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Erin Poe Ferranti April 10, 2013

Dietary Quality and Cardiometabolic Risk after Gestational Diabetes

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Dietary Quality and Cardiometabolic Risk after Gestational Diabetes

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Abstract

Dietary Quality and Cardiometabolic Risk after Gestational Diabetes
By Erin Poe Ferranti

Background: Women with previous gestational diabetes mellitus (pGDM) are at significant risk for the development of type 2 diabetes mellitus (T2DM) and metabolic syndrome (MetS). Healthy diets, particularly the Alternate Healthy Eating Index (AHEI) dietary pattern is protective for disease development, but women with pGDM have suboptimal diet quality. Few studies have investigated the influences of diet quality in women with pGDM.

Purpose: This study examined individual, family, and social-level influences of diet quality. An exploratory focus assessed cardiometabolic risk status in relationship to AHEI diet quality.

Sample and Design: This was a cross-sectional descriptive study guided by a synthesis of the Health Belief Model and the ecological framework for eating behavior. Women aged 18-45 years, within five years of their pGDM pregnancy, completed questionnaires about demographic factors, individual perceptions of risk, benefits and barriers to healthy eating, dietary self-efficacy, general social support, components of family functioning, and habitual dietary intake. A basic cardiometabolic health assessment was performed to determine the presence of MetS or T2DM risk defined by abnormal hemoglobin A1C values. Analyses included descriptive, bivariate, multivariate linear and logistic regression.

Results: Participants (n = 75) included women (55% Minority) who were within a mean of 2.6 years since their pGDM pregnancy. AHEI diet quality was suboptimal (M = 47.6, SD = 14.3). Individual factors that significantly predicted better AHEI diet quality were higher levels of education status and dietary self-efficacy (R^2 = .36, $F(6, 66) = 6.19$, p = <.0001). No social or family-level factor predicted diet quality beyond the individual factors. Nearly half (47%) had abnormal hemoglobin A1C levels, and 19% were at risk for MetS. AHEI diet quality was not associated with risk for either T2DM or MetS.

Discussion: These findings highlight the prevalence of cardiometabolic risk factors, the suboptimal AHEI diet quality, and the modifiable influences that contribute to AHEI dietary quality in women with pGDM. Interventions designed to improve diet quality in women with pGDM should incorporate enhancing dietary self-efficacy. This study provides a foundation to further investigate dietary influences in a longitudinally designed study to assess the causal direction of the associations.

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CHAPTER 1: Introduction

Significance of the Problem

Gestational diabetes mellitus (GDM) is the most common complication of pregnancy in the United States, with a prevalence that has more than doubled in the past decade, largely mirroring the increasing rates of obesity and type 2 diabetes mellitus (T2DM) in the general population.[1] New diagnostic criteria proposed in March 2010 for GDM diagnosis lowers the threshold of diagnosis with a one-step approach at lower glucose levels, compared to the current two-step process.[2] The implications of adopting this approach would be a significant increase in GDM prevalence, with estimates ranging from 18%[2] to 28% of pregnant women.[3] A very recent (March 6, 2013) draft consensus statement released by the National Institute of Health, Diagnosing Gestational Diabetes Mellitus Conference, has made the recommendation to continue with the two-step approach in light of insufficient evidence to demonstrate the benefit of the one-step approach, but to reconsider as the uncertainties of its benefit resolve.[4] The American Diabetes Association and the American College of Obstetricians and Gynecologists continue to recommend the two-step diagnostic approach.[5] However, because of both the proposed diagnostic criteria and the growing epidemics of obesity and T2DM, GDM will likely continue to increase in prevalence.

GDM is a sentinel event for cardio-metabolic disease risk, resulting in a seven-fold increased risk for the development of T2DM,[6] with the greatest risk occurring within the first five years following delivery.[7] Women with previous GDM (pGDM) also are at significant risk for the development of metabolic syndrome and cardiovascular disease.[8-

[12] Multiple modifiable risk factors have previously been associated with the progression to T2DM, including poor diet quality, sedentary lifestyle, and overweight/obesity.[13] Greater duration of lactation is also associated with less risk for T2DM development, metabolic syndrome, and cardiovascular risk factors.[14]

Despite these known risks, there is no consensus among providers regarding clinical practice guidelines or risk counseling and dietary management after delivery for women with pGDM. It is not surprising therefore, that these women do not perceive themselves to be at elevated risk for T2DM, nor are they engaging in risk reduction behaviors, such as healthy eating or increased physical activity.[15,16] In a recent study of women with pGDM, only 5% were consuming the recommended five servings/day of fruits and vegetables.[17] Yet, intensive lifestyle interventions that include a healthy diet and physical activity have been successful in reducing the risk for T2DM in women with pGDM by 53%.[18]

Determinants of diet quality include multiple intrapersonal, interpersonal, and environmental factors; thus it is essential to understand eating behavior within these broader contexts.[19] Dietary patterns or eating behaviors are known to be influenced by threat of disease, and perceptions of dietary benefits as well as self-efficacy in other populations.[20,21] Additionally, studies have confirmed the critical role and influence of family on childhood diet quality;[22] however, very little is known about the influence of the interpersonal family relationship with diet quality in early-stage, at-risk adults, specifically in women with pGDM. Due to the multifactorial complexity of the obesity epidemic, there is a resurgence of interest in designing family-based interventions to target both childhood and adult obesity.[23] Supportive social environments have been

demonstrated to be important in supporting dietary change,[24] and the family context may be the social context which is most likely to support making health behavior changes.[23] Although social support plays a key role in influencing diet quality,[24] the degree to which the family environment and support affects adult diet quality has been largely unexplored.

Purpose

A review of the literature yielded little empirical evidence on the influence of intra- and interpersonal influences of diet quality among the at-risk population of women with pGDM. This study, therefore, aimed to determine the individual and interpersonal social/family-level influences associated with diet quality among women with pGDM, and to examine the contribution of diet quality to cardio-metabolic risk and T2DM risk status while controlling for other contributing variables.

Specific Aims and Research Questions

The focus of this study was an examination of the influence of individual beliefs and specific social and family-level factors on the diet quality of women with pGDM during a critical preventative timeframe of one-five years following delivery. Furthermore, an exploratory focus examined the cardio-metabolic risk and T2DM risk status of these women in relation to their diet quality. The following specific aims, associated hypotheses (H) and research questions (RQ) were addressed:

Specific Aim 1*:* Examine the relationship between individual perceived beliefs (threat of T2DM, perceived diet benefits, barriers, and self-efficacy) and diet quality, controlling

for age, race/ethnicity, knowledge, education and depressive symptoms in women with pGDM.

H1A: Women with pGDM with higher perceptions of the threat of T2DM and greater perceived self-efficacy have higher diet quality than those with lower threat and self-efficacy perceptions.

H1B: Women with pGDM who report greater perceived diet benefits and lower perceived diet barriers have higher diet quality than those who report fewer benefits and greater barriers.

H1C: Individual perceived beliefs in pGDM women influence diet quality when controlling for age, race/ethnicity, knowledge, education and depressive symptoms.

Specific Aim 2: Determine the contribution of general social support and family-level influences (family functioning and family food interaction) to diet quality in women with pGDM.

H2A: Higher levels of general social support are associated with higher diet quality.

H2B: Higher levels of family functioning (general functioning, problem-solving, communication) and higher levels of family food interaction are associated with higher diet quality.

H2C: Higher family functioning and higher family food interaction contribute to additional variance of diet quality over that contributed by individual beliefs (threat of T2DM, perceived self-efficacy, and perceived benefits and barriers),

controlling for the other contributing factors (age, race/ethnicity, knowledge, education, depressive symptoms and social support).

Secondary Aim: Explore the relationship between diet quality and risk of CMR (elevated waist circumference, hypertension, dyslipidemia, hyperglycemia) and T2DM (Hemoglobin A1C $\geq$ 5.7) at 1-5 years post-GDM, controlling for physical activity, BMI, prior breastfeeding duration and age.

RQ 1: What is the cardio-metabolic risk (CMR) and T2DM risk status of women 1-5 years post-GDM?

RQ 2: Does diet quality predict risk status (either CMR or T2DM), controlling for physical activity, BMI, breastfeeding duration and age?

Conceptual Framework

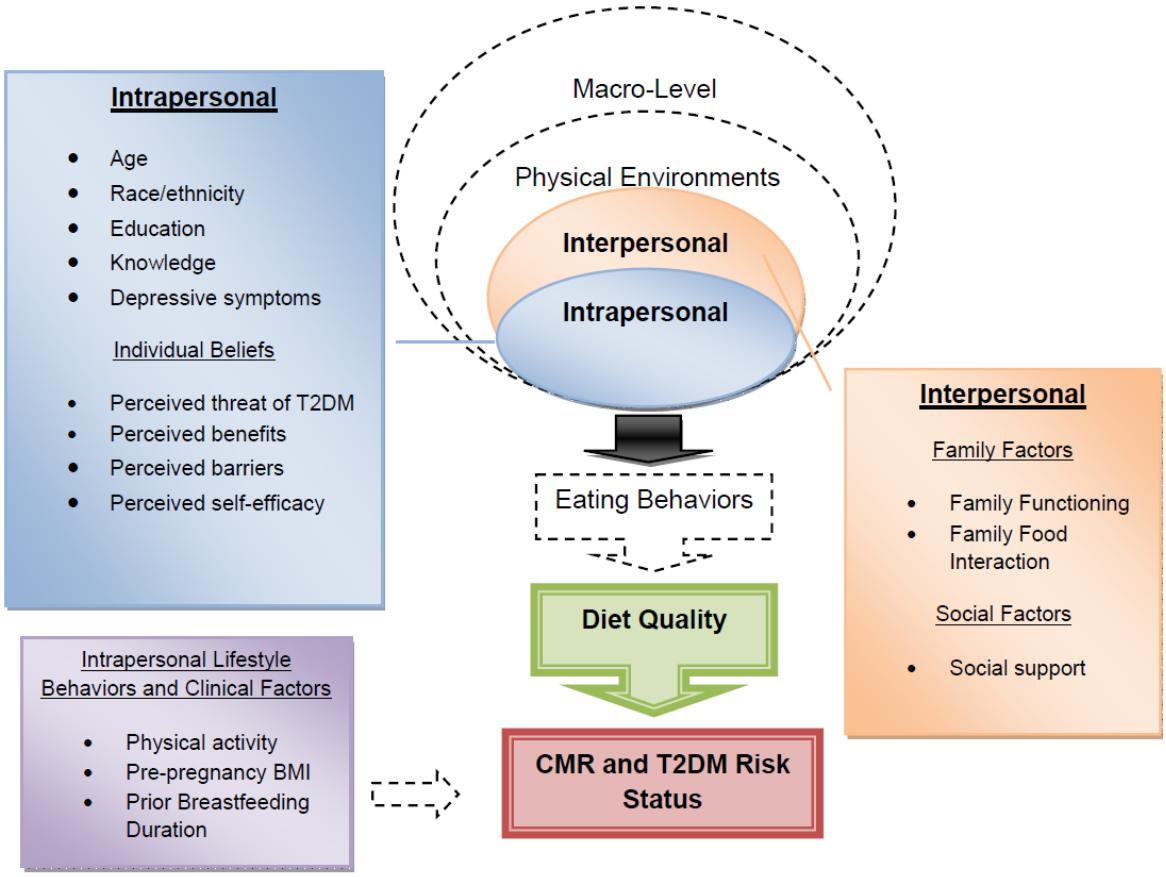
The framework that guided this study was a synthesis of the Health Belief Model (HBM) and the ecological model with adaptation by Story and colleagues for eating behavior.[19] The HBM is one of the earliest models to explain health behavior and has been a key influential model in health promotion.[25] It originated in public health to explain why people did not participate in screening programs to prevent or detect disease and has been further developed and tested since its development. The key constructs in the HBM are perceived threat, perceived benefits, perceived barriers and perceived self-efficacy. Perceived threat is the combination of perceived susceptibility (beliefs about the likelihood of disease) and perceived severity (beliefs about the seriousness of disease). Perceived benefits and barriers are defined as the positive and negative aspects of health actions to reduce disease threat. Finally, self-efficacy is defined as the conviction that behavior can be successfully enacted to produce outcomes.[26]

Because the HBM is focused primarily on the individual, and this study aimed to understand the family-level influences on eating behavior, this study was further guided by the ecological framework designed by Story and colleagues[19] to depict the multiple influences of eating behavior. The ecological model describes four broad contexts that influence health; intrapersonal (individual), interpersonal (social environments), settings (physical environments), and macro-level environments. The intrapersonal influences include individual cognitions, behaviors, biological and demographic factors. As depicted in Figure 1, this study specifically examined the contributing demographic and knowledge factors and individual beliefs. The interpersonal or social environment included the interactions with family, friends, peers and community members, with this study specifically focusing on general social support and the family-level influences. For this study, family was defined broadly to include census (blood-relatives, marriage, adoption), biologic (genetic), household (co-habitants) and functional (involved in the everyday routines) configurations.[27] Furthermore, family functioning was understood through three dimensions; problem solving, defined as the family's ability to resolve problems at a level sufficient for family functioning; communication, defined as how the family exchanges information; and general functioning or adaptability, defined as overall family functioning. [28] Family food interaction was defined as the interaction between family members that relate to decisions and activities around food choices.[29] Social support is the perception and belief that one is cared for and loved, esteemed and a member of a mutually obligated network or group.[30]

Physical environments include settings such as worksites, home, school, childcare, neighborhoods, restaurants, and retail food outlets, while macro-level

environments encompass the legislative and policy influences related to the food system. Influencing factors within the physical and macro-level environments, while important, were beyond the scope of this project and were not addressed. Because eating behavior is complex and influenced by all these contexts, an ecological model was an ideal framework for understanding eating behavior. This study provided an opportunity for examination of eating behavior of an at-risk population beyond the more commonly examined individual level factors. Figure 1 depicts the synthesized Health Belief Model and ecological model (Story and colleagues). The individual and interpersonal influences are posited to influence eating behavior, which then determines diet quality. Diet quality promotes protection from or development of CMR status.

Figure 1. Synthesis of the Health Belief Model and the Ecological Framework for Eating Influences demonstrating influences of diet quality and outcomes of cardio-metabolic risk (CMR) and Type 2 Diabetes (T2DM) risk status for women with previous gestational diabetes mellitus.



Note. The Ecological Framework for Eating Influences was adapted from Story et al. (2008) and combined with the Health Belief Model. Republished with permission of *Annual Review of Public Health*, from "Creating healthy food and eating environments: Policy and environmental approaches", Story M. et al., *29*, 2008 permission conveyed through Copyright Clearance Center, Inc. This study was limited in focus to assessing specific intrapersonal and interpersonal factors as depicted in the colored boxes in this figure. The concepts highlighted by dotted lines are recognized to be important environmental influences of diet quality, but were not measured in this study. Individual beliefs reflect the perceptions as defined by the Health Belief Model for eating behavior in relation to T2DM development. Family functioning is defined by the McMaster Model of Family Functioning and includes the concepts of general family functioning, communication and problem-solving. Family Food Interaction describes the degree to which family members interact over food preferences and nutrition. Social support is the perception and belief of being cared for and part of a mutual network/group. Physical activity, pre-pregnancy body mass index (BMI), and prior breastfeeding duration are known to influence cardio-metabolic and T2DM risk status and were measured to adjust for these risk status outcomes.

Background and Significance

Gestational Diabetes Mellitus

Gestational diabetes mellitus (GDM), defined as carbohydrate intolerance that is first detected in pregnancy and resolves following delivery,[31] currently affects at least 7% of all pregnancies or 200,000 women per year in the United States.[32,33] However, the exact incidence of GDM is unknown and the differences in reported incidence are based on the population studied and the diagnostic criteria used.[34] In Georgia, an 11.6% increase in incidence was observed between 2003 and 2004.[35] GDM is associated with obesity and the prevalence of type 2 diabetes (T2DM) in the population, and therefore parallels the increase of both of these conditions.[1,36] GDM is associated with a seven-fold increased risk for the development of T2DM,[6] with greatest risk in the first five years following delivery.[7] Women with previous gestational diabetes (pGDM) also have a GDM recurrence rate as high as 70% in subsequent pregnancies.[37]

Having GDM also puts women at elevated risk for metabolic syndrome and cardiovascular disease. [8,9,11,12] Poor diet quality, sedentary lifestyle, and overweight/obesity present the most significant modifiable risk factors in progression to T2DM, metabolic syndrome and CVD.[13] Longer duration of breastfeeding reduces T2DM risk and long-term cardio-metabolic risk (CMR) in non-pGDM women, however this has not been well-studied in women with pGDM.[38-41] However, duration of lactation has an inverse association with metabolic syndrome in both non-pGDM and pGDM populations.[42] Non-modifiable risk factors for GDM include advance age, race/ethnicity, socioeconomic status, family history of T2DM, and increase parity. [10,13,43]

There are conflicting recommendations for post-partum follow up screening for women with pGDM. No recommendations exist regarding risk education or preventive measures even though intensive lifestyle interventions were demonstrated to reduce the risk for T2DM by 53% among the cohort of women with pGDM enrolled in the Diabetes Prevention Program (DPP).[18] The American College of Obstetricians and Gynecologists, consistent with the American Diabetes Association recommend that all women with pGDM be screened for abnormal glucose tolerance 6-12 weeks following delivery,[44] yet as many as 67% of women with pGDM do not get screening at the post-partum visit.[45-47] Another study also found that women with the most severe GDM are least likely to return for post-partum follow-up visits.[48] Furthermore, there are no recommendations concerning patient education regarding risk status or dietary interventions specific to this population aimed at delaying or preventing the onset of T2DM. Consequently, many women with pGDM do not perceive themselves to be at elevated risk for T2DM,[15] nor are they engaging in risk reduction behaviors.[16] For those who receive some lifestyle counseling from their providers, it is insufficient to affect improvements in diet or activity or the intention to improve these behaviors.[49] The intensity of care that is directed at GDM women during the pregnancy is not followed through after delivery,[50] and little is known about how women perceive or understand their CMR, or their level of engagement in preventive lifestyle dietary and physical activity behaviors. The *Healthy People 2020 goals* specifically address the need to increase the proportion of people at risk for diabetes who are engaged in risk reduction activities.[51]

Cardiometabolic Risk and Diabetes

Cardiometabolic risk (CMR) is defined as the combination of modifiable and non-modifiable risk factors associated with cardiovascular disease (CVD) and diabetes which include age, race/ethnicity, gender, family history, overweight, abnormal lipid metabolism, inflammation, hypertension, smoking, physical inactivity, unhealthy diet and insulin resistance.[52] Studies examining the CMR profile of women with pGDM at different time points following a GDM diagnosis have shown multiple cardio-metabolic abnormalities,[13,53-55] and significant elevated risk for CVD.[8,56] In addition to the high risk of T2DM, women with pGDM women are at elevated risk of metabolic syndrome.[10,11] These studies highlight the elevated CMR that a diagnosis of GDM poses to the woman, however there is limited data regarding these risks in relation to diet quality during the high-risk time period for the development of T2DM.

Diabetes is the seventh leading cause of death in the U.S. and affects 23.6 million children and adults, while another 57 million people have pre-diabetes.[57] Relative 5-year risk of total mortality is increased by 50-60% and CVD mortality is increased by 150% among pre-diabetic populations. [58] The significant co-morbidities associated with diabetes include high blood pressure, kidney disease, neuropathy, blindness and amputation. Death rates from CVD are two to four times higher among adults with diabetes than those without the disease.[57] Approximately $1 in $5 health care dollars is spent on caring for someone with diabetes, with diabetics averaging 2.3 times higher health care expenditures than the general populous.[59] The estimated total cost of diabetes in 2007 was $174 billion.[59] Furthermore, a study in the early 1990's projected that if 50% of women with pGDM progressed to develop T2DM, an additional $331 million would be added to the total cost of diabetes care.[60] This further illustrates the critical need that

populations at elevated risk for T2DM be targeted for preventative interventions including those related to diet.

As demonstrated in the Diabetes Prevention Program (DDP) trial, intensive lifestyle interventions focused on low-fat, high-nutrient diets, weight loss and increased physical activity can provide a 58% relative reduction of T2DM incidence among pre-diabetic populations.[61] A recent review examining the cost effectiveness of such interventions determined that there is significant cost savings per life year gained.[62] Not only are these interventions very cost effective, they are supported by very strong evidence and should be used to improve clinical practice. Since the DPP published results in 2002, there have been efforts to translate the intervention into other settings. Although studies have been testing the lifestyle intervention in various community and clinical settings,[63,64] most have been modeled after the DPP program with a focus solely on individual factors of health behavior. Examining the influence of family and social factors with specific, validated dietary patterns is an important next step in understanding socio-ecological aspects of dietary patterns with at-risk populations.

Diet Quality

Diet Patterns

Although the Dietary Guidelines for Americans promote a healthy diet, it is estimated that as few as 3-4% of Americans follow all the national recommendations and virtually no one meets recommendations for vegetable and whole grain consumption.[65-67] The typical American diet is low in micronutrient (vitamin, mineral, trace element) density and high in saturated fat, sugar and sodium.[68] Georgia ranks lower than the national average in fruit and vegetable intake, with only 13.13% of adults consuming at

least 2 fruit and 3 vegetable servings per day.[69] In a recent study of women with pGDM, only 44% were consuming ≥ 2 daily servings of fruit, and only 5% were consuming five servings/day of fruit/vegetables.[17] Other studies with this population have found similar results.[16,70]

As demonstrated in the DPP, a 10% weight loss conferred the greatest benefit in preventing or delaying T2DM development in at-risk groups and these lifestyle interventions have been successful over time in preventing T2DM.[71,72] Though this was achieved through diet and physical activity, evidence from other intervention studies suggest that improvement in dietary quality may be the more critical factor compared to physical activity in achieving weight loss.[73] In contrast, the Da Qing trial and other more recent studies have demonstrated that exercise alone can significantly reduce risk factors for diabetes and metabolic syndrome.[74-76] It is well-established that diet and exercise are more successful when combined than either is alone for weight loss and improving cardio-metabolic risk factors.[77-82] However, it has been recently suggested that modern living presents challenges to incorporate sufficient physical activity, especially with recent trends in excessive caloric intake. This challenge to balance excessive dietary calories with enough physical activity to prevent weight gain suggests that a focus on diet should be a higher priority.[83]

The dietary patterns of the major diabetes prevention intervention studies, including the DPP, the Finnish Diabetes Prevention Study (DPS), and the Da Qing study (DQS) were characterized by a reduction in energy intake, with decreased fat intake and increased intake in fiber-rich foods such as fruits and vegetables.[74,84] A 2008 Cochrane review that aimed to identify the optimal diet for the prevention of T2DM only included

two clinical trials, the Da-Qing trial and the Oslo Diet and Exercise study, concluding that there was insufficient evidence and a need for more long-term, well-designed studies to determine the efficacy of dietary interventions in the prevention of T2DM.[85] Further conclusions included that the available data suggest that an energy-controlled diet with a high consumption of fruits and vegetables and a low intake of simple sugars seems to offer benefit.[85] This is in line with a more recent study in which the Mediterranean diet significantly reduced risk for T2DM.[86] Furthermore, the Mediterranean diet as a prescriptive, intervention diet is preventative of major cardiovascular events in patients who have T2DM.[87]

Although there is evidence that diet interventions are effective in decreasing the incidence of T2DM, more studies are needed to determine intervention efficacy, and to assess morbidity, mortality, and quality of life.[85] More importantly, there is a need to translate these findings into clinical practice and begin implementing dietary interventions that are feasible. Early evidence suggests that translation prevention programs may not be as successful as the more structured clinical trials[88] and so continued research on optimal methods to prevent T2DM are warranted. Multi-level strategies offer the best model to tackle the many influences of health behavior, particularly eating behavior.[89] It is useful to consider other studies that have examined the diet-disease relationship, and data are accumulating from observational studies in multiple populations that support the significant role of diet in T2DM development. A common characteristic among the dietary patterns associated with protective effects are that they reduce postprandial glycemia and insulinemia.[90]

Examining general dietary patterns and risk for diabetes has resulted in commonalities among patterns that are protective for T2DM. Many studies have determined that a higher intake of fruits and vegetables is protective,[91-94] while dietary patterns reflecting intakes of low nutrient value have demonstrated higher risk. Low nutrient profiles often contain higher intakes of meats, fatty foods, potatoes, sugar-sweetened beverages, snack foods, refined grains and low intakes of vegetables, olive oil, fruits, whole grains, fish, and alcohol.[95-99] Patterns that have demonstrated protection from T2DM are characterized by higher intakes of fruits, vegetables, monounsaturated fat, whole grains, dietary fiber, dairy, salad, fish, and moderate intakes of alcohol.[96-101]

Another way to examine dietary patterns is by the degree of adherence to a pre-specified recommendation. The Mediterranean diet is a pattern that is characterized by high intakes of fruits, vegetables, whole grains, monounsaturated fats, fish, legumes, and moderate wine consumption and has been associated with lower incidence of T2DM.[102,103] Its anti-inflammatory properties seem to be one of the major protective factors in T2DM and other inflammatory diseases.[104-107] The Dietary Approaches for Stopping Hypertension (DASH) diet has also been examined in relation to T2DM risk. Although originally designed as an anti-hypertensive diet, its high nutrient properties have been demonstrated to be protective in T2DM.[108] In one recent study, greater adherence to the DASH diet was associated with improved insulin sensitivity.[109] Among a population of subjects with T2DM, adherence to the DASH diet was associated with decreased fasting blood glucose and lower hemoglobin A1C.[110] Greater adherence to the Dietary Guidelines for Americans has also been associated with decreased risk factors for T2DM.[111]

The Alternate Healthy Eating Index (AHEI) is a diet index that evolved from the Healthy Eating Index and has been demonstrated to be a better predictor of chronic disease, especially cardiovascular disease risk.[112,113] Examining diet quality using the AHEI score demonstrated that higher adherence was associated with lower risk for T2DM in a large prospective cohort study of women.[114] A more recent study in women with pGDM has also demonstrated a significant reduction (57%) in T2DM development with greater adherence to the AHEI. Adherence to the AHEI dietary pattern was more protective in this population than either the Mediterranean or DASH diet patterns – 40% and 46% respectively.[115] This dissertation study also defined diet quality by the AHEI, so a brief review of the association of the individual components with T2DM is discussed below. The nine components that comprise the AHEI are vegetables, fruit, nuts/soy, ratio of white to red meat, cereal fiber, trans fat, polyunsaturated fat to saturated fat ratio, duration of multivitamin use and alcohol.

Dietary Components of the AHEI

Fruit and Vegetables. Although there are few studies that examine vegetables or fruit alone, there are many that examine them together and have found them to be protective in T2DM development.[91-94] A higher consumption of fruits and vegetables was a primary component of the protective diet patterns that were discussed above. A recent study did find that vegetables and not fruit were protective in Chinese women.[116] Furthermore, a meta-analysis examining the impact of fruit and vegetable consumption concluded that green leafy vegetables and not total fruit and vegetable consumption, offer the greatest protective benefit for the development of T2DM.[93]

Nuts. Two recent reviews synthesizing the studies that examined the association between nut consumption and T2DM concluded that nut intake is associated with important micronutrients that contribute to reducing the risk of coronary heart disease and should be considered to be included in the diets of those with T2DM.[117,118] Although these reviews did not examine this in relation to prevention of T2DM, other studies did find that soy and nut consumption improved glycemic control and lipid profiles in postmenopausal women with metabolic syndrome, and almond consumption was associated with improvements in CVD risk factors in those with prediabetes.[119,120]

Meat/Fish. A higher white meat to red meat ratio is considered ideal by the AHEI, since white meat (fish, poultry) has been associated with lower rates of chronic disease and red meat (beef, pork, lamb), especially processed meat, has been associated with higher rates of chronic diseases.[112] Processed meat is associated with T2DM development, [100,121] and a recent meta-analysis determined that meat intake was associated with a higher incidence of T2DM.[122] The risk was highest with red meat and processed meat consumption.[122]

Grains/Cereal Fiber. Higher consumption of whole grains are associated with lower fasting glucose and insulin[123] and a high consumption of cereal fiber is associated with decreased risk for T2DM.[124,125] Furthermore, higher intakes of magnesium, which is found in whole grains, has also been associated with decreased incidence of diabetes.[126]

Fat. Dietary fat intake has been divided into two separate components in the AHEI; one reflects the percentage of energy from *trans* fatty acids and the other represents the ratio of polyunsaturated to saturated fat ratio. This percentage and ratio is

supported by their individual contributions to coronary heart disease. [112,127,128] In relation to the association of these fats to diabetes, the results for both the role of saturated fatty acids and *trans* fatty acids is mixed.[129-131] Some studies have found that *trans* fatty acids have no effect on risk for T2DM,[132] while others have found a positive association.[133] The AHEI was not designed solely for the examination of diet quality in relation to T2DM, so this component of fat serves a purpose in other diet-disease relationships, specifically cardiovascular disease. However, the association of dietary fat with T2DM is inconclusive and ongoing research will continue to clarify the relationship.

Alcohol. Moderate intake of alcohol has been associated with a decreased risk for T2DM,[134-136] but does not seem to improve insulin sensitivity.[137] Multiple studies have found a U-shaped relationship with alcohol consumption and T2DM in western populations, highlighting the importance of moderate consumption.[138-140] Comparatively, in a Chinese population, a J-shaped curve association was found.[141] It is clear that alcohol consumption seems to offer protection for CVD risk and T2DM[142] when consumed in moderation, but higher intake is associated with greater risk for T2DM.[143]

Multivitamins. There is little research focused specifically on the use of multivitamins and risk for T2DM, however, micronutrient deficiencies have been found in T2DM patients[144] A recent large cohort study of older adults found no association between multivitamin use and risk for T2DM,[145] supporting an earlier study with similar findings.[146] However, Song et al. did identify a protective effect associated with the use of vitamin C and calcium supplementation.[145] Another study concluded that vitamin D and calcium may be protective in the risk for T2DM in women[147] and calcium and magnesium were found to be protective among Chinese women.[148]

Factors Influencing Diet Quality

Individual Influences

Individual influences on healthy eating have been widely studied among many populations, and multiple intrapersonal factors have been associated with diet quality. As depicted in Story et al.'s ecological framework of the multiple influences of eating behavior, the intrapersonal influences include cognitions, skills and behavior, lifestyle, biological, and demographics.[19] Demographic factors influence diet quality, with most studies finding that increased age, higher education, higher income and non-minority race/ethnicity are associated with higher diet quality.[149-151] Knowledge and self-efficacy are strong predictors of diet quality with post-partum and in women with pGDM.[17,150,152] Depression and anxiety are strongly associated with lower diet quality,[153] with some recent studies suggesting that poor diet quality may predict depressive symptoms, especially in women of childbearing age.[154,155]

Because the post-partum period is a time of altered individual lifestyle and family adjustment, there may be unique needs related to influences on diet quality specific to this population. There are no studies that have examined dietary attitudes from pre-pregnancy to postpartum in women with pGDM, however in studies with non-GDM women, attitudes about diet did not change from prepregnancy to postpartum.[156,157] Intrapersonal influences of healthy eating have not been well-studied in women with pGDM, so little is known regarding the individual beliefs about healthy eating in this high-risk population.

Family-Level Influences

Three main sources constitute the family-level influences on health: genetics, a shared physical environment and a shared social environment.[27] Specific family-level influences that have been demonstrated to affect health promoting behavior include family rules, emotional support, encouragement, reinforcement, and family member participation.[158] There is a substantial body of literature regarding the importance of family influence on children's eating patterns,[159,160] but less attention has been devoted to the family influences on adult eating patterns. This is particularly true for populations not on a prescriptive diet for a specific disease.[161] In a study examining family influences with diabetic children's adherence behaviors and metabolic control, family cohesion and family conflict (components of family functioning) were important factors in adherence and metabolic control.[162] Studies examining family functioning with adult diabetics and heart failure patients have found family functioning and support to be strongly related to dietary behavior.[161,163,164]

There has been greater attention focused on designing family-based interventions to target both childhood and adult obesity.[23] Supportive social environments, particularly the family environment may be beneficial in supporting health behavior change, including dietary change.[24] The family context provides reinforcement of beliefs and health behaviors throughout the lifetime[165] and provides social support that directly impacts health, specifically cardiovascular health.[166] Depending on family structure, as much as 4.5% - 26.1% of the variance in individual health status could be determined by family influence.[167] Furthermore, interventions aimed at the whole family may be more successful in this population of women and young children due to the mother's more intense focus on her children's health, as opposed to her own health.[168] The National

Diabetes Education Program advocates for the families of women with pGDM to follow a healthy diet,[169] however, there are no studies to date examining the family-level influences on eating behavior with a population of at-risk women with pGDM.

Social Support

Social support has long been recognized as an important influence of health and is a major factor in determining diet quality and predicting success in diet-related interventions. [24,170,171] Particularly in interventions focused on improving adherence to prescriptive diets, higher levels of social support result in better dietary outcomes.[172] A recent study examining the influence of social support on diet quality among healthy working adults, found social support to be a key influencing factor in determining diet quality.[173] Being married has also been associated with higher diet quality, particularly fruit and vegetable intake.[174] Furthermore, the quality of the marital relationship is important in determining prescriptive diet adherence.[175]

Summary

Gestational diabetes mellitus is a serious health problem associated with significant risk for cardiometabolic and cardiovascular disease for both women and children of the GDM pregnancies. Since a diagnosis of GDM represents a significant risk factor for the development of T2DM, metabolic syndrome, and CVD, greater attention must be devoted to the modifiable risk factors associated with the progression of these disease states, most notably diet quality. Though reduction of risk factors for all prediabetic populations is important, women with pGDM represent a unique population that is more easily identifiable than other high-risk groups. The identification of prediabetes is incumbent upon individuals with few, if any, symptoms to be seeking care,

and the diagnosis is complicated by inconsistent results among the screening tools. This presents challenges of accurately identifying the incidence and prevalence of prediabetes, thereby further complicating decisions about how to allocate resources for this disease. However, the diagnosis of GDM is more straightforward, and the women are a captured patient population accessing health care during the last trimester of their pregnancy, which sets the stage and foundation for intense follow-up. It is an ideal population to focus resources and intensify prevention efforts. However, for such prevention efforts directed at improving diet quality to be successful, a greater understanding of the individual and family-level influences of eating behavior must be better understood.

By examining multi-level factors including the combined individual and family influences that contribute to eating behaviors and diet quality among an at-risk population, this study fills a gap in the understanding of modifiable factors that can improve diet quality. The findings will guide the development of future studies and testing of interventions to improve diet quality for these at-risk women, which not only serve to benefit the individual woman, but have potential for improving diet quality for her at-risk family.

Research Design and Methods

Design

A descriptive, cross sectional design was selected to examine correlates of diet quality among women with previous gestational diabetes (pGDM). This design was selected for its utility in the exploratory and descriptive focus of this initial pilot study examining variables that have not been studied previously in this population and to generate hypotheses for future studies. Individual beliefs, along with social support and family-level factors were examined in association with diet quality as defined by the Alternate Healthy Eating Index (AHEI). Questionnaires were completed for a single time point. Clinical and anthropometric factors were measured at one study visit and assessed in relation to diet quality.

Before the start of any recruitment or data collection, Institutional Review Board (IRB) approval was granted from Emory University. The approval for this study (#IRB00046666) included a partial HIPAA waiver to allow for medical chart reviews to identify potential participants. All recruitment sites, strategies, forms, and instruments were approved by the Emory IRB. Additional approvals were granted by the Grady Research Oversight Committee and the Hall County Health Department. All IRB-specific documents, including approval letters, consent forms and waivers are included in Appendix A. The Emory University IRB stipulates that any patient contact must come from the patient's individual provider. The PI collaborated with providers at each site to design site-specific recruitment tools to contact patients.

Settings and Recruitment Strategies

Participants were recruited from obstetrics and gynecology (OB/GYN) offices associated with the Emory Clinic, Grady Memorial Hospital, the Hall County Health Department (HCHD), and Centro International de Maternidad (CIMA). Potential participants were identified through medical chart reviews. Letters of invitation (see Appendix B) were sent by the medical provider for patients identified through Emory Clinic, Grady, and an initial sample of HCHD patients.

Emory Clinic. The PI collaborated with team members of the OB/GYN clinic at the Emory Clinic to identify patients who had been treated through the clinic or delivered at Emory Midtown Hospital with a GDM diagnosis ICD-9 code, "648.0" within the previous five years. A password protected Excel spreadsheet was generated in March 2012 that included 458 patient names and addresses. A form letter was drafted, signed by Dr. Mary Dolan, Division Director General Obstetrics and Gynecology, and mailed to all 458 identified patients (Appendix B). Instructions in the letter directed interested participants to contact the PI by email or phone for more information and to determine eligibility. Undeliverable letters could not be tracked since the return address was not directed to this study. This recruitment strategy yielded 12 enrolled participants.

Grady Memorial Hospital. A similar strategy was implemented through the OB/GYN clinic at Grady. However, electronic medical charts were not available for identifying patients. We collaborated with the primary nurse in the clinic who sees all the high-risk OB patients. She keeps a clinic file specifically for each GDM patient. A manual chart review was conducted to identify potential participants. From that, a list of 361 patient names and addresses was generated. Since so many participants were identified as Spanish-speakers, the recruitment letter for this site included both English and Spanish

instructions (Appendix B). Because all Spanish-speaking inquiries needed to be directed to the part-time bilingual work-study students, a separate research phone line with voice messaging capacity was designated for Spanish-speaking women. Again, similar challenges existed with the inability to track undeliverable mail with this site, since we could not use the study office for a return address. This strategy and site resulted in 7 enrolled participants.

Hall County Health Department. The recruitment strategy at the HCHD was altered when it was determined that home mailing addresses may not have been accurate or updated in medical charts. The principal investigator began weekly chart reviews for women's health patients scheduled for appointments the following week. Every woman who had an appointment in the Women's Health Clinic for the following week had her chart pulled and stacked by the medical records personnel by the previous Thursday. Each chart was reviewed and determined for eligibility by GDM diagnosis. If the patient met GDM diagnosis and timeframe criteria, a Spanish or English language recruitment flyer was placed on her chart (see Appendix B). HCHD providers were asked to share the flyer with the patient. The patient could leave the tear-off section at the bottom of the flyer with the provider or receptionist indicating that she was interested and granted permission to be contacted by research staff to be screened for the study. The bilingual research assistants contacted all Spanish-speaking women and the PI contacted English speaking women by telephone or email as requested by the patient. A total of 84 flyers were placed on patient charts and 9 participants were recruited with this strategy.

Other Sites. An IRB application was submitted and reviewed by Northside Hospital requesting medical chart review and recruitment solicitation by letter. The application

was denied, due to protection of patient privacy. The letter of denial is included in Appendix A.

CIMA agreed to assist with recruitment. Spanish and English flyers (see Appendix B) were posted in each of the clinics. No participants, however, were screened or recruited from these clinics.

Community Recruitment. Self-referred recruitment was solicited by phone wait-time advertisement messages on the Emory Healthcare phone system and through flyers located in community OB/GYN offices, pediatrician offices, family practice offices, child care centers, worksites, churches in metro-Atlanta and throughout Emory University campus. The Emory phone-wait advertisement (see script in Appendix B) was aired during 5 months and resulted in 6-10 interested callers/month. A total of 13 participants were enrolled from this recruitment strategy. Community flyers resulted in 8 participants enrolled, primarily from the two Clifton School child care center campuses (n = 5).

An email blast was sent by a colleague to a parent-employee list-serv at the Centers for Disease Control and Prevention. This resulted in 2 women enrolled. Another email blast was sent by a day care provider owner to all of her parents, however this strategy yielded no callers or enrollees.

A Facebook media page was created for the study in December 2011. We posted links and stories about gestational diabetes, as well as study information. We also ran a continuous advertisement campaign from March 2012 – November 2012 that targeted women in metro-Atlanta. The advertisement and Facebook page contained a link to an online IRB-approved Survey Monkey questionnaire (see Appendix B) where interested

women could complete the questionnaire and indicate their willingness to be contacted for more study information. Most women requested to be contacted by email (see scripted email response in Appendix B). A total of 61 women completed the questionnaire, and of those that were able to be contacted and deemed eligible, 10 were enrolled (see Table 1.1).

Overall, potential participants were screened through a 2-step process. Approximately 1,004 potential participants were preliminarily screened through medical chart review, the Survey Monkey questionnaire, or through a brief overview of the study by phone. The majority of those who were preliminarily screened did not proceed to the secondary, formal screening through lack of response from the study invitation letters, medical chart flyers, or email sent following the completion of the Survey Monkey questionnaire (n = 886). Other common reasons for not proceeding to the secondary screening were: > 5 years since the most recent GDM pregnancy (n = 17), currently breastfeeding (n = 9), currently pregnant (n = 7) or had developed T2DM (n = 6). Every potential participant who completed the secondary screening and met all eligibility criteria agreed to enroll (n = 80). Five participants dropped from the study after enrollment; 3 were lost to follow-up; 1 became pregnant; 1 withdrew due to life stressors.

Potential participants who were self-identified from community recruitment strategies were questioned about their gestational diabetes medical history with greater depth to verify the prerequisite diagnosis for study eligibility. This screening included the date of GDM diagnosis, the delivery date of the GDM pregnancy, the method of GDM treatment (lifestyle, oral medications, or insulin) and their recall of the frequency

of daily finger-prick, glucose checks. Self-report of gestational diabetes medical history has been found to be a reliable method of identifying the pGDM population.[176]

Table 1.1

Recruitment Strategies and Success Rates

Recruitment Site	Recruitment Method	Number Screened	Participants Enrolled	Success Rate
Recruitment by Medical Chart Review				
The Emory Clinic	Mailed Letters	458	12	2.6%
Grady OB/GYN Clinic	Mailed Letters	361	7	1.9%
Hall County Health Department	Medical Chart Flyers	84	9	10.7%
Total Enrolled by Medical Chart Review			28	
Recruitment by Community Self-Referral				
Emory Healthcare Phone Wait Advertisement	Phone Advertisement	30-50 callers	13	32.5%
Facebook Advertisement	Paid advertisement on Facebook with Survey Monkey questionnaire link	61	10	16.4%
Community Flyers	Flyer		8	
Email Blast	Email		2	
Other/Referral			14	
Total Enrolled by Self-Referral			47	

Sample characteristics by recruitment strategy, medical chart review versus community self-referral, were examined. Those who were identified through medical chart review were more likely to be Minority ($X^2 = 7.45$, $p = .006$) and have lower education levels ($t = 3.93$, $p = <.001$) than those who were recruited by community self-referral. These differences are likely related to the clinical sites which serve a large

Minority, low socioeconomic status population of women. No differences were found by age.

Sample

The target population for this study included women aged 18-45 years, with a diagnosis of gestational diabetes (GDM) within the past one-five years. Eligibility criteria included: cohabitation with at least $\geq$ 2 family members, one of whom is at least $\geq$ 13 years of age.[177] Participants had to be English or Spanish-speaking. Exclusion criteria included: (1) a diagnosis of Type 1 or T2DM (2) currently consulting with a dietician, (3) on any prescriptive diet, (4) enrolled in a lifestyle intervention-focused research study, (5) enrolled in a diet-focused weight-loss program, (6) untreated depression, determined by scoring either $\geq$ 20 or $\geq$ 16, with suicidal ideations on the Patient Health Questionnaire-9 (PHQ-9), (7) currently breastfeeding, (8), currently pregnant, (9) diagnosed with polycystic ovary syndrome, and (10) evidence of behaviors that would interfere with ability to participate in the study.

Rationale for the Inclusion and Exclusion Criteria

The ages of 18-45 years were chosen since these are the key childbearing years for women. All racial and ethnic groups were included, however to effectively target high-risk Hispanic women, all study materials were translated into Spanish. Projected enrollment reflected the population demographics of the metropolitan Atlanta area; 64% white (n=50), 25% African-American (n=25), 3% Asian (n=3), and 5% Hispanic (n=4). Recruitment sites were chosen specifically to reflect diverse patient populations; of the GDM patients at Emory Midtown Hospital who delivered in 2009, 70% were African-

American, 17% were white, and 6% Hispanic; Grady Memorial Hospital's high risk OB/GYN clinic serve a large minority population (56% African-American, 38% Hispanic); and greater than 95% of the patients in the maternity/women's health clinic at the Hall County Health Department are Hispanic. Oversampling of minority participants was done to assure targeted enrollment goals were met. Continuous evaluation of enrollment and retention were monitored with specific attention to minority subjects. The final study sample (n = 75) resulted in 45.3% non-Hispanic Caucasian (n=34), 32% African-American (n=32%), 2.7% Asian (n=2), 5.3% Other (bi-racial, multi-racial/ethnic) (n=4), and 14.7% Hispanic (n=11).

Recruitment approaches were altered as needed and additional sites were added. Since both HCHD and Grady serve a large Hispanic population and Hispanic women are disproportionately affected by GDM and T2DM, alterations in the study protocol were made to facilitate the inclusion of Spanish-speaking participants. Two bilingual research assistants joined the research team; one of whom was a native Spanish speaker of Mexican descent, which reflected the ethnic background of the majority of our Hispanic participants. All study forms were translated, back-translated, and approved by IRB. Since most of the instruments did not have a valid, reliable Spanish version, all data collection was conducted via one-on-one interview between the participant and the bilingual research assistant.

Since the risk for T2DM is highest within the first five years following delivery,[7] the timeframe of one-three years following delivery was initially selected as the target timeframe. When recruitment targets were not being met, the timeframe since post-delivery was expanded out to five years.

Since family functioning and family food interaction were key variables in this study, potential participants must have cohabitated with at least $\geq$ 2 family members, one of whom is at least $\geq$ 13 years.[177] This age cutoff results in at least one family member who was an adolescent or adult and would likely have meaningful interactions, influence and decision-making responsibilities with the participants over food choice. Fluency in English or Spanish was necessary to comprehend and complete the study forms and to communicate with the researcher or to complete the interview with the bilingual research staff.

Medical history that would have excluded the participant includes Type 1 or 2 diabetes, polycystic ovary syndrome, untreated depression, and currently pregnant or breastfeeding. The pathophysiology, disease management, and risk factors for Type 1 diabetes is significantly different from gestational diabetes and T2DM. Furthermore, any women who had T2DM would already have the disease intended to be prevented in this dissertation study. Polycystic ovary syndrome is associated with metabolic abnormalities including insulin resistance, impaired glucose tolerance, type 2 diabetes mellitus, and adverse cardiovascular risk profiles, so the pathophysiology and mechanisms for prevention of cardiometabolic diseases is unique to this syndrome.[178]

Depression is so highly related to diet quality,[155] that those with untreated depression had to be excluded so that variance in diet quality could more accurately be attributed to the intra- and interpersonal variables being measured in this study. Finally, both pregnancy and breastfeeding require special nutritional needs which would not be representative of a normal dietary pattern for an adult woman.[179] Moreover, pregnancy

and breastfeeding would have altered the metabolic lab profiles and would not be reflective of a woman in the non-pregnant and non-lactating state.

Since habitual diet quality was the main outcome of interest in this study, women who may have been participating in any diet-altering program were excluded from this study. Diet altering programs included consultation with a dietician, a prescriptive diet for another disease, enrollment in a weight-loss program with a dietary component or enrollment in another lifestyle management research study.

Evidence of behaviors that would interfere with participation in the study included an inability to appropriately answer screening questions or demonstrate understanding of the study protocol.

Sample Size

A sample size to achieve adequate statistical power to address primary specific aims 1 and 2 was calculated using Power Analysis and Sample Size (PASS) software. The analysis was conducted based on plans for multiple linear regression models to detect a medium effect size[180] with variation in diet quality. This effect size was determined based on previous studies that examined the individual beliefs (perceived threat, perceived self-efficacy, perceived barriers and benefits) with diet quality, specifically fruit and vegetable consumption among diverse adult populations, with R^2 ranging from 0.12-0.38.[24,181-183] It was determined that a sample size of 78 would achieve 80% power to detect an R^2 of 0.13 attributed to six independent variables (perceived threat, perceived self-efficacy, perceived barriers, benefits, family functioning, and family food interaction) using an F-Test with a significance level (alpha) of 0.05. The

variables tested were adjusted for an additional six control variables (age, race/ethnicity, education, knowledge, depressive symptoms, and social support) with an R^2 of 0.20. These control variables have demonstrated explained individual variance (R^2) with diet quality ranging from 0.03 – 0.21.[181,184] This sample size was deemed adequate for the exploratory, descriptive nature of the secondary aim examining diet quality with CMR and T2DM risk status. A follow-up power analyses was conducted to confirm the adequacy of the actual sample size of 75.

A total of 81 women were enrolled, with 75 who fully completed the study. Five women dropped out of the study before completing the study questionnaires or clinical data and one participant fully completed the study, but had a diagnosis of T2DM that made her ineligible. The final sample size of 75 was used in the analyses for both Aim 1 and Aim 2. One participant had very high levels of hemoglobin A1C and fasting glucose, likely representing an undiagnosed case of T2DM. Due to her outlier results, she was dropped from the analysis for the secondary aim, resulting in a final sample size of 74 for that analysis.

Instruments

All instruments used in this study were previously validated and deemed adequately reliable in previous samples of racially and ethnically diverse women. Inter-item correlation reliability analyses (Cronbach's alpha) were performed for this study sample for each of the instruments and are reported below. A table highlighting

Contributing Factors

Demographics and Medical History. Demographic data, medical history, pre-pregnancy body mass index (BMI), and breastfeeding duration were ascertained through self-report, with verification obtained from medical chart review on a subsample of 28 participants (37% of the sample). Demographic data included age, race/ethnicity, household income, highest attained educational level, marital status, and household cohabitants. Medical history was focused on the GDM pregnancy experience, including pre-pregnancy weight, weight gain during the pregnancy, type(s) of GDM treatment during the pregnancy, delivery date, and risk screening and follow-up during post-partum. Furthermore, cardiometabolic risk factors were assessed and known influences of CMR were ascertained, including duration of lactation, parity, history of overweight/obesity, history of hypertension, high cholesterol, and current medications.

Depressive Symptoms. Depressive symptoms were measured with the 9-item *Patient Health Questionnaire (PHQ-9*). It was developed for use in primary care population samples and has been validated in a large OB/GYN sample,[185] as well as a general population.[186] Sensitivity was 88%, and specificity was also 88% for identifying major depression.[187] Furthermore, it has been tested and validated for use in telephone screening, with internal consistency ratings of .79-.85, and test-retest correlations ranging from .90 - .95.[188] Telephone administration was used in this study, resulting in a reliability coefficient of .79.

Scores can range from 0-27, with higher scores representing more severe depression.[187] A score of $\geq$ 20 or a response of 2 or 3 (indicating more than half the days, or nearly every day, respectively) on at least five items would be indicative of major depression.[187] Any potential participant that scored in this range was excluded

from the study and referred to her primary care provider for further follow-up. One potential participant was screened out with this criterion. If the potential participant scored $\geq$ 16 and expressed suicidal ideations (answering more than several days to item #9), she was excluded and referred to emergency psychiatric-mental health assistance immediately; Georgia Crisis and Access Line (1-800-715-4225). This incident also happened with one participant. We followed this protocol and further followed up with the participant and assured that she had been able to successfully contact the crisis line.

Physical Activity. Physical activity was measured with the validated *CARDIA Physical Activity History*, a 60 item, branched interview survey that captures levels of activity in leisure, work and household within the past year. It has been tested in multiethnic populations of women with test-retest reliability (Pearson's r = 0.77 – 0.84) comparable to other physical activity measures.[189] It is scored by determining the sum of exercise units, where 100 exercise units are approximately equivalent to engaging in high intensity activity for four months of the year.[189]

Knowledge of Dietary Guidelines. Knowledge of dietary guidelines was measured with an 11-item questionnaire (10 knowledge questions and 1 Likert question for perceived knowledge) adapted from a survey designed to test knowledge of the 2005 Dietary Guidelines for Americans among community health advisors in Alabama and Mississippi.[190] The researchers established content validity with an expert review panel and then pilot-tested the survey with a community sample. The questionnaire was adapted for this study to reflect the most current 2010 Dietary Guidelines for Americans.[179] Items were adapted to reflect the energy and food group recommendations for women aged 19-50 years old.

Individual Beliefs

Perceived Threat. Perceived threat was measured with a 23-item questionnaire incorporating three subscales (Personal Control, Optimistic Bias, Knowledge, and items addressing risk perception and lifestyle behavior) of the *Risk Perception Survey for Developing Diabetes* (RPS-DD), developed for the Diabetes Prevention Program study[191] and adapted for women with pGDM.[15] Cronbach's alpha coefficients for the pGDM population ranged from 0.65 – 0.72.[15] In this sample subscale reliability coefficients were: Personal Control, .62; Worry, .81; and Optimistic Bias, .73.

Perceived Barriers of Healthy Eating. Perceived barriers of healthy eating was measured with the 16-item *Barriers to Healthy Eating Scale* (BHES).[192] It was designed from Pender's Health Promotion model to assess barriers of healthy eating among pregnant women.[192] It is a Likert-type scale assessing barriers such as transportation/access, cost, cooking ability and preferences. It is scored from 16-80 with higher scores indicating greater perceived barriers to healthy eating. Test-retest reliability for the BHES were Pearson's r=0.79 and validity was determined with Cronbach's alpha coefficient of 0.71 and 0.77.[192] In this study sample, the reliability coefficient was .67.

Perceived Benefits of Healthy Eating. Few tools have been constructed to examine perceived benefits of healthy eating and none have been designed for a population of adults at risk for cardiometabolic diseases. Therefore, an instrument was designed for this study, called the *Perceived Benefits of Healthy Eating Scale for Adults at Risk of Cardio-Metabolic Diseases*. Content validity of the scale was established with

an expert review panel and then pilot-tested in a convenience sample (n = 91) of adults who had any cardiometabolic risk factor. Items address benefits such as healthy eating: "can help prevent diabetes," "can help control my weight,", and "can help me feel better." Scores range from 9 – 45, with higher scores indicative of higher perceived benefits of healthy eating. Cronbach's alpha coefficient in the unpublished pilot study was .88 and in this sample was .92.

Perceived Self-Efficacy for Healthy Eating. Perceived self-efficacy was measured with the 16-item *Cardiac Diet Self Efficacy* s*cale,* which is a general nutritional self-efficacy scale addressing healthy dietary behavior.[193] It is a five-level, Likert-type scale assessing confidence levels in adopting healthy eating behavior. Scores can range from 12 – 60, with higher scores indicative of greater self-efficacy. In other samples, Cronbach's alpha coefficients were 0.89-0.92 and test-retest correlation was 0.86.[193] In this study sample, the reliability coefficient was .92.

Social and Family-Level Factors

Social Support. Social support was measured with the 7-item ENRICHD Social Support Instrument (ESSI). The ESSI was developed for use in the Enhancing Recovery in Coronary Heart Disease (ENRICHD) clinical trial in 2000 and has since been widely used in more recent trials.[194] It assesses all four attributes of social support; (1) emotional, defined as the provision of caring, empathy, love and trust; (2) instrumental, defined as the provision of tangible goods or services; (3) informational, defined as the support of information needed to problem-solve during times of stress and; (4) appraisal or affirmational support, defined as the supportive expressions that affirm the appropriateness of acts or statements.[195] The total ESSI scores can range from 8-34, with

those ≥ 18 indicating high levels of social support. The instrument is reliable (Cronbach's α of 0.86) and has been validated in multiple samples.[194,196] In this study sample, the reliability coefficient was .87.

Family Functioning. Family Functioning was measured with three subscales (27 items) of the *McMaster Family Assessment Device* (FAD); Problem Solving (reliability 0.66) Communication (reliability, 0.72), and General Functioning (reliability, 0.71).[197] Developed in 1983 in accordance with the McMaster Model of Family Functioning,[198] the FAD has been used in many populations. It has been shown to be a valid measure of whole family functioning.[199] Items are answered with a 4-level, Likert scale of strongly agree – strongly disagree. Negatively worded items are reverse-scored and the responses are summed and divided by the number of subscale items to calculate a mean score. Each subscale is scored individually and healthy/unhealthy cut-off scores have been determined.[197] Scores that are equal to or greater than the cut-off scores indicate unhealthy functioning in that dimension. For the subscales being used in this study, those scores are as follows: Problem-Solving – 2.20, Communication – 2.20 and General Functioning – 2.0.[197] Reliability analysis of each subscale was assessed in this study and results for this sample were: General Family Functioning, .90; Family Communication, .79; and Family Problem-Solving, .81.

Family Food Interaction. Family Food Interaction was measured with six items adapted by Schafer and colleagues[29] from the original scale[200] to measure the degree of interaction within the family over food preferences and nutrition. The items address discussion and decision-making about nutrition among family members and the frequency of sharing mealtimes with family members. Scores range from 6-30, with

higher scores reflecting higher levels of interaction among family members. Reliability for this version of the scale was determined to be 0.66,[29] and in this sample was also .66.

Outcomes

Dietary Assessment and Quality. The Block food frequency (FFQ) 110 item questionnaire was used to measure the usual dietary pattern over the past year. The Block FFQ has been validated among other FFQ's and has been found to be comparable to other major FFQ's.[201] Earlier versions of the Block FFQ have demonstrated reliability with repeated FFQ administration and validity with 24-hour food recalls in women.[202] Analysis for the FFQ was provided by Nutrition Quest for specific daily nutrient intake and daily servings for each of the food groups.

Diet quality was defined by the Alternate Healthy Eating Index (AHEI) diet score. The AHEI is scored from 2.5 to 87.5 with higher scores indicating better diet quality.[112] The AHEI was scored in accordance with the methods designed by McCullough and colleagues.[112] Eight components scored from 0 points to 10 points include vegetables, fruits, nuts and soy protein, ratio of white to red meat, cereal fiber, *trans* fat, polyunsaturated to saturated fat ratio, and sex-specific alcohol intake. The ninth component of multivitamin use is scored from 2.5 – 7.5. Maximum points are awarded if the intake meets the serving criteria, indicating a high level of dietary adherence, whereas a score of 0 (or 2.5 points for no multivitamin use) indicates the least adherent to that diet component. Intermediate intakes are scored proportionately between 0 and 10. The AHEI scoring method and total scores are outlined in Table 1.2.

Table 1.2

Alternate Healthy Eating Index (AHEI) Scoring Criteria

Component	**Criteria for minimum score**	**Criteria for maximum score**
Vegetables (servings/day)	0	5
Fruit (servings/day)	0	4
Nuts and soy protein (servings/day)	0	1
Ratio of white to red meat	0	4
Cereal fiber (grams/day)	0	15
Trans Fat (% of energy)	≥4	≤0.5
Polyunsaturated to Saturated Fat ratio	≤0.1	≥1
Duration of multivitamin use	<5 y	≥5 y
Alcohol (servings/day)	Men: 0 or >3.5 Women: 0 or >2.5	Men: 1.5–2.5 Women: 0.5-1.5
Total score (range)	2.5	87.5

Note. Scoring ranges from 0 as the minimum to 10 as the maximum, with intermediate intakes scored proportionately for all categories except for multivitamin use. Multivitamin use is scored from 2.5 as the minimum and 7.5 as the maximum with no proportionate scoring.

Cardiometabolic Risk: Metabolic Syndrome and T2DM Risk Status

Metabolic syndrome was determined by the presence of ≥ 3 risk factors present as recommended by the American Heart Association and the National Heart, Lung and Blood Institute. Risk factors are defined by the Third Report of the National Cholesterol Education Program (NCEP) Expert Plan on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults;[203] (waist circumference >88 cm, blood pressure ≥ 130/85 mmHG, fasting triglyceride ≥ 150 mg/dl, HDL cholesterol <50 mg/dl, fasting glucose ≥ 100 mg/dl). T2DM risk was defined by a Hemoglobin A1C of ≥ 5.7% , with 5.7-6.4% = prediabetes; ≥ 6.5%=diabetes.[204,205]

Height, weight and waist circumference was measured in accordance with National Health and Nutrition Examination Survey protocols.[206] The Charder HM200P Portstad Portable Stadiometer was used for measuring height. The Lifesource UC-321 scale was used to measure weight. Waist circumference was measured at the area above the ilium (mean of 2 measurements). Blood pressure was manually auscultated and measured according to Joint National Committee 7 guidelines (mean of 2 readings)[204] with the participant resting quietly in a seated position. A latex-free blood pressure kit by American Diagnostic Corporation was used. This kit has a lifetime calibration warranty.

Lipids and fasting glucose were measured with a CardioChek PA point of care monitor. The CardioChek PA is certified by the Center for Disease Control and Prevention's Cholesterol Reference Method Laboratory Network.[207] The CardioChek PA monitor provided accurate lipid measurements assessed on 100 subjects and concurrently tested with clinical diagnostic laboratory methods; total cholesterol (83%), triglyceride (94%), HDL cholesterol (72%), and LDL cholesterol (86%).[208] The most recent

certification of the CardioCheck PA demonstrated a coefficient of variation of 0.9%-2.0%, average bias of -1.6% to -1.9% and total error of 3.4%-5.9%.[209]

Hemoglobin A1C was measured with the Bayer A1C Now+ point-of-care meter which is certified by the National Glycohemoglobin Standardization Program and has demonstrated 99% accuracy.[210] The coefficient of variation ranges from 3.0 - 4.02%.[211] Both the CardioChek PA and the Bayer A1C Now+ monitors will were used in accordance with the manufacturers' guidelines. Pre-pregnancy BMI, gestational weight gain and medical history was determined by self-report. All study variables and associated instruments with reliability data are outlined in Table 1.3.

Table 1.3

Variables, Instruments and Reliability Data

Study Variable	Instrument	# of Items	Potential Score Range	Reported Reliability	Reliability for this study sample
Demographics and Medical History	Demographic and Medical History Form	29			
Physical Activity	CARDIA Physical Activity History	60		*r* = .77 - .84	
Dietary Knowledge	Dietary Guidelines for Americans Knowledge Questionnaire	11	0 - 100		.69
Depressive Symptoms	Patient Health Questionnaire – 9 (PHQ-9)	9	0 - 27	.79 - .85	.79
Perceived threat	Risk Perception Survey for Developing Diabetes	23			
	Personal Control		1 – 4	.72	.62
	Optimistic Bias		1 – 4	.65	.73
	Worry		1 – 4		.81
	Knowledge		0 - 100	.70	.59
Perceived diet benefits	Perceived Benefits of Healthy Eating Scale for Adults at Risk of Cardiometabolic Diseases	10	9 - 45	.88	.92
Perceived diet barriers	Barriers to Healthy Eating Scale	16	16-80	.71 – .77	.67
Perceived self-efficacy	Cardiac Diet Self-Efficacy Scale	16	16-80	.89 - .92	.92
Family functioning	McMaster Family Assessment Device*	27			
	General Family Functioning		1 – 4	.71	.90
	Family Communication		1 – 4	.72	.79
	Family Problem-Solving		1 – 4	.66	.81
Family Food Interaction	Family Food Interaction Scale	6	6 - 30	.66	.66
Social Support	ENRICHD Social Support Instrument	7	16 - 80	.86	.87
Diet Quality	Block Food Frequency Questionnaire	110		Median *r* = .75 [202]	
	Alternate Healthy Eating Index		2.5 – 87.5		
Metabolic Syndrome	Charder HM200P Portstad Portable Stadiometer Lifesource UC-321 scale Latex-free blood pressure kit by American Diagnostic Corporation CardioCheck PA			COV = 0.9 – 2.0%	
T2DM Risk	Bayer A1C Now+ Meter			COV = 3.0 – 4.0%	

Note. *With exception to the subscales of the McMaster Family Assessment Device (FAD), all instruments' scoring range indicates that with a higher score, there is a higher degree of that construct. Higher scores on the FAD subscales indicate greater levels of unhealthy functioning. T2DM = Type 2 diabetes mellitus. COV = Coefficient of Variation.

Data Collection Procedures

A partial HIPAA waiver was approved from the Emory University IRB to allow for medical chart reviews for screening and recruitment purposes. Potential subjects were identified by self-referral or by letter of invitation. Once the subject contacted the PI or research assistant, the study was explained, determination of basic eligibility criteria for screening was made and verbal informed consent was obtained to complete the screening. English-speaking women who were successfully screened and agreed to enroll were sent a study packet with an instruction letter, written informed consents (Appendix A), and a bound copy of all the questionnaires. An appointment was made with the Spanish-speaking participants to complete the full questionnaire and clinical data collection by one-on-one interview.

An appointment was made with participants to complete the clinical data collection. The PI often met women at their home or workplace, the Emory School of Nursing, or a safe, private place of convenience which was facilitated by the portability of the anthropometric and laboratory equipment. Women were instructed to complete the questionnaires and be fasting for $\geq$ 8 hours prior to the appointment.

Before any data collection began, the PI assured a thorough informed consent process, including the witnessed signature of consent forms. Clinical measures began with blood pressure measurements with the participant in a seated position resting for five minutes. Two measurements were taken and the mean was calculated. Next, height

and weight measurements were completed with participants fully clothed, but without their shoes. Waist circumference was measured at the uppermost border of the ilium. The participant was asked to lift their shirt to expose only their mid-section, with arms crossed and placed on their opposite shoulder. Two measures were taken and the mean calculated.

The examiner then prepared the CardioCheck and A1CNow+ meters, handwashed, gloved, prepped the participants' finger with alcohol, allowed the area to dry and then punctured with a lancet. Thirty microliters of blood was collected first for the CardioCheck monitor and then 5 microliters was collected for the A1CNow+meter. A bandaid was applied to the puncture site. Once the results were displayed, the participant was offered a healthy snack to discontinue the fasting state. Participants were provided a copy of their clinical and anthropometric measures with normal values noted and were encouraged to share with her primary care provider. Participants were instructed that these tests served only as a screening tool and were not diagnostic. Participants were strongly encouraged by the PI to follow-up any abnormal values with their primary provider.

Finally, the examiner reviewed the questionnaires with the participant to complete omitted questions. At the close of the visit, the examiner assessed the puncture site to note any early adverse effects. Instructions for dealing with any adverse effects were reiterated to the participant at this time. All participants received a gift bag filled with information about healthy diets and other health promotion information for the prevention of T2DM. All participants received a $25 gift card at the end of the session, and those who traveled to Emory received a $15 gas card for travel reimbursement.

Data Analysis

Analyses was performed using SPSS statistical software version 20.0 with an alpha set at $p < .05$. All instruments were scored according to the instructions developed by the author. Initial data analysis included descriptive statistics on sample characteristics and examination for type and extent of missing data. Data was reviewed for potential outliers and assessed for accuracy. Distributions were examined to determine required normality assumptions for the statistical tests.

Specific Aim 1. Correlation associations (Pearson's or Spearman's Rho, as appropriate) were examined for the bivariate relationship between each of the independent variables for individual beliefts (scores from perceived threat of T2DM, perceived self-efficacy, perceived benefits, perceived barriers scales) and the outcome variable (diet quality measured by the AHEI). Two-sample t-tests were also used to assess bivariate relationships. Multiple linear regression modeling was used to examine the contribution of the independent and contributing variables to the variance in diet quality. The control variables of age, race, dietary knowledge, educational attainment, and depressive symptoms were held constant in the model testing, with each of the independent variables added to the model to be examined for contribution and significance in predicting diet quality. Independent variables that were not significant ($\alpha > .05$) were excluded from the final model.

Specific Aim 2. Correlation associations (Pearson's or Spearman's Rho, as appropriate) were examined for the bivariate relationship between each of the independent variables for family/social influences (social support, family functioning [problem solving, communication, general family functioning], family food interaction)

and the outcome variable of diet quality (AHEI score). Two-sample t-tests were also used to assess bivariate relationships. Multiple linear regression modeling was used to examine the contribution of the independent and contributing variables to the variance in diet quality. The control variables of age, race, dietary knowledge, educational attainment, depressive symptoms, and dietary self-efficacy – determined by significant findings from Aim 1, were held constant in the model testing, with each of the independent variables added to the model to be examined for contribution and significance in predicting diet quality. Independent variables that were not significant ($\alpha > .05$) were excluded from the final model.

Secondary Aim. Bivariate associations (Pearson's or Spearman's Rho correlation, two-sample t-tests) were assessed between the independent variable (diet quality) and the clinical outcome measures. Descriptive statistics categorized the percent of participants who were abnormal with each of the risk factors as well as the percent with metabolic syndrome and T2DM risk status. Finally, logistic regression models were fit to examine the associations between the diet quality and the outcomes of diabetes risk and metabolic syndrome, controlling for the other contributing socio-demographic and individual variables (age, BMI, physical activity level, and breastfeeding duration). The independent variable of AHEI dietary quality met linearity assumption associations with the outcome of metabolic syndrome, but not diabetes risk. For the logistic model with diabetes risk as the outcome, AHEI was divided into quartiles and examined by dietary categories.

Protection of Humans Subjects

The protocol for this study was approved by the Institutional Review Board (IRB) at Emory University. Appendix A contains all current IRB approvals, consents and HIPAA forms.

Potential Risks. Participation in this study posed minimal risk and included: the inconvenience of completing questionnaires (1-2 hours total), which could be done in several sessions at the participant's convenience, and participating in a 30 minute - 1 hour session for clinical data collection. Physical risk may have included complications associated with a finger prick; localized infection, bruising, or soreness. No such adverse events were reported throughout the study. Physical risk may also have involved the side effects of fasting $\geq$ 8 hours, however all efforts were made to schedule morning appointments or times requested by the participant to accommodate her comfort with a fasting state. A healthy snack was also provided to each participant at the conclusion of clinical data collection.

Psychological risk may have included distress associated with an increased awareness of risk for diabetes and cardiovascular disease or distress perpetuated by questions about family functioning and depressive symptoms. Each participant was assessed for her experience in completing the questionnaires. No participant reported any adverse effect. Psychological risk also included the identification of women with unassessed or undiagnosed depressive symptoms. Women one year following delivery are no longer considered post-partum, and their risk for depression was considered that of the general female population. This study included a protocol to refer any woman who reported depressive symptoms, especially for anyone who reported suicidal ideations.

Informed Consent. Potential subjects were screened over the telephone and if inclusion criteria were met, they were verbally consented by the PI or research assistant for participation. Before any data collection began, the PI/research assistant first reviewed the informed consent in detail to assure that the participant fully understood the study and her rights as a research participant. Written witnessed informed consent was obtained prior to any other study activities and the PI assured that all participants knew how to contact study staff for any further questions or reports of adverse events.

Protections Against Risk. The informed consent process occurred prior to any data collection or study procedures. The PI and research assistants were appropriately trained and certified in human subjects research. The PI was also fully trained in the preparation of the skin site as well as obtaining the specimen from finger prick to avoid infection or excessive bruising. Any adverse events would have been reviewed and promptly reported to the Emory IRB, although none were reported.

Standardized procedures and protocols were established to manage the data to assure confidentiality. The PI and research assistants were the only people who had access to individually identifiable private information about the participants. All subjects were given a study identification number and only their demographic data sheet included identifying information. All other data collection tools were coded with the study identification number. Each participant has a file folder labeled with their study identification number. File folders of the hard-copy data are kept in a locked file cabinet at Emory University School of Nursing. A password protected electronic database has been maintained for this study. Access to this database has been limited to the PI and research assistants. Non-identifying data has been shared with consultants

(biostatistician) as needed for data analysis. All hard-copy data will be destroyed after ten years and electronic data de-identified in accordance with Emory University policy. Any publications from this study will not name or describe individual participants in any identifiable way.

Participants were given a hard-copy of their clinical study results outlining their height, weight, body mass index (BMI), blood pressure, fasting glucose, serum lipids, and hemoglobin A1C, compared to normal ranges for each parameter. Participants with abnormal results were encouraged to share them with their primary care provider.

Potential Benefits. There were no known direct benefits for the individual participants in the study. However, through participation in this study, participants may have increased their knowledge and awareness of the risk for T2DM as a result of their GDM diagnosis and chosen to have implemented protective health behaviors. The data from this study will be used to design future studies and test interventions specifically for the population of women with a previous GDM to delay or prevent the development of T2DM. Interventions designed for this population that specifically address potential individual and family-level influences may serve to benefit this population. Each participant received a $25 gift card at the end of participation and $15 gas card, as appropriate in appreciation for their travel and inconvenience.

Summary

A descriptive, cross-sectional study was conducted to examine factors associated with diet quality and cardiometabolic risk status among a population of women with a recent history of gestational diabetes. Each aim of the study has been addressed in a manuscript written for publication in peer-reviewed journals. The papers are included in

this dissertation as Chapters 2 – 4. A comprehensive summary of the findings with a discussion about implications for research and practice is presented in Chapter 5.

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Chapter 2: Intrapersonal Influences of Diet Quality in Women with Previous Gestational Diabetes

Abstract

Background: Women with previous gestational diabetes mellitus (pGDM) are at significant risk for future cardiometabolic diseases related to low-quality diets, and yet little is known about what may be important targets of influence to improve diet quality in this at-risk population.

Objective: The aim of this study was to analyze the association of intrapersonal influences of diet quality as defined by the Health Belief Model constructs in women with a recent history of gestational diabetes.

Methods: This was a descriptive, correlational cross-sectional design to analyze relationships between diet quality and intrapersonal influences of perceptions of threat of T2DM development, benefits and barriers of healthy eating, and dietary self-efficacy in a convenience sample of community-dwelling women with pGDM. Diet quality was defined by the Alternate Healthy Eating Index (AHEI). Multiple regression was used to identify predictors of AHEI diet quality.

Results: Women (n = 75; 55% Minority; age M= 35.5, SD = 5.5 years) had moderate AHEI diet quality (M= 47.6, SD = 14.3). Only higher levels of education ($p < .001$) and self-efficacy ($p=0.002$) significantly predicted better AHEI diet quality, controlling for other contributing variables ($R^2 = .36$, $F(6,66)=6.19$, $p<0.0001$).

Discussion: There is a significant opportunity to improve diet quality in women with pGDM. Improving self-efficacy may be an important component to include in nutrition

interventions. In addition to identifying other important individual components, future studies of diet quality in women with pGDM are needed to investigate the scope of influence beyond the individual to potential family/social and environmental factors.

The incidence of gestational diabetes mellitus (GDM) has more than doubled in the past decade[1] and affects at least 7% of all pregnancies, or 200,000 women per year in the US.[2,3] GDM is the most common complication of pregnancy, with incidence paralleling that of type 2 diabetes mellitus (T2DM) prevalence in the general population.[4] Women with previous gestational diabetes (pGDM) are at elevated risk for cardiovascular disease[5] and have a seven-fold increased chance of developing T2DM,[6] usually in the first five years following delivery.[7] Despite these known risks, there is no consensus among providers regarding risk-counseling and dietary management after delivery for women with pGDM. It is not surprising therefore that women with pGDM do not perceive themselves to be at elevated risk for T2DM,[8] nor are they engaging in risk reduction behaviors, such as healthy eating or physical activity.[9] The reduced attention to risk in women with pGDM is surprising in view of published research findings.

Intensive lifestyle interventions have demonstrated the potential to decrease the risk of T2DM with the pGDM cohort in the Diabetes Prevention Program trial demonstrating a 53% risk reduction for T2DM.[10] In a separate study, adherence to healthy dietary patterns has shown a significant reduction in T2DM development risk in the pGDM population,[11] while other studies have demonstrated that a healthy diet confers a protective effect and reduces cardiometabolic risk (CMR) and T2DM risk in women from the Nurses' Health Study and among British working adults.[12,13] Improving the diet quality in women with pGDM is an effective means of reducing CMR and T2DM in this at-risk group, however identifying important modifiable influences to improve dietary intake must be addressed to effectively promote healthy dietary pattern adherence. The

purpose of this study was to examine the association between the intrapersonal factors of socio-demographics, depressive symptoms, perceptions of T2DM risk, benefits and barriers to healthy eating, and self-efficacy with diet quality among women within five years of a GDM pregnancy.

Diet quality

Few studies have examined modifiable, cardiometabolic risk factors, specifically diet quality, among this high risk population. Among the general U.S. population, as few as 3% fully adhere to the Dietary Guidelines for Americans, with poorest adherence in the categories of vegetables, legumes, and whole grains.[14] Despite intensive dietary counseling and monitoring aimed at carbohydrate restriction[15] for gestational diabetic women during pregnancy, there is poor adherence to dietary recommendations following delivery. Fruit and vegetable consumption has been found to be particularly low in this population,[16] with only 5% consuming at least five servings per day of fruit or vegetables.[17] A recent study demonstrated a 57% lower risk for T2DM development among pGDM women with greater adherence to the Alternate Healthy Eating Index (AHEI) dietary pattern.[11] These findings are promising, especially in light of the fact that the mean AHEI dietary score among the highest quartile of participants was 52.4 (6.7) on a scale that ranged from 2.5 – 87.5. This suggests that increasing adherence along this continuum can contribute to significant risk reduction in this population.

The AHEI dietary index, created in 2002, evolved from the Healthy Eating Index as an alternative dietary index to better predict chronic disease risk.[18] As noted previously, adherence to the AHEI has been associated with decreased risk for

diabetes,[11,19] as well as lower risk for cardiovascular disease,[20] cancer,[21] and the reversal of metabolic syndrome.[22] Because this dietary pattern has demonstrated such beneficial risk reduction in a pGDM population, it was selected for determining diet quality in this study. Identifying the factors that can be modified to improve adherence to the AHEI dietary pattern is an important next step in mitigating risk reduction in this population. The American Diabetes Association does not specifically recommend any particular dietary pattern for those at-risk for T2DM, but recommends programs that assist in promoting weight loss and increased physical activity.[23]

Determinants of diet quality include multiple intrapersonal, interpersonal, and environmental factors, and it is essential to understand eating behavior within each of these contexts.[24] Framed within the eating behavior ecological model by Story and colleagues,[24] and specifically guided by the Health Belief Model to understand intrapersonal factors, this study focused on examining the contribution of perceived threat of T2DM, benefits and barriers to healthy eating, and self-efficacy with diet quality (Figure 1). We hypothesized that women with pGDM with higher perceptions of the threat of T2DM, along with greater perceived self-efficacy and benefits of healthy eating, and lower perceptions of healthy eating barriers would have higher diet quality.

Methods

Study Design, Setting, and Participants

This was a cross-sectional, descriptive, quantitative study conducted from August 2011 through December 2012. Participants were recruited from the community and through women's health clinics of an academic health center, an inner-city public

hospital, and a public health department. Eligible participants were women who were (a) within 5 years of a GDM pregnancy, (b) aged 18-45 years, (c) fluent in English or Spanish, (d) with no history of polycystic ovary syndrome and no development of T2DM, (e) not currently pregnant or breastfeeding, (f) not following a prescriptive or weight-loss diet, and (g) no more than moderate depressive symptoms (score of $\geq$ 20 on the Patient Health Questionnaire-9). The study protocol was approved by the university institutional review board and by the clinic sites where recruitment occurred.

Measurements

Dependent Variable. Diet was measured with the Block 110-item semi-quantitative food frequency questionnaire (FFQ) to assess usual dietary intake in the past year. The Block FFQ has been validated among other major FFQ's and has been found to be comparable.[25] Earlier versions of the Block FFQ have demonstrated reliability with repeated FFQ administration and validity with 24-hour food recalls in women.[26] Analysis for the FFQ was provided by Nutrition Quest (Berkeley, CA) for specific daily nutrient intake and daily food servings. The Block analysis was then scored into the *Alternate Healthy Eating Index* dietary score. The *AHEI* is scored from 2.5-87.5, with greater adherence (better diet quality) reflected in higher scores. Eight of the nine components of the *AHEI* are scored from 0 (recommendations were not met) to 10 (recommendations were met fully). Intermediate intakes are scored proportionately between 0 and 10. The final component of multivitamin use is scored as 2.5 points for no use and 7.5 points for use.[18]

Independent Variables. Demographics and basic, pertinent medical history were collected on a form designed for this study and included age, race/ethnicity, education, income, delivery date of most recent GDM pregnancy, and current medications.

Perceived threat of type 2 diabetes (T2DM) was assessed with a 23-item questionnaire incorporating three subscales (*Personal Control, Optimistic Bias, Knowledge*, and an additional seven items addressing risk perception and lifestyle behaviors) of the *Risk Perception Survey for Developing Diabetes* (*RPS-DD*), developed for the Diabetes Prevention Program trial [27] and adapted for women with pGDM.[8] Reported Cronbach's alpha coefficients for the pGDM population ranged from 0.65 – 0.72.[8] In this sample, Cronbach's alpha coefficients were 0.62 for the *Personal Control* subscale, 0.81 for the *Worry* subscale, and 0.73 for the *Optimistic Bias* subscale. Each item is scored from 1 – 4, summed and averaged for a total subscale score, also ranging from 1-4. For all subscales, higher scores are equivalent to higher levels of that component.

Beliefs about the benefits of diet and exercise and individual risk perception with an additional seven items on the *RPS-DD* were assessed, replicating the assessment of risk perception in women with pGDM as conducted by Kim and colleagues.[8] Three items, on a 5-point Likert scale (strongly agree – strongly disagree) addressed beliefs about the benefits and burden associated with regular exercise and following a diet.[8] Risk perception for developing diabetes was assessed with the item: "What do you think your risk or chance for getting diabetes is over the next 10 years?", with responses of, "almost no chance", "a slight chance", "a moderate chance", or "a high chance." To determine if participants had already made or were planning to make lifestyle changes to

mitigate their risk, we asked: “Have you recently made changes in any lifestyle behaviors that you believe will lower your chance of getting diabetes?” and “Are you planning to make changes in any lifestyle behaviors that you believe will lower your chance of getting diabetes?” Finally, to address risk perception among women who had already or were planning make lifestyle changes, we asked: “If you don’t change your lifestyle behaviors, such as diet or exercise, what is your risk or chance of getting diabetes over the next 10 years?”

Perceived benefits of healthy eating was assessed with a 9-item, 5-point Likert instrument designed specifically for this study. At the time that this study was being designed, there were no published instruments that examined the concept of healthy eating benefits, especially in a population at risk for cardiometabolic diseases. Content validity of the scale was established with an expert review panel and then pilot-tested in a convenience sample (n = 91) of adults who had any cardiometabolic risk factor. Items address benefits such as healthy eating: “can help prevent diabetes,” “can help control my weight,” and “can help me feel better.” Scores range from 9 – 45, with higher score indicating greater perceived benefits. Cronbach’s alpha coefficient in the unpublished pilot study was acceptable at .88 and in this sample was .92.

Perceived barriers of healthy eating was assessed with the *Barriers to Healthy Eating Scale (BHES)*, a 16-item scale originally developed to assess healthy eating barriers in pregnant women.[28] It addresses areas related to unavailability of food, expense, inconvenience, preferences and inability to engage in healthy eating. The *BHES* is a 5-item Likert scale instrument, which is summed for total scores ranging from 16-80. Higher scores indicate greater perceived barriers to healthy eating. Initial reliability

testing of this instrument resulted in Cronbach's alpha coefficient ranges of .71 - .77.[28] In our sample, the Cronbach's alpha coefficient was .67.

The 16-item *Cardiac Diet Self-Efficacy Scale* was used to measure self-efficacy related to healthy eating. It is a general nutrition self-efficacy scale addressing healthy dietary behavior.[29] For example, the scale addresses confidence levels in "Staying on a healthy diet on special occasions or holidays" and "Knowing what foods I should eat on a healthy diet". Each item is a 5-point Likert scale, which is summed and scored from 16-80, with higher scores indicating greater self-efficacy. Cronbach's alpha coefficients ranged from .89 - .92 in other samples, and .92 in this sample.

Contributing Variables. Knowledge and depressive symptoms are known to influence dietary quality, especially in women of child-bearing age.[30,31] Dietary knowledge was assessed with an 11-item questionnaire (10 knowledge questions and 1 Likert questions for perceived level of dietary knowledge) to assess awareness of the 2010 Dietary Guidelines for Americans. This instrument was adapted from a survey designed to test knowledge of the 2005 Dietary Guidelines for Americans from a study with community health advisors.[32] The investigators established content validity with an expert review panel and then pilot-tested the survey with a community sample. For this study, an adapted and updated version of the questionnaire to reflect the 2010 guidelines specifically for women aged 18-45 was used.[33] The knowledge questions are each 4-item multiple choice items, which test the participants' understanding of recommended daily calories, daily servings of grain, fruits and vegetables, dairy, protein, fiber, sodium, and amount and types of fat. The questionnaire is scored for number correct and recorded as

a percentage on a scale from 0-100, with higher scores indicating greater dietary knowledge.

Knowledge of diabetes risk factors was assessed with the knowledge subscale of the *Risk Perception Survey for Developing Diabetes (RPS-DD),* an 11-item, 4-point Likert questionnaire. Items related to race, ethnicity, age, family medical history, GDM history, and lifestyle factors are rated as: "Increases the risk", Has no effect on the risk", "Decreases the risk" and "Don't know." Items were scored for number correct and recorded as a percentage on a scale from 0-100, with higher scores indicating greater diabetes risk knowledge.

Depressive symptoms were assessed with the *Patient Health Questionnaire-9 (PHQ-9),* a 9-item, 4-point Likert scale that was designed to be a brief assessment of depressive symptoms. It has been tested in multiple samples, including women of childbearing age[34] and deemed a reliable and valid measure of depression severity. Scores range from 0-27, with higher scores indicating greater depressive symptoms. Telephone administration of the *PHQ-9* has been tested in a primary-care patient sample and demonstrated a sufficient internal consistency of .82.[35] In this study sample, the *PHQ-9* was administered by phone during the screening procedure, demonstrating a Cronbach's alpha coefficient of .79.

Procedures. Upon receiving a study letter of invitation or seeing/hearing an advertisement, interested women contacted the lead researcher or bilingual research assistant by email or telephone. The study was fully explained, initial verbal telephone consent completed, and eligibility criteria determined. English-speaking women who

chose to enroll were mailed the questionnaire packet. Enrolled Spanish-speaking women completed questionnaires in an interview format with the bilingual research assistant. The research staff met participants in the setting chosen by the participant, usually the home or workplace. Questionnaire completion time ranged from 1 to 2 hours. Participants were compensated with a $25 gift card and presented with individualized cardiometabolic health and nutrition education materials for their participation in the study.

Data Analyses

Data were analyzed with IBM SPSS version 20.0. Descriptive statistics were used to assess sample characteristics and underlying distribution assumptions. Race and ethnicity data were collapsed into two categories representing non-Hispanic Caucasian women (n = 34) and Minority women (n = 41). The Minority group consisted of 24 African-American, 11 Hispanic, 2 Asian, and 4 multiracial/ethnic women. Bivariate correlation analyses were used to determine significant associations ($p \leq .05$) between the contributing and independent variables with diet quality. Mean differences in diet quality were examined with two sample t-tests by race, education status, and level of risk perception. Multiple linear regression modeling was used to examine the contribution of the independent and contributing variables to the variance in diet quality. The control variables of age, race, dietary knowledge, educational attainment, and depressive symptoms were held constant in the model testing, with each of the independent variables added to the model to be examined for contribution and significance in predicting diet quality. Each independent variable was individually tested in regression models

regardless of bivariate analysis significance. Independent variables that did not remain significant ($p > .05$) were excluded from the final model.

Results

The sample included 75 women (45% Caucasian, 55% Minority - 32% African-American, 15% Hispanic), with a mean age of 35.5 years (*SD* = 5.5), who were 2.6 years (*SD* = 1.6) since their last GDM delivery, and a mean parity of 2.7 (*SD* = 2.1). Most were married (73%). More than half (58%) had a Bachelor's degree or higher and 52% were employed full-time. During their pregnancy, the majority of women (63%) were managed with lifestyle interventions however, 24% were also treated with insulin (Table 2.1).

AHEI scores indicated an average level of diet quality (*M* = 47.6, *SD* = 14.3), with a range of scores from 20.5 – 77.5. No participant fully met the AHEI recommendations. The dietary components with the poorest scores included alcohol consumption and red to white meat ratio, indicating that most women were consuming less than the suggested moderate alcohol intake per day of 0.5 – 1.5 servings per day and that red meat intake was higher than consumption of poultry and fish (Table 2.2).

Half of the participants (49%) believed that they had a moderate to high chance of developing diabetes in the next ten years, while the other half perceived their risk to be none or slight. There was no difference in diet quality between those with none/slight perception and those with moderate/high ($t = -0.23$, $p = .82$). Nearly everyone (97%) believed that regular exercise and diet may prevent T2DM development. While 83% believed that doing regular exercise and following a diet required a lot of effort, 81% also

believed that the benefits outweighed the effort of doing it. Participants reported a high level of personal control for preventing diabetes (M = 3.2, SD = 0.5), and a moderate amount of worry about future T2DM development (M = 2.7, SD = 0.8). Participants, on average, did not feel that they were any more or less susceptible to the development T2DM or other serious disease compared to other women, with a mean Optimistic Bias score of 2.1 (SD = 0.7).

Barriers to healthy eating were low (M = 27.3, SD = 6.5), with items related to distance greater than two miles for food and fresh fruits/vegetables as the more commonly reported barriers. Participants also reported a high level of perceived benefit to healthy eating (M = 42.2, SD = 3.1), and had relatively high levels of dietary self-efficacy (M= 21.9, SD = 12.7).

Despite a high level of education among participants, knowledge of dietary guidelines was rather poor, with an average test score of 42.2% (SD = 24.6). While 89% of the participants recognized that having had GDM increased risk for T2DM, overall risk knowledge was moderate with a mean test score of 60.7% (SD = 18.4). Most participants reported minimal depressive symptoms (68%), with scores ranging from 0 – 15 (M = 4.1, SD = 4.1).

Bivariate associations were examined between diet quality, demographics, dietary knowledge, depressive symptoms, and perceived beliefs. Non-Hispanic Caucasian race, higher levels of education, and higher self-efficacy were all significantly associated with higher levels of diet quality (Table 2.4).

Non-Hispanic Caucasian women had higher AHEI scores compared to Minority women (t = -2.4, p = .02). The greatest mean difference in diet quality was between women with a Bachelor's degree or higher, compared to those who did not complete college (t = -5.0, p = < .0001), with a mean AHEI score difference of 14.5 points.

Each of the seven independent variables (*Personal Control, Worry, Optimistic Bias subscale scores, Diabetes Risk Knowledge* score, perceived benefit score, perceived barrier score and dietary self-efficacy score) were entered individually into a multiple regression model with all four control variables (race, education status, depressive symptoms and dietary knowledge). *Personal Control, Worry, Optimistic Bias, Diabetes Risk Knowledge*, perceived benefits and barriers did not contribute to variance in diet quality. Controlling for all other variables, only higher levels self-efficacy significantly predicted better AHEI diet concordance (R^2 = .36, F(6, 66) = 6.19, p = <.0001). The final model with education status and self-efficacy as significant predictors, explained 36% of the variance in diet quality. The parameter estimates of the predictors in the regression model further suggest that education status was the strongest predictor of AHEI diet quality (Table 2.5).

Discussion

Diet quality in this sample of women with pGDM was moderate, with a substantial opportunity to improve intake to be consistent with protective diets such as the AHEI. Inadequate diet quality in the pGDM population has been reported previously,[16,17] with one other study examining AHEI dietary concordance in pGDM women.[11] The increasingly beneficial T2DM risk reduction demonstrated along the

continuum of AHEI scores by Tobias and colleagues (2012) suggests the significant need to improve diet quality in women with pGDM. Identifying the important factors that predict diet quality is an important next step in designing diet improvement interventions. The findings of this study highlight the importance of educational attainment and dietary self-efficacy in promoting better diet quality, supporting components of our hypotheses. However, neither the perceptions of T2DM threat, nor the perceptions of healthy eating benefits and barriers contributed to the variance in diet quality in this sample. The finding that risk perception is not a significant predictor of diet quality mirrors previous findings in women with pGDM.[8]

Higher levels of education were demonstrated in this study to be predictive of higher diet quality, which likely contributes to overall better dietary and disease risk/health promotion knowledge.[36] In a recent study specifically examining women with pGDM, higher levels of education were associated with better adherence to dietary recommendations.[37] In this sample, education levels were highly correlated with T2DM risk knowledge (Spearman's *rho* = .42, $p = <.0001$) and dietary knowledge (Spearman's *rho* = .52, $p = <.0001$). Although education level may not be a modifiable factor easily addressed in adult populations, diabetes risk knowledge and dietary knowledge can certainly be improved through education interventions. Improving health knowledge and health literacy at levels appropriate for individual educational attainment has been demonstrated to improve health behavior.[38] Enhancing diabetes and diet specific knowledge and health literacy may be an important component in designing multi-strategy dietary interventions for pGDM women.[39,40]

This study's finding regarding the influence of dietary self-efficacy with diet quality supports previous findings in the pGDM population[17] and in general adult populations.[41] These findings are promising for designing nutritional interventions, since self-efficacy can be modified to improve diet quality.[42] Intervention studies that have specifically developed dietary self-efficacy through education, problem-solving, role-playing, and planning have demonstrated improvements in diet quality.[43-45]

The demographic factors of age and ethnicity had no associations with diet quality in our sample and race did not remain a significant predictor of diet quality in the regression modeling. These findings are in contrast with multiple studies that have demonstrated the significant influence of age, race, and ethnicity with diet quality.[36,46,47] Our study sample ranged in age from 18 – 48 years, with the largest subset (50%) of the participants between 32 and 37 years. This limited age variance may explain the lack of association with diet quality. Similarly, Hispanic women comprised 15% of the sample, which may not have represented a sufficient sub-sample size to observe any variance in diet quality by ethnicity. Non-Hispanic Caucasian women had higher diet quality than the minority participants however, non-minority race was also significantly associated with higher levels of education. This relationship may explain the bivariate association between race and diet quality, but when entered into a regression model, educational attainment became the stronger demographic predictor of diet quality in this sample.

This study did not find any association between depressive symptoms and diet quality. Variance in depressive symptoms was limited (*PHQ-9* scores ranged from 0 – 15), with 88% reporting minimal or mild symptoms. The association between depressive symptoms and diet quality is well-established, with studies demonstrating both that poor

diet quality predicts depression[48] and that higher levels of depressive symptoms contribute to poor diet.[49] The lack of association in this study's findings is likely due to the low variance and minimal depressive symptoms reported by the participants.

Risk perception or threat of T2DM did not have an influence in predicting variance in diet quality. In general, participants had realistic risk perceptions with half believing that they had none/slight chance of T2DM within ten years. A higher percentage of women in this study sample believed their risk to be moderate/high than in a previous study with pGDM women.[8] The higher perception of risk in this sample may be due to selection bias– those with higher risk perceptions may be more likely to enroll in a study about diet quality and cardiometabolic risk. However, those that believed they had a moderate/high risk did not have any difference in diet quality as compared to those with lower perceived risk. Furthermore, neither perceptions about personal control, worry, nor optimistic bias contributed to variance in AHEI diet scores. These findings are similar to those reported in other studies in which risk perception did not influence health behavior in women with pGDM.[50]

Perceptions about barriers or benefits to healthy eating also were not associated with diet quality. Participants reported high levels of perceived benefits and low levels of barriers to healthy eating, but similar to another study,[51] these factors did not contribute to variance in diet quality. Investigators from another study about healthy eating benefits and barriers found that these perceptions were related to levels of education.[52] An association between lower perceived barriers and higher levels of education (r = -.26, p = .03) was found in this study sample, but there was no association with perceived benefits.

The importance of self- efficacy in health promoting behavior has been demonstrated both in this population and in other populations. The association of self-efficacy with diet quality supports part of this study's hypotheses and one component of the Health Belief Model. However, the lack of association between T2DM risk perception, barriers, and benefits of healthy eating with diet quality refutes the other hypotheses and does not support these constructs of the Health Belief Model. Perceptions or beliefs seem to have less influence on dietary outcomes than self-efficacy and knowledge.[41] Although this study was largely guided by the Health Belief Model and focused on examining individual influences and perceptions, it was embedded within an ecological model with recognition that achieving optimal dietary quality is complex and multifactorial.

In addition to the potential social and environmental influences that were beyond the investigative scope of this study, there may be other important individual influences that impact diet quality in women with pGDM. Time constraints, fatigue, work obstacles, and childcare duties have been identified as major barriers to diet and exercise activities in a qualitative investigation with women with pGDM.[53] These identified barriers require further study to test their contribution to diet outcomes. Additionally, dietary restraint,[54] perceived stress[55] and sleep quality[56] have been associated with diet quality in other populations of women, but have not been investigated in women with pGDM.

Limitations. There are a few limitations of this study which are worth noting. First, as a cross-sectional study, only associations could be identified between the variables, but no causality could be determined. Longitudinal studies in women with pGDM are needed

to identify and understand the directionality of potential influences of diet quality. Second, while this sample size was adequate to determine the effect size of individual perceptions on diet quality, it was too small to detect differences by specific socio-demographic characteristics. The convenience sampling approach should be considered when generalizing this sample to other studies in women with pGDM.

Strengths. This study has several strengths as well. It is one of few studies that have examined overall diet quality in pGDM women in addition to investigating associated socio-demographic and intrapersonal beliefs. Inadequate diet quality in pGDM women has been established in previous studies, but little was known about what might influence dietary adherence in this population. This study suggests that self-efficacy and education in particular may be important predictors of diet quality in pGDM women. Although a convenience sample, the study participants were recruited from multiple community and health care settings, which resulted in a socio-demographically diverse group of women. This diversity enhances the generalizability of these findings to pGDM women of multiple races, Hispanic ethnicity, and a wide range of education and income levels.

Conclusion

Level of education and dietary self-efficacy are important predictors of AHEI diet quality in women with pGDM. Interventions aimed at improving diet quality in these high-risk women should address strategies to increase dietary self-efficacy and address dietary knowledge and T2DM risk knowledge appropriate to individual health literacy and education levels. There is a considerable need to improve diet quality in pGDM women as this study supports previous work confirming that these at-risk women are not

adhering fully to protective diets to prevent T2DM development. In addition to physical activity, a healthful diet is a critical component in preventing the progression to T2DM in at-risk populations. Future studies of diet quality among pGDM women should investigate intrapersonal influences of diet quality with a longitudinal design and expand the scope of influence beyond the individual to potential family/social and environmental factors.

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Figure 2.1

Intrapersonal Influences of Diet Quality in Women with pGDM

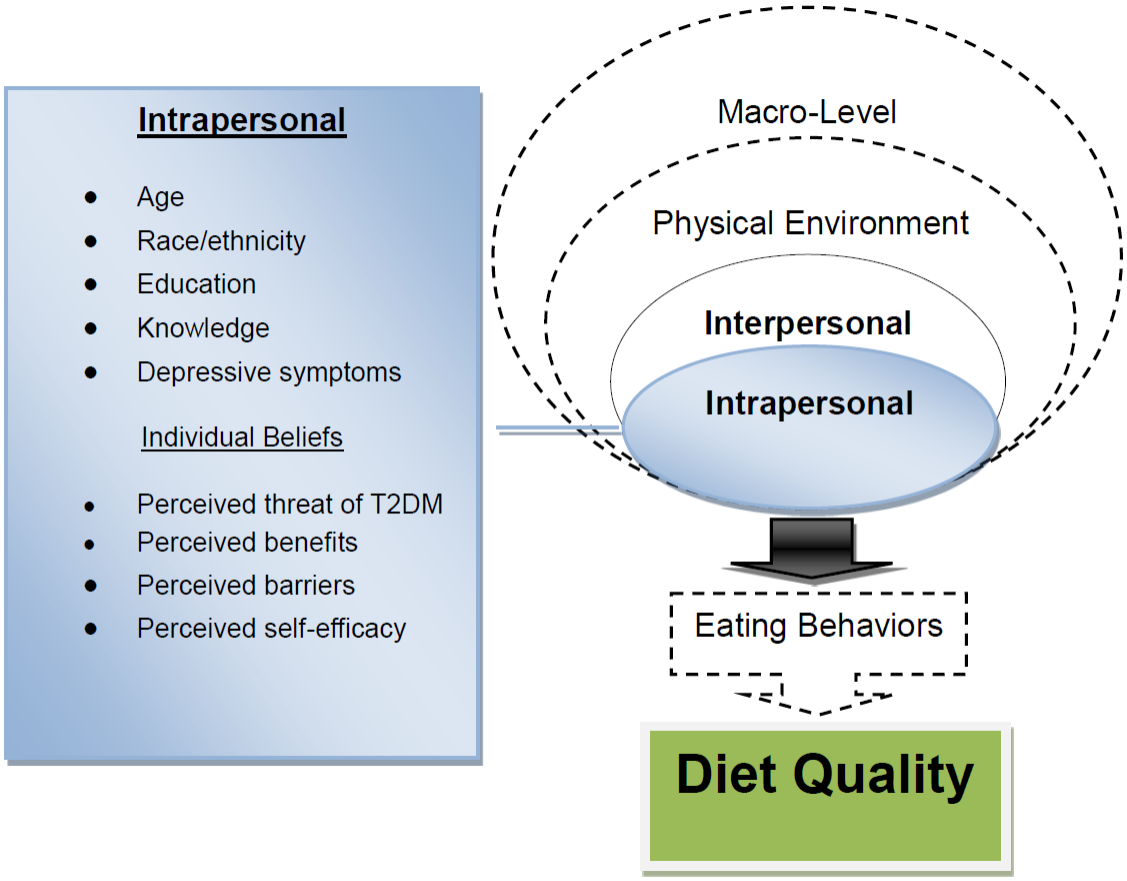

Table 2.1

Characteristics of the Sample (N = 75)

Characteristic	Study Sample
Age, mean years (*SD*)	35.5 (*5.5*)
Race/Ethnicity, %	
Non-Hispanic Caucasian	45.0
Minority	55.0
African-American	32.0
Hispanic	15.0
Asian	3.0
Multiracial	5.0
Education, %	
< 4 years college	41.3
≥ Bachelor's degree	58.7
Marital status, %	
Married	73.3
Employment Status, %	
Unemployed	33.0
Part-time employed	16.0
Full-time employed	51.0
Family History of T2DM, %	35.0
Family History of CVD, %	64.0
Current Smoker, %	12.0
Time since last GDM pregnancy, mean years (*SD*)	2.6 (*1.6*)
Parity, mean (*SD*)	2.7 (*2.1*)
GDM Pregnancy Treatment, %	
Lifestyle	63.0
Oral Medication	13.0
Insulin	24.0

Table 2.2

Alternate Healthy Eating Index (AHEI) scoring method and total scores

Component	Criteria for Minimum Score[a]	Criteria for Maximum Score[a]	Participant AHEI scores, mean points (*SD*)
Vegetables (servings/day)	0	5	5.41 (*2.84*)
Fruit (servings/day)	0	4	4.96 (*2.38*)
Nuts and soy protein (servings/day)	0	1	6.00 (*4.93*)
Ratio of white to red meat	0	4	2.44 (*2.57*)
Cereal fiber (grams/day)	0	15	8.08 (*2.74*)
trans Fat (% of energy)	≥4	≤0.5	7.49 (*1.19*)
Polyunsaturated to Saturated Fat ratio	≤0.1	≥1.0	7.29 (*1.83*)
Duration of multivitamin use[b]	<5 years	≥5 years	3.77 (*2.19*)
Alcohol (servings/day)	0 or >2.5	0.5 – 1.5	2.13 (*3.95*)
Total Score	2.5	87.5	47.58 (*14.25*)

Note. [a]Intermediate intakes were scored proportionately between 0 and 10. [b]Minimum score is 2.5 and maximum score is 7.5.

Table 2.3

Participant Scores on Intrapersonal Measures

Instrument	Study Sample
10 year Risk Perception	
Almost no/Slight chance, %	50.7
Moderate/High chance, %	49.3
Personal Control, mean (*SD*)	3.15 (*0.5*)
Worry, mean (*SD*)	2.73 (*0.75*)
Optimistic Bias, mean (*SD*)	2.10 (*0.65*)
Barriers to Healthy Eating, mean (*SD*)	27.29 (*6.52*)
Benefits to Healthy Eating, mean (*SD*)	42.23 (*3.07*)
Dietary Self Efficacy, mean (*SD*)	51.89 (*12.72*)
Knowledge	
Diabetes Risk, mean (*SD*)	60.96 (*18.43*)
Dietary Guidelines, mean (*SD*)	42.23 (*24.64*)
Depressive Symptoms, mean (*SD*)	4.08 (*4.06*)
Minimal, %	68.0
Mild, %	20.0
Moderate, %	10.7
Moderately Severe, %	1.3

Table 2.4

Summary of Bivariate Associations with AHEI Diet Quality

Variable	Correlation Association	Two-sample T-test
Age	.18	
Minority versus Non-Hispanic Caucasian		-2.41*
Education (<Bachelor's degree versus ≥ Bachelors)		-5.00**
Depressive Symptoms (PHQ-9)	-.10	
Dietary Knowledge	.21	
Threat of T2DM		
Personal Control	.17	
Worry	.00	
Optimistic Bias	.16	
Risk Knowledge	.22	
10-year Risk (No/slight chance versus Moderate/High chance)		-.23
Perceived dietary benefits	.20	
Perceived dietary barriers	-.18	
Dietary Self-Efficacy	.33**	

Note. *$p < .05$; **$p < .001$. PHQ-9 = Patient Health Questionnaire; T2DM = type 2 diabetes.

Table 2.5

Multiple Linear Regression Analysis Summary for Intrapersonal Variables and AHEI Diet Quality

Variable	***B***	***SE B***	**β**	***t***	***p***
Age	-0.23	0.28	-.09	-0.82	.41
Non-Hispanic Caucasian Race	3.93	3.31	.14	1.19	.24
Education Status	3.51	0.89	.08	3.18	<.001
Depressive Symptoms	0.28	0.36	.51	0.76	.45
Dietary Knowledge	-0.08	0.07	-.13	-1.05	.30
Dietary Self Efficacy	0.37	0.12	.33	3.18	002

Note. R^2 = .36, F (6, 66) = 6.19, p = <.0001

Chapter 3: The Influence of Family and Social Factors on Diet Quality in Women with Previous Gestational Diabetes

Abstract

Background: Women with previous gestational diabetes mellitus (pGDM) are at increased risk for the development of type 2 diabetes and have suboptimal adherence to risk-reduction behaviors such as healthy eating. Influences of healthy eating in women with pGDM have not been fully investigated. Family and social factors are important influences in adherence to dietary patterns in other populations, but the association in women with pGDM is largely unknown.

Objective: The purpose of this study was to determine the contribution of family and social influences on diet quality in this high-risk population within five years of their most recent gestational diabetic pregnancy.

Methods: A cross-sectional, descriptive, quantitative design was used to evaluate diet quality (Block 2005 food frequency questionnaire and scored with the Alternate Healthy Eating Index), social support (ENRICHD Social Support Instrument), family food interaction (Family Food Interaction scale) and family functioning (McMaster Family Assessment Device). Analysis included descriptive statistics, bivariate analyses, and multivariate linear regression analyses.

Results: Overall diet quality was moderate in this sample (n = 75; 55% Minority; age M= 35.5, SD = 5.5 years) with a mean AHEI score of 47.6, (SD = 14.3). Bivariate analyses resulted in significant associations between diet quality and social support (r = .31, p =.01), general family functioning (rho = -.25, p = .04), family communication (r = -.24, p

=.05), and family food interaction (r = .27, p =.02). Multivariate linear regression analyses revealed no significant social or family predictors for AHEI diet quality after controlling for education status and dietary self-efficacy.

Conclusions: General social support and components of family functioning did not explain variance in diet quality in women with pGDM beyond the individual predictors of education status and dietary self-efficacy. Contextual aspects of social and family support specific to dietary behavior may need to be explored further in this population.

Gestational diabetes mellitus (GDM) is the most common complication of pregnancy, with incidence paralleling the increasing prevalence of type 2 diabetes (T2DM).[1] Most women return to a normoglycemic state following delivery, but as many as 50-60% will go on to develop T2DM within ten years.[2] Women with previous gestational diabetes mellitus (pGDM) are at significantly elevated risk for cardiovascular disease.[3,4] The cardiometabolic profile of women with pGDM at different timepoints following a GDM diagnosis has shown multiple abnormalities,[5-8] with higher prevalence of metabolic syndrome.[9,10] Despite these known risks, there is little consistency in risk-counseling and dietary management after delivery. Many women with pGDM do not perceive themselves to be at elevated risk for T2DM,[11] and research reveals that most do not participate in risk reduction behaviors, such as healthy eating or physical activity.[12]

Adherence to healthy dietary patterns provides a substantial protective effect in women with pGDM.[13] Studies have demonstrated that a healthy diet reduces cardiometabolic risk (CMR) and T2DM risk in women and working adults.[14,15] Improving the diet quality in women with pGDM is an effective means of reducing CMR and T2DM in this at-risk group, however identifying important modifiable influences to improve dietary intake must be addressed to effectively promote healthy dietary pattern adherence. Two studies to date, have examined family support and social support on outcomes of diet in this population of women, but had conflicting findings.[16,17] One study assessed family and friend-level social support specific to healthy eating behavior and found a potential association between higher support and better diet quality,[17] while the other study found no association.[16] Neither study examined general family functioning components, level of family food interaction, or general social support in

relation to diet quality. The purpose of this study was to determine the contribution of specific family and social influences on diet quality in this high-risk population. The investigators in this study hypothesized that higher levels of social support and family food interaction and healthier components of family functioning would predict better diet quality beyond that associated with individual demographic factors and dietary self-efficacy.

Background

Theoretical Framework

The ecological framework adapted for eating behavior by Story and colleagues[18] served as the theoretical framework for this study. This framework outlines a multilevel, multicontextual depiction of four broad environmental influences of eating behavior, including the individual factors, social environments, physical and macro-level environments. The recognition that individual behavior requires supportive environments for healthy choices, particularly dietary decisions, has gained greater attention in public health policy and research. For this study, the influence of the social environment on dietary quality was the focus of investigation. The social environment within the framework depicts that friends, family, and peers are posited to influence eating behavior through role modeling, social support, and social norms.[18] Because so little is known about the influence of family-level factors with diet quality in women with pGDM, this study concentrated on specific components of family functioning, interaction and general social support. An adapted version of the Story et al framework is presented in Figure 1. The investigators of this study hypothesized that women with pGDM who had greater

social support and higher levels of general family functioning, problem-solving, communication, and food interaction would have higher diet quality.

Family and Social Influences with Diet Quality

Three main sources constitute the family-level influences on health: genetics, a shared physical environment and a shared social environment.[19] Specific family-level influences that have been demonstrated to affect health promoting behavior include family rules, emotional support, encouragement, reinforcement, and family member participation.[20] There is a substantial body of literature regarding the importance of family influence on children's eating patterns,[21,22] but less attention has been devoted to family influences on adult eating patterns. This is particularly true for populations not on a prescriptive diet for a specific disease.[23] In a study examining family influences with diabetic children's adherence behaviors and metabolic control, family cohesion and family conflict (components of family functioning) were important factors in adherence and metabolic control.[24] Studies examining family functioning with adult diabetics and heart failure patients have found family functioning and support to be strongly related to dietary behavior.[23,25 26]

Due to the multifactorial complexity of the obesity epidemic, family-based interventions have been suggested to target both childhood and adult obesity.[27] Gruber and Haldeman[27] contend that the family is the social context which is most likely to support making health behavior changes. The family context shapes individual beliefs and health behaviors throughout the lifetime[28] and provides specific social support that directly impacts health, specifically cardiovascular health.[29] Family-level influences associated with adult eating behaviors have received little attention in research and

clinical practice. Among the few studies that have examined family influences specifically on adult eating patterns, most have focused on the experience of patients and families managing a prescriptive diet for a disease, i.e. sodium restriction for heart failure[30] or sugar/carbohydrate restriction for diabetes management,[31] while other studies have examined outcomes such as disordered eating or obesity.[32] Three nursing reviews within the past decade have described family-level influences in adult health behavior, with a focus on heart-failure management,[26] diabetes self-management,[31] and family assessment within the context of a critical care setting.[26,33] These reviews highlight the role of family influence within the contexts of a chronic disease and a specific health care setting, but there is little research dedicated to examining family functioning in relation to general dietary patterns in adults.

Supportive social environments are beneficial in supporting dietary adherence and improvement.[34,35] Multiple studies have demonstrated that higher levels of social support were predictive of increased intake of fruits and vegetables.[36] Lower levels of social support were related to lack of adherence to healthy dietary patterns in a research intervention trial for family members of patients with cardiovascular disease.[37] In addition to the effect of social support with dietary adherence, there is a relationship between higher incidence of disease outcomes, such as metabolic syndrome in those with low social support.[38] Social support seems to be especially important in facilitating healthy behavior in postpartum women[39] and those with pGDM.[17,40]

Diet Quality

Despite intensive lifestyle interventions for gestational diabetic women during pregnancy, adherence to dietary recommendations following delivery is poor. Low

consumption of fruits and vegetables was found to be particularly low in this population,[41] with only 5% consuming at least five servings per day.[16] Yet the risk for developing T2DM has been shown to decrease by 57% in pGDM women with greater adherence to the Alternate Healthy Eating Index (AHEI) dietary pattern.[13] Increasing benefit was gained with greater adherence to the AHEI, suggesting that incremental improvements in diet quality have significant risk-reduction potential.

The AHEI dietary index, created in 2002, evolved from the Healthy Eating Index as an alternative dietary index to better predict chronic disease risk.[42] Adherence to the AHEI has been associated with decreased risk of diabetes,[13,43] as well as lower risk of cardiovascular disease,[44] cancer,[45] and the reversal of metabolic syndrome.[46] Because this dietary pattern has demonstrated beneficial risk reduction in at-risk populations, and specifically in women with pGDM, it was selected for determining diet quality in this study.

Methods

Study Design, Setting, and Participants

This was a cross-sectional, descriptive, quantitative study conducted from August 2011 through December 2012. Participants were recruited from the community and through women's health clinics of an academic health center, an inner-city public hospital, and a public health department through letters, poster flyers, and media advertising. Eligible participants were women who were (a) within 5 years of a GDM pregnancy, (b) aged 18-45 years, (c) fluent in English or Spanish, (d) with no history of polycystic ovary syndrome and no development of T2DM, (e) not currently pregnant or

breastfeeding, (f) not following a prescriptive or weight-loss diet, and (g) no more than moderate depressive symptoms (score of $\geq$ 20 or a score $\geq$ 16 with suicidal ideations on the *Patient Health Questionnaire-9*).

Measurements

Dependent Variable. Diet was measured with the Block 110-item semi-quantitative food frequency questionnaire (FFQ) to assess usual dietary intake in the past year. The Block FFQ has been validated among other major FFQ's and has been found to be comparable.[47] Earlier versions of the Block FFQ have demonstrated reliability with repeated FFQ administration and validity with 24-hour food recalls in women.[48] Analysis for the FFQ was provided by Nutrition Quest for specific daily nutrient intake and daily servings. The Block analysis was then scored into the Alternate Healthy Eating Index dietary (AHEI) score. The AHEI is scored from 2.5-87.5, with greater adherence (better diet quality) reflected in higher scores. Eight of the nine components of the AHEI are scored from 0 (recommendations were not met) to 10 (recommendations were met fully). Intermediate intakes are scored proportionately between 0 and 10. The final component of multivitamin use is scored as 2.5 points for no use and 7.5 points for use.[42]

Independent Variables. Demographics and basic, pertinent medical history were collected on a form designed for this study and included age, race/ethnicity, education, income, delivery date of most recent GDM pregnancy, and current medications.

Three scales of the *McMaster Family Assessment Device (FAD)*[49] were used to measure family functioning - the *General Family Functioning* scale (12-items), the *Communication* scale (9-items), and the *Problem Solving* scale (6-items). Scores for each

scale are calculated by summing and averaging the responses, with each scale score ranging from 1-4. Higher scores indicate poorer functioning, with the unhealthy cutoff for the *General Family Functioning* scale set at > 2.0 and 2.2 for the *Communication* and *Problem Solving* scales.[50] The FAD has been validated in previous studies[49,50] and reliability found adequate in a general community adult sample; α= .87 for *General Family Functioning*; α= .74 for *Communication*; α= .74 for *Problem Solving*.[51] In this study, Cronbach's alphas for each of the subscales were: *General Family Functioning*, .90; *Family Communication*, .79; *Family Problem-Solving*, .81.

Family food interaction was measured with the six item *Family Food Interaction* scale to measure the degree of interaction within the family over food preferences and nutrition. The version used in this study was one that was adapted[52] from the original scale.[53] Items are rated on a 5-point Likert scale and include, for example, "I let my family/spouse/partner know what foods I like best" and "I help decide what foods to prepare for family meals." Item answers are summed for a total score ranging from 6 – 30. Higher scores indicate higher levels of family food interaction. Schafer and colleagues determined reliability for this version of the scale to be .66.[52] The reliability coefficient was also .66 for our study.

Social support was measured with the *Enhancing Recovery in Coronary Heart Disease (ENRICHD) Social Support Instrument (ESSI)*, a 7-item scale developed to measure perceived social support among cardiac patients.[54] The scale measures the structural, instrumental, and emotional aspects of social support. Scores range from 8-34, with those $\geq$ 18 indicating high levels of social support. The instrument has demonstrated

reliability (alpha = .86 and .88) in two adult samples with cardiovascular disease,[54,55] and found to be similar in this study at .87.

Contributing Variables. Since individual factors contribute to diet quality, we did measure and account for these likely influencing factors. Specifically, we assessed socio-demographic factors (age, race/ethnicity, educations status, and marital status) and depressive symptoms, T2DM risk perception, perceived benefits/barriers of healthy eating, dietary knowledge, and dietary self-efficacy.

Depressive symptoms were assessed with the *Patient Health Questionnaire-9 (PHQ-9).* The *PHQ-9* is a 9-item, 4-point Likert scale that was designed to be a brief assessment of depressive symptoms. It has been tested in multiple samples, including women of childbearing age[56] and deemed a reliable and valid measure of depression severity. The *PHQ-9* has been used in a primary-care patient sample and demonstrated an acceptable internal consistency of .82.[57] In this study sample, the reliability coefficient was .79.

Risk perception was assessed with the *Risk Perception Survey for Developing Diabetes (RPS-DD),* developed for the Diabetes Prevention Program study[58] and adapted for women with pGDM.[11] Reported Cronbach's alpha coefficients for the pGDM population ranged from 0.65 – 0.72.[11] In this sample, Cronbach's alpha coefficients were 0.62 for the *Personal Control* subscale, 0.81 for the *Worry* subscale, and 0.73 for the *Optimistic Bias* subscale.

Perceived benefits of healthy eating was assessed with a 9-item, 5-point Likert instrument designed specifically for this study. At the time that this study was being designed, there were no published instruments that examined the concept of healthy

eating benefits, especially in a population at risk for cardiometabolic diseases. Cronbach's alpha coefficient in the unpublished pilot study was acceptable at .88 and in this sample was .92.

Perceived barriers of healthy eating was assessed with the *Barriers to Healthy Eating Scale (BHES)*, a 16-item scale originally developed to assess healthy eating barriers in pregnant women.[59] It addresses areas related to availability of food, expense, inconvenience, preferences and inability to engage in healthy eating. The *BHES* is a 5-item Likert scale instrument, which is summed for total scores ranging from 16-80. Higher scores indicate greater perceived barriers to healthy eating. Initial reliability testing of this instrument resulted in Cronbach's alpha coefficient ranges of .71 - .77.[59] In our sample, the Cronbach's alpha coefficient was .67.

Dietary knowledge was assessed with an 11-item questionnaire (10 knowledge questions and 1 Likert questions for perceived level of dietary knowledge) to assess awareness of the 2010 Dietary Guidelines for Americans. This instrument was adapted from a survey designed to test knowledge of the 2005 Dietary Guidelines for Americans from a study with community health advisors,[60] where content validity was established with an expert review panel and then pilot-tested with a community sample. An adapted and updated questionnaire to reflect the 2010 guidelines specifically for women aged 18-45 was used for this study.[61] The 16-item *Cardiac Diet Self-Efficacy Scale* was used to measure self-efficacy related to healthy eating. It is a general nutrition self-efficacy scale addressing healthy dietary behavior.[62] Each item is a 5-point Likert scale, which is summed and scored from 16-80, with higher scores indicating greater self-efficacy.

Cronbach's alpha coeffiencts ranged from .89 - .92 in other samples, and .92 in this sample.

Procedures. Potential participants were recruited by letters of invitation following a medical chart review or by self-referral from community advertisements. Interested women contacted the lead researcher or bilingual research assistant by email or telephone. The study was fully explained, initial verbal telephone consent completed, and eligibility criteria determined. English-speaking women who met eligibility criteria and chose to enroll were then mailed a packet of study materials, including the informed consent, hard-copy questionnaires, and the semi-quantitative food frequency questionnaire. The research staff met participants in the setting chosen by the participant, usually the home or workplace. Study questionnaires were collected by the lead researcher. Enrolled Spanish-speaking women completed questionnaires in an in-person interview format with the bilingual research assistant. Questionnaire completion ranged from 1 to 2 hours. Participants were compensated with a $25 gift card and presented with education materials upon completion of the study activities. The study protocol was approved by the Emory University institutional review board and by the clinic sites where recruitment occurred.

Data Analyses

Data were analyzed with IBM SPSS version 20.0. Descriptive statistics were used for assessing sample characteristics, evaluating underlying distribution assumptions and checking for missing data. Race and ethnicity data were collapsed into two categories representing non-Hispanic Caucasian women (n = 34) and Minority women (n = 41). The Minority group consisted of 24 African-American, 11 Hispanic, 2 Asian, and

4 multiracial/ethnic women. Bivariate correlation analyses determined significant associations ($\alpha \leq .05$) between the contributing and independent variables with diet quality. Two sample t-tests were also used to examine differences in mean AHEI diet quality by dichotomized scales at the healthy/unhealthy cutoff scores for the subscales of family functioning, problem solving and communication and the cutoff of high (scores $\geq$ 18) versus low social support. Multiple linear regression modeling was used to examine the contribution of the independent and contributing variables to the variance in diet quality. The control variables of age, race, dietary knowledge, educational attainment, depressive symptoms, and dietary self-efficacy were held constant in the model testing, with each of the independent variables added to the model to be examined for contribution and significance in predicting diet quality. Independent variables that were not significant ($\alpha > .05$) were excluded from the final model.

Results

The sample included 75 women (45% Caucasian, 32% African-American, 15% Hispanic), with a mean age of 35.5 years (*SD* = 5.5), who were 2.6 years (*SD* = 1.6) since their last GDM delivery, and a mean parity of 2.7 (*SD* = 2.1). Most were married (73%). More than half (58%) had a Bachelor's degree or higher and 52% were employed full-time. The majority of women (63%) were managed with lifestyle interventions during their GDM pregnancy, however 24% had been treated with insulin (Table 3.1).

Overall AHEI diet quality was moderate (*M* = 47.6, *SD* = 14.3), with a range of scores from 20.5 – 77.5, indicating that no participant had full adherence to the dietary pattern. Poorest adherence was among the components of meat ratio, indicating a higher red meat to white meat intake and low moderate alcohol consumption, with less than the

recommended intake of 0.5 – 1.5 drinks per day. Highest adherence was among the components of cereal/fiber intake, fat consumption, and nuts/legumes (Table 3.2).

Most of the participants (89%) reported high social support, with a mean ESSI score of 27.3 (*SD* = 5.9). Higher levels of social support were associated with higher diet quality (r = .31, p = .01).

Mean scores on the McMaster Family Assessment Device subscales were in the healthy ranges - general family functioning (*M* = 1.8, *SD* = 0.51), family communication (*M* = 2.0, *SD* = 0.47), and family problem-solving (*M* = 1.93, *SD* = 0.51). Results from correlation analyses showed that higher diet quality scores were significantly associated with lower family communication scores (Pearson's r = -.24, p = .05) and lower general family functioning scores (Spearman's *rho* = -.25, p = .04), but not associated with family problem-solving scores (Pearson's r = -.10, p = .38), indicating that better family functioning and communication were associated with better AHEI diet quality. When considering the dichotomized cutoffs of the FAD subscales, two sample t-tests showed no difference in diet quality between those reporting healthy communication compared to those reporting unhealthy communication (t = -1.8, p = .08), or in those reporting high family functioning versus low family functioning (t = -1.5, p = .15). Participants reported a high level of family food interaction (*M* = 25.0, *SD* = 4.0). Higher levels of family food interaction were found to be associated with better diet quality (Pearson's r = .27, p = .02) (Table 3.4).

Each of the five independent variables (*ESSI* scores, *Family Food Interaction*, and *General Family Functioning*, *Problem-Solving* and *Communication* subscale scores) was entered individually into a multiple regression model with all five control variables

(race, education status, depressive symptoms, dietary knowledge and dietary self-efficacy scores). General social support (p = .50), family food interaction (p = .37) and components of family functioning (general family functioning, (p = .62); problem-solving, (p = .76); family communication (p = .88)) did not contribute to variance in diet quality. Controlling for all other variables, only higher levels of educational attainment and dietary self-efficacy significantly predicted better AHEI diet adherence (R^2 = .36, $F(6, 66) = 6.19$, p = <.0001). The final, most parsimonious model with only education status and self-efficacy as significant predictors, explained 36% of the variance in diet quality (Table 3.5).

Discussion

Diet quality in this study sample of women with pGDM was moderate, indicating an opportunity to increase adherence to protective diets such as the AHEI in this at-risk population. Promoting the AHEI dietary pattern in women with pGDM may offer substantial protection from T2DM risk[13] and other cardiometabolic diseases.[46,63] To promote adherence, important influences of diet quality require greater understanding and identifying the contribution of specific family and social factors to diet quality among women with pGDM was an important next step of inquiry within the ecological framework of eating behavior.

This study did not reveal that social or family factors contributed to any variance in AHEI diet quality beyond that of the individual factors of educational status and dietary self-efficacy. General family functioning, family communication, family food interaction and social support were each moderately and significantly correlated with

AHEI diet quality, suggesting that they may be important distinct influences, but may not be as influential when examined in combination with the individual influences of educational status and dietary self-efficacy. The lack of a strong association between family and social support with dietary quality was also found in another sample of women with pGDM.[17] In the study by Kim and colleagues,[17] family and social support were measured with two instruments specific to family support for healthy eating and friend support for healthy eating.[64] Although there was a trend of a positive association between higher support and higher adherence by quartiles of diet quality, the association did not reach statistical significance. In another study in women with pGDM, social support for healthy eating did not remain predictive of higher diet quality,[16] however the assessment of social support was not measured with a validated instrument. Although women with pGDM have identified social support as an important factor in adhering to a healthy lifestyle in qualitative studies,[40,65] it does not seem to be the most influencing factor predicting adherence to a healthy diet.

Findings from multiple studies in other populations have indicated that family and social factors are predictive of diet quality in generally healthy children and adults, and in adherence to prescriptive diets in both children and adults managing diet-specific chronic diseases. More specifically, dietary adherence interventions that have targeted improving family communication and enhancing autonomy have been successful in improving sodium restriction in heart failure patients.[30] Family communication, family support, and family functioning have also been identified as important in diabetic diet adherence and diabetes self-care management.[66,67,68]

Social support has been established as an important influence on health and a major factor in determining diet quality and predicting success in diet-related interventions.[69] Interventions that have focused on improving adherence to prescriptive diets demonstrated that higher levels of social support resulted in better dietary outcomes.[70] Social support has also been a key influencing factor in determining diet quality among general populations.[71]

Further investigating contextual aspects of family and social support is needed in this population. For example, a greater understanding of family-level support, healthcare-level support, worksite support, and peer support would add greater depth to the type of social support that may be most influential in determining diet quality and in designing future interventions.[72] Some studies in women with pGDM have identified social and family support as important influences in predicting adherence to a healthy lifestyle, particularly physical activity behaviors.[17,40,73,74] Two of these studies were qualitative in design. For those that were quantitative,[17,74] family and social support were measured with instruments specific to physical activity.

In contrast, this study measured a more global assessment of social support and specific aspects of family support with the FAD subscales, which may not have been specific enough to dietary behavior to capture associations diet-related associations. Furthermore, global social support may capture components of support from family, friends and peers. When measured together with components of general family functioning, the two may not be discrete measures of family-specific or friend-specific support. The assessment of family food interaction was more specific to dietary behavior, but with most participants reporting a high level of interaction, there may not have been

enough variance in reported interaction to predict diet quality variance even with the bivariate association between the two variables. Though social support, components of family functioning, and family food interaction did not individually contribute to additional variance in diet quality, perhaps due to their shared constructs, it may be worth exploring combining these similar measures of family/social support into a single factor and examining the additional contribution to diet quality.

Limitations and Strengths. Our study is limited to only examining associations between the family/social factors and diet quality. Due to the cross-sectional design, no relationships of causality could be explored. Second, our sample size was small, although represented a socio-demographically diverse group of women drawn from multiple community and health care settings. This diversity enhances the generalizability of our findings.

Implications. This study supports previous findings that diet quality needs to be improved in women with pGDM.[16] Improving adherence to dietary patterns such as the AHEI offers substantial protection in risk for T2DM development.[13] Future studies should further investigate the role of family and social factors specific to supporting improved dietary behavior among women with pGDM.

Conclusion

Diet quality in this sample of women with pGDM was moderate and not predicted by the general family and social factors that were measured in this study. This area of inquiry remains understudied and requires further investigation to determine what type of family and social factors, if any, may influence diet quality. Improving diet quality in women with pGDM is essential to mitigate cardio-metabolic risk and prevent or delay the

development of T2DM. Supportive environments that promote healthy eating are critical however, the aspects of the social environment that would affect the greatest improvements in diet quality require further investigation.

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Figure 3.1

Intra- and Interpersonal Influences of Diet Quality in Women with pGDM

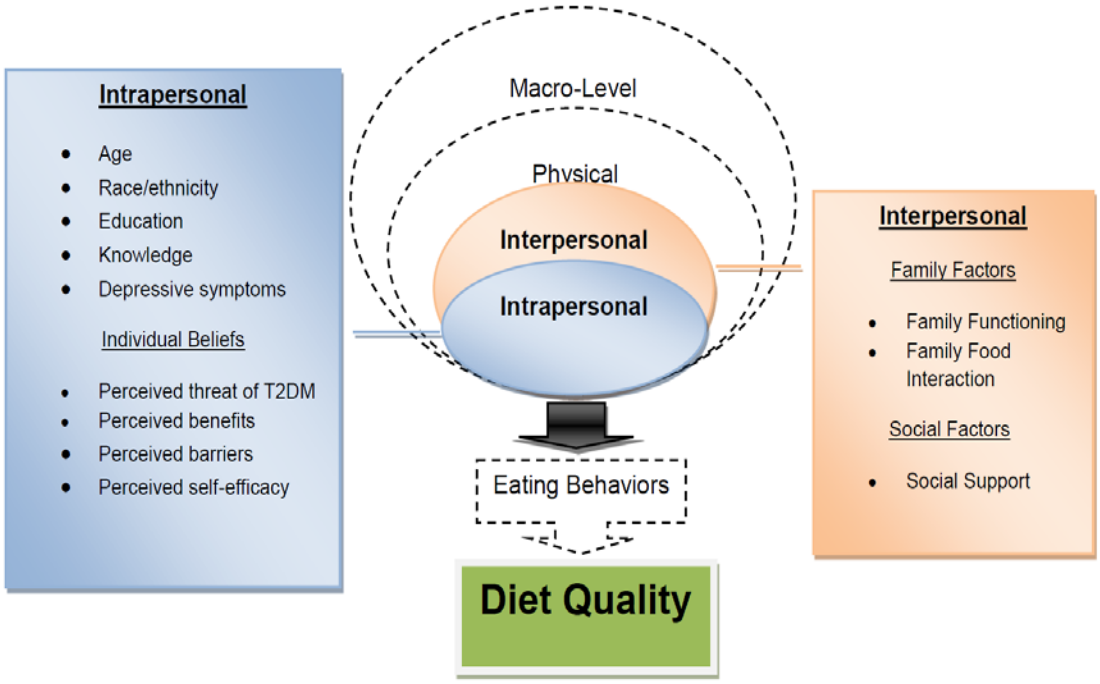

Table 3.1

Characteristics of the Sample (N = 75)

Characteristic	Study Sample
Age, mean years (*SD*)	35.5 (*5.5*)
Race/Ethnicity, %	
Non-Hispanic Caucasian	45.0
Minority	55.0
African-American	32.0
Hispanic	15.0
Asian	3.0
Multiracial	5.0
Education, %	
< 4 years college	41.3
≥ Bachelor's degree	58.7
Marital status, %	
Married	73.3
Employment Status, %	
Unemployed	33.0
Part-time employed	16.0
Full-time employed	51.0
Family History of T2DM, %	35.0
Family History of CVD, %	64.0
Current Smoker, %	12.0
Time since last GDM pregnancy, mean years (*SD*)	2.6 (*1.6*)
Parity, mean (*SD*)	2.7 (*2.1*)
GDM Pregnancy Treatment, %	
Lifestyle	63.0
Oral Medication	13.0
Insulin	24.0

Note. T2DM = type 2 diabetes mellitus; CVD = cardiovascular disease

Table 3.2

Alternate Healthy Eating Index (AHEI) scoring method and total scores

Component	Criteria for Minimum Score[a]	Criteria for Maximum Score[a]	Participant AHEI scores, mean points (*SD*)
Vegetables (servings/day)	0	5	5.41 (*2.84*)
Fruit (servings/day)	0	4	4.96 (*2.38*)
Nuts and soy protein (servings/day)	0	1	6.00 (*4.93*)
Ratio of white to red meat	0	4	2.44 (*2.57*)
Cereal fiber (grams/day)	0	15	8.08 (*2.74*)
trans Fat (% of energy)	≥4	≤0.5	7.49 (*1.19*)
Polyunsaturated to Saturated Fat ratio	≤0.1	≥1.0	7.29 (*1.83*)
Duration of multivitamin use[b]	<5 years	≥5 years	3.77 (*2.19*)
Alcohol (servings/day)	0 or >2.5	0.5 – 1.5	2.13 (*3.95*)
Total Score	2.5	87.5	47.58 (*14.25*)

Note. [a]Intermediate intakes were scored proportionately between 0 and 10. [b]Minimum score is 2.5 and maximum score is 7.5.

Table 3.3

Participant Scores on Individual, Family, and Social Measures

Instrument	Study Sample
Depressive Symptoms (PHQ-9), mean (*SD*)	4.08 (*4.06*)
Risk Perception Scale for Developing Diabetes	3.15 (*0.5*)
Personal Control, mean (*SD*)	2.73 (*0.75*)
Worry, mean (*SD*)	2.10 (*0.65*)
Optimistic Bias, mean (*SD*)	
Benefits to Healthy Eating, mean (*SD*)	42.23 (*3.07*)
Barriers to Healthy Eating, mean (*SD*)	27.29 (*6.52*)
Knowledge	
Diabetes Risk, mean (*SD*)	60.96 (*18.43*)
Dietary Guidelines, mean (*SD*)	42.23 (*24.64*)
Dietary Self Efficacy, mean (*SD*)	51.89 (*12.72*)
Social Support (ESSI), mean (*SD*)	27.3 (*5.87*)
Low social support, %	10.8%
High social support, %	89.2%
Family Functioning (FAD)	
General Family Functioning, mean (*SD*)	1.8 (*0.51*)
Healthy, %	60.6%
Unhealthy, %	39.4%
Problem-Solving, mean (*SD*)	1.9 (*0.51*)
Healthy, %	75.0%
Unhealthy, %	25.0%
Communication, mean (*SD*)	2.0 (*0.47*)
Healthy, %	61.4%
Unhealthy, %	38.6%
Family Food Interaction, mean (*SD*)	25.0 (4.0)

Table 3.4

Summary of Bivariate Associations with AHEI Diet Quality

Variable	Correlation Association	Two-sample T-tests
Age	.18	
Minority versus Non-Hispanic Caucasian		-2.41*
Education (<Bachelor's degree versus ≥ Bachelors)		-5.00**
Depressive Symptoms (PHQ-9)	-.10	
Dietary Knowledge	.21	
Threat of T2DM		
Personal Control	.17	
Worry	.00	
Optimistic Bias	.16	
Risk Knowledge	.22	
10-year Risk (No/slight chance versus Moderate/High chance)		-.23
Perceived dietary benefits	.20	
Perceived dietary barriers	-.18	
Dietary Self-Efficacy	.33**	
Social Support (ESSI)	.29**	
McMaster Family Assessment Device		
General Family Functioning	-.25*	-1.46
Problem-Solving	-.10	
Communication	-.24*	-1.76
Family Food Interaction	.27*	

Note. *$p < .05$; **$p < .001$. PHQ-9 = Patient Health Questionnaire; T2DM = type 2 diabetes.

Table 3.5

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality

Variable	***B***	***SE B***	**β**	***t***	***p***
Age	-0.23	0.28	-.09	-0.82	.41
Non-Hispanic Caucasian Race	3.93	3.31	.14	1.19	.24
Education Status	3.51	0.89	.08	3.18	<.001
Depressive Symptoms	0.28	0.36	.51	0.76	.45
Dietary Knowledge	-0.08	0.07	-.13	-1.05	.30
Dietary Self Efficacy	0.37	0.12	.33	3.18	.002

Note. R^2 = .36, F (6, 66) = 6.19, p = <.0001. Each family and social variable was added to the model individually to test for significance. None remained significant and are therefore not presented in this table. A table demonstrating the model parameters for each family and social variable follow.

Table 3.6

What is New?

- Women within five years of their most recent gestational diabetes mellitus pregnancy have inadequate diet quality and significant cardiometabolic risk factors.
- General social support and components of family functioning did not influence diet quality in women with pGDM beyond that associated with educational status and dietary self-efficacy. Social and family support specific to dietary behavior are areas for further study.

Note. This table is a requirement for the intended journal: *Journal of Cardiovascular Nursing*

Additional Tables

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality: Social Support

Variable	*B*	*SE B*	*t*	*p*
Age	-0.26	0.28	-0.89	.38
Non-Hispanic Caucasian Race	3.95	3.33	1.19	.24
Education Status	3.48	1.00	3.18	<.001
Depressive Symptoms	0.41	0.39	1.06	.29
Dietary Knowledge	-0.08	0.07	-1.03	.31
Dietary Self Efficacy	0.35	0.12	2.94	.01
Social Support (ESSI)	0.20	0.29	0.69	.50

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality: General Family Functioning

Variable	*B*	*SE B*	*t*	*p*
Age	-0.23	0.30	-0.77	.44
Non-Hispanic Caucasian Race	2.93	3.51	.83	.44
Education Status	3.80	0.94	4.03	<.001
Depressive Symptoms	0.04	0.39	0.09	.93
Dietary Knowledge	-0.07	0.07	-0.91	.37
Dietary Self Efficacy	0.36	0.12	3.02	<.01
General Family Functioning (FAD)	1.63	3.25	0.50	.62

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality: Family Problem-Solving

Variable	*B*	*SE B*	*t*	*p*
Age	-0.29	0.30	-0.95	.35
Non-Hispanic Caucasian Race	3.39	3.58	0.95	.35
Education Status	3.65	0.92	3.98	<.001
Depressive Symptoms	0.32	0.37	0.86	.40
Dietary Knowledge	-0.07	0.07	-0.91	.37
Dietary Self Efficacy	0.37	0.12	3.13	<.01
Problem-Solving (FAD)	0.90	2.96	0.30	.76

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality: Family Communication

Variable	*B*	*SE B*	*t*	*p*
Age	-0.32	0.30	-1.05	.30
Non-Hispanic Caucasian Race	2.66	3.57	0.74	.46
Education Status	3.70	0.98	3.79	<.001
Depressive Symptoms	0.20	0.39	0.50	.62
Dietary Knowledge	-0.06	0.07	-0.80	.43
Dietary Self Efficacy	0.36	0.12	3.00	<.01
Communication (FAD)	-0.52	3.39	-0.15	.88

Multiple Linear Regression Analyses Summary for Family and Social Influences on Diet Quality: Family Food Interaction

Variable	*B*	*SE B*	*t*	*p*
Age	-0.25	0.28	-0.87	.90
Non-Hispanic Caucasian Race	3.09	3.44	0.90	.33
Education Status	3.38	0.90	3.76	<.001
Depressive Symptoms	0.28	0.36	0.77	.45
Dietary Knowledge	-0.06	0.07	-0.86	.39
Dietary Self Efficacy	0.35	0.12	2.94	<.01
Communication (FAD)	-0.35	0.39	0.91	.37

Chapter 4: Diet Quality and Cardio-metabolic Risk in Women with a Recent History of Gestational Diabetes

Abstract

Objective: To assess the relationship of diet quality, as defined by the Alternate Healthy Eating Index (AHEI), with cardio-metabolic risk factors, including metabolic syndrome and type 2 diabetes (T2DM) risk in women with previous gestational diabetes mellitus (GDM).

Design: A cross-sectional, descriptive design.

Participants and Setting: Women (n = 74) within 5 years of their most recent GDM delivery were recruited from community and clinic sites in a southeast metropolitan area.

Methods: Habitual diet intake was assessed by self-report with the 2005 Block Food Frequency Questionnaire and scored into the AHEI. Medical history data was provided by self-report. Metabolic syndrome was defined as the presence of $\geq$ 3 risk factors as recommended by the American Heart Association and the National Heart, Lung and Blood Institute. Diabetes risk was defined as a hemoglobin A1C level $\geq$ 5.7%. Clinical and anthropometric data were collected with point-of-care meters and other portable medical equipment at scheduled study visits in the participants' home, workplace, or other setting.

Results: Participants had significant cardio-metabolic risk factors; 66.3% were overweight or obese, 47% had abnormal hemoglobin A1C levels, and 19% had metabolic syndrome. No differences in diet quality were found among those classified in risk categories versus those who were not. Diet quality was not predictive of either risk for

metabolic syndrome or T2DM risk in this sample. Only higher BMI was significantly associated with metabolic syndrome (p = .004) and diabetes risk (p = .01).

Conclusion: Women with pGDM are at significant risk for cardio-metabolic diseases. Although diet quality was not associated with specific clinical risk factors in this sample, further studies with larger sample sizes are needed to investigate the association between diet quality and risk in this vulnerable population.

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance that is first detected in pregnancy and resolves following delivery.[1] The exact incidence of GDM is unknown, and the differences in reported incidence vary by the population studied and the diagnostic criteria used.[2] However, recent trends have shown that GDM has more than doubled in the past decade[3] and currently affects between 7%-15% of all pregnancies. New diagnostic criteria proposed in March 2010 for GDM diagnosis lowers the threshold of diagnosis with a one-step approach at lower glucose levels, compared to the current two-step process.[4] The implications of adopting this approach would be a significant increase in GDM prevalence, with estimates ranging from 18%[4] to 28% of pregnant women.[5] A very recent draft consensus statement released by the National Institute of Health, *Diagnosing Gestational Diabetes Mellitus Conference*, has made the recommendation to continue with the two-step approach in light of insufficient evidence to demonstrate the benefit of the one-step approach, but to reconsider as the uncertainties of its benefit resolve.[6] The American Diabetes Association and the American College of Obstetricians and Gynecologists continue to recommend the two-step diagnostic approach.[7] Regardless of more stringent screening criteria, the incidence of GDM is increasing due to its' association with the increasing prevalence of type 2 diabetes (T2DM) and obesity in the general population.[8,9] GDM is a sentinel event for cardiometabolic disease risk, resulting in a 7-fold increased risk[10] for the development of T2DM, greatest within the first 5 years following delivery.[11] Women with previous gestational diabetes mellitus (pGDM) are also at significant risk for metabolic syndrome and have a 70% higher risk for cardiovascular disease.[12-16]

Despite these known risks, there is poor post-partum follow-up and risk assessment by providers. No recommendations exist regarding risk education or preventive measures even though intensive lifestyle interventions were demonstrated to reduce the risk for T2DM by 53% among the cohort of women with pGDM enrolled in the Diabetes Prevention Program (DPP).[17] The American College of Obstetricians and Gynecologists, consistent with the American Diabetes Association recommend that all women with pGDM be screened for abnormal glucose tolerance 6-12 weeks following delivery,[18] yet as many as 67% of women with pGDM do not get screening at the post-partum visit.[19-21] Another study also found that women with the most severe GDM are least likely to return for post-partum follow-up visits.[22]

Furthermore, there are no recommendations concerning patient education regarding risk status or dietary interventions specific to this population aimed at delaying or preventing the onset of T2DM. Consequently, many women with pGDM do not perceive themselves to be at elevated risk for T2DM,[23] nor are they engaging in risk reduction behaviors.[24] For those who receive some lifestyle counseling from their providers, it is insufficient to effect improvements in diet or activity or the intention to improve these behaviors.[25] The intensity of care that is directed at GDM women during the pregnancy is not followed through after delivery,[26] and little is known about how women perceive or understand their cardio-metabolic risk, or how lifestyle dietary and physical activity behaviors relate to risk factors. The purpose of this study was to assess the diet quality and associated cardio-metabolic profile of women within five years of their most recent GDM pregnancy.

Diet Quality in Women with pGDM

Many studies have determined that a higher intake of fruits and vegetables is protective against diabetes,[27-30] while dietary patterns reflecting intakes of low nutrient value have demonstrated higher risk. Low nutrient profiles often contain higher intakes of meats, fatty foods, potatoes, sugar-sweetened beverages, snack foods, refined grains and low intakes of vegetables, olive oil, fruits, whole grains, fish, and moderate alcohol.[31-35] Patterns that have demonstrated protection from T2DM are characterized by higher intakes of fruits, vegetables, monounsaturated fat, whole grains, dietary fiber, dairy, salad, fish, and a moderate consumption of alcohol.[32-37]

Several studies have found that women with pGDM do not adhere to healthy dietary patterns following delivery and have inadequate consumption of fruits and vegetables.[38,39] A more recent study demonstrated that women with pGDM who had the greatest adherence to the Alternate Healthy Eating Index (AHEI) dietary pattern had a 57% lower risk of T2DM development.[40] Adherence to the AHEI dietary pattern provided greater risk reduction than adherence to a Mediterranean diet pattern (40% lower risk) or the DASH pattern (46% lower risk). These findings are the first to report clinical outcomes associated with different dietary patterns in this population.

Although the Tobias et al. study is the first to report outcomes associated with AHEI dietary pattern adherence in women with pGDM, the AHEI pattern has been associated with lower risk for diabetes in other populations,[41,42] as well as lower risk for cardiovascular disease,[43] and the reversal of metabolic syndrome.[44] This study aimed to explore the degree to which the dietary patterns of women with pGDM within five years of their most recent GDM pregnancy reflect the AHEI dietary pattern and determine if

greater concordance was associated with decreased prevalence of diabetes risk and metabolic syndrome.

Demographic and Clinical Risk Factors

In addition to the influence that poor diet quality has on cardio-metabolic risk in women with pGDM, there are other important non-modifiable and modifiable risk factors that are associated with increased disease risk. Many of the same risks that contribute to the development of GDM are also associated with the development of T2DM and metabolic syndrome. Minority race, Hispanic ethnicity, increased age, family history of cardio-metabolic diseases, and increasing parity are the major non-modifiable risks associated with disease progression.[14,45] Protective, modifiable risk factors include weight-management, higher levels of physical activity, and longer duration of breastfeeding.[46-48]

Methods

Design, Setting, and Participants

This was an exploratory analysis from a cross-sectional, descriptive study about individual, family and social level influences of diet quality in women with pGDM. Participants were recruited from the community and through women's health clinics of an academic health center, an inner-city public hospital, and a public health department. Eligible participants were women who were (a) within 5 years of a GDM pregnancy, (b) aged 18-45 years, (c) fluent in English or Spanish, (d) with no history of polycystic ovary syndrome and no development of T2DM, (e) not currently pregnant or breastfeeding, (f) not following a prescriptive or weight-loss diet, and (g) no more than moderate depressive symptoms (score of $\geq$ 20 on the *Patient Health Questionnaire-9*). Most

participants (64%) self-identified as previous gestational diabetics and 37% were verified with medical chart review. Potential participants who were self-identified from community recruitment strategies were questioned about their gestational diabetes medical history with greater depth to verify the prerequisite diagnosis for study eligibility. This screening included the date of GDM diagnosis, the delivery date of the GDM pregnancy, the method of GDM treatment (lifestyle, oral medications, or insulin) and their recall of the frequency of daily finger-prick, glucose checks. Self-report of gestational diabetes medical history has been found to be a reliable method of identifying the pGDM population.[49]

Measurements

Dependent Variables. Elevated CMR, or metabolic syndrome was determined by the presence of $\geq$ 3 risk factors as recommended by the American Heart Association and the National Heart, Lung and Blood Institute. Risk factors were defined by the Third Report of the National Cholesterol Education Program (NCEP) Expert Plan on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults[50] (waist circumference >88 cm for women, blood pressure $\geq$ 130/85 mmHG, fasting triglyceride $\geq$ 150 mg/dl, HDL cholesterol <50 mg/dl, fasting glucose $\geq$ 100 mg/dl). Lipids and fasting glucose were measured with a CardioChek PA point of care monitor. The CardioChek PA is certified by the Center for Disease Control and Prevention's Cholesterol Reference Method Laboratory Network.[51] The CardioChek PA monitor provided accurate lipid measurements when compared to lab measurements; total cholesterol (83%), triglyceride (94%), HDL cholesterol (72%), and LDL cholesterol (86%).[52] The most recent certification of the CardioCheck PA demonstrated an acceptable coefficient of variation

of 0.9% to 2.0%, average bias of -1.6% to 1.9% and total error of 3.4% to 5.9%.[53] Blood pressure was manually auscultated with a latex-free sphygmomanometer by American Diagnostic Corporation that has a lifetime calibration warranty.

T2DM risk was defined by a Hemoglobin A1C of $\geq$ 5.7% (5.7-6.4% = pre-diabetes; $\geq$ 6.5% = diabetes).[54,55] The American Diabetes Association approved the use of the hemoglobin A1C test in 2010 for screening and diagnosing pre-diabetes and diabetes.[7] Although it is not recommended for use in women with pGDM in the early post-partum time period because it may still reflect elevations associated with pregnancy,[7,56] there is no contraindication to its use thereafter in this population.

Hemoglobin A1C was measured with the Bayer A1C Now+ point-of-care meter which is certified by the National Glycohemoglobin Standardization Program and has demonstrated 99% accuracy.[57] The coefficient of variation ranges from 3.0 - 4.02%.[58]

Independent Variable. Diet was measured with the Block 110-item semi-quantitative food frequency questionnaire (FFQ) to assess usual dietary intake in the past year. The Block FFQ has been validated among other major FFQ's and has been found to be comparable.[59] Earlier versions of the Block FFQ have demonstrated reliability with repeated FFQ administration and validity with 24-hour food recalls in women.[60] Analysis for the FFQ was provided by Nutrition Quest for specific daily nutrient intake and daily servings. The Block analysis was then scored into the Alternate Healthy Eating Index dietary score. The AHEI is scored from 2.5-87.5, with greater adherence (better diet quality) reflected in higher scores. Eight of the nine components of the AHEI are scored from 0 (recommendations were not met) to 10 (recommendations were met fully). Intermediate intakes are scored proportionately between 0 and 10. The final component

of multivitamin use is scored as 2.5 points for no use and 7.5 points for use.

Contributing Variables. Demographics and basic, pertinent medical history were collected on a form designed for this study. Socio-demographic data included age, race/ethnicity, marital status education, and income. Medical history data included delivery date of most recent GDM pregnancy, total breastfeeding duration, parity, pre-pregnancy BMI and current medications. Physical activity was measured with the validated *CARDIA Physical Activity History*, a 60 item, branched interview survey that captures levels of activity in leisure, work, and household within the past year. It has been tested in multiethnic populations of women with test-retest reliability (Pearson's r = 0.77 – 0.84) comparable to other physical activity measures.[61] Scores are calculated by multiplying a pre-set exercise intensity level by the frequency of that exercise participation, resulting in "exercise unit" scores for moderate activity and heavy activity. Total scores are the sum of the moderate and heavy activity scores, with 100 exercise units approximately equivalent to engaging in a heavy intensity activity for four months of the year.[61]

Body mass index (BMI) was calculated from height and weight using the iPhone application calculator from the National Heart, Lung and Blood Institute. The Charder HM200P Portstad Portable Stadiometer was used for measuring height. The Lifesource UC-321 scale was used to measure weight, zeroed before each use.

Procedures

Potential participants were recruited by letters of invitation following a medical chart review or by self-referral from community advertisements. Interested

women contacted the lead researcher or bilingual research assistant by email or telephone. The study was fully explained, initial verbal telephone consent completed, and eligibility criteria determined. English-speaking women who met eligibility criteria and chose to enroll were then mailed a study packet including the written informed consents, hard-copy questionnaires, and the semi-quantitative food frequency questionnaire. The questionnaires were collected by the lead researcher at the study appointment and missing data completed with investigator questioning. Enrolled Spanish-speaking women completed questionnaires in an interview format with the bilingual research assistant. The research staff met participants in the setting chosen by the participant, usually the home or workplace. Before any data collection began, written informed consent was obtained.

Most appointments were scheduled in the morning to facilitate the 8-hour fast required for the clinical lab measures. Clinical assessment began with blood pressure measurements with the participant in a seated position. Blood pressure was manually auscultated and measured according to Joint National Committee 7 guidelines (mean of 2 readings)[54] with a latex-free blood pressure sphygmomanometer. Height, weight, and waist circumference were measured in accordance with National Health and Nutrition Examination Survey protocols.[62] Waist circumference was measured at the uppermost border of the ilium, with two measurements taken and the mean calculated. A portable stadiometer and scale were used to measure height and weight. Body mass index (BMI) was calculated from the measured height and weight.

Clinical lab measures were assessed by a single finger-stick blood sample with two point-of-care meters; the CardioCheck PA for glucose, HDL-cholesterol, and

triglycerides and the Bayer A1CNow+ meter for assessing hemoglobin A1C. Participants were provided a copy of their clinical and anthropometric measures with normal values noted, abnormal values highlighted with basic health counseling provided. Participants were encouraged to share their results with their primary care provider. At the close of the visit, the examiner assessed the puncture site to note any bleeding or bruising, and instructions were provided should these occur. Participants were compensated with a $25 gift card and presented with education materials for their participation in the study. The study protocol was approved by the university institutional review board and by the clinic sites where recruitment occurred.

Data Analyses

Data were analyzed with IBM SPSS version 20.0. Descriptive statistics were used for assessing sample characteristics, evaluating underlying distribution assumptions and checking for missing data. Race and ethnicity data were collapsed into two categories representing non-Hispanic Caucasian women (n = 34) and Minority women (n = 40). The Minority group consisted of 23 African-American, 11 Hispanic, 2 Asian, and 4 multiracial/ethnic women. The association between dietary quality and the clinical outcomes of diabetes risk and metabolic syndrome were examined using two-sample t-tests. Correlation analyses were performed to evaluate the bivariate associations between diet quality and the continuous values of the clinical outcomes: BMI, hemoglobin A1C, diastolic and systolic blood pressure, waist circumference, fasting glucose, triglycerides and HDL-cholesterol. Finally, logistic regression models were fit to examine the associations between the diet quality and the outcomes of diabetes risk and metabolic syndrome, controlling for the other contributing socio-demographic and individual

variables (age, BMI, physical activity level, and breastfeeding duration). The independent variable of AHEI dietary quality met linearity assumption associations with the outcome of metabolic syndrome, but not diabetes risk. For the logistic model with diabetes risk as the outcome, AHEI was divided into quartiles and examined by dietary categories.

Results

The sample included 74 women (46% Caucasian, 54% Minority - 31% African-American, 15% Hispanic), with a mean age of 35.6 years (*SD* = 5.5), who were 2.5 years (*SD* = 1.6) since their last GDM delivery, and a mean parity of 2.7 (*SD* = 2.1). Most were married (74%). More than half (59%) had a Bachelor's degree or higher and 52% were employed full-time. The majority of women (61%) were managed with lifestyle interventions during their GDM pregnancy, however 24% were also treated with insulin. Although the majority (61%) reported having had a diabetes screening test at their postpartum visit, only 35% report receiving any lifestyle counseling at any postpartum visit. Physical activity scores on the CARDIA questionnaire indicated that participants were active, especially with moderate activity (see Table 4.1). The main activities that participants engaged in were walking (91%), home maintenance (92%), strength training (59%) and running/jogging (43%).

The majority of the participants had risk factors for cardio-metabolic disease in addition to their pGDM history. The mean BMI was 29.4 (*SD* = 7.0), with 66.3% in BMI categories of overweight, obese or morbidly obese. Abnormal hemoglobin A1C levels categorized 39.2% within pre-diabetic ranges and 8.1% in the diabetic range, resulting in nearly half of the sample (47%) at significant risk for T2DM. Mean hemoglobin A1C levels were 5.75% (*SD* = 0.57), and ranged from 4.8 – 7.8%. However, only 5.4% had

abnormal fasting glucose levels. Although only 19% of the women had metabolic syndrome, many had at least one major risk factor, with the most prevalent being high blood pressure (47%) and large waist circumference (60%) (see Table 4.2). Minority women had a proportionately higher prevalence of risk factors with 75% overweight/obese, 63% with diabetes risk, and 20% with metabolic syndrome, compared to the non-Hispanic Caucasian women – 56%, 29%, and 17.6% respectively.

Overall AHEI diet quality was moderate (mean = 47.9, SD = 14.0), with a range of scores from 20.5 – 77.5, indicating that no participant had full concordance to the dietary pattern. The dietary components with the poorest AHEI scores included low levels of multivitamin intake, poor ratio of white to red meat characterized by higher levels of red meat intake, and minimal alcohol consumption which did not meet the AHEI guidelines of 0.5 – 1.5 servings/day. Highest adherence was among the components of cereal/fiber intake, fat consumption, and nuts/legumes (Table 4.3).

Mean diet quality differed by race groups, with non-Hispanic Caucasian women having significantly higher AHEI mean scores than Minority women (t = -2.25, p = .03). Compared by the individual AHEI dietary components, non-Hispanic Caucasian women had higher intakes of vegetables (t = -3.08, p = .003) and a higher intake of alcohol meeting the AHEI moderate consumption guidelines (t = -2.33, p = .023) than Minority women.

In bivariate analyses, higher diet quality was associated with lower BMI (Pearson's r = -.23, p = .05), and lower fasting blood glucose (r = -.23, p = .05), but not with continuous levels of hemoglobin A1C (Pearson's r = -.17, p = .16). When examined by clinical cutoffs for hemoglobin A1C, two sample t-tests resulted in no differences in

diet quality between those with elevated hemoglobin A1C ($\geq$ 5.7) and those with normal levels (t = 1.24, p = .22). (Table 4.4)

No significant difference in diet quality was found in those with metabolic syndrome and those without (t = 1.82, p = .07), however the t-test indicated that those with metabolic syndrome had lower diet scores. Of the five clinical components that determine metabolic syndrome, lower levels of fasting blood glucose (r = -.23, p = .05) and lower levels of average diastolic blood pressure had any association with better diet quality (r = -.25, p = .03).

Multivariate logistic regression analyses modeling for diet quality and metabolic syndrome (Table 4.5) showed that only higher BMI was significantly associated with greater risk of metabolic syndrome (p = .004), after controlling for age, race, breastfeeding duration, physical activity, and diet quality. AHEI diet quality did not predict risk for metabolic syndrome in this sample. No differences in association were found when energy intake was included in the model, even when dropping BMI from the model.

Multivariate logistic regression analyses of diet quality with T2DM risk (Table 4.6) showed that only higher BMI was associated with increased T2DM risk (p = .01), when controlling for age, breastfeeding duration, physical activity, and diet quality. Greater adherence to the AHEI diet quality in any quartile was not associated with decreased risk of T2DM risk in this sample. This lack of association remained when energy intake was considered and BMI was dropped from the model.

Considering that many women with pGDM did not consume alcohol, the AHEI pattern excluding alcohol was also examined in relation to the outcomes of BMI,

metabolic syndrome, and diabetes risk. This scoring change had no significant effect on the association between AHEI diet quality and metabolic syndrome or diabetes risk, but did result in a loss of association between BMI and AHEI diet quality (r = -.16, p = .19). Further analyses by AHEI dietary component revealed that the only component independently associated with diabetes risk or metabolic syndrome was a moderate consumption of alcohol. Participants reported a mean intake of 0.44 (SD = .64) servings per day of alcohol. Greater alcohol consumption was associated with lower levels of hemoglobin A1C (rho = -.45, p = <.0001). There was also a statistically significant higher intake of alcohol among those without diabetes risk (M = .59, SD = .66 servings per day) compared to those with diabetes risk (M = .27, SD = .58 servings/day; p = .03), suggesting that a moderate consumption of alcohol offers some protective effects in levels of hemoglobin A1C and risk for T2DM in women with pGDM. No mean differences in alcohol consumption were found between those with or without metabolic syndrome.

Discussion

These study findings suggest that women in the first several years following their most recent GDM pregnancy are at significant risk for the development of cardio-metabolic diseases, have sub-optimal diet quality, and may not be receiving proper clinical follow-up. Overweight/obesity, large waist circumference, and abnormal hemoglobin A1C levels were the most prevalent risk factors in our sample of participants. Although diet quality was not found to be associated with the major clinical outcomes in this study, previous longitudinal studies have demonstrated that poor diet quality is predictive of T2DM development in women with pGDM.[40] The cross-sectional design,

inclusion of participants within the first five years following a GDM pregnancy, and focus on earlier prediabetic risk factors, may have limited the ability of this study to detect a significant association between AHEI diet quality and metabolic syndrome or diabetes risk. There was a trend approaching statistical significance ($p = .07$) found in the 7.5 point higher AHEI mean score between those without metabolic syndrome compared to those with metabolic syndrome. The small number of participants with metabolic syndrome ($n = 14$) compared to those without ($n = 60$) likely contributed to the difference being statistically nonsignificant.

In the retrospective cohort study conducted by Tobias and colleagues (2012),[40] participants ($n = 4413$) had a follow-up time of sixteen years, with a mean of 13.8 years from GDM diagnosis to T2DM development at an average age of 46.5 years. The sample was 90% non-Hispanic Caucasian. The design and timeframe of sixteen years was sufficient to examine the protective influence of AHEI dietary adherence with T2DM development. Tobias and colleagues did not examine metabolic syndrome outcomes or associations with earlier diabetes risk factors such as the presence of prediabetes in the shorter timeframe of five years since delivery.

Another study that did include women ($n = 181$, 94% non-Hispanic Caucasian) who were within a 4-year mean timeframe of their GDM pregnancy did result in an association with adherence to at least one preventive practice (either regular physical activity, higher scores [≥ 47 out of a possible total of 70 points] on an adapted AHEI, or exclusive breastfeeding for 6 months) and lower clinical risk factors.[63] This study by Gingras and colleagues[63] (2012) assessed diet intake for the previous month with a food frequency questionnaire. They adapted the AHEI scoring to include dairy components

and exclude nuts/soy and multivitamin intake, resulting in an index with a maximum possible score of 70 points. To define a healthy diet, the adapted AHEI was dichotomized so that any score ≥ 47 was considered a healthy diet. They found significantly less risk for insulin sensitivity in the 103 (57%) women with pGDM who had a healthy diet. Although these investigators assessed diet quality with an adapted and unvalidated measure of AHEI, it does suggest the potential for protective effects in specific T2DM risk factors.

To the authors' knowledge, this study is the first to examine the association of the validated AHEI diet score with metabolic syndrome or diabetes risk assessed by hemoglobin A1C in a racially diverse sample of women with pGDM. The protective influence of a healthy dietary pattern like the AHEI may be beneficial over time at older ages with a stronger association beyond the 5-year timeframe for the major clinical outcomes of T2DM and metabolic syndrome. The advantages of the AHEI diet pattern within five years following a GDM pregnancy may be associated with benefits in clinical measures of T2DM risk, such as fasting glucose and insulin sensitivity as opposed to hemoglobin A1C. Although not statistically significant, the trend of higher AHEI diet quality had protective effects in both hemoglobin A1C levels and metabolic syndrome. Higher AHEI diet quality was significantly associated with lower fasting blood glucose and lower BMI, suggesting that the dietary pattern may be protective for overweight status as one of the strongest risk factors of poor cardio-metabolic outcomes and the most significant predictor of metabolic syndrome and diabetes risk in this sample. These study findings do highlight the need for improved adherence to healthy dietary patterns in this group of at-risk women, since mean AHEI scores were moderate.

The finding that moderate alcohol consumption may be protective in T2DM risk in women with pGDM was also found in the Tobias et al. study.[40] A review published in 2010 of multiple studies that have examined alcohol intake with T2DM supports the protective effect of moderate alcohol intake, noting the critical J or U-shaped association indicating the risk associated with absolutely no intake as well as the detrimental effects of high intake.[64] The mechanism behind the protective effect of alcohol intake may be related to the beneficial effect that ethanol has on insulin sensitivity.[64]

Nearly half of the participants (47%) were at significant T2DM risk by hemoglobin A1C criterion, yet only 5% had elevated fasting glucose levels ($\geq$ 100 mg/dL). This discrepancy highlights an important area for investigation in determining the appropriate screening and diagnostic criterion in women with pGDM. The recent inclusion of hemoglobin A1C in 2010 by the American Diabetes Association as a screening and diagnostic criterion for pre-diabetes and diabetes has not allowed sufficient time for longitudinal investigations or determination of the utility of hemoglobin A1C as a screening/diagnostic tool in women with pGDM. Some recent studies have determined that A1C does not provide a sensitive and specific diagnosis of diabetes risk in women with pGDM when compared to fasting plasma glucose (FPG) or a glucose tolerance test.[56,65] The study comparing A1C to FPG was conducted in a small sample (n = 54) of pGDM women who were primarily non-Hispanic white (73%), suggesting that more studies are required in larger, more diverse samples and examined in regard to other clinical outcomes.[56]

We examined additional clinical factors between participants with elevated hemoglobin A1C levels and those with normal levels and found a poorer cardio-

metabolic profile on those with hemoglobin A1C levels ≥ 5.7%. They had significantly higher mean BMI (t = -3.56, p = .001), waist circumference (t = -2.35, p = .02), systolic blood pressure (t = -1.98, p = .05), fasting glucose (t = -3.89, p = <.001) and lower HDL-cholesterol (t = 2.96, p = .004)) compared to women with normal A1C levels. The convenience of A1C testing is appealing, especially in this population where screening is suboptimal.[56] Hemoglobin A1C is an important screening tool and may add to the portfolio of risk assessment in women with pGDM.

The prevalence rate of metabolic syndrome in this sample differed by age group compared to the age-specific rate of US women;[66] higher among participants aged 30-39 years (18.4% versus 16.9%) and lower in participants aged 20-29 (0% versus 10%) and 40-49 years (29.4% versus 31.8%). The majority of our participants were aged 30-39 years (66.2), which represented the group with the higher prevalence rate of metabolic syndrome. The lower prevalence rate in older participants may be partially explained by high education status of older-aged participants (p = .01) and the inverse association that has been observed between education status and metabolic syndrome.[66]

The prevalence of overweight/obesity in this study sample was slightly higher than the general US female population. Over 66% of participants were classified as overweight (BMI ≥ 25) and 38% were considered obese (BMI ≥ 30), compared to 64% and 35.5% respectively in the general US female population.[67] BMI status of overweight/obese represents one of the single most influential determinations of T2DM development in women with pGDM,[68,69] yet these at-risk women may be less likely to be attempting weight loss than overweight women without a history of pGDM.[70] For women at such significant cardio-metabolic risk, postpartum follow-up appears to be

inadequate with so few (35%) reporting receiving any lifestyle counseling at their post-partum visits. Furthermore, only 61% report having had diabetes screening at their postpartum visit. Poor follow-up and lack of screening in women with pGDM has been reported elsewhere[71,72] and highlights an important area for interventions aimed at provider adherence to clinical practice guidelines.

The prevalence of poorer diet quality, inactivity, diabetes risk, metabolic syndrome and overweight/obesity was disproportionately higher in Minority women than in non-Hispanic Caucasian women with pGDM. Although minority women have greater risk for T2DM development following GDM,[73] much of the disparity in T2DM incidence can be attributed to lifestyle factors.[74] These study results highlight the important disparities in clinical risk factors, but also demonstrate a significant opportunity to improve lifestyle behaviors in minority women with pGDM. With a large proportion of Minority women in this study, our findings address a significant gap in the research about diet quality and clinical outcomes in women with pGDM.

Implications for Clinical Practice

These study findings have significant implications for public health and nursing practice. Though many of the study participants met the criteria for having prediabetes, few reported receiving the care that has been recommended by the American Diabetes Association (ADA) standards of medical care, specifically referrals to weight-loss support programs, lifestyle counseling, annual screening or metformin therapy.[7] Although this study did not specifically investigate adherence to ADA recommendations, some findings indicate an opportunity for improving clinical practice.

This study excluded participants who may have been participating in any formal weight-loss program to avoid confounding influences on diet quality. However, no potential participant was screened out for this reason, indicating that even among those with high BMIs and potential pre-diabetes, referrals to a weight loss program may not have been made. Women could have also chosen not to participate in such programs.

Many participants (63%) reported receiving no lifestyle counseling during their postpartum visits. Given the high level of lifestyle counseling and attention that most women with GDM receive during their pregnancies, it is doubtful that this lack of counseling is due to lack of provider knowledge. Although it has been reported that recall of advice has not influenced diet quality or physical activity in women with pGDM,[25] other studies have demonstrated that provider counseling does improve diet quality[75] and improve adherence to physical activity recommendations.[76]

Postpartum glucose screening was suboptimal (61%), and even among those with pre-diabetes, only 40% reported having had an annual glucose screening. There are multiple patient characteristics,[19,77] and provider or health care system factors that influence postpartum screening.[78] Determining clinical procedures and environments that support the ongoing follow-up, screening, and lifestyle counseling of these at-risk women is essential to mitigate the progression to T2DM. The implementation of a health care system program that incorporated provider education, updated GDM patient care protocols, and instituted electronic reminders to providers to contact pGDM women who missed postpartum screening resulted in a significant increase in postpartum diabetes screening.[79]

The ADA recommends metformin therapy for those diagnosed with pre-diabetes, especially in women with pGDM.[7] Although many of the participants in this study met the hemoglobin A1C screening criteria for pre-diabetes, no participant had been placed on metformin therapy at the time of her study participation. There could be several explanations for this including that participants did not meet pre-diabetes diagnoses with other screening criteria, some participants may not have been appropriately screened at all, or providers and/or patients chose to implement lifestyle strategies before considering pharmaceutical therapy. The reasons for lack of metformin therapy were not explored in this study, so no conclusions can be made. However, it may be another indicator of the lack of appropriate screening and follow-up in this population, which has been discussed in this study and well documented in other studies.[21,72,80]

Limitations and Strengths. This is a cross-sectional study, so only associations could be examined between diet quality and clinical outcomes. More longitudinal studies are needed to identify dietary patterns that are most protective for women with pGDM. This study relied on self-report of physical activity and dietary intake with a food frequency questionnaire (FFQ). Validity studies have determined that women,[81] especially those with higher BMI's[82] tend to under-report energy and protein intake with FFQ assessments. An under-reporting of energy and macronutrient intake can result in lower diet quality scores due to reporting less overall food consumption. Physical activity levels are also prone to invalid self-report with a tendency to over-report.[83] It has been found that women with young children tend to have lower levels of physical activity,[84] so the levels of moderate activity reported in this study may be over-reported. The combination of under-reporting energy and over-reporting physical activity may have

attenuated the associations with the major clinical outcomes examined. However, when the associations were examined controlling for energy intake, there were no changes in the associations with either clinical outcome.

The study sample was racially diverse, but the size may have limited the power to detect associations between diet quality and major clinical outcomes, especially limiting the power to stratify by racial groups. Finally, excluding the measured clinical anthropometric and lab data, most of the data reflects participant self-report, which could have introduced recall bias, particularly in reporting postpartum care follow-up. Self-reported postpartum care data was not verified by medical chart, however it has been previously determined that self-report of GDM is reliable in this population.[49]

Women with a recent history of pGDM are a challenging group to target as evidenced by poor follow-up related to unattended postpartum visits. Child-care and work responsibilities also compete for time and priority when considering participation in a research study. The investigators of this study recognized those challenges in targeting this vulnerable population and designed the study to be conducted in the community. Most study visits occurred at the home of the participants, minimizing participant need for travel or child-care issues. This convenience was noted by many participants as a benefit to participation and likely contributed to the successful ability to recruit the sample.

This is one of few studies that have examined overall diet quality and major cardio-metabolic clinical outcomes in the first several years following delivery in women with pGDM. Much more work needs to be done to identify early cardio-metabolic risk

and strategies for prevention, especially related to improving diet quality in women with pGDM. This study also represents a socio-demographically diverse sample, which enhances the generalizability of the findings.

Conclusion

Women with pGDM are at significant risk for cardio-metabolic diseases and have suboptimal adherence to protective dietary patterns. Furthermore, women with pGDM are not being adequately screened for cardio-metabolic risk factors following delivery. Future studies should address key influences of dietary patterns in this population to inform intervention efforts aimed at improving diet quality. Studies are also needed to identify barriers to screening – both among providers and patients and to address the lack of health promotion offered by providers.

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Table 4.1

Characteristics of the Sample (N=74)

Characteristic	Study Sample
Age, mean years (*SD*)	35.5 (*5.5*)
Race/Ethnicity, %	
Non-Hispanic White	46%
Minority	54%
African-American	31%
Hispanic	15%
Asian/Other	8%
Education, %	
< 4 years college	40.5%
≥ 4 years college	59.5%
Marital status, %	
Married	74.3%
Employment Status, %	
Unemployed	32.0%
Part-time employed	16.0%
Full-time employed	51.0%
Health Insurance Status, %	
Uninsured	16.2%
Medicaid	13.5%
Private	70.3%
Time since last GDM pregnancy, mean years (*SD*)	2.5 (*1.6*)
Parity, mean (*SD*)	2.7 (*2.1*)
GDM Pregnancy Treatment, %	
Lifestyle	60.8%
Oral Medication	13.5%
Insulin	24.7%
Glucose Screening at Post-partum visit	
Yes	60.8%
No	33.8%
Lifestyle Counseling at Post-partum visit	
Yes	35.1%
No	62.2%
CARDIA score, exercise units	
Moderate Activity Score, mean (SD)	224.66 (*172.43*)
Heavy Activity Score, mean (SD)	181.76 (*187.76*)
Total Score, mean (SD)	406.42 (*285.94*)

Table 4.2

Clinical Characteristics of Participants (N = 74)

Clinical Outcome	**Mean (SD)**	**Range**	**Percentage**
BMI, kg/m^2	29.4 (7.0)	17.8 – 46.2	
Underweight			1.4%
Normal			32.4%
Overweight			28.4%
Obese			28.4%
Morbidly obese			9.5%
Hemoglobin A1C, %	5.7 (0.57)	4.8 – 7.8	
Normal			52.7%
Pre-diabetic			39.2%
Diabetic			8.1%
Metabolic Syndrome			
Yes			18.9%
No			81.1%
Blood Pressure, SBP/DBP, mm/Hg	111.7 (12.1) / 76.8 (9.0)	91-140 / 58-94	
Normal			52.7%
Pre-hypertensive			35.1%
Hypertensive			12.2%
Waist Circumference, (centimeters)	92.7 (15.0)	64 – 126	
Normal			39.0%
At-Risk (≥88 cm)			60.0%
Fasting Glucose, mg/dL	78.6 (12.9)	54 – 115	
Normal			94.6%
Elevated			5.4%
Triglycerides, mg/dL	112.5 (70.1)	50 – 381	
Normal			82.4%
High			17.6%
HDL-Cholesterol, mg/dL	49.8 (13.3)	29 - 91	
Normal			77.0%
Low, At-Risk			23.0%

Note. SBP = systolic blood pressure; DBP = diastolic blood pressure; HDL = high density lipoprotein.

Table 4.3

Alternate Healthy Eating Index (AHEI) scoring method and total scores

Component	Criteria for Minimum Score[a]	Criteria for Maximum Score[a]	Participant AHEI scores, mean points (*SD*)
Vegetables (servings/day)	0	5	5.46 (*2.83*)
Fruit (servings/day)	0	4	5.03 (*3.35*)
Nuts and soy protein (servings/day)	0	1	6.08 (*4.92*)
Ratio of white to red meat	0	4	2.45 (*2.59*)
Cereal fiber (grams/day)	0	15	8.16 (*2.66)*
trans Fat (% of energy)	≥4	≤0.5	7.50 (*1.20*)
Polyunsaturated to Saturated Fat ratio	≤0.1	≥1.0	7.30 (*1.84*)
Duration of multivitamin use[b]	<5 years	≥5 years	3.78 (*2.20*)
Alcohol (servings/day)	0 or >2.5	0.5 – 1.5	2.16 (*3.97*)
Total Score	2.5	87.5	47.92 (*14.04*)

Table 4.4

Summary of Bivariate Associations with AHEI Diet Quality

Variable	Correlation Association	Two-sample T-tests
Age	.18	
Minority versus Non-Hispanic Caucasian		-2.25*
BMI	-.23*	
Fasting Blood Glucose	-.23*	
Hemoglobin A1C	-.16	
No Diabetes Risk versus Diabetes Risk		1.24
No Metabolic syndrome versus Metabolic Syndrome		1.82
Systolic Blood Pressure	-.17	
Diastolic Blood Pressure	-.25*	
Waist Circumference	-.19	
Triglycerides	-.17	
HDL-cholesterol	-.07	

Note. $*p < .05$

Table 4.5

Logistic Regression Analyses for AHEI Diet Quality and Metabolic Syndrome

Variables	Odds Ratio	p-value	95% Confidence Interval for Odds Ratio	
			Lower	Upper
Age	1.07	.33	.93	1.24
BMI	1.16	.004	1.05	1.28
Breastfeeding Duration	1.01	.82	.95	1.07
CARDIA, Physical Activity	1.00	.89	1.00	1.01
AHEI Score	.96	.12	.91	1.01

Note. BMI = body mass index; AHEI = Alternate Healthy Eating Index.

Table 4.6

Logistic Regression Analyses for AHEI Diet Quality and T2DM Risk

Variables	Odds Ratio	p-value	95% Confidence Interval for Odds Ratio	
			Lower	Upper
Age	0.99	.90	0.90	1.10
BMI	1.14	.01	1.04	1.23
Breastfeeding Duration	0.98	.40	0.92	1.03
CARDIA, Physical Activity	1.0	.82	0.99	1.00
AHEI Score		.48		
AHEI 2nd quartile versus 1st	0.72		0.16	3.23
AHEI 3rd quartile versus 1st	2.06		0.44	9.73
AHEI 4th quartile versus 1st	0.71		0.16	3.16

Note. BMI = body mass index; AHEI = Alternate Healthy Eating Index.
AHEI 1st quartile represents the lowest 25% adherence; AHEI 4th quartile represents the 25% highest adherence.

Chapter 5: Summary and Conclusion

This purpose of this dissertation study was to examine individual, family and social-level influences of diet quality and to assess the cardio-metabolic risk status in an at-risk population of women with previous gestational diabetes (pGDM). Diet quality was defined by the Alternate Healthy Eating Index (AHEI) which has demonstrated protection from disease development in this population.[1] The first aim was guided by the constructs of the Health Belief Model and focused on examining the influence of demographic factors and individual-level perceptions about threat of type 2 diabetes (T2Dm), benefits and barriers to healthy eating, and dietary self-efficacy with diet quality. The second aim examined components of the social environment, including social support and components of family functioning, as described in the ecological framework for eating behavior.[2] Finally, the exploratory aim assessed the cardiometabolic risk profile of women with pGDM in relation to AHEI diet quality.

The three manuscripts (Chapters 2-4) included in this dissertation research document the suboptimal adherence to a protective dietary pattern in women with a recent history of gestational diabetes, which supports and extends previous research findings in this population. This research study adds a unique contribution to the literature with the focus on family-level influences on diet quality and the use of point-of-care screening tools to assess cardio-metabolic risk, particularly using hemoglobin A1C to defineT2DM risk. The findings in this dissertation study about important influences of diet quality support previous work in this area, specifically identifying the significant effects that higher education status[3] and self-efficacy[4,5] have on improved diet quality in

women with pGDM. The findings also highlight the prevalence of cardio-metabolic risk factors in women who are within five years of their most recent GDM pregnancy.

The first manuscript (Chapter 2) describes the study findings based on the examination of diet quality influences outlined by the Health Belief Model constructs. In this aim of the study, the influence of socio-demographic factors and the individual beliefs of perceived threat of T2DM (including subscales of *Personal Control*, *Worry*, *Optimistic Bias*, *Knowledge* and specific risk perception/lifestyle behaviors), perceived benefits and barriers to healthy eating, and dietary self-efficacy were examined in association with diet quality. Only higher education status and better dietary self-efficacy predicted better diet quality. Although perceived risk had no influence on diet quality, participants reported a realistic perception of their personal risk for T2DM development with nearly half believing that they had a moderate to high chance of developing T2DM within ten years. They also reported a moderate amount of worry about their risk, but indicated a high level of personal control to prevent diabetes. Combined with the association and predictive influence of higher dietary self-efficacy in determining better diet quality, women with pGDM may especially benefit from interventions aimed at capitalizing on the sense of personal control by improving dietary self-efficacy.

Women in this study sample reported few barriers and high benefits to healthy eating, however as noted, had suboptimal adherence to a healthy dietary pattern defined by the Alternate Healthy Eating Index (AHEI). With a moderate amount of variance (36%) in diet quality explained by educational attainment and dietary self-efficacy, there is still a need to identify other important, modifiable factors, particularly beyond the individual level, that influence dietary quality in this population.

The second aim of this dissertation study described in Chapter 3, sought to identify the contribution of social support, family functioning components (general family functioning, communication and problem-solving) and family food interaction to diet quality guided by the ecological model for eating behavior[2] in this sample of women with pGDM. The family contribution to diet quality in adult populations is largely understudied and no studies had investigated this association in women with pGDM. Overall, participants reported high levels of social support, healthy levels of family functioning, and high levels of family food interaction. Bivariate correlation analyses indicated that higher social support, healthier family communication and family functioning, and better family food interaction were associated with higher diet quality. However, in regression modeling, no social or family factor was predictive of AHEI diet quality beyond the significant individual predictors of education status and dietary self-efficacy in this population.

In multiple studies in women with pGDM, social and family support has been identified as an important influence in predicting adherence to a healthy lifestyle, particularly physical activity behaviors.[4,6-10] Family and social support has not been as influential with dietary behavior.[4,5] In the study conducted by Kim and colleagues where social support for dietary behavior was measured, the instruments were specific to friend-level and family-level social support for dietary behavior, and although higher levels of friend and family-level social support were found to have a trend with higher diet quality, it was not statistically significant.[4] In contrast, this dissertation study measured a more global assessment of social support and family functioning, which were statistically associated with diet quality in bivariate analyses, however no family or social influence

remained significant in regression modeling, after controlling for education status and dietary self-efficacy. Although women with pGDM have identified social support as an important factor in adhering to a healthy lifestyle in qualitative studies,[9,11] it does not seem to be the most influencing factor predicting adherence to a healthy diet.

The findings with the first two study aims indicate the need for improved diet quality in women with pGDM and suggest that interventions targeting knowledge appropriate for the individual's educational attainment and improving dietary self-efficacy should be developed and tested for their effects on improving dietary quality. Health literacy in relation to dietary quality in women with pGDM should be examined given the importance of educational attainment as a significant factor in the models. It has been established that healthy eating, particularly higher adherence to the AHEI dietary pattern, is associated with significant risk reduction in women with pGDM.[1]

The third aim of this study was an exploratory examination of cardio-metabolic risk (T2DM and metabolic syndrome) and AHEI dietary concordance in women within the critical five years of their last GDM pregnancy. Many of the participants in this study had significant cardio-metabolic risk factors. Most (66.3%) were overweight or obese. Nearly half of the sample (47%) was classified as pre-diabetic or diabetic by the hemoglobin A1C screening guidelines and 19% met the criteria for metabolic syndrome. Furthermore, post-partum follow-up diabetes screening was suboptimal and few (35%) recalled receiving any lifestyle counseling at any post-partum visit.

AHEI diet quality was not predictive of risk for either metabolic syndrome or T2DM risk, when controlling for other contributing factors. Only higher BMI levels

significantly predicted poorer risk profiles of both metabolic syndrome and T2DM risk. This is not a surprising finding, since weight status is such a strong determinant of cardio-metabolic risk.[12] The cross-sectional design and focus within the first five years following a GDM pregnancy may have limited the ability of this study to detect a significant association between AHEI diet quality and major outcomes of cardio-metabolic risk. In the retrospective cohort study conducted by Tobias and colleagues,[1] participants had a mean follow-up time of sixteen years. This design and timeframe was sufficient to examine the protective influence of AHEI dietary adherence with T2DM development. Earlier indicators of T2DM risk such as pre-diabetes status and metabolic syndrome outcomes were not examined in the Tobias et al study. This dissertation study is the first to examine the association of AHEI diet quality with pre-diabetes and metabolic syndrome in women with pGDM. Similar to the association with T2DM risk, the protective influence of a healthy dietary pattern like the AHEI may be beneficial over time with a stronger association beyond the 5-year timeframe of the most recent GDM pregnancy or beneficial in other measures of T2DM risk such as insulin sensitivity.[13]

Although the original AHEI pattern was used in this study and had demonstrated to be the most beneficial of the three dietary patterns in the Tobias et al. study,[1] a more updated version of the pattern has been developed with the AHEI-2010.[14] The AHEI-2010 incorporates specific dietary components reflecting more recent scientific evidence related to diet and chronic disease. Compared to the original AHEI, the AHEI-2010 does not include multivitamin intake, but does include sugar-sweetened beverages, sodium, and discrete components of red meat and fish intake.[14] Given that many of the AHEI-2010 components influence diabetes outcomes, examining the relationship between the

AHEI-2010 and the outcomes of metabolic syndrome and diabetes risk, defined by hemoglobin A1C in this population warrants further study.

An important finding that was noted in Chapter 4 was the discrepancy in T2DM risk classification by hemoglobin A1C versus fasting glucose. With hemoglobin A1C, many more participants (47%) in our sample were classified in T2DM at-risk categories compared to only 5.4% by fasting glucose. The utility of hemoglobin A1C as a screening and diagnostic method, specifically in postpartum women with pGDM requires further investigation,[15,16] however there are no contraindications for its use outside the early post-partum timeframe. This discrepancy prompted the investigators in this study to further assess the risk profile of those with abnormal hemoglobin A1C versus those with normal levels. Significantly higher risk factors were found among women with elevated hemoglobin A1C levels, including higher mean BMI, waist circumference, systolic blood pressure, fasting glucose and lower HDL-cholesterol. These findings suggest that hemoglobin A1C may be an important component of a comprehensive, early screening plan among this high-risk population. Assessing hemoglobin A1C is more convenient than other diabetes screening tests, since it does not require a fasting state or an extended 2-hour test. This convenience may promote higher screening adherence in this population of women, who have not had optimal postpartum risk assessment or screening,[17,18] despite multiple longstanding clinical guidelines by both the American Congress of Obstetricians and Gynecologists and the American Diabetes Association (ADA).[19,20] The ADA 2013 Standards of Medical Care in Diabetes recommends annual monitoring of those with pre-diabetes, and yet even among those with pre-diabetes, only 40% reported having had an annual glucose screening. Further investigation into the

barriers of 6-week postpartum diabetes screening, as well as annual screening for women with pGDM who are pre-diabetic are warranted.

Collectively, these dissertation study findings highlight the prevalence of significant cardio-metabolic risk factors, the suboptimal adherence to a healthy dietary pattern, and the modifiable influences that contribute to AHEI dietary adherence in women with pGDM. These findings provide a substantial foundation to further study these influences in a longitudinally designed study to assess the causal direction of the associations. Furthermore, the findings suggest that women within the first five years of their most recent GDM pregnancy have significant cardio-metabolic risk factors that may accelerate their progression to T2DM, metabolic syndrome, and cardiovascular disease.

Limitations and Strengths

The cross-sectional design of this dissertation study limited the ability to investigate causal inferences between the proposed predictors and outcomes. The study sample size was small and was recruited by convenience sampling and self-selection, which could have subjected the study to selection bias. Women with pGDM least likely to perceive themselves at future risk of T2DM may have been missed through the recruitment strategies employed. A more active recruitment approach through methods such as direct provider referrals may have resulted in a greater proportion of participants who were not as aware of their T2DM risk and less likely to be engaging in healthy behaviors. By potentially missing participants with lower risk perceptions, this study sample may have represented those with less denial, less optimistic bias, and higher perceptions of personal control for the prevention of T2DM.

Although most of the participants self-identified as previous gestational diabetics, only 35% of the sample was able to be verified by a medical chart review. It has been previously determined that self-report of GDM is reliable in this population.[21] The medical history data collection relied on self-report and was not able to be verified by a medical chart review for accuracy. Assessment of dietary intake by a food frequency questionnaire and physical activity was also conducted by self-report. This method of data collection can result in recall bias, as well as under-reporting of energy intake and protein intake[22,23] and over-reporting of physical activity.[24] The misreporting of these key variables could have attenuated the association with cardio-metabolic outcomes.

This study also has notable strengths. Despite the small sample size, the participants consisted of a socio-demographically diverse group of women. This enhances the generalizability of the findings. This is the first study in women with pGDM to find a significant association between dietary self-efficacy and diet quality and between family and social factors with diet quality. Previous studies in this population have examined these variables, measured with different instruments than in this dissertation study, but did not find significant associations with overall diet quality.[4,5]

This study is also the first to examine the association of the validated AHEI diet score with metabolic syndrome or diabetes risk assessed by hemoglobin A1C in a racially diverse sample of women with pGDM. The protective influence of a healthy dietary pattern like the AHEI may be beneficial over time at older ages with a stronger association beyond the 5-year timeframe for the major clinical outcomes of T2DM and metabolic syndrome. The advantages of the AHEI diet pattern within five years following a GDM pregnancy may be associated with benefits in clinical measures of

T2DM risk, such as fasting glucose and insulin sensitivity as opposed to hemoglobin A1C. Although not statistically significant, the trend of higher AHEI diet quality had protective effects in both hemoglobin A1C levels and metabolic syndrome. Higher AHEI diet quality was significantly associated with lower fasting blood glucose and lower BMI, suggesting that the dietary pattern may be protective for overweight status as one of the strongest risk factors of poor cardio-metabolic outcomes and the most significant predictor of metabolic syndrome and diabetes risk in this sample.

These dissertation study results provide the initial foundation for further study of dietary quality influences in this population. The findings suggest potential modifiable factors of diet quality such as dietary self-efficacy, social support, and components of family functioning which could be targeted in intervention studies to improve diet quality. Furthermore, the significant association between better AHEI diet quality and lower fasting glucose and BMI, as well as the trend in lower risk for diabetes risk and metabolic syndrome suggest that AHEI diet quality may provide protective cardio-metabolic benefit in women within five years of their most recent GDM pregnancy.

Implications for Theoretical Framework

This study was guided by a synthesis of the Health Belief Model (HBM) and the ecological model with adaptation by Story and colleagues for eating behavior (see Figure 1 in Introduction Chapter).[2] The first aim of the study tested the associations between the HBM constructs with diet quality and found that self-efficacy was the only perception that predicted diet quality. No other perception or belief had an influence on diet quality. Although Social Cognitive Theory was considered for the individual-level focus of this

study, its' lack of focus on perceptions of risk made it less suitable. In a population at-risk for cardio-metabolic disease, understanding how that risk perception may or may not shape diet-related behavior was an important preliminary step. However, that risk perceptions were not associated with diet quality in this study supported previous work in this population,[25,26] and suggests that risk perception does not seem to influence dietary behavior in women with pGDM. The HBM constructs of perceived barriers and benefits were also not associated with diet quality in this study. The study findings do not support the HBM constructs in determining influence of diet quality in women with pGDM. The influence of self-efficacy on diet in this study and other studies[4,5] lends greater support to theories with self-efficacy as a leading individual construct/determinant in the population of women with pGDM.

The scope of the ecological framework for eating behavior by Story and colleagues is multidimensional and multicontextual[2] and was selected for this study because of its' recognition of the multi-level, complex influences of eating behavior. This dissertation study focused on examining concepts within the sphere of social environmental influences, including general social support and specific components of family functioning and family food interaction.

The intent of this dissertation study was not to test the utility of this framework. Since few studies have examined family-level influences with diet quality in adult populations and two studies measuring diet-specific family and social-level support had been conducted in a population of women with pGDM, the focus of the dissertation study was to explore the associations between general social support and specific components of family functioning and family food interaction with diet quality. Based on previous

findings in an adult population adhering to a prescriptive diet,[27] this study focused on examining components of family functioning and hypothesized that higher social support and healthier levels of family functioning components would be associated with better diet quality. The significant bivariate family and social associations with diet quality in this study supports the framework, identifying general social support and components of family functioning as important influences within the sphere of the social environment. The study of environmental influences on diet quality is still a new and developing field of study, requiring a focus on exploratory associations. This study supports that future studies should investigate the role of social and family support specific to dietary behavior in this population.

Implications for Future Research

Although this study provides the initial foundation for understanding influences of diet quality in women with pGDM, no determination of causality can be made, so it is essential for further investigations to use study designs that can test the direction of these relationships. Furthermore, much variance in diet quality was unexplained in this study, so other potential diet quality influences should be investigated, including, for example, perceived stress levels, time constraints, and environmental factors. A more focused examination of family and social support factors specific to dietary behavior needs to be conducted through rigorous methods. Most of the evidence of the association between family and social factors with diet quality in this population stems from qualitative investigations. Because significant bivariate correlations were found indicating that higher social support, healthier family communication, healthier family functioning, and

better family food interaction were associated with higher diet quality, further study of these variables in a larger sample warrant investigation.

Most of the studies that have examined diet quality in women with pGDM have included samples that were predominantly non-Hispanic Caucasian.[1,4,13] Although the sample of this dissertation study was racially diverse (55% Minority) , the small sample size of this study prohibited accurate examination of subgroup analyses. There may be important differences in individual, family, and social-level influences with diet quality by different racial or ethnic groups that could not be fully explored in this study and warrant further investigation.

The suboptimal level of diet quality that was found in our sample extends the findings of other studies in this population,[4,5] and supports the need for the design and testing of dietary improvement interventions in this population. Few interventions to improve diet quality have been designed and tested specifically for women with pGDM. The Diabetes Prevention Program (DPP) trial, which included a cohort of women with pGDM, and an intervention trial modeled after the DPP for women with pGDM have focused primarily on decreasing dietary fat.[28,29] In combination with the other lifestyle interventions, incidence of T2DM was decreased in pGDM women in the DPP trial,[28] so the contribution of the dietary intervention alone cannot be determined. In the intervention trial modeled after the DPP for women with pGDM, dietary fat was significantly decreased, but outcomes of weight loss were less successful.[29] An intervention with a small cohort of women with pGDM (n = 38) established that motivational interviewing was a successful strategy in improving dietary components of

total fat, total carbohydrate, and glycemic load.[30] No interventions have specifically addressed dietary self-efficacy, family, or social factors in this population.

Women with pGDM have significant cardio-metabolic risk factors, most notably high BMI and abnormal hemoglobin A1C levels, and yet are not being appropriately screened or counseled according to clinical guidelines. This suboptimal care is multifaceted and contributable to patient, provider, and environmental influences.[31] The implementation of a health care system program that incorporated provider education, updated GDM patient care protocols, and instituted electronic reminders to providers to contact pGDM women who missed postpartum screening resulted in a significant increase in postpartum diabetes screening.[32] Empowering patients to expect diabetes screening and follow-up may be another strategy to test.

Implications for Practice

These study findings have significant implications for public health and nursing practice. Though many of the study participants met the criteria for having prediabetes, few reported receiving the care that has been recommended by the American Diabetes Association (ADA) standards of medical care, specifically referrals to weight-loss support programs, lifestyle counseling, annual screening or metformin therapy.[20] Although this dissertation study did not specifically investigate adherence to ADA recommendations, some findings indicate there is an opportunity for improving clinical practice.

This study excluded participants who may have been participating in any formal weight-loss program to avoid confounding influences on diet quality. However, no

potential participant was screened out for this reason, indicating that even among those with high BMIs and potential pre-diabetes, referrals to a weight loss program may not have been made. Women could have also chosen not to participate in such programs or may have been referred but were not able to participate due to cost or lack of medical insurance coverage.

Many participants (63%) reported receiving no lifestyle counseling during their post-partum visits. Given the high level of lifestyle counseling and attention that most women with GDM receive during their pregnancies, it is doubtful that this lack of counseling is due to lack of provider knowledge. Furthermore, postpartum glucose screening was suboptimal (61%), and among those with pre-diabetes, only 40% reported having had an annual glucose screening. Determining clinical procedures or environments that support the ongoing follow-up, screening, and lifestyle counseling of these at-risk women is essential to mitigate the progression to T2DM.

The ADA recommends metformin therapy for those diagnosed with pre-diabetes, especially in women with pGDM.[20] Although many of the participants in this study met the hemoglobin A1C screening criteria for pre-diabetes, no participant had been placed on metformin therapy at the time of her study participation. There could be several explanations for this including that participants did not meet pre-diabetes diagnoses with other screening criteria, some participants may not have been appropriately screened at all, or providers and/or patients chose to implement lifestyle strategies before considering pharmaceutical therapy. The reasons for lack of metformin therapy were not explored in this study, so no conclusions can be made. However, it may be another indicator of the

lack of appropriate screening and follow-up in this population, which has been discussed in this study and well documented in other studies.[18,33,34]

Implications for Policy

Considering the multiple cardio-metabolic risk factors among this sample and the apparent lack of adherence to the ADA clinical guidelines, there is a significant opportunity to identify strategies which facilitate participation in risk-reduction, lifestyle programs. The coverage of such programs by health insurance plans would remove a significant barrier both on the part of provider referrals and patient participation.[35] Nearly 70% of the participants were covered by private health insurance yet, not one participant or potential participant was enrolled in a lifestyle program. Out of pocket cost for patients is a major deterrent to participation.[35,36]

Since 2010, the Y (formerly the YMCA) and UnitedHealth Group (UHG), in collaboration with the Centers for Disease Control and Prevention (CDC) have been implementing a community-based Diabetes Prevention Program (DPP), modeled after the successful DPP trial. This program has been implemented in 23 states, with over 1700 people who have completed the program. Those who have completed the program have had an average of a 5% weight loss. The UHG estimates that the savings resulting from reduced medical spending will surpass the initial costs within three years.[36,37] The UHG is unique among private payers in that it also offers this program to some of its private employer-sponsored beneficiaries,[38] but such programs are not offered through most other private insurers or through Medicare and Medicaid.[37] Through this community-based DPP program and the implementation of the Affordable Care Act, there is a

substantial opportunity to expand the program coverage and availability to at-risk populations,[39] especially women with pGDM.

Summary

This descriptive, cross-sectional study was undertaken to examine individual and family/social level of influences on dietary quality, and explore the cardio-metabolic risk associated with diet quality in women with a recent history of gestational diabetes. The theoretical framework for this study was provided by the combination of the Health Belief Model (HBM) and the ecological framework for eating behavior.

The main outcomes of this study indicated that women with pGDM are consuming a suboptimal quality diet defined by the Alternate Healthy Eating Index (AHEI) and have significant risk factors for both type 2 diabetes (T2DM) and metabolic syndrome. Of the variables studied, only education status and individual dietary self-efficacy predicted better diet quality. Most of the HBM constructs and no family/social level variable added any further influence to explain variance in diet quality.

These findings suggest multiple opportunities for improving clinical practice with better adherence to ADA recommendations and a need for further research to determine important predictors of diet quality in women with pGDM. Regression modeling with education status and dietary self-efficacy as the significant predictors explained 36% of the variance in diet quality in this study, suggesting other important factors influence diet quality. Family and social factors may be important influences, however, may need to be investigated from a less general or global focus in relation to dietary behavior.

The public health epidemics of diet-related diseases such as obesity, T2DM, and cardiovascular disease are threatening to overwhelm health care resources. A diagnosis of gestational diabetes is a significant predictor of future risk for disease. Women with pGDM should be targeted for an aggressive strategy of risk-reduction activities, particularly related to improving dietary quality. However, until important influences of diet quality are better understood in this population, targeted interventions may not be effective to substantially prevent or delay associated diseases. Enhancing dietary self-efficacy appears to be one important strategy to incorporate in interventions aiming to improve diet quality in women with pGDM.

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Appendix A: Institutional Review Board Documents

EMORY UNIVERSITY

Institutional Review Board

TO: Erin Ferranti
Principal Investigator
Graduate Nursing

DATE: October 31, 2011

RE: **Continuing Review Expedited Approval**
CR1_IRB00046666
IRB00046666
Dietary Quality and Cardiometabolic Risk after Gestational Diabetes

Thank you for submitting a renewal application for this protocol. The Emory IRB reviewed it by the expedited process on 10/28/2011, per 45 CFR 46.110. This reapproval is effective from **12/1/2011** through **11/30/2012** . Thereafter, continuation of human subjects research activities requires the submission of another renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above.

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, study design, you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you.

Sincerely,

Andrea Goosen, MPH, CIP
Research Protocol Analyst
This letter has been digitally signed

CC:

Dunbar	Sandra	Nursing - Main
Venkat Narayan	Kabayam	Global Health

Grady

Research Oversight Committee (ROC)
Division of Medical Affairs
80 Jesse Hill Jr. Drive SE
P. O. Box 26118, Atlanta, GA 30303

Research Administration
Office: 404-616-7289
Fax: 404-616-0747

PI Name: FERRANTI, ERIN
C/O: FERRANTI, ERIN
Organization: EMORY (SOM)
Department:
Office: (404) 808-3685
Fax: (404) 727-0536

Date: 2/6/2012

IRB#: 000-46666
IRB Expires: 11/30/2012
ROC Expires: 11/30/2012
CT Plan Code: N/A

Protocol Title: Diatary Quality and Cardiometabolic Risk after Gestational Diabetes

Re: **Research Protocol: RENEWAL**

The Grady Research Oversight Committee (ROC) has reviewed and **APPROVED** the documents submitted for your research protocol.

Please note the ROC Expiration date listed above. Thereafter, continued approval is contingent upon the submission of a renewal form that must be reviewed and approved by the ROC prior to the expiration date of this study.

Please note the clinical trial insurance plan code assigned to your study, IF APPLICABLE. You will need to use this code when registering patients for Grady services related to this research protocol.

Also, please notify the ROC when this proposal has been terminated or completed. All inquiries and correspondence concerning this protocol must include the IRB # and the name of the Principal Investigator. Any further reviews by the IRB pertaining to this proposal should be submitted to the ROC. This includes: Approved IRB Renewals, Modifications (Protocol, Informed Consent, Personnel, etc.) and any Adverse Events.

The committee would be interested in receiving the report of your research results and copies of any publications or presentations resulting from this research.

Sincerely,

Curtis A. Lewis, MD
Sr. Vice President and Chief of Staff
Chairman, Research Oversight Committee

DIETARY QUALITY AND CARDIOMETABOLIC RISK AFTER GESTATIONAL DIABETES AGREEMENT

This Dietary Quality and Cardiometabolic Risk after Gestational Diabetes Agreement (the "Agreement") is entered into as of the 9th day of September 2011, by and between Emory University, through its Nell Hodgson Woodruff School of Nursing, a Georgia nonprofit corporation ("Emory") and Hall County Health Department ("Hall County").

WHEREAS, the Agreement outlines the understanding of Emory and Hall County with respect to a research collaboration between the Hall County Health Services and Emory University, Nell Hodgson Woodruff School of Nursing ("Emory School of Nursing ").

WHEREAS, under the proposed research collaboration, Hall County shall:

1. Assist Emory in recruitment efforts for volunteer participants by posting study information flyers in the clinic,
2. Assist Emory in recruitment efforts for volunteer participants by allowing the Emory study staff to review medical charts to screen for eligibility criteria and either send a study invitation letter (postage paid by Emory) signed by the Hall County Health Department provider, or distribute a study flyer to an identified eligible patient and collect the "tear-off" section of that flyer to deliver to the study staff.

Collectively, the efforts described in (1) and (2) above are referred to in this agreement as the "Project." Further, Emory and Hall County Health Department may be referred to individually in this agreement as a "Party" and collectively as the "Parties."

NOW, THEREFORE, for and in consideration of the mutual premises, promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

I. DUTIES OF **Emory School of Nursing**. For so long as Emory elects, in its sole discretion, to conduct and continue the Project:

1) The Emory School of Nursing will be responsible for all phases of the Project in recruitment, screening for eligibility, data collection, and analysis.

2) The Emory School of Nursing shall obtain Emory IRB approval and a partial HIPAA waiver for all phases of the project. Emory anticipates the collaboration contemplated by the agreement to last approximately 21 months, September, 2011 – May, 2013.

3) Emory will provide logistical information requests, such as meeting room reservations, if needed, in a timely manner (five (5) days prior to the conduct of data collection) as described below.

4) Emory will acknowledge the contribution of Hall County Health Department when publishing papers from this research.

5) Emory will not provide Workers Compensation coverage for any and all claims, demands, losses, liabilities, actions, lawsuits, or other proceedings for any Hall County employee who is participating in this project pursuant to this Agreement.

II. DUTIES OF **Hall County.** During the term of this agreement:

1) Hall County will provide assistance in project promotion and recruitment through its community health centers and programs.

2) All the flyers posted should have the Hall County Health Department collaboration logo and a contact number of the Hall County personnel as well.

3) Hall County will not provide Workers Compensation coverage for any and all claims, demands, losses, liabilities, actions, lawsuits, or other proceedings for any Emory employee or faculty member who is participating in this project pursuant to this Agreement.

IV. TERM & TERMINATION

Agreement shall be for a period of 21 months from September, 2011 – May, 2013. Either Party may terminate this Agreement by providing the other with thirty (30) days prior written notice.

V. CONFIDENTIALITY REQUIREMENTS

1. The Parties to this Agreement shall treat all information that is obtained or viewed by it or through its staff and subcontractors performance under this Agreement as confidential information and shall not use any information so obtained, in any manner, except as may be necessary for the proper discharge of its obligations.

2. The Parties to this Agreement also agree to comply with all applicable laws, statutes, rules and regulations applicable to them in the performance of this agreement, including, if applicable, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its amendments, rules, procedures, and regulations.

VI. CONFLICT RESOLUTION

Except for the right of either party to apply to a court of competent jurisdiction for a temporary restraining order or other provisional remedy to preserve the status quo or prevent irreparable harm or to preserve the confidentiality of confidential information, the parties agree to attempt in good faith to promptly resolve any dispute, controversy or claim arising out of or relating to this Agreement, including but not limited to payment disputes, through negotiations between senior management of the Parties.

This Agreement shall be subject to, governed by and construed in accordance with the laws of the State of Georgia.

VII. NOTICE

All notices under this Agreement shall be deemed duly given upon delivery, if delivered by hand, or three (3) calendar days after posting, if sent by registered or certified mail, return receipt requested, to a party hereto at the addresses set forth below or to such other address as a party may designate by notice pursuant hereto.

FOR EMORY:

Sandra B. Dunbar, RN, DSN, FAAN, FAHA
Associate Dean for Academic Advancement
Charles Howard Candler Professor
Emory University
Nell Hodgson Woodruff School of Nursing
1520 Clifton Road, Room 402B
Atlanta, GA 30322
Tel: (404) 727-6939
FAX (404) 7274645
sbdunba@emory.edu

Erin Poe Ferranti, RN, MSN, MPH
PhD Candidate
Nell Hodgson Woodruff School of Nursing
Emory University
1520 Clifton Road NE Atlanta, GA
Tel: 404-712-9551
Fax: 404-727-9382
epoe@emory.edu

FOR HALL COUNTY HEALTH DEPARTMENT

Alan Satterfield, RN
County Nurse Manager
1290 Athens Street
Gainesville, GA 30507
Telephone: 770-531-5600
FAX: 770-531-6035
alsatterfield@dhr.state.ga.us

VIII. AMENDMENT IN WRITING

No amendment, waiver, termination or discharge of this Agreement, or any of the terms or provisions hereof, shall be binding upon either Party unless confirmed in

writing. Nothing may be modified or amended, except by writing executed by both Parties.

IX. CONTRACT ASSIGNMENT

Neither Party to this Agreement shall assign this Agreement, in whole or in part, without the prior written consent of the other Party, and any attempted assignment not in accordance here with shall be null and void and of no force or effect.

X. SEVERABILITY

Any section, subsection, paragraph, term, condition, provision, or other part of this Agreement that is judged, held, found or declared to be voidable, void, invalid, illegal or otherwise not fully enforceable shall not affect any other part of this Agreement, and the remainder of this Agreement shall continue to be of full force and effect as set out herein.

XI. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior negotiations, representations, or contracts. No written or oral agreements, representatives, statements, negotiations, understandings, or discussions that are not set out, referenced, or specifically incorporated in this Agreement shall in any way be binding or of effect between the Parties.

XII. MISCELLANEOUS

Each party agrees not to discriminate in administering this Agreement on the basis of race, sex, age, national origin, color, religion, disability, or sexual orientation.

IN WITNESS WHEREOF, the Parties state and affirm that they are duly authorized to bind the respected entities designated below as of the day and year indicated.

EMORY UNIVERSITY, THROUGH ITS NELL HODGSON WOODRUFF SCHOOL OF NURSING:

BY: Erin Ferranti

PRINTED NAME: **Erin Poe Ferranti, RN, MSN, MPH**
TITLE: **PhD Candidate, Nell Hodgson Woodruff School of Nursing, Emory University**

HALL COUNTY HEALTH DEPARTMENT:

BY: David Westfall, M.D.

PRINTED NAME: **David N. Westfall, M.D., MPH, CPE**
TITLE: **Health Director, District 2 Public Health**

NORTHSIDE HOSPITAL

March 1st, 2012

Erin Poe Ferranti, RN, MSN, MPH
Emory University
1520 Clifton Road, NE.
Atlanta, GA 30322

Re: Protocol Title – Dietary Quality and Cardiometabolic Risk After Gestational Diabetes

Dear Erin:

Thank you very much for considering Northside Hospital for your research project. Northside greatly values its research program and prides itself on the contributions the program has made. It welcomes studies which are well designed and which address health issues which affect our community as yours does.

Northside's Research Oversight Committee (ROC) reviewed the submission noted above at the February 29th meeting. The Committee found that your proposal was a very interesting and valuable study. However, at this time, Northside is unable to grant approval because the risk to Northside of the potential or perceived breach of patient information absent considerable effort on the part of the hospital to eliminate the risk.

The Research Oversight Committee performs a scientific, operational, and feasibility assessment to evaluate the risks and benefits involved with carrying out the research project to protect the interests of Northside Hospital (NSH) and its patients involved in the research program. Based upon their review of the Feasibility Assessment Form (FAF) and other information provided, the Committee is unable to approve this study. Releasing patient names to an outside entity for the purposes of conducting this research project could potentially breach confidentiality.

We do wish you well in your endeavors. If you have any questions or concerns, please do not hesitate to call me at 404-303-3355.

Sincerely,

E. Lisa Austin

E. Lisa Austin
Director of Research
Northside Hospital

Emory University
Verbal Consent to be a Research Subject
Phone Script

I am asking you to take part in a research study because you are between the ages of 18-45 years old and recently had gestational diabetes. This is a health problem which is found in pregnant women and causes high blood sugar during the pregnancy. Most women with gestational diabetes have normal blood sugar after the pregnancy. However gestational diabetes may be a risk factor for future problems, and we are trying to understand how eating patterns are related. The purpose of the study is to measure what you are eating and to examine some possible individual and family influences related to eating.

Right now, I am asking your permission to ask you some screening questions to see if you are eligible to be in the study. I will ask some questions about your gestational diabetes medical history, who you live with, whether or not you are on a diet and how you are feeling in regard to mood. If you are eligible and would like to be in the study, I will make an appointment with you at a site of your choice. For example, the visit can take place at your home, the Emory School of Nursing, or the Clinical Research Center at Emory. Then I will send a set of questionnaires for you to answer before your visit as well as an informed consent document. The informed consent will discuss the rest of the study procedures. You can either sign the document before your appointment or you can wait until the day of the appointment. Either way, you will be able to ask as many questions as you want at the appointment, and you will be able to make a decision then about whether or not you want to be in the study. The questionnaires will be about what you eat, your physical activities, your feelings, and your medications. It will take around 60- 90 minutes to complete the questionnaires. The day before your appointment you will be asked not to eat or drink anything except water after midnight. At the beginning of the appointment, we will talk about the study again and you will have to opportunity to ask any questions you have. Then, if you would like to continue your participation, you will be asked to sign the consent document (if you have not already done so). The appointment will take around 1 hour. During that time, I will take a blood sample and measurements of your blood pressure, height, weight, and waist. These procedures will be described in more detail in the consent document that I will send to you.

There are no forseeable risks to you by participating in this screening. You are not likely to get any direct benefit.

All information collected during this screening will be kept as private as possible. This information will be kept in a locked file cabinet in my locked office at the School of Nursing.

Your participation is completely voluntary. You may refuse to answer any question. You have the right to stop the screening at any time without penalty.

If you agree to participate in this screening, you will be giving permission to the researchers working on this study at Emory to use the health information that you will provide during this screening. This information includes gestational diabetes medical history, who you live with, whether or not you are on a diet and how you are feeling in regard to mood. This health information may be used by and/or disclosed to all investigators and team members involved with the study. Also, people and committees at Emory who are responsible for making sure that research is conducted correctly will have access to this information to provide oversight for the study.

Emory is required by the HIPAA Privacy Rule to protect your health information. By giving your consent to participate in the screening, you are authorizing Emory to use and/or disclose your health information for this research. Those who receive your health information may not be required by Federal privacy laws to protect it and may share his/her information without your permission, if permitted by laws that govern them.

You may change your mind and take back this Authorization at any time. To revoke this Authorization you must write to Erin Ferranti, Emory School of Nursing, 1520 Clifton Road, NE, Atlanta, GA 30322. If you revoke your authorization, you will no longer be allowed to participate in this research. This Authorization will expire at the end of the research study. This study is expected to last until May 2013.

If you have any questions about the study, you can contact me at 404-712-9551 or epoe@emory.edu. If you have any questions about your rights as a research subject, you can contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

Do you have any questions?

Do you consent to participate in the screening to see if you are eligible for this study?

☐ YES

Okay, let's get started with the screening questions

☐ NO

Okay, thank you for your time.

Emory University
Consent to be a Research Subject

Title: Dietary Quality and Cardiometabolic Risk after Gestational Diabetes

Principal Investigator: Erin Poe Ferranti, RN, MSN, MPH

Sponsor: Sandra B, Dunbar, RN, DSN, FAAN, FAHA

Study-Supporter: National Institutes of Health, National Institute of Nursing Research and American Heart Association

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

Study Overview

You are being asked to take part in a study because you are between the ages of 18-45 years old and recently had gestational diabetes. This is a health problem which is found in pregnant women and causes high blood sugar during the pregnancy. Most women with gestational diabetes have normal blood sugar after the pregnancy. However gestational diabetes may be a risk factor for future problems, and we are trying to understand how eating patterns are related. The purpose of the study is to measure your usual eating patterns and to examine some possible individual and family influences related to eating. The study will also measure some clinical tests to assess risk for developing diabetes and/or metabolic syndrome. Metabolic syndrome is a combination of medical disorders that increase the risk of developing heart disease and diabetes. About 78 women in metropolitan Atlanta will be asked to take part in the study.

Procedures

If you decide to be in this study, an appointment will be made with you at a site of your choice (e.g. your home, an office in the Emory School of Nursing or the Clinical Research Center (called the CIN) at Emory University).

- You will be sent a set of questionnaires to answer before your visit. These questionnaires will be about what you eat, your physical activities, your feelings, and your medications. It will take around 60- 90 minutes to complete the questionnaires.
- The day before your appointment you will be asked not to eat or drink anything except water after midnight.
- During the appointment (which will take around 60 minutes), you will also:
    - Have your blood pressure, height, weight, and waist measured
    - Have a blood test from a finger-stick taken to measure blood sugar, hemoglobin A1C (another measure of blood glucose), and blood fats (HDL cholesterol, triglycerides).

Testing.

Blood Tests: A small amount of blood (estimated at about 4-5 drops) from a finger-stick will be taken to measure the risk of diabetes and metabolic syndrome. These tests are for fats and blood sugar. No sample will be saved or stored following the test result. A code will be used to link your blood sample to your results.

Risks and Discomforts

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

- minor discomfort and possible bruising from the needle used to prick your finger to obtain your blood from a finger-stick.

The less common risks and discomforts expected in this study are:

- major discomfort, bruising or infection at the finger-stick site.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. You may benefit by learning how to take better care of your health. This study is designed to learn more about influences of eating behavior and how to reduce the risks for diabetes and metabolic syndrome. The study results may be used to help others in the future.

Compensation

We will provide a $25 gift card for your time in participating and completing all aspects of data collection (questionnaires and study visit).

Confidentiality

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the sponsor(s), the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research. Study sponsors

may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient you do not have one. Please note that an Emory Healthcare medical record will **not** be created for you just because you are in this study.

To better protect the confidential nature of your research information, the results from these study tests and procedures will **not** be included in any medical record you have:

- Height, weight and calculated body mass index
- Waist circumference
- Blood pressure
- Blood fats: high density lipoprotein (HDL), triglycerides
- Blood sugar: fasting glucose, hemoglobin A1C (a measure of average glucose levels over past 3 months)

These research results will be kept by the researchers only in a research record. The researchers will take steps to make sure that these results are **not** placed in your Emory Healthcare medical record. The results will **not** be made available to any other healthcare providers who may be giving you treatment. It will be up to you to let your healthcare providers know that you are in a research study. We will provide you a copy of the blood test results so that you can share these with your provider if you wish.

The researchers will review the results of certain study tests and procedures only for the research. The researchers **will not** be looking at the results of these test and procedures to make decisions about your personal health or treatment. For this study, those things include:

- Height, weight and calculated body mass index
- Waist circumference
- Blood pressure
- Blood fats: high density lipoprotein (HDL), triglycerides
- Blood sugar: fasting glucose, hemoglobin A1C (a measure of average glucose levels over past 3 months)

We encourage you to let your health care provider know if you decide to take part in this study. We also encourage you to share your clinical lab results with your provider so that they can have extra information that can help them to make decisions about your health care.

In Case of Injury

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Neither Emory, Grady Health System nor the sponsor have set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this trial, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Erin Ferranti, RN, MSN, MPH at telephone number 404-712-9551. You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Questions

Contact Erin Ferranti, RN, MSN, MPH at 404-712-9551:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research subject
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System, and you have a question about your rights, you may contact Dr. Curtis Lewis, Senior Vice President for Medical Affairs at (404) 616-4261.

Consent

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

Follow up:
In the future, we would like to contact you either by phone or through the mail. One reason would be to update our records. Another would be to tell you and ask you about taking part in other studies. This future contact would be made by one of the investigators or study staff. Would you be willing to be contacted in the future?

_____Yes

_____No

_____
Subject's signature Date: Time

Emory University School of Nursing Research Subject HIPAA Authorization to Use or Disclose Health Information that Identifies You for a Research Study

Name of Study: Dietary Quality and Cardiometabolic Risk after Gestational Diabetes
Study Number: IRB00046666

Name of Principal Investigator: Erin P. Ferranti

Subject Name:_____

The privacy of your health information is important to us. In protecting your health information that identifies you, we will follow all requirements of the Health Insurance Portability and Accountability Act ("HIPAA" for short) that apply. This form will let you know how we will use any health information that you give us for this study that identifies you.

Please read this form carefully and if you agree with it, sign it at the end.

Research Study: The purpose of this study is to get information on factors that may influence how people eat. This information will lead to better ways of teaching about what to eat, especially in women who may be at risk for Type 2 diabetes and metabolic syndrome.

People That Will Use or Disclose Your Health Information that Identifies You and Purpose of Use/Disclosure:

The following people and groups will use and disclose your health information in connection with the study. In this form, all of these people and groups are called the "Information Users":

> The principal investigator, her research staff and people and organizations that she uses to help him conduct the Research Study will use and disclose your health information to do this work.
>
> The sponsor(s) and all other people and organizations that the sponsor(s) retain(s) to help it conduct and oversee the Research Study may use and disclose your health information to make sure that the research is being done correctly and to collect and analyze the results of the research.
>
> There are a number of University persons/units, government agencies and other individuals and organizations that may use and disclose your health information to make sure that the Research Study is being conducted correctly and safely, and to monitor and regulate the research or public health issues. These people and organizations include the following: the Emory University Institutional Review Board; the Emory University Office for Clinical Research; the Emory University Office of Research Compliance; research monitors and reviewers; data safety

monitoring boards; any government agencies who regulate the research including the Office of Human Subjects Research Protections and public health agencies.

By signing this document you agree to allow any of these Information Users to use or disclose your health information that identifies you in order to conduct the Research Study, or to monitor or regulate research. In addition, we will comply with any laws that require us to disclose your health information, such as laws that require us to report child abuse or elder abuse. We also will comply with legal requests, or orders that that require us to disclose your health information, such as subpoenas or court orders. Finally, we may share your health information with a public health authority that the law authorizes to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.

Description of Health Information that Identifies You that Will be Used or Disclosed

The Information Users may use or disclose the information on your completed questionnaires.

Revoking your Authorization:
You do not have to sign this Authorization. In addition, if you sign this Authorization, later, you may change your mind at any time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to: Erin Ferranti, Nell Hodgson Woodruff School of Nursing, Emory University, 1520 Clifton Road, NE, Atlanta, GA 30322.

If you revoke your Authorization, the Researchers will not collect any more health information that identifies you, but they may use or disclose identifiable information that you already gave them in order to notify any of the other Information Users that you have taken back your authorization; to maintain the integrity or reliability of the Research Study; and to comply with any law that they are required to obey.

Other Items You Should Know:

HIPAA only applies to people or organizations that are health care providers, health care payers or healthcare clearinghouses. HIPAA may not apply to all Information Users. If HIPAA doesn't apply to an Information User, then that User doesn't have to follow HIPAA requirements when it uses or discloses your health information.

You do not have to sign this authorization form, but if you do not, you may not participate in the Research Study or receive research-related treatment. You may still receive non-research related treatment.

If the Research Study involves medical treatment, then, in order to maintain the integrity of the research study, you generally will not have access to your personal health information related to this Research Study until the study is complete. When the study is complete, then, at your request, you may generally have access to any of your personal

health information related to the research that makes up a part of the medical information and/or other records that your health care providers use to make decisions about you. If access to this information is needed before the end of the Research Study for your treatment, then the information may be provided to your physician.

If your identifying information is removed from your health information, then the information that remains will not be subject to this authorization or covered by HIPAA, and it may be used or disclosed to other persons or organizations, and/or for other purposes.

Expiration Date: This authorization will expire when the research study ends on May 15, 2013.

As a study participant, if you any questions regarding the study, you may call Erin Ferranti, the study's Principal Investigator at (404)-712-9551. If you have any questions regarding your rights as a study subject, you may contact:

Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

A copy of this authorization form will be given to you.

_____
Signature of Study Subject OR Subject's Legal Authorized Representative

Date _____ Time_____

_____
Printed Name of Study Subject OR Subject's Legally Authorized Representative

If Representative, Relationship to Study Subject: _____

_____
Signature of Person Obtaining Authorization

_____ _____
Date Time

Emory University
El Consentimiento Verbal para ser un Sujeto de Investigación
El guion de teléfono

Se solicita participar en este estudio porque tiene 18-45 años y tuvo diabetes gestacional recientemente. Esto es un problema de salud que es encontrado en las mujeres embarazadas y causa niveles altas de azúcar en la sangre durante el embarazo. La mayoría de las mujeres con diabetes gestacional tiene niveles normales de azúcar en la sangre después del embarazo. Sin embargo, diabetes gestacional puede ser un factor de riesgo de problemas futuros, y nosotros estamos tratando de entender cómo patrones de comer están relacionados. El propósito de este estudio es medir sus patrones normales de comer y examinar algunas posibles influencias individuales y familias relacionadas con comer.

Ahora mismo, estoy pidiendo permiso a usted para hacer algunas preguntas para ver si usted es elegible. Yo voy a hacer algunas preguntas sobre su historia médica de diabetes gestacional, con quien usted vive, si está a dieta o no, y como se siente con respecto a humor. Si usted está elegible y le gustaría participar en el estudio, concertaré una cita con usted en un lugar de su elección. Por ejemplo, la visita puede tener lugar en su casa, la escuela de enfermería de Emory, o el centro de investigación clínica de Emory. Luego, le mandaré algunos cuestionarios para responder antes de su visita además de un documento de consentimiento informado. El consentimiento informado discutirá el resto de los procedimientos del estudio. Usted puede firmar el documento antes de su cita o puede esperar hasta el día de la cita a firmarlo. De todas formas, usted tendrá la oportunidad de hacer todas las preguntas que quiera durante la cita, y podrá hacer una decisión sobre si quiere participar en el estudio. Los cuestionarios tratarán de lo que usted come, sus actividades físicas, sus sentimientos, y sus medicamentos. Tardará alrededor de 60-90 minutos en completar los cuestionarios. El día antes de su cita se le pedirá que no coma o beba nada excepto de agua después de medianoche. En el principio de la cita, hablaremos otra vez sobre el estudio y usted tendrá la oportunidad de hacer cualquieras preguntas que tenga. Después, si le gustaría continuar su participación, se le solicitará que firme el documento de consentimiento (si todavía no lo ha firmado). La cita durará alrededor de una hora. Durante la cita tomaré una muestra de sangre y medidas de su presión, estatura, peso, y cintura. Estos procedimientos se describirán en más detallo en el documento de consentimiento que le mandaré a usted.

No hay ningunos riesgos previsibles a usted para participar en este examen. Es improbable que usted reciba ningún beneficio directo.

Toda la información colectada durante esta cita será guardada tan privada como posible. Esta información estará guardada en un armario cerrado en mi oficina cerrada en la escuela de enfermería.

Su participación es completamente voluntaria. Usted puede negarse a responder a cualquiera pregunta. Tiene el derecho de retirarse del estudio sin castigo en cualquier momento.

Si acuerda participar en este examen, estará dando a los investigadores del estudio permisión para usar la información de salud que usted proporcionará durante este examen. Esta información incluye su historia médica de diabetes gestacional, con quien usted vive, si usted está en una dieta, y como se siente con respecto a humor. Esta información de salud puede ser usada y/o revelada a todos los investigadores y miembros del equipo implicados en el estudio. También, las personas y comités de Emory que son responsables de asegurarse de que el estudio de investigación se realiza debidamente tendrán acceso a esta información para proporcionar supervisión para este estudio.

Emory es requerido por la regla de intimidad HIPPA a proteger su información de salud. A consentir en participar en el examen, usted está autorizando a Emory a usar y/o divulgar su información de salud para esta investigación. Es posible que los que reciben su información de salud no sean obligados de las reglas federales de intimidad para protegerla y puedan compartir su información sin su permisión, si permitido por las reglas que los gobiernan.

Usted puede cambiar de opinión y revocar esta autorización en cualquier momento. Para revocar esta autorización usted debe escribir a Erin Ferranti, Emory School of Nursing, 1520 Clifton Road, NE, Atlanta, GA 30322. Si usted revoca su autorización, ya no será permitida participar en esta investigación. Esta autorización expirará al fin del estudio de investigación. Se supone que este estudio dure hasta Mayo 2013.

Como participante en el Estudio de Investigación, si tiene alguna duda con respecto al mismo puede llamar a Erin Ferranti, la investigadora en jefa del estudio al 404-712-9551 o epoe@emory.edu. Si tiene alguna duda sobre sus derechos como individuo que participa en un estudio investigación, puede comunicarse con la Junta de Revisión Institucional de la Universidad de Emory llamando al 404-712-0720 o 877-503-9797 o irb@emory.edu.

¿Tiene alguna pregunta?

¿Consiente en participar en el examen para ver si usted es elegible para este estudio?

☐ SÍ

Muy bien, vamos a empezar con las preguntas

☐ NO

Muy bien, gracias por su tiempo.

Escuela de Enfermeria de la Universidad Emory
Consentimiento para Participar como Sujeto de una Investigación

Título: La Calidad Dietetica y el Riesgo Cardiometabolico despues del Diabetes Gestacional

Investigador Principal: Erin Poe Ferranti, RN, MSN, MPH

Patrocinador: Sandra B. Dunbar, RN, DSN, FAAN, FAHA

Colaboradores del estudio: National Institutes of Health, National Institute of Nursing Research and American Heart Association

Introducción

Se solicita su participación en un estudio de investigación. Este formulario está diseñado para informarle todo lo que debe saber antes de decidir dar su consentimiento (aceptar) para formar parte del estudio o no hacerlo. **La elección es únicamente suya. Si decide participar, puede cambiar de opinión más adelante y retirarse del estudio de investigación.** Esta decisión de unirse al estudio de investigación no hará que pierda los beneficios médicos. Si decide no participar en el estudio, su médico continuará brindándole tratamiento.

- Lea atentamente el presente formulario o pida a alguien que se lo lea
- Escuche las explicaciones del médico del estudio o del personal del estudio
- Realice preguntas acerca de lo que no le parezca claro
- Puede llevar una copia de este formulario a su domicilio y tomarse el tiempo necesario para reflexionar y conversar acerca del estudio con sus familiares o amigos

Después de conversar acerca de la información de este formulario de consentimiento con el equipo del estudio, debería saber:

- Por qué se realiza este estudio
- Qué sucederá durante la investigación
- Qué partes del estudio son experimentales y qué partes conforman la atención médica estándar
- Si este estudio utiliza un fármaco o dispositivo, si posee la aprobación o no de la Administración de alimentos y fármacos de los Estados Unidos
- Los posibles beneficios para usted. La mayor parte de las investigaciones se realiza para aprender cuestiones que ayudarán a los pacientes en el futuro. Nadie puede garantizar que el estudio sea de ayuda para usted.
- Los posibles riesgos para usted. Considere detenidamente los riesgos.
- Qué otra atención médica puede buscar en lugar de participar en este estudio de investigación y
- Cómo se tratarán los problemas durante el estudio y una vez finalizado.
- Quién tendrá acceso a su información del estudio

Si acepta participar en este estudio de investigación, recibirá una copia de este consentimiento con su firma y la fecha, para que conserve. No firme este formulario de consentimiento a menos que haya tenido la oportunidad de hacer preguntas y obtener las respuestas que considere adecuadas. Ninguna sección de este formulario le otorga derechos legales. Al firmar este formulario no renunciará a sus derechos legales.

Propósito

Se le pide participar en este estudio porque tiene 18-45 anos y tuvo diabetes gestacional recientemente. Esto es un problema de salud que es encontrado en las mujeres embarazadas y causa niveles altas de azúcar en la sangre durante el embarazo. La mayoría de las mujeres con diabetes gestacional tiene niveles normales de azúcar en la sangre después del embarazo. Sin embargo, diabetes gestacional puede ser un factor de riesgo de problemas futuros, y nosotros estamos tratando de entender cómo patrones de comer están relacionados. El propósito de este estudio es medir sus patrones normales de comer y examinar algunas posibles influencias individuales y familias relacionadas con comer. También el estudio medirá algunas pruebas clínicas para evaluar el riesgo de desarrollar diabetes y/o el sindroma metabólico. El sindroma metabólico es una combinación de dolencias médicas que aumenta el riesgo de desarrollar cardiopatía y diabetes. Unas 78 mujeres en el área metropolitano de Atlanta se le pidieron participar en el estudio.

Procedimientos

Si decide participar en este estudio, se le hará una cita con usted en un lugar de su elección (ej. su casa, una oficina en Emory School of Nursing (la escuela de enfermería) o en el Clinical Research Center (se llama el CIN – el centro de investigación clínica) en Emory University.

- Se le mandará una serie de cuestionarios para contestar antes de su cita. Estos cuestionarios se tratarán de lo que come, sus actividades físicas, sus sentimientos, y sus medicamentos. Tardará unos 60-90 minutos para completar.
- El día antes de su cita usted se le pedirá que no coma ni beba nada excepto de agua después de la medianoche.
- Durante la cita (que tardará unos 60 minutos), también:
    - Se medirá su presión, estatura, peso, y cintura
    - Tendrá tomado una prueba de sangre de una punción de dedo para medir el azúcar de sangre, hemoglobina A1C (otra medida de glucosa de sangre), y las grasas de sangre (HDL, colesterol, triglicéridos).

Pruebas de Sangre: Se tomará una cantidad poca de sangre (estimado a 4-5 gotas) de una punción de dedo para medir el riesgo de diabetes y el sindroma metabólico. Estas pruebas son para grasas y azúcar de sangre. Ninguna de las muestras se guardará ni almacenará después del resultado de la prueba. Un código se utilizará para coincidir su muestra de sangre con sus resultados.

Riesgos y molestias

Podría haber efectos secundarios de los procedimientos del estudio que no se conocen en este momento.
Los riesgos y las molestias más frecuentes que puede esperar del estudio son:

- Incomodidad menor y posible hematoma de la aguja que se usa para pinchar su dedo para obtener su sangre de la punción dedo.

Los riesgos y las molestias menos frecuentes que puede esperar del estudio son:

- Incomodidad considerable, moretones o infección en el lugar de la punción de dedo.

Información nueva

Es posible que los investigadores aprendan algo nuevo durante el estudio, en relación con los riesgos de su participación. Si esto sucede, lo informarán acerca de dichos riesgos, para que pueda decidir si desea continuar

participando en el estudio o no. Es posible que deba firmar un nuevo formulario de consentimiento que incluya la información nueva si decide permanecer en el estudio.

Beneficios

Este estudio no está diseñado para que usted obtenga un beneficio directo. Se podría beneficiar por aprender cómo cuidar mejor de su salud. Este estudio esta diseñado para aprender mas de las influencias de comportamiento de comer y como reducir los riesgos de diabetes y el sindroma metabólico. Los resultados del estudio pueden utilizarse para ayudar a otros pacientes en el futuro.

Pago por su participación

Proporcionaremos una tarjeta de regalo de $25 por su tiempo participando y completando todos los aspectos de la recopilación de datos (los cuestionarios y la visita del estudio).

Otros tratamientos fuera de este estudio

Este no es un estudio de tratamiento. Usted puede elegir no participar.

Confidencialidad

Determinados consultorios y personas que no sean los investigadores podrán tener acceso a sus estudios médicos y a los registros del estudio. Las agencias de gobierno y los empleados de Emory que supervisen la conducta adecuada del estudio podrán tener acceso a sus registros del estudio. Los patrocinadores del estudio también podrán tener acceso a sus registros del estudio. Entre las oficinas se incluyen [Oficina para la protección de los seres humanos en la investigación, el/los patrocinador/es, el Comité de revisión institucional de Emory, la Oficina de cumplimiento con las investigaciones de Emory y la Oficina de investigaciones clínicas]. Emory conservará la privacidad de los registros de investigación producidos, de conformidad con la ley. Siempre que sea posible, se utilizará un número del estudio, en lugar de su nombre, en los registros del estudio. No aparecerán su nombre ni otros datos que puedan identificarlo en la presentación del estudio o en la publicación de los resultados.

Se pueden abrir los registros del estudio mediante una orden judicial o en respuesta a una citación o solicitud de presentación de los documentos, a menos que se haya implementado un Certificado de confidencialidad para el estudio.

Si usted es o ha sido paciente en Emory Healthcare, usted posee una historia clínica de Emory Healthcare. Si usted no es y nunca ha sido paciente en Emory Healthcare, no posee historia clínica. Tenga en cuenta que la historia clínica de Emory Healthcare **no** se crea debido a que usted participa en este estudio.

Para proteger mejor la confidencialidad de su información de la investigación, **no** se debe incluir los resultados de estas pruebas y procedimientos del estudio en ninguna historia clínica:

Estos resultados de la investigación se conservarán en una historia clínica sólo para los investigadores. Los investigadores tomarán medidas para asegurar que estos resultados **no** se incluyan en su historia clínica de Emory Healthcare. Los resultados **no** estarán disponibles para otros proveedores de atención médica que puedan tratarlo. Dependerá de usted que sus proveedores de atención médica sepan que forma parte de un estudio de investigación.

Otros resultados útiles del estudio que no forman parte de esta lista **se incluirán en su historia clínica de Emory Healthcare**. Cualquier persona que tenga acceso a su historia clínica podrá acceder a todos los resultados que aquí se incluyen. Emory Healthcare puede utilizar estos resultados para su atención. La confidencialidad de la información del estudio en su historia clínica estará protegida por leyes como la Regla de privacidad HIPAA. Por otro lado, es posible que algunas leyes y reglas estatales y federales no protejan a la información de investigación de ser divulgada.

Emory no controla los resultados de las pruebas y los procedimientos realizados en otros lugares. De modo que estos resultados no se colocarán en su historia clínica de Emory Healthcare. Tampoco es probable que estén disponibles para su atención en Emory Healthcare. Emory no controla otras historias clínicas que usted pueda tener con otros proveedores de atención médica. Emory no enviará resultados de pruebas o procedimientos del estudio a estos proveedores. De modo que, si decide participar en este estudio, dependerá de usted cuánto se les informe a estos proveedores.

Algunas pruebas y procedimientos que pueden realizarse durante este estudio **sólo** se revisarán para los fines de la **investigación**, **no para fines de su atención médica**. Estos resultados no se revisarán con el fin de tomar decisiones en relación con su salud personal o su tratamiento. Las pruebas o los procedimientos específicos, si hay, que se revisarán sólo para fines de la investigación incluyen:

- Estatura, peso y índice de masa corporal (IMC)
- Circunferencia de cintura
- Presión arterial
- Grasas de sangre: Lipoproteína de alta densidad (LAD), triglicéridos
- Azúcar de sangre: Glucosa en ayunas, hemoglobina A1C (una medida del promedio de los niveles de glucosa durante los últimos 3 meses)

Para proteger mejor la confidencialidad de su información, **no** se debe incluir una copia del Consentimiento informado firmado ni del formulario de Autorización del Paciente de HIPAA en su historia clínica. Si posee una historia clínica en Emory Healthcare, no se colocarán en ella copias de estos formularios.

Los investigadores revisarán los resultados de ciertas pruebas de estudio y procedimientos solo para la investigación. Los investigadores **no** estarán mirando a los resultados de estas pruebas y procedimientos para hacer decisiones sobre su salud personal o tratamiento. Para este estudio, esas cosas incluyen:

- Estatura, peso e índice de masa corporal
- Circunferencia de cintura
- Presión arterial
- Grasas de sangre: Lipoproteína de alta densidad (LAD), triglicéridos
- Azúcar de sangre: Glucosa en ayunas, hemoglobina A1C (una medida del promedio de los niveles de glucosa durante los últimos 3 meses)

Le recomendamos que haga saber a su proveedor de atención médica si decide participar en este estudio. De ese modo, pueden brindarle más información útil a la hora de tomar una decisión en relación con su atención médica.

En caso de lesión

Si usted se enferma o lesiona debido a su participación en este estudio, Emory le brindará o hará los arreglos necesarios para que reciba atención médica de urgencia. A continuación, se explica quién pagará la atención médica:

¿La pagará Emory? Emory no posee reservados fondos para pagar la atención médica de urgencia. Además, Emory no posee reservados fondos para otorgarle en caso de que se enferme o lesione debido a su participación en este estudio. La única excepción a esta política es si se comprueba que su enfermedad o lesión fue directamente provocada por la negligencia de un empleado de Emory. "Negligencia" significa la imposibilidad de seguir las normas habituales de atención.

¿La pagará el patrocinador del estudio? El patrocinador del estudio no posee fondos reservados para pagar la atención médica de urgencia. Además, el patrocinador del estudio no posee fondos reservados para otorgarle en caso de que se enferme o lesione debido a su participación en este estudio.

Si usted se esta enferma o herida por participación en este estudio, su asegurador se le cobrará por el costo del tratamiento. Si no tiene el seguro, o si su asegurador no le paga, entonces usted tendrá que pagar estos costos.

Si cree que ha resultado lesionado debido a esta investigación, comuníquese Erin Ferranti, RN, MSN, MPH en numero de teléfono 404-712-955.

Costos adicionales que deberá pagar si participa en este estudio:
No habrá ningún costo para usted por participar en este estudio que no sea los gastos básicos como transportación. No se le cobrará por ningún de los actividades de investigación.

Retiro del estudio

Tiene derecho a retirarse del estudio en cualquier momento sin recibir una sanción por ello. La investigadora y el patrocinador del estudio también tienen derecho a interrumpir su participación en este estudio sin su consentimiento si:

- Creen que es a favor de sus intereses;
- Objeta futuros cambios que puedan realizarse en el plan del estudio;
- u otro motivo.

Preguntas

Comuníquese con Erin Ferranti, RN, MSN, MPH al 404-712-9551:

- si tiene preguntas relacionadas con la totalidad o parte de este estudio,
- si cree que ha resultado lesionado debido a la investigación, o
- si tiene alguna pregunta, inquietud o queja en relación con la investigación

Si tiene alguna pregunta acerca de sus derechos como sujeto de una investigación o preguntas, inquietudes o quejas en relación con la investigación, puede comunicarse con el Comité de revisión institucional de Emory al 404-712-0720 o al 877-503-9797. también puede informar al IRB sobre su experiencia como participante de investigación por nuestro Research Participant Survey (encuesta de participante de estudio) a http://www.surveymonkey.com/s/6ZDMW75.

Si usted es una paciente que recibe atención del Grady Health System, y tiene una pregunta sobre sus derechos, puede contactar con Dr. Curtis Lewis, Vicepresidente Principal para Asuntos Médicos a (404) 616-4261.

Consentimiento

He leído este formulario de consentimiento (o me ha sigo leído). Se han respondido todas mis preguntas sobre el estudio y mi participación. Doy mi consentimiento libremente para participar en este estudio de investigación.

Al firmar este formulario de consentimiento, no renuncio a mis derechos legales.

_____

Nombre del sujeto

_____ _____

Firma del sujeto Fecha

_____ _____

Firma del representante legalmente autorizado (cuando corresponda) Fecha

_____

Autoridad del representante legalmente autorizado o relación con el sujeto (cuando corresponda)

_____ _____

Firma de la persona que explica el Consentimiento informado Fecha

Autorización dada por un individuo objeto de una investigación a la Escuela de Enfermería de la Universidad de Emory, de conformidad con la Ley de Responsabilidad y Transferibilidad de Seguros Médicos, para usar o divulgar en una investigación datos sobre su salud que lo identifican

Nombre del Estudio: Calidad de la dieta y el riesgo cardiometabólico después de la diabetes gestacional

Número de Estudio: IRB00046666

Nombre de la Investigadora en jefa: Erin P. Ferranti

Nombre del individuo:_____

Para nosotros es importante que toda información sobre su salud sea confidencial. A fin de proteger cualquier dato sobre su salud que lo identifique, seguiremos las disposiciones estipuladas en la Ley de Responsabilidad y Transferibilidad de los Seguros Médicos (HIPAA, por su sigla en inglés) pertinentes al caso. Para la realización del presente estudio, usted nos ha proporcionado información sobre su persona; por medio de este formulario sabrá en qué forma usaremos cualquier dato sobre su salud que lo identifique.

Lea este formulario detenidamente y, si está conforme, fírmelo en la última hoja.

Estudio de Investigación: El propósito de este estudio es para obtener información sobre los factores que pueden influir cómo la gente come. Esta información dará lugar a mejores formas de enseñar acerca de que comer, especialmente en mujeres que puedan estar en riesgo de diabetes tipo 2 y síndrome metabólico.

Personas que usarán o divulgarán información sobre su salud que lo identifica y propósito de tal uso o divulgación:

Las personas o grupos que se mencionan a continuación usarán o divulgarán datos sobre su salud recabados para el presente estudio. En este formulario, todas estas personas y grupos se denominarán en lo sucesivo "Usuarios de la Información".

La investigadora en jefa, su equipo de investigación y las personas u organizaciones a las cuales recurra para ayudarlo a realizar el Estudio de Investigación usarán o divulgarán datos sobre su salud para realizar este proyecto.

Los patrocinantes y todas las personas u organizaciones que, según los patrocinantes, ayuden en la realización y supervisión del presente estudio de investigación pueden usar y divulgar datos sobre su salud a los fines de asegurarse de que la investigación se está realizando de manera correcta y de analizar los resultados de la investigación.

Ciertas personas o departamentos adscritos a universidades, organismos públicos y otras instituciones pueden usar y divulgar información sobre su salud para

asegurarse de que el estudio de investigación se realiza debidamente y sigue todos los lineamientos de seguridad pertinentes, así como para vigilar y controlar asuntos relacionados con la investigación o la salud pública. Entre ellos pueden encontrarse las siguientes: la Junta de Revisión Institucional de la Universidad de Emory; el Departamento de Investigaciones Clínicas de la Universidad de Emory; el Departamento de Control de Investigaciones de la Universidad de Emory; las personas encargadas de controlar y revisar la investigación; los organismos responsables de controlar la seguridad de los datos; los organismos públicos que controlan las investigaciones, como la Oficina de Protección de Seres Humanos Participantes en Investigaciones (OHRP, por su sigla en inglés) y agencias de salud pública.

Al firmar este documento acepta que cualquiera de estos Usuarios de la Información usen o divulguen información sobre su salud que lo identifique para realizar el Estudio de Investigación, o bien para controlar o vigilar la conducción o los resultados de dicho estudio. Adicionalmente, cumpliremos con lo estipulado en cualquier ley que nos exija revelar información sobre su salud, como las leyes que nos obligan a informar sobre maltrato de niños o personas de la tercera edad. Asimismo, cumpliremos con cualquier solicitud u orden legal que nos exija revelar información sobre su salud, como citaciones o resoluciones judiciales. Por último, podemos suministrar datos sobre su salud a cualquier organismo de salud pública que, conforme a la ley, recopile información de esta naturaleza a los fines de evitar o controlar enfermedades, lesiones o discapacidades o realizar controles, investigaciones o intervenciones relacionados con la salud pública

Descripción de la información sobre su salud que lo identifica que se usará o se divulgará en el Estudio de Investigación:

Los Usuarios de la Información pueden usar o divulgar la información de los cuestionarios completados.

Cómo revocar esta autorización:
Usted no está obligado a firmar esta Autorización. Además, si firma este formulario, puede cambiar de opinión en cualquier momento en el futuro y revocar la Autorización que otorga por medio del presente documento. Si desea revocar la presente Autorización, debe escribir a: Erin Ferranti, Nell Hodgson Woodruff Escuela de Enfermería, Universidad de Emory, 1520 Clifton Road, NE, Atlanta, GA 30322.

Si revoca la Autorización, los Investigadores no recopilarán más información sobre su salud que lo identifique, pero pueden usar o revelar información que lo identifique que usted ya les haya proporcionado a fin de notificarle a cualquier otro Usuario de la Información que usted ha revocado su Autorización, mantener la integridad o confiabilidad del Estudio de Investigación y respetar cualquier ley con la cual deban cumplir.

Otros asuntos de su interés:

La HIPAA sólo se aplica a personas u organizaciones que proporcionan servicios de atención médica, que tienen bajo su responsabilidad el pago de estos servicios o que procesan información relacionada con dichos servicios. Es posible que la HIPAA no se aplique a todos los Usuarios de la Información. Si la HIPAA no se aplica a un Usuario de la Información en particular, dicho Usuario no está obligado a cumplir con las disposiciones de la HIPAA cuando use o divulgue información sobre su salud.

Usted no está obligado a firmar este formulario de Autorización, pero si no lo hace no podrá participar en el Estudio de Investigación ni recibir tratamiento relacionado con dicha investigación. Sin embargo, usted puede recibir tratamiento no relacionado con la investigación.

Si el Estudio de Investigación requiere que usted se someta a tratamiento médico, por lo general sólo tendrá acceso a información personal sobre su salud relacionada con el Estudio de Investigación cuando éste se concluya; esto se hace para mantener la integridad del estudio. Cuando finalice el Estudio de Investigación, usted, si lo solicita, puede tener acceso a información personal sobre su salud relacionada con el estudio que forme parte de los expedientes médicos o de cualquier otro registro que sus proveedores de atención médica usen para tomar decisiones sobre su persona. Si a los fines de cumplir su tratamiento se requiere tener acceso a esta información antes de que finalice el Estudio de Investigación, la información que se necesite podrá suministrarse a su médico.

Si la información que lo identifica se elimina de los registros de información sobre su salud, la información restante no será objeto de esta autorización ni estará cubierta por lo estipulado en la HIPAA, y puede ser usada o revelada a otras personas u organizaciones o para otros fines.

Fecha de expiración: La presente autorización expirará cuando el Estudio de Investigación finalice el15 de mayo de 2013.

Como participante en el Estudio de Investigación, si tiene alguna duda con respecto al mismo puede llamar a Erin Ferranti, la investigadora en jefa del estudio al (404) -712 a 9551. Si tiene alguna duda sobre sus derechos como individuo que participa en un estudio investigación, puede comunicarse con la Junta de Revisión Institucional de la Universidad de Emory llamando al 404-712-0720 o 877-503-9797 o irb@emory.edu.

Se le entregará una copia de este formulario de autorización.

_____
Firma del participante O del representante legal del participante de estudio

Fecha: _____ Hora:_____

_____
Nombre impreso del participante O del representante legal del participante

Si usted es representante, indique su relación con el participante:
_____

_____
Firma de la persona que obtiene la autorización

_____ _____
Fecha: Hora:

Appendix B: Recruitment Strategies

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

Did you have diabetes (gestational) during your pregnancy?

If so, you may be eligible to participate in a study directed at examining influences of eating patterns. This study will include questionnaires and lab tests and involve one short (1-hour) visit with a nurse.

To be eligible you must:

- **Have had gestational diabetes (diabetes only during your pregnancy) within the past five years.**
- **Be ages 18-45 and English speaking.**
- **Be willing to complete questionnaires and have one (1-hour) study visit at a place of your convenience.**

Benefits of participation will be a no cost health check and some educational materials. Eligible participants who complete the study will receive a $25 gift card.

Principal Investigator: Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing
1520 Clifton Road NE
Atlanta, GA 30322

To find out more contact:
Erin Ferranti
Principal Investigator
epoe@emory.edu
404-981-2511

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

¿Tuvo diabetes gestacional durante su embarazo?

En ese caso, es posible que usted reúna los requisitos para participar en un estudio que examina las influencias de los patrones alimenticios.

Este estudio incluirá cuestionarios y pruebas de laboratorio e implicará una visita breve (1 hora) con la enfermera.

Para ser elegible usted debe:

- **Haber tenido la diabetes gestacional (la diabetes sólo durante el embarazo) dentro de los últimos cinco años.**
- **Tener 18-45 años.**
- **Estar dispuesta a completar un cuestionario y tener una visita de estudio (de 1 hora) en un lugar de su conveniencia.**

Los beneficios de participación serán un chequeo gratis y algunos materiales educativos. Los participantes elegibles que completen el estudio recibirán un certificado de regalo de $25.

Investigadora Principal:
Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing
1520 Clifton Road NE
Atlanta, GA 30322

Para más información, llame y por favor deje su información en un mensaje. Su llamada será regresada por alguien que hable español:

Erin Ferranti
Investigadora Principal
epoe@emory.edu
404-712-9551

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

Did you have diabetes (gestational) during your pregnancy?

If so, you may be eligible to participate in a study directed at examining influences of eating patterns. This study will include questionnaires and lab tests and involve one short (1-hour) visit with a nurse.

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- **Have had gestational diabetes (diabetes only during your pregnancy) within the past five years.**
- **Be ages 18-45 and English speaking.**
- **Be willing to complete questionnaires and have one (1-hour) study visit at a place of your convenience.**

Benefits of participation will be a no cost health check and some educational materials. Eligible participants who complete the study will receive a $25 gift card.

Principal Investigator: Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing

1520 Clifton Road NE
Atlanta, GA 30322

To find out more contact:
Erin Ferranti
Principal Investigator
epoe@emory.edu
404-981-2511

GDM-Eating Study
Erin Ferranti epoe@emory.edu
404-981-2511

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

¿Tuvo diabetes (gestacional) durante su embarazo?

En ese caso, es posible que usted reúna los requisitos para participar en un estudio que examina las influencias de los patrones alimenticios. Este estudio incluirá cuestionarios y pruebas de laboratorio e implicará una visita breve (1 hora) con la enfermera.

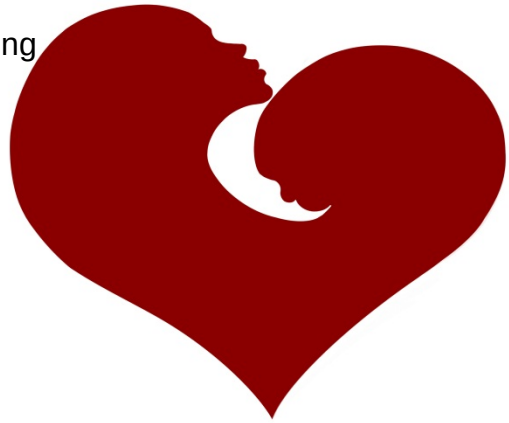
Para ser elegible usted debe:

- **Haber tenido la diabetes gestacional (la diabetes sólo durante el embarazo) dentro de los últimos tres años.**
- **Tener 18-45 años y hablar inglés.**
- **Estar dispuesta a completar un cuestionario y tener una visita de estudio (de 1 hora) en un lugar de su conveniencia.**

Los beneficios de participación serán un chequeo gratís y algunos materiales educativos. Los participantes elegibles que completen el estudio recibirán un certificado de regalo de $25.

La Investigadora Principal: Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing

1520 Clifton Road NE
Atlanta, GA 30322



Para más información contacte a:

Erin Ferranti
Investigadora Principal
epoe@emory.edu
404-712-9551

GDM-Eating Study
Erin Ferranti epoe@emory.edu
404-981-2511

Facts about Gestational Diabetes

- Most common complication of pregnancy
- Affects 2-10% of all pregnancies
- New diagnostic criteria could increase incidence to 18%
- It is increasing along with increases in overweight, obesity and Type 2 diabetes in the population
- More common among Native American, Asian, Hispanic, African -American and Pacific Islander women
- Women who have had gestational diabetes are much more likely to have it again in future pregnancies

American College of Obstetricians and Gynecologists, 2009; National Institutes of Health, 2011

EMORY

NELL HODGSON WOODRUFF SCHOOL OF NURSING

Scholarship, Leadership, and Social Responsibility

Dietary Quality and Cardiometabolic Risk after Gestational Diabetes Study

Contact: 404-981-2511 or epoe@emory.edu

This study is supported by a grant to Emory University by the National Institute of Nursing Research and the American Heart Association

A research opportunity for

Women with previous Gestational Diabetes

Principal Investigator:

Erin Poe Ferranti, RN, MSN, MPH

Emory University School of Nursing

(404)-981-2511

epoe@emory.edu

A Study of Dietary Quality and Cardiometabolic Risk

This is a research study to better understand eating patterns and risk for future cardio-metabolic disease among women who have had gestational diabetes.

Please consider joining us to benefit women and families who have been affected by gestational diabetes.

Become a part of better understanding eating patterns and improving health in women and families affected by gestational diabetes by enrolling in this research study.

Who can take part?

- ***Women age 18-45 years who:***
- ***Have had gestational diabetes within the past 3 years***
- ***Are no longer breastfeeding***
- ***Are not currently pregnant***
- ***Understand English***
- ***Are not working with a dietician, a formal weight-loss program or on a prescriptive diet***
- ***Have no history of Type 1 or Type 2 diabetes***
- ***Have no history of polycystic ovary syndrome***

What is involved?

Volunteers will complete questionnaires and participate in a single study visit to complete a basic health assessment.

Transportation costs will be reimbursed and a $25 gift card will be provided for completing the study.

How to Volunteer

Call (404) 981-2511 or email epoe@emory.edu

to find out if you're eligible.

Datos sobre la diabetes gestacional

- La complicación más frecuente del embarazo
- Afecta a un 2-10% de todos los embarazos
- Nuevos criterios de diagnóstico podrían aumentar la incidencia de un 18%
- Se está aumentando junto con aumentos en sobrepeso, obesidad y diabetes tipo 2 en la población
- Más común entre las mujeres nativos americanas, asiáticas, hispánicas, afro-americanas e isleñas del Pacífico
- Las mujeres que han tenido la diabetes gestacional son más propensas a tenerla de nuevo en futuros embarazos.

American College of Obstetricians and Gynecologists, 2009; National Institutes of Health, 2011

EMORY

NELL HODGSON WOODRUFF SCHOOL OF NURSING

Scholarship, Leadership, and Social Responsibility

Educación, liderazgo y la responsabilidad social

Un estudio sobre la Calidad de la dieta y el Riesgo Cardiometabolico

Comuníquese con Erin Ferranti al 404-712-9551 y deje un mensaje con su nombre y número de teléfono o mande un correo electrónico a

Este estudio está financiado por una beca a la Universidad de Emory por el Instituto Nacional de Investigación de Enfermería y la Asociación Americana del Corazón

Una oportunidad para participar en un estudio para

mujeres que han tenido la diabetes gestacional

Investigadora principal :
Erin Poe Ferranti, RN, MSN, MPH
Escuela de Enfermeria de la Universidad de Emory
404-712-9551
epoe@emory.edu

Un estudio sobre la Calidad de la dieta y el Riesgo Cardiometabolico

Este es un estudio de investigación con el propósito de mejor entender los patrones de alimentación y el futuro riesgo de la enfermedad cardiometabolico entre mujeres que han tenido la diabetes gestacional.

Por favor considere unirse a nosotros para beneficiar a las mujeres y familias que han sido afectadas por la diabetes gestacional.

Sea parte de un mejor entendimiento sobre los patrones de alimentación y el mejoramiento de salud en mujeres and familias afectadas por la diabetes gestacional al inscribirse en este estudio de investigación.

Quien puede participar?

Mujeres que tiene entre 18 a 45 años de edad y que:

- ***Han tenido la diabetes gestacional entre los últimos 3 años.***
- ***No están amamantando actualmente.***
- ***No están embarazadas.***
- ***No están trabajando con un dietista, un programa formal para perder peso o en una dieta prescrita.***
- ***No tienen un historial de la diabetes tipo 1 o tipo 2.***
- ***No tienen un historial del síndrome de ovario poliquístico.***

Que involucra este estudio?

Voluntarios completarán cuestionarios y participarán in una visita de estudio para completar una evaluación básica de salud.

Los costos de transportación serán rembolsados y una tarjeta de regalo de $25 será dada por completar este estudio.

Como participar

Llame al 404-712-9551 y deje un mensaje con su nombre y número telefónico o mande un mensaje por correo electrónico a epoe@emory.edu
Le llamarémos para ver si es elegible para el estudio.

Emory Healthcare Script of GDM Phone Wait Message

(IRB # 00046666)

Did you have gestational diabetes during your pregnancy? If so, then you may be eligible for a research study at Emory University School of Nursing that focuses on understanding influences of eating patterns and assessment of your risk for Type 2 diabetes and heart disease. In the study you will be asked to complete questionnaires about your health, feelings and health habits; and provide a finger-stick blood sample for heart and diabetes analysis. Eligible participants will receive compensation for completing the study. For more information or to enroll call 404-981-2511

EMORY UNIVERSITY SCHOOL OF MEDICINE

Department of Gynecology and Obstetrics
Division of General Obstetrics and Gynecology at Emory

Mary S. Dolan, MD, MPH, Director
Jessica Arluck, MD; Penny Castellano, MD; Elizabeth (Betsy) Collins, MD, MPH
Alisa Gambrell, MD; Khadeja Haye, MD; John P. Horton, MD; Kurt Martinuzzi, MD;
Stephen H. Weiss, MD, MPH

April 30, 2012

Dear Ms. Participant:

This letter is an invitation to you to consider participating in a nursing research study at Emory University that is examining eating patterns and risk for metabolic syndrome and Type 2 diabetes among mothers with young children. Because you delivered your baby at Emory University Hospital Midtown within the past five years, you may be eligible for this research study.

Metabolic syndrome is a cluster of medical conditions (elevated blood pressure, elevated blood fats, elevated blood sugar and large waist circumference) that increase the risk for heart disease and Type 2 diabetes. We are trying to understand how eating patterns are related to future disease risk so that we can design more effective ways to assist women to stay healthy. The purpose of the study is to measure diet patterns and to examine some possible individual and family influences related to eating. The study will also include some tests to assess risk for developing diabetes and/or metabolic syndrome. About 78 women in metropolitan Atlanta will be asked to take part in the study.

By participating in this study, you will be asked to complete some questionnaires and to meet with a research nurse for one visit, lasting about one hour. That visit may be conducted in your home or another place of convenience of your choosing. The study visit will include some clinical measurements including a finger-stick to check your blood for fats and sugar levels. Waist circumference, weight, height and blood pressure measurements will also be done. You will be given a copy of your clinical results and will be reimbursed with a $25 gift card for your time.

For more information, please contact Erin Ferranti, RN, MSN, MPH at 404-981-2511 or epoe@emory.edu.

Thank you,

Mary S. Dolan, MD, MPH
Assistant Professor and Director
Emory General Obstetrics and Gynecology

Emory University School of Medicine
Division of General Obstetrics and Gynecology
550 Peachtree Street, 9th Floor MOT
Atlanta, GA 30308

Tel 404.778-3401
www.gynob.emory.edu

GRADY LETTERHEAD

Dear Ms. Participant:

This letter is an invitation to you to consider participating in a nursing research study at Emory University that is examining eating patterns and risk for metabolic syndrome and Type 2 diabetes among women who had gestational diabetes during their pregnancy.

Metabolic syndrome is a cluster of medical conditions (elevated blood pressure, elevated blood fats, elevated blood sugar and large waist circumference) that increase the risk for heart disease and Type 2 diabetes. We are trying to understand how eating patterns are related to future disease risk so that we can design more effective ways to assist women to stay healthy. The purpose of the study is to measure diet patterns and to examine some possible individual and family influences related to eating. The study will also include some tests to assess risk for developing diabetes and/or metabolic syndrome. About 78 women in metropolitan Atlanta will be asked to take part in the study.

By participating in this study, you will be asked to complete some questionnaires and to meet with a research nurse for one visit, lasting about one hour. That visit may be conducted in your home or another place of convenience of your choosing. The study visit will include some clinical measurements including a finger-stick to check your blood for fats and sugar levels. Waist circumference, weight, height and blood pressure measurements will also be done. You will be given a copy of your clinical results and will be reimbursed with a $25 gift card for your time.

For more information, please contact Erin Ferranti, RN, MSN, MPH at 404-981-2511 or epoe@emory.edu.

Thank you,

Johnnie Hall, RN, BSN
Nurse Case Manager
Women's Health Services

Si usted ha tenido diabetes durante su embarazo y quiere enterarse más de este estudio de investigación y como participar, favor llame a 404-712-9551 y deje un mensaje con su nombre y su número de teléfono. Se habla español y le devolveremos el llamado a usted para decirle más sobre el estudio de investigación.

Emory University
1520 Clifton Road NE
Atlanta, GA 30322-4201
www.nursing.emory.edu
The Robert W. Woodruff Health Sciences Center

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

Did you have diabetes (gestational) during your pregnancy?

If so, you may be eligible to participate in a study directed at examining influences of eating patterns.

This study will include questionnaires and lab tests and involve one short (1-hour) visit with a nurse.

To be eligible you must:

- **Have had gestational diabetes (diabetes only during your pregnancy) within the past five years.**
- **Be ages 18-45 and English speaking.**
- **Be willing to complete questionnaires and have one (1-hour) study visit at a place of your convenience.**

Benefits of participation will be a no cost health check and some educational materials. Participants who complete the study will receive a $25 gift card.

Principal Investigator: Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing
1520 Clifton Road NE
Atlanta, GA 30322

To find out more contact:
Erin Ferranti
Principal Investigator
PhD Candidate
epoe@emory.edu
404-981-2511

Or tear-off at the dotted line and leave with the receptionist before you check-out. Thanks.

\- -

Are you interested in learning more about this study?
__Yes
__No

Do you agree to have the principal investigator contact you to tell you more about the study?
___Yes. (please complete your name and contact info below)
___No, thank you (please complete your name only below)

Name:

____

Best method to reach you: Phone: ____________Email: ______________________

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

¿Tuvo diabetes (gestacional) durante su embarazo?

En ese caso, es posible que usted reúna los requisitos para participar en un estudio que examina las influencias de los patrones alimenticios.

Este estudio incluirá cuestionarios y pruebas de laboratorio e implicará una visita breve (1 hora) con la enfermera.

Para ser elegible usted debe:

- **Haber tenido diabetes gestacional (la diabetes sólo durante el embarazo) dentro de los últimos tres años.**
- **Tener 18-45 años y hablar inglés.**
- **Estar dispuesta a completar un cuestionario y tener una visita de estudio (de 1 hora) en un lugar de su conveniencia.**

Los beneficios de participación serán un chequeo gratis y algunos materiales educativos. Los participantes elegibles que completen el estudio recibirán un certificado de regalo de $25.

Investigadora Principal: Erin Ferranti, RN, MSN, MPH
Emory University, Nell Hodgson Woodruff School of Nursing
1520 Clifton Road NE
Atlanta, GA 30322

Para más información contacte a:
Erin Ferranti
Investigadora Principal
Candidata PhD
epoe@emory.edu
404-712-9551

O corte por la línea de puntos y deje con la recepcionista antes de irse. Gracias.

_ _

¿Está interesada en aprender más acerca de este estudio?
__Sí
__No

¿Está de acuerdo en que la investigadora la contacte a usted para decirle más acerca del estudio?
___Sí. (Por favor escriba su nombre e información de contacto abajo)
___No, gracias (Por favor escriba sólo su nombre abajo)
Nombre:_____

La mejor manera de contactarlo a usted:_____

Teléfono:_____ Email/Correo

electrónico:_____

Facebook Survey Monkey

Did you have gestational diabetes during your pregnancy? If so, please complete this quick survey and we will follow-up with you to determine if you meet the eligibility criteria.

This research study is examining influences of eating patterns, risk for Type 2 diabetes and metabolic syndrome. This survey will ask you some general questions about your gestational diabetes history and your preferred method of contact to learn more about the study. All information collected from this survey will be kept as private as possible through a password protected database. By completing this survey, you are giving permission for the study staff to contact you with more information about the study. Your survey information will be deleted as soon as your participation eligibility is determined.

Survey Monkey Questionnaire

1. Please provide the following information:
    a. Name
    b. Email
    c. Phone

2. When was the delivery date of your most recent gestational diabetic pregnancy?

3. Are you currently pregnant?
    a. Yes
    b. No
4. Are you currently breastfeeding?
    a. Yes
    b. No
5. Are you interested in learning more about this study through:
    a. Phone
    b. Email
6. Do you live in Georgia?
    a. Yes
    b. No

Email Response for the Survey Monkey Survey

Thank you for completing the Survey Monkey questionnaire for our study.

This is a study that is examining eating patterns and cardiometabolic risk status within 1-5 years following a gestational diabetic pregnancy. It primarily involves answering 11 questionnaires, which are mailed to your home/office. They take about 60-90 minutes to complete and can be done in one sitting or a bit at a time. There is one study visit which takes less than 1 hour and can be done at a place of your convenience (your home, office, or at Emory School of Nursing). It involves measuring height, weight, waist circumference and blood pressure. It also includes a fingerstick to assess glucose, HDL-cholesterol, triglycerides and hemoglobin A1C (a measure of average glucose over a 3-month period). The benefits to participating include some education materials and a basic cardiometabolic health assessment where you receive a copy of your results for you to keep. There is also a $25 gift card to compensate for your time.

The main inclusion criteria include:

-Age 18-45
-Gestational diabetes within the past 5 years with no history of Type 1 or Type 2 diabetes
-No history of polycystic ovary syndrome
-Not currently pregnant or breastfeeding (however, if you are, we can delay enrollment)
-Household residence to include someone >13 years of age (spouse/partner, older child)
-Not currently enrolled in a lifestyle study, a weight-loss program or consulting with a dietician.

Please let me know if you would like to know more. If you are interested in participating, we can complete a screening form by phone and go from there.

I look forward to hearing back from you and thank you again for your interest.

Sincerely,

Erin Poe Ferranti, RN, MSN, MPH
Principal Investigator

EMORY
NELL HODGSON WOODRUFF SCHOOL OF NURSING

Dear Ms. Participant:

Thank you for participating in the research study, *Dietary Quality and Cardiometabolic Risk after Gestational Diabetes.* Enclosed are the questionnaires for you to complete before our appointment. There are 11 questionnaires that may take about 1 hour total to complete. Please answer them in the order in which they appear in this packet, however, feel free to complete them at your own pace (in one sitting or at different times), but please have them done before we meet. I will collect them at our appointment. Also enclosed is the written informed consent to continue participation in this study. We will review that and sign it together at our meeting. Please do not sign the consent before the study visit. If you have any questions or concerns, do not hesitate to call me.

We can determine the appointment day and time. Since the appointment requires you to be fasting (no eating or drinking), it would be ideal if we schedule it during the morning. I will email you in a week or so to set that up.

As a reminder, during the study appointment, we will review your questionnaires. I will also be asking you about your usual physical activity, as well as taking your height, weight, waist circumference and blood pressure measurements. Finally, I will be doing a finger-stick to test your blood. You will have your lab results right away. This visit should take no longer than one hour. At the completion of all data collection procedures, you will receive a $25 gift card for your time and participation.

I look forward to seeing you. Please contact me with any concerns or questions at 404-808-3685 or epoe@emory.edu.

Thank you,

Erin Poe Ferranti, RN, MSN, MPH
Principal Investigator
PhD Candidate

Appendix C: Permissions

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Apr 10, 2013

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Duration of use	Current edition and up to 5 years
Creation of copies for the disabled	no
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For distribution to	Worldwide
In the following language(s)	Original language of publication

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Made available in the following markets	academia
Specified additional information	Adapting the figure only to focus on the two spheres of individual and social, with specific constructs in each. For the individual: demographics, depressive symptoms, and perceived beliefs. For the social: Family functioning, family food interaction and social support. The other spheres were outside the scope of the study. I would like to add an additional box below the diagram indicating "Diet Quality" and then another below that indicating "Cardiometabolic Risk".
The requesting person/organization is:	Erin Ferranti
Order reference number	
Author/Editor	Erin Ferranti
The standard identifier	Ferranti.4122013
Title	Dietary Quality and Cardiometabolic Risk after Gestational Diabetes
Publisher	ProQuest
Expected publication date	May 2015
Estimated size (pages)	300
Total (may include CCC user fee)	0.00 USD
Terms and Conditions	

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The following terms are individual to this publisher:

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Other Terms and Conditions:

None

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From: Fowles, Eileen R [efowles@mail.nur.utexas.edu]
Sent: Wednesday, March 24, 2010 3:13 PM
To: Ferranti, Erin
Subject: RE: Barriers to Healthy Eating Scale

Erin, I am sooo sorry to delay responding to you. I was out of town last week and this file was on my other computer.

OF COURSE you have my permission to use the instrument---it is attached to this message. Items 1-2 are related to transporation barriers; items 3-5 are related to cost barriers; Items 6-11 are related to ability to cook healthy meals; and items 12-16 are related to preferences. Scoring on items 1-5 are reversed so that a higher score indicates more barriers to healthy eating.

Hope this helps and I do sincerely apologize for the delay in responding.