-49), by BMI category[2], NHANES 1999-2008.

	Under or Normal Weight BMI (n=1118, $n_{weighted}$=23,213,172)		Overweight BMI (n=640, $n_{weighted}$=12,462,018)		Obese or morbidly obese (n=830, $n_{weighted}$=16,222,072)	
	Crude model	Adjusted model[1]	Crude model	Adjusted model[1]	Crude model	Adjusted model[1]
	PRR (95% CI)	PRR (95% CI)	PRR (95% CI)	PRR (95% CI)	PRR (95% CI)	PRR (95% CI)
Race/ethnicity						
Non-Hispanic White	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*
Non-Hispanic Black	1.81(1.09,3.01)	1.86(1.16,2.98)	1.54(1.06,2.24)	1.55(1.03,2.34)	0.99(0.75,1.30)	1.06(0.81,1.39)
Mexican American	2.12(1.37,3.30)	2.23(1.38,3.60)	1.41(0.87,2.29)	1.28(0.73,2.26)	0.94(0.72,1.23)	0.99(0.74,1.32)
Education						
≥ High school		*Ref.*		*Ref.*		*Ref.*
< High school		2.24(1.34,3.77)		1.71(1.04,2.81)		1.09(0.87,1.36)
Waist circumference						
≤ 88 cm		*Ref.*		*Ref.*		*Ref.*
> 88 cm		2.30(1.21,4.38)		1.89(1.00,3.57)		1.21(0.30,4.80)
Poverty income ratio (PIR)						
Middle class +		*Ref.*		*Ref.*		*Ref.*
Near poor		0.76(0.44,1.33)		1.20(0.67,2.14)		1.00(0.75,1.33)
Below poverty line		0.78(0.42,1.46)		0.69(0.30,1.63)		1.21(0.95,1.59)
C-reactive Protein (CRP)						
≤ 0.3 mg/dL		*Ref.*		*Ref.*		*Ref.*
> 0.3 mg/dL		1.30(0.78,2.15)		0.94(0.60,1.48)		1.41(1.02,1.96)

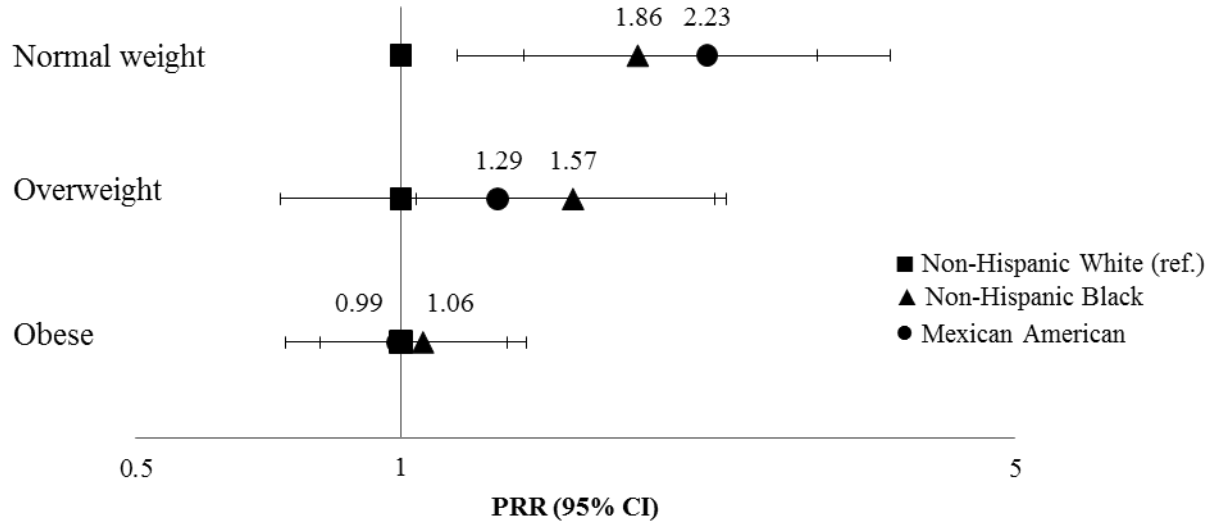
1 Adjusted for age (continuous), waist circumference (<88 cm or ≥88 cm), education (< high school or high school or greater), poverty income ratio (PIR: < 1 (poor), ≥ 1 but < 2 (near poor), or ≥ 2 (middle or high income) and C-reactive protein (CRP: ≤0.3 mg/dL or > 0.3 mg/dL).
2 Normal and underweight: BMI < 25.0 kg/m^2, overweight: BMI 25-29.99 kg/m^2, and obese or morbidly obese: BMI ≥ 30 kg/m^2.

Figure 4. 1 Prevalence of under/normal weight, overweight and obese (by BMI cut-offs) among nonpregnant U.S. women of childbearing age (15-49), for total population and by race/ethnicity, NHANES 1999-2008.



Solid bars represent prevalence for the total population; hatched bars represent non-Hispanic White (NHW); shaded bars represent non-Hispanic Black (NHB); and dotted bars represent Mexican American (MA). * $p \leq 0.05$ vs. NHW.

Figure 4. 2 Adjusted[1] prevalence risk ratios (95% CIs) for dysglycemia in different race/ethnicities, in nonpregnant U.S. women of childbearing age, stratified on BMI category.[2]



■ – Non-Hispanic White (ref.), ▲ – Non-Hispanic Black, ● – Mexican American

1 Adjusted for age (continuous), waist circumference (<88 cm or ≥88 cm), education (< high school or high school or greater), poverty income ratio (PIR: < 1 (poor), ≥ 1 but < 2 (near poor), or ≥ 2 (middle or high income) and C-reactive protein (CRP: ≤0.3 mg/dL or > 0.3 mg/dL).

2 Under or normal weight: BMI < 25.0 kg/m^2 (n=1118, $n_{weighted}$=23,213,172), overweight: BMI 25-29.99 kg/m^2 (n=640, $n_{weighted}$=12,462,018), and obese or morbidly obese: BMI ≥ 30 kg/m^2 (n=830, $n_{weighted}$=16,222,072).

Appendix Table 1. Crude and adjusted[1] odds ratios (ORs) and 95% confidence intervals (CIs) for dysglycemia in nonpregnant U.S. women of childbearing age (15-49), by BMI category[2], NHANES 1999-2008.

	Under or Normal Weight BMI (n=1118, $n_{weighted}$=23,213,172)		Overweight BMI (n=640, $n_{weighted}$=12,462,018)		Obese or morbidly obese (n=830, $n_{weighted}$=16,222,072)	
	Crude model	Adjusted model[1]	Crude model	Adjusted model[1]	Crude model	Adjusted model[1]
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Race/ethnicity						
Non-Hispanic White	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*
Non-Hispanic Black	1.91(1.09,3.36)	2.05(1.17,3.59)	1.69(1.08,2.65)	1.79(1.06,3.02)	0.98(0.63,1.53)	1.11(0.68,1.81)
Mexican American	2.30(1.40,3.76)	2.56(1.43,4.59)	1.51(0.85,2.70)	1.38(0.67,2.83)	0.91(0.60,1.38)	0.98(0.60,1.61)
Education						
≥ High school		*Ref.*		*Ref.*		*Ref.*
< High school		2.54(1.37,4.82)		2.01(1.00,4.05)		1.16(0.78,1.74)
Waist circumference						
≤ 88 cm		*Ref.*		*Ref.*		*Ref.*
> 88 cm		2.66(1.20,5.88)		2.17(1.03,4.57)		1.37(0.16,12.09)
Poverty income ratio (PIR)						
Middle class +		*Ref.*		*Ref.*		*Ref.*
Near poor		0.74(0.39,1.38)		1.26(0.59,2.70)		1.00(0.61,1.63)
Below poverty line		0.76(0.37,1.53)		0.64(0.23,1.79)		1.45(0.90,2.36)
C-reactive Protein (CRP)						
≤ 0.3 mg/dL		*Ref.*		*Ref.*		*Ref.*
> 0.3 mg/dL		1.35(0.74,2.44)		0.93(0.52,1.64)		1.77(1.05,2.96)
Age (y)		1.06(1.04,1.09)		1.06(1.02,1.11)		1.07(1.05,1.10)

1 Adjusted for age (continuous), waist circumference (<88 cm or ≥88 cm), education (< high school or high school or greater), poverty income ratio (PIR: < 1 (poor), ≥ 1 but < 2 (near poor), or ≥ 2 (middle or high income) and C-reactive protein (CRP: ≤0.3 mg/dL or > 0.3 mg/dL).
2 Normal and underweight: BMI < 25.0 kg/m^2, overweight: BMI 25-29.99 kg/m^2, and obese or morbidly obese: BMI ≥ 30 kg/m^2.

CHAPTER 5: EXPANDED METHODS

To address some of the issues raised in the previous chapters, we conducted a pilot study to assess the feasibility of implementing a lifestyle intervention during pregnancy among overweight and obese urban Black women, incorporating both quantitative and qualitative research methods. Our goal was to deliver a lifestyle intervention and improve diet and physical activity (PA) within this underserved population. We hypothesized that improving diet and (PA) during pregnancy can have an effect on keeping a woman within gestational weight gain (GWG) recommendations, and potentially prevent the progression to gestational diabetes (GDM) (Figure 5.1). This pilot study will allow us to understand the underpinnings of these relationships within an underrepresented population in order to develop a larger study for GDM prevention.

Study design and intervention

Study site and population

We developed the Healthy Moms, Happy Babies study as a randomized, controlled, clinical feasibility trial, for implementation at Grady Memorial Hospital in downtown Atlanta, GA. The 7th largest hospital in the U.S. (165), Grady Hospital works to improve the lives of those in Atlanta, with a mission of serving the poor and uninsured and those suffering from health disparities. At its center, Grady Memorial Hospital has been the public hospital for the city of Atlanta since 1982. The Grady Health System (GHS) is one of six regional perinatal centers in the state of Georgia and serves as the primary referral center for high risk patients in the 40-county North Georgia area. It also accepts maternal transports from outside of the 40-county referral base, from other

perinatal centers and their affiliated hospitals that are not equipped to care for high acuity or complexity pregnancies. GHS serves patients with highly diverse racial and socioeconomic profiles. The obstetric clinic at Grady sees over 3,700 deliveries each year (Dr. Michael Lindsay, personal communication). The study was approved by both the Emory University Institutional Review Board and Grady Memorial Hospital Research Oversight Committee, and is registered at clinicaltrials.gov (identifier: NCT01084941). It received assistance from the Atlanta Clinical and Translational Science Institute, as well as the Race and Difference Initiative at Emory University.

All women presenting for their first prenatal care visit at the hospital's obstetric services were screened for inclusion into the study via questionnaire. This questionnaire solicited information on the woman's age, self-reported weight and height, self-identified race/ethnicity, approximate week of pregnancy (if known) or date of last menstrual period, and brief health history with information relating to study eligibility. Women were eligible for enrollment if they were 1) Black/ African-American; 2) <20 weeks gestation; 3) 18-49 years of age; 4) overweight or obese (BMI $\geq$25 kg/m^2 based on self-reported pre-gravid weight and height); 5) experiencing a singleton pregnancy; and 6) planning to take their pregnancy to term. Women with a history of diabetes (GDM, type 1 or type 2), cardiovascular disease, chronic kidney disease or active liver disease; who were currently taking anti-hypertensive medications or medications that would alter glucose metabolism (steroids); who were anemic (hemoglobin <10 g/L or hematocrit <32%); had contraindications to participating in physical activity; or who lacked the mental capacity to participate in the intervention were not eligible for participation. This information was pulled from the patient's medical record. Women meeting all

aforementioned eligibility criteria were asked to return for baseline testing, scheduled within 1-2 weeks of their first prenatal visit, at which point written informed consent for participation in the study was obtained.

Randomization and study groups

To control for potential confounding by BMI category, we utilized block randomization techniques, stratified on BMI category (overweight [25 ≤ BMI < 30] and obese [BMI ≥ 30]). Study group assignments were concealed in opaque security envelopes prepared by the study coordinator. Participants enrolled into the study were randomly assigned to one of two groups: 1) regular standard of care from their obstetrician (RC); or 2) regular care plus a lifestyle intervention (LSI) (Figure 5.2).

Regular care group (RC)

Women assigned to the RC group received information outlining healthy eating practices and the safety of PA during pregnancy, published by the March of Dimes. They attended prenatal care visits as regularly scheduled, and received standard counseling provided by physicians, nurses, dieticians and counselors from the hospital obstetric clinics and Women, Infants, Children's (WIC) state program, as eligible and needed.

Lifestyle intervention group (LSI)

Women assigned to the LSI group received all aspects of standard care at the hospital, as well as monthly study sessions where they met one-on-one with a health educator and discussed strategies for healthy eating and increasing time spent in PA, as outlined in Table 5.1. The sessions were held monthly, beginning at the baseline testing visit and lasting through to delivery, and the topics covered in each session can be found in Appendix 2. The sessions were based on teachings from the Diabetes Prevention

Program (DPP) (166) and were designed by a medical student and nutrition doctoral student, with guidance from diabetes educators, WIC counselors, dieticians, nurses, endocrinologists and obstetricians from the Grady Hospital community. Each session coincided with the participant's prenatal care visit, lasting 30 minutes to 1 hour in duration, and covered such topics as GWG goals, healthy eating from each of the food groups, hidden fats and sugars in foods, and healthy choices for eating outside of the home. The PA portion of the intervention was based on a walking program designed to increase time spent per day engaged in moderate PA. This plan was presented at the baseline testing for those women randomized into the LSI group, and asked the participant to start with 15 minutes of walking per day on at least 4 days of the week, adding 2 extra minutes of walking per day each week until reaching a final goal of 40 minutes of walking per day on at least 4 days of the week (Table 5.2). Each participant in the intervention group received a pedometer (Omron HJ-112) to encourage her progress toward meeting activity goals and help track her daily and weekly number of steps. Each pedometer was programmed for each participant's specific stride length, to more accurately measure that participant's step count. Utilizing dual-axis technology, this particular pedometer tracked regular and brisk steps separately, stored up to seven days of information, and automatically re-set each day to more accurately track participants' steps. Participants set weekly goals for healthy eating and PA based on the topics covered in each session, and were asked to report on progress toward these goals at the beginning of each subsequent session. In the case these goals were not met, the participant identified potential barriers for reaching her goals; methods of overcoming these barriers were discussed and incorporated into the next goal-setting activity. There were seven

sessions total as part of the LSI program; 3 for before midpregnancy (24-28 weeks) and 4 for between midpregnancy and delivery. Additionally, each participant in the intervention group received a booster follow-up phone call or text message every two weeks, to chart progress toward her self-determined goals for healthy eating and PA and provide motivation for meeting these goals. During these follow-up phone/ text conversations, the participant reported her step counts for the previous seven days, as well as any progress made toward the identified goals from the previous session. She also reported if there were difficulties in reaching these goals, and potential means of overcoming these difficulties.

Data collection

The timetable for data collection is depicted in Table 5.3. All women presented for baseline testing at <20 weeks gestation. For this visit, all participants arrived at the Grady Memorial Hospital Clinical Interaction Site after an overnight fast of ≥8 hours. Upon randomization into study groups, women were assigned a unique identification number; this number was used for all subsequent analyses so that all data were de-identified. All participants, regardless of study group, returned for study testing at two subsequent study visits: one midpregnancy (24-28 weeks) and one postpartum (6 weeks after delivery), after an overnight fast as indicated for baseline testing. All paper forms containing any level of participant data were stored in a locked filing cabinet in a locked office at the Diabetes Clinic of Grady Memorial Hospital, accessible only by clinic staff with proper keycard clearance.

Descriptive data

Information on participant's age, educational experience and training, occupation, household income level, insurance status, participation in the hospital's WIC program, smoking history, and family history of diabetes was ascertained via a demographic questionnaire at the baseline study visit. This information obtained from the questionnaire was validated and supplemented with data from the participant's medical record. Additionally, information on participants' pregnancy histories was pulled from the medical record.

Primary outcomes

Feasibility measures

Length of time for recruitment and recruitment rate

We considered the actual time needed to reach our target number for enrollment (n=60) and calculated our recruitment rate based on screening for participation and entrance into the study. Recruitment was evaluated by comparing the sample sizes of individuals who were screened for the study, who passed the screening criteria, who presented for baseline testing, and who enrolled into the study. Recruitment into the program was assessed by tracking on a daily basis how many women were screened for enrollment, and calculating the percentage of those screened who were eligible for recruitment.

Participation, adherence to intervention, and completeness of data collection

We analyzed participation rate at each study session by assessing the number of LSI sessions attended by each participant. The LSI program was designed so that each participant would receive three LSI sessions prior to midpregnancy testing, and seven LSI sessions prior to delivery. A participant was considered adherent to the intervention

if she attended 85% or more of her scheduled LSI sessions (i.e., ≥6 sessions). Nonadherence was also considered. A follow-up phone call occurred on the day following a participant's missed visit. This activity served to ascertain why the participant missed her visit: if it was due to a conflict, if she forgot, if she was unhappy with the study, or another related issue (i.e. she was ill, etc.). We followed-up with participants by phone until an answer was obtained, she appeared for her study visit or she was no longer eligible for her study visit, whichever milestone was reached first. In cases where it was feasible, participants were rescheduled for their missed visit until no longer eligible for that visit. Information from follow-up phone calls helped aid in understanding the adherence to the intervention as well as the acceptance of the intervention by the study participants. Assessment of the completeness of data collection was measured by calculating the number of completed study questionnaires and proportion of blood samples collected. Participants continued to be enrolled in the study unless they expressed interest to withdrawal from the study (n=2). In these instances, participants were notified of their right to withdrawal from the study, and mailed a revocation letter with return postage included to inform study personnel of their desire for continuation of data collection.

Retention rate and loss to follow-up

Percent retention (loss to follow-up) was measured by subtracting the number of individuals in each arm of the study returning for each data collection timepoint from the total number enrolled in the study and dividing by total enrollment. Of those women who were eligible for recruitment, we calculated the percentage of those who then returned for their baseline visit and were enrolled into the program. Retention was tracked by noting

of those enrolled participants, how many women returned for their monthly visits (LSI group only), midpregnancy visit and postpartum visit (both RC and LSI groups).

PA and dietary indices

Adherence to the lifestyle program was measured by self-reported PA and dietary intakes (Table 5.3). At each study visit, all participants completed the self-administered Pregnancy Physical Activity Questionnaire (PPAQ) (167) to measure self-reported PA. A semi-quantitative questionnaire, the PPAQ assessed duration, frequency and intensity of total PA for the previous 3 months (or, trimester). Respondents selected the category that best represented the amount of time spent in 35 activities, including household/caregiving activities, occupational activities, sports/exercise, and transportation. It also assessed levels of inactivity. The self-reported duration of time spent in each activity was multiplied by its corresponding MET intensity according to the Compendium of Physical Activities (168) and summed to arrive at a measure of average weekly energy expenditure (MET-hrs/ week) attributed to each activity. For those activities determined to have different intensities during pregnancy, a modified compendium value was used. This questionnaire was validated using ActiGraph accelerometers and has been used in several diverse populations (167). From responses on this questionnaire, participants were categorized on whether or not they met physical activity goals as dictated by both the American College of Obstetricians and Gynecologists (ACOG) and the American College of Sports Medicine (ACSM) -- i.e., 450 MET-min/week (169). Additionally, participants in the LSI group were asked to record their steps as measured from the pedometer.

In addition to the PPAQ, each participant completed one 24 hour food recall interview during the baseline, midpregnancy, and postpartum testing. Dietary data were collected and analyzed using the Nutrition Data System for Research (NDSR) software version 2009, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN. The 24 hour recall method has been shown to provide an accurate snapshot of individuals' dietary intakes at a specified time. The multi-pass nature of the interview allowed respondents repeated times to recall their intakes in the 24 hours prior to the interview, providing detailed food descriptions. Nutrient intakes and servings consumed were calculated using the NCC Food and Nutrient Database and Food Group Serving Count System. Servings consumed of individual food groups were calculated by summing the servings consumed of each individual food item belonging to the specific food groups, as defined by the NCC database.

Secondary outcomes

Blood pressure, weight, height and calculated BMI

Blood pressure, height and weight were measured at baseline, midpregnancy and postpartum visits for all participants; additionally, for participants in the LSI group these measures were taken at each monthly LSI session. Prepregnancy BMI was calculated by dividing the self-reported prepregnancy weight (in kg) by the square of the participant's height (in cm^2), as measured during baseline testing. Weight (to the nearest kg) and height (to the nearest cm) was measured and recorded by ACTSI nursing staff using a calibrated, standardized scale and stadiometer, respectively. All participants were asked to remove their shoes, outer clothing garments and items from their pockets before taking these measurements. Rate of gestational weight gain (GWG) at midpregnancy was

calculated by subtracting the baseline weight from the midpregnancy visit weight and dividing by the number of weeks between the two measurements. These were compared with 2009 IOM recommendations for rate of GWG, as indicated in Table 3.1 (127). Total GWG was calculated by subtracting the weight at baseline testing from the delivery weight. Using the 2009 IOM Guidelines, participants were categorized as having insufficient, sufficient, or excessive rate of GWG (at midpregnancy) or total GWG (at delivery), according to 2009 IOM recommendations for GWG. Postpartum weight retention was calculated by subtracting the weight at the baseline visit from the weight at the postpartum visit. Pulse and blood pressure was measured using a calibrated electric sphygmomanometer while the participants were seated, after a 5 minute rest.

Glucose, insulin, and GDM diagnosis

During the baseline testing, participants completed a 75-g 2 hour oral glucose tolerance test (OGTT) with blood collections at 0, 30, 60, 90 and 120 minutes. Whole blood glucose (in mg/dL) was measured at each timepoint using the YSI 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI Inc., Yellow Springs, OH). Serum insulin (in uIU/mL) was measured via a commercially prepared radioimmunoassay kit (Siemans, Los Angeles, CA) with an interassay coefficient of variation (CV) of 11.68% at 3.41 uIU/mL, 9.02% at 22.04 uIU/mL, and 8.85% at 102.18 uIU/mL, and an intra-assay CV of 6.75% at 44.59 uIU/mL. The OGTT was repeated at the midpregnancy and postpartum visits for each participant.

GDM was considered following two levels of criteria: 1) ADA 2009 criteria for the 75-g OGTT (15), and 2) proposed criteria from the International Association for the Study of Diabetes in Pregnancy (IADPSG) (18). For the ADA 2009 criteria, GDM was

considered present if two or more values from the OGTT met or exceeded: 95 mg/dL at fasting, 180 mg/dL at 60 minutes, and 155 mg/dL at 120 minutes. For the IADPSG criteria, a positive diagnosis of GDM was considered if one or more values from the OGTT met or exceeded: 92 mg/dL at fasting, 180 mg/dL at 60 minutes, or 153 mg/dL at 120 minutes.

Calculated glucose metabolism and insulin resistance indices

The homeostasis model assessment of insulin resistance (HOMA-IR) was calculated by multiplying the fasting plasma insulin concentration (in uIU/mL) and the fasting plasma glucose concentration (in mg/dL) and then dividing by 405 (170). The insulinogenic index was calculated as Δ insulin/ Δ glucose from 0 to 30 minutes of the OGTT (171). The corrected insulin release at 30 minutes (CIR_{30}) was calculated by multiplying the insulin value at 30 minutes by 100 and dividing this by the product of the glucose value at 30 minutes and the glucose value at 30 minutes – 70 (172). The total area under the curve (AUC) for glucose was calculated using the trapezoidal rule (173).

Delivery and birth outcomes

At delivery, obstetric records were abstracted to obtain information on maternal and fetal birth outcomes including: gestational age at delivery and presence of preterm delivery (<37 weeks gestation) or still birth; method of delivery (i.e., Cesarean section or vaginal); infant birth weight (g), and presence of low birth weight (birth weight $<10^{th}$ percentile for gestational age), large for gestational age (birth weight $> 90^{th}$ percentile for gestational age), or macrosomia (birth weight >4000 g); Apgar scores (at 1 and 5 minutes); and presence or absence of the following pregnancy complications, as noted in the medical chart: pregnancy induced hypertension (PIH) or preeclampsia, respiratory

distress syndrome (RDS), shoulder dystocia, or jaundice. At the postpartum visit, we ascertained whether participants had breastfed their infant at any point during the postpartum period (yes/ no).

Power calculation and statistical analysis

We hypothesized that a lifestyle intervention would result in increased PA when compared with women receiving standard care. We aimed to recruit n=60 subjects for our study, with 30 women in each of the study groups. We assumed that 20% of subjects would be lost to follow-up or have missing data; accordingly, we expected n=48 women to complete the study. Based on our primary outcome as the proportion of women meeting PA guidelines (30 minutes/day, 5 days a week; or 450 MET-min/week (169)), at a significance level of 0.05, assuming 13% of women in the regular care group would meet these PA recommendations (153), a sample size of n=48 achieves 80% power to detect an approximate four-fold increase in PA in the intervention group, with 55% reaching PA guidelines (Table 5.4). This proportion is plausible based on previous studies (174).

Baseline descriptive statistics were calculated for all study variables. Outcome variables were assessed for normality by plotting the residuals, and log-transformed as necessary and appropriate to conduct statistical tests. Descriptive values were expressed as mean ± standard deviation (SD) or median (inter-quartile range) for continuous variables, and as n (%) for categorical variables. Between-group differences in continuous variables at baseline, midpregnancy, and postpartum were determined by the student's t-test and Wilcoxon Mann-Whitney U test for normally and non-normally distributed variables, respectively. Between-group differences in categorical variables

were determined by the Chi-square test or Fisher's Exact test for small sample sizes, with and without adjustment for BMI by the Cochran-Mantel-Haenszel test, to account for the randomization design. Because there were no differences by BMI category, we report here a non-stratified analysis. Successful randomization was assessed by comparing baseline variables between the two study arms. Within group differences from baseline to midpregnancy, delivery and postpartum were tested using the paired t-test or Wilcoxon signed-rank test for continuous variables, and McNemar's test for categorical variables. The efficacy of the intervention at midpregnancy and at postpartum was assessed by considering the differences between groups in the primary outcomes of PA and dietary factors at those timepoints. To further assess the effect of the intervention on PA, we conducted multiple logistic regression with our dichotomous outcome as "meets recommendations for PA (yes/no)", and calculated odds ratios (ORs) and 95% confidence intervals (CIs) for meeting these guidelines for PA. Baseline demographic indices (prepregnancy BMI, age, education level, parity level, smoking status, family history of diabetes, and history of birth by Cesarean section), PA level, and energy intake, as well as the gestational age at the time of outcome measurement, were all assessed as possible confounders, and were controlled for if their exclusion changed the OR by >10% (175).

Although the study was not powered to detect significant differences in our secondary outcome measures, we compared group effects of these measures to show expected trends for designing a larger trial. Between-group and within-group differences at each study timepoint were conducted as described above for continuous and categorical outcomes. We calculated ORs and corresponding 95% CIs using multiple logistic regression models, testing the effect of the intervention on dichotomous outcomes

(i.e., presence/absence of GDM by either criteria; presence/absence of adverse delivery outcome; and meet/do not meet recommendations for GWG by rate (at midpregnancy) or total (at delivery) of GWG). We also calculated beta estimates via multiple linear regression models, testing the effect of the intervention on the continuous outcomes of total AUC for glucose and HOMA-IR (log-transformed) at midpregnancy and postpartum. To account for repeated measures of weight during gestation, we conducted a longitudinal repeated measures analysis, and explored the effect of the intervention using a generalized linear regression model (SAS *Proc Mixed* procedures). We considered a variety of correlation structures, and decided to assume unstructured correlation, to account for the correlation among repeated observations for weight for a given subject, using intervention group as a fixed factor and time as a covariate. The between-subjects factor was 2 intervention groups (intervention or control) and the within-subjects factor was intervention effects (from start to finish of intervention, as measured by gestational week). Between-group differences in intervention effect would be indicated by a significant interaction between intervention effect and intervention group. This is exemplified by the following model:

$$\text{Outcome} = \beta 0 + \beta 1 \text{ x time} + \beta 2 \text{ x intervention group} + \beta 3 \text{ x time x intervention group} + \text{Bi x other covariates}$$

We considered baseline demographic and metabolic indices for confounding, and controlled for these measures if they changed the point estimate by >10% (175). All statistical tests were two-tailed and significance was considered at $p<0.05$. All analyses of quantitative variables were conducted using SAS statistical software, version 9.3 (SAS Institute, Cary, NC).

Qualitative one-on-one structured interviews

We also conducted structured one-on-one in-depth interviews with participants in the LSI group to assess, using a qualitative approach, the acceptability of the intervention and evaluate the overall program. Specifically, we sought to determine what aspects of the program were effective and relevant to participants, and where there may be areas for improvement. The purpose of these interviews was multifold: 1. To assess the acceptability of the intervention among participants in the LSI group; 2. To provide information on why the intervention may or may not have worked within this setting; and 3. To advise changes within the intervention curriculum to increase its applicability and efficacy.

The aim of our research was to evaluate the LSI program; therefore, we invited all participants enrolled in the LSI program during their pregnancy (n=28) to return for an in-depth interview following the delivery of their infant, during their final study visit. Of the 28 women who were enrolled in the LSI program, 18 women were reached by telephone or mail following the delivery of their infant, and scheduled for an interview. Five of these women did not present for their scheduled interview, and were not able to be reached to re-schedule, resulting in 13 women who participated in the interview. The interview occurred, on average, at 6-7 weeks post-delivery. The average age of women interviewed was 26 years (range: 19-34), and for 7 women, this was their first pregnancy (number of previous pregnancies ranged from 1 to 8). The women's education levels ranged from grade school to some college, with 7 women having at least a high school education or more. Most women reported receiving assistance from both the state's Medicaid program, as well as the Women, Infants, Children (WIC) program. The

average BMI of women interviewed was 34.8 kg/m^2 (range: 26-44), and most women (10 of 13) reported a family history of diabetes.

Data collection and preparation

Each participant was consented individually, and provided a copy of consent for her records. Multiple attempts were made to schedule interviews with women who remained in the study but did not return for their study visits. Women were offered the choice of completing the interview in-person or over the phone, during their final study visit or at a later time, at the hospital or in a more convenient location. We welcomed participants to bring their child/ren for their interview. All women opted for in-person interviews; for 12 women the interview was conducted at the hospital in a quiet, private office, following their final study visit, while for one woman the interview was conducted at a later date at a quiet location more convenient to her home. Each interview lasted 45-60 minutes, and each participant received a $25 Visa® gift card for her participation in the interview.

Questions for the interview guide were piloted and revised over several iterations; the final version can be found in Appendix 3. The semi-structured interviews used open-ended questions with extensive probing, as well as specific questions geared toward specific program components. Because recruitment for the overall study was low, we asked participants to describe their motivation for participating in and continuing with the study. Additionally, to evaluate the LSI program and the curriculum presented through the program, participants were asked to describe their experience with the LSI program, including what they liked and did not like about the individual program curriculum components, as well as the program delivery; what they felt they gained by participating

in the program; and finally their recommendations for improvement of the program curriculum and structure. The order of questions followed the LSI curriculum structure, and participants had access to program materials to refer to during the interview. Both interviewers for the study were trained in qualitative data collection and were not affiliated with any other aspect of the LSI program, in order to avoid bias in participants' responses. Interviewers were specifically trained for the purpose of this study over two sessions, each session lasting three hours in length. All interviews were digitally recorded with the participant's permission and field notes were taken by the interviewer. Interviews were transcribed verbatim by the interviewer, and typed transcripts were cross-referenced with the recording by the author of this dissertation. When necessary, the interviewer and author of this dissertation discussed discrepancies between the typed transcript and recording, and consulted an outside party if agreement could not be reached.

Analysis

Our evaluation of the LSI program involved a thematic analysis, based on themes identified in the interview responses. All transcripts were de-identified and entered into MaxQDA 2007 software (VERBI Gmbh, Berlin, Germany) for analysis. We conducted concurrent data analysis during data collection to develop emerging themes and inform or refine questions for the interview guide. After several readings through transcripts, we noticed similar themes emerging between respondents with regard to motivation for participation, as well as perceived benefits from participation in the LSI program. We used these themes to create inductive codes from the data, and searched the data to arrive at a thick description for each theme based on participants' responses. We verified these themes by comparing across respondents. Additionally, we also utilized deductive codes

from specific questions on the interview guide; thus, our final codebook incorporated both inductive and deductive codes. We continued searching for codes until a point of saturation, which we reached through the 13 interviews, as evidenced by no new ideas emerging from the transcripts. The author of this study coded each transcript line-by-line using the codebook of inductive and deductive codes. To assess the reliability of both the coding and the codebook, we assessed inter-coder agreement (ICA) using MaxQDA, which assesses simple agreement between coding of two independent coders. Our initial ICA value was 67%; further refining of the codebook led to an ICA of 92%.

Protection of Human Subjects

Risks to Human Subjects

Human subjects' involvement and characteristics

This study requires the involvement of human subjects. Particularly, this study involves only women of self-identified African American/ Black status in their first trimester of pregnancy, to be followed the duration of their pregnancy and into the postpartum period. The inclusion criteria have been previously described. Since this intervention focuses on the feasibility of a lifestyle intervention during pregnancy in an underserved population, it is imperative that we include pregnant women as our study participants. Also, because of underrepresentation of minorities in the literature, we have chosen to restrict our sample to minority women.

Recruitment, sources of material, and measures of confidentiality

All data were obtained with informed consent. Data were collected from two sources, following regulations of the Health Insurance Portability and Accountability Act

(HIPAA): hospital records and study-specific collection of outcome measures. We referred to hospital electronic medical records of patients presenting for their first prenatal visit for information on prepregnancy weight and age, as well as obstetric history and history of diabetes or GDM. We also referred to medical records for measures that were part of standard visits (e.g., weight and blood pressure). Study personnel strictly complied with both HIPAA and hospital standards and protocols when accessing medical records.

Study-specific measures involving blood sampling were collected following hospital protocol by trained clinical research nurses from the Grady Hospital ACTSI. All blood sampling occurred in a private, relaxed setting of the Grady Hospital ACTSI. Questionnaires and interviews were completed in the same private, quiet setting. Only study personnel, including the research coordinator, PI, and research assistants had access to study data. Paper forms were kept in a locked filing cabinet of a locked office at Grady Hospital, accessible only by secure key card entry. Computer data files were stored on individual password-protected, HIPAA-approved drives through the Emory University School of Medicine/ Rollins School of Public Health network. Only the research coordinator was able to access these drives. All study participants were given a computer-generated unique study identification number upon enrollment into the study. Data collected on study forms and biological samples were labeled with this unique study identifier, and no participant names were used to identify samples or forms. Participant names were used only to refer to the participant on a personal level (i.e., for scheduling visits and conversation). Coded forms were kept separately from the code list to maintain confidentiality.

Informed consent

Informed consent was obtained from every participant before enrollment, following the protocol of Emory University's IRB and Grady Hospital's ROC. Each participant was informed both in writing and verbally about the study purpose and protocol, as well as her right to withdrawal from the study, and provided a copy of their signed consent – with the phone number for both the principal investigator (PI) and the study coordinator -- for her records. The original copy of the letter of informed consent was stored in a locked filing cabinet at Grady Hospital. Only participants who agreed to participate by signing a letter of informed consent were randomized into the study.

Potential risks

Potential risks from this study were assumed to be minimal. The protocol was developed according to ACOG and ADA Guidelines, in consideration of the participant's stage of pregnancy and in accordance with practicing physicians. As described in Chapter 2, clinical studies have established the safety and efficacy of diet and moderate PA interventions during pregnancy for reducing excessive gestational weight gain and in improving glucose concentrations during pregnancy. Additionally, recommendations from the experienced study personnel aided in developing the safest intervention possible. As assurance to the study participants, the research team had regular contact with study participants to answer any concerns of possible risks to the participant.

Protection against risk

Protocols were strictly followed to protect participants from the risk of adverse events (AEs). All dietary recommendations followed those of the ADA, Institute of Medicine (IOM) and Centers for Disease Control and Prevention guidelines for pregnancy, specific to the woman's age and medical history. PA guidelines followed ACOG recommendations and were assumed to pose no additional risk to the participant. Additionally, no participant was forced to perform any activity with which she was uncomfortable; the intervention focused on working with the participant to make the achievement of improved diet and PA during pregnancy more attainable. Ensuring that all professional recommendations were followed, and that only the study personnel had access to study data, helped to enhance the effectiveness of protecting participants from possible threats to privacy as posed from the study.

Potential benefits of proposed research to human subjects and others

The potential benefits to human subjects and others as a result of this research are many. First and foremost, we aim to show that it is feasible to develop and implement an intensive lifestyle intervention in an underserved pregnant population. We anticipate findings from this study to be translated to larger populations of the same minority group, or even other minority groups. Secondly, we project that our intervention will decrease rates of change of glucose levels during pregnancy, as well as reduce the rate and/or time to onset of GDM. This finding will be significant in developing a larger study aimed at reducing rates of GDM in minority populations, and therefore could have implications in making recommendations for women at high-risk of developing the condition, and ultimately would lower the rates of GDM.

Monitoring adverse events and the Data Safety Monitoring Plan

Our Data Safety Monitoring Plan (DSMP) was approved by both the Emory University IRB and Grady Hospital ROC, to ensure the safety of study participants and to maintain validity of study data. Since weight and blood pressure measures were collected during regular prenatal visits, these outcomes were monitored by both study staff and prenatal care personnel (in most cases, the patient's obstetrician or nurse/midwife). Abnormal or unexpected changes in weight and/or blood pressure were assessed by the research coordinator and clinicians and reported to the PI. Data from glucose testing were collected and analyzed by the research coordinator (Marcinkevage); values considered abnormal by clinical standards were immediately reported to both the PI and the participant's obstetrician. Additionally, during study sessions (LSI group) and study testing (both groups), participants were asked if they had experienced any discomfort, pain, or overall felt not themselves since the last meeting/ testing. These responses were recorded and monitored by the research coordinator; any abnormal observations (e.g., extreme or long-lasting headaches, dizziness, abdominal pain, shortness of breath, loss of appetite) were reported to both the PI and participant's obstetrician.

All unexpected AEs (including but not limited to premature labor or vaginal bleeding), were noted by the research coordinator (Marcinkevage) and/or clinician and immediately reported to the PI (Umpierrez). The PI determined the relationship of the

AE with the intervention, and decided the proper course of action for that participant. We identified no adverse events to be attributable specifically to the study protocol. The DSMP required the annual report of all AEs as well as participants who were discontinued from the study to the Emory University DSMP. Three such reports were filed, checked, and approved by the Emory University IRB.

Figure 5. 1. Conceptual framework for lifestyle intervention study in pregnancy.

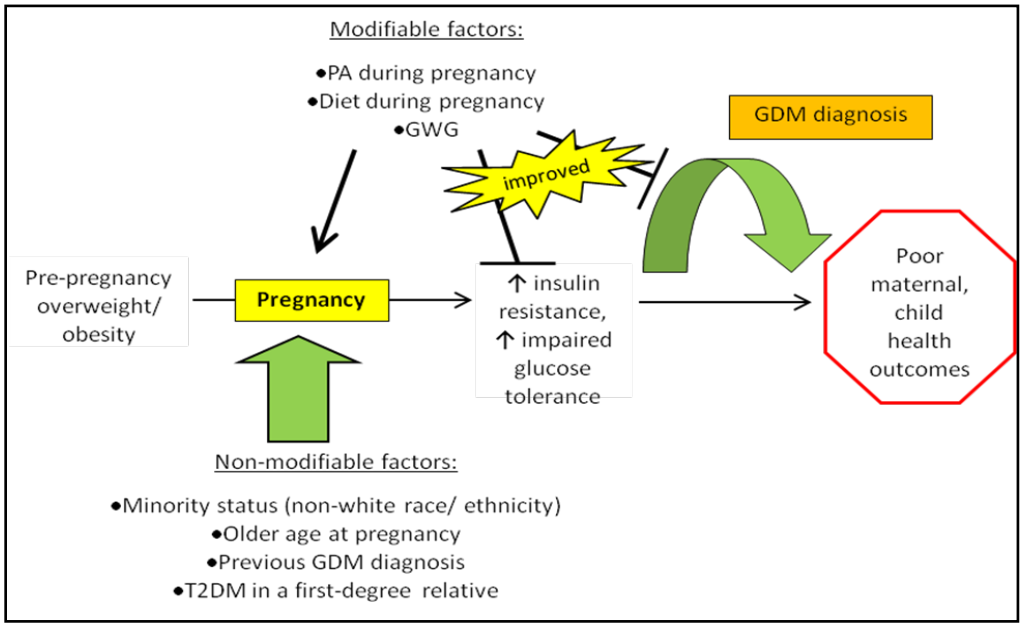


Figure 5. 2. Study design, from inclusion criteria of participants, to consent, to randomization into study groups.

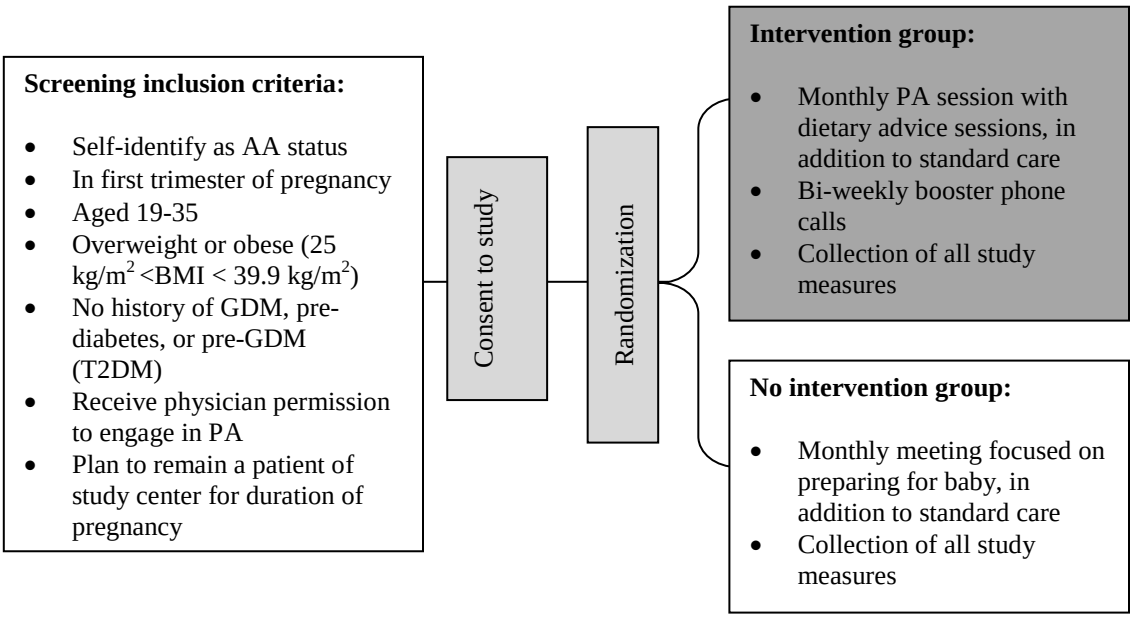


Table 5. 1. Outline of topics included in the on-on-one sessions for the intervention group.

Session	Gestation	Topics discussed	
		Dietary	Exercise
1	<16 (20) weeks (BASELINE TESTING)	Weight gain goals, extra caloric requirement, 24-h food recall Activity: Healthy examples to achieve extra caloric requirement	Walking program and pedometer fitting; exercise safety Activity: personal examples of how to be active
2	16-20 weeks	MyPyramid for Moms Activity: "Rate your plate" exercise	Working "hard enough" Activity: Measuring heart rate
3	20-24 weeks (MIDPREGNANCY TESTING)	Vitamins and minerals important for pregnancy Activity: Reading a food label	Exercising in cold/hot weather Activity: Safe stretches for pregnancy
4	24-28 weeks	Hidden calories, fats and sugars in food Activity: Identify what's hiding in your food…	Hidden time for exercise Activity: Identify how you can uncover exercise in your day
5	28-32 weeks	Healthy eating outside of home, 24-h food recall Activity: Choosing healthy options in restaurants	"Strive to be F.I.T.T." Activity: Walkability test
6	32-36 weeks	After delivery: lactation requirements Activity: Plan for postpartum weight loss	After delivery: getting "out and about" Activity: Plan for postpartum exercise
7	36-40 weeks	Healthy Family Home™: Involving the family in healthy food choices Activity: Recipe makeover	Healthy Family Home™: Involving the family in exercise choices Activity: Family-centered exercise and activities

Table 5. 2. Walking program presented to participants in the intervention group.

Sample Walking Program			
Warm-up Time	**Fast-walk Time**	**Cool-down Time**	**Total Time**
Week 1			
Walk slowly 5 minutes	Walk briskly 5 minutes	Walk slowly 5 minutes	15 minutes
Week 2			
Walk slowly 5 minutes	Walk briskly 7 minutes	Walk slowly 5 minutes	17 minutes
Week 3			
Walk slowly 5 minutes	Walk briskly 9 minutes	Walk slowly 5 minutes	19 minutes
Week 4			
Walk slowly 5 minutes	Walk briskly 11 minutes	Walk slowly 5 minutes	21 minutes
Week 5			
Walk slowly 5 minutes	Walk briskly 13 minutes	Walk slowly 5 minutes	23 minutes
.	.	.	.
.	.	.	.
Week 12			
Walk slowly 5 minutes	Walk briskly 27 minutes	Walk slowly 5 minutes	37 minutes
Week 13			
Walk slowly 5 minutes	Walk briskly 30 minutes	Walk slowly 5 minutes	40 minutes

Table 5. 3. Timeline of data collection measures. OGTT: Oral glucose tolerance test, with collection points at 0, 30, 60, 90, and 120 minutes.

Measure	**Screen** (<20 wk)	**Baseline** (<20 wk)	**Monthly visits**	**Midpregnancy** (24-28 wk)	**Delivery** (40 wk)	**Postpartum** (6 wk post-delivery)
Screening questionnaire						
Descriptive data questionnaire						
Height						
Weight						
Blood pressure						
OGTT						
Insulin						
PA						
Diet						
Birth outcome birth weight						

Table 5. 4. Power achieved for two PA outcomes, with n=60 and assuming 20% loss to follow-up.

Mean difference, minutes/ week of moderate PA	Power level achieved (n=48)		Percentage meeting PA recommendations	Power level achieved (n=48)
80	50%		45%	55%
90	60%		50%	70%
100	70%		55%	80%

CHAPTER 6: FEASIBILITY OF A LIFESTYLE INTERVENTION DURING PREGNANCY IN HIGH-RISK, LOW-INCOME URBAN BLACK WOMEN

Introduction

Regular physical activity (PA) during pregnancy has been associated with improvement of several maternal and fetal outcomes, including decreased risks of preeclampsia (176), excessive gestational weight gain (GWG) (140, 143), and gestational diabetes mellitus (GDM) (60, 61). Similarly, a healthy diet during pregnancy has also been associated with decreased risks in such pregnancy outcomes as GDM (54), preeclampsia (177), macrosomia (178), preterm delivery and shoulder dystocia (179). Although there is valid concern regarding changing lifestyle habits during pregnancy and the impacts it could have on either the mother or baby or both, results from these studies and several others show the safety of intervening during this particular period of a woman's life (180). Pregnancy provides an opportune time for a woman to make lasting changes to her lifestyle (75); if behavioral modifications are made during pregnancy, it is hoped these changes will last through postpartum, and also benefit the offspring's health.

Leading professional organizations – including the American College of Obstetricians and Gynecologists (ACOG), the American College of Sports Medicine (ACSM), and the U.S. Department of Health and Human Services – recommend for healthy pregnant women, without any contraindications for exercise, to participate in at least 30 minutes of moderate intensity PA and exercise on most days of the week (168, 181). However, studies show that fewer women are physically active in pregnancy than before pregnancy, and more than one-third of women are sedentary in pregnancy(63), with only 13-20% meeting PA guidelines (64, 65). These rates also tend to differ by

race/ethnicity (182, 183) with minorities less likely to meet guidelines than non-Hispanic Whites. In the latest report on the guidelines for weight gain in pregnancy (127), the Institute of Medicine recommends individualized attention to weight gain in pregnancy by health care providers, encouraging the utilization of consults with dieticians and healthy advisors for improving lifestyle measures such as diet and physical activity. The report also highlights the need for focused attention on low-income and minority women, who may be at greatest risk for both adverse pregnancy outcomes and worsened lifestyle factors.

An important specific benefit of lifestyle intervention during pregnancy is the potential of preventing glucose intolerance by limiting GWG. Several intervention studies have indeed focused on limiting GWG and ameliorating blood glucose metabolism during pregnancy by methods of a lifestyle intervention. However, these studies have conflicting results. Research supports healthy diet and PA lifestyle interventions for controlling weight gain as well as preventing type 2 diabetes (98, 101); whether modifying these factors during pregnancy will have the same effects on weight control and – subsequently – progression to GDM is inconclusive (113). What is more, despite the disparities outlined here, and the call for action by leading organizations, few studies have focused specifically on this problem among low-income minorities. To address these issues, we have conducted a pilot randomized controlled clinical trial to assess the feasibility of implementing a lifestyle intervention during pregnancy among overweight and obese low-income urban Black women. We have employed a mixed methods approach to evaluate the feasibility of this intervention in this challenging setting, incorporating both quantitative and qualitative research methods. This pilot study

was developed to help elucidate the underpinnings of PA, diet, GWG and glucose metabolism within an underrepresented population in order to help develop a larger study for GDM prevention. We hypothesized that a lifestyle intervention would increase PA and improve dietary intakes compared with regular standard of care, leading to improved glucose metabolism during pregnancy (Figure 6.1).

Materials and Methods

Study population and setting

The Healthy Moms, Happy Babies study was a pilot randomized controlled clinical trial for women receiving prenatal care at Grady Memorial Hospital in downtown Atlanta, GA. Located within the nation's 7th largest public hospital (165), the perinatal center of the Grady Health System serves patients with highly diverse racial and socioeconomic profiles, with more than 3500 deliveries per year. The study was approved by the Emory University Institutional Review Board and Grady Memorial Hospital Research Oversight Committee, and is registered at clinicaltrials.gov (identifier: NCT01084941). It received assistance from the Atlanta Clinical and Translational Science Institute.

All women presenting for their first prenatal care visit at the hospital's obstetric clinic were screened for inclusion into the study, in-person via questionnaire as well as by review of medical records. Women were considered eligible for enrollment into the pilot study if they were 1) Black; 2) <20 weeks gestation; 3) 18-49 years of age; 4) overweight or obese (body mass index [BMI] ≥25 kg/m^2 based on self-reported pre-gravid weight and height); 5) experiencing a singleton pregnancy; and 6) planning to take their pregnancy to term. Women who had a history of diabetes (type 1, type 2 or GDM in a

previous pregnancy), cardiovascular disease, chronic kidney disease or active liver disease; were currently taking anti-hypertensive medications or medications that would alter glucose metabolism (steroids); had anemia (hemoglobin <10 g/L or hematocrit <32%); had contraindications to participating in physical activity; lacked the mental capacity to participate in the intervention; or who were delivering at a hospital outside of the Grady system were not included for participation. Women who passed this screening were asked to return for baseline testing, scheduled within 1-2 weeks of their first prenatal care visit, at which point written informed consent for participation in the study was obtained.

Study design

Randomization and study groups

Randomization was by blocks, stratified on BMI category (overweight [25 ≤ BMI < 30] and obese [BMI ≥ 30]). Study group assignments were concealed in opaque security envelopes prepared by the study coordinator. Participants enrolled into the study were randomly assigned to one of two groups: 1) regular standard of care (RC) or 2) regular standard of care plus a lifestyle intervention (LSI).

Regular care group (RC, control)

During their baseline testing, women assigned to the RC group received information outlining healthy eating practices and the safety of physical activity during pregnancy, as presented by the March of Dimes. These informational materials represented self-help literature that was high-quality, standard, low-cost and accessible to the general public. Women in the RC group attended prenatal care visits as regularly scheduled, and received standard counseling provided by physicians, nurses, dieticians

and counselors from the hospital obstetric clinics and the Georgia Women, Infants, Children (WIC) state program. They additionally received a booster phone call one month before each expected study visits, in order to schedule their upcoming study visit.

Lifestyle intervention group (LSI)

Women assigned to the LSI group received all aspects of standard care at the hospital. In addition, they were asked to attend monthly study sessions where they met one-on-one with a health educator and discussed strategies for healthy eating and increasing time spent in physical activity. The sessions were based on teachings from the Diabetes Prevention Program (DPP) and designed by a medical student and nutrition doctoral student, with guidance from diabetes educators, WIC counselors, dieticians, endocrinologists and obstetricians from the Grady community. The sessions were held monthly, beginning at the baseline testing visit and lasting through to delivery, according to the participant's prenatal schedule. All sessions lasted 30 minutes to 1 hour in duration, and covered such topics as GWG goals, healthy eating from each of the food groups, hidden fats and sugars in foods, and healthy choices for eating outside of the home (Table 6.2). Specific attention was paid to increase fruit and vegetable intakes, as well as whole grain intakes, and decrease intakes of sugary beverages. The PA portion of the intervention was based on a walking program designed to increase time spent per day engaged in moderate PA. This plan was presented at the first session, and asked the participant to start with 15 minutes of walking/ day on at least 4 days of the week, adding 2 extra minutes of walking/ day each week until reaching a final goal of 40 minutes of walking/ day on at least 4 days of the week. Each participant in the intervention group received a pedometer (Omron HJ-112) to encourage her progress and help track her daily

and weekly number of steps. The pedometer was able to store up to seven days of information on step counts, and automatically re-set each day to more accurately track participants' steps. With the health educator's guidance, participants set weekly goals for healthy eating and PA based on each session's topic, reported on progress toward these goals at the beginning of each session. Additionally, each participant in the LSI group received a booster phone call or text message every two weeks for the duration of her pregnancy and into the postpartum period, to chart progress toward her self-determined goals for healthy eating and PA and provide motivation for meeting these goals.

Data collection

All women presented for baseline testing at <20 weeks gestation. For this visit, all participants arrived at the Grady Memorial Hospital Clinical Interaction Site after an overnight fast of ≥8 hours. All participants, regardless of study group, returned for study testing at two subsequent study visits: one midpregnancy (24-28 weeks) and one postpartum (6 weeks after delivery), after an overnight fast as indicated for baseline testing. Each participant received a $25.00 Visa® gift card after her baseline, midpregnancy, and postpartum visits; additionally, to aid with transportation costs, participants in the LSI group received $5.00 for each monthly LSI session attended.

Primary outcome measures

Physical activity

At each study visit, all participants completed the self-administered Pregnancy Physical Activity Questionnaire (PPAQ) (167) to measure self-reported PA. A semi-quantitative questionnaire, the PPAQ assessed duration, frequency and intensity of total PA for the previous 3 months (or, trimester). Respondents selected the category that best

represented the amount of time spent in 35 activities, including household/caregiving activities, occupational activities, sports/exercise, and transportation. It also assessed levels of inactivity. The self-reported duration of time spent in each activity was multiplied by its corresponding MET intensity according to the Compendium of Physical Activities (168) and summed to arrive at a measure of average weekly energy expenditure (MET-hrs/ week) attributed to each activity. For those activities determined to have different intensities during pregnancy, a modified compendium value was used. This questionnaire was validated using ActiGraph accelerometers and has been used in several diverse populations (167). From responses on this questionnaire, participants were categorized on whether or not they met physical activity goals as dictated by both ACOG and ACSM -- i.e., 450 MET-min/week (169). Additionally, participants in the LSI group were asked to record their steps as measured from the pedometer, and bring their pedometer records, along with the pedometer, to each study visit.

Diet

Each participant completed one 24 hour food recall interview during the baseline, midpregnancy, and postpartum testing. Dietary data were collected and analyzed using the Nutrition Data System for Research software version 2009, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN. The 24 hour recall method has been shown to provide an accurate snapshot of individuals' dietary intakes at a specified time. The multi-pass nature of the interview allowed respondents repeated times to recall their intakes in the 24 hours prior to the interview, providing detailed food descriptions. Nutrient intakes and servings consumed were calculated using the NCC Food and Nutrient Database and Food Group Serving Count

System. Servings consumed of individual food groups were calculated by summing the servings consumed of each individual food item belonging to the specific food groups, as defined by the NCC database.

Acceptability and feasibility measures

Recruitment into the program was assessed by tracking on a daily basis how many women were screened for enrollment, how many passed screening, how many returned for their baseline visit and how many were enrolled into the program. Retention was tracked by noting how many women return for their monthly visits (intervention group only), midpregnancy visit (both groups) and postpartum visit (both groups). Adherence to the lifestyle program was measured by the PPAQ and 24-hour recalls administered at both the midpregnancy and postpartum visits.

Covariates

During baseline testing, all participants were asked to complete a 20-item demographic questionnaire to obtain information on their level of education, income, health insurance/Medicaid status, and participation in the state WIC program. Additionally, the medical records for all participants were reviewed to obtain information on obstetric history, smoking history, and family history of diabetes.

Methods for improving participant recruitment and retention rates

Several steps were taken to assist with participant recruitment and retention rates. Women who passed screening and expressed interest in enrolling into the study were phoned to schedule their baseline testing visit. Participants were phoned once weekly until they presented for baseline testing, were no longer eligible (i.e. > 20 weeks gestation), or no longer interested, whichever milestone came first. Upon enrollment into

the study, each participant was mailed a hand-written note card welcoming her into the study. Participants in the LSI group scheduled their LSI meetings two weeks in advance, during the booster follow-up phone calls. We phoned participants in the RC group 2-4 weeks prior to their expected visit time (based on gestational week) to schedule their midpregnancy and postpartum visits. In cases where the participant was not able to be reached (due to insufficient phone minutes, a change of phone number, or a disconnected phone line), the emergency contact was called. In several cases where phone contact was not able to be achieved, the study coordinator was able to meet with the participant during her scheduled clinic time and schedule her upcoming or make-up study visit in person. Participants were phoned twice weekly until contact was achieved, or until they were considered no longer eligible for the study visits (past the eligible gestational week for measures taken during pregnancy; >6 months postpartum for post-delivery measures). Upon delivery of her infant, each participant was mailed a hand-written congratulatory note card and asked to call the study office to schedule her postpartum visit. Accommodations were made in instances where the mother needed to bring her baby or other child/ren during her study visits.

Power calculation and statistical analysis

We hypothesized that a lifestyle intervention would result in increased PA when compared with women receiving standard care. We aimed to recruit n=60 subjects for our study, with 30 women in each of the study groups. We assumed that 20% of subjects would be lost to follow-up or have missing data; accordingly, we expected n=48 women to complete the study. Based on our primary outcome as the proportion of women meeting PA guidelines (30 minutes/day, 5 days a week; or 450 MET-min/week (169)), at

a significance level of 0.05, assuming 13% of women in the regular care group would meet these PA recommendations (153), a sample size of n=48 achieves 80% power to detect an approximate four-fold increase in PA in the intervention group, with 55% reaching PA guidelines. This proportion is plausible based on previous studies (174).

Analyses followed an intention-to-treat principle, and all analyses of quantitative variables were conducted using SAS statistical software, version 9.3 (SAS Institute, Cary, NC). Statistical significance was considered as a probability of <0.05. Baseline descriptive statistics were calculated for all study variables. Differences between study arms in continuous variables at baseline, midpregnancy, and postpartum were determined by the student's t-test and Wilcoxon Mann-Whitney U test for normally and non-normally distributed variables, respectively. Differences in categorical variables were determined by the Chi-square test or Fisher's Exact test for small sample sizes, with and without adjustment for BMI by the Cochran-Mantel-Haenszel test, to account for the randomization design. The effectiveness of the intervention from baseline to midpregnancy and from baseline to postpartum was assessed by considering the differences between groups in the primary outcomes of PA and dietary factors. To further assess the effect of the intervention on PA, we conducted multiple logistic regression and calculated odds ratios (ORs) and 95% confidence intervals (CIs) for meeting guidelines for PA. Baseline demographic and metabolic indices – including BMI, age, parity and smoking status – were assessed as possible confounders, and were controlled for if their exclusion changed the OR by >10% (175).

Monitoring adverse events

Abnormal or unexpected changes in weight and/or blood pressure were assessed by the research coordinator and clinicians and reported to the PI. Data from glucose testing were collected and analyzed by the research coordinator (Marcinkevage); values considered abnormal by clinical standards were immediately reported to both the PI and the participant's obstetrician. Additionally, during study sessions (LSI group) and study testing (both groups), participants were asked if they had experienced any discomfort, pain, or overall felt not themselves since the last meeting/ testing. These responses were recorded and monitored by the research coordinator; any abnormal observations (e.g., extreme or long-lasting headaches, dizziness, abdominal pain, shortness of breath, loss of appetite) were reported to both the PI and participant's obstetrician.

All unexpected AEs (including but not limited to premature labor or vaginal bleeding), were noted by the research coordinator (Marcinkevage) and/or clinician and immediately reported to the PI (Umpierrez). The PI determined the relationship of the AE with the intervention, and decided the proper course of action for that participant. We identified no adverse events to be attributable specifically to the study protocol.

Results

Recruitment, enrollment and baseline characteristics

From April, 2010 to March, 2012 we screened 1,147 women presenting for prenatal care at Grady Memorial Hospital, Atlanta, GA. Of these women, 965 (84.1%) did not meet criteria for inclusion into the study. The top reasons for not passing this screen were having a gestational age > 20 weeks (46.6%), a BMI < 25 kg/m^2 (31.6%), and not being of Black race/ethnicity (10.4%) (Figure 6.2). All 182 women who were

eligible for inclusion into the study were invited back for baseline testing; 57 (31.3%) presented for baseline testing, consented, and were enrolled into the study. Those women who did not enroll into the study but who were considered eligible for enrollment (n=125) did not differ significantly in age (mean [SD]: 25.2[4.9] years), prepregnancy BMI (33.2[6.4] kg/m2), or gestational age at screening (12.1[3.4] weeks) when compared with those women who enrolled into the study. Because of HIPAA regulations, we were not able to compare more characteristics than these between the two groups. The majority of women who did not enroll into the study (63%) were not able to be reached by telephone or mail following the screening.

The 57 women enrolled into the study were subsequently randomized into the LSI group (n=28) and the RC group (n=29). Overall there were no significant differences in baseline characteristics between the two intervention groups (Table 6.2). We recruited participants at a mean gestational age of 12 weeks. Our sample was young, with a mean age of 24 years. Nearly all women were living on a yearly income that was <$15,000, and receiving assistance from both Medicaid and WIC. The majority of participants were currently unemployed, and 30% had less than a high school education. Though we enrolled both overweight and obese women, the majority of our participants were obese or morbidly obese (66%), with a mean (SD) BMI of 35.0 (7.9) kg/m^2. Most participants also had a history of diabetes in first-degree relatives, and a considerable proportion was either former smokers or current smokers (31%).

Retention of participants

Women in the LSI group attended between one (n=1) and three (n=15) LSI sessions prior to midpregnancy testing, and one (n=1) to seven (n=5) LSI sessions prior

to delivery, with the majority (54%) of participants attending at least 85% of all sessions (n=15, Table 6.3). While three participants (2 LSI, 1 RC) expressed a lack of desire to attend study visits, no participants officially requested to withdraw from the study. For both groups, the midpregnancy visit occurred ~12 weeks following baseline testing. Overall, 22 (79%) women in the LSI and 25 (86%) women in the RC group returned for midpregnancy testing, representing 82% of the original sample. Supplemental information on weight was available from the medical charts of the prenatal care visit for one additional person in the LSI group. At delivery, information was available for 25 women in the RC group and 27 women in the LSI group. At the post-partum visit, only 14 women in the LSI (50%) and 23 women in the RC (79%) group returned for testing, representing 65% of the original sample. This visit occurred on average ~7 weeks post-delivery. Supplemental data on weight were available for six additional participants in the LSI group and one additional participant in the RC group, resulting in 79% of the original sample with at least partial follow-up data. No adverse events were attributed to the intervention. There were no differences in baseline data between women who presented for midpregnancy testing vs. those women who did not. Women who did not attend the post-partum visit presented at an earlier gestational week than those women with information on delivery outcomes ($p<0.05$).

Primary outcomes

Physical activity

Measures of physical activity are presented in Table 6.4. At baseline, participants reported spending 23% of their total activity in sedentary activities (i.e. reading, watching television). Time spent in household/caregiving activities accounted for the largest

proportion of total activity reported, at 43%. Additionally, almost half of all women reported meeting recommendations for exercise at their baseline visit. At the midpregnancy visit, both groups reported spending more time in sport/exercise activities compared with baseline values (change from baseline: 2.2 MET-h/wk, RC and 2.4 MET-h/wk, LSI). Also at this visit, a greater proportion of women in the LSI group met recommendations for PA compared with women in the RC group (66.7% vs. 52%, respectively); however, this difference was not significant (Figure 6.3). Logistic regression models confirmed a trend for women in the LSI group having greater odds of meeting recommendations for PA (adjusted OR (95% CI): 4.33 (0.73, 25.66), results not shown). Women in the RC group reported spending more time in occupational activities at midpregnancy vs. baseline, while women in the LSI group reported spending less time in these activities at this visit. By postpartum, both groups reported less time spent in occupational activity. Women in the RC group reported a significant increase in time spent in sport/exercise activity at postpartum compared with baseline figures ($p \leq 0.05$); there was no change for the LSI group.

We found low levels of adherence to the use of the pedometer. Of the 27 women who attended 2 or more LSI sessions (Table 6.3), we observed that only 12 women (44%) remembered to bring the pedometer back to at least one subsequent study visit in order to obtain and record a value for her step counts for the previous week. Pedometer step counts were available for 58% of all sessions attended by these 12 women. Per participant, the number of visits with eligible pedometer step count data ranged from 1 to 4; only 2 women remembered her pedometer for 100% of her visits.

Diet

At baseline, we observed no differences between groups in the total calories consumed or in the proportion of calories attributed to each macronutrient (Table 6.4). Overall, participants reported consuming a mean (SD) of 1980 (885.9) kcal/day, with 50% and 35% of their total energy intake coming from carbohydrates and fat, respectively (Figure 6.4). Participants reported consuming a median of 2 servings of sweetened beverages/ day, 0 servings of fruit, 1.6 servings of vegetables, and 0 servings of whole grains. There were no significant differences between groups in any of the dietary variables at midpregnancy, or at postpartum. Women did not report a significant increase in their caloric intakes as their pregnancy progressed; rather, self-reported energy intakes stayed the same or decreased into the postpartum period. At midpregnancy, women in the RC group reported consuming fewer servings of sweetened beverages (1.9 v. 0.9, $p<0.05$), and more servings of whole grains (0 vs. 1.1, $p<0.05$, Figure 6.5). Women in the LSI group reported significantly less calories from protein compared with baseline values (15.3% vs 13.3%, $p<0.05$, Figure 6.4). Additionally, they increased their whole grain intake by 2 servings/ day ($p<0.05$).

Discussion

Our results show the feasibility of implementing a clinic-based lifestyle intervention during pregnancy in a high-risk challenging urban population. Our intervention was low-cost, and used minimal resources available to ease in the delivery. We were able to recruit and subsequently follow almost 80% of our sample through to delivery. Recruitment proceeded more slowly than expected, resulting in an extension of the time to recruit our target sample size. Our retention rates were high for data collection

at both the midpregnancy visit (82%) and delivery (91%), though post-partum retention rates were low (65% of total sample presented for study visits). However, the majority of participants in the LSI group (54%) attended at least 85% of program sessions prior to delivery.

The baseline characteristics of our sample describe a population that is not well represented in the literature on lifestyle interventions in pregnancy – young, very poor, mostly unemployed women with low education levels, high parity levels and high BMI. Several were current or former smokers, with a history of diabetes in their family. Although we recruited both overweight and obese women, the majority of participants were obese or morbidly obese (66%), with a mean (SD) BMI of 35.0 (7.9) kg/m^2. Our participants were apparently fairly active at baseline compared with findings from previous studies (153, 184), reporting spending ~1 hour /day in exercise-level activity. Almost half of women were already meeting recommendations for physical activity at their baseline visit, based on self-report. Despite this observation, a quarter of the total time reported for activity was spent in sedentary activities (i.e. reading, watching television). Additionally, the baseline dietary intakes show a high fat, low nutrient dietary profile, with 35% of total energy intake coming from fat, much higher than previous findings (177).

We observed no significant differences in PA levels between the LSI group and the RC group at the midpregnancy visit, based on self-reported measures. However, by the midpregnancy visit, the proportion of women in the LSI group meeting recommendations for PA was greater than that for the RC group (66.7% vs. 52%, respectively; adjusted OR (95% CI): 4.33 (0.73, 25.66)). The effect of LSI on PA in

pregnancy is inconclusive, leading to increased PA vs. control groups in some studies (184, 185) but not all (138). Our observation of no change in PA measures could be as a result of the self-report nature of PA level. Our sample was also noticeably more "active," according to self-reported activity levels, compared with previous research (63-65, 153). At baseline, almost half of all women were already meeting guidelines for exercise. This is in stark contrast to the 13-20% listed in previous studies (63-65, 153). Since our sample size was small, and the baseline values were higher than expected, it is possible we did not have enough power to detect a significant difference in the percentage of women meeting recommendations for PA. This is highlighted by the large confidence interval surrounding our OR for this outcome. However, women in our sample were highly dependent on public transportation, and might have engaged in higher levels of PA as a result of getting to and from work, hospital appointments, school and other commitments. It is also possible that social desirability cues led to inaccurate responses on the questionnaire, inflating self-report of time spent in activity (186).

There were no significant differences in change of macronutrient intakes at midpregnancy or at postpartum, within or between groups. While some studies have noted improved dietary intakes as a result of interventions during pregnancy (138, 143, 185), particularly among non-Hispanic White populations, several others have not (140, 187). A study of intensive dietary counseling in pregnant women in Finland (mean BMI=27.2) showed no effect of counseling on lowering intakes of either total fat or saturated fat, and no effect on total energy intake, compared with results from the control group (187). The researchers also observed no significant changes in micronutrient intakes between the study groups. These results were based on 4-day food records,

considered the “gold standard” of dietary measurement. In the U.S., a study among low-income women showed no significant effect of a lifestyle intervention on fat intake from high-fat foods (140), either in normal or overweight (BMI > 26.0) women. The population of this latter study was similar to ours, with 57% unemployed and 45% with high school education or less, and a similar BMI in the overweight group as in our total sample.

These results highlight the difficulty with affecting dietary behavior change within this population. Several factors might be responsible for this, including lack of access to healthier foods (188, 189) and social desirability to not eat healthier foods (155). Among our group, several women did indicate that they lived with other family members (boyfriend/ father of child, children, mother, grandmother), and that eating healthy was something they tried to do with their whole family, but in several cases received some push-back from other family members, hindering them from reaching their goals for healthy eating. Therefore, family approaches might be a promising route for pregnancy interventions within our population. These approaches have worked in other situations related to changing health behavior (190, 191).

Our sample is exemplary of a very disadvantaged, high-risk population. All of our participants relied on Medicaid for their health insurance, and most received assistance from other need-based programs, such as WIC. The majority did not drive or have access to a car, and relied on public transportation (bus, train) for travel to study visits. Several women in the study were reliant upon state-issued cell phones with pre-loaded minutes as their source for contact; in many cases, when minutes would expire, there was no additional way to reach participants. Several steps were taken to ensure

reliable contact with participants, including staying in touch with other family members close to the participant, visiting with the participant during her clinic or other hospital visits, and sending hand-written letters to encourage participation in follow-up visits. Despite these efforts, we did experience a noteworthy loss to follow-up rate: 18% of the original sample at the midpregnancy visit, and 35% of the original sample at the postpartum visit. Supplemental data were available from the medical charts for several participants. Other studies of lifestyle interventions during pregnancy have experienced similar rates of loss to follow-up (139, 140, 142, 145, 148). Among a diverse group of pregnant women in Boston one study (184) found that of 208 women enrolled in a PA intervention, 41% were unable to be reached for follow-up measurements. Similarly, in a clinic-based intervention targeting several behavioral and psychosocial risk factors for adverse birth outcomes in African American women in Washington, DC, 43% of 1,044 women randomized did not complete the first follow-up interview, and 31% did not complete the 2nd follow-up interview (158). These findings indicate the potential difficulty with working in underserved, pregnant populations.

Also of note is that several of our participants who were lost to study follow-up were also lost to their regular prenatal care. A recent review of obstetric outcomes and care show African American women at higher risk for poorer quality of prenatal care than non-Hispanic whites, i.e. late entry into prenatal care, and fewer prenatal care visits (192). We observed this as well, as a top reason for not meeting inclusion criteria was having a gestational age > 20 weeks, indicating that many women attending our clinic begin prenatal care mid-way through their pregnancy. As well, 9 of the 10 women who

did not return for their midpregnancy study visit also did not return for their midpregnancy prenatal care visit.

There were several strengths to our study. The intervention program itself was relatively low-cost and easy to administer, and was closer to what may happen in a real-life setting. The program sessions were well-received by most participants, and the majority of participants who were not lost to follow-up attended most if not all study sessions. We were able to keep contact with most participants, despite extenuating circumstances with changing phone numbers and residences among participants. Additionally, our collection of real-time information on diet quality and PA practices during pregnancy using rigorous, validated instruments adds to the literature of lifestyle practices for the neediest of populations.

We also acknowledge several limitations to our study. First, both the dietary intakes and physical activity measures were based on self-report. While we used high quality software to capture most accurately the nutrient intakes, as well as validated instruments developed specifically for capturing PA during pregnancy, the outcomes were still contingent upon participant memory and therefore may be subject to recall bias. Also, because the recall was administered by an interviewer, there is potential for social desirability or approval bias to affect respondents' answers. However, we believe that both groups would be equally affected by these phenomena. Additionally, although our PA questionnaire was developed specifically for a pregnant population, it is possible the questionnaire method does not capture PA expenditure as well as other, more rigorous methods (193). Second, several women were affected by nausea during the first (and second) trimesters of pregnancy, which may have affected both her diet and physical

activity (154). Unfortunately we did not collect detailed information on nausea. Third, the setting of our study is a teaching hospital for two different Universities; as such, our patients could have received varying levels of "standard care" depending on their provider. However, randomization of participants should have accounted for this. Additionally, because of the specific setting of our study and specific inclusion criteria, our results are not necessarily generalizable to other study populations. However, the purpose of our study was to highlight and profile the situation among fairly specific conditions. Fourth, our small sample size may have limited our power to detect any significant effects of the intervention.

Women participating in our study were affected by several risk factors prior to joining the study, not limited to diet and PA, which could have affected uptake of the intervention. A recent analysis of the association of biomedical, psychosocial and behavioral risks and adverse pregnancy outcomes in African American women in Washington, D.C. showed the strongest predictors of poor pregnancy outcomes were BMI, employment status, intimate partner violence, and depression (163). Low-income women are more likely to have to endure multiple hardships during pregnancy compared with higher-income women (162). Although we did not measure individual hardships affecting our participants, anecdotal evidence from participants showed that our women were experiencing hardships above and beyond choosing healthy foods and adding time for PA. Additionally, because of the efforts to maintain contact with participants despite conditions, the RC group was not limited to only regular prenatal care. They had exposure to the research staff, and were given initial information on diet and PA that was not provided by their prenatal care visits, as highlighted by responses from the

interviews. Even though they were not followed as closely and intensively as the LSI group, there is possibility for behavior change to have occurred in this group simply from the knowledge that they were being followed (186, 188, 189). Previous studies have shown the utility of a brochure for improving GWG when compared with regular care (194).

Conclusion

Our findings highlight important factors learned about the implementation of a lifestyle intervention during pregnancy in low-income, underserved communities. Despite difficulty with recruitment and scheduling of participants, we found that recruitment rates were acceptable, retention rates were similar to other studies conducted in more favorable environs, and implementation was successfully achieved. We were able to increase the percentage of women meeting guidelines for PA, as well as consumption of healthy foods, such as whole grains. Future studies within this population must consider limiting factors unique to this population, such as uptake of prenatal care, transportation and communication issues, dependence on self-report for dietary and PA measures, and barriers to care. These findings add to the growing body of literature showing the feasibility and efficacy of clinic-based interventions for promoting the health of disadvantaged, underserved groups at highest risk for adverse pregnancy outcomes.

Figure 6. 1. Conceptual framework for pilot feasibility study on lifestyle intervention in pregnancy for GDM prevention in a disadvantaged population, Atlanta, GA.

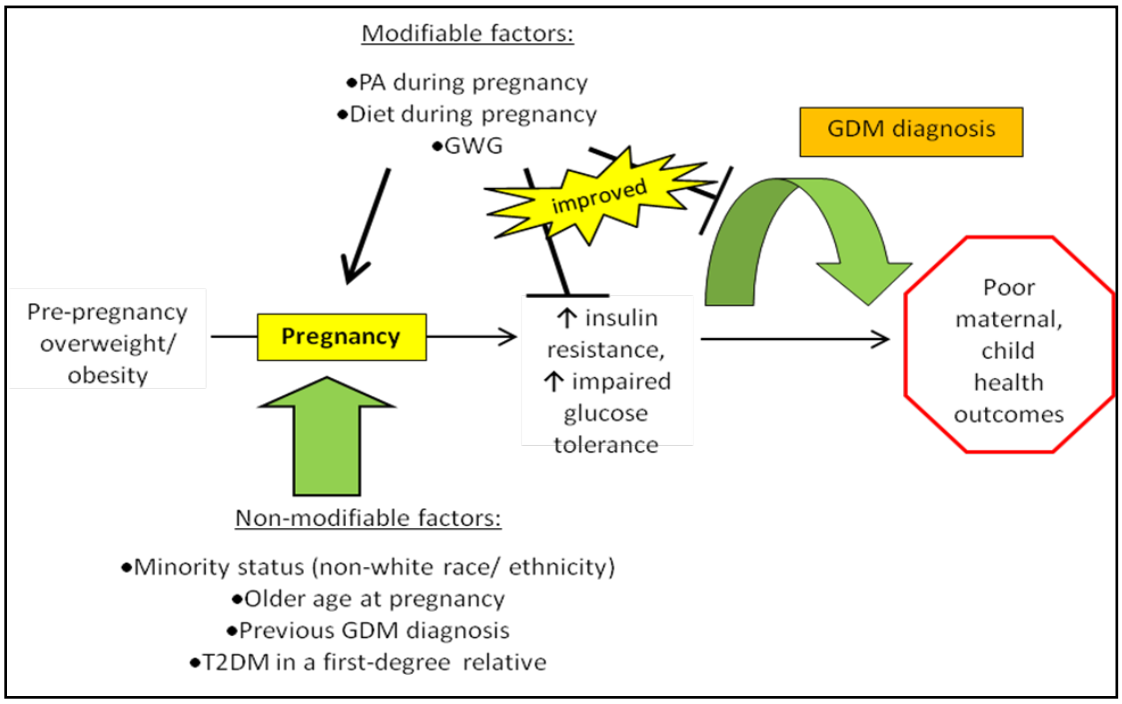


Table 6. 1. Topics for monthly sessions of the Healthy Moms, Healthy Babies pilot study, Atlanta, GA.

Session	Gestation	Topics discussed	
		Dietary	Exercise
1	< 20 weeks *(BASELINE TESTING)*	Weight gain goals, extra caloric requirement, 24-h food recall Activity: Healthy examples to achieve extra caloric requirement	Walking program and pedometer fitting; exercise safety Activity: personal examples of how to be active
2	16-20 weeks	MyPyramid for Moms Activity: "Rate your plate" exercise	Working "hard enough" Activity: Measuring heart rate
3	20-24 weeks	Vitamins and minerals important for pregnancy Activity: Reading a food label	Exercising in cold/hot weather Activity: Safe stretches for pregnancy
4	24-28 weeks (*MIDPREGNANCY TESTING)*	Hidden calories, fats and sugars in food Activity: Identify what's hiding in your food…	Hidden time for exercise Activity: Identify how you can uncover exercise in your day
5	28-32 weeks	Healthy eating outside of home, 24-h food recall Activity: Choosing healthy options in restaurants	How to be F.I.T.T. Activity: Walkability test
6	32-36 weeks	After delivery: lactation requirements Activity: Plan for postpartum weight loss	After delivery: getting "out and about" Activity: Plan for postpartum exercise
7	36-40 weeks	Healthy Family Home™: Involving the family in healthy food choices Activity: Recipe makeover	Healthy Family Home™: Involving the family in exercise choices Activity: Family-centered exercise and activities

Figure 6. 2. Flow of screened and enrolled patients in Healthy Moms, Happy Babies study.

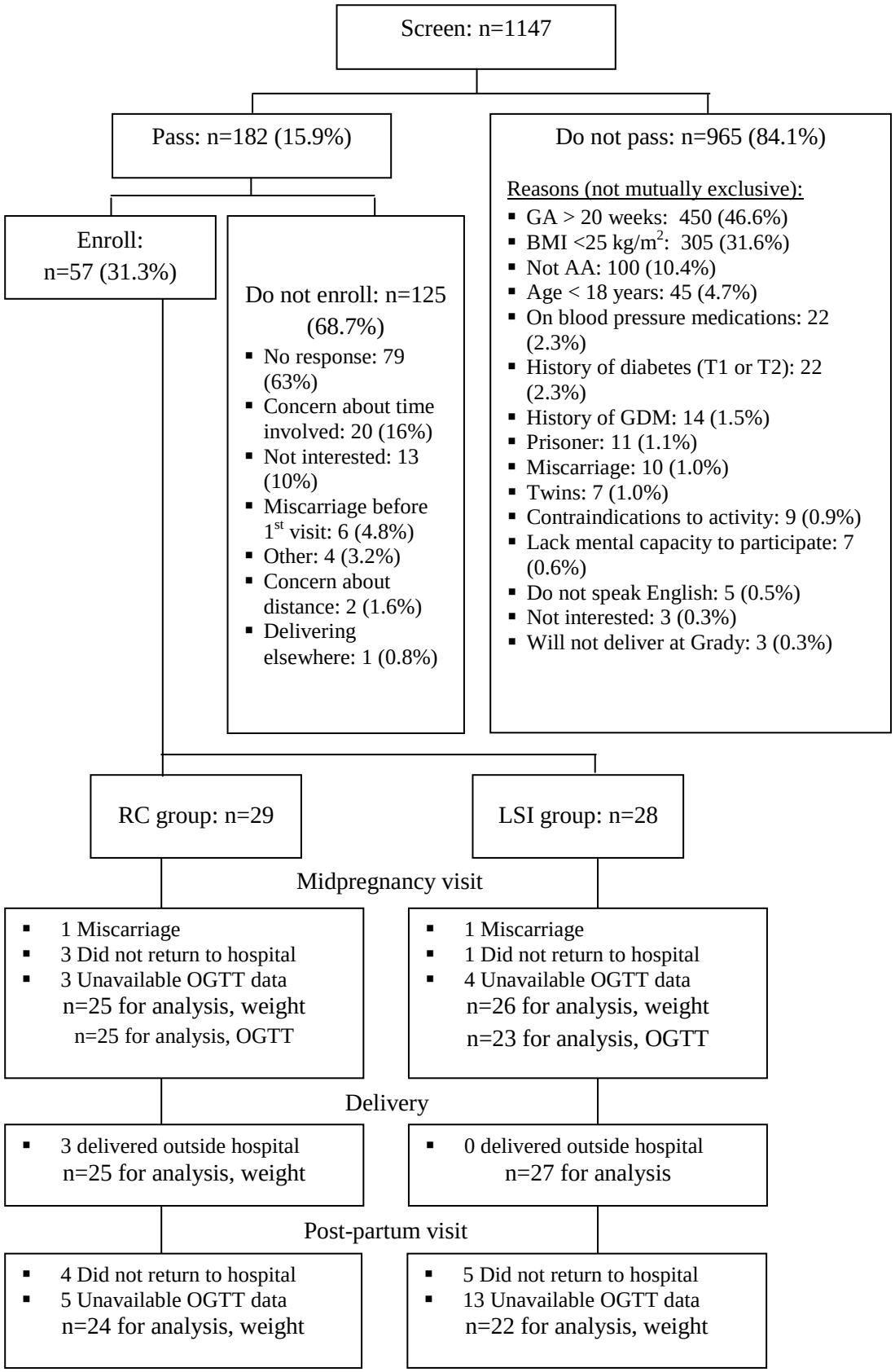


Table 6. 2. Baseline characteristics of study population – total sample and by randomization group.

Variable	Total group (n=57)	Regular care (RC) (n=29)	Lifestyle intervention (LSI) (n=28)	*p*-value
Age	24.8 (4.6)	24.38 (4.21)	25.25 (5.05)	0.48
Prepregnancy weight (kg)	92.9 (22.2)	92.79 (22.96)	92.97 (21.86)	0.98
Prepregnancy BMI	35.0 (7.9)	34.65 (7.93)	35.28 (7.94)	0.76
Overweight	19 (33.3%)	9 (31%)	10 (35.7%)	0.79
Obese	25 (43.9%)	14 (48.3%)	11 (39.3%)	
Morbidly obese	13 (22.8%)	6 (20.7%)	7 (25%)	
Gestational Age at Recruitment	12.4 (3.5)	12.19 (3.09)	12.64 (3.85)	0.63
Gravidity	2.7 (2.2)	2.55 (1.59)	2.89 (2.64)	0.56
1	21 (36.8%)	7 (24.1%)	14 (50%)	0.06‡
2	14 (24.6%)	11 (37.9%)	3 (10.7%)	
3	9 (15.8%)	6 (20.7%)	3 (10.7%)	
4+	13 (22.8%)	5 (17.3%)	8 (28.6%)	
Gestational week, visit 1	14.4 (2.9)	14.46 (3.01)	14.38 (2.85)	0.92
Weight, visit 1	96.6 (23.2)	95.80 (23.01)	97.31 (23.82)	0.81
Pulse	82.0 (12.7)	82.83 (10.69)	81.07 (14.58)	0.61
Systolic BP	117.6 (13.3)	115.45 (11.34)	119.82 (15.00)	0.22
Diastolic BP	66.9 (7.8)	66.62 (6.14)	67.18 (9.28)	0.79
MedicAid Recipient	55 (96.5%)	29 (100%)	26 (92.9%)	0.24‡
WIC Recipient	51 (91.1%)	24(82.8%)	27 (96.4%)	0.19‡
Employed	23 (40.4%)	10 (34.5%)	13 (46.4%)	0.36
Household income <$15,000/	52 (91.1%)	28 (96.5%)	24 (85.7%)	0.19‡
Educational level				
< 5 years	1 (1.8%)	0 (0%)	1 (3.6%)	0.2‡
Between 5-8 years	2 (3.5%)	0 (0%)	2 (7.1%)	
Between 8-12 years	16 (28.1%)	6 (20.7%)	10(35.7%)	
High school graduate or	29 (50.1%)	17 (58.6%)	12 (42.9%)	
College or more	9 (15.8%)	6 (20.7%)	3 (10.7%)	
Smoker				
Never smoker	39 (67.9%)	19 (65.5%)	20 (71.4%)	0.42
Current smoker	6 (10.1%)	2 (6.9%)	4 (14.3%)	
Former smoker	12 (21.4%)	8 (27.6%)	4 (14.3%)	
Family history of diabetes	39 (69.6%)	21 (72.4%)	18 (64.3%)	0.51
History of delivery by C-section	6 (10.5%)	4 (13.8%)	2 (7.1%)	0.67‡
History of preeclampsia	5 (8.8%)	2 (6.9%)	3 (10.7%)	0.67‡

Data presented are means (SD) for continuous variables or n (%) for categorical variables.

p-values are based on student's t-test for continuous variables and Chi-square test for categorical variables, unless otherwise noted. ‡ Fisher's exact test for categorical variables

Table 6. 3. Number of sessions attended by participants receiving the lifestyle intervention (LSI).

	Total number of sessions attended before delivery						
	One	Two	Three	Four	Five	Six	Seven
Number of participants attending	1	3	4	2	3	10	5

Table 6. 4. Physical activity and dietary intakes at baseline, midpregnancy and postpartum study visits, by study group.

	Regular Care (RC) Group			**Lifestyle Intervention (LSI) Group**		
	Baseline (n=29)	Midpregnancy (n=25)	Postpartum (n=23)	Baseline (n=28)	Midpregnancy (n=22)	Postpartum (n=14)
Gestational week/ weeks postpartum	14.46 (3.01)	26.47 (2.38)	6.64 (0.83)	14.38 (2.85)	26.33 (2.72)	6.95 (2.45)
Physical activity (MET-h/wk)						
Total activity	374.64 (173.78)	404.81 (217.7)	422.32 (275.18)	365.76 (166.51)	343.55 (174.21)	347.30 (152.45)
Housecare activity	155.29 (95.09)	164.83 (97.86)	218.04 (97.57)[a]	133.08 (82.72)	127.43 (79.09)	165.27 (95.01)
Occupational activity	23.10 (0, 131.08)	65.10 (0, 228.73)	0 (0, 162.75)	78.23 (6.13, 135.8)	59.85 (0, 146.30)	43.75 (0, 85.05)
Sport/exercise activity	6.83 (3.55,10.58)	9.4 (2.83, 21.00)	10.83 (3.58, 26.9)[a]	8.13 (2.36, 15.09)	10.48 (4.80, 14.10)	9.19 (5.95, 37.88)
Sedentariness	87.26 (21.88)	83.7 (50.26)	78.58 (48.04)	84.32 (42.71)	84.63 (46.11)	85.46 (42.36)
Meets ACSM recommendations^	13 (44.8%)	13 (52%)	14 (61%)	15 (53.6%)	14 (66.7%)	8 (57%)
*Percent of total activity**						
Sedentary	22%	19%	19%	27%	23%	24%
Sport/exercise	2%	3%	4%	2%	2%	4%
Household	43%	43%	60%	38%	41%	52%
Occupational	5%	5%	0%	22%	17%	15%
Dietary intakes						
Energy (kcal)	1994.09 (1037.17)	1980.94 (1242.82)	1688.68 (1024.01)	1966.92 (715.43)	1841.14 (764.73)	1943.18 (852.10)
Carbohydrate (g)	245.32 (148.5)	239.89 (160.7)	186.51 (125.10)	247.61 (114.54)	240.09 (98.33)	221.42 (70.16)
Protein (g)	55.52	55.98	62.85	67.00	58.97	76.26

	(36.48, 95.14)	(34.70, 83.68)	(40.41, 80.55)	(46.69, 93.51)	(45.22, 75.00)[a]	(54.15, 87.14)
Fat (g)	82.60 (46.51)	58.74 (11.29, 316.36)	49.50 (11.51, 221.66)	78.3 (34.9)	73.61 (41.10)	69.89 (28.17, 251.68)
Sodium (mg)	3889.47 (2307.18)	3449.81 (2287.72)	3135.37 (2017.14)	4061.13 (2123.69)	3280.38 (1364.77)	3572.86 (1415.05)
Iron (mg)	11.10 (6.67, 15.24)	11.25 (6.94, 18.21)	8.55 (5.53, 12.20)	11.64 (8.32, 13.49)	10.31 (8.09, 14.91)	11.27 (10.34, 14.08)
Folate (µg)	268.14 (157.67, 376.64)	250.35 (166.10, 442.96)	187.02 (123.39, 380.07)	291.67 (209.84, 406.12)	270.46 (218.37, 429.78)	311.05 (143.13, 391.60)
Added sugar (g)	75.29 (49.90, 113.39)	60.14 (25.17, 145.93)	59.23 (27.62, 83.59)	75.88 (46.89, 113.89)	72.47 (46.26, 103.52)	89.05 (51.72, 133.01)
Daily supplements taken (#)						
0	1 (3.5%)	8 (32%)	5 (21.7%)	1 (3.6%)	5 (22.7%)	3 (21.4%)
1	25 (86.2%)	6 (24%)	10 (43.5%)	22 (78.6%)	2 (9.1%)	7 (50%)
2 or more	3 (10.3%)	11 (44%)	8 (34.8%)	5 (17.9%)	15 (68.2%)	4 (28.6%)

Data presented are means (SD) for continuous variables or n (%) for categorical variables, unless otherwise noted.

†Median (interquartile range)

^Recommendations of 150 min moderate activity/week

* Does not total 100%, as only limited to calculable activity domains.

a. $p \leq 0.05$ vs visit 1

Figure 6. 3. Change from baseline to midpregnancy in percentage of participants meeting guidelines for physical activity according to self-report (p=0.4). RC = regular care; LSI = lifestyle intervention (LSI).

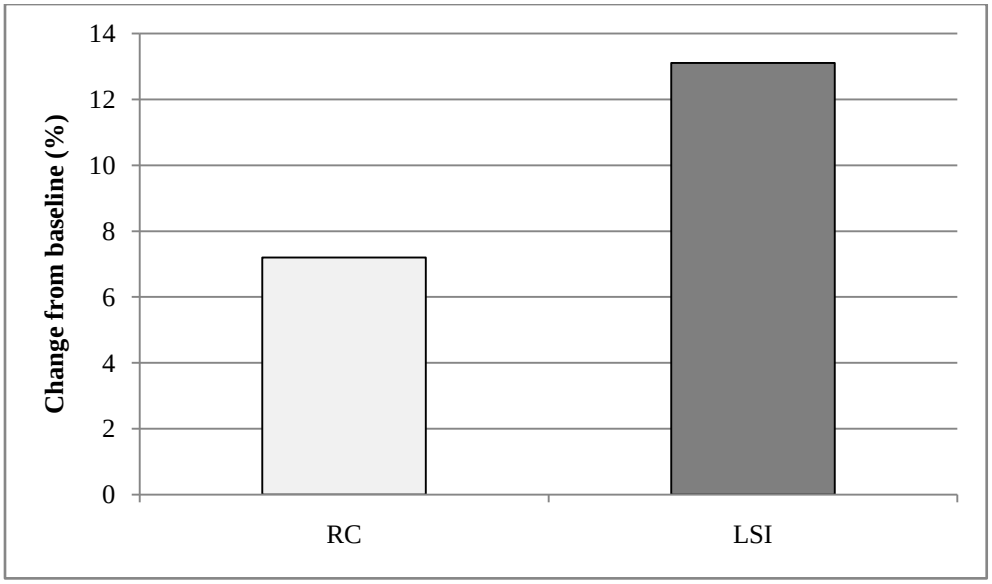
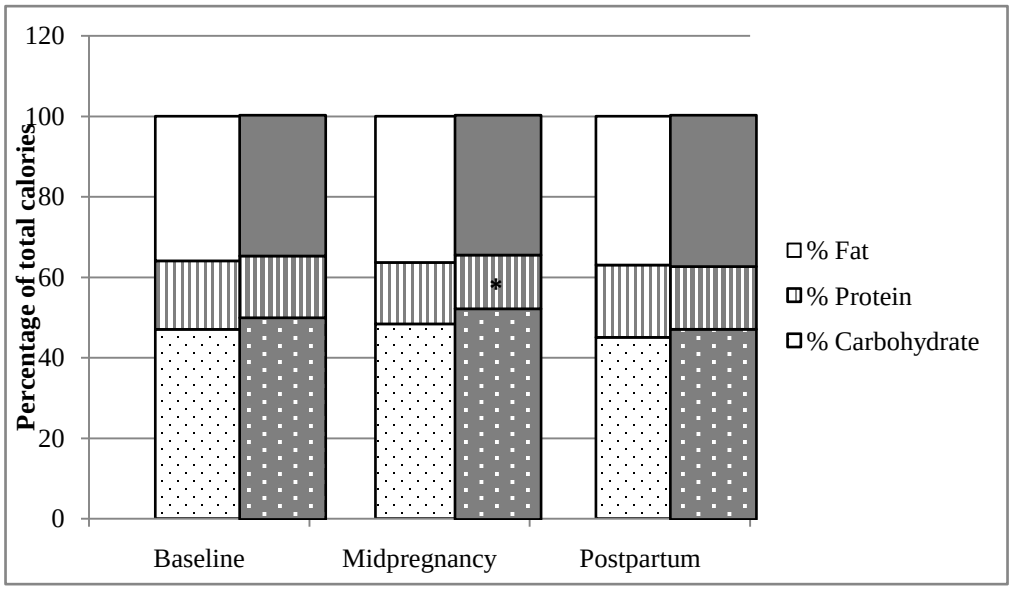
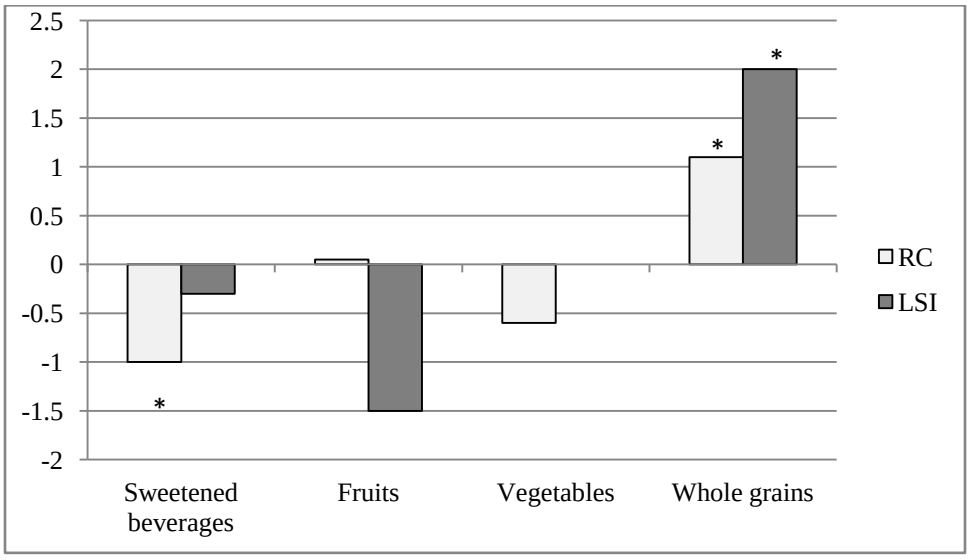


Figure 6. 4. Percentage of calories from each macronutrient at baseline, midpregnancy, and postpartum visits, by study group.



No fill=regular care; Gray fill = lifestyle intervention. * p≤0.05 vs. baseline.

Figure 6. 5. Change from baseline in median serving intakes of selected food groupings.



CHAPTER 7: LIFESTYLE INTERVENTION DURING PREGNANCY MAY ALTER GLUCOSE METABOLISM AND IMPROVE BIRTH OUTCOMES IN A HIGH-RISK UNDERSERVED POPULATION: RESULTS FROM A PILOT FEASIBILITY TRIAL

Introduction

Recent reports show that in the U.S., almost two-thirds of women of reproductive age are overweight or obese (BMI $\geq$ 25.0 kg/m^2); for non-Hispanic Black women, this measure is closer to 80% (195). Estimates vary by state, with the highest prevalences seen in the South (118). This is cause for concern, since maternal overweight and obesity during pregnancy increases the risk for such complications as pregnancy-induced hypertension and preeclampsia (119-121), large for gestational age/ macrosomia (119, 120, 122), birth defects (81, 123), cesarean delivery (119, 120, 124), postpartum infection (120) and gestational diabetes (GDM) (38). Women with GDM are at increased risk for such birth outcomes as maternal hypertensive disorders (87); large for gestational age/ macrosomia (69, 78, 79) and subsequently, Caesarean section deliveries (15); shoulder dystocia and hypoglycemia upon birth (80); birth defects (81); as well as overt type 2 diabetes in the future (85). Furthermore, the child of a mother with GDM is at increased risk for subsequent development of obesity and overt type 2 diabetes (196-198). Racial differences affect the complication rates in overweight and obese pregnant women, with minority women having higher rates of diabetes and high blood pressure before entering pregnancy (30, 31, 136).What is more, minorities -- particularly Black women and Latinas -- are more likely to enter pregnancy overweight or obese (26, 27).

Additionally, in the U.S., more than two-thirds of pregnant women gain more weight during their pregnancy than is recommended by leading medical institutions (127). Higher gestational weight gain (GWG) in excess of recommended goals has been associated with increased risk for cesarean delivery (128, 129), impaired glucose tolerance in pregnancy (130), pregnancy-induced hypertension and preeclampsia (128), and large for gestational age and macrosomia (129, 131-133). In 2009, the Institute of Medicine released new recommendations for weight gain during pregnancy based on a woman's prepregnancy body mass index (BMI) (127) as an update to their previous 1990 recommendations. For the first time, these recommendations included a specific upper limit for obese women. In the past, interventions to limit excessive GWG have in the past focused on normal weight and overweight women (140, 141, 199) without specifically separating out obese women, and conducted largely in Caucasian populations (142, 143, 145, 148, 185, 200). The need to explore the impact of these new recommendations specifically among obese minority women is apparent.

Research supports healthy diet and physical activity lifestyle interventions for controlling weight gain as well as preventing type 2 diabetes (98, 101); whether modifying these factors during pregnancy will have the same effects on weight control and – subsequently – progression to GDM is inconclusive (137, 139, 142, 145, 201). What is more, despite the racial differences outlined here, few studies of lifestyle interventions in pregnancy have focused specifically on this problem among urban Black women. We therefore conducted a pilot trial to assess the feasibility of implementing a lifestyle intervention during pregnancy among overweight and obese urban Black women. We hypothesized that changing diet and physical activity would have an effect

on keeping a woman within GWG recommendations, thereby improving glucose metabolism during pregnancy.

Materials and methods

Study population and setting

The Healthy Moms, Happy Babies study was a pilot randomized controlled clinical trial for women receiving prenatal care at Grady Memorial Hospital, the 7th largest public hospital in the U.S. (165), located in downtown Atlanta, GA. The perinatal center within the Grady Health System serves patients with highly diverse racial and socioeconomic profiles, with recent delivery rates at ~3500 per year. The study was approved by the Emory University Institutional Review Board and Grady Memorial Hospital Research Oversight Committee, and is registered at clinicaltrials.gov (identifier: NCT01084941). It received assistance from the Atlanta Clinical and Translational Science Institute (ACTSI).

All women presenting for their first prenatal care visit at the hospital's obstetric services were screened for inclusion into the study. Women were considered eligible for enrollment into the pilot study if they were 1) self-identified as being Black; 2) <20 weeks gestation; 3) 18-49 years of age; 4) overweight or obese (BMI $\geq$25 kg/m^2 based on self-reported pre-gravid weight and height); 5) experiencing a singleton pregnancy; and 6) planning to take their pregnancy to term. Exclusions included, women with a history of diabetes (GDM, type 1 or type 2), cardiovascular disease, chronic kidney disease or active liver disease; who were currently taking anti-hypertensive medications or medications that would alter glucose metabolism (steroids); had anemia (hemoglobin <10 g/L or hematocrit <32%); had contraindications to participating in physical activity; who

lacked the mental capacity to participate in the intervention; or who were delivering at a hospital outside of the Grady system. Women who passed this screening were asked to return for baseline testing, scheduled within 1-2 weeks of their first prenatal visit, at which point written informed consent for participation in the study was obtained.

Study design

Randomization and study groups

Block randomization was used, stratified on BMI category (overweight and obese). Study group assignments were concealed in opaque security envelopes prepared by the study coordinator. Participants enrolled into the study were randomly assigned to one of two groups: 1) regular standard of care (RC), or 2) regular standard of care plus a lifestyle intervention (LSI).

Regular care group

During their baseline testing, women assigned to the RC group received information outlining healthy eating practices and the safety of physical activity during pregnancy, as presented by the March of Dimes. These informational materials represented self-help literature that was high-quality, standard, low-cost and accessible to the general public. They attended prenatal care visits as regularly scheduled, and received standard counseling provided by physicians, nurses, dieticians and counselors from the hospital obstetric clinics and the Georgia Women, Infants, Children (WIC) state program. Women in the RC group received a booster phone call 1 month before their expected midpregnancy visit, and 1 month following the delivery of their infant.

Lifestyle intervention group

Women assigned to the LSI group received all aspects of standard care at the hospital. In addition, they were asked to attend monthly study sessions where they met one-on-one with a health educator and discussed strategies for healthy eating and increasing time spent in physical activity. The sessions were based on teachings from the Diabetes Prevention Program, and designed by a medical student and nutrition doctoral student, with guidance from diabetes educators, WIC counselors, dieticians, endocrinologists and obstetricians from the Grady community. Each session coincided with the participant's prenatal care visit schedule, lasted 30 minutes to 1 hour in duration, and covered such topics as GWG goals, healthy eating from each of the food groups, hidden fats and sugars in foods, and healthy choices for eating outside of the home (Table 5.1). The physical activity portion of the intervention was based on a walking program designed to increase time spent per day engaged in moderate physical activity. This plan was presented at the first session, and asked the participant to start with 15 minutes of walking/ day on at least 4 days of the week, adding 2 extra minutes of walking/ day each week until reaching a final goal of 40 minutes of walking/ day on at least 4 days of the week (Table 5.2). Each participant in the intervention group received a pedometer to encourage her progress and help track her daily and weekly number of steps. The pedometer was able to store up to seven days of information, and automatically re-set each day to more accurately trace participants' steps. With the health educator's guidance, participants set weekly goals for healthy eating and physical activity based on each session's topic, and were asked to report on progress toward these goals at the beginning of each session. There were seven sessions total as part of the LSI program; 3

for before midpregnancy (24-28 weeks) and 4 for between midpregnancy and delivery. Additionally, each participant in the LSI group received a booster phone call or text message every two weeks for the duration of her pregnancy and into the postpartum period, to chart progress toward her self-determined goals for healthy eating and physical activity and provide motivation for meeting these goals. Participants in the LSI group received $5 for each monthly visit, to assist with paying for transportation to the clinic.

Data collection

All women presented for baseline testing at <20 weeks gestation. For this visit, all participants arrived at the Grady Memorial Hospital Clinical Interaction Site after an overnight fast of ≥8 hours. Participants returned for midpregnancy testing between 24-28 weeks gestation, and postpartum testing at 6 weeks after delivery. Additional information on delivery outcomes were pulled from the participant's medical records. All participants received a $25 gift card for their participation at each of the study visits.

Baseline demographic indices

Demographic information was collected at baseline testing via questionnaire or from the participant's medical record. This included information on education, income, employment, insurance status, pregnancy/obstetric history, family history of disease, and smoking status.

Outcome measures

Biochemical and anthropometric outcomes

Blood pressure, height and weight were measured at baseline, midpregnancy and postpartum visits for all participants; additionally, for participants in the LSI group these measures were taken at each monthly LSI meeting. Prepregnancy BMI was calculated by

dividing the self-reported prepregnancy weight (in kg) by the square of the participant's height (in cm^2), as measured during baseline testing. Weight (to the nearest kg) and height (to the nearest cm) was measured and recorded by ACTSI nursing staff using a calibrated, standardized scale and stadiometer. All participants were asked to remove their shoes, outer clothing garments and items from their pockets before taking these measurements. Rate of gestational weight gain (GWG) at midpregnancy was calculated by subtracting the baseline weight from the midpregnancy visit weight and dividing by the number of weeks between the two measurements. These were compared with 2009 IOM recommendations for rate of GWG (127). Total GWG was calculated by subtracting the weight at baseline testing from the delivery weight. Using the 2009 IOM Guidelines, participants were categorized as having insufficient, sufficient, or excessive rate of GWG (at midpregnancy) or total GWG (at delivery), according to 2009 IOM recommendations for GWG. Postpartum weight retention was calculated by subtracting the weight at the baseline visit from the weight at the postpartum visit. Pulse and blood pressure was measured using a calibrated electric sphygmomanometer while the participants were seated, after a 5 minute rest.

Glucose, insulin, GDM diagnosis, and calculated glucose metabolism indices

During the baseline visit, participants completed a 75-g 2 hour oral glucose tolerance test (OGTT) with blood collections at 0, 30, 60, 90 and 120 minutes. Whole blood glucose (in mg/dL) was measured at each timepoint using the YSI 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI Inc., Yellow Springs, OH). Serum insulin (in uIU/mL) was measured via a commercially prepared radioimmunoassay kit (Siemans, Los Angeles, CA) with an interassay coefficient of variation (CV) of 11.68% at 3.41 uIU/mL, 9.02% at 22.04 uIU/mL, and 8.85% at 102.18 uIU/mL, and an intra-assay CV of

6.75% at 44.59 uIU/mL. The OGTT was repeated at the midpregnancy and postpartum visits for each participant.

GDM was considered following two levels of criteria: 1) ADA 2009 criteria for the 75-g OGTT (15), and 2) proposed criteria from the International Association for the Study of Diabetes in Pregnancy (18). For the ADA 2009 criteria, GDM was considered present if two or more values from the OGTT met or exceeded: 95 mg/dL at fasting, 180 mg/dL at 60 minutes, and 155 mg/dL at 120 minutes. For the IADPSG criteria, a positive diagnosis of GDM was considered if one or more values from the OGTT met or exceeded: 92 mg/dL at fasting, 180 mg/dL at 60 minutes, or 153 mg/dL at 120 minutes. The homeostasis model assessment of insulin resistance (HOMA-IR) was calculated by multiplying the fasting plasma insulin concentration (in uIU/mL) and the fasting plasma glucose concentration (in mg/dL) and then dividing by 405 (170). The insulinogenic index was calculated as Δ insulin/ Δ glucose from 0 to 30 minutes of the OGTT (171). The corrected insulin release at 30 minutes (CIR_{30}) was calculated by multiplying the insulin value at 30 minutes by 100 and dividing this by the product of the glucose value at 30 minutes and the glucose value at 30 minutes – 70 (172). The total area under the curve (AUC) for glucose was calculated using the trapezoidal rule (173).

Delivery and birth outcomes

At delivery, obstetric records were abstracted to obtain information on maternal and fetal birth outcomes including: gestational age at delivery and presence of preterm delivery (<37 weeks gestation) or still birth; method of delivery (i.e., Cesarean section or vaginal); infant birth weight (g), and presence of low birth weight (birth weight $<10^{th}$ percentile for gestational age), large for gestational age (birth weight $> 90^{th}$ percentile for

gestational age), or macrosomia (birth weight >4000 g); Apgar scores (at 1 and 5 minutes); and presence or absence of the following pregnancy complications, as noted in the medical chart: pregnancy induced hypertension (PIH) or preeclampsia, respiratory distress syndrome (RDS), shoulder dystocia, or jaundice. At the postpartum visit, we ascertained whether participants had breastfed their infant at any point during the postpartum period (yes/ no).

Power calculation and statistical analysis

This study was a secondary analysis of a feasibility study for lifestyle intervention during pregnancy. For the design of that study, we hypothesized that a lifestyle intervention would result in increased PA when compared with women receiving standard care. We aimed to recruit n=60 subjects for our study, with 30 women in each of the study groups. We assumed that 20% of subjects would be lost to follow-up or have missing data; accordingly, we expected n=48 women to complete the study. Based on our primary outcome as the proportion of women meeting PA guidelines (30 minutes/day, 5 days a week; or 450 MET-min/week (169), at a significance level of 0.05, assuming 13% of women in the regular care group would meet these PA recommendations (153), a sample size of n=48 achieves 80% power to detect an approximate four-fold increase in PA in the intervention group, with 55% reaching PA guidelines. This proportion is plausible based on previous studies (174).

Analyses followed an intention-to-treat principle. Descriptive statistics were calculated for all study variables. At baseline, midpregnancy, delivery and postpartum visits, the differences between study groups in continuous variables were determined by the student's t-test and Wilcoxon Mann-Whitney U test for normally and non-normally

distributed variables, respectively, and differences in categorical variables were determined by the Chi-square test or Fisher's exact test for small sample sizes. Within group differences from baseline to midpregnancy, delivery and postpartum were tested using the paired t-test or Wilcoxon signed-rank test for continuous variables, and McNemar's test for categorical variables. We calculated odds ratios (ORs) and corresponding 95% confidence intervals (CIs) using multiple logistic regression models, testing the effect of the intervention on dichotomous outcomes (i.e., presence/absence of GDM by either criteria; presence/absence of adverse delivery outcome; and meet/do not meet recommendations for GWG by rate (at midpregnancy) or total (at delivery)). We also calculated beta estimates via multiple linear regression models, testing the effect of the intervention on the continuous outcomes at midpregnancy and postpartum. To account for repeated measures of weight during gestation, we explored the effect of the intervention using a generalized linear regression model (SAS *Proc Mixed* procedures), assuming unstructured correlation, to account for the correlation among repeated observations for weight for a given subject. We considered baseline demographic and metabolic indices for confounding, and controlled for these measures if they changed the point estimate by >10% (175). All statistical tests were two-tailed and significance was considered at $p<0.05$. All analyses of quantitative variables were conducted using SAS statistical software, version 9.3 (SAS Institute, Cary, NC).

Results

The flow chart for study participants through the trial is presented in Figure 7.1. From April, 2010 to March, 2012 we screened 1,147 women presenting for prenatal care at Grady Memorial Hospital. Of these women, 965 (84.1%) did not meet criteria for

inclusion into the study. The top reasons for not passing this screen were having a gestational age > 20 weeks (46.6%), a BMI < 25 kg/m^2 (31.6%), and not being of Black race/ethnicity (10.4%) (Figure 7.1).

We recruited and randomized 57 participants at a mean gestational age of 12 weeks. Overall there were no significant differences in baseline characteristics between study groups (Table 7.1). Our sample was young, with a mean age of 24 years. Nearly all women were living on a yearly income of <$15,000, and receiving assistance from both Medicaid and WIC. The majority of participants were currently unemployed, and 30% had less than a high school education. Though we enrolled both overweight and obese women, the majority of our participants were obese or morbidly obese (66%), with a mean (SD) BMI of 35.0 (7.9) kg/m^2. Most participants also had a history of diabetes in first-degree relatives, and a considerable proportion were either former smokers or current smokers (31%).

For both groups, the midpregnancy visit occurred ~12 weeks following baseline testing. Overall, 22 women in the LSI and 25 women in the RC group returned for midpregnancy testing, representing 82% of the original sample. Supplemental information on weight, blood pressure, and glucose was available from the medical charts of the prenatal care visit for one additional person in the LSI group. At delivery, information was available for 25 women in the RC group and 27 women in the LSI group. At the post-partum visit, only 14 women in the LSI (50%) and 23 women in the RC (79%) group returned for testing, representing 65% of the original sample. This visit occurred on average ~7 weeks post-delivery. Supplemental data on weight and blood pressure were available for six additional participants in the LSI group and one additional

participant in the RC group, leaving 79% of the original sample with at least partial follow-up data. No adverse events were attributed to the intervention. There were no differences in baseline measures between women who presented for midpregnancy testing vs. those women who did not. Women who were missing information on delivery outcomes presented for baseline testing at an earlier gestational week than those women with information on delivery outcomes ($p<0.05$). A similar observation occurred for women who did not present for postpartum testing.

Primary outcomes

Pulse and blood pressure

At the midpregnancy visit, we observed higher pulse readings in both groups when compared with baseline values [RC: 91.1 (12.5) vs. 82.8 (10.7) beats per minute (bpm); LSI: 81.1 (14.6) vs. 87.4 (15.2) bpm, $p<0.05$ for each]. For both RC and LSI participants, pulse values were significantly lower at postpartum than at baseline (each $p<0.05$). There were no differences in systolic or diastolic blood pressure readings within groups from baseline to midpregnancy; at the postpartum visit, both groups had significantly higher systolic and diastolic blood pressure when compared with baseline values ($p<0.05$ for each). There were no differences between groups in either pulse or blood pressure at either the midpregnancy or the postpartum visit.

Total GWG and IOM recommendations for GWG

There were no significant differences between groups in GWG at midpregnancy or at delivery, or in the rate of weight gain at midpregnancy (each $p>0.15$, Table 7.2). Compared with women in the RC group, a greater percentage of women in the LSI group

exceeded recommendations for GWG at midpregnancy (68.2% vs. 44%, LSI vs. RC, p=0.25) and delivery (57.5% vs. 50%, LSI vs. RC, p=0.68). However, within the LSI group, the percentage of women with excessive GWG decreased from midpregnancy to delivery (68.2% to 57.5%) whereas, for the RC group, this proportion increased (44% to 50%, Figure 7.2). Longitudinal multiple regression analyses showed no effect of LSI on total GWG (Figure 7.3); however, a significant predictor of GWG was prepregnancy BMI (β-estimate (SE), prepregnancy BMI*gestational week: -0.02 (0.004), $p<0.01$). Additionally, a history of delivery by Cesarean section was associated with total GWG (β-estimate (SE), history*gestational week: 0.23 (0.11), $p<0.05$). At postpartum, there was no difference between groups in amount of weight retained; the median weight retained by each group was < 2 kg (Figure 7.3).

Glucose, total AUC for glucose, and GDM diagnosis

Results from the baseline OGTT are presented in Figure 7.4. Overall, we noticed no difference at any timepoint of the OGTT between the RC and LSI groups at baseline testing. Four women (1 RC, 3 LSI) were not able to complete the OGTT during baseline testing due to nausea and vomiting; for these women, samples were collected only at fasting and 30 minutes. At the midpregnancy visit, one woman each in the RC (4%) and LSI (4%) group was diagnosed with GDM by 2009 ADA standards. Using IADPSG standards, this increased to 6 (24%) women in the RC group and 5 women (22%) in the LSI group. Multiple logistic regression models showed a trend for reduced odds of GDM for the LSI group using either criteria for diagnosis, after adjusting for potential confounding factors (aOR_{IADPSG} [95% CI]: 0.58 [0.01, 19.46], Table 7.5). At the midpregnancy visit, there were no significant differences between groups in fasting, 60, 90 or 120 minute blood glucose values ($p>0.2$, all). However, at this visit, within the RC

group, the mean (SD) 30-minute glucose value was higher compared with baseline 30-minute glucose values (125.7 (22.5) mg/dL vs. 115.5 (18.8), $p< 0.05$)), and was significantly higher than in the LSI group (111.6 (15.7) mg/dL, $p<0.05$, Figure 7.4). Correspondingly, the total AUC for glucose increased significantly from baseline to midpregnancy for the RC group ($p<0.05$). The same was not observed for the LSI group from baseline to midpregnancy total AUC for glucose, and values at midpregnancy were lower in LSI group compared with the RC group. This was confirmed with results from linear regression models, showing a trend toward reduced AUC for glucose for the LSI group vs. the RC group (β-estimate: -700, 95% CI: -2009.95, 614.7, results not shown). There were no observable differences in glucose measures within groups or between groups at the postpartum visit.

Insulin and calculated glucose metabolism indices

Fasting insulin values were similar between groups at baseline, midpregnancy, and postpartum visits (Table 7.3). At the midpregnancy visit, in the RC group, the 30-minute insulin was significantly higher compared with the LSI group, and significantly different than at baseline (each $p<0.05$). Correspondingly, midpregnancy HOMA-IR values were higher in the RC group vs. the LSI group. Additionally, from baseline to midpregnancy testing, HOMA-IR values increased in the RC group but decreased in the LSI group (Figure 7.5); however, these comparisons were not significantly different ($p=0.5$). From baseline to midpregnancy, CIR_{30} values decreased for both groups (each within-group $p=0.04$) and were lower for the LSI group $p=0.9$). The same trend was observed for insulinogenic index at midpregnancy ($p=0.9$). During the postpartum visit, both groups had significantly lower 30-minute insulin compared with baseline (each

$p<0.05$), and CIR_{30} decreased significantly for both groups from baseline levels (each $p<0.05$). There were no significant differences between or within groups in insulinogenic index or HOMA-IR at this visit.

Delivery and birth outcomes

Infant and delivery outcomes are presented in Table 7.4. No adverse outcomes were considered attributable to the study. There were no significant differences between the LSI and RC groups in average infant birth weight (3297±445 g vs. 3258±368 g, $p=0.7$) or number of infants LGA (n=1, each group). One instance of macrosomia occurred in the LSI group, and one case of shoulder dystocia occurred in the RC group. Apgar scores at 1 and 5 minutes were similar between both groups. Only 1 infant in the LSI group (3.6%) had a low Apgar score (<7) at 1 minute, vs. 3 infants (10.3%) in the RC group. There were no infants with low Apgar scores at 5 minutes. A slightly higher proportion of infants of mothers in the RC group had a diagnosis of respiratory distress syndrome at birth compared with infants of mothers in the LSI group (12.5%, $p=0.34$).

We observed a higher proportion of mothers in the RC group with pregnancy-induced hypertension/ preeclampsia compared with mothers in the LSI group (20.8% vs. 11.5%, respectively, $p=0.5$), as well as deliveries by Cesarean section (25% vs. 19.2%, $p=0.5$). PIH/preeclampsia was diagnosed at delivery, leading to induction of delivery, for 2 of the 3 women in the LSI group and 3 of the 5 women in the RC group. For the third woman in the LSI group, this was diagnosed at 30 weeks gestation, and she received diet therapy only. For the RC group, one woman was diagnosed at 19 weeks gestation and received blood pressure medication, and the final woman was diagnosed at 33 weeks gestation with diet therapy only. Overall, 46% of all participants with delivery data had

record of at least one adverse delivery outcome (i.e. stillbirth, preterm labor, delivery by C-section, PIH/preeclampsia, Apgar < 7 at 1 minute, jaundice, LGA/macrosomia, shoulder dystocia, and/or respiratory distress syndrome). A greater proportion of mothers in the RC group were affected by an adverse delivery outcome compared with mothers in the LSI group (54.2% vs. 38.5%, p=0.39). Results from multiple logistic regression modeling showed a trend toward lower adjusted odds of having an adverse delivery outcome in the LSI group (aOR (95% CI): 0.28 (0.03, 2.5)).

Discussion

The purpose of our study was to examine the effects of a pilot lifestyle program for pregnant women at risk for GDM and other adverse pregnancy outcomes. We were able to successfully implement a clinic-based lifestyle intervention for pregnancy in an underserved urban obstetric clinic. Results from our pilot study show the potential amelioration of pregnancy-induced insulin resistance from a simple diet and exercise intervention implemented in early pregnancy, though there was no difference in insulin response between the two groups. While RC participants saw significantly increased total AUC for glucose from baseline to midpregnancy, a similar observation was not true for LSI participants. At midpregnancy, RC participants showed higher total AUC for glucose than LSI participants though this difference was not significant. While there was no difference in total GWG between groups, LSI participants tended to gain slightly more weight. However, there was a hint at reduction of adverse delivery outcomes from the intervention.

Other studies have looked at the utility of exercise (145, 180, 201-203), diet (57, 187) or both (143, 148) for prevention of GDM in different populations, and have found

mixed results. A recent meta-analysis (179) showed a 61% reduction in GDM among participants receiving diet-alone interventions, compared with regular care. In interventions of PA-alone or mixed diet and PA interventions, there was no significant difference between lifestyle and regular care groups in GDM incidence (179). These studies all took place in very different settings than our pilot study, and several incorporated more intensive lifestyle interventions. An exercise intervention study in obese Australian women, while not powered to show differences in GDM incidence, showed to have a modest effect on increasing PA and improving both fasting glucose and insulin compared with regular care; however, there was no distinguishable effect on HOMA-IR between groups (201). In obese pregnant Caucasian women in Denmark, those women who received a dietary intervention to limit GWG showed attenuation of fasting insulin, leptin and glucose, though there was no effect on 2-h glucose (143). Our mixed intervention of both dietary and PA advice, while it did not reduce GDM incidence, did show a possible amelioration of glucose metabolism and potential insulin resistance, and should be investigated further.

Pregnancy naturally induces a state of increased insulin resistance, in order to provide nutrients for the developing baby (9, 204). With advancing gestation, there is an increase in insulin secretory response to glucose. We observed a trend toward lower insulin resistance at midpregnancy with a simple lifestyle intervention. Although insulin response at 30 minutes, at noted by the CIR_{30}, was not as relatively high for LSI participants as for RC participants, this could be a result of the relatively decreased insulin resistance seen in LSI participants compared with RC participants. Additionally, we did not observe any differences in insulin sensitivity between the two groups, as noted

by the insulinogenic index. For both groups, these values decreased with advancing gestational age, with a slightly higher decrease in the LSI group. It is difficult to compare these findings with other clinic populations. Previous research comparing the utility of various insulin indices for measuring insulin response in pregnancy have shown mixed results on the response in GDM vs. normal glucose tolerance. In one clinic population, obese women with GDM had a greater second-phase insulin secretory response compared with normal glucose tolerant women (205); however, a different clinic population showed reduced response in late pregnancy (3). In terms of valid indices for insulin sensitivity, HOMA-IR has been criticized as being more reflective of changes in hepatic insulin sensitivity, and may not represent well total body insulin sensitivity (205). However, this index has been shown to correlate well with gold-standard measures of insulin indices in pregnancy in both GDM and NGT women (205), in early and late gestation, showing to be a valid and useful tool for assessing maternal insulin status.

We saw no differences between groups in those meeting IOM recommendations for GWG, either by rate of GWG at midpregnancy or total GWG at delivery. While several studies have shown a positive effect of lifestyle intervention on GWG and adherence to recommendations(138, 143, 185), other results are conflicting, perhaps due to differential results by BMI (137, 139, 140). In low-income women in Pittsburgh, PA (39% Black, 57% unemployed), a lifestyle intervention showed to be effective for reducing excessive GWG (1990 IOM Guidelines) during pregnancy when compared with standard of care in normal weight women but not overweight women (BMI >26.0 kg/m^2). In overweight women (mean±SD BMI: 31.4±6.0 kg/m^2), there was no effect of intervention on GWG; at delivery, a greater percentage of women in the intervention

group exceeded GWG goals compared with the control group (59.3% vs. 31.8%) (140). We observed a similar trend, and observed the proportion of participants with excessive GWG -- having used 2009 IOM Guidelines – to be closer to those of that study's intervention group. For both groups, this proportion was still lower than data published previously (127). Similar to these findings, a more recent clinic-based study in Charlotte, NC (24% African American, 67% < high school graduation), showed that women receiving lifestyle intervention, while they gained significantly less weight than women receiving standard care, had no difference in the rate of adherence to 1990 IOM guidelines for GWG compared with women receiving standard of care (137). Additionally, women in overweight and obese BMI groups were less likely to adhere to guidelines compared with normal weight women (137). It is possible that a more intensive approach might be needed for overweight and obese women to affect GWG, in order to deal with more long-standing troubles with weight maintenance as evidenced by their preexisting overweight/obesity status. Additionally, the explanation for not seeing a difference between groups in our study could be as a result of our efforts to maintain contact with study participants. In doing so, the RC group was not necessarily limited to only regular prenatal care. They had exposure to the research staff, and were given initial information on diet and PA that was not provided by their prenatal care provider. Even though they were not followed as closely and intensively as the LSI group, there is possibility for behavior change to have occurred in this group simply from the knowledge that they were being followed (186).

Our sample is exemplary of a very disadvantaged, high-risk population, as evidenced by the high rate of adverse delivery outcomes; almost 45% of our sample had

at least one adverse delivery outcome. The proportion of women affected by any adverse delivery outcome was higher in the RC group compared with the LSI group (54.2% vs. 38.5%, respectively). For many outcomes, we observed higher proportions than expected from previous studies or national data, including for RDS (206), shoulder dystocia (207) and pregnancy induced hypertension/ preeclampsia (208). Rates of both preterm birth and delivery by Cesarean section were lower than those observed in the national population (9.6% and 21.2%, our sample, vs. 17.1% and 35.5% for U.S. non-Hispanic Blacks, respectively, (209), with only one baby born low birthweight. That we saw any level of change in any index within this difficult population is promising for future research and highlights the need to address the issue within this high-risk population.

There are several strengths to our study, including the characteristics of our study sample, measures of glucose and insulin indices, close follow-up of patients, and reliable medical records. Of note, our study was conducted in a very underserved population, as evidenced by the high levels of obesity, poverty, and smoking present. We consider this a strength, as this population is not well represented in the literature, and we were able to see signs of change under difficult conditions. We utilized current, rigorous practices for the OGTT, collecting measurements every half hour for the duration of the 2-hour test, at two points during pregnancy and one point post-delivery. Many studies on lifestyle interventions during pregnancy have collected fasting measures only (143, 145) or rely on only a midpregnancy measure (140). We are thus able to compare not only between group differences but also within group differences in total glucose metabolism, over the course of pregnancy, providing a level of data not often seen in the literature for a group at high-risk for pregnancy complications and future diabetes. We utilized standardized

scales for measurement of weight for both groups and did not have to rely on self-report for either early pregnancy weight, delivery weight, or postpartum weight, as done in previous studies (210). We were also able to follow-up with women using electronic medical records directly from the hospital to obtain accurate information on delivery outcomes.

We also acknowledge limitations to our study. Because it was a pilot/feasibility trial, our sample size was not large enough to detect meaningful differences in our outcomes. Second, several women were affected by nausea during the first (and second) trimesters of pregnancy, and were not able to tolerate the OGTT drink. This more negatively affected women in the LSI group (n=3 vs. n=1). Third, we experienced a noteworthy number of women who were lost to follow-up: 18% of the original sample at the midpregnancy visit, and 35% of the original sample at the postpartum visit. However, we were able to use supplemental data on weight, blood pressure, and glucose from the medical charts for several participants. Fourth, we were dependent upon medical records for report of delivery weight, and not our clinic scale. It is possible that this might result in under- or over-estimation of total GWG; however, we do not expect this had a differential effect between study groups. Finally, the setting of our study is a teaching hospital for two different Universities; as such, our patients could have received varying levels of "standard care" depending on their provider. However, randomization of participants should have accounted for this potential difference.

Conclusion

We present data from a pilot feasibility lifestyle intervention trial in underserved, high-risk, pregnant women receiving care from an urban obstetric clinic. While our

sample size was not sufficient to detect meaningful differences in maternal and fetal outcomes, our results highlight the potential of a low-cost lifestyle intervention for improving glucose metabolism and insulin resistance indices during pregnancy, as well as reducing the rate of adverse delivery outcomes. Our findings show that lifestyle interventions can effectively be administered in this high-risk population, and can benefit those women in greatest need for improvement of pregnancy outcomes.

Figure 7. 1. Flow of participants through screening and study visits.

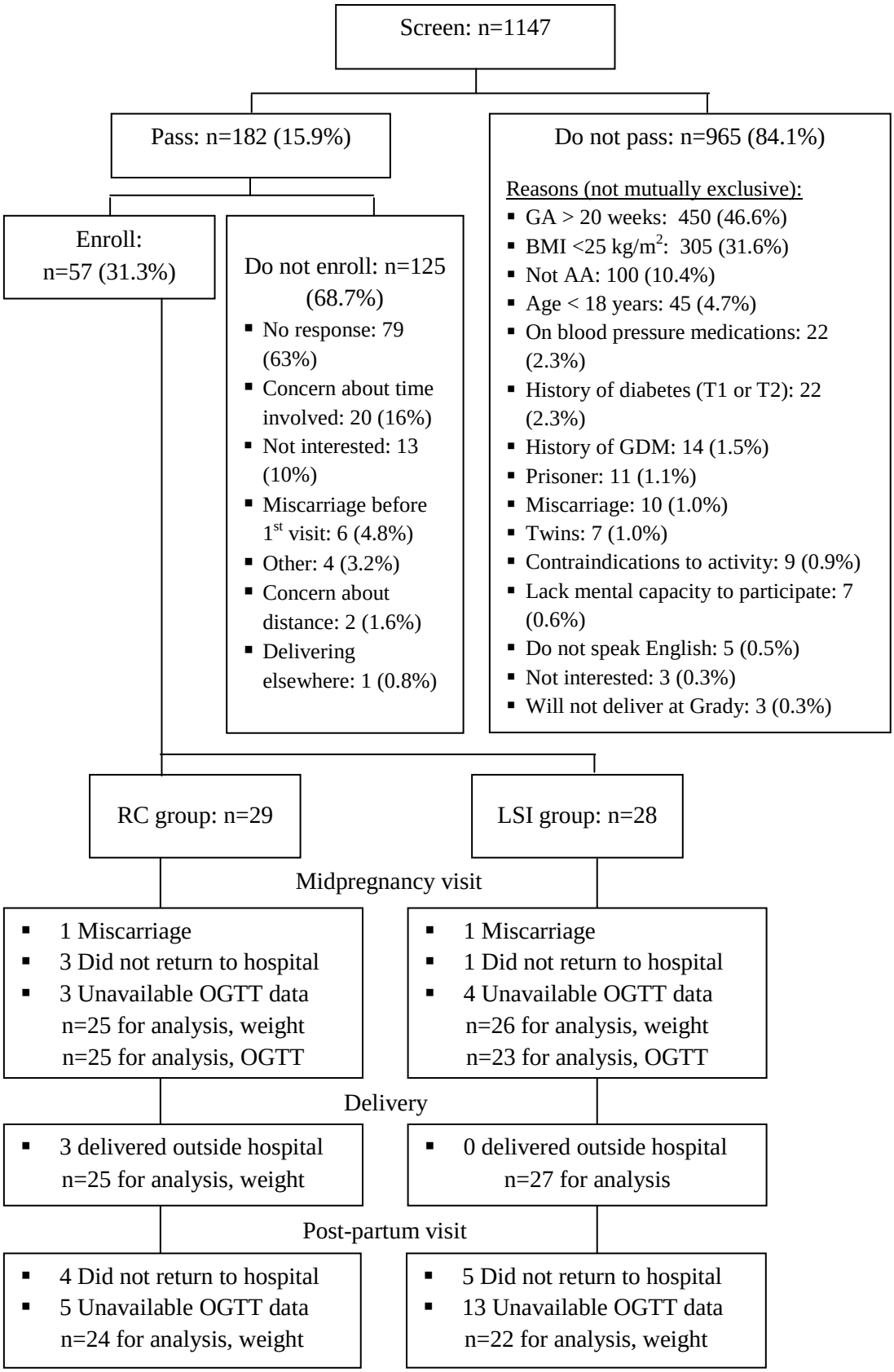


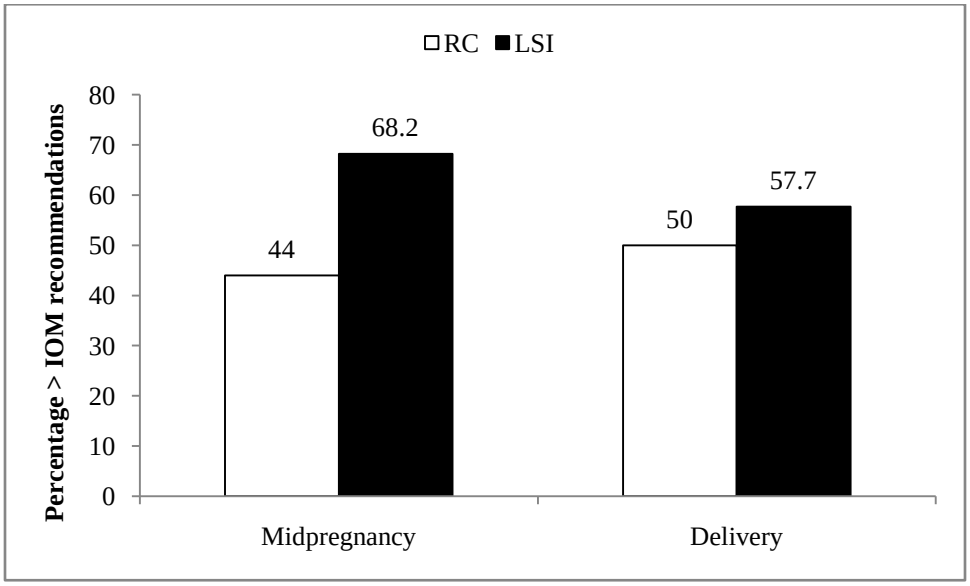
Table 7. 1. Baseline characteristics of study population, by treatment group

Variable	Total group (n=57)	Regular care (RC) (n=29)	Lifestyle intervention (LSI) (n=28)	*p*-value
Age	24.8 (4.6)	24.38 (4.21)	25.25 (5.05)	0.48
Prepregnancy weight (kg)	92.9 (22.2)	92.79 (22.96)	92.97 (21.86)	0.98
Prepregnancy BMI	35.0 (7.9)	34.65 (7.93)	35.28 (7.94)	0.76
Overweight	19 (33.3%)	9 (31%)	10 (35.7%)	0.79
Obese	25 (43.9%)	14 (48.3%)	11 (39.3%)	
Morbidly obese	13 (22.8%)	6 (20.7%)	7 (25%)	
Gestational age at recruitment	12.4 (3.5)	12.19 (3.09)	12.64 (3.85)	0.63
Gravidity	2.7 (2.2)	2.55 (1.59)	2.89 (2.64)	0.56
1	21 (36.8%)	7 (24.1%)	14 (50%)	0.06‡
2	14 (24.6%)	11 (37.9%)	3 (10.7%)	
3	9 (15.8%)	6 (20.7%)	3 (10.7%)	
4+	13 (22.8%)	5 (17.3%)	8 (28.6%)	
Gestational week, visit 1	14.4 (2.9)	14.46 (3.01)	14.38 (2.85)	0.92
Weight, visit 1	96.6 (23.2)	95.80 (23.01)	97.31 (23.82)	0.81
Pulse	82.0 (12.7)	82.83 (10.69)	81.07 (14.58)	0.61
Blood pressure				
Systolic	117.6 (13.3)	115.45 (11.34)	119.82 (15.00)	0.22
Diastolic	66.9 (7.8)	66.62 (6.14)	67.18 (9.28)	0.79
Medicaid Recipient	55 (96.5%)	29 (100%)	26 (92.9%)	0.24‡
WIC Recipient	51 (91.1%)	24(82.8%)	27 (96.4%)	0.19‡
Employed	23 (40.4%)	10 (34.5%)	13 (46.4%)	0.36
Income <$15,000/ year	52 (91.1%)	28 (96.5%)	24 (85.7%)	0.19‡
Educational level				
< 5 years	1 (1.8%)	0 (0%)	1 (3.6%)	0.2‡
Between 5-8 years	2 (3.5%)	0 (0%)	2 (7.1%)	
Between 8-12 years	16 (28.1%)	6 (20.7%)	10(35.7%)	
High school graduate	29 (50.1%)	17 (58.6%)	12 (42.9%)	
College or more	9 (15.8%)	6 (20.7%)	3 (10.7%)	
Smoking status				
Never smoker	39 (67.9%)	19 (65.5%)	20 (71.4%)	0.42
Current smoker	6 (10.1%)	2 (6.9%)	4 (14.3%)	
Former smoker	12 (21.4%)	8 (27.6%)	4 (14.3%)	
Family history of diabetes	39 (69.6%)	21 (72.4%)	18 (64.3%)	0.51
History, delivery by C-section	6 (10.5%)	4 (13.8%)	2 (7.1%)	0.67‡
History, preeclampsia	5 (8.8%)	2 (6.9%)	3 (10.7%)	0.67‡

Data presented are means (SD) for continuous variables or n (%) for categorical variables. p-values are based on student's t-test for continuous variables and Chi-square test for categorical variables, unless

otherwise noted. * Wilcoxon signed-rank test, ‡ Fisher's exact test for categorical variables.

Figure 7. 2 Percentage of participants, by intervention group, exceeding 2009 IOM recommendations for gestational weight gain, at midpregnancy and delivery.



Regular care represented by unfilled bars (□), lifestyle intervention (LSI) represented by filled bars (■). IOM: Institute of Medicine

Figure 7. 3. Weight change profile for participants in the Healthy Moms, Happy Babies program, Atlanta, GA, from baseline (~12 weeks gestation) to midpregnancy, to delivery, to postpartum (~6 weeks), by intervention group.

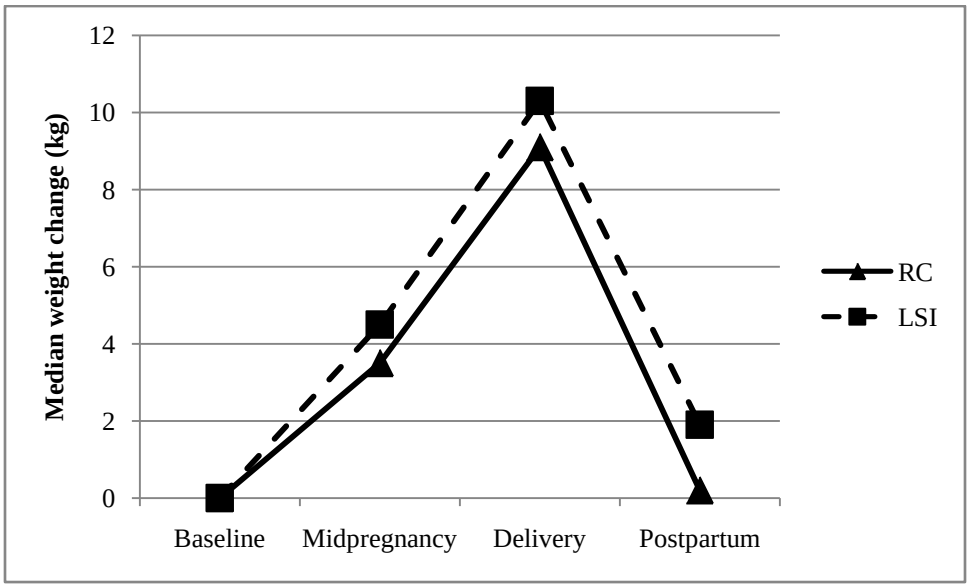
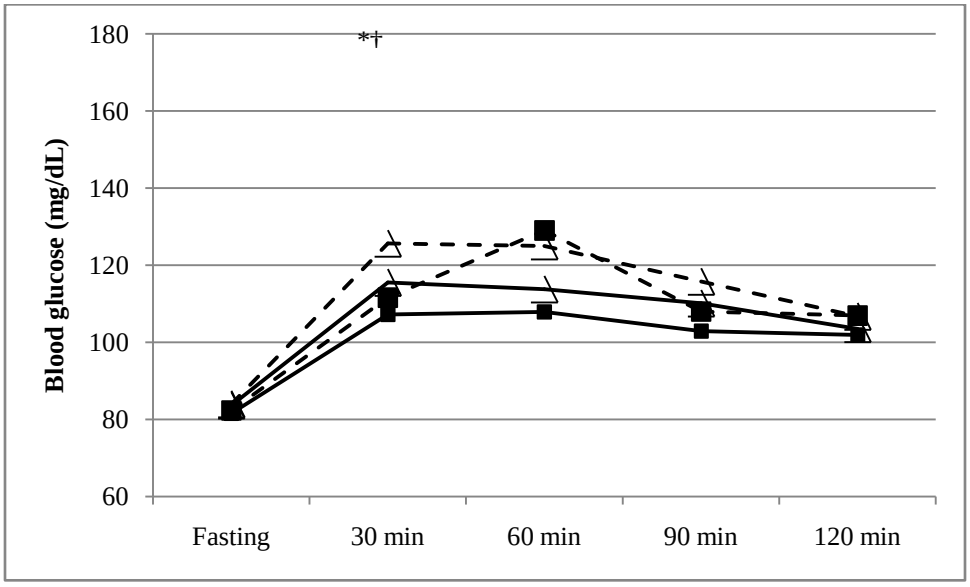
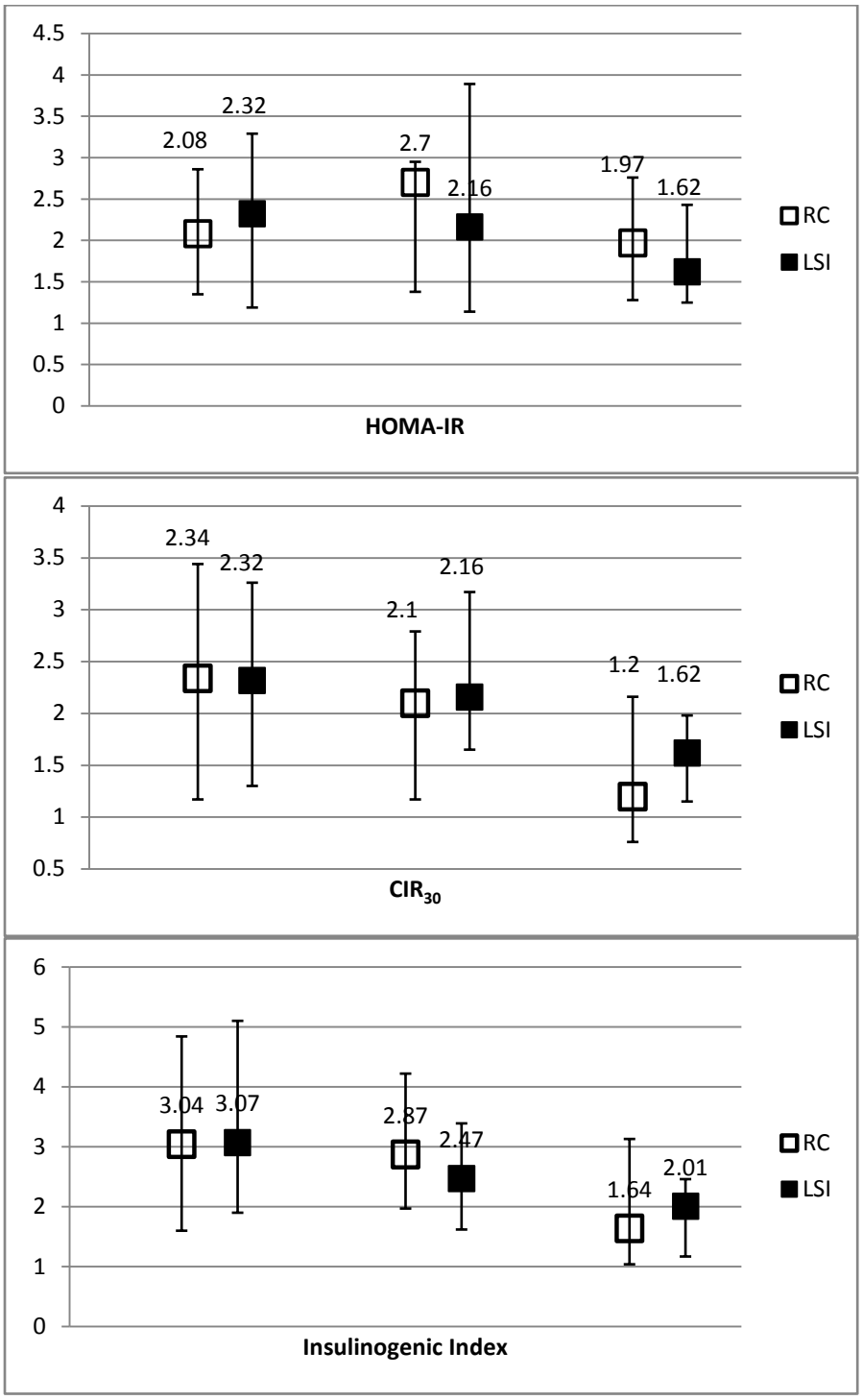


Figure 7. 4. Baseline (solid line) and midpregnancy (dashed line) values from a 75-g oral glucose tolerance test (OGTT), presented for each randomization group.



The regular care group (RC) is noted by ▲, and the lifestyle intervention (LSI) group is noted by ■. Solid red lines note cut-offs for diagnosis of gestational diabetes (GDM). * $p<0.05$ from baseline to midpregnancy, RC group; † $p<0.05$ at midpregnancy, between groups.

Figure 7. 5. Median (interquartile range) of calculated insulin and glucose metabolism indices between two study groups at baseline, midpregnancy, and postpartum.



HOMA-IR, the homeostasis model assessment of insulin resistance; CIR_{30}, the corrected insulin response at 30 minutes. White boxes (□) represent regular care (RC) participants; solid boxes (■) represent lifestyle intervention (LSI) participants.

Table 7. 2. Anthropometric measures of participants in the Healthy Moms, Healthy Babies study, by randomization group.

	Regular Care (RC) Group				Lifestyle Intervention (LSI) Group			
	Baseline	**Mid-pregnancy**	**Delivery**	**Postpartum**	**Baseline**	**Mid-pregnancy**	**Delivery**	**Postpartum**
	(n=29)	(n=25)	(n=25)	(n=23, 24*)	(n=28)	(n=26)	(n=27)	(n=14, 22*)
Gestational week[1]	14.46	26.47 (2.38)	38.7 (1.2)	6.61 (0.82)*	14.38	26.33 (2.72)	39.0 (1.4)	6.62 (2.63)*
Pulse	82.83 (10.69)	91.13 (12.46)[a]	---	77.55 (12.81)[a]	81.07 (14.58)	87.38 (15.21)[a]	---	69.71 (12.09)
Weight gained from baseline	---	3.50 (1.1,5.8)	9.1 (3.0, 12.8)	---	---	4.50 (2.2,7.1)	10.3 (4.9,13.0)	---
Rate of weight gain	---	0.24 (0.12, 0.47)	---	---	---	0.42 (0.17, 0.56)	---	---
Weight retained from baseline†	---	---	---	0.2 (-5.1, 3.9)	---	---	---	1.9 (-4.2, 5.1)*
Recommendations for GWG[2]‡								
Under	---	8 (32%)	7 (29.2%)	---	---	5 (22.7%)	8 (30.8%)	---
Meets	---	6 (24%)	5 (20.8%)	---	---	2 (9.1%)	3 (11.5%)	---
Exceeds	---	11 (44%)	12 (50%)	---	---	15 (68.2%)	15 (57.7%)	---
Blood pressure								
Systolic	115.5 (18.8)	114.7 (14.7)	---	127.5 (16.5)*[b]	119.8 (15.0)	117.5 (11.9)	---	127.8 (14.0)*[a]
Diastolic	66.8 (6.1)	64.7 (7.0)	---	73.9 (9.6)*[b]	67.2 (9.3)	66.9 (7.3)	---	76.9 (12.67)*[b]

Data presented are means (SD) for continuous variables or n (%) for categorical variables, unless otherwise noted.

1 Weeks postpartum for postpartum measures; 2 GWG: gestational weight gain. †Median (interquartile range); ‡ 2009 IOM recommendations for gestational weight gain, a. $p \leq 0.05$ vs visit 1; b. $p < 0.01$ vs visit 1; c. $p < 0.05$ vs RC.

Table 7. 3. Glucose and insulin measures at three study visits, upon administration of a 75-g oral glucose tolerance test (OGTT).

	Regular Care (RC) Group			**Lifestyle Intervention (LSI) Group**		
	Baseline (n=29)	**Midpregnancy** (n=25)	**Postpartum** (n=23)	**Baseline** (n=28)	**Midpregnancy** (n=23)	**Postpartum** (n=14)
Gestational week[1]	14.5 (3.0)	26.5 (2.4)	6.6 (0.8)	14.4 (2.9)	26.3 (2.7)	7.0 (2.4)
Glucose (mg/dL)						
Fasting	83.6 (10.2)	84.0 (18.6)	85.6 (10.5)	81.6 (10.7)	82.3 (10.8)	85.3 (7.7)
30 min	115.47 (18.8)	125.7 (22.5)[a,c]	119.2 (23.3)	107.2 (16.1)	111.6 (15.7)	113.4 (12.6)
60 min	113.8 (20.5)	124.9 (25.5)	113.6 (27.7)	107.8 (24.1)	129.0 (28.1)	110.5 (24.3)
90 min	110.1 (18.2)	115.8 (24.4)	107.8 (23.0)	102.9 (28.1)	107.9 (25.1)	102.6 (19.2)
120 min	103.5 (19.4)	106.7 (21.7)	94.5 (16.9)	101.9 (25.5)	106.9 (28.5)	97.1 (17.0)
Total AUC glucose[2] (mg/dL/2h)	12990.5 (1718.2)	13851.4 (2339.1)[a]	12860.1 (2178.1)	12284.1 (2340.0)	12933.1 (1945.6)	12536.9 (1652.9)
GDM[3]						
Diagnosed		1 (4%)			1 (4.4%)	
IADPSG[4]		6 (24%)			5 (21.7%)	
Insulin (uU/mL)†						
Fasting	9.5 (6.5,13.7)	11.5 (7.0,17.7)	9.7(6.0,13.6)	11.8 (6.5,14.7)	11.4 (6.6,19.2)	8.8 (6.0,11.2)
30 min	88.8 (64.0,129.2)	103.0 (83.5,221.5)[a,c]	64.1 (45.5,109.0)[b]	98.0 (49.9,121.2)	85.8 (58.8,97.0)	58.4 (44.0,72.1)[b]
HOMA-IR[5]†	2.1 (1.4,2.9)	2.7 (1.4,3.0)	2.0 (1.3,2.8)	2.3 (1.2, 3.3)	2.2 (1.1,3.9)	1.6 (1.3,2.4)
CIR_{30}[6]†	2.3 (1.2,3.4)	2.1 (1.2,2.8)	1.2 (0.8,2.2)[b]	2.6 (1.6,3.5)	1.7 (1.2,2.7)	1.3 (0.8,1.6)[a]
Insulinogenic	3.0 (1.6, 4.8)	2.9 (2.0, 4.2)	1.6 (1.0, 3.1)	3.1 (1.9, 5.1)	2.5 (1.6, 3.4)	2.0 (1.2, 2.5)

Data presented are means (SD) for continuous variables or n (%) for categorical variables, unless otherwise noted. †Median (interquartile range)

1 Weeks post-delivery for postpartum visit, 2 AUC: area under the curve, 3 GDM: Gestational diabetes mellitus, 4 IADPSG: International Association for Diabetes in Pregnancy Study Groups, 5 HOMA-IR: Homeostasis model of insulin resistance, 6 CIR_{30}: Corrected insulin response at 30 minutes.
a. $p \leq 0.05$ vs visit 1, b. $p < 0.01$ vs visit 1, c. $p < 0.05$ vs RC

Table 7. 4. Delivery outcomes by study group.

	Regular care (RC) (n=24)	**Lifestyle intervention (LSI) (n=26)**	**p-value**
Maternal outcome			
Preterm labor	2 (8.3%)	3 (11.5%)	0.99‡
Delivery by C-section	6 (25%)	5 (19.2%)	0.74
PIH/ preeclampsia[1]	5 (20.8%)	3 (11.5%)	0.46‡
Infant outcomes			
Breastfed	12 (50%)	15 (57.7%)	0.43
Sex*			0.33
Male	10 (40%)	13 (48.1%)	
Female	15 (60%)	14 (51.9%)	
Infant birth weight (g)*	3258.56 (368.33)	3297.11 (445.52)	0.74
Low birth weight[2]	1 (4%)	0 (0%)	0.48
Apgar score			
1 minute	7.29 (2.37)	7.16 (2.06)	
5 minutes	8.75 (0.68)	8.72 (0.54)	
Low Apgar (<7), 1 minute	3 (12.5%)	1 (3.8%)	0.35
Jaundice			
Yes	2 (8.3%)	2 (7.7%)	0.99‡
No	22 (91.7%)	24 (92.3%)	
Large for gestational age[3]			
Yes	1 (4.2%)	1 (3.9%)	0.99‡
No	23 (95.8%)	25 (96.2%)	
Macrosomia[4]			
Yes	0 (0%)	1 (3.9%)	0.99‡
No	24 (100%)	25 (96.2%)	
Shoulder dystocia			
Yes	1 (4.2%)	0 (0%)	0.48‡
No	23 (95.8%)	26 (100%)	
Respiratory distress syndrome			
Yes	3 (12.5%)	1 (3.9%)	0.34‡
No	21 (87.5%)	25 (96%)	
Any adverse delivery outcome	13 (54.2%)	10 (38.5%)	0.39

Data presented are means (SD) for continuous variables or n (%) for categorical variables, unless otherwise noted. p-values are based on student's t-test for continuous variables and Chi-square test for categorical variables, unless otherwise noted. *n=25 for RC, 27 for LSI for infant birth weight and sex, ‡ Fisher's exact test for categorical variables. 1 PIH: Pregnancy-induced hypertension, 2 Low birth weight: birth weight < 10^{th} percentile for gestational age, 3 Large for gestational age: birth weight > 90^{th} percentile for gestational age

Table 7. 5. Odds ratios (ORs) and 95% confidence intervals (CIs) for the effect of the intervention on selected study outcomes.

Outcome	Adjusted OR	95% CI
GDM (IADPSG)[1]	0.56	0.05, 5.7
Meet (or below) IOM recommendations for GWG at delivery[1]	0.15	0.02, 1.21
Adverse delivery outcome[2]	0.28	0.03, 2.49

GDM: Gestational diabetes, IADPSG: International Association of Diabetes in Pregnancy Groups criteria for GDM diagnosis, GWG: gestational weight gain, IOM: Institute of Medicine.
1 Adjusted for: Prepregnancy BMI, age, gestational age at recruitment, gravidity, education status, employment status, gestational week at time of measurement, and smoking status.
2 Adjusted for: Prepregnancy BMI, age, gestational age at recruitment, gravidity, education status, employment status, gestational week at time of measurement, and smoking status, and history of Cesarean section.

CHAPTER 8. QUALITATIVE EVALUATION OF A LIFESTYLE INTERVENTION DURING PREGNANCY FOR LOW-INCOME OVERWEIGHT/OBESE WOMEN

Introduction

In the latest report on the guidelines for weight gain in pregnancy, the Institute of Medicine (IOM) recommends individualized attention to gestational weight gain by health care providers (127), including tracking weight through a weight gain chart, as well as consultation with a dietician and health advisor for improving lifestyle measures such as diet and physical activity. The report also highlights the need for focused attention on low-income and minority women, who may be at greatest risk for both adverse pregnancy outcomes and worsened lifestyle factors. Yet a significant proportion of women report either never having received this advice or having received the wrong advice during their pregnancies (211, 212). Several intervention studies have focused on limiting gestational weight gain and ameliorating blood glucose metabolism during pregnancy by methods of a lifestyle intervention (117, 138-145, 148, 184, 185, 200, 202, 213). However, these studies have conflicting results. What is more, despite this call for action by leading organizations, few studies have focused specifically on this problem among low-income minorities. The current literature shows a dearth of information for guiding such interventions in the most under-served communities, where participants might benefit the most from such services.

To address these issues, we conducted a pilot randomized controlled clinical trial utilizing mixed methods research to assess the feasibility of implementing a lifestyle intervention during pregnancy among overweight and obese urban Black women.

Quantitative findings from this study have been presented in the previous two chapters. In this chapter, we present qualitative data from semi-structured, in-depth, one-on-one interviews with women who received the intervention, detailing their experiences with the intervention program. We chose to conduct a *qualitative* evaluation of the program components and acceptance by participants to gain a more detailed account of participant experiences in order to fill the current gaps in the literature for this important -- yet underrepresented -- population, as well as to inform methods for future lifestyle interventions for similar populations.

Methods

Healthy Moms, Happy Babies: A Lifestyle Intervention during Pregnancy

The Healthy Moms, Happy Babies study was a pilot randomized controlled feasibility trial for women receiving prenatal care at Grady Memorial Hospital in downtown Atlanta, GA. Grady is the largest hospital in the state of Georgia and serves as *the* public hospital for residents of the metropolitan Atlanta area. Details of the trial have been described previously in Chapters 5, 6, and 7. The study was approved by the Emory University Institutional Review Board and Grady Memorial Hospital Research Oversight Committee, and is registered at clinicaltrials.gov (identifier: NCT01084941). It received assistance from the Atlanta Clinical and Translational Science Institute (ACTSI), as well as the Emory University Race and Difference Initiative.

The Healthy Moms, Happy Babies trial enrolled women who self-identified as Black/ African American, who were < 20 weeks into their pregnancy, and who were considered overweight or obese (body mass index [BMI] $\geq$25 kg/m^2 based on self-reported pre-gravid weight and height), with no prior history of diabetes. In all, 187 of

1147 women screened for inclusion into the study (15.9%) passed screening criteria. Of these 182 women, 57 (31.3%) returned for baseline testing and were enrolled into the study. They were randomized to receive either regular standard of prenatal care as offered by the hospital (n=29), or a lifestyle intervention (LSI) program consisting of monthly one-on-one health education sessions focused on improving dietary intakes and increasing physical activity in order to meet recommendations for gestational weight gain (n=28). More information on the LSI program curriculum is presented in Chapter 5. All women were followed for the duration of their pregnancy, until six weeks post-delivery, at which point the final study measures were collected.

The aim of our research was to evaluate the LSI program; therefore, we invited all participants enrolled in the LSI program during their pregnancy (n=28) to return for an in-depth interview following the delivery of their infant, during their final study visit. Of the 28 women who were enrolled in the LSI program, 18 women were reached by telephone or mail following the delivery of their infant, and scheduled for an interview. Five of these women did not present for their scheduled interview, and were not able to be reached to re-schedule, resulting in 13 women who participated in the interview. The interview occurred, on average, at 6-7 weeks post-delivery. The average age of women interviewed was 26 years (range: 19-34), and for 7 women, this was their first pregnancy (number of previous pregnancies ranged from 1 to 8). The women's education levels ranged from grade school to some college, with 7 women having at least a high school education or more. Most women reported receiving assistance from both the state's Medicaid program, as well as the Women, Infants, Children (WIC) program. The

average BMI of women interviewed was 34.8 kg/m^2 (range: 26-44), and most women (10 of 13) reported a family history of diabetes.

Data collection and preparation

Each participant was consented individually, and provided a copy of consent for her records. Multiple attempts were made to schedule interviews with women who remained in the study but did not return for their study visits. Women were offered the choice of completing the interview in-person or over the phone, during their final study visit or at a later time, at the hospital or in a more convenient location. We welcomed participants to bring their child/ren for their interview. All women opted for in-person interviews; for 12 women the interview was conducted at the hospital in a quiet, private office, following their final study visit, while for one woman the interview was conducted at a later date at a quiet location more convenient to her home. Each interview lasted 45-60 minutes, and each participant received a $25 Visa® gift card for her participation in the interview.

Questions for the interview guide were piloted and revised over several iterations; the final version can be found in Appendix 3. The semi-structured interviews used open-ended questions with extensive probing, as well as specific questions geared toward specific program components. Because recruitment for the overall study was low, we asked participants to describe their motivation for participating in and continuing with the study. Additionally, to evaluate the LSI program and the curriculum presented through the program, participants were asked to describe their experience with the LSI program, including what they liked and did not like about the individual program curriculum components, as well as the program delivery; what they felt they gained by participating

in the program; and finally their recommendations for improvement of the program curriculum and structure. The order of questions followed the LSI curriculum structure, and participants had access to program materials to refer to during the interview. Both interviewers for the study were trained in qualitative data collection and were not affiliated with any other aspect of the LSI program, in order to avoid bias in participants' responses. Interviewers were specifically trained for the purpose of this study over two sessions, each session lasting three hours in length. All interviews were digitally recorded with the participant's permission and field notes were taken by the interviewer. Interviews were transcribed verbatim by the interviewer, and typed transcripts were cross-referenced with the recording by the author of this dissertation. When necessary, the interviewer and author of this dissertation discussed discrepancies between the typed transcript and recording, and consulted an outside party if agreement could not be reached.

Analysis

Our evaluation of the LSI program involved a thematic analysis, based on themes identified in the interview responses. All transcripts were de-identified and entered into MaxQDA 2007 software (VERBI Gmbh, Berlin, Germany) for analysis. We conducted concurrent data analysis during data collection to develop emerging themes and inform or refine questions for the interview guide. After several readings through transcripts, we noticed similar themes emerging between respondents with regard to motivation for participation, as well as perceived benefits from participation in the LSI program. We used these themes to create inductive codes from the data, and searched the data to arrive at a thick description for each theme based on participants' responses. We verified these

themes by comparing across respondents. Additionally, we also utilized deductive codes from specific questions on the interview guide; thus, our final codebook incorporated both inductive and deductive codes. We continued searching for codes until a point of saturation, which we reached through the 13 interviews, as evidenced by no new ideas emerging from the transcripts. The author of this study coded each transcript line-by-line using the codebook of inductive and deductive codes. To assess the reliability of both the coding and the codebook, we assessed inter-coder agreement (ICA) using MaxQDA, which assesses simple agreement between coding of two independent coders. Our initial ICA value was 67%; further refining of the codebook led to an ICA of 92%.

Results

Our findings from this evaluation study were that overall the LSI program was well-received by the participants interviewed. Women reported enjoying coming to their monthly sessions, and having learned information about healthy eating and physical activity during pregnancy, as well as focusing their attention on weight gain in pregnancy. We now spend more time on the specific findings from the evaluation.

<u>"I wanna be healthy for the baby, and myself as well": Motivation for participation</u>

Participants provided a variety of responses regarding their desire to join the study, explaining what they hoped to gain by participating. All women saw the program as a way for them to "be healthy" during their pregnancy, describing three components to their concept of being healthy: weight, eating habits, and exercising habits. Their rationale for wanting to participate in the study (specifically, their desire to be in the LSI group) as a means to "be healthy" could be grouped into one of two categories: 1) as a

method of prevention, delaying problems related to health in the future; and 2) as a method of amelioration, identifying habits from the past that they wished to improve.

Prevention

Several women viewed their participation in the program as part of preventative health, to avoid an adverse health outcome during pregnancy, at birth, or post-delivery. These women identified feeling at risk for something negative happening unless they took action, and utilized the program as way to lessen this perceived risk. An example of this can be seen in a woman's response regarding her risk for gestational diabetes:

"I know I'm at risk for gestational diabetes, or something of that nature, because of my race, so wanted to learn steps to improve my own health." (GWG042)

Almost all of the women interviewed who had had a previous pregnancy (5 of 6) identified their weight gain in a previous pregnancy as a motivating factor for participation. For several women, their experience with weight gain in a previous pregnancy was unpleasant -- i.e., they gained more weight than desired or anticipated, and once gained, they were not able to lose the weight -- and they wanted to prevent this from happening again with this pregnancy. These women mentioned having gained between 20-80 pounds in previous pregnancies, and all but one voiced frustration with not being able to lose that weight before beginning their current pregnancy.

In addition to their struggles with weight gain, two of the participants with a previous pregnancy also experienced an adverse health event during a previous pregnancy (i.e. hypertension) that they felt was associated with their health behaviors at

that time. Their concern for that adverse event happening again in this pregnancy, and desire to prevent this from occurring, influenced their decision to participate.

For other participants, it was not their own experience during a previous pregnancy but the pregnancy experience of a friend or family member that motivated them to join the program. For example, some participants described unhealthy eating behaviors of friends and family members during their pregnancies (e.g. unhealthy foods, large portion sizes); as recounted by one participant, seeing her pregnant friend eat a large milkshake every day made her scared to think what would happen to her during her own pregnancy. For other participants, witnessing a friend or family member's experience with weight gain during pregnancy was motivation to join the program. This is exemplified by the following quote from a participant for whom this was her first pregnancy:

"I was scared when I was pregnant, that I'm gonna gain too much weight… this was my first baby, but this happened with my sister. And so I was worried that, she was much more slimmer than I was, and so… okay maybe this was going to be a big problem for me, so that's why when she told me about it, oooh okay, oh okay this would be a nice thing to do... So that's why I participated."(GWG030)

Family history of disease was also mentioned as a motivating factor for preventative health measures. For women who identified this as a motivating factor, seeing what family members must endure to deal with such conditions as diabetes, hypertension, and heart disease contributed to their desire to prevent the same from

happening to them. Several women stated their increased risk of specific health conditions, because they "ran in the family". These women saw participation in the program as a means for preventing developing this condition themselves.

Amelioration

Other participants identified their participation in the program as a means for amelioration, specifically related to health behaviors. Several women identified poor eating habits and/or physical activity practices before becoming pregnant. These habits included frequently eating outside of the home, especially fast food, not eating fruits and vegetables, "overdoing it" with large food portions, and "being lazy" by not engaging in physical activity. These participants expressed a desire to ameliorate these behaviors specifically during pregnancy, in an effort to better provide for the baby. Two women specifically mentioned that pregnancy was a special time to focus on improving health behaviors, maybe not so much for her benefit, but definitely for the baby's benefit, as detailed below.

"I didn't really pay attention to it when I wasn't pregnant, 'cause there wasn't a baby… I didn't have to eat healthy if I didn't want to." (GWG040)

Other women expressed their desire to ameliorate their current body weight status as motivation for joining the program. These women felt unsatisfied with their current weight status, and wanted to learn ways to improve it. Three women identified specifically their desire to lose weight and wanting to learn how. Two of these women attributed some of their current weight to weight retained from a previous pregnancy; for

the third, this was her first pregnancy. One additional woman mentioned that she had been told by her doctor she was "a little overweight", and that this had heightened her awareness of her weight status, and desire to change it. For these women overall, participation in the program was a means to improve some underlying weight issues they were experiencing before becoming pregnant. One woman describes her experience leading up to her pregnancy here.

"I wasn't actually just sayin' "I'm about to lose this weight" "I'm just fat…" I just thought about it… Sometimes, different points of my life where I look at myself and say, "Hold on now…" You know. I see, I see other people with this stuff, and I don't want this... on me."(GWG051)

"I learned more about me, my weight, and what I need to eat": Unique opportunity for education

Participants named several perceived benefits from their participation in the program. When asked about the individual program sessions, every participant identified learning something from their attendance at program sessions, and that the program provided them with education on specific topics. For many women, this included learning about their weight gain in pregnancy, specifically how much weight gain was appropriate for them and whether or not they were meeting recommendations for their gestational weight gain. Many women referred to the program-specific weight gain chart as a helpful tool for learning this. Importantly, participants' responses also indicated that the topic of weight gain during pregnancy was not commonly discussed as part of their prenatal care outside of the program. When probed on how or where they learned about

their weight gain in pregnancy, respondents largely referred to the program, and not to anything their doctor had said or provided. Only three women mentioned talking about weight gain with her provider, and that when this was brought up, it was only discussed superficially. One woman mentioned that her doctor brought it up once, but that she "did not go into detail" on her appropriate weight gain. Another woman showed agreement with this, recounting that her doctor told her "not to eat," as she would "get really big."

In addition to learning about appropriate weight gain in pregnancy, respondents indicated that they learned more about foods through the program, specifically 1) foods to avoid during pregnancy and 2) healthy eating options. According to interview responses, these were novel factors for several women, topics not covered as part of their regular prenatal care or in other facets of life. For some women the program provided them with initial education on which foods to avoid during pregnancy (e.g., specific fishes and cheeses not recommended for pregnant women to consume). For other women, who identified knowing the foods to avoid during pregnancy, the program provided more detailed information on these foods. For example, two women acknowledged their awareness to avoid fish during pregnancy, but through the program learned what <u>specific</u> fish (and <u>how much</u> of each) she should or should not eat. For these women, the program provided an educational resource for specific dietary recommendations in pregnancy.

Respondents also indicated that the program taught them about healthier eating options in general. When discussing this, respondents identified that they were made more aware of the vitamins and nutrients in different foods, and the importance of these for themselves and their babies, through the program lessons. Many women noted that

they were not aware of “the choices” available to them for eating healthy, whether when preparing their own food or eating out in a restaurant, until receiving this information from program lessons. Some women specifically identified the utility of learning how to read the nutrition label as a result of the program, and that this learned skill contributed to their knowledge of “choices” for healthy eating.

Overall, from participants’ responses, it was clear that both the level of education provided by the program and the topical information therein was not something that was discussed during doctor’s appointments, or at any other point in their prenatal care; rather, participants identified the material as being unique to the program. All women interviewed mentioned that a positive component of the program were the visuals it provided, and that these were a huge aid for their learning comprehension. One woman’s recounted her experience with the weight gain chart, saying:

“The chart was helpful, because I could see where I was in the process, and how I was doing, and it was better than just telling me numbers, but showing me good or bad or something else.” (GWG051)

For many women, the educational aspect of the program was important not only for their benefit, but also for the benefit of other family members and friends. They engaged in knowledge sharing, utilizing the information they learned through the program lessons to teach others. Many women identified a sense of empowerment gained from the information they learned from the program, because they were able to share this information with others. One participant’s experience with this is highlighted here.

"Now I can tell other people… because I'm learnin' and givin' at the same time. Givin' people advice and good information. The same way as you're givin' and I'm receivin', and it's just like, y'all are helpin' me, and I'm helpin' others." (GWG054)

For other women, the information covered by the program was empowering for them not simply because they could share it with others, but also because it was a unique opportunity that other women (whether during pregnancy or not) did not have access to. They relayed gaining a sense of empowerment from telling others about their monthly meetings with a nutritionist, in such a setting as the public hospital where they were receiving their prenatal care, and that the program was important to them because it set them apart from others' experiences during pregnancy.

"Before I was pregnant… I was just totally lazy": Self-perceived behavior change

All women identified at least one perceived behavior change as a result of participating in the program, often times as a result of something they reported learning. For several women, these reported changes in behavior were a result of setting weekly or monthly goals for healthy eating and/or physical activity. As with the visuals, this goal-setting component of the program was mentioned as a unique aspect that they did not encounter anywhere outside of the program. Several women identified the utility of goal-setting for either dietary or physical activity changes. In many cases, this aspect of the program provided motivation for behavior change, including increased consumption of healthier foods as well as time spent in physical activity. Setting goals, and writing them

down in their journal, held participants accountable for behavior change and provided motivation for inducing change. Participants reported using goal-setting to aid in cutting back on their consumption of fried foods and sugary beverages; increasing their consumption of fruits, vegetables, and foods with whole grains; and incorporating more time for physical activity into their day.

In addition to the educational components for behavior change mentioned previously (e.g. identifying healthier food options, interpreting a nutrition label), providing a tool for monitoring behavior was also helpful for participants' perceived behavior changes, especially regarding increasing time spent in physical activity. This was true specifically with regard to the pedometer that participants were given at the beginning of the program, to aid in tracking their physical activity by keeping a daily count of the number of steps walked. Almost all women spoke positively about the utility of the pedometer as a tool for increasing physical activity levels above what would have been "normal" for them. The pedometer was viewed useful as a visual cue, as well as for goal-setting purposes. Several women identified that having a visual cue of their physical activity achievement – as indicated by the total number of steps counted by the pedometer –provided continuing motivation to meet their goals, thereby increasing their physical activity. Participants identified feeling satisfied after reaching their goals, and encouraged to continue reaching their goals so in order to feel that satisfaction. They identified that the program leader was helpful for this; having to report progress toward their goals made them feel accountable for reaching them. Some participants also identified that they felt challenged to meet program goals, thereby affecting their

behavior. A participant's positive experience with goal-setting through the pedometer is provided here.

"It let me keep an eye on what I was doing… as long as I did the 5,000 steps, then I was doing good… and, you know, when you get that 6,000 you're like, 'Wow! I did really good today!'" (GWG012)

"The program helped me deliver a healthy baby": Participation essential for change and pregnancy well-being

An additional theme from participants' responses that we identified as a perceived benefit from participation was a feeling of the program being essential to their health. For example, when women described their perceived behavior changes – either adoption of healthy behaviors, or abstention from unhealthy behaviors – they usually attributed these changes to their participation in the program. In these situations, women indicated that no change would have occurred had they not participated.

"Well, I used to walk to my friend's house, like before pregnancy… but now we would take longer distances, like I would walk to her house and we would walk to the mall, and then we would walk to her house and then we'd walk back home. So I don't think I would've stretched it out, and been like, 'Oh, I'm tired…' and walk up there and then get on the bus. So I think it encouraged me to walk more." (GWG018)

Support

Though the program was not designed specifically to be a support group, several participants voiced feeling comfort or support from their participation in the program, and looked forward to coming to program sessions as a result. When probed further on

this aspect, this feeling of support arose as a result of communication with the program leader, as well as from the timing of program sessions. For many women, having a consistent person to talk with about the program topics – such as their weight gain and dietary and physical activity practices – as well as other issues during their pregnancy gave them a sense of feeling supported. Several participants identified their appreciation of having someone check in on them especially with the booster follow-up phone calls, to see how these issues were progressing with their pregnancy, and that this was something unique that the program provided. As one participant identified, the program was "like a second mom" for her because of this aspect. Other participants identified the timing of program sessions as essential in their feeling of support. This involved both the flexibility of scheduling and re-scheduling missed appointments, as well as taking extra time in addition to the allotted time for answering questions specific to the participant. Women voiced appreciation for the program to make things, "all about her," and for many women this provided them with a feeling of support.

"It was kind of like a support group… a blessing to me, because sometimes you cannot talk to the doctors that much, they're rushing, but this helped me a lot. I mean, the doctors are rushing you. I'm not complaining that they're doing their job this way or that way, but this way, you know, you're not scared to ask, or you're not being rushed, it felt like it was just a good support for me." (GWG030)

In addition to this, several women attributed their pregnancy's overall "success" – e.g., delivery of a healthy baby, absence of any adverse pregnancy outcome, and sufficient amount of weight gained – directly to their participation in the program. These women identified having a healthy pregnancy as a result of healthier behaviors they adopted

during their pregnancy, which they attributed to the education they received from attending program sessions. Respondents overwhelmingly identified that they would recommend the program to other pregnant women, because of their perceived "successful" results (e.g., learning to be healthy, adopting healthy behaviors, and having a healthy pregnancy).

"It's like you're on a high and then somebody just drops you off:" Recommendations for improvement

Although respondents overall provided positive feedback on the program materials and their experience with participation in the program, there were recommendations for improvement. One key recommendation was to incorporate group meetings into the program structure. Many women mentioned that having the opportunity to meet with other pregnant women and discuss their experiences (e.g. struggles with achieving behavior change, and tricks to overcoming these struggles) would have been helpful for them. However, in every instance when this was mentioned, it was a suggestion in addition to the one-on-one meetings. As noted earlier, most women appreciated the one-on-one setting of program meetings because of the support they felt in meeting and talking with the program leader, as well as the personalization of timing allowed by the sessions, and they did not wish to sacrifice this for group meetings. Rather, they would prefer to have group sessions with other pregnant women in addition to the one-on-one meetings with the program leader.

Another suggestion that arose through interview responses was the need for program meetings during the postpartum period. For most women, their last program session was approximately two weeks before delivery; a follow-up phone call after

delivery was all they received before their six-week postpartum visit. Many women expressed the need for better follow-up after delivery on their behavior changes made during pregnancy, and this was viewed largely as a form of support. In some cases, like the one mentioned here, women felt that in the postpartum period they regressed on the behavior changes they made during pregnancy as a result of not having regular program meetings to attend.

"I mean, I actually wrote down something and said this is what I'm going to do, these are the things that I'm going to change… and I gradually changed those things but over time some of them have come back, without someone constantly checking me… and that's terrible because I'm grown, you know, I shouldn't need that… but it's like, "Mom!" She pushed me out of the next to fly!"(GWG012)

Discussion

Through our interviews with program participants we identified that the program was highly accepted by those women interviewed. Many women were motivated to participate in a program such as this because of a desire to either prevent a perceived adverse outcome from occurring or improve an identified "unhealthy" diet or activity habit. By attending program sessions, women conveyed their learning information on different topics such as gestational weight gain and healthy eating; changing of dietary and activity behaviors; and feeling of support for making behavior changes. It was apparent from interview responses that this program was unique in the information it provided to participants and the knowledge gained by the participants, as well as the

setting in which it was introduced. Participants also identified the usefulness of group meetings in addition to one-on-one meetings for presenting program material, and the need for increased follow-up meetings during the postpartum period.

Current research supports that there are two important factors contributing to long-term development of overweight and obesity in women: excess weight gain during pregnancy and failure to lose this weight after pregnancy (125, 126). For women in our study -- all of whom were either overweight or obese -- who had had a previous pregnancy, their personal experience with these phenomena were large contributors toward their decision to participate. Many women conveyed that a factor for their motivation to join the study was an experience with excessive weight gain in a previous pregnancy, and their subsequent inability to lose this weight before entering the current pregnancy. Similar findings from focus group discussions of low-income African-American women in Philadelphia, PA have previously been reported (214). Additionally, the responses suggesting more intervention for the postpartum period highlight the struggles that some women face with losing weight they gained during their pregnancy. These responses highlight the weight struggles that many women face surrounding their pregnancy, and the need for programs or interventions targeting these issues.

Despite a call for action for prenatal care providers to counsel women on appropriate weight gain during pregnancy (127), our participants indicated receiving little information on this topic from their prenatal care visits. The program was identified as their main source not only for information on appropriate weight gain in pregnancy, but also healthy ways of achieving that weight gain. Previous studies have shown that a high proportion of women reported receiving either no advice on how much weight to gain

during pregnancy or were advised to gain outside of the recommended range (211, 212). Moreover, interviews with prenatal care providers show several barriers for gestational weight gain counseling among providers, including insufficient training on nutrition, concern of approaching a sensitive topic (i.e., weight), and potential stress or negative emotions this may cause, and concerns for its effectiveness (215). Current IOM recommendations draw special attention to counseling on healthy gestational weight gain in low-income and minority women, as these women are at higher risk of being overweight or obese at the time of conception, consuming diets of lower nutritional value, and performing less recreational physical activity (127). Responses from our participants show little guidance from health care providers on appropriate weight gain, and methods to achieve this weight gain, as seen in previous research on low-income African-American women (214). Additionally, although access to healthy foods has frequently been identified as another potential barrier for lifestyle changes in underserved populations such as ours (188, 189, 216), in our interviews, only one woman identified that "eating healthier" was harder because of lack of access to or pricing of healthy foods. This is similar to findings from focus groups investigating risk factors for excessive gestational weight gain, in which two factors commonly associated with poor diet and obesity -- food insecurity and participation in food assistance programs – were seldom mentioned by low-income participants (156).

Findings from the interviews with intervention participants showed high acceptability of the intervention. The most successful components of the program were the visuals provided and goal-setting activities. This finding is well-represented in the literature on lifestyle interventions for pregnancy (149). Respondents identified several

components of the program that were both unique to the program and helpful for behavior change. The most effective program components were the visuals provided and the goal-setting activities conducted. Previous studies have shown these strategies to be effective for behavior change in pregnancy (149). Several women reported changing their behaviors (i.e., adopting healthier lifestyle) as a direct result from attending program sessions, as has been seen from other lifestyle intervention studies in pregnancy (217). All women would (or did) recommend the program to a friend or family member, showing the suitability of such an intervention for this population and setting.

Respondents also noted that a benefit of the program was the support they felt by attending program sessions, largely due to communication with the program leader, indicating that they might not have been receiving this support in other facets of their lives. Some women even expressed a sense of empowerment gained from the study sessions. This has been observed elsewhere, where women receiving diet counseling in pregnancy expressed appreciation at encouragement of eating healthy (217). It is also possible that participants interpreted this communication as a type of coaching, thus their identification of feeling support from coming to program sessions. In other settings, coaching has been proven an effective tool for inducing behavior change specifically related to physical activity (218, 219).

Many women identified that a benefit of the program was the education it provided and the subsequent behavior changes they made as a result. As we highlighted in a previous chapter, women in our program were at very high risk for adverse pregnancy outcomes because of their engagement in risky behaviors (i.e. smoking), BMI status, dietary quality, and poverty level. Several previous studies on lifestyle

interventions during pregnancy incorporated populations with very different background characteristics (117, 138-143, 145, 148, 185, 200, 202). The fact that several of our participants identified making behavior changes solely from their participation in the program is promising for the design of future interventions in this high-risk group.

We acknowledge several limitations to our study. First, our sample was a convenience sample of women who had participated in the program and returned for their postpartum visit. Of the 28 women randomized to receive the intervention, only 14 returned for their postpartum study visit. We were able to interview 13 of the 14 women who returned for this visit. It is possible that the women who returned for the postpartum visit had a different experience than those women not returning for the visit, so the responses analyzed and presented here might not be representative of the intervention group as a whole. Despite many efforts to contact those participants who did not return, for at least 6 months following their delivery, we were not able to locate several of these missing women, so have no way of knowing their experiences with the program. Additionally, the questions for the interviews were limited in their scope to exploring participants' perspective of the acceptability and usefulness of the program. We did not specifically elicit responses on more general factors such as participants' views on physical activity and healthy eating during pregnancy. Including questions where these issues may have been answered could have provided a more complete understanding of how and why the program worked or did not work for the individual woman, and offer better insight into improving program components for similar populations. However, this also would have increased the time spent for each interview, therefore increasing participant burden. Finally, we did not interview participants in the study who were

allocated to the regular care group. Knowing their experiences through pregnancy could have helped better identify and isolate program components that contributed to the greatest behavior change between the two study groups.

Conclusion

We have presented qualitative data evaluating the acceptability of a lifestyle intervention program during pregnancy in an underserved population. While several trials have looked at the efficacy of lifestyle interventions during pregnancy, we are one of few to have examined the feasibility or acceptability using qualitative practices. Additionally, this is one of few studies to investigate these issues in a low-income, overweight/obese minority population. Our findings support that such a lifestyle intervention can be successfully implemented in a high-risk population, and be well-received by program participants. Women participating in our intervention perceived the intervention not simply as acceptable, but also as helpful and essential for both the health of their pregnancy and infant. These results can be used to help design successful intervention in populations at high risk for adverse pregnancy outcomes.

CHAPTER 9: SUMMARY AND DISCUSSION

Summary of findings

In our presentations herein, we highlighted two important factors to consider in the realm of glucose metabolism in women of childbearing age: 1) the underlying disparities by race/ethnicity in dysglycemia among women of childbearing age; and 2) the feasibility of a lifestyle intervention for prevention of GDM in a high-risk, disadvantaged urban population. Our findings illuminate issues affecting these two very important populations, and can provide insight into the design and development of interventions to improve health outcomes not only for women today but also for future generations.

In Chapter 5, using results from national surveys from 1999-2008, we showed that nearly 1 in 5 U.S. women of childbearing age is affected by some form of abnormal glucose tolerance. While disparities by race/ethnicity were evident, these appeared to be restricted to those women who were of normal BMI; the prevalence of dysglycemia did not vary by race/ethnicity among obese individuals. Although both minority race/ethnicity and overweight/obesity are identified risk factors for diabetes, among obese individuals in this young age-group we saw no increased prevalence of dysglycemia for minority women when compared with non-Hispanic white women. In other words, contrary to previous literature (220, 221), we found that disparities by race/ethnicity in abnormal glucose metabolism was not explained by the obesity of the individual, rather by differences existing among women who were normal weight or less, according to either BMI or waist circumference. Research interventions for diabetes

prevention have typically focused on high risk individuals, including older, overweight or obese men and women (98, 101). Obesity is a known contributor to insulin resistance because of its inflammatory properties (222). However, in non-obese states we saw increased dysglycemia in minority women compared with non-Hispanic white women, indicating that within this group, insulin resistance may not be the lead contributing factor to racial and ethnic disparities in dysglycemia prevalence. Further research into insulin sensitivity measures as well as beta-cell function should be incorporated for further elucidation of driving forces behind these disparities in dysglycemia. Additionally, regardless of BMI, our findings highlight the need to divert attention from strictly overweight/obese population to incorporate normal weight women – from a clinical perspective, attention to identifying risk factors for diabetes not only in overweight/ obese individuals, but also in those in a lesser risk category (i.e. normal weight), and from a public health perspective, interventions of diabetes prevention incorporating this specific risk group.

These findings are also of interest in light of our findings from a lifestyle intervention for pregnancy in women at high-risk for GDM, as depicted in Chapters 6 and 7. Despite our strictly overweight/obese minority population, we experienced better measures of glucose metabolism during pregnancy than expected, according to previous studies. Only two of our total participants with available midpregnancy data (4.1%) were diagnosed with GDM by current methods of assessment, compared with estimates seen in previous studies of 3.9-9.8% for overweight/obese African American women (39, 43). Levels of self-reported physical activity were also far greater than expected. Reported caloric intakes were lower than previously published for similar populations, though

dietary indices showed a high-fat, low-nutrient dietary make-up. We did not see improved GWG in women receiving the lifestyle intervention; rather, women in the LSI group were more likely to gain weight in excess of the IOM recommendations for gestational weight gain. However, despite not affecting weight change through lifestyle intervention, we did notice slight differences in glucose metabolism and insulin sensitivity, specifically at the 30 minute timepoint. Overall, women receiving the lifestyle intervention showed a trend toward lower glucose AUC and improved HOMA-IR at their midpregnancy visit compared with women receiving regular standard of care.

In Chapter 8, through analyses of in-depth interview responses, we showed that women who received the lifestyle intervention and returned for their postpartum visit overall found the intervention program to be very acceptable. They were willing to participate in the research program out of concern for preventing an adverse outcome from occurring during their pregnancy. Many women also identified a diet and/or physical activity behavior they wished to improve, and expressed their success at doing so as a result of their participation in the program. The educational components were helpful for affecting behavior change, as were activities that involved goal-setting and direct monitoring. Women reported feeling a sense of support from coming to the program sessions, largely due to open communication with the program leader and flexible timing of the program sessions. While not an opinion held by every respondent, several participants expressed a desire to interact with other women during their pregnancy, and suggested incorporation of group sessions for this purpose. Additionally, many women expressed the need for such a program – providing education and support –

for the postpartum period, to help keep up with behavior changes made during pregnancy.

We centered our feasibility study on the concept of GDM prevention. However, the nation's health care system is in a state of flux regarding screening and diagnosing GDM. One major criticism of the adoption of the IADPSG criteria, as mentioned in Chapter 2, for GDM diagnosis is the increased burden it presents to the health care system, as more women have the potential to be diagnosed with the condition. Even within our small sample, we noticed an approximate 3-fold increase in GDM prevalence using IADPSG criteria compared with standard criteria. This is consistent with findings from other studies (32-34). In a setting such as ours, where the first-line treatment for GDM – diet and physical activity – may be difficult to implement, this has huge implications for the health system and services, as more women will need to receive these services. Although self-report levels of physical activity were high, we observed a very poor quality of diet within our participants. Previous studies highlight underreporting of caloric intakes during pregnancy, particularly among overweight and obese women and women with lower educational levels (223). Even still, we found much lower levels of energy intake than previously published results for similar populations (138, 223) . Moreover, the diets characterized by our participants were of very low nutrient value and very high fat content, with almost 35% of total energy coming from fat, a figure well on the upper end of current recommendations (224). Significantly affecting diet, as necessary for GDM treatment, may be harder to achieve in populations such as ours, and will require more directed advice.

However, we have shown that a lifestyle intervention can be successfully implemented within this setting, despite unique barriers affecting our population (outlined below). What is more, even though self-reported measures of dietary intakes did not show significant improvement in women receiving the intervention, there was indication of more women meeting guidelines for physical activity, as well as improved glucose metabolism and reduced occurrence of GDM. Participants receiving the intervention spoke very highly of the knowledge they gained from the program, the perceived behavior changes they made as a result of participation, and their overall experience going through the intervention. Most notably, participants identified that the information covered by the program was unique, and not included within other facets of their prenatal care. Although leading medical organizations recommend counseling on gestational weight gain through regular prenatal care visits, including referrals for dietary and exercise education, studies have shown that a significant proportion of women report having not received this information, or having been misinformed on appropriate gestational weight gain (211, 212, 225). Our findings present a feasible way to incorporate this education as part of prenatal care services in an underserved population.

Previous studies on lifestyle intervention in pregnancy have focused on primarily Caucasian populations (142, 144-146), non-obese women (141) , and populations of high or mixed socio-economic status (138, 145, 185). Populations such as ours are not well-represented in the published literature. However, the most recent IOM recommendations for weight gain during pregnancy highlight the need for focused attention on low-income and minority women for intervention studies on gestational weight gain, as these women are at risk of being overweight or obese at the time of conception, consuming diets of

lower nutritional value, and performing less recreational physical activity (127). Our experience therefore is promising, as our findings indicate real opportunity for lifestyle intervention within a difficult population.

Strengths and limitations

Strengths

We identify several strengths to our studies. For our epidemiological study we were able to incorporate a large sample size, representing over 50 million women of childbearing age over a 10-year period. This population and these measures are not well-represented in the literature. Additionally, for this analysis we used not only self-report measures but also laboratory measures for diagnosing diabetes and prediabetes. We also utilized rigorous statistical analyses to capture the true burden of dysglycemia in women of childbearing age.

Our clinical trial of a lifestyle intervention for pregnancy incorporated another population that is often overlooked by the literature. We utilized rigorous, real-time methods for measuring diet and physical activity. Our multi-point OGTT provided estimates of glucose metabolism during pregnancy – both in early pregnancy and at midpregnancy – and postpartum, at a level not often seen in similar-sized studies. We collected information on several maternal and fetal outcomes, and were able to utilize electronic medical records for these measures, therefore not relying on self-report. Finally, we utilized a mixed methods approach, providing both quantitative and qualitative outcome data to better assess the intervention's feasibility in this setting.

Limitations

We also acknowledge several limitations to our studies. First, regarding our NHANES analysis, we did not include information on diet or physical activity for the prediction of our outcome, dysglycemia. Including measures of these lifestyle factors may have shed additional light on disparities by race/ethnicity. Additionally, the use of BMI (and waist circumference) may not have effectively captured body weight status. BMI has often been criticized as a crude measure for body weight status and not truly reflective of the underpinnings of obesity that are contributing to adverse health outcomes. A better measure might have been percent body fat.

Regarding our feasibility study, we required additional time to recruit subjects than initially planned. This was as a result of difficulty with scheduling participants for their initial study visit, for reasons to be discussed in the next section. We observed that of all women screened, only ~30% were willing to participate and make their baseline visit. Additionally, we saw relatively high levels of loss to follow-up at the postpartum visit. In some cases we were able to supplement data using information from the medical record, thus improving our loss to follow-up rate; however, for our main outcome measures of physical activity and diet, we saw ~50% lost within the intervention group. Also, our regular care group was not a true control group, as they received at least some level of intervention. From the interviews, most women identified that they did not receive information on healthy eating or physical activities during their previous pregnancies. The fact that our regular care group received any educational materials, even in the form of a pamphlet, was therefore above anything provided through standard care at the clinic. Previous studies on lifestyle interventions during pregnancy have

shown that even information provided through pamphlets is sufficient to achieve change in behavior (194).

Additionally, as mentioned by women in the interviews, a perceived benefit from the intervention program was the support that participants received from meeting with the program leader. Participants in the regular care group were exposed to the same leader, just not at the same frequency; however, they did visit with the leader at least twice before their return for their midpregnancy visit. They were also able to call and visit the program office if desired. Therefore, it is likely they could have received a residual effect of the intervention simply by having a consistent contact for the study, and knowing they were being monitored for their behaviors during their pregnancy. This level of contact may have been sufficient to impact behavior change. Finally, our sample is very specifically composed of overweight/obese, low-income Black women, living under difficult conditions; therefore our results may not be generalizable to other populations or in other settings. We were not able to determine if an intervention such as ours would be as effective – or, perhaps, more effective – in less difficult circumstances.

Contribution to public health

National estimates show that 1.85 million women of reproductive age are currently living with diabetes; about 500,000 of these women – or, 27% -- do not know they have the condition (30). In addition, we have shown that almost 20% of all women of reproductive age have some form of dysglycemia, increasing their risk for adverse health outcomes over the course of their lifetimes. Compared with men, women on average have far more contact with the health care system over the course of their lifetimes, a result of increased health care needs especially during the reproductive years.

Although women are just as likely as men to be uninsured, they are more likely to fall into financial trouble as a result of health problems and inability to cover health care costs. New provisions under the Affordable Care Act will make health care for women – especially women of reproductive age – much more accessible. Our findings highlight the need for increased screening for altered glucose metabolism among women of childbearing age. While the use of traditional risk factors for screening – e.g., BMI – may prove effective for some populations, our analysis of NHANES data has shown that these may not be suitable for all populations to recognize those at greatest risk. More work must be done to identify race/ethnic-specific risk factors that are not only clinically relevant but also easily measured to ensure the uptake of screening. Additionally, public health practices should incorporate targeted educational messages, especially for minorities, on their increased risk for diabetes, regardless of weight status.

Furthermore, our findings from a feasibility study for lifestyle intervention during pregnancy highlight the need for integrated education on improved lifestyle factors for under-served, overweight/obese women during pregnancy. Although these women are at the greatest risk for several adverse maternal and fetal pregnancy outcomes, they are often the most overlooked populations for directed interventions and educational programs. Future efforts should focus on better incorporation of this group in public health messaging and educational programs for healthy lifestyle practices during pregnancy in order to successfully affect change. Community-based programs can help to disseminate and reinforce these messages. Although further research must be done to identify the true efficacy of a lifestyle intervention during pregnancy within this population, findings from our in-depth interviews show that clinical practices would do

well to integrate education on healthy eating and physical activity practices as part of regular prenatal care services. As we have shown, these may have modest effects on lifestyle outcomes and measures of glucose metabolism in this high-risk population. Providing these resources and offering these opportunities to disadvantaged populations specifically may work well to help reduce health inequities that continue to plague the nation today.

Lessons learned for future studies

Barriers specific to population and setting

Findings from our feasibility study highlight the reality of the situation for our participants, as they face several barriers to care. Most participants were unemployed, living well below the poverty line, and obese or morbidly obese. A notable number were either current or former smokers. Most women were unmarried and lived in multigenerational households with their parents, grandparents, siblings or cousins. While approximately 1/3 were primiparous, many women were on their fourth pregnancy or more. Although not presented within this dissertation, several women voiced facing multiple hardships and stressors during their pregnancy, including domestic violence, court dates, incarceration, unhealthy home environments due to drugs and alcohol, and homelessness.

In many cases, these hardships negatively affected our ability to keep in contact with participants, particularly due to changing phone numbers. Georgia is one of nine states participating in the Lifeline/Safelink program (226) which provides cellular phone service to low-income individuals at a reduced cost. For many women, this phone was

their primary source for communication. Under the program, participants would pay a small fee and receive a cellular phone pre-loaded with a limited amount of minutes and text messages. Once those minutes/messages expired, it was up to the individual to 'reload' the phone. In many cases, when a participant's phone minutes expired, she would not have sufficient funds to pay to reload her phone. This most often resulted in the equivalent of a disconnected number, as no voice message could be left by the caller or received by the participants at this point. In several cases when this happened, participants would request for a completely different phone (and, therefore, phone number), constantly changing their point of contact number. It was helpful to have access to the clinic, to meet with women during their clinic visits in the case that this happened; however, this was not always possible, as participants would often times miss their clinic appointments, and in many cases it was not highly feasible for the time involved. Additionally, contact by mail was often times impossible as participants frequently changed residences during their time in the study; therefore, any correspondence by mail would be returned with no additional information on the addressee's current location. It helped to have information of an emergency contact, such as a mother, sister, grandmother, or boyfriend, in instances such as those described, though sometimes this resulted in the same outcome as for the participant herself.

Thus, many women participating in our study already began their pregnancies predisposed to unfavorable pregnancy outcomes. Their difficult lives above and beyond the study eligibility criteria created an environment conducive for increased stress and depression. This could have negatively affected our recruitment; as observed, only 30% of eligible women were "willing" to participate in the study, as exemplified by their

return for baseline testing. To truly have an impact on improving pregnancy and birth outcomes among disadvantaged women such as those in our study, there is a need to address the social and economic inequalities in which they live. As discussed in previous studies, psychosocial factors such as stress and depression are common among low-income (157), minority (158, 159) and obese (160, 161) women. Enduring multiple hardships, such as those mentioned previously, that might potentially lead to stress and depression is unfortunately common among low-income women. One recent study showed that 14% of low-income women reported enduring at least 4 stresses or hardships during their pregnancy (162), including domestic violence, smoking, poor diet, and homelessness. In addition, we observed a very poor dietary profile within our participants, in early pregnancy, midpregnancy, and in the postpartum period. Two important factors that may affect dietary quality are knowledge of and access to healthy foods. As indicated through the interviews, participants reported learning about options for healthy eating through the program sessions. For many participants, this was helpful for their perceived dietary improvements. When asked if they encountered any difficulties making these changes, only one participant indicated that a potential barrier for her was access to healthy foods, specifically due to the higher cost of healthy foods. This did not come up in other responses; in fact, another participant stated her realization that eating healthier was not as costly as she had thought prior to participation in the program. Thus, the first line of intervention for this group should focus on education, and include suggestions for improved access.

Finally, of note is that several of our participants who were lost to study follow-up were also lost to their regular prenatal care. A recent review of obstetric outcomes and

care show African American women at higher risk for poorer quality of prenatal care than non-Hispanic whites, i.e. late entry into prenatal care, and fewer prenatal care visits (192). We observed this as well, as a top reason for not meeting inclusion criteria was having a gestational age > 20 weeks, indicating that many women attending our clinic begin prenatal care mid-way through their pregnancy. As well, 9 of the 10 women who did not return for their midpregnancy study visit also did not return for their midpregnancy prenatal care visit. Future studies focusing on this and similar populations, implemented in a clinical setting, must consider these challenges.

Considerations for future studies

Based on our experiences of delivering a lifestyle intervention during pregnancy in an underserved urban population, we highlight points to consider for the use of designing a larger study within this setting.

- Enrollment criteria: We chose to enroll only women who were overweight or obese, as this population is commonly underrepresented in the literature for lifestyle interventions during pregnancy. However, the exclusion of normal weight women greatly affected our recruitment rate, increasing our time to meet enrollment goals. Additionally, normal weight women are also at risk for increased gestational weight gain, especially within minority populations. Our program curriculum incorporated lessons and activities that would apply to all women, regardless of their BMI, and specifically utilized individual goal-setting strategies. Therefore, we suggest future studies relax the BMI eligibility criteria to enroll normal weight, overweight and obese women.

- Recruitment techniques: We incorporated very active recruitment techniques. In addition to flyers in all of the patient rooms, clinicians' offices, and clinic waiting areas, we were on site to talk with patients and recruit participants at the clinic in person. We worked alongside the patient schedulers, nurses, and lab technicians to become a familiar part of the clinic setting. Although all clinicians were aware of the study and asked for patient referrals, this did not prove to be the most effective mode for recruitment of participants, as only a handful of participants were recruited by this method. Additionally, we found flyers not particularly effective for recruitment of participants; although several participants mentioned after enrollment into the study seeing flyers for the study posted in the clinic, only one participant was actually recruited by this method. Thus, the most effective technique for recruitment in this setting was by direct contact.
- Length of recruitment: Despite our rigorous efforts for recruitment, we required one year longer to recruit participants than anticipated, and still fell slightly short of our goal for recruitment. Based on our screening records, the majority of women did not meet screening criteria due to their gestational age; i.e. they were already mid-way through their pregnancy before starting their prenatal care. As previous studies have shown, when compared with other groups, our particular population is at increased risk for poorer antenatal care, including late entry into prenatal care services. Efforts to increase early entry into prenatal care for this specific group of women would not only improve recruitment efforts for interventions such as ours but also improve overall pregnancy outcomes. Additionally, better education for women during the prepregnancy period on such

topics as healthy eating, PA as part of every-day life, weight gain, as well as risks associated with increased BMI is necessary to truly reach this population.

- Scalability: We found that our intervention program was well-accepted by many of our participants. Additionally, we saw an indication of improvement in such health outcomes as glucose metabolism and insulin resistance during pregnancy, as well as improved delivery and birth outcomes. We feel a program such as the one implemented would be a low-cost addition to regular prenatal care services in this and similar settings. From our experience, offering a monthly, 30-minute to one-hour session focused on healthy eating, physical activity, and weight gain would augment current prenatal care services, without creating extra burden on the system. As many participants who were interviewed identified, just having an extra person to consult with and talk to about these topics was beneficial. Such sessions could be conducted in the waiting room, in group settings, or even via video/television.
- Participant-specific recommendations:
    - Communication: As previously mentioned, a barrier to working in this population was difficulty in achieving communication with participants. We employed a host of efforts to improve communication – and, therefore, retention of patients – including communication by phone, text message, hand-written cards, and face-to-face meetings. We were also familiar with many participants' emergency contact references, including mothers, sisters, and boyfriends, in order to keep in good communication with our participants. Additionally, we were available by phone or text

message outside of traditional business hours in case participants needed to call to schedule/reschedule or follow-up with study visits. Despite these efforts, we did lose contact with a sizeable number of participants by delivery, and especially in the postpartum period. One reason for this was a change in phone number, as described in the previous section. It might therefore be of benefit for future intervention efforts to offer phone minutes as an incentive for participation.

- Transportation: The majority of our participants relied on public transportation (i.e., bus or train) to travel to and from study visits. Our particular clinic is located three blocks away from a rail station, and there are 3 bus lines that serve the vicinity, so this proved very helpful for getting our participants to their study visits. Additionally, we provided compensation for these travel expenses. However, because several women did rely on public transportation, we were very flexible with study times to accommodate their transportation schedule (i.e., starting late if a participant missed her scheduled bus).
- Measurement of dietary/ PA indices: We relied on one 24-hour recall for measurement of dietary intakes. A more rigorous method would be to collect food records from participants; however, this would greatly increase participant burden, and from our experience does not seem highly feasible for this population. Another method of measuring dietary intakes, the food frequency questionnaire (FFQ) could also provide useful measurement of participants' dietary intakes. However, based on our

experience with the 24-hour food recalls – i.e., participants' inability to recall foods/ eating times, fatigue during interview, mis-perceived quantities of food consumed compared to actual measured values – the FFQ may also have its limitations in this population. Additionally, our measurement of PA was via a self-administered questionnaire, and we received higher levels of reported PA than previously published. While the pedometer provides a more accurate assessment of actual PA, and several participants report its utility for increasing time spent in PA, within our population it did not seem a highly feasible measure for PA, as many participants would fail to wear it, to bring it to their study visits, or to record their steps regularly.

- Pedometer: Additionally, although we provided a pedometer to every woman in the intervention group, we found adherence to its use to be rather low. In some cases, participants reported losing (or nearly losing) the pedometer as they were walking, because of the positioning of the pedometer clipped onto their clothing, particularly at their waist. Therefore this particular instrument and model might not have been the best choice for a pregnant woman. Additionally, a few women reported simply forgetting their pedometer when they would go somewhere; despite discussing techniques to help make wearing the pedometer a part of everyday life, this still posed a problem. Future studies should therefore consider the use of instruments – pedometers or accelerometers --

that can be worn like a watch, or attached to a shoe, to potentially increase adherence to usage.

- Tolerability of OGTT: Many participants reported nausea and vomiting during their pregnancy, especially during the first trimester. This affected uptake of the baseline OGTT, as four women were not able to complete the test due to their nausea. Two additional participants were required to re-schedule their midpregnancy OGTT due to nausea. Additionally, during the interviews, when participants were asked their least favorite part of the program, three responded the OGTT/ blood draws. Any future study must consider how these tests will affect participation and compensate for this in their methods. For some participants, ice chips aided in easing their nausea; for others, drinking the glucose drink through a straw prevented a feeling of nausea.
- Intervention content: Our intervention was very low-cost, and provided participants education on and encouragement for healthy eating and physical activity practices as part of everyday life. Participants identified having learned about healthy eating from the educational sessions provided by the program. However, we did not see a significant change in self-reported dietary intakes or PA over the course of the intervention. From the responses of interviewed participants, it is evident that education must be included as part of any future intervention program. However, in order to induce meaningful change, a more rigorous approach might be necessary, including time for monitored activity, as well as more frequent

meetings/ assessment of diet and physical activity, observed to be effective in previous studies (202) .Supportive environment: Participants also identified that they felt support from coming to program sessions. It is important to understand that many women in this population may be enduring multiple hardships (e.g. drugs, domestic violence, homelessness) that could affect her uptake of the program intervention. Future interventions should be prepared to deal with these programs, by providing a supportive environment and trustworthy leader, as well as referrals to outside professionals when necessary, to increase retention rates and program uptake.

- Flexible timing: We were very flexible with scheduling study visits, and this was a strength of the intervention, as noted by responses during participant interviews. Although most visits were scheduled along with the participant's clinic visit, we were very accommodating in the instance she needed to arrive late, leave early, or reschedule altogether.
- Central location: Our clinic was located in the heart of downtown Atlanta, and accessible by various methods of public transportation. Participants would come to the clinic regularly for health services, either their own, or those of a family member. This proved helpful for getting participants to their study visits. As noted by some responses from the interviews, the program offered by this intervention was very unique to the setting, and not expected to be seen within the services provided by our clinic. While this is encouraging, as it could indicate a way to set the clinic apart from

others in the area, it also may indicate a negative feeling surrounding care provided by the clinic. This may affect several aspects of an intervention program in similar settings, including recruitment, retention, and program uptake. Advertising and recruitment efforts therefore must consider the unique aspect of this program to a clinic such as ours, as well as overcoming a potential negative perception of the clinic to promote the intervention's potential benefits.

We trust that consideration of these factors, as well as the results presented in this dissertation, can aid in the development and implementation of interventions for GDM in high-risk, underserved populations, targeting those individuals who may need it most.

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APPENDIX 1. Gestational diabetes mellitus: taking it to heart

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Gestational diabetes mellitus: taking it to heart

Abstract

Globally, cardiovascular disease (CVD) accounts for 1/3 of all deaths to women. While much research identifies the increased risk in CVD associated with pre-diabetes measurements, there is growing interest in the role of gestational diabetes mellitus (GDM) – a condition of glucose intolerance diagnosed during pregnancy – as a potential CVD risk factor. This article reviews existing evidence supporting this association, particularly regarding GDM and type 2 diabetes, hypertension, atherogenic dyslipedmia, and CVD events. Finally, it discusses the research and clinical ramifications of identifying GDM as a CVD risk factor, highlighting the need for more rigorous research on this topic.

Conflict of interest: none

Gestational diabetes mellitus: taking it to heart

Cardiovascular disease (CVD), the largest single cause of mortality worldwide, accounts for 1/3 of all deaths among women [1]. In Europe, 54% of female deaths are attributable to CVD [2], while one in three adult American women has some form of CVD [3]. It is not a disease of the wealthy; in low and middle-income countries, more women die from CVD than from pregnancy-related complications [4]. Risk also increases with age. Although men in their 40s have higher coronary heart disease (CHD) risk than women of the same age, as women reach menopause, their risk increases to almost that of men [3].

Type 2 diabetes mellitus (T2DM) has long been associated with increased CVD risk. Research supports that pre-diabetes measurements – namely, impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) – are also associated with increased CVD risk [5, 6], and IGT has specifically been labeled by the World Health Organization and American Diabetes Association a major risk factor for CVD [7]. Several studies assessing the possibility of delaying progression to diabetes in IGT individuals show success from both pharmaceutical and lifestyle interventions [8], and some studies show a positive impact on CVD risk factors [9].

Current literature on gestational diabetes mellitus (GDM) parallels early literature on IGT identifying IGT as a CVD risk factor. Once thought a transient condition, GDM proves to be of greater concern for both mother and child for adverse effects not only during pregnancy but also in the postpartum period. This article discusses the potential increased risk of CVD among women with previous GDM (pGDM). We highlight

existing evidence supporting this association, and the research and clinical ramifications of identifying GDM as a CVD risk factor.

Definition and classification

GDM is defined as a degree of glucose intolerance with onset or first recognition during pregnancy [10]. Changes in such hormones as human placental lactogen, progesterone, prolactin, cortisol, and TNF-alpha -- particularly during late pregnancy -- antagonize the effects of insulin, triggering a state of insulin resistance, thereby increasing insulin requirements (Figure 1). These changes in the hormonal milieu, along with the manifestation of subclinical inflammation [11, 12], create a 'diabetogenic' environment in which insulin resistance can -- and does -- naturally result. When a woman's body is exacerbated by this environment, glucose intolerance increases and manifests as a positive GDM diagnosis. GDM is thus a result of both pancreatic beta-cell insufficiency and increased insulin resistance, though genetic factors and other processes might also be involved. Since the majority of cases return back to normo-glycemic levels postpartum, GDM has been considered a 'transient condition'. However, mounting evidence suggests that GDM should be viewed more as a marker for chronic disease.

Figure 1. *Insulin requirements vs. production in normal pregnancy and pregnancy with gestational diabetes.*

Epidemiology

GDM affects ~7% of all pregnancies in the US [13], and 2-6% of pregnancies in Europe [14]. Globally, prevalence estimates vary greatly depending on the population studied and the diagnostic test used [13], from 1% among Nigerian women [15] to 19% among women of Chennai, India [16]. Several studies also indicate disparities by race/ethnicity, with higher prevalence among minorities [17, 18]. GDM rates are increasing [17-20], with a 100% increase in incidence for some ethnic groups compared to 20 years ago [20]. This observation mirrors the increasing rates of both diabetes [13] and obesity [21], particularly among women pre-pregnancy [22]. GDM rates tend to follow T2DM rates, and both increased pre-pregnancy BMI and weight gain in adulthood are risk factors for GDM [23, 24]. A recent systematic review shows overweight women are almost twice and obese women more than three times as likely to develop GDM compared with normal weight women [25].

Risks in pre- and postnatal period

During pregnancy, GDM is associated with increases in frequency of maternal hypertensive disorders, including preeclampsia [26-28]; likelihood of large-for-gestational-age/macrosomic babies, and, subsequently, Caesarean section deliveries [13, 28-30]; and risk of intrauterine fetal death [13]. Advanced hyperglycemia in pregnancy not diagnostic of GDM is also associated with adverse outcomes [31, 32]. Results from the Hyperglycemia and Adverse Pregnancy Outcomes study (HAPO), a multi-center study to assess the effects of gestational hyperglycemia on birth outcomes, show adverse events – including birthweight $\geq 90^{th}$ percentile and preeclampsia – from degrees of maternal glucose intolerance less severe than overt GDM [27].

Risk for chronic disease

There are also lasting effects of GDM. Compared with women with no GDM history, women with pGDM are more likely to be obese, insulin resistant, and symptomatic of the metabolic syndrome (Figure 2) [19, 33-37]. These findings highlight how GDM can present increased risk for CVD.

Figure 2. *Link between GDM and CVD risk profile.*

GDM and CVD risk factors

Overweight and obesity

Overweight and obese women have increased risk of developing GDM [25]. A higher rate of weight gain, especially during the first trimester, is also implicated as a GDM risk factor when compared with lower rates of weight gain [38]. In the postpartum period, women with pGDM are more likely to be not only of higher BMI but also obese compared with women with no GDM history [39-41].

Type 2 Diabetes

Diabetes in women is a concern; it not only affects future pregnancies, but also increases risk of developing fatal CHD, to almost twice that of men with diabetes [42]. Though

women usually develop CHD at an older age than men, women with diabetes seem to lose this age advantage [43], with CHD in diabetic women occurring around the same age as for men. A recent systematic review shows women with pGDM have >7 times the risk of women with no GDM history for developing T2DM anywhere from 5-20 years postpartum [35]. A previous report shows progression to T2DM among women with pGDM increases steeply within the first 5 years post-delivery, leveling off at 10 years, with T2DM progressing at similar rates for different race categories [44]. Feig et al. show the rate of developing diabetes after a GDM pregnancy is ~20% by 9 years [19] though others estimate double this– 51% -- by 8 years postpartum, with increased risk in both women with two or more live births and obese women [36].

Madarasz and colleagues show that the spectrum of glucose intolerance (T2DM, IFG and IGT) later in life is more prevalent within pGDM women compared with controls [45]. Collectively these abnormalities occur ~3 times more frequently in women with pGDM. Additionally pGDM women have lower insulin sensitivity indices after 4 years [45], suggesting increased insulin resistance. These women also have lower insulinogenic indices, suggesting disturbed insulin secretion as well. Similarly, among French women participating in the DIAGEST2 study, the postpartum prevalence of any glucose abnormality is higher among women with pGDM vs. controls [46]. This higher prevalence is also seen among women with abnormal glucose tolerance in gestation (but not diagnosed GDM) vs. controls, though to a lesser degree. Other studies support that women with pGDM have significantly increased glucose measures [47] and decreased

insulin secretion or production later in life [48, 49], suggesting that carbohydrate metabolism during pregnancy is linked to carbohydrate metabolism later in life.

Blood pressure

During pregnancy, women with GDM are at increased risk of severe preeclampsia, mild preeclampsia and gestational hypertension (odds ratios [ORs] (95% confidence interval [CI]): 1.5 (1.1, 2.1), 1.5 (1.3, 1.8), and 1.4 (1.2, 1.6), respectively) [50]. Gestational hypertension is also more likely with not only GDM but also abnormal glucose screens (adjusted OR (95% CI): 2.8 (1.03, 7.6)) [51]. Further evidence shows women with pGDM at increased risk for high blood pressure in the postpartum period. One study shows higher central systolic pressure and mean arterial pressure in women with pGDM than in control women, as well as higher levels of peripheral resistance and lower mean stroke volume and cardiac output than controls, after adjusting for BMI [47].

Lipid profile: total cholesterol, LDL, HDL and triglycerides

Women with pGDM might be at greater risk for developing atherogenic dyslipedemia [48]: that is, higher levels of triglycerides (TGs), lower levels of HDL cholesterol, and a greater percentage of LDL cholesterol that is small and dense [52]. At 24-28 weeks gestation, Mediterranean women with GDM have reduced LDL particle size, although there is no difference in the overall lipid profile between these women and controls [53]. Similar results among pregnant women are seen when comparing women with GDM with

women with T2DM and normo-glycemic women. TG levels increase for all three groups as pregnancy progresses; however, this increase occurs earlier in pregnancy for GDM women. Similarly, as pregnancy progresses, concentrations of smaller, denser LDL particles increase, with the greatest increase seen in GDM women [54]. Initial studies on lipid levels in women with pGDM show significantly higher levels of TGs [55, 56], total cholesterol, and LDL cholesterol [55], and lower levels of HDL cholesterol [56] compared with controls. Other studies show similar results, after adjusting for BMI [47], and in women with current diabetes [57]. Even with lipid values in normal ranges, women with pGDM are more likely to have concomitant low levels of HDL and borderline high TGs compared with controls, indicative of the atherogenic lipid profile [56]. Volpe et al. show significantly increased TGs and oxidized LDL in patients with pGDM compared with control patients, with oxidized LDL predictive of reduced vascular function [39]. However, not all studies have shown unfavorable lipid profiles among pGDM women [40].

Metabolic syndrome

The risk of CVD attributable to the metabolic syndrome is particularly high among women, with an estimated half of CHD events in women related to metabolic syndrome [58]. Several studies investigating the association between metabolic syndrome prevalence and pGDM show higher prevalence in women with pGDM compared with controls (estimates: 21-27% vs. 4.5-10%, respectively) [33, 41, 48, 59]. A key difference in these studies is the current diabetic status of women with pGDM. While

one large multi-center trial shows significant increases in the number of metabolic syndrome components among women with pGDM, women included also have a family history of T2DM in 1st or 2nd degree relatives, making this a particularly high-risk population [60]. Analyses from the US National Health and Nutrition Examination Surveys (NHANES) III population (1988-1994) yield similar results among women with pGDM but no current T2DM, highlighting that T2DM may not be wholly responsible for the increased risk of metabolic syndrome in these women [40]. These findings might also be affected by the severity of GDM (whether insulin was required) or socio-economic factors [48]. A recent cohort study shows glucose intolerance of any level during pregnancy may pose a risk for subsequent metabolic syndrome. Metabolic syndrome increases stepwise with worsening glucose intolerance level during pregnancy: 8.9% to 15.4% to 16.8%, between normo-glycemic, gestational impaired glucose tolerant, and GDM women, respectively (p=0.046). This trend persists after removing waist circumference as a metabolic syndrome component, to account for gestational weight retention, and is observed at only 3 months postpartum [61].

GDM and CVD events

Whether the increased risk of CVD is apart from the increased T2DM prevalence among women with pGDM is uncertain. When looking at CVD events one study shows women with no pGDM have higher rates of event-free survival when compared with pGDM women (hazard ratio [HR] (95% CI): 1.71 (1.08-2.69)). However, this association loses significance after adjustment for subsequent T2DM development [62]. Within the same population, women with overt pGDM have cardiovascular event rates of 4.2 per 10,000

person years after a median follow-up time of 11.5 years. For previous mild gestational glucose intolerant women (women with abnormal glucose screening values but a negative oral glucose tolerance test [OGTT]) and normo-glucose tolerant women, this rate is 2.3 and 1.9 per 10,000 person years, respectively. After adjustment for age, year of delivery, and other confounders, hazard ratios for CVD both among women with GDM and women with mild glucose intolerance remain significant, at 1.66 (95% CI: 1.3, 2.13) and 1.19 (95% CI: 1.02, 1.39), respectively, compared with normo-glycemic women; however, these results lose significance after adjusting for subsequent diabetes (HRs (95% CI): 1.25 (0.96, 1.62) and 1.16 (0.99-1.36), respectively). Still, among this young population there is the indication of increased CVD risk with pGDM [61]. This is noted as well through the multi-center trial of Carr et al, which shows increased levels of CVD risk factors in women with both pGDM and a 1st or 2nd degree relative with T2DM, and occurrence of CVD at a younger age within women with GDM histories [60].

GDM, CVD biomarkers and surrogate CVD measures

Several markers of vascular endothelial dysfunction and inflammation are associated with CVD risk, rendering them useful for identifying at-risk individuals. Using vascular endothelial dysfunction markers such as circulating levels of E-selectin, vascular adhesion molecule-1 (VCAM-1), and intercellular adhesion molecule-1 (ICAM-1); surrogate measures of CVD such as arterial wall thickness or intima-media thickness (IMT); and inflammatory markers like interleukin-6 (IL-6) and C-reactive protein (CRP), studies show a connection between pGDM and future CVD risk.

Endothelial dysfunction

Caucasian women 6.5 years after a GDM pregnancy show significantly higher levels of E-selectin and ICAM-1 compared with controls, regardless of current metabolic status [33]. Several studies show endothelial dysfunction among women with pGDM, expressed through common carotid IMT, with greater thickness observed in women with pGDM [39, 63]. Bo et al. shows significantly higher levels of IMT in pGDM women compared with controls, in all four arterial areas measured [33]. Among Greek women with pGDM, flow mediated dilation (FMD) – another endothelial function marker – is significantly lower compared with non-GDM controls (7.5% vs. 10.3%) [64]. However, within a different population this difference in FMD is not seen [65] though other markers measured show signs of vascular impairment. FMD is also significantly lower among Italian women with pGDM compared with normo-glycemic controls (4.1 +/-0.9% vs. 10.9 +/- 1.1%, respectively; $p<0.001$) [66]. Other studies suggest endothelial dysfunction in pGDM women by showing poorer arterial relaxation [67] and decreased vasodilator levels [68] in these women.

Atherosclerosis

Two trials—one using thiazolidine and one using pioglitazone treatment – show the possibility of reducing atherosclerosis progression in women with pGDM. Women receiving thiazolidine see at least 31% lower mean rates of change in central IMT (CIMT) compared with women not receiving treatment [69]. However, this study is

affected by some participation bias through the follow-up period. Similar results are observed with pioglitazone treatment, after a follow-up period of only three years [70]. These results suggest that women with pGDM are at risk of progressing to CIMT levels implicative of subclinical atherosclerosis and that treatment to slow atherosclerosis progression are effective for this population.

Inflammatory markers

Results from the Women's Health Study highlight the increased risk of vascular events among women with higher levels of heat-sensitive C-reactive protein (hs-CRP), an inflammatory marker, and there is heightened interest in these markers as CVD risk factors [71]. Among Italian women, those women with pGDM but no signs of metabolic syndrome have significantly higher levels of hs-CRP compared with control women [72]. Dimethyl-L arginine might also be significantly increased in women with pGDM, independent of other risk factors or surrogate markers for diabetes or CVD [73]. Other studies show similar results for inflammatory markers, after adjustment for different co-factors [33, 47, 74].

Implications and future directions

This review highlights the importance of considering the implications of GDM for future disease risk. This risk is not limited to T2DM, rather could involve the larger spectrum of CVD.

Strengths and limitations of published results. The association between GDM and future T2DM risk is apparent; however, evidence in support of other CVD risk factors requires more research. As Table 1 shows, the majority of studies on pGDM and CVD surrogate measures are case-control or small, hospital-based analyses, and do not incorporate multi-ethnic populations. This has the potential of introducing participant bias, as well as limiting power to detect specific outcomes, and also limits the generalizeability of results. The shorter follow-up period (average: 2.5 years) also might affect results, and perhaps more conclusive evidence would exist for longer follow-up periods. However, the trend toward a direct positive relationship between pGDM and surrogate CVD measures implies GDM poses increased risk for CVD as well.

Also, since the majority of studies are among white women, the effects on different racial/ethnic groups are virtually unknown. While the disparity in risk for both GDM and CVD in different racial/ethnic populations is known, the role of race/ethnicity on the association between pGDM and future CVD risk has yet to be explored. Finally, the role of exercise and diet must be considered, and should be controlled for in studies on pGDM and CVD risk. When diagnosed with GDM, many women are prescribed medical nutritional therapy as the first-line treatment; though many fall off of this dietary regimen in the postpartum period, it may affect their future behaviors and subsequent risk of chronic disease, such as T2DM and CVD.

Recommended future directions. Because of the strong association between GDM and future T2DM, many organizations worldwide recommend regular postpartum screenings for T2DM among pGDM women. Furthermore, recent findings from the aforementioned

HAPO study carry large implications for the screening and diagnosis of GDM [75]; the changes to screening methods and diagnostic criteria that result from these findings, when practiced, could amplify the burden of GDM worldwide. Policies for the postpartum period should involve concomitant screening not only for T2DM, but also for CVD risk factors, such as blood pressure and lipid levels. Also of interest are future studies investigating the role of pGDM on CVD risk through prospective longitudinal or intervention studies, when mothers could be followed not only during pregnancy but also well into the postpartum period to measure CVD risk.

In conclusion, several studies highlight the potential association between pGDM and CVD risk. However, more solid evidence is necessary as would be achieved through larger, prospective trials, to solidify this association. Nevertheless, women with pGDM present a unique population in which early interventions targeting improvement of CVD risk factors can benefit a significant portion of the female population.

Conflict of interest: none

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APPENDIX 2. Healthy Moms, Happy Babies Program Curriculum

APPENDIX 3. Interview guide for qualitative, in-depth interviews

Evaluation of a program promoting healthy diet and active lifestyle for healthy weight gain during pregnancy

Opening statement

Hi there. Thanks so much for coming today. My name is _____ and I am from Emory University. I am here today to help Dr. Umpierrez and Jessica evaluate their Weight Gain in Pregnancy program, that you participated in during your pregnancy. We are really interested in knowing what parts of the program you liked, or felt really worked, and also what parts of the program you might not have liked, or you felt didn't work, and also to get some ideas on how to make this program useful and helpful to all women coming for OB care at Grady. Your thoughts, opinions and ideas are valuable. We will be holding similar discussions with the other participants, to gain a sense of how the group felt about the program. This will be an interview format, and I have some questions to ask you—please answer all openly and honestly, as there really are no right or wrong answers. We also welcome any ideas you might have, and can spend more time at the end talking about these

Your participation today is completely voluntary, as stated on the consent form, and you can choose not to participate at any time. Everything we talk about today will be kept confidential and will only be used for the purposes of evaluating the program. No one outside of the study team will have access to your responses. And remember, there are no right or wrong answers to the questions we'll be talking about today, we will simply be discussing your thoughts, opinions, and experiences with the weight gain in pregnancy program, so please feel free to state what you really think or feel. I will be writing some notes to keep track of your responses, but – because it's really hard to catch every word -- in case I miss something I also have a tape recorder and would like to record your responses. Again, your responses on the tape will be kept confidential and in a secure, locked cabinet, only accessible to the study team. Is it okay with you if we use the tape recorder? (TURN ON RECORDER IF PARTICIPANT ANSWERS "YES".)

The interview should take about 30-45 minutes, and if you need to pause to get something to drink, use the restroom, or anything else, please let me know. Do you have any questions before we begin?

Introduction

1. Let's begin by you taking me back, to before your pregnancy. Can you tell me a little bit about what your eating habits were like?

Probes:

- Types of foods/beverages eaten
- How often you would eat

- Where you ate mostly (outside of home or inside)
- How was food prepared (self-prepared, someone else prepared, prepared outside of home)

2. Similarly, now for exercise. What were your exercise or activity habits like before your pregnancy?

Probes:

- Types of activity
- How often or how much time spent
- Desire to be active
- Motivation to engage in activity
- Barriers to activity (neighborhood, feeling tired, family, job, access)

3. Ok great. I think I have a little glimpse of what your life was like before you were pregnant. Now, let's think about this pregnancy, when you were actually pregnant and coming to Grady. You come for your ob visit, and you hear about this program, the Weight Gain in Pregnancy Program. Can you tell me a little bit about why you were interested in joining or participating in the Weight Gain in Pregnancy Program?

Probes:

- What did you want to learn?
  - EXAMPLES
- Describe more what it means to you to "be/eat healthy"
  - EXAMPLES
- How did you want it to "help"
  - What do you mean by help?
- Influence of others (doctor, family, friends)
  - How did that motivate you to join?
- Previous experience – **IF APPLICABLE** (from past pregnancy: of gaining weight during/after or of losing weight after)
  - Describe what happened
  - Why do you think that happened?
  - How did you think things would be different for this pregnancy?

Program: Contents

4. Now let's think about the program, in general. Overall, when you think about the program, can you tell me what topic or session or activity you liked most from the program?

Probes:

- What do you remember most? What stuck out about this session?
- What did you like about this topic/ session/ activity?

In a similar way: can you remember a topic or session or activity that you just didn't like?

Probes:

- What didn't you like about this topic/ session?
- What would you change about it?

5. How do you believe your eating habits (what kinds of foods you ate, or when or where you ate) during pregnancy might have been different, if at all, if you hadn't participated in the program?

Probes:

- Types of foods eaten, cravings
- Motivation

*Refer to responses from **Question 1** for some comparisons/ ideas.*

6. How do you believe your exercise or physical activity during pregnancy might have been different, if at all, if you hadn't participated in the program?

Probes:

- Time spent in it
- Types of activities
- Motivation

*Refer to responses from **Question 2** for some comparisons/ ideas.*

7. Was the pedometer helpful for you?

Probes:

- If so/not then in what way was/wasn't it helpful (setting goals, motivation, remembering to wear)?

Ok great. Now, we're going to highlight a few of the activities that were part of the program. Since I unfortunately wasn't able to be here when you had your classes, I appreciate your honest opinion of these parts of the sessions.

Examples of questions to ask:

- Do you remember talking about (activity)?
- Did you like this activity? What did/didn't you like about this activity?
- Did this work for you? Why or why not?
- What could have made it more helpful for you?

Session 1

A. Weight gain chart

B. Eating for two (was this new information for you?)

C. Walking plan

Session 2

A. Food groups

B. Taking pulse

Session 3

A. Vitamins and minerals

Session 4

A. Hidden fats and sugars

Session 5

A. Healthy eating out

Session 6

A. Plan for post-delivery

Program Structure

8. Now we'll talk about the structure of the program sessions. Please tell me, how well did the program sessions fit into your prenatal or OB schedule?

Probes:

- Frequency of program visits – scheduling with OB appointments

- Duration of program sessions
- If did not fit with schedule: when would be better?

9. Overall, how well did you feel the lessons fit with where you were in your pregnancy, how far along you and your baby were each time you came for a program visit?

Probes:

- What information was relevant OR irrelevant
- If program "works" for pregnancy
    - Worth it to have it before/ after pregnancy instead of or in addition to during?

10. Can you tell me about your interaction with the people involved in the program -- particularly, the nurses and program leader, Jessica?

Probes:

- What made you feel most comfortable?

What made you feel least comfortable?

Follow-up: Would you have preferred someone from the African-American community? Why or why not?

11. We are thinking of holding this program in a group setting, where you meet with other moms to learn about healthy eating and exercise. If we offered this in a group setting, how would that have affected your participation?

- What might be better about having it as a group? What might be worse/ not as good?
- Should this be in addition to or in place of meeting one-on-one?

12. Outside of this program, did you receive information or encouragement about what to eat during pregnancy? Or exercise that you could do?

- Where did you receive this information?
- What kind of information did you receive?

13. Many women have said that they felt support from coming to the sessions. Did you experience this?

- (IF YES) What made you feel supported? (EXPLAIN, GIVE EXAMPLES)
- What could be done differently to feel more support? (EXPLAIN, GIVE EXAMPLES)

Overall/ wrap-up

14. A lot of times it's helpful to talk with friends about things. What are some things you would tell a friend about the program, after participating in it?

Probes:

- What did you learn?
- Would you recommend the program to friends?
- Would you participate in a future pregnancy if it's available?
  - Probe: Feel good about using the information in a future pregnancy
- Would you do it all over again if you had the choice?

Follow-Up: Was there anything not covered in the sessions that you wish would have been? (Explain, give examples)

Thank you so much for your time. I enjoyed talking with you today, and wish you the best with your new baby!

Healthy Moms, Happy Babies Session Binder

Healthy Moms, Happy Babies

Diet and exercise for a healthy pregnancy

Name:

_____

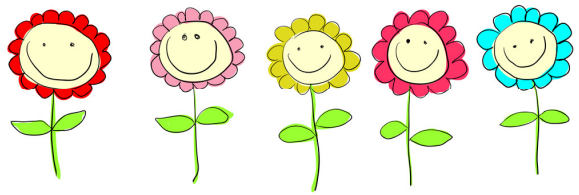
Due Date:

_____

Call if you have concerns or questions: 404-616-3718

Getting started

- We are interested in finding out more about weight gain during pregnancy in Black women. Gaining just the right amount of weight during pregnancy can lead to healthy outcomes for both mom and baby.



- A healthy diet and active lifestyle might help a woman gain just the right amount of weight during her pregnancy. The purpose of this project is to compare the impact of a diet and exercise program and usual care on weight gain during pregnancy in Black women.

Session 1: Welcome!

I am participating in the study, *Healthy Moms, Happy Babies,* because:

_____

_____

_____

_____

By being a member of the study, *Healthy Moms, Happy Babies,* I hope to achieve or learn:

_____

_____

_____

_____

Look at me and my baby grow!

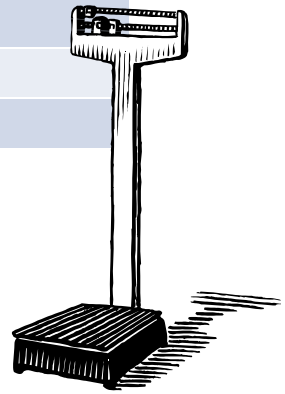
It is important to gain the right amount of weight during your pregnancy.

My goal is to gain about _____ pounds during my pregnancy. That means I will weigh about _____ pounds.

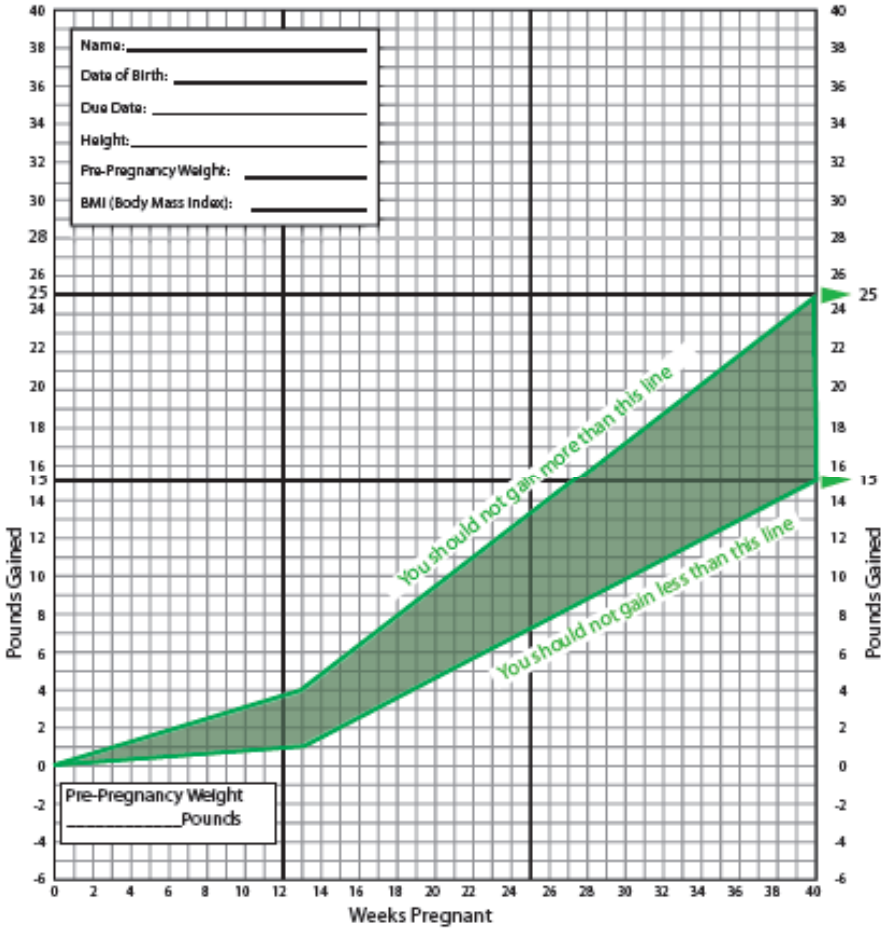
Look at me and my baby grow!

How much are my baby and I growing?

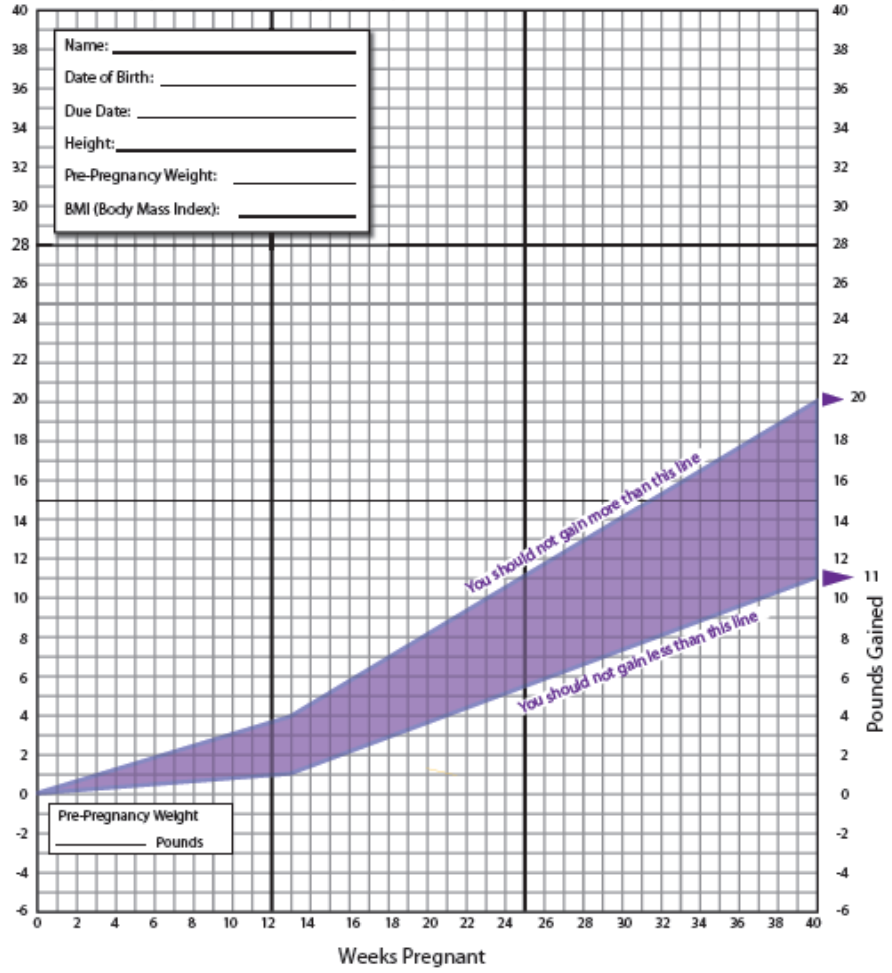
Weeks pregnant	Target weight	Weight



Charting my weight gain



Charting my weight gain



Why eat healthy?

Although you need more energy and nutrients during pregnancy, it is not an excuse to eat anything and everything in sight.

Eating healthy during pregnancy is important to:

Prevent problems for <u>your baby</u>.

Everything *you* eat, *your baby* eats. It's <u>what</u> you eat that matters most.

- ❑ Your baby needs many vitamins and nutrients for healthy development and growth. Most of these you can provide by eating healthy foods!

Prevent problems for <u>you</u>.

<u>Your</u> body needs extra nutrients during this physically demanding time, too.

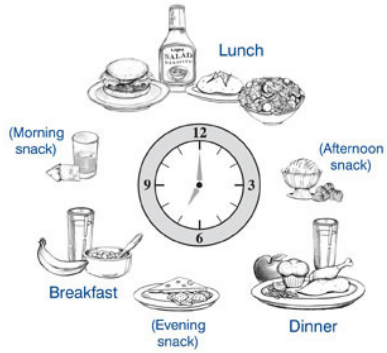
Help make pregnancy <u>easier</u>.

Good nutrition helps prepare your body for the challenges ahead.

Eating times

- Following a schedule for meals and snacks will help with keeping your eating habits in check. During this first session, we suggest eating at 6 times in the day:

  - ❑ Breakfast
  - ❑ Mid-morning snack
  - ❑ Lunch
  - ❑ Afternoon snack
  - ❑ Dinner
  - ❑ Evening snack



- Eating smaller meals throughout the day can also help with:
  - ❑ Morning sickness
  - ❑ Heartburn

<u>Avoid empty calories:</u>

• Choose nutritious foods for snacks and meals to provide the extra energy needed for pregnancy, and vitamins and nutrients required for healthy growth– both for you and your baby!

• Limit foods high in sugar and fats, such as chips, ice cream and pastries.

Eating for two?

Many people think you need to "eat for two" during pregnancy. But your body only needs about 300-450 extra calories a day, and that's only in the second and third trimester.

Choose nutritious options, like fruits and vegetables. They provide vitamins and minerals you and your baby need. Here are some examples:

- 1 cup of non-fat fruit yogurt and a medium apple
- 1 piece of whole wheat toast with 2 tablespoons peanut butter
- 1 cup of raisin bran cereal with 1/2 cup of non-fat milk and a small banana
- 3 ounces roasted lean ham or chicken breast and 1/2 cup sweet potatoes

Healthy eating: some tips

Here are some tips for healthy eating:

➢Choose nutritious options – like fruits, vegetables, nuts and yogurt – to provide the extra energy needed for pregnancy. Healthy foods provide essential vitamins and nutrients required for healthy growth– for both you and your baby!

➢ Avoid empty calories: limit foods high in sugar and fats, such as chips, ice cream and pastries.

<u>Foods to avoid:</u>

•Beer, wine and alcoholic beverages
•Mexican and other soft cheeses
•Unpastuerized dairy products
•Uncooked seafood, meat or poultry
•Refrigerated smoked seafood, like salmon
•Hot dogs, lunch and deli meats, unless thoroughly reheated to steaming
•Fish high in mercury: swordfish, king mackerel shark

Session 1: Physical Activity

Exercise during Pregnancy

Why exercise during pregnancy?

- ❑To increase your energy level
  - ➢Helps with sleep
- ❑**To prevent too much weight gain**
- ❑To strengthen muscles
- ❑To decrease some discomforts felt during pregnancy
- ❑**It helps during labor and delivery**
- ❑**It helps after delivery**
  - ❑To recover faster after delivery
  - ❑To lose weight after delivery

What kind of exercise can I do during pregnancy?

- The best exercise for pregnancy is low-impact with little risk of falling
  - Walking
  - Swimming
  - Dancing
  - Water aerobics
  - Yoga
  - Stationary biking

What kind of exercise do you enjoy most?

_____

Exercises to avoid

•Contact sports (soccer, basketball, hockey, etc.)

•Sports with risk of falling

What keeps you from exercising?

Everyone is so busy. Many women, especially pregnant women, have trouble finding time, money or energy to exercise. What makes it hard for you to exercise?

_____

_____

Can you think of any solutions to these problems?

_____

Goal for the next month:

_____

Walking with a pedometer

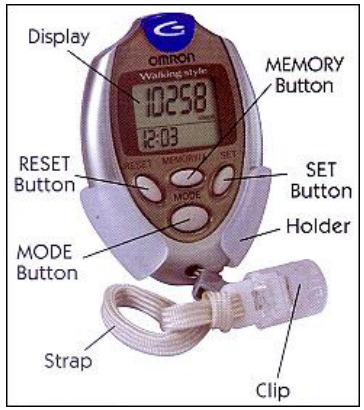
- Exercise idea
  - Start with 15 minutes of walking
  - Try to walk 5 times during the week
  - Increase walking by 2 minutes every week
  - Wear pedometer to see progress
  - Can break 15 minutes up during the day

Sample Walking Program			
Warm-up Time	**Fast-walk Time**	**Cool-down Time**	**Total Time**
Week 1			
Walk slowly 5 minutes	Walk briskly 5 minutes	Walk slowly 5 minutes	15 minutes
Week 2			
Walk slowly 5 minutes	Walk briskly 7 minutes	Walk slowly 5 minutes	17 minutes
Week 3			
Walk slowly 5 minutes	Walk briskly 9 minutes	Walk slowly 5 minutes	19 minutes
Week 4			
Walk slowly 5 minutes	Walk briskly 11 minutes	Walk slowly 5 minutes	21 minutes
Week 5			
Walk slowly 5 minutes	Walk briskly 13 minutes	Walk slowly 5 minutes	23 minutes
.	.	.	.
.	.	.	.
Week 12			
Walk slowly 5 minutes	Walk briskly 27 minutes	Walk slowly 5 minutes	37 minutes
Week 13			
Walk slowly 5 minutes	Walk briskly 30 minutes	Walk slowly 5 minutes	40 minutes

Alternative Plan:

- You can split walking time throughout day to fit your schedule
- Example: Walk 5 minutes before work, 5 minutes during work, 5 minutes after work

Working your pedometer



The study coordinators will set up your pedometer with your weight and stride length.

Press the **MODE** button to change the display from steps and time to steps and minutes. Press it again to switch to calories or miles.

To check your weekly step count, press the **MEMORY** button until you reach 7 days. It will also show you your daily step count.

The **RESET** button sets the step count back to zero. <u>Don't press this unless the study coordinators tell you.</u>

The **SET** button is used to set the time, weight, and stride length. There should be no need to reset anything, so don't use this button unless the study coordinators tell you.

Always be cautious when exercising

- ❑ Always breathe normally during activities
- ❑ Warm-up and cool-down to prevent injuries
- ❑ Eat a healthy, well-balanced diet
- ❑ Drink water before, during, and after activity
- ❑ Avoid becoming too hot; don't exercise in hot, humid conditions.
- ❑ Avoid activities that require you to lay on your back after 3 months of pregnancy
- ❑ Listen to your body and know your limits
- ❑ Wear comfortable clothing that will help you remain cool
- ❑ Wear a supportive bra that supports your breasts

Reasons to stop and talk to a doctor:

- Dizziness or faintness
- Continuous contractions
- Severe nausea or vomiting

- Any gush of water or bleeding from your vagina
- Severe headaches or blurred vision
- Sudden swelling of ankles, feet, calves or face
- Change in baby's movement
- Increasing back pain, pelvic pain, or pain in the abdomen

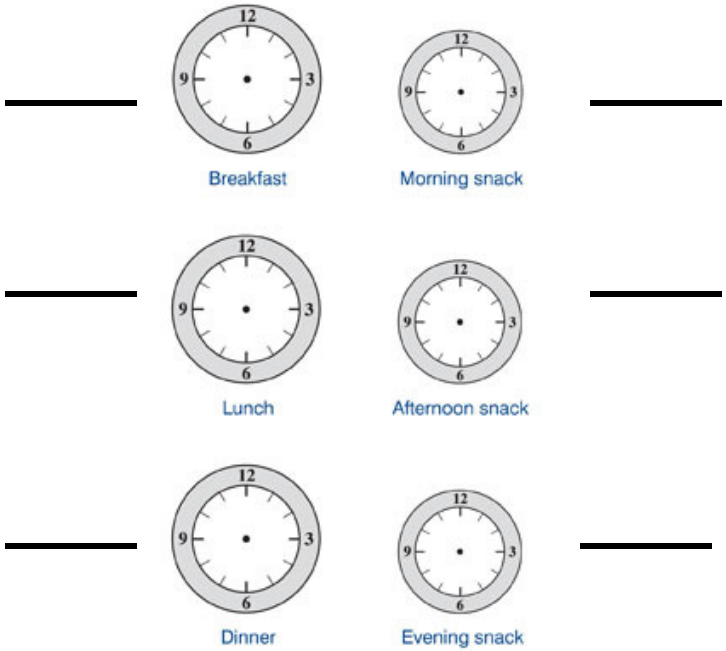
Appendix

Walking Correctly:

- Walk with chin up and shoulders held slightly back
- Walk so the heel of your foot touches the ground first. Roll your weight forward.
- Walk with your toes pointed forward
- Swing your arms as you walk

Eating times

- Fill in the times in these clocks when you plan to eat these meals and snacks.



Session 2

Healthy Eating

Review from last session

- Did you make any changes to your diet from last session? If so, what were they?

  _____

  _____

- What problems (if any) did you have?

  _____

  _____

- How did you solve them?

  _____

  _____

  _____

MyPyramid:
Your guide to healthy eating

Grains	Vegetables	Fruit	Milk products	Meat and beans

Breaking down the pyramid…

Make ½ your grains whole!

Grains	Eat at least ounces a day	Examples: Brown rice, oatmeal, pasta, bread, pretzels, cereals

1 ounce = 1 slice bread, ½ cup cooked rice, pasta or hot cereal, 1 cup dry cereal

Vegetables	Eat at least cups a day	Vary your veggies: Try leafy greens, deep oranges and reds, and starchy vegetables

1 cup = 1 cup raw or cooked vegetables or vegetable juice, or 2 cups raw leafy greens

Fruits	Eat at least cups a day	Fruits like bananas and grapes make great snacks. Limit juice intake, for the extra sugar.

1 cup = 1 cup raw or cooked fruits or ½ cup dried fruits

Milk products	Eat at least cups a day	Choose low fat varieties of milks and cheese, like skim milk, light yogurt and fat-free cheese.

1 cup = 1 cup milk or yogurt, 1½ ounces of natural cheese, or 2 ounces processed cheese

Meats and beans	Eat at least ounces a day	Choose low-fat or lean meats and poultry, like chicken and fish. Bake it, broil it, or grill it!

1 ounce = 1 ounce of meat, poultry or fish, ¼ cup cooked dry beans, 1 egg, 1 tablespoon of peanut butter, or ½ ounce of nuts or seeds

<u>Avoid empty calories</u>

•Limit foods high in sugar and fats, like soda, ice cream, cakes and pies, donuts, french fries and chips.

Why eat healthy?

Eating healthy during pregnancy is important to:

Prevent problems for <u>your baby</u>.

Everything *you* eat, *your baby* eats. It's <u>what</u> you eat that matters most.

- ❑ Your baby needs many vitamins and nutrients for healthy development and growth. Most of these you can provide by eating healthy foods!

Prevent problems for <u>you</u>.

<u>Your</u> body needs extra nutrients during this physically demanding time, too.

Help make pregnancy <u>easier</u>.

Good nutrition helps prepare your body for the challenges ahead.

MyPyramid: Low-fat choices

Grains

Vegetables

Fruit

Milk products

Meat and beans

Grains
_____
_____

Vegetables
_____
_____

Fruits
_____
_____

Milk products
_____
_____

Meat and beans
_____
_____

Rate Your Plate

- Now we will go over the recall we did from last month and "Rate Your Plate". We can identify areas where you can make small changes that can have a big difference.

- We'll check 1 box for every serving you ate from the MyPyramid food groups. The shaded boxes show the minimum number of servings recommended to eat.

Date: _____

Grains										
Vegetables										
Fruits										
Milk products										
Meats and beans										
Fats and oils										

- ✓ How many ounces of ***grains*** did you eat? _____

  How much was whole grain? _____
- ✓ How many cups of *vegetables* did you eat? _____
- ✓ How many cups of *fruits* did you eat? _____
- ✓ How many cups of *milk products* did you eat? _____
- ✓ How many ounces of *meat and beans* did you eat? _____

What could *you* do to improve your plate?

Group		Breakfast	Lunch	Dinner	Snacks	Goal
Grains	*Whole grains*					
Vegetables						
Fruit						
Milk products						
Meat and beans						

Easy measurements

3 ounces
1 serving of meat, chicken, turkey, or fish

1 cup
1 serving of cooked vegetables, salads,
casseroles or stews; milk

½ cup
1 serving of fruit or fruit juice
pinto beans and other dried beans
rice or noodles, dry cereal

1 ounce
1 serving of snack food
cheese (1 slice)

1 tablespoon
1 serving of salad dressing
cream cheese

1 teaspoon
1 serving of margarine or butter,
oil, mayonnaise

Session 2: Exercise

The past month

- How did the pedometer work for you? How many steps did you walk in the past week?

_____

Last week's steps _____

- What problems have you encountered?

_____

- Are you enjoying walking or is there another activity you'd rather be doing?

_____

Working just hard enough to be healthy

During pregnancy, you are carrying much more weight than you used to. This is more work for your body and heart.

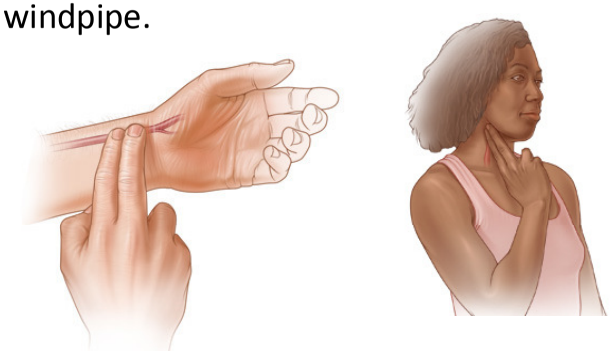
To make sure you are exercising at just the right amount for you and your baby you can check your heart rate or pulse. The following heart rates are based on a pregnant woman's age and weight.

Ages 20-29: 110-131 beats per minute

Ages 30-39: 108-127 beats per minute

How to take your pulse

1. Place the tips of your index and second fingers on the palm side of your other wrist below the base of the thumb. Or, place your fingers on your lower neck on either side of your windpipe.



2. Press lightly with your fingers until you feel the blood pulsing beneath your fingers. You may need to move your fingers around slightly, up or down until you feel the pulsing.
3. Use a watch with a second hand, or look at a clock with a second hand.
4. Count the beats you feel for 15 seconds. Multiply this number by 4 to get your heart rate (pulse) per minute.

Another way to check how hard you're working

Another way to make sure you are not working too hard is to use the talk test.

Doing the same thing everyday can get boring

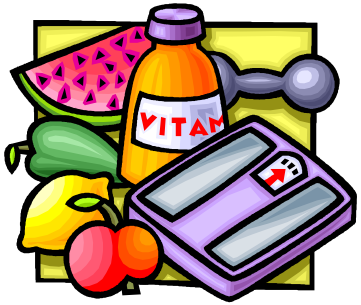
Try finding an exercise partner.

Time goes by much faster when you have someone to talk with. People who exercise with a buddy are more likely to stick with their exercise plan.

Try changing locations.

Walking over and over again in the same area can become boring. Your muscles can get used to the ups and downs of your normal walking path. If you change where you exercise, you will be more interested mentally and will be challenging your body to a new course.

Session 3:
Vitamins and minerals



From last session…

Did you make any changes during the month to better match *MyPyramid*? If yes, what were they?

_____

_____

_____

What problems did you have with reaching your *MyPyramid* food group goals? How did you solve them?

_____

_____

_____

Healthy eating: some tips

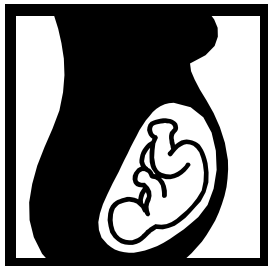
➢ Choosing healthy foods during pregnancy can provide your – and your baby's – body with vitamins and nutrients that are important for healthy growth.

Important vitamins and minerals when you are pregnant:

- Folic acid
- Iron
- Calcium
- Omega-3 fatty acids (DHA)

Folic acid

- Folic acid (or folate) is needed for healthy development of your baby's brain and spinal cord. Too little folic acid in your diet could cause birth defects.
- Folic acid is also good for your health. It can help prevent stroke, cancer, and heart problems later in life.
- Folic acid isn't only for pregnant women– every woman needs folic acid, whether she's pregnant or thinking of becoming pregnant.



How can I get enough folic acid?

- Every pregnant woman needs about **600 micrograms** of folic acid a day. This is how much is in a prenatal vitamin.

- Good sources of folic acid are:
  - Prenatal vitamins (the best way!)
  - Dry cereals, made with fortified wheat flour (check the label!)
  - Oranges and orange juice
  - Green leafy vegetables, like spinach, collards, and kale
  - Broccoli, asparagus, kidney beans and lima beans

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugar 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%
Folate	30%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	30mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrates		300g	375g
Dietary Fiber		25g	30g

Find folate. Read across to see how much folic acid is in your food.

Iron

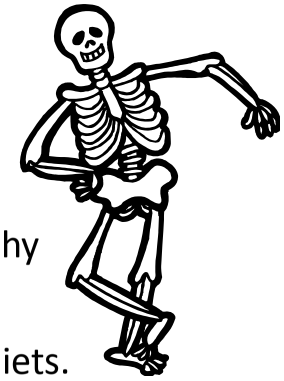
- Iron is important for strong muscles for you and your baby.
- When your body doesn't have enough iron, you can develop a condition called *anemia*. Getting enough iron in your diet can help prevent this condition.
- Iron might also prevent your baby from being born with a low birth weight, or from being born too early.

How can I get enough iron?

- Your **prenatal vitamin** should provide enough iron for your daily needs.
  - Take your vitamin with orange juice or lemonade. The vitamin C in the juice helps your body absorb the iron.

- Good sources of iron are:
  - Prenatal vitamins
  - Lean red meat (pair it with a leafy salad for maximum effect)
  - Foods fortified with iron (check the label!)
  - Eggs, beans and lentils

Calcium



- Calcium is important for healthy teeth and bones.
- Moms need calcium in their diets.

If there is not enough calcium from your diet during pregnancy, your body starts taking calcium from your bones to meet your growing baby's needs.

- Calcium is also important for the baby's nerves, brain, blood, heart and muscles.
- Eating enough calcium now can help you have strong bones later in life.

How can I get enough calcium?

- Dairy foods are great sources of calcium. **Choose low-fat options**, like skim milk, low-fat cheese and low-fat yogurt.

- Other sources of calcium are:
  - Orange juice and other juices **SUPPLEMENTED** with calcium (check the label!)
  - Kale, collards and bok choy

- Exercising (walking, lifting light weights) can also help with strong bones.

- Taking vitamin D with calcium is good. It helps your body absorb the calcium better.

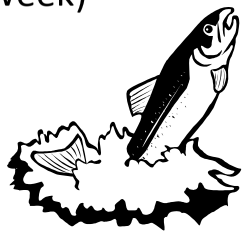
DHA

- DHA is an important omega-3 fatty acid that can help with your baby's brain development.
- It also helps your baby's eyes develop.
- After pregnancy, DHA is still good for your baby and can be found in breast milk. It can help in mental, visual and motor skill development while your baby is growing through infancy.

How can I get enough DHA?

- Every pregnant woman needs about **200 milligrams** of omega-3 fatty acids, like DHA, a day. Some prenatal vitamins have DHA added to them.

- Good sources of DHA are:
  - Prenatal vitamins, if DHA is added (check the label!)
  - A vitamin supplement (ask your doctor!) or fortified foods
  - Salmon, sardines, catfish, or fresh-water trout (<12 oz a week)
  - Albacore tuna (< 6 oz/ week)



Remember…

- Pregnant moms need to be careful about the kinds of fish they eat. Some fish are high in mercury and can be harmful to the baby.

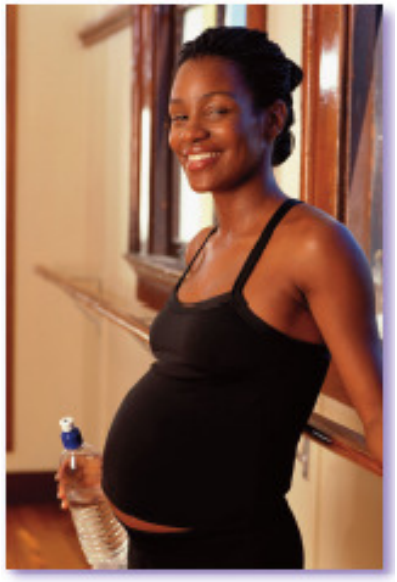
<u>Avoid these fish completely:</u>

- King mackerel and tile fish
- Shark and swordfish
- Orange roughy and red snapper

<u>Limit how much you eat of these fish:</u>

- Salmon (<12 oz/ week)
- Sardines (<12 oz/ week)
- Herring (<12 oz/ week)
- Albacore tuna (<6 oz/ week)

Exercise



The past month

- How many steps did you walk in the past week?

  _____

  Last week's steps _____

- How many minutes per day did you walk?

  _____

- What problems have you encountered?

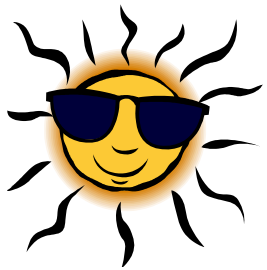
  _____

- Possible solutions to the problems:

  _____

Exercising in the Summer

- Any exercise you can do during pregnancy, you can also do during the summer.
- You just have to be smart about the heat and take care of your body.



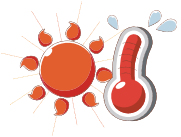
- Find something you really like to do and keep it up. The benefits of exercising make it worth the effort to manage the summer heat.

How to be safe in hot weather

- **How does hot weather affect my body?**
  - Exercising in hot weather puts extra stress on your heart and lungs.
  - Both the exercise itself and the air temperature increase your body temperature. Plus, if the humidity is high it's even harder to cool your body down.

- **Take it slow.**
  - If you're used to exercising indoors or in cooler weather, take it easy at first. As your body adapts to the heat, gradually increase the length and intensity of your workouts.

Some ideas for exercising in the heat

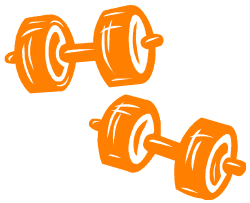


- **Wake up early.**
  - Wake up 30 minutes earlier and take a brisk walk around your neighborhood. Some research suggests that people who exercise in the morning are more likely than are others to stick with it.

- **Make household chores count.**
  - Mop the floor, scrub the bathtub or do other housework at a pace fast enough to get your heart pumping.

❑ Be active while watching TV.

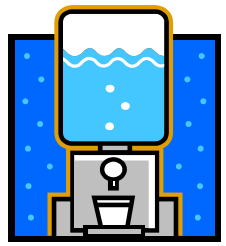
- Use hand weights or do a stretching routine during your favorite shows. Get off the couch to change the channel or adjust the volume.



❑ Involve the whole family.

- Take group walks before or after dinner. It's best to build up to about 30 minutes of continuous activity, but you can exercise in shorter bursts, too.

❑ Drink plenty of fluids.



- Drink plenty of water while you're working out — even if you don't feel thirsty. Avoid drinks that contain caffeine or alcohol, which actually promote fluid loss.

❑ Dress appropriately.

- Wear lightweight, loose-fitting clothing to help keep your body cool. Avoid dark colors, which can absorb the heat. A light-colored hat can limit your exposure to the sun.

❑ **Avoid midday sun.**

- Exercise in the morning or evening, when it's likely to be cooler outdoors, rather than the middle of the day. If possible, exercise in the shade or in a pool.

❑ **Wear sunscreen.**

- A sunburn decreases your body's ability to cool itself.

❑ **Have a backup plan.**

- If you're concerned about the heat or humidity, stay indoors. Walk laps inside the mall or climb stairs inside an air-conditioned building.

Know when to STOP

❑ During hot-weather exercise, be on the lookout for these signs of heat-related illness:

Weakness

Headache

Dizziness

Muscle cramps

Nausea or vomiting

Rapid heartbeat

Importance of warm-up and cool-down

- A warm-up and cool-down is recommended with all physical activity routines. It helps to prevent injuries and keep you comfortable during your routine.

- In general, your exercise routine should be at least 30 minutes long, including your warm-up and cool-down.

Warm-up

1.Start with some light activity to get your heart pumping, such as walking at a slower pace. This will get the blood flowing to your muscles and prepare your muscles for stretching and exercise.

2.Follow your light activity with some stretching.

Cool-down

Follow your exercise routine with a slow walk and some light stretching.

- This will get your heart back to a normal heart rate and prevent the feeling of sore and cramped muscles the next day.

Session 4
What's hiding: calories and exercise

From last session…

Any changes from last month to match *MyPyramid,* or some of the vitamins important for pregnancy?

_____
_____

Did you have any problems making these changes to your diet or routine? How did you solve them?

_____
_____

How much extra?

- 2nd trimester (weeks 13-28)

300 extra calories

- 3rd trimester (weeks 29-40)

450 extra calories

Hidden fats

Many foods "hide" that they're unhealthy.

How? They might contain:

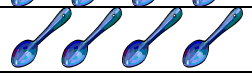
1. A lot of fat
2. A lot of sugar

…and only a little of the things your body <u>really</u> needs.

High fat foods = high calorie foods

Most fat we eat is hidden in our foods.

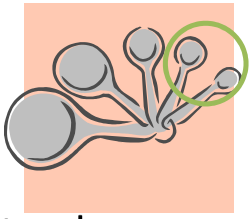
Let's uncover it! Here's a lunch menu:

Food	Teaspoons of fat
Fried fish sandwich	
Large french fries	
Apple turnover	
Ice cream milkshake	
Total:	**20 teaspoons** (That's about 1 stick of butter or margarine!)

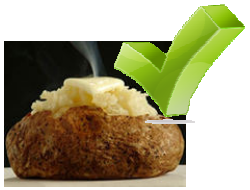
3 ways to eat less fat

1. Eat high-fat foods *less often*.

2. Eat *smaller amounts* of high-fat foods.



3. Eat *lower fat* foods instead.



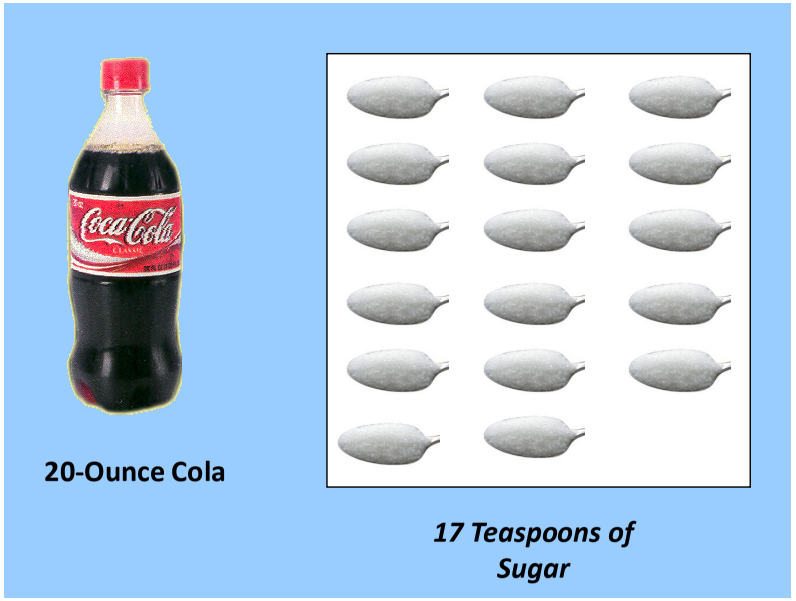
Why?

Sugary drinks

- Drinks sweetened with sugar– like soda, sweet tea and fruit juices– can also be high in calories.

Sugary drinks = high calorie drinks

Where do calories hide?



Just 1 bottle of soda has about 17 teaspoons of sugar!

Other examples

Drink*	Teaspoons of sugar
Hawaiian Punch	180 calories
Nestea sweet tea with lemon	125 calories
Welch's 100% Grape Juice	255 calories
Gatorade "G" orange	90 calories

*12 ounces

Now let's think of your plan!

My top 5 high-fat or high-sugar foods	The 3 ways to cut back		
	I will eat it only this (less) often:	I will eat only this (smaller) amount:	I will eat this (lower-fat/ lower-sugar) food instead:
1.			
2.			
3.			
4.			
5.			

Exercise:
The past month

- How many steps did you walk in the past week?

_____

Last week's steps _____

- How many minutes per day did you walk?

_____

- What problems have you encountered?

_____

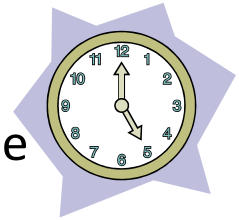
- Possible solutions to the problems:

_____

How are you doing?

Sample Walking Program			
Warm-up Time	**Fast-walk Time**	**Cool-down Time**	**Total Time**
Week 1			
Walk slowly 5 minutes	Walk briskly 5 minutes	Walk slowly 5 minutes	15 minutes
Week 2			
Walk slowly 5 minutes	Walk briskly 7 minutes	Walk slowly 5 minutes	17 minutes
Week 3			
Walk slowly 5 minutes	Walk briskly 9 minutes	Walk slowly 5 minutes	19 minutes
Week 4			
Walk slowly 5 minutes	Walk briskly 11 minutes	Walk slowly 5 minutes	21 minutes
Week 5			
Walk slowly 5 minutes	Walk briskly 13 minutes	Walk slowly 5 minutes	23 minutes
.	.	.	.
.	.	.	.
Week 12			
Walk slowly 5 minutes	Walk briskly 27 minutes	Walk slowly 5 minutes	37 minutes
Week 13			
Walk slowly 5 minutes	Walk briskly 30 minutes	Walk slowly 5 minutes	40 minutes

Hidden time for exercise



- You <u>can</u> find the time to be active!
  - ✓ Set aside 1 block of time for activity, OR
  - ✓ Look for "free time" (10-15 min) during the day to be active.

I can be active during this block of time:

_____

I have 10-15 min that I could be active when I:

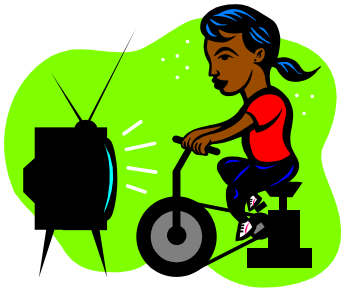
_____

✓ Make active choices during the day.

Some *active* choices I can make are:

_____

✓ Turn *inactive time* into active time.



My goal

- ❑ This week I will be active for _____ minutes.

Day	I will…	When?	Minutes
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Total:			

References

- About.com: pregnant woman with hand weights picture (istock photo); http://pregnancy.about.com/od/stayinghealthy/a/morepgexercise.htm
- Sugar content of drinks: *The Nutrition Source*, Harvard School of Public Health. http://www.hsph.harvard.edu/nutritionsource/files/how-sweet-is-it-bw.pdf

My top high-fat foods are…	Instead of this, I can eat…
1.	
2.	
3.	
4.	
5.	

Session 5:
Get out!

Guide for healthy eating out and being FITT outside your home

From last session…

Any changes from last month, thinking about hidden fats and sugars in foods?

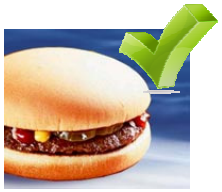
_____
_____

Did you have any problems making these changes to your diet or routine? How did you solve them?

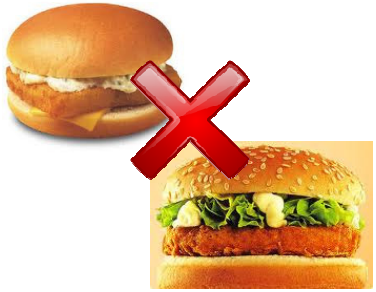
_____
_____

Healthy eating out

Healthy options: fast food



Where's the change? _____



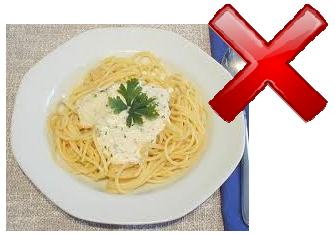
Where's the change? _____

Where's the change? _____

Where's the change? _____

Where's the change? _____

Where's the change? _____



Where's the change? _____

Where's the change? _____

Where's the change? _____

Eating out: A plan

A problem I have when I eat out is:

_____

Physical activity:

Let's be F.I.T.T.!

Exercise:
The past month

- How many steps did you walk in the past week?

_____

Steps/ day _____

- How many minutes per day did you walk?

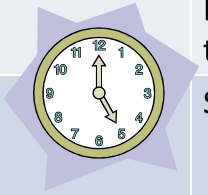
_____

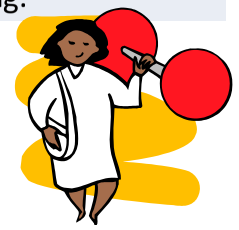
- What problems have you encountered?

_____

- Possible solutions to the problems:

_____

F.I.T.T.	
Frequency (How often you're active.)	Be active on <u>most</u> days of the week.
Intensity (How hard you work; how fast your heart beats.)	Stay in your target heart rate. **Your target heart rate** is _____ to _____ beats per minute. If you have trouble breathing and talking, slow down.
Time 	Stay active for at least **10 minutes**. **GOAL: 40 minutes a day, or 200 minutes a week**
Type of activity	Use those big muscles! Example: Brisk walking.



Don’t be bored…

- Try a new activity!

  Right now I: _____

  But I could: _____

- Try walking in a new place.

  Right now I: _____

  But I could: _____

- Be active and be social.

  People I could walk with:

  _____

- Make being active fun!
- Have a *destination*.

  From my house I could walk to:

  _____

  From work I could walk to:

  _____

“Walkability” Test

Visit www.walkscore.com

In my neighborhood I found

_____ markets

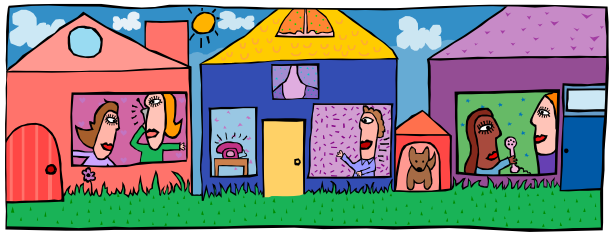
_____ parks

_____ bus stations

_____ schools

_____ restaurants

… all a short walk from my house!



- ✓ Pick 1 or 2 new places to walk to this month.

  This month I will walk to _____.

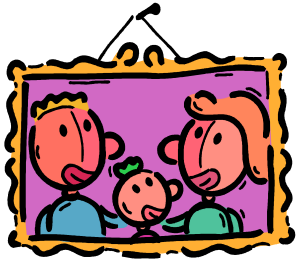
- ✓ Choose how often you will do this.

  I will walk there _____ times a day/week/month.

- ✓ Add in the extra minutes.

  This will be about _____ minutes of walking each way.

Session 6
After delivery:
Involving the family



From last session…

Any changes from last month, and choosing healthy options for eating out?

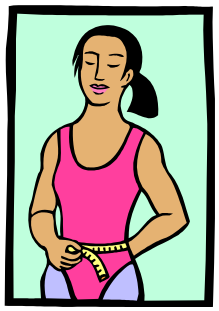
_____
_____

Did you have any problems making these changes to your diet or routine? How did you solve them?

_____
_____

Caring for your baby

- Even after delivery, your body is still changing. Your belly will take some time to return back to its normal size, and your body gets ready to produce breast milk for your baby.



Lactation after delivery

- After delivery, your body starts making milk, or lactating, in order to provide for your new baby. Lactating moms require even more energy than pregnant moms, especially the first 6 months after delivery.

500 extra calories

- This is really important if you are breastfeeding your child, and should be lower if you stop breastfeeding or decide not to breastfeed.

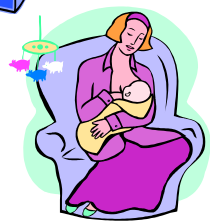
http://www.fao.org/docrep/007/y5686e/y5686e0b.htm

Losing postpartum weight

Your body won't go back to normal overnight, but you can lose some pregnancy weight by:

- ✓ Being active

- ✓ Breastfeeding

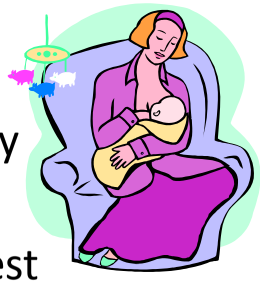


- ✓ Eating healthy foods

Losing postpartum weight

- <u>Be active!</u> Keeping up with your **walking** can help:

  - ✓ Lose weight
  - ✓ Boost spirits
  - ✓ Be social
- Think about **breastfeeding** your baby, even for a little bit. Breastfeeding:



  - ✓Helps you lose weight
  - ✓Gives a chance for baby bonding time
  - ✓Gives your baby the best nourishment possible

Losing postpartum weight

- <u>Eat healthy!</u> Sticking to healthy foods like **fruits, vegetables** and **whole grains** can help you:
  - ✓ Lose weight
  - ✓ Provide you and your baby with vitamins and nutrients
  - ✓ Help create a healthy family

What is your plan?

Exercise:
The past month

- How many steps did you walk in the past week?

  _____

  Steps/ day _____

- How many minutes per day did you walk?

  _____

- What problems have you encountered?

  _____

- Possible solutions to the problems:

  _____

Your family is growing!

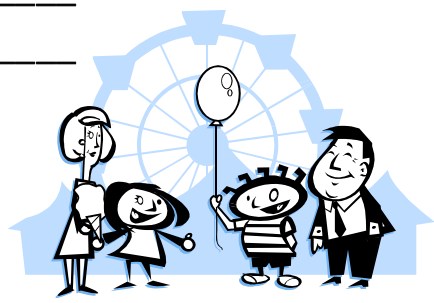
- With a new addition to your family, it's important to be healthy together. It's fun and easy to involve other family members in your choices to live a healthier life.

- Can you think of some things you like to do with family members and friends?

  _____

  _____

  _____



Involve the family

- Set a regular "**Activity Date**" a with family member or friend, like taking a walk to see Grandma.

- Have a family member or friend help: split dessert, cook at home together, or go for walks together outside or in the mall.

- Do activities that moms, dads and kids can do **together**.
  - ✓Family chores with music
  - ✓Outdoor activities
  - ✓Hikes or walks in local parks
  - ✓Pool time!

You and your family

- Who are some family or friends you can be active with?

  _____

- What are some ways you will be active with friends or family?

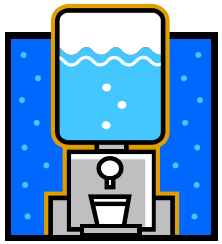
  _____

  _____

  _____

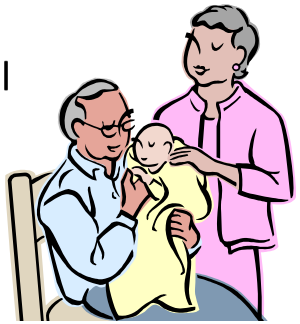
Healthy Family Home™
Guidelines for eating healthy

- Serve fruits and veggies at every snack and meal.
- Make water the main drink choice every day.
- Include whole grains in meals and snacks.
- Provide healthy, unsaturated-fat foods at meals and snacks.
- Remember: moderation, balance and variety.



Healthy Family Home™ Family time

- Have at least 1 meal together each day
- Involve kids and other family members in the meal preparation, serving, and clean-up
- Do activities that moms, dads and kids can do together
  - Family chores with music
  - Outdoor activities
  - Hikes or walks in local parks
  - Pool time!



Recipe makeover

- Paste your favorite recipe here, and we'll do a healthy makeover!

References

- References: Healthy Family Home™, YMCA
- http://www.ymca.net/healthyfamilyhome/welcome.html