Community Doula Support for Promoting Healthy Gestational Weight Gain: A Randomized Controlled Trial

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COMMUNITY DOULA SUPPORT FOR PROMOTING HEALTHY GESTATIONAL WEIGHT GAIN: A RANDOMIZED CONTROLLED TRIAL

A Thesis Presented to The Faculty of the School of Medicine
Yale University

In Candidacy for the degree of Master of Medical Science

April 24th, 2020

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Abstract

Appropriate gestational weight gain is important for a healthy pregnancy. Poor weight gain and excess weight gain are associated with increased risk of numerous adverse pregnancy outcomes. Doulas—trained professionals who provide continuous physical, emotional, and informational support to mothers before, during, and shortly after childbirth—have been shown to foster numerous health benefits for both mother and child. However, no studies to date have examined the effects of doula support on gestational weight gain. We propose a randomized controlled trial in pregnant women to determine whether community doulas are effective in promoting adherence to established gestational weight gain guidelines. We hypothesize that women with doula support will be more likely to adhere to recommended weight gain compared to women without doula support. The results of this study may help guide health policy towards improving access to doulas and reducing health disparities in maternal morbidity and mortality.
Chapter 1: Introduction

1.1 Background

Gestational weight gain (GWG) is the weight gained during pregnancy between conception and just before delivery of the infant. The majority of normal weight gain during pregnancy can be explained by normal physiologic changes to accommodate the growing fetus, prepare the mother for the physiologic stress of labor, and enable the mother to provide breastmilk for the infant after birth. Such changes affect every organ system of the body, and yet result in minimal residual effects in women with uncomplicated pregnancies. Those changes that contribute to normal GWG include uterine cellular division and hypertrophy, ductal growth and alveolar hypertrophy in the breasts, increased blood volume and extracellular fluid, and growth of the fetus, amniotic fluid, and placenta.\textsuperscript{1} Proper GWG is a key component of the health of both mother and child; a fine balance must be reached in order for the fetus to grow and develop appropriately, while at the same time not compromising the short-term or long-term health of the mother.\textsuperscript{1}

Inadequate and excessive weight gain during pregnancy (defined as GWG below and above the IOM GWG recommended ranges, respectively) are each associated with adverse outcomes.\textsuperscript{2} Inadequate weight gain during pregnancy has been shown to be associated with increased risk of having a small for gestational age (SGA) or low birthweight (LBW) infant,\textsuperscript{3-10} and may be associated with increased risk of preterm birth (defined as < 37 completed weeks of gestation).\textsuperscript{10-14} Evidence for increased risk for having an SGA and LBW infant points to inadequate weight gain principally in the second and third trimesters of pregnancy rather than the first trimester.\textsuperscript{8,15,16} This association may be explained by the non-linear nature of weight gain during pregnancy: weight gain tends to be slowest during the first trimester of pregnancy, and then
increases at a relatively steady rate in the second and third trimesters.\textsuperscript{17} Evidence for the association between inadequate GWG and preterm birth is less clear, given that preterm birth inherently clouds the causal relationship between the two outcomes (women who deliver early inherently have less time to gain gestational weight).\textsuperscript{17} We may therefore conclude that women with inadequate GWG are at increased risk of SGA or LBW, and that inadequate GWG may or may not increase the risk of preterm birth.

Most women in the United States gain excessive weight during their pregnancy.\textsuperscript{6,7,18} According to data from the Pregnancy Risk Assessment Monitoring System between 2010 and 2011, 47.2\% of women gained excessive weight, compared to 20.9\% with inadequate weight gain and 32.0\% with weight gain within recommended guidelines.\textsuperscript{18} Excessive GWG has been shown to be associated with numerous adverse maternal outcomes, including increased rates of hypertensive disorders of pregnancy, gestational diabetes mellitus (GDM), LGA neonates, cesarean delivery, and increased PPWR.\textsuperscript{7,8,10,19-25} Excessive maternal GWG impacts the growth and development of the offspring as well, as it is associated with increased rates of childhood obesity and asthma.\textsuperscript{23,26-33}

Women with pre-pregnancy overweight or obesity—more than half of all women of childbearing age in the US\textsuperscript{34}—are even more likely to gain excessive weight during pregnancy, at rates of 64.1\% and 63.5\% respectively.\textsuperscript{18} Obesity independently increases the risk of many adverse maternal and neonatal outcomes such as preterm birth, gestational diabetes, hypertensive disorders of pregnancy, fetal macrosomia, cesarean section, congenital anomalies, and childhood overweight/obesity.\textsuperscript{35-37} Additionally, when coupled with excess weight gain in pregnancy, maternal obesity leads to long-term maternal
obesity, and therefore long-term health risks for the mother.\textsuperscript{38} These risks are that much greater for low-income women and women of color, who have higher rates of obesity, and who face more challenges accessing healthy food or safe places to exercise in pregnancy.\textsuperscript{39-44}

A woman would ideally be counseled on losing weight prior to conception.\textsuperscript{35} However, given that nearly half of all pregnancies in the U.S. are unplanned\textsuperscript{45} and that more women than ever before are entering pregnancy with overweight or obesity,\textsuperscript{17,46} this strategy is not realistic. GWG therefore may represent a critical juncture for interventions to prevent progression to long-term overweight/obesity, and prevent obesity-related complications of future pregnancies.

Ideal GWG has been long studied and debated. A total weight gain of 6.8 kg, irrespective of prepregnancy weight, was initially recommended in the 1930s, in an attempt to limit higher birthweights and maternal weight gains.\textsuperscript{47} After numerous revisions based on up-to-date data, the Institute of Medicine (IOM) published the most recent updated guidelines in 2009, which were reaffirmed again in 2016 (Table 1).\textsuperscript{48}

\textbf{Table 1. Institute of Medicine Weight Gain Recommendations for Pregnancy}\textsuperscript{48}

<table>
<thead>
<tr>
<th>Prepregnancy Weight Category</th>
<th>Body Mass Index*</th>
<th>Recommended Range of Total Weight (lb)</th>
<th>Recommended Rates of Weight Gain** in the Second and Third Trimesters (lb) (Mean Range [lb/wk])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>Less than 18.5</td>
<td>28 – 40</td>
<td>1 (1 – 1.3)</td>
</tr>
<tr>
<td>Normal Weight</td>
<td>18.5 – 24.9</td>
<td>25 – 35</td>
<td>1 (0.8 – 1)</td>
</tr>
<tr>
<td>Overweight</td>
<td>25 – 29.9</td>
<td>15 – 25</td>
<td>0.6 (0.5 – 0.7)</td>
</tr>
<tr>
<td>Obese (includes all classes)</td>
<td>30 and greater</td>
<td>11 – 20</td>
<td>0.5 (0.4 – 0.6)</td>
</tr>
</tbody>
</table>

*Prepregnancy weight category defined by the World Health Organization\textsuperscript{49}  
**Body mass index is calculated as weight in kilograms divided by height in meters squared or as weight in pounds multiplied by 703 divided by height in inches.  
***Calculations assume a 1.1 – 4.4 lb weight gain in the first trimester.
This update is based on recent changes in U.S. demographics, with more women carrying multiples, being older, carrying more pre-pregnancy weight, and gaining excess weight during pregnancy. The current IOM guidelines recommend ranges of weight gain—to account for women of all ages, ethnicities, and heights—according to prepregnancy body mass index (BMI, a measure of body fat based on weight and height).

While it is clear why all pregnant women should adhere to the IOM GWG guidelines, it is less clear how best to help women accomplish this. The IOM recommends healthcare providers determine a woman’s BMI and discuss appropriate weight gain, diet, and exercise at her first prenatal visit. Discussions around goal weight, diet, and exercise should take place throughout the pregnancy, and providers should continue to track GWG, referring back to the guidelines as necessary. However, despite these recommendations, studies have reported that up to 50% of pregnant women are not counseled on the risks of excessive GWG during their prenatal care. Standard care groups in studies focused on reducing excess GWG have varied greatly in their inclusion of baseline diet and exercise discussions and information regarding healthy GWG. Some prenatal care providers cite lack of time, knowledge, and/or skills to initiate these discussions with their patients, or feel the discussion is futile in changing a patient’s behavior and therefore ultimate GWG outcome.

The IOM also endorses the regular monitoring and recording of prepregnancy height and weight and the use of personalized GWG charts (Appendix A)—in which the provider plots weight gain per week of pregnancy with the woman’s highlighted goal range according to her BMI—as potential tools to aid adherence to guidelines. However, such tools are underutilized, and have been shown to only marginally reduce total
GWG without significant improvement in adherence to GWG guidelines. New and effective methods to help women, especially low-SES women, achieve goal GWG are needed.

1.2 Statement of the Problem

Pregnancy presents a unique opportunity to improve health outcomes. The pregnant woman is more engaged in healthcare than perhaps any other time in her life, and is highly motivated to make healthy choices during pregnancy for the health of her child. GWG may represent a critical target for interventions to prevent adverse maternal and neonatal outcomes, and promote the long-term health and well-being of mother and child.

Most interventions focused on reducing excess GWG and/or promoting adherence to IOM GWG guidelines have been focused on diet, exercise, or both; the majority of these studies have shown minimal reductions in total GWG but no significant effect on adherence to IOM GWG guidelines. Some recent studies involving health coaching—in which allied health professionals used methods grounded in behavior change theory in order to empower pregnant women to set and achieve health goals—have shown efficacy in reducing total GWG and improving adherence to the IOM GWG guidelines, but have had no effects on adverse maternal or neonatal outcomes. Another promising study expanded on a national home-visiting program to include a lifestyle curriculum for promotion of healthy GWG. However, few studies have examined GWG interventions for low-income women and/or women of color, whom are at higher risk of adverse maternal and child outcomes yet face more barriers to attain a healthy lifestyle during pregnancy. Further research is needed to establish practical and effective strategies in prenatal care to promote not only healthy GWG, but also the short-term and long-term health outcomes for these vulnerable populations.
A literature search of Ovid Medline, Embase, and CINAHL reveals that doulas have never been studied in the context of promoting appropriate GWG. Doulas provide continuous physical, emotional, and informational support to women in the prenatal, intrapartum, and postpartum periods. Doulas have been shown to significantly reduce the risk of numerous adverse maternal and neonatal outcomes—including cesarean deliveries and preterm birth\textsuperscript{85-88}—as well as promote healthy behaviors such as breastfeeding initiation and putting infants on their backs to sleep.\textsuperscript{85,89-93} Doulas may serve even further utility as an efficient, cost-effective\textsuperscript{94} option to promote healthy GWG. Doulas may be in a unique position to influence appropriate GWG given their close personal relationships with mothers, as well as their roles in patient-provider communication, informational support, and advocacy and empowerment of mothers. Community doula programs—in which women that share similar backgrounds with their clients and incorporate home visiting—may be particularly useful for vulnerable populations.\textsuperscript{95,96} The proposed study will utilize the community doula model to promote healthy GWG.

1.3 Goals and Objectives

The goal of this study is to evaluate the ability of doulas to support women in achieving healthy GWG. This study will couple standardized GWG counselling (via the use of personalized GWG charts and provision of informational booklets on healthy GWG) with community doulas to support pregnant women achieve IOM-recommended GWG.

This study will primarily measure the proportion of women that adhere to IOM GWG guidelines. This study will also measure total GWG, various maternal and neonatal outcomes, breastfeeding initiation, duration of labor, and patient satisfaction.
This study will take place in Federally Qualified Health Centers in Connecticut, which is representative of low-income populations nationwide. If doulas can be shown to significantly improve adherence to GWG guidelines and improve other maternal and neonatal outcomes, this study may help guide health policy towards improving access to doulas and reducing health disparities for vulnerable women and children.

1.4 Hypotheses

First, we hypothesize that the proportion of women that adhere to IOM GWG guidelines will be significantly greater in the Information with Doula Support group than in the Standard Prenatal Care group.

Second, we hypothesize that the proportion of women that adhere to IOM GWG guidelines will be significantly greater in the Information with Doula Support group than in the Information-Only group.
References


Chapter 2: Review of the Literature

2.1 Introduction & Literature Search Criteria

We conducted the literature search between December 2019 and April 2020 using Ovid Medline, Embase, and CINAHL. For literature on GWG (sections 2.2 and 2.3), “gestational weight gain” was searched as a keyword and subject heading. The search was limited to randomized controlled trials published in the last 5 years. Titles and abstracts were read to determine relevance to the proposed study. Those interventions during the prenatal period that targeted GWG as either a primary or secondary outcome were included. Interventions that were done exclusively prior to conception or limited to the postpartum period were excluded. Pharmacologic interventions, feasibility studies, and studies without published results were also excluded. Additional articles relevant to the proposed study were consulted from the reference lists of these studies.

For the section on doulas (section 2.4), “doula” was searched as a keyword, which was omitted and replaced as “labor support” or “labor coach.” The search was limited to randomized controlled trials only, without constraints on year of publication. Titles and abstracts were read to determine relevance to the proposed study. Additional articles relevant to the proposed study were consulted from the reference lists of these studies.

This review of the literature will examine data on optimal GWG, risks of inadequate and excessive GWG, and the GWG guidelines; recent interventions targeting GWG; and the promise of doula support for the promotion of optimal GWG.
2.2 Overview of Optimal Gestational Weight Gain and Recommended Guidelines

2.2.1 Adverse Outcomes Associated with Inadequate Gestational Weight Gain

Both inadequate and excessive GWG have been associated with health risks to mother and child. According to the 1990 IOM report on GWG, extremes of gain have been shown to be predictive of neonatal mortality, even after controlling for gestational age.¹

Poor nutrition, while associated with overweight and obesity in the U.S. today, has been historically associated with hunger and underweight.²,³ Initial GWG guidelines, therefore, primarily focused on preventing inadequate GWG. Inadequate GWG has been associated with increased risk of having a LBW or SGA infant, and may or may not be associated with increased risk of preterm birth. The first study to examine inadequate GWG came in 1944, in which researchers examined pregnant women during the Dutch famine. This calorie restriction resulted in an average decrease in birthweight of 250 grams.⁴ Many studies and meta-analyses have since reported that women who gain inadequate gestational weight are at increased risk of intrauterine growth restriction (IUGR) during pregnancy,⁵,⁶ and up to two-fold increased risk of giving birth to an infant that is SGA or LBW.⁶⁻¹¹ These risks may be graded, with one systematic review reporting that the lower the GWG, the higher the risk of having an infant with LBW.⁶

These adverse outcomes may vary with the timing of inadequate weight gain during pregnancy. GWG is non-linear throughout pregnancy; gain is slower in the first trimester and then increases at a relatively steady rate in the second and third trimesters.¹² Nutritional insult later in pregnancy is more likely to affect fetal growth and possibly influence the initiation of labor.¹³ Studies have found inadequate GWG during the second and third trimesters is associated with increased risk for preterm birth, IUGR, and having
a baby that is SGA or LBW, but have found fewer associations for inadequate GWG during the first trimester.\textsuperscript{9,14,15}

Risks associated with inadequate GWG may be modified by parity and prepregnancy BMI. Some studies have shown that odds inadequate GWG leading to birth of a SGA or LBW infant may be greater for nulliparous women,\textsuperscript{8} implying that risks of SGA and LBW may be higher in a woman’s first pregnancy but lower in subsequent pregnancies. Related to prepregnancy BMI, women that begin their pregnancies underweight inherently have an increased risk of delivering LBW or SGA infants.\textsuperscript{16} Women with elevated BMIs, conversely, may be at decreased risk of these outcomes. Some of the studies that report positive associations between inadequate GWG and IUGR and delivery of LBW or SGA infants were not statistically significant for overweight and/or obese women,\textsuperscript{5,7,8} or found these risks to decrease with increasing BMI.\textsuperscript{6,11}

There is some evidence to suggest that inadequate GWG may also associated with increased risk of preterm birth. Many studies have reported an association between inadequate GWG and preterm delivery,\textsuperscript{11,17-20} and report that weight gain is protective against preterm delivery.\textsuperscript{17-21} Many of these studies, however, used total GWG as a primary outcome without adjusting for gestational age, confounding these associations. Without adjusting for gestational age, any positive associations between inadequate GWG and preterm birth may be reverse causation, given that women who deliver early inherently have less time to gain adequate gestational weight. In order to account for gestational age, some studies examined rate of GWG in second and third trimesters by assuming constant GWG in first trimester (assuming that first trimester gain is less informative, which isn’t supported by clear evidence).\textsuperscript{17,22,23} Other studies examined GWG up to a given gestational week achieved by all pregnancies and then determined differences among those who eventually delivered at term or preterm.\textsuperscript{11,18,19,21} Studies based on weekly
GWG or GWG up to a certain gestational age may therefore hold more clout than those studies that examine total GWG without adjusting for gestational age at the time of delivery.

The nonlinear nature of GWG contributes to this reverse causation as well, given that women who deliver early will miss out on the higher rates of GWG in the second and third trimesters of pregnancy. A large study of GWG, infant birthweight, and preterm birth among pregnant adolescent women\textsuperscript{23} found that there was no increased risk of preterm birth for those women with inadequate GWG before 24 weeks, but found 1.69 increased odds with inadequate GWG after 24 weeks gestation. Other studies\textsuperscript{24,25} have supported similar findings, suggesting that not only the total GWG but also the pattern and timing of GWG throughout pregnancy are important predictors of preterm birth.

Some protective effects may also be conferred with inadequate GWG, such as reduced risk of fetal macrosomia, LGA, and PPWR.\textsuperscript{7,8,11,26} One large retrospective cohort study\textsuperscript{7} found that inadequate GWG was associated with decreased odds of LGA, and another meta-analysis found that women with inadequate GWG had lower risks of fetal macrosomia and delivering an LGA infant than women with appropriate GWG.\textsuperscript{11} Inadequate GWG may also result in a negative PPWR,\textsuperscript{8} which may decrease a woman’s odds of future overweight or obesity.\textsuperscript{27} These benefits must be weighed with the known risks of inadequate GWG.

In conclusion, inadequate GWG is associated with various adverse outcomes such as IUGR, preterm birth, and delivering a LBW or SGA infant. These risks may be higher for women with underweight or normal BMIs than for women with overweight or obese
BMIs, and must be weighed against inadequate GWG’s risk reduction of PPWR, fetal macrosomia, and delivery of an LGA infant.

2.2.2 Adverse Outcomes Associated with Excessive Gestational Weight Gain

Excessive GWG is associated with various adverse outcomes such as increased risk of hypertensive disorders of pregnancy, GDM, delivering an LGA infant, cesarean delivery, and increased PPWR.\textsuperscript{8,9,11,28-34} Excessive GWG has also be associated with adverse outcomes for the long-term health of the child, such as increased risk of childhood obesity and asthma.\textsuperscript{32,35-42} Almost half of all women in the United States gain excessive weight during pregnancy; according to data from the Pregnancy Risk Assessment Monitoring System between 2010 and 2011, 47.2\% of women gained excessive weight.\textsuperscript{43}

Excessive GWG has been shown to be associated with increased risk of gestational hypertension and preeclampsia,\textsuperscript{8,29-32} both of which can be associated with numerous short-term and long-term adverse outcomes for the mother and fetus/infant.\textsuperscript{44,45} Obesity is a known risk factor for hypertensive disorders of pregnancy,\textsuperscript{46-49} but excessive GWG alone may be an independent risk.\textsuperscript{8,50} One Norwegian randomized controlled trial demonstrated that a one kg increase in GWG was associated with 1.3 times higher odds of preeclampsia, even after adjusting for age, education level, prepregnancy BMI, randomization, and fat mass.\textsuperscript{50} Another study found that excessive GWG was associated with increased odds of gestational hypertension, preeclampsia, and emergency cesarean delivery for both nulliparous and parous women, although the increased odds of gestational hypertension was not statistically significant for underweight or obese women.\textsuperscript{8} While the evidence for a causal relationship is inconclusive,\textsuperscript{12} excessive GWG and obesity (which predisposes women to excessive GWG)\textsuperscript{43} both seem to be modifiable risk factors for hypertensive disorders of pregnancy.
Excessive GWG is associated with increased risk of fetal macrosomia and having an LGA infant.9,11,32,33 One retrospective cohort study found that women that gained excessively were at 2.86 increased odds of delivering an LGA infant irrespective of prepregnancy BMI class,33 while another have found odds to be highest among overweight women.7 Goldstein’s review of 23 studies found excessive GWG was associated with an overall 1.85 times odds of delivering an LGA infant, with adjusted odds ratios highest for obese women and lowest for underweight women.11 Therefore, excessive GWG increases women’s risk of fetal macrosomia and delivering an LGA infant, and the risk of delivering an LGA infant is likely graded.

Women with excessive GWG or obesity may also at increased risk of cesarean delivery.8,11,32,34 A retrospective cohort study found a 6-8% increased odds of cesarean delivery for each 1-point increase in BMI during pregnancy.34 Another study found elevated risk of cesarean delivery for excessive GWG among normal weight and overweight women only.8 Similar findings were reported in Goldstein’s review, but with results statistically significant for underweight women only.11 More research is needed to further study the effects of excessive GWG on cesarean delivery across all prepregnancy BMI classes.

Women that gain excessive gestational weight have been shown to be at higher risk of increased PPWR and overweight/obesity later in life. One prospective cohort study found that excessive GWG resulted in increased risk of PPWR > 2 kg in both nulliparous and parous women of all BMI classes, but that most women returned to their prepregnant BMI class by 18 months post-partum.8 Another meta-analysis, however, suggests that increased PPWR may have a compounding effect over time; a meta-analysis of
9 observational studies found that excessive GWG was associated with an additional 3.06 kg (95% CI, 1.50-4.63 kg) and 4.72 kg (95% CI, 2.94-6.50 kg) postpartum weight at 3 and 15 years respectively, when compared to women with appropriate GWG. This increased PPWR may cause women to move to higher BMI classes, putting women at higher risk of adverse outcomes in future pregnancies, as well as long-term obesity-related complications.

In addition to adverse maternal and obstetrical outcomes, excessive GWG is also associated with adverse childhood health outcomes such as childhood obesity and childhood asthma. A large prospective cohort study found a 46% increased odds of obesity in 2-5 year-old offspring of women who gained excessively during pregnancy when compared to women that gained appropriately. Excessive GWG may also lead to permanent alterations in metabolism and affect developmental programming of later childhood, further compounding their risk of overweight/obesity of adulthood. The mother’s dietary patterns and/or chronic inflammatory state of obesity may also contribute to fetal immune and pulmonary development and eventually the development of asthma in the offspring. One review of 14 studies found slightly increased odds of childhood asthma or ever wheezing in children with mothers with high GWG, and greater odds for children with obese mothers with high GWG. Such long-term adverse outcomes for children require further exploration, but provide further evidence of long-term negative consequences of excessive GWG.

There is conflicting evidence to suggest a causal relationship between excessive GWG and GDM. Some research suggests that early excessive GWG may lead to an early increase in insulin resistance and consequent exhaustion of the pancreatic beta cells, reducing the woman’s ability to compensate for further insulin resistance in pregnancy and therefore increasing her risk of developing GDM. The IOM’s literature review for the 2009 GWG guidelines initially
found sufficient evidence to support the association between excessive GWG and GDM,\textsuperscript{12,59,61,62} but later removed the evidence from its consideration due to inconsistent definitions of GDM and heterogenous findings.\textsuperscript{12,63,64} Many studies have used total GWG to predict GDM diagnosis, which includes the weight gained following diagnosis and therefore does not control for reverse causation.\textsuperscript{65,66} Some studies suggest that only excessive GWG in \textit{early} pregnancy confers risk of GDM,\textsuperscript{32,59,62,64,67,68} while others have found associations that vary with prepregnancy BMI class.\textsuperscript{59,67,68} A retrospective cohort study found that obese women were at almost 3 times higher risk of developing GDM than normal weight women, and that excessive GWG was not associated with GDM after adjusting for prepregnancy BMI.\textsuperscript{69} Thus, the relationship between GDM, excessive GWG, and prepregnancy BMI appears to be complex.

Some protective effects are also conferred with excessive GWG. Excessive GWG may decrease the risk of preterm birth and having an SGA infant.\textsuperscript{7,8,32} One retrospective cohort study found that excessive GWG was associated with decreased odds of having an SGA infant.\textsuperscript{7} A meta-analysis reported that of six studies that examined the relationship between delivery of an SGA infant and excessive GWG, four studies found a protective effect, while two found no effect.\textsuperscript{70} Another study found excessive GWG to be protective for both preterm birth and delivering an SGA infant.\textsuperscript{32}

In order to achieve the best possible outcomes for both mother and child, the numerous known adverse outcomes associated with excessive GWG must be weighed with the possible benefits. These risks must also be considered closely with respect to prepregnancy BMI, a major confounder of the vast majority of these studies.
2.2.3 Institute of Medicine Guidelines for Gestational Weight Gain

GWG recommendations have guided prenatal care providers since the 1930s. Initially, all women were recommended to gain 6.8 kg total, regardless of prepregnancy weight, based on data that suggested that increased GWG increased infant birthweight. The guidelines were revised in 1970 to suggest a more robust total weight gain of 9.0-11.4 kg in response to growing evidence that low GWG increased the risk of LBW. The guidelines were revised yet again in 1990—in response to new data on GWG, preterm birth, and LBW—when the IOM concluded that a single recommendation was unlikely to benefit all women, and published guidelines according to BMI (low, normal, and high), as well as more specific recommendations for adolescents, African Americans, and women of short stature. Most recently, the IOM updated its guidelines in 2009, which were reaffirmed in 2016. With more women entering pregnancy at older ages and higher BMIs, women gaining more weight during pregnancy, and growing evidence of poor maternal and child health outcomes associated with overweight and obesity, the IOM’s committee examined new evidence for the causal relationship between GWG and short-term and long-term maternal and child outcomes.

Upon review of the evidence, the committee cited a number of recommendations for healthy weight gain during pregnancy. After concluding that prepregnancy BMI was an important predictor of adverse maternal and neonatal outcomes, they recommended that all women conceive at a normal BMI. However, given a record high number of women of childbearing age with obesity and that over half of all pregnancies in the U. S. are unintentional, they acknowledged that this recommendation is difficult to attain for many women. They recommended that women adhere to a range of total GWG and weekly rate of GWG per prepregnancy BMI class (Table 1). The IOM GWG guidelines are endorsed by the American College of
Obstetricians and Gynecologists (ACOG) and serve as standard of care in the U.S. as well as a number of other countries such as Canada, Denmark and Switzerland.  

Optimal GWG for overweight and obese women has been particularly difficult to define. For overweight women, the IOM recommended a specific range of 6.8-11.3 kg GWG. However, several studies demonstrated that a reduced gain of 2.7-6.4 kg had less PPWR but similar fetal growth and perinatal/neonatal outcomes compared to overweight women who gained within the recommended range.  

Similarly for obese women, studies have found recommended GWG ranges to be too restrictive.  

Studies have cited that obese women that gain less than the recommended guidelines, or even lose weight during pregnancy, may not have increased risks for adverse maternal or neonatal outcomes. Other studies have suggested that ranges of optimal GWG may vary by obesity class, although the IOM committee deemed this evidence insufficient. The IOM concluded that for overweight or obese women, healthcare providers should discuss the risks and benefits with their patients on an individual basis, and that low GWG in the setting of an appropriately growing fetus does not necessarily merit the encouragement of more weight gain.  

For all women, the IOM recommends that providers establish a woman’s prepregnancy BMI at the first visit, as well as discuss diet and exercise recommendations for the pregnancy. ACOG recommends diet and exercise counselling according to U.S. federal guidelines; diets should include balanced meals rich in protein, iron, calcium, and folic acid, with an extra 300 kcal per day during the last 6 months of pregnancy, and women should participate in at least 150 minutes of moderate aerobic activity throughout the
week during pregnancy and postpartum.\textsuperscript{93} The guidelines recommend referral to a dietician or physical activity specialist when warranted.\textsuperscript{12}

The IOM also recommends regular monitoring and recording of prepregnancy height and weight, and the sharing of personalized GWG charts (Appendix A) with the patient in order to track goal GWG for the patient’s BMI at each visit.\textsuperscript{74} Providers should share the GWG guidelines with the patient and discuss these topics throughout the pregnancy and refer back to the guidelines as needed. The guidelines call for an evaluation of modifiable risk factors that might cause women to gain inadequately or excessively, such as lack of money to buy food, chronic health conditions, stress, etc. and to connect patients with community resources and encourage involvement of family/support people when applicable.\textsuperscript{12}

According to data from the Pregnancy Risk Assessment Monitoring System between 2010 and 2011, only 32\% of women gain gestational weight within the recommended guidelines. The majority of women (47.2\%) gain excessive gestational weight, while 20.9\% gain inadequately.\textsuperscript{43} Women who are underweight are most likely to gain inadequately (39.3\%), while women who begin pregnancy at overweight or obese BMIs are more likely to gain excessively (at rates of 64.1\% and 63.5\%, respectively).\textsuperscript{43} Interestingly, although black and Latina women are disproportionately affected by obesity, they not more likely to gain excessive gestational weight than Caucasian women, with Latinas significantly less likely (RR 0.84, 95 \% CI 0.8–0.9).\textsuperscript{94}

The potential causes of excessive GWG are multifactorial. Higher rates of excessive GWG may reflect the lower ranges of optimal total and weekly GWG for overweight and obese women, but may also reflect the many social and structural factors that may contribute to excessive GWG. Women of low socioeconomic status are at higher risk of entering pregnancy with overweight or obesity,\textsuperscript{95-98} and despite limited data available to sufficiently identify a causal
relationship between socioeconomic status and GWG, it is thought that low-income women are at increased risk of both inadequate and excessive GWG.\textsuperscript{99,100} Women with few resources are more likely to exercise less, live in neighborhoods with few safe spaces for exercise, live further from the grocery store where they could access healthy food, and have diets of poor nutritional quality.\textsuperscript{101-107} Barriers such as these make it immensely difficult for low-income women to achieve a healthy lifestyle in pregnancy and adhere to recommended GWG guidelines. More research is needed to investigate how to best support this vulnerable population.

A woman is more likely to adhere to GWG guidelines if she receives GWG advice from her provider, yet provider counseling on GWG varies widely in clinical practice.\textsuperscript{108} Studies have reported that up to 50\% of pregnant women are not counseled on the risks of excessive GWG during their prenatal care.\textsuperscript{108-110} Many prenatal care providers find GWG to be a sensitive topic, and do not feel well-prepared for these discussions, citing lack of time, lack of knowledge, and lack of skill.\textsuperscript{111-113} If discussed at all, the quality and content of those discussions may be limited; many providers give inaccurate GWG information, and many more providers report that they have given counseling than patients report that they have received it.\textsuperscript{114-117} There is a clear need to improve GWG counselling and ensure that the standard of care is truly standard.

Psychosocial factors related to excess GWG have been extensively researched as well. Most women do not know about the risks posed by gaining excessive or inadequate gestational weight, and do not know appropriate GWG for their BMI class.\textsuperscript{118} Without any GWG counselling from their providers, women of higher BMIs will assume they should gain more weight, while women of lower BMIs will assume they should gain less
weight than is recommended for their BMI. Women value having conversations around weight gain and goal setting, yet may not initiate conversations themselves due to lack of knowledge around the importance of GWG, lack of trust with the provider, or poor continuity of care. Furthermore, psychosocial factors such as depressive symptoms, body image dissatisfaction, and low levels of social support and intimate relationships are also associated with greater GWG.

Given that most women gain outside the recommended GWG range, and the various adverse maternal and neonatal outcomes associated with inadequate and excess GWG, it is critical that we assist women in achieving optimal GWG. The IOM report called for more research on GWG in vulnerable populations (particularly low-income, obese women), as well as new interventions to improve adherence to optimal GWG guidelines.

### 2.3 Review of Empirical Studies Aimed at Optimizing Gestational Weight Gain

Recent interventions to promote healthy GWG have been focused on modest improvements to existing standard prenatal care, varying combinations of diet and exercise counseling, health coaching, as well as other novel interventions. Given that most women gain excessively, many interventions focused on reducing total GWG and/or the proportion of women with excessive GWG, rather than improving adherence to GWG guidelines. Overall, these interventions have resulted in modest improvement in GWG outcomes, with heterogenous results for adverse maternal and neonatal outcomes.

Some studies have built upon existing prenatal care infrastructure to determine if simple, low-cost interventions could make improvements towards healthy GWG. Some researchers have thought that simply weighing a woman at each visit may be enough to facilitate conversations between healthcare providers and patients and encourage appropriate GWG accordingly.
These studies focused on routine weighing have shown no significant difference in GWG between intervention and control groups.\textsuperscript{126-128} However, many of the studies included in this review incorporated some version of routine weighing into their study protocols, and some even provided standardized scales to study participants to encourage routine weighing and self-monitoring at home.\textsuperscript{129-132} Other tools to promote self-monitoring—such as FitBits or pedometers to track physical activity, or smartphone applications to track dietary habits—have also been used in GWG interventions with varying success.\textsuperscript{130,132-143}

Given the large discrepancy between provider reports of counselling on GWG and patient reports of having received it, some studies have focused on the standardized provision of GWG information and counselling. One study introduced a best practice electronic medical alert for prenatal care providers, which included a script for GWG counselling, guidelines for healthy GWG for the patient’s BMI, a template for documentation, and an informational handout on GWG for the patient. The best practice alert resulted in significant improvements in the rate of provider counselling on IOM-recommended GWG (from 2.6\% to 51.0\%, \( p < 0.001 \)).\textsuperscript{111} Another sent women with GDM tailored letters with GWG information and recommendations for their BMI class, and lifestyle tips to assist them in meeting their goals. The tailored letter resulted in statistically significant increases in adherence to IOM GWG guidelines (72.6\% vs. 67.1\%), as well as improvements in postpartum weight goals (41.8\% vs. 37.4\%), but without any differences in other maternal or neonatal outcomes.\textsuperscript{144} While this preliminary research is promising, more studies are needed to improve GWG counselling by prenatal care providers.

The use of personalized GWG charts may bolster standard GWG counselling (Appendix A). In one study, women that used these charts to plot their weights at home had
small but statistically significant reductions in weekly GWG (-0.02 kg/week).\textsuperscript{145} Another study used these GWG charts in an online and mobile phone application, which resulted in reduced risk of excessive GWG (RR 0.73, \( p = 0.002 \)), and reduced mean total GWG (~2.35 kg, \( p < 0.0001 \)).\textsuperscript{136} Many interventions have included these charts as part of their GWG counselling, but only some have resulted in small but significant improvements in healthy GWG.\textsuperscript{138,142,143,146-151} This simple modification may be a low-cost tool to improve standard GWG counselling.

Most recent interventions to improve adherence to GWG guidelines or reduce excessive GWG have been focused lifestyle interventions in the form of diet and/or exercise counseling during pregnancy. These interventions have varied widely in their methods, with widely varying combinations of diet (meal replacement,\textsuperscript{130,143} caloric restriction,\textsuperscript{152,153} diet counseling from registered dieticians,\textsuperscript{150,153-155} healthy recipe booklets,\textsuperscript{139,156} highly-specified diets,\textsuperscript{133,141} diet logs/self-monitoring tools,\textsuperscript{136,139,143,152} etc.) and/or exercise (exercise counselling from a physical trainer,\textsuperscript{155,157} group exercise classes,\textsuperscript{157} pedometers/FitBits to track physical activity,\textsuperscript{132,133,135,139-141,148,150,158} free gym memberships,\textsuperscript{159} etc.). Diet and/or exercise interventions have been shown to make marginal reductions in total GWG and significant reductions in excessive GWG, yet mixed evidence for improvement in maternal and neonatal outcomes.

Interventions focused on diet and/or exercise have been shown to have quite modest effects on total GWG. Of the 26 diet and/or exercise interventions reviewed for this study, just over half of the studies had statistically significant reductions in total GWG. Reductions in total GWG, if any, were quite small, ranging from ~0.4 kg\textsuperscript{160} to ~5.2 kg,\textsuperscript{154} with one intervention resulting in higher mean GWG.\textsuperscript{161} These findings are consistent with reviews and meta-analyses. One review of 12 randomized controlled trials found an average reduction in total GWG of ~1.25 kg (95% CI ~2.39 to ~0.11),\textsuperscript{162} and a 2015 Cochrane meta-analysis of 65 randomized controlled
trials on diet and/exercise concluded that only 5 studies reported mean differences of > 5 kg in total GWG.\textsuperscript{163}

Such differences in total GWG may or may not impact a woman’s adherence to IOM GWG guidelines. Our literature review concluded that of the interventions that focused on diet and/or exercise, only seven studies had any statistically significant increases in the proportion of women adhering to recommended GWG ranges or reductions in the proportion of women with excessive GWG.\textsuperscript{130,141,148,164-167} A small 2014 study of a diet and exercise intervention by Petrella et al. resulted in a large reduction in the proportion of women exceeding GWG guidelines (33.3\% of the intervention group vs. 60.1\% of the control group), however this result was only statistically significant for obese women.\textsuperscript{164} The Norwegian Fit for Delivery Trial, which included one in-person visit, weekly mailed materials on appropriate GWG and health eating/exercise, personalized GWG charts, and telephone-based feedback, resulted in a decreased proportion of women who exceeded IOM GWG guidelines (40.2\% compared with 52.1\%; P = 0.003).\textsuperscript{129} Cochrane’s 2015 meta-analysis concluded that of the 24 studies that studied the reduction in the proportion of women with excessive GWG, there was an average risk reduction of 20\% (RR 0.80, 95\% CI 0.73 to 0.87).\textsuperscript{163} Thus, studies that focused on diet, exercise, or both have been able to improve adherence to the guidelines and reduce the proportion of women with excessive GWG.

These types of interventions, however, varied widely in their impacts on adverse maternal and neonatal outcomes, and some had no statistically significant reductions in any adverse outcomes studied.\textsuperscript{130,132,141,168-171} Results of the 2015 Cochrane meta-analysis found no significant differences between groups for most maternal and neonatal
outcomes such as preterm birth, preeclampsia, induction of labor, PPWR and delivery of an SGA or LGA infant; however, pooled data suggested possible reductions in the incidence of maternal hypertension, and could not rule out possible reductions in the incidence of fetal macrosomia or cesarean delivery. Additionally, high-risk women (women with prepregnancy overweight or obesity, or who have or are at risk of GDM) may have had a 15% reduced risk of fetal macrosomia (average RR 0.85, 95% CI 0.73-1.00; moderate-quality evidence).\textsuperscript{163} Another meta-analysis found that diet alone may reduce the risk of preeclampsia, GDM, and gestational hypertension among women with overweight or obesity, but found no effect on fetal weight.\textsuperscript{172} Thus, the reduced risk of adverse outcomes offered by diet and/or exercise interventions may vary widely.

Studies involving health coaches may provide a useful framework for more individualized care to promote healthy lifestyle in pregnancy. Health coaching is a well-established, cost-effective care model for patients with chronic disease. Health coaches are allied health professionals that empower patients to adopt healthy lifestyles based in behavior change theory, problem solving, and goal-setting. Counselling may be over the phone or in person, and is tailored to meet the patient’s individual needs.\textsuperscript{173} One large international study, the DALI lifestyle study, utilized both over the phone and in-person health coaching to promote healthy eating and/or physical activity and limit GWG in obese pregnant women. The study resulted in less mean total GWG in the healthy eating and physical activity group compared to controls (\(-2.02\) kg, 95% CI \(-3.58\) to \(-0.46\) kg).\textsuperscript{174} Another health coach study resulted in an 11.0% improvement in the proportion of women adherent to GWG guidelines, although this difference was not found to be statistically significant.\textsuperscript{175} Other health coach studies have made improvements in secondary outcomes such as sleep quality, physical activity, reduced dietary glycemic load, readiness to change, and improved knowledge and understanding of the importance of and how to achieve
healthy GWG. Importantly, midwives and physicians in one study reported that having a health coach helped to facilitate conversations about weight with their patients. Health coaches may reduce stigma for sensitive topics like weight through regular contact with their clients, and may motivate them to weigh the risks and benefits, seek more information, and have discussions with their providers. Health coaches’ intermediary role in enhanced patient-provider communication may improve women’s knowledge and understanding of healthy GWG (which makes them more likely to gain gestational weight within guidelines) and further influence healthy behavior in pregnancy.

Certain aspects of interventions to promote healthy GWG may be key to intervention success or lack thereof. Interventions with a single focus may hold advantages over multi-level/mixed interventions; the interventions may be delivered in a more vigorous way if researchers are not spreading their focus over multiple components, and participant compliance may be favored for interventions that are perceived as simpler. For example, diet interventions alone were overall more effective than combined diet and exercise interventions, and even some of the most intensive lifestyle interventions lacked success. The GeliS trial, which provided an intensive intervention of lifestyle counseling on healthy diet, physical activity, healthy GWG, and self-monitoring, resulted in no significant reduction in proportion of women with excessive GWG or GDM. Intensity of study intervention, therefore, does not necessarily correlate with more robust results. Interventions that are disseminated in a more streamlined fashion may be similarly beneficial; lifestyle counselling provided by the prenatal care provider directly may be more impactful than counselling in separate appointments with registered dieticians or
Interventions that are easier (or perceived to be easier) on participants may add to study participation, feasibility, and efficacy.

Many of the interventions that focused on behavior change theory, goal-setting, self-monitoring, and patient-centered care have shown to be successful. Health coaches in particular best modeled these aspects, and importantly, formed the relationships necessary to promote behavior change, open communication, and motivation for their clients. Personal and social components of other interventions—such as supportive text messaging, motivational interviewing, group prenatal care, and provider training in healthy conversation skills—were shown to be effective and well-received by women. Considering that psychosocial factors contribute significantly to excessive GWG, interventions that involve emotional and social support are particularly interesting; forming relationships, enhancing communication/support, and individualizing care may play significant roles in the promotion of healthy GWG.

Few studies have evaluated the effects of lifestyle interventions on disadvantaged women, whom often face more barriers to access or engage in healthy behaviors. Many of the lifestyle interventions included in this review would likely not meet the needs of disadvantaged women; low-income women tend to live in areas that are further from the grocery store and lack safe spaces to exercise, and are unable to afford the higher costs of fresh nutritious foods. Furthermore, competing demands such as childcare or work are often significant barriers to attending supplementary appointments with dieticians or trainers.

One unique intervention addressed these barriers through a home visit model. This randomized controlled trial assigned 267 socioeconomically disadvantaged African-American women with overweight or obesity to an existing nationally standard home visit intervention to promote positive child development and school readiness (Parents as Teachers, or PAT), or to the
same standard home visit intervention with an embedded lifestyle intervention (PAT+) to improve adherence to GWG guidelines. Both groups received 10 biweekly home visits during pregnancy for the standard PAT curriculum, while the PAT+ group also received a lifestyle curriculum. Based on cognitive behavior change theory, the PAT+ lifestyle curriculum included self-directed goals for achieving appropriate GWG, routine self-weighing, and healthy eating and physical activity education/counselling, all of which were adapted to the individual and her circumstances. The study resulted in statistically significant less weekly (0.4 kg v. 0.5 kg per week, \( p = 0.04 \)) and total GWG (8.0 kg v. 9.6 kg, \( p = 0.02 \)) as well as significant reductions in maternal body fat and lesser relative increases in systolic blood pressure, but with no differences in other obstetrical or neonatal outcomes. Fewer women in the PAT+ gained excessive gestational weight (36.1% vs 45.9%), although this result did not reach statistical significance. While no standard prenatal care group was included in this trial, baseline data from the study’s prenatal clinic suggests that the study’s effects would have had an even greater effect if PAT+ had been compared to standard prenatal care.\(^{131}\)

The success of the PAT+ trial opens a new avenue in which to explore more effective interventions to promote healthy GWG. PAT+ successfully incorporated many methodological aspects of other successful GWG interventions—notably many of the same strategies utilized by health coaches—into a home visiting model. The home visit model may promote perceived ease of the intervention for participants, as well as allow the formation of the relationships necessary to promote behavior change. Doulas, especially community doulas, may easily step into this role for the promotion of healthy GWG.
2.4 The Benefits of Doulas

Doulas, or “labor coaches” or “laypersons,” have been essential in the age-old tradition of supporting women through childbirth. The role of the doula was modernized in the 20th century as women as births that were traditionally done at home were shifted to hospital settings. Doulas are not medical professionals, but work alongside healthcare providers to provide physical, emotional, and social support during pregnancy, labor and delivery, and the postpartum period. Typically, doulas are trained to be familiar with female anatomy and physiology, non-pharmacologic pain management techniques, and routine interventions during labor and delivery through both classes and hands-on training. They are required to attend a certain number of births and sign a code of ethics before certification. National and state regulations, however, are rare, creating a certain variability in baseline training and knowledge.

Professionally associations across the world vary widely in their educational models and philosophies according to different locations and different maternity care practices. Typically, doulas meet with women in the prenatal period to build rapport, elicit women’s pregnancy and postpartum goals, and discuss their birthing preferences. During labor and delivery, doulas support women through praise and encouragement, and helping them feel more comfortable in an unfamiliar environment. Doulas may help with relaxation techniques and physical support such as assistance with optimal positioning of the pelvis for birth or rubbing the woman’s back for comfort. Immediately following delivery, doulas facilitate contact with the baby to promote mother-child bonding and breastfeeding if desired. Doulas may also work further into the postpartum period to continue to support women with breastfeeding, soothing, and other practices to help facilitate the health and well-being of both mother and child.
Doulas also play a role in advocacy and informational support. Doulas do not give medical advice or speak for their clients, but instead serve an intermediary role. They act as advocates for the mother, bridging patient-provider communication gaps, legitimizing women’s desires for more information, and encouraging and empowering women to speak up for themselves. This woman-centered, needs-led approach supports the woman in voicing her own questions and concerns and enables her to play an active role in decision making for the health of herself and her child.\textsuperscript{185,188,192,193} For example, if an obstetrician or nurse midwife mentions that the laboring woman may need a cesarean delivery, the doula can help facilitate the conversation between the woman and her provider; the woman can more easily understand the medical risks and benefits, while the provider is made aware of the woman’s concerns and goals. Their role in advocacy is critical, especially when their clients are in such vulnerable positions such as the stress, exhaustion, pain, and fear that women often experience in labor. With the support of a doula, the woman can actively participate and make the informed decisions necessary for the health of herself and her baby.\textsuperscript{185}

Doulas’ advocacy role is sometimes perceived to create a ‘power struggle’ between the doula and the healthcare provider. Some reports of interprofessional tensions may arise from doulas being perceived as interfering with clinical care. Doulas may sometimes advocate for fewer medical interventions in obstetric care than deemed clinically necessary by the obstetrician or nurse midwife. Midwives in one qualitative study in Australia reported that doulas diminished their relationship with their patients and may overstep professional boundaries.\textsuperscript{194} However, midwives in a Swedish study have described doulas as assets to their practice, offering a continuity of care that is often
difficult to achieve with intrapartum care.\textsuperscript{195} It is possible that healthcare providers are not well trained on how to integrate doulas into hospital-based care models, likely contributing to their view that doulas interfere with clinical care.\textsuperscript{185} However, when well-integrated into the model of care, many obstetricians and midwives find that doulas are beneficial and work well as part of the care team.\textsuperscript{185,196,197}

Doulas’ emotional and social connection with women may confer many benefits. Evidence supports that having a doula during prenatal care may lower maternal stress and enhance a woman’s confidence and feelings of control over her pregnancy.\textsuperscript{185,198} Women with doula support are more likely to have a positive experience of pregnancy, birth, and mothering, and increased scores of self-worth and achievement. Women with doula support tend to be highly satisfied with their care; one meta-analysis of 26 trials for continuous support during childbirth reported that women with continuous support were less likely to report negative feelings about her childbirth experience (average RR 0.69, 95\% CI 0.59 to 0.79).\textsuperscript{199} Many immigrant and/or refugee women have reported that the involvement of a community doula enabled them to experience culturally-competent care.\textsuperscript{194,200} Many women feel close with their doulas and describe their relationships “like family,”\textsuperscript{185} possibly putting doulas in a unique position to positively influence health behaviors.

Doulas are known to confer many health benefits for both mother and child. The first known randomized controlled trial on doulas was conducted by Sosa et al. in Guatemala in 1980, in which laboring mothers were assigned to continuous doula support or standard care. Mothers in the doula group had reduced rates of cesarean delivery and meconium staining, had shorter labors, and stroked, smiled, and talked to their babies more than mothers in the standard care group.\textsuperscript{201} Studies conducted since have demonstrated that women with doula support are

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significantly less likely to undergo cesarean delivery need instrumental (forceps or vacuum extraction) vaginal birth, need oxytocin for labor induction, experience preterm birth and have a LBW baby or have a baby with a low 5-minute Apgar score.\textsuperscript{198,199,202-204}

Women with doulas are also more likely to forego pain management during labor, initiate breastfeeding, have shorter labors, attend childbirth-preparation classes, put infants on their backs to sleep, utilize car seats at three weeks post-delivery, and have overall positive childbearing experiences.\textsuperscript{185,198,199,204-208} A meta-analysis of 22 trials of continuous support during labor found that women with continuous support had shorter labors and were less likely to have a cesarean delivery, receive regional analgesia, have a baby with a low 5-minute Apgar score, or report dissatisfaction with their birthing experience. However, the meta-analysis found no statistical difference between groups for breastfeeding outcomes,\textsuperscript{199} despite individual randomized controlled trials that have reported statistically significant increased rates breastfeeding initiation.\textsuperscript{204,206,207}

Studies have shown that these benefits may be greater among vulnerable populations—such as women who are socially disadvantaged, low income, unmarried, primiparous, giving birth in a hospital without a companion, or who experience language and cultural barriers—especially if these services are delivered by community doulas.\textsuperscript{207,209} In addition to providing continuous support during labor and delivery, community doulas come from the same ethnic, religious, or cultural communities as their clients and extend doula services to the home during pregnancy and postpartum. Home visits with community doulas cover topics that focus on pregnancy health, childbirth preparation, mother-child bonding, child health, and breastfeeding.\textsuperscript{185,206,207} In one randomized controlled trial by Edwards et al., African American women either received support from a community
doula (an average of 10 prenatal and 12 postpartum home visits, in addition to continuous support during labor and delivery) or standard care. The community doula group was more likely to attempt to breastfeed (64% vs 50%; p = .02) and breastfeed > 6 weeks (29% vs 17%; p = .04), and to wait to introduce complementary food until 4 months of age (21% vs. 13%, p = 0.008). A similar community doula model was studied in 2018 in a predominantly African American and Latina population, and resulted in higher rates of breastfeeding initiation (81 vs. 74%; OR=1.72, p < .05) and reduced rates of epidural analgesia use (72 vs. 83%; OR=0.49, p<.01), but found no differences in rates of cesarean delivery, birthweight, prematurity, or postpartum depression. Despite these initial results, few studies examine the community doula model; more research is needed to determine community doulas’ effects on maternal and child outcomes.

Doulas are thought to be sought in response to deficits in modern maternity care, namely women seeking the sort of continuity of care that is not supported by the modern medical system. As little as 6% of pregnant women in the U.S. use doulas at some point in their maternity care, and tend to be white middle-upper class. Unfortunately, many barriers exist for low-income women and/or women of color to access doula services. Most medical insurers do not cover doula services, and the out-of-pocket cost of a doula (ranging from $300-$1200) is often prohibitive for women with fewer financial resources. Low-income women and women of color—who are at the higher risk of negative birth outcomes—are the most likely groups that report wanting, but not having access to doula support.

Economic analyses of doulas indicate that doulas are cost-effective. Most analyses are based on doulas’ known efficacy in reducing rates of cesarean delivery, a more costly procedure than a vaginal delivery. One study found that labor support may yield a cost saving of $424.14-$530.89 per birth, and a national analysis of Medicaid-funded births from 2013 found
that the reduced odds of cesarean delivery (40.9% lower for doula-supported births, aOR = 0.59; \( p < .001 \)) indicated likely savings in all U.S. states, even with a reimbursement rate of $300 per birth.\(^{216} \) This data has driven states to increasingly explore programs that would expand access to doula services.\(^{218} \) It is our hope that the results of this study—looking to identify further benefits doulas may offer—will add to this data and lend even more support to the expansion of coverage for doula services.

Doulas, shown to be effective in other maternal and child outcomes, have never been studied in the context of GWG. Doulas may be in a unique position to influence healthy lifestyle in pregnancy given their close personal relationships with mothers, and their roles in patient-provider communication, informational support, advocacy, and empowerment of mothers. Doulas may bridge the gap between patients and providers, creating a safe environment for patients to share goals and ask questions, and giving providers opportunities to share knowledge around healthy GWG and lifestyle in pregnancy. Community doulas may be especially useful for high-risk groups; doulas from these programs can meet women where they are to provide individually-tailored, culturally-competent support for those who typically face many barriers to healthy lifestyle in pregnancy.\(^{191,209} \) Our study will determine whether community doulas can assist vulnerable pregnant women achieve optimal GWG.

2.5 Review of Relevant Methodology

2.5.1 Study Design and Setting

Much of our proposed study design is based on previous randomized controlled trials aimed at controlling GWG. Most of these studies were designed with a wide variety of diet and/or exercise protocols group to be compared with a standard prenatal care control group.
many of which were underpowered to detect significance between groups for adherence to GWG guidelines or other maternal and/or neonatal outcomes. Among those randomized controlled trials with doulas as the intervention, no studies examined GWG as an outcome. Therefore, a large, well-designed randomized controlled trial is necessary to examine the effects of doula support on healthy GWG and maternal and neonatal outcomes.

Previous randomized controlled trials examining maternal and neonatal outcomes with doula support have taken place at a wide variety of health centers and among widely varied populations. Our proposed study will take place at all Federally Qualified Health Centers (FQHCs) that deliver prenatal care in the state of Connecticut. FQHCs serve predominantly low-income women and women of color, who are at higher risk for poor birth outcomes yet less likely to be able to afford the cost of a doula. In choosing to study the possible effect of doula care on GWG in high risk populations, our study may provide further evidence of the potential benefits of improving access to doula care.

2.5.2 Selection Criteria

Inclusion and exclusion criteria in the reviewed studies varied widely, likely due to the wide variation in duration and intensity of the GWG interventions. Almost all interventions included only singleton gestations. Only one study included parity in its selection criteria; all other studies included nulliparous and multiparous women. All studies excluded women younger than 18 years of age. Some studies limited inclusion to an upper age limit (with age cutoffs at 35, 40, 43, 45, and 49), but most studies had no cap on maternal age. Many studies included overweight/obese women only and some studied women diagnosed with or at high
risk for GDM only.\textsuperscript{59,131,169} Although it is reasonable to study only these populations given their higher risk of gaining excessive gestational weight,\textsuperscript{43} this approach limits external validity.

Among reviewed studies, there was wide variability in gestational age at time of recruitment. Some studies limited inclusion to as early as \( \leq 14 \) weeks gestation,\textsuperscript{145,159} with the majority limiting inclusion to \(< 20 \) weeks gestation. Among the randomized controlled trials with doula interventions, some included women with gestational age of the fetus as late as \( 34 \) weeks at the time of recruitment.\textsuperscript{206,207,209,228,234} Given these trends and the general trends in GWG—slow in the first trimester and significant steady rates of gain in the second and third trimesters—it is important to begin an intervention earlier in the pregnancy, when possible.

Most studies excluded women with a wide variety of medical conditions that may affect birth outcomes and/or healthy GWG: preexisting diagnosis of diabetes mellitus types 1 or 2,\textsuperscript{138-142,150,153,158,166,170,171,174,219,223,233,235} history or current diagnosis of gestational diabetes,\textsuperscript{166,167,174,219,223,233} other metabolic disorder indicating primary need for nutritional advice,\textsuperscript{137,153,236} Crohn disease,\textsuperscript{236} chronic kidney disease,\textsuperscript{236} “complicated pregnancy,”\textsuperscript{149,152,165,166} untreated thyroid disease,\textsuperscript{139,140,143,164,170,220} history of or current eating disorder,\textsuperscript{135,146,150,237} prior bariatric surgery,\textsuperscript{137,141,143,153,164} major emotional or psychiatric conditions,\textsuperscript{130,132,135,139,143,148,160,170,174,222,223,232} and current tobacco or other substance use.\textsuperscript{126,130,131,133,135,137,140,141,143,148,155,160,164,170,171,219,222,223,233,235} Chronic kidney disease would be a major consideration in a trial with a strict dietary component, but would otherwise not affect participation or outcomes. Women with a “complicated pregnancy” will still receive all prenatal care and referrals necessary for healthy pregnancy, and so should be included in order to maintain external validity.
2.5.3 Randomization and Blinding Technique

All trials randomized their subjects. Among those trials that explicitly described their randomization techniques, the vast majority used computer-generated random assignment to treatment or control by fixed allocation blocks. Some trials stratified the blocks based on race/ethnicity, maternal age, prepregnancy BMI, income, health center, facility size, parity, presence or absence of risk factors, and smoking status. It is important to stratify block randomization in order to minimize selection bias.

Most GWG interventions were not blinded at all, while some trials were single-blinded and one was double-blinded. Blinding subjects in this study would be difficult due to the nature of doula care, however investigators and study staff may be blinded to group assignment.

2.5.4 Intervention

Our Information-Only intervention will largely be based off of Jeffries et al. and Ronnberg et al., both of which reviewed IOM guidelines for healthy GWG with mothers during their antenatal care and provided personalized GWG charts (Appendix A) highlighting the mother’s weekly and total goal ranges.

Our information with doula support intervention will largely be based off of three randomized controlled trials that utilized the community doula model. There was variation between studies regarding the number of antepartum, peripartum, and postpartum visits or points of contact to be made between doulas and mothers (ranging 8-12 prenatal contacts and 1-12 postpartum contacts). All doulas in the interventions had roots in the communities they served, and all underwent pre-determined training and certification, although this varied widely.
2.5.5 Confounding Variables

Prepregnancy BMI category is a known confounder in adherence to GWG guidelines. Overweight and obese pregnant women are more likely to gain excessive gestational weight.\(^{238}\) Overweight and obese women are also more likely to give birth to a neonate with macrosomia, regardless of GWG within or outside the IOM guidelines.\(^ {239}\) Among the trials reviewed, many of the trials included only overweight and/or obese women,\(^ {130-133,135,137-236}\) limiting the studies’ external validity. Studies may include women of all BMI categories if women are randomized in blocks stratified by prepregnancy BMI to assure baseline uniformity between groups, and post-hoc tests are run between groups for all prepregnancy BMI categories.

2.5.6 Primary and Secondary Outcome Measures

The vast majority of studies reviewed measured mean total GWG\(^ {126,132,133,141,143,151,153,158,161,165,167,169,174,176,221,233,235,237}\) and/or proportion of women gaining excessive gestational weight\(^ {131,132,137,146,149,164,165,167,176,222,232}\) as primary outcomes. While total GWG, a continuous variable, is an easier choice to power the study, the IOM recommends GWG ranges based on clinical data for optimal maternal and neonatal outcomes. A small difference in total GWG between groups may be a reportable outcome for a given intervention, but may not make a clinically significant difference in maternal or neonatal outcomes. Measuring the proportion of women that gain excessive gestational weight may not account for those women that gain inadequately, which is also associated with adverse outcomes.\(^ {4-11,17-20}\) Measuring the proportion of women that adhere to IOM GWG guidelines is important to determine the intervention’s effect on clinically optimal GWG.
Secondary outcomes for our study are based on results of randomized controlled trials that targeted GWG, as well as both randomized controlled trials and observational studies on doula support. Some GWG interventions included in this literature review were associated with several positive maternal and neonatal outcomes: reductions in the incidence of LGA/fetal macrosomia, low birthweight, hypertensive disorders of pregnancy, GDM, cesarean sections, preterm birth, PPWR, and length of postpartum stay in the hospital. Shoulder dystocia was also commonly included as a secondary outcome, although no studies in our review reported statistically significant differences.

Results of several doula interventions have shown that community doulas may increase rates of breastfeeding initiation and reduce rates of cesarean and operative vaginal deliveries. Doula studies also measured induction of labor, patient satisfaction with care, length of hospital stay and duration of labor as secondary outcomes.

2.5.7 Statistical Significance and Power

The vast majority of randomized controlled trials targeting GWG chose a significance level of 5% and a power of 80%. This was true also among those studies with the same primary outcome as our study. Other trials either did not study the same primary outcome, or did not report on their selection of statistical significance and power.

2.5.8 Sample Size Calculation

Our sample size has been calculated so that it is large enough to find a significant effect size in the primary outcome: proportion of women that gain within IOM GWG guidelines. Given that there are no studies to date examining the effect of doula support on GWG, we will use data from a study on health coaches. Health coaches are qualified health professionals who use...
behavior change theory to support clients in achieving their health goals, and assist clinicians to improve the overall health of the client. The relationship formed between the coach and client, as well as the breadth of health and wellness topics they counsel on, may be equated to the kinds of services a community doula or labor coach would provide.175,206,207

Our sample size will be based on a 2019 study by Rissel et al., which randomly assigned pregnant women to receive information only or a telephone-based health coach intervention. Women in the information only arm received GWG counselling from their providers, had one 20-30-minute information-only telephone call about appropriate GWG, and received written materials on weight gain in pregnancy. Women in the health coach arm received up to 10 health coaching calls in which they were counseled on many of the same topics a community doula or labor coach would counsel on, such as common problems in pregnancy, the benefits of breastfeeding, healthy eating, and other pregnancy health topics. 42.9% of women in the health coach arm adhered to IOM GWG guidelines, compared to just 31.9% in the information-only arm, a 34% relative effect175. Given that provision of information has been shown to be more effective than standard care in improving women’s adherence to GWG guidelines,144 our study assumes that our doula intervention—equated to the health coach intervention—will have an even greater effect on the standard care group. We will therefore use a 34% relative effect of the health coach intervention to calculate our sample size.

Our expected rate of attrition will be based on data from the 2016 national birth file. Among women who receive prenatal care in the first trimester, 1.2% receive inadequate care (defined as < 50% of recommended prenatal visits) by the end pregnancy.
indicating dropout and/or lost to follow-up.\textsuperscript{241} We will round this rate to 2\% attrition for our study.

2.6 Conclusion and Rationale for Proposed Study

Lifestyle and other interventions to promote healthy GWG or reduce excessive GWG have lacked consistency in methodology and results. While some lifestyle interventions have been wildly successful in their GWG outcomes, others (some even more intensive) interventions have resulted in no statistically significant differences between groups. Furthermore, the wide heterogeneity of their effect in reducing adverse maternal and neonatal outcomes—the very purpose of recommending specific GWG ranges—may negate any positive GWG outcomes found. Regardless, some trends in intervention design stand out: provision of baseline GWG information by medical providers, the use of personalized GWG charts, perceived simplicity in design and execution, individualization and/or social components, and home visiting. Doulas, although never studied in the context of GWG, have been shown to be beneficial in numerous maternal and neonatal outcomes, and show promise as a convenient and efficient option to support women in healthy behaviors in pregnancy and postpartum. Community doulas may be especially important for vulnerable women, who have more difficulty achieving healthy lifestyles in pregnancy. Studying community doula support for women seeking prenatal care at FQHCs—representative of low-income groups nationwide\textsuperscript{231}—may reveal a novel intervention to promote healthy GWG and improve maternal and neonatal outcomes among these vulnerable populations.

Important methodology considerations include randomizing and stratifying by prepregnancy BMI and parity (including post-hoc analyses), beginning the intervention early in pregnancy, assigning minimum numbers of prenatal and postpartum doula visits, excluding women
that may have preexisting conditions that would affect GWG, and powering the study to the proportion of women adherent to GWG guidelines.
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Chapter 3: Methods

3.1 Study Design

We will conduct a prospective multi-centered randomized controlled trial among pregnant women receiving prenatal care at Ferally Qualified Health Centers (FQHCs) in the state of Connecticut. Women will be randomized to one of three groups: Standard Prenatal Care, Information-Only, or Information with Doula Support. Women randomized to the Standard Prenatal Care group will attend regularly scheduled visits with prenatal care providers and receive standard nutrition and physical activity counseling. Women in the Information-Only group will receive standard prenatal care, with extra information on healthy GWG (including a discussion about GWG with their prenatal care providers, an informational booklet on GWG (Appendix D), and personalized GWG chart (Appendix A) to track their GWG with their provider). Women in the Information with Doula Support Group will receive the same information as the Information-Only group, and be assigned community doulas with whom they will work for the remainder of their pregnancy until 6 weeks postpartum.

3.2 Study Population and Sampling

The study population will include all pregnant women seeking prenatal care at FQHCs in Connecticut that meet our inclusion criteria. The study will include all pregnant women who are age 18 years or older and ≤ 16 weeks singleton gestation, and who speak English, Spanish, or both. Following scheduling of the woman’s first prenatal appointment and medical record screening by a member of the research team, eligible women will be identified and contacted via phone to give informed consent. A medical clearance letter (Appendix B) will be requested from the patient’s provider verifying that the woman meets eligibility criteria for the study. Women will be excluded from the study if they have a multi-fetal gestation, have type 1 or 2 diabetes
mellitus, have an untreated thyroid disease or other condition that might affect body weight, have a history of bariatric surgery or significant recent weight loss (> 4.5 kg in past 3 months), or have an unstable emotional or psychiatric condition that would interfere with their participation in the study. After agreeing to participate and providing informed consent (Appendix C), women will be electronically randomized in blocks stratified by prepregnancy BMI category and parity to one of three arms: Standard Prenatal Care, Information-Only, or Information with Doula Support. Randomization status will be concealed in opaque envelopes prepared by the study statistician, and statistical analyses will be performed blinded for allocation.

3.3 Subject Protection and Confidentiality

This study proposal will be reviewed by The Program of Applied Translational Research (PATR), a program dedicated to the development and design of clinical studies and trials within the Yale School of Medicine. This program will convene various physicians and scientists with expertise in GWG to review and approve this study, and then submit the study proposal to the Institutional Review Board (IRB) at study centers. In addition to the information provided in the current version of this proposal, our study will provide comprehensive details on funding resources, members of the research team, training to be completed by research staff and doulas, and protective measures to be taken to ensure participant confidentiality.

Our study will require all participants to provide and sign informed consent (Appendix C), and provide a copy of the signed consent form for the participants’ personal records. All research staff will successfully complete Health Insurance Portability and Accountability Act (HIPAA) training prior to study initiation. Participants will be given a brochure detailing their rights under HIPAA prior to signing informed consent.
Participant medical information and other information obtained throughout the study will be stored on a secure server with data encryption software. This information will be password-protected and only accessible to members of the research team. Participant identifiers will be replaced by a computer-generated, randomized identification numbers accessible to members of the research team only.

3.4 Recruitment

Researchers will screen all pregnant women at least 18 years old and ≤ 16 weeks gestation seeking prenatal care at a Federally Qualified Health Center in Connecticut. Researchers will review the potential participants’ medical records to screen for any exclusion criteria that would otherwise make them ineligible for the study, and will obtain a medical clearance letter from their healthcare provider (Appendix B). Researchers will call the potential participants following scheduling of their first prenatal care appointment and provide informed consent (Appendix C). All patients deemed ineligible for the study will be notified by recruiters, and personal identifiers/study identification number will be destroyed.

3.5 Allocation of Intervention

All participants who meet selection criteria and give informed consent will be randomized to one of three groups upon study enrollment: Standard Prenatal Care, Information-Only, and Information with Doula Support. Participants allocated to the Standard Prenatal Care group will attend all regularly schedule prenatal visits, and receive standard GWG, nutrition, and physical activity counseling at the discretion of their prenatal care providers (in accordance with ACOG recommendations). Referrals to registered dieticians and/or other specialists will be made as the provider deems necessary. Participants
will have a routine postpartum visit 6 weeks after delivery. Weight will be recorded at every pre-
natal and postpartum visit, as well as just before delivery.

Participants allocated to the Information-Only group will receive the same care as the
Standard Prenatal Care group, but will also have a discussion about healthy GWG with their pre-
natal care provider at their first prenatal visit. Participants will also receive a personalized GWG
chart (Appendix A) and informational booklet on healthy GWG (Appendix D) at their first visit.
Providers will encourage participants to use the chart to plot their weight gain at home, and will
also plot their weight at each prenatal visit on a chart embedded in the participant’s electronic
medical record. Participants will be weighed at every prenatal and postpartum visit, and provid-
ers will refer back to IOM GWG guidelines and counsel on GWG as they deem necessary.

Participants allocated to the Information with Doula Support group will receive the same
care as the Information-Only group, but will be assigned to a community doula. Community dou-
las will be certified by an accredited training program but will otherwise not receive further edu-
cation on healthy GWG or healthy lifestyle in pregnancy in order to maintain external validity.
Doulas will reside in the same areas as the FQHC prenatal clinics. Participants will be assigned a
doula who speaks the same language (English or Spanish). The doula will be introduced to the
participant by her prenatal care provider at her first prenatal visit. The doula and participant will
then schedule a time and place to meet at the participant’s convenience, in order to review expec-
tations; go over goals and expectations for the participant’s prenatal, intrapartum, and postpartum
care; and discuss how the doula may best help the participant achieve her goals. The community
doula will attend all prenatal care visits with the participant, and will meet her a minimum of 8
times outside of the prenatal care clinic (at the participant’s home, at the local park or grocery
store, etc.) in order to counsel the participants on various wellness topics, such as childbirth.
breastfeeding, pregnancy health, and newborn care. Doulas will refer participants to information provided at prenatal visits, and otherwise encourage participants to ask questions and/or seek information from their providers, as needed. The doula will provide continuous support during the participant’s labor and delivery, and will stay with her and the child for up to 2 hours after birth to assist with mother-child bonding and breastfeeding, if the participant desires. Doulas will meet with participants at least 3 times in the postpartum period to assist with feeding and soothing practices, and otherwise troubleshoot any issues. Doulas’ last contact with participants will be at the 6-week postpartum visit.

3.6 Statistical Analysis and Multi-Variate Analysis Description

Baseline characteristics among the three groups will be presented as frequencies for categorical variables (prepregnancy BMI class, race, education, and parity), and means with standard deviations for continuous variables (maternal age at enrollment, week of gestation at study entry, and BMI).

Differences between groups for the study’s primary outcome—proportion of women adherent to GWG guidelines—will be detected via $\chi^2$ test. For continuous variables (PPWR, total GWG, duration of labor), differences between groups will be detected via ANOVA (if normally distributed) or Kruskal Wallis tests (if not normally distributed). For categorical variables (LGA, fetal macrosomia, SGA, gestational hypertension, preeclampsia/eclampsia, GDM, unplanned cesarean delivery, preterm birth, induction of labor, shoulder dystocia, antepartum hospitalization, length of postpartum hospital stay $\geq$ 4 days, patient satisfaction with care, use of epidural analgesia, and breastfeeding initiation), differences between groups will be detected via $\chi^2$ test. All variables will undergo post-hoc tests between all prepregnancy BMI classes, and between nulliparous and multiparous women. All data included for primary analysis will from full-term
deliveries only; secondary analysis will be performed for preterm deliveries after adjusting for gestational age at the time of delivery. A $p$-value of $< 0.05$ will be defined as significant. All analyses will be by intention-to-treat.

### 3.7 Study Variables, Measures, and Collection Methods

All data will be collected from medical records of prenatal appointments, labor and delivery, and at the patient’s 6 weeks postpartum visit. Each group will be weighed at each prenatal appointment using standardized scales provided by the study. Prepregnancy BMI category will be calculated based on self-reported prepregnancy weight, and height recorded at her first prenatal care appointment. Total GWG will be calculated based on self-reported prepregnancy weight and final weight recorded before delivery. Fetal weight will be estimated from any ultrasound performed during the third trimester of pregnancy. Pre- and post-intervention questionnaires will be administered at the first prenatal visit and 6-week postpartum visit, respectively.

The primary outcome of the study will be the proportion of women that adhere to IOM total GWG guidelines. Secondary outcomes of the study will include PPWR, total GWG, duration of labor, LGA, fetal macrosomia, SGA, gestational hypertension, preeclampsia/eclampsia, GDM, unplanned cesarean delivery, preterm birth, induction of labor, shoulder dystocia, antepartum hospitalization, length of postpartum hospital stay, patient satisfaction with care, use of epidural analgesia, and breastfeeding initiation. These outcomes will be assessed via medical chart review.

### 3.8 Sample Size Calculation

For a thorough rationale for the selection of control and intervention values for our sample size calculation, please refer to the sample size section in Chapter 2. Sample size was calculated using Power and Precision software for $\chi^2$ test of two independent samples. The study will be
powered at 80% to detect an effect size of at least 34% increase in the proportion of women adherent to IOM GWG guidelines between the Information with Doula Support group and Standard Care group, as well as between the Information with Doula Support group and the Information-Only group. The sample size is calculated assuming a two-tailed alpha of 0.05 and a beta of 0.20. With an attrition rate of 2%, we estimate that we will need a sample size of 372 in each study group, a total sample size of 1,116 participants.

3.9 Timeline and Resources

The study will take place over 2 years, including recruitment and protocol completion. Prior to recruitment, we anticipate that the Human Investigation Committee (HIC) will need 2-3 months to approve the project. Rolling recruitment will begin in Spring of 2021 and continue over 13 months. Participants will be randomized to the Standard Prenatal Care group, Information-Only group, or Information with Doula Support group immediately following study enrollment. Study protocol will be administered as participants are randomized throughout the rolling recruitment period, and will continue for 11 more months until study completion. We expect data analysis will take place in the 2-3 months following study completion.
Chapter 4: Conclusion

4.1 Advantages and Disadvantages

This is the first study that aims to test the effects of doulas, in comparison to various forms of support currently given to women in prenatal care. Given that GWG have never been studied in the context of doulas, we used data from health coaches to power our study. Assuming that health coaches confer similar benefits to doulas may be an over- or underestimation of doulas’ effects, and the study may be underpowered as a result. However, given health coaches’ goal-directed methods and the relationships formed with clients, we believe doulas will be at least as effective. This extrapolation is unavoidable given the novelty of the proposed intervention.

Secondary outcomes for the study will not be sufficiently powered. This is an unavoidable disadvantage of the study, but will lend data towards the benefits offered by community doulas and assist with future research. Additionally, our primary outcome (proportion of women adherent to GWG guidelines) inherently requires us to power the study for women who deliver at term. Therefore, data from mothers and children who deliver preterm must be analyzed separately in order to account for GWG in the context of gestational age at the time of delivery. Despite this lack of power, data from preterm births will be useful for future studies examining GWG in women who do not deliver at term.

Blinding is not possible due to the nature of the study. Participants in the intervention groups will be aware of the treatment they are receiving and may therefore experience a placebo effect. Data collectors and outcome assessors will, however, be blinded in order to avoid detection bias.
Self-reported prepregnancy weight may lead to misclassification of prepregnancy BMI. Studies have shown, however, that self-reported prepregnancy weight is a fairly accurate and practical way to predict actual prepregnancy BMI. Women will also be randomized and stratified by BMI and parity to limit confounding of the intervention groups, and ensures that any demographic differences between groups are by chance alone.

Using certified community doulas from accredited training programs, may limit the external validity of our study. Given that the community doula model has no national standard for training and/or certification, this may vary widely by program and make the study difficult to reproduce. Curriculum for these training programs is accessible to the general public, however, which may aid future research on the subject.

Lastly, this study will take place in prenatal care clinics in FQHCs across Connecticut, inherently limiting the study’s external validity. However, the methodology, broad design, and specific strategies to promote recommended GWG would likely work for other low-income populations nationwide.

4.2 Clinical and Public Health Implications

This study is the first to examine the effects of doulas on GWG. Doula support, known to be both beneficial for mom and baby, may improve other pregnancy outcomes not yet studied. Doulas’ strong bonds with women puts them in a unique position to influence behavior, especially at a time in women’s lives when then are most likely to make healthy choices. Doulas’ relationships with mothers may improve their self-efficacy and feeling of control over their pregnancy and outcomes, empowering them to improve their own health and the health of their children. Doulas may also significantly improve communication between the women and their providers; doulas may encourage women to ask
more questions or seek more information, assist providers in their understanding of their patients’ needs and goals, and create the necessary space for providers and their patients to have discussions around healthy pregnancy and healthy weight gain.

Elevating the doula’s role in standard prenatal care via the community doula model may prove to be a practical, cost-effective way to improve outcomes for women and children. Community doulas may be especially beneficial for low-income women, who face many barriers in achieving healthy GWG. Providing extra information and support for these women in an individualized, woman-centered manner may help women meet many health goals for herself and her baby. If successful, this study will lend further evidence towards the health benefits of doulas, and propose a new cost-effective way to promote healthy GWG.
References

Appendices

Appendix A: Personalized GWG Charts.¹ To be provided to all patients in Information-Only and Information with Doula Support groups

[Graphs showing recommended pregnancy weight gain for underweight and normal weight mothers, with weight gain in pounds and kilograms.]
Recommended Pregnancy Weight Gain
for overweight mothers

This graph displays the median (solid color) and range (faded color) of recommended weight gain (lbs) for pregnant women within overweight BMI categories.

Recommended Pregnancy Weight Gain
for obese mothers

This graph displays the median (solid color) and range (faded color) of recommended weight gain (lbs) for pregnant women within obese BMI categories.
Appendix B: Medical Clearance Letter

MEDICAL CLEARANCE FOR CLINICAL TRIAL WITH INFORMATION AND/OR DOULA SUPPORT

Patient name: __________________________________________

DOB: ____________________________

Initial each of the following eligibility criteria for the patient:

___ 18 years of age or older
___ ≤ 16 weeks singleton gestation
___ Speaks English or Spanish or both
___ No known diagnosis of diabetes mellitus type 1 or 2
___ No known/untreated thyroid disease
___ No history of bariatric surgery
___ No significant recent weight loss (> 4.5 kg in past 3 months)
___ No other known condition that would affect body weight
___ No known unstable emotional or psychiatric condition that would interfere with study participation

I, __________________________________________ (MD/DO/APRN/PA) have examined this patient, checked appropriate lab work and tests, and certify that to the best of my knowledge there is no known medical contraindication for receiving extra information regarding pregnancy health and/or having doula support throughout prenatal, intrapartum, and postpartum care.

If special instructions are required, I have indicated them here:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

_______________________________________________  __________________________
Provider’s name                             Degree

_______________________________________________  __________________________
Provider’s signature                         Date
Appendix C: Consent

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 7 (2016-1)

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH
CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Study Title: Community Doula Support for Promotion of Healthy Gestational Weight Gain: A Randomized Controlled Trial
Principal Investigator: Katherine Campbell, MD, MPH

Invitation to Participate and Brief Description of the Project
You are invited to participate in a research study. The primary purpose of this study is to test an intervention designed to improve long-term non-communicable disease (NCD) outcomes in mothers and their children. The study will determine whether a community doula intervention or information-only intervention can successfully improve adherence to the optimal pregnancy weight gain range for your body mass index (your weight for your height). You have been asked to participate because you are pregnant and currently receiving prenatal care.

In order to decide whether or not you wish to be a part of this research study, you should know enough about the risks and benefits of the interventions to make an informed decision. This consent form gives you detailed information about the research study, which will be discussed with you by a member of the research team. This discussion will cover all aspects of the research, including the purpose of the study, the interventions, the risks and benefits of the interventions, and possible alternative treatments. Once you understand the study, you will be asked if you would like to participate; if so, you will be asked to sign this form. This process is known as informed consent. You will receive a copy of this signed form for your records.

Description of Procedures
We expect that a total of 1,110 pregnant women will be enrolled into the study. If you agree to participate in the study, your participation will begin today and continue throughout your prenatal and postpartum care until 6 weeks postpartum. During that time, you will continue to attend all routinely scheduled prenatal care visits at your prenatal clinic. There will be three study groups; you will be randomly assigned to “standard prenatal care,” “information-only,” or “information with doula support.”

If you decide to participate in the study, we will ask you to complete a few activities today that will take approximately 1 hour to complete:
1. We will measure your height and weight
2. We will ask you to complete some questionnaires that ask about you, your health, and some general information about your current family
After you complete these activities, you will be “randomized” into one of three study groups for the remainder of the study. Randomization means that you are put into a group by chance. It is like flipping a coin and you will have an equal chance of being placed in one of the three groups.

1. **Standard Prenatal Care Group**

   If you are randomized to the Standard Prenatal Care group, you will continue to attend your routine prenatal care visits at your prenatal care clinic for the duration of your pregnancy. Your appointments will be scheduled with your provider, and you will receive standard pregnancy education, testing, and treatment (if required). You will attend your routine postpartum visit with your prenatal care provider 6 weeks after giving birth, and will complete an assessment at that visit. Your weight will be recorded at every prenatal and postpartum visit, as well as just before delivery.

2. **Information-Only Group**

   If you are randomized to the Information-Only group, you will continue to attend your routine prenatal care visits at your prenatal care clinic for the duration of your pregnancy. Your appointments will be scheduled with your provider, and you will receive standard pregnancy education, testing, and treatment (if required). During your first visit, your prenatal care provider will discuss healthy pregnancy weight gain, provide you with a personalized chart for you and your provider to track gestational weight at each visit, and provide you with an informational booklet on healthy pregnancy weight gain. You will also attend your routine postpartum visit with your prenatal care provider 6 weeks after giving birth, and will complete an assessment at that visit. Your weight will be recorded at every prenatal and postpartum visit, as well as just before delivery.

3. **Information with Doula Support Group**

   If you are randomized to the Information with Doula Support group, you will be assigned to a community doula, who will work with you throughout your pregnancy, labor and delivery, and the postpartum period. Community doulas are not medical professionals, but have training and experience focused on pregnancy and childbirth. Community doulas offer continuous physical, emotional, and informational support to mothers before, during, and after childbirth.

   You will meet your doula at your first prenatal care visit. You will attend the visit together, along with any other support person you would like, and will attend all prenatal care visits together going forward. Your appointments will be scheduled with your provider, and you will receive standard pregnancy education, testing, and treatment (if required). During your first visit, your prenatal care provider will discuss healthy pregnancy weight gain, provide you with a personalized chart for you and your provider to track gestational weight at each visit, and provide you with an informational booklet on healthy pregnancy weight gain.

   You and your doula will set aside time after the appointment or another time so that your doula can go over your goals regarding yours and your baby’s health and wellness, and brainstorm how she may help you achieve those goals throughout the pregnancy and postpartum period. You and your doula will work together to schedule a minimum of 8 visits throughout your pregnancy, in which you and your doula will discuss various health and wellness topics such as pregnancy health, childbirth preparation, fetal and infant bonding, and breastfeeding, among others. These visits could take place in your home, or they could be at a coffee shop.
near your workplace, at the park so you can walk together, at the grocery store to assist with food shopping, etc. Your doula will be flexible to meet your needs.

Your doula will support you at the hospital during your labor and birth. She will assist you physically and emotionally throughout labor, as well as seek out/share information from or coordinate with your obstetrician or nurse midwife. Following birth, she will stay with you and your baby for up to 2 hours to help facilitate bonding with your baby and provide breastfeeding support if desired.

Your doula will meet with you at least 3 times in the 6 weeks following birth, and will be available by phone up to 6 weeks postpartum to answer questions, troubleshoot any issues, and otherwise support the health and wellness of you and your baby. You and your doula will attend your routine postpartum visit with your prenatal care provider 6 weeks after giving birth, and will complete an assessment at that visit. Your weight will be recorded at every prenatal and postpartum visit, as well as just before delivery.

Follow-Up Assessments
Regardless of the group you are assigned to, you will complete a follow-up assessment. This will be similar to the assessment you complete today.
1. We will measure your height and weight
2. We will ask you to complete some questionnaires about your pregnancy health, your baby’s health, you infant feeding practices, and satisfaction with your prenatal care.

Medical Record Review
If you agree to participate in the study, we will access your medical records pertaining to your current pregnancy, including medical records for your baby’s first 6 weeks of life. We will do this so that we can collect some objective information about you and your baby’s health during pregnancy and postpartum.

A description of this clinical trial will be available at www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You will be told of any significant new findings that develop during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences
The risks of participating in this study are considered to be small. There are no physical risks associated with participating in this study. Some of the questions in the initial and follow-up questionnaires may make you feel uncomfortable. If this occurs, you may refuse to answer. There is also a possible risk of breach of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Participation in this study may involve risks that are not currently known.

If you are assigned to the Information with Doula Support group, you may feel uncomfortable discussing personal information with a doula. The doula will work with you to try to make you comfortable and meet your goals, however this is something you should consider before consenting to be a part of the study.
Regardless of what intervention arm you are assigned to, you will be working with a prenatal care provider—obstetrician or nurse midwife—who is certified to practice in the U.S. He or she closely follows the prenatal curriculum set by the American College of Obstetrics and Gynecology and/or the Association of Women's Health, Obstetric and Neonatal Nurses standard.

The information provided on pregnancy weight gain and pregnancy health in general is considered standard of care in the U.S. If you are assigned to the Information with Doula Support group, your doula will not be permitted to share knowledge that differs from that which is shared by your prenatal care provider. She will only refer back to information already given in the informational given or discussed during a prenatal care appointment, or assist you in seeking information from the prenatal care provider directly. Your weight will be monitored at each prenatal care visit and your prenatal care provider will adjust lifestyle and weight gain recommendations for you at his/her discretion if necessary.

Benefits
There are many benefits of participating in this study. If you are assigned to the Information-Only group, you are likely to receive all the knowledge benefits of healthy weight gain in pregnancy, which may assist you in goal pregnancy weight gain and consequently reduce the risk of some complications for you and your baby. If you are assigned to the Information with Doula Support group, you will receive the same benefits, plus the added benefits that doulas provide, such as reduced risk of needing an emergency c-section and help with breastfeeding your baby. Regardless of the group you are assigned, we hope that just by participating in this intervention you may be more inclined to think more about your health choices that impact you and your baby. Generally speaking, we hope that the results of this study help scientists and clinicians improve the health of mothers and children and explore different ways we can optimize their outcomes.

Economic Considerations
There will be no change in the cost of your prenatal or obstetric care if you choose to enroll in this study. You will still be responsible for all of your prenatal/obstetric/postpartum costs and copays. Choosing to participate in this study will not affect your access to the prenatal clinic.

Treatment/Study Alternatives
You may elect to receive standard prenatal care from your prenatal clinic without enrolling in this study. If you would like further information on how you can reduce your risks of complications for you and your baby, you may ask your prenatal care provider for this information. If you wish to have a doula for your labor and delivery without participating in the study, you may call your insurance company and ask if they cover this type of service, or you may use a local agency and pay out-of-pocket. If you desire more information on breastfeeding, you may contact your local WIC office.

Confidentiality
All identifiable information obtained from this study will remain confidential and will only be disclosed with your permission or if required by law (in the case of child abuse, elder abuse, or certain reportable diseases).
Your completed study questionnaires will have numbered responses and be linked by codes with your participant number. These files will be stored in a locked facility. When results are published and/or presented, all identifiers will be removed from the information unless your consent is obtained separately. Representatives from the Yale Human Research Protection Program, and/or the Yale Human Investigation Committee may inspect study records during internal auditing procedures. However, these representatives are required to keep all subject information confidential.

Your medical records for your prenatal, intrapartum, and postpartum care, as well as medical records for your baby’s first 6 weeks of life, will be accessible to clinicians at your FQHC facility so that they may make sound clinical decisions regarding you and your baby’s care.

In Case of Injury
If you are injured while participating in the study, seek treatment and contact the study physician when you are able.

The Yale School of Medicine and FQHCs of Connecticut do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You and/or your insurance company will be expected to pay the costs of your treatment for research-related injury. You do not give up your legal rights by signing this consent.

Voluntary Participation
Participation in this study is voluntary. You may choose to not take part in the study. Refusing participation in the study will result in no penalty to you or loss of benefits to which you are entitled, or affect your relationship with your FQHC clinic or prenatal care provider. However, you will not be able to enroll in this research study if you do not allow the use of your information as part of the study.

Withdrawing from the Study
If you choose to participate in the current study, you are free to stop/withdraw from the study at any time. If you wish to withdraw, you may call any member of the research team at any time and state that you would like to withdraw. This will cancel any future appointments with study personnel/your doula. No further information will be collected, however, some information already collected before withdrawal may be used by researchers to ensure the accuracy of the results.

Withdrawal from the study will involve no penalty or loss of benefits to which you are entitled, or affect your relationship with your FQHC clinic or prenatal care provider. You will continue to be provided with the standard prenatal care offered by your prenatal care provider.

Questions
If you have questions about any of the items listed on this form, don’t understand something, or have any questions pertaining to your participation in the study or the study itself, please don’t hesitate to contact the principal investigator, Dr. Katherine Campbell (203-526-9486). It is important to take as long as you need to consider your consent to participate.
Authorization
I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement, and possible hazards/inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this signed consent form.

Name: ___________________________ Date: __________

Signature: ___________________________

___________________________________

___________________________________

Person Obtaining Consent (Print and Sign) Date

If, after you have signed this form, you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919. If you would like to talk to someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.
Appendix D: Informational Booklet on Healthy GWG, written and published by the IOM and National Research Council of the National Academies. 

Guidelines on Weight Gain & Pregnancy

INSTITUTE OF MEDICINE
AND NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES
Being healthy is a topic that is on everyone’s minds these days. If you are pregnant or may become pregnant in the future, it’s **really** important. In 2009, the Institute of Medicine and the National Research Council published updated guidelines on weight gain during pregnancy that enhance your ability to have a healthy pregnancy and baby.
I heard that if I am overweight and become pregnant, it can affect my health. Is that true? Can being overweight affect my baby?
Begin pregnancy at a healthy weight

The best way to begin a pregnancy is at a healthy weight. Your weight before you become pregnant has a big effect on your health during pregnancy and on the health of your baby. But please remember, no matter what your weight is before becoming pregnant, how much weight you gain during pregnancy is important!

Women who are overweight or obese when they become pregnant have a higher risk of having a C-section. They also tend to have trouble losing weight after the baby is born. Mothers who are overweight or obese when they conceive are more likely to have children who become overweight or obese.
Women who are underweight when they become pregnant have a higher risk of having a preterm or low-birthweight baby. This can cause health problems for the baby, including breathing, heart, and digestive problems.

Talk to your health care providers about your eating and physical activity choices so that you can be in the best shape possible when you become pregnant.
I just found out
I am pregnant,
so now I can eat
all I want and just
lose the weight
afterward, right?
Gain the right amount of weight during pregnancy

You need to gain weight to have a healthy pregnancy, but many pregnant women gain either too much or too little weight. The amount of weight you should gain during pregnancy depends on your weight before you conceive and whether your weight is right for your height. Your health care provider can help you determine which weight category you’re in.
If before pregnancy you are...  During pregnancy, you should gain...

**Underweight**  28-40 lbs

**Normal (healthy) weight**  25-35 lbs

**Overweight**  15-25 lbs

**Obese**  11-20 lbs
I gained about 10 pounds more during my pregnancy than I planned on. Do I really need to worry about that if I am planning on having another baby?
Return to a healthy weight after your baby is born

Starting out at a healthy weight and gaining within the recommended range will make it easier to return to a healthy weight after your baby is born. Returning to a healthy weight after delivery is good for your overall health and it puts you on the right track for a healthy pregnancy in the future.
I really want to try to lose weight before I become pregnant but I don’t know where to turn. There is so much information out there, how do I know what is best for me?
Things you can do to make sure you gain the right amount of weight during pregnancy

Talk with your provider (family physician, obstetrician, midwife, nurse practitioner, or other skilled professional, such as a dietitian, or physical activity specialist). Ask him or her for information and advice about eating right and being active so that you reach a healthy weight before you become pregnant, gain the right amount during pregnancy, and return to a healthy weight after your baby is born.
Your provider should:

**Keep track of your height and weight.** That means measuring and recording your height and weight before you are pregnant. You may decide that it’s best if you lose or gain some weight before becoming pregnant. Then, once you are pregnant, your provider should chart your weight gain throughout the pregnancy to make sure you’re gaining within the guidelines. At each visit, talk with your provider about the results so that you know how you are doing with your weight gain goals.

**Give you referrals.** If you want extra help with healthy eating and physical activity, ask your provider to refer you to a dietitian or physical activity specialist.
Notes
Additional resources

AMERICAN ACADEMY OF FAMILY PHYSICIANS
www.aafp.org

AMERICAN COLLEGE OF NURSE-MIDWIVES
www.midwife.org  www.ourmomentoftruth.com

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
www.acog.org  www.acog.org/for_patients

AMERICAN PUBLIC HEALTH ASSOCIATION
www.apha.org

ASSOCIATION OF WOMEN’S HEALTH, OBSTETRIC AND NEONATAL NURSES
www.awhonn.org  www.health4mom.org
www.health4women.org

HEALTHPARTNERS INSTITUTE FOR EDUCATION AND RESEARCH
www.hprf.org

MARCH OF DIMES
www.marchofdimes.com

NATIONAL WIC ASSOCIATION
www.nwica.org

SOCIETY OF MATERNAL-FETAL MEDICINE
www.smfm.org
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