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The Blossom Project Online: Use of a behaviorally-based website to promote physical activity and prevent excessive gestational weight gain in previously sedentary pregnant women

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The Blossom Project Online: Use of a behaviorally-based website to promote physical activity and prevent excessive gestational weight gain in previously sedentary pregnant women

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ABSTRACT

Obesity and incidence of chronic disease continue to rise in the United States. The current medical paradigm focuses on treatment of chronic disease. A shift from the management of disease to prevention of obesity and its associated co-morbidities including diabetes mellitus and cardiovascular disease is necessary to protect the health of future generations. Pregnancy is a "teachable moment" offering a time when many women are motivated to make healthier lifestyle choices to optimize the health of their unborn child. This critical stage of the life cycle offers a unique opportunity to influence the health of future generations by modifying the lifestyle of the expectant mother.

An abundance of evidence exists to associate excessive gestational weight gain (GWG) with adverse maternal and infant outcomes. Prenatal physical activity (PA) has been recommended to curtail the increasing rates of excessive weight gain during pregnancy yet few pregnant women meet current PA guidelines. Furthermore, the ability to accurately assess PA during pregnancy is convoluted by many factors, most notably the uncomfortable waist-worn placement of many commonly used activity monitors. Therefore, to make considerable strides in improving the health of future generations, it is imperative that strategies are developed to increase and accurately evaluate prenatal PA and explore its potential relationship with improved maternal and infant outcomes.

In order to provide possible answers to these issues, the Blossom Project at Iowa State University conducted two studies. The first study evaluated the validity of the SenseWear® Mini armband (SWA) to estimate energy expenditure (EE) in pregnant women. Multiple activities of daily living ranging in intensity from sedentary to moderate walking on a treadmill were performed while EE was measured by the SWA and indirect calorimetry. The results of the study showed significant overestimation by the SWA compared to indirect calorimetry (0.57 ±0.06 $kcal \cdot min^{-1}$) but average individual correlation coefficients revealed good overall agreement between methods (mean $r = 0.93$). Due to the convenient location worn on the upper-arm, the SWA is a plausible method to estimate EE and PA during pregnancy. Future studies should develop pregnancy-specific algorithms to further improve estimation of EE in this population.

The second study was a pilot randomized-controlled trial entitled "The Blossom Project Online". The study had two aims: 1) To evaluate the efficacy of a behaviorally-based website (based on Social Cognitive Theory; SCT) to increase intentional PA in sedentary pregnant women; and 2) To explore the impact of the PA intervention in pregnancy on maternal and infant outcomes. Fifty-one participants were enrolled while 50 were randomized to either usual care (UC) or a behaviorally-based intervention (BI-group) and received access to the study website with a username and password. Forty-five women completed the study (n=21 UC; n=24 BI-group). Participants receiving usual care could only view general diet and PA recommendations during pregnancy while intervention participants had access to all of the website features including the diet and PA recommendations, exercise goal-setting modules, problem-solving modules, a journal, a calendar to track all of their exercise through delivery, and a community forum to interact with other participants in the intervention group. Intervention participants were encouraged to work up to at least 150 minutes of moderate-vigorous PA (MVPA) per week (in at least 10-minute bouts) by week 19 of pregnancy and sustain at least this amount until delivery. All women were categorized into tertiles of website engagement to evaluate the efficacy of the website to increase PA. Additional outcomes of interest included adherence to PA guidelines, weekly MVPA, GWG, maternal weight-retention at 1-month postpartum and infant body composition at 1-month postpartum.

Results of the behaviorally-based randomized controlled trial indicated a significant increase from baseline of 95 (67-130) minutes per week in weekly intentional PA according to the website among the BI-group ($P < 0.0001$). Weekly PA reported by the BI-group on the website was 124 ± 44 minutes. On average 31.8% of women met the goal each week of $\geq$ 150 minutes of PA. Objective MVPA assessment by the SWA confirmed significantly more MVPA sustained in 20- and 30-minute bouts among BI-group compared to UC at weeks 24-26 of pregnancy ($P = 0.005$ and $P = 0.0008$, respectively), and this MVPA in BI-group was significantly greater than baseline assessment (20-min: 61.3 ± 21.9 min; 30-min: 39.6 ± 14.8 min, both $P <0.05$). Those participants engaging in a greater amount of website activity completed more sustained MVPA than their not-engaged counterparts (118 ± 102 vs 57 ± 63 minutes per week, $P < 0.05$).

However, the significant increase in MVPA among the BI-group did not prevent excessive GWG. Excessive total GWG occurred in 62.2% of all participants, and in 42.1%, 82.4%, and 66.7% of normal weight, overweight, and obese women, respectively, with no differences in GWG, adherence to GWG recommendations, or weight retention between groups. Interestingly, energy intake significantly increased in the BI-group between baseline and weeks 24-26 of pregnancy (336 ± 127 kcals, $P = 0.04$) and was significantly greater than energy intake by UC (2503 ± 703 vs 1894 ± 594, $P = 0.005$). No differences were seen between groups in infant birth outcomes or weight, length, and body composition at 1-month of age. However, while group randomization assignment was not a significant predictor of infant body composition at 1-month of age, when combined with MVPA sustained for at least 30-minutes and diet quality at 24-26 weeks of pregnancy, 22% of the total variation in infant body composition was explained.

In conclusion, the SWA correlates well with indirect calorimetry to provide estimates of EE and PA during pregnancy. Further refinement of the algorithms may improve the validity of the monitor while currently available algorithms allow for PA to be assessed objectively during pregnancy with minimal user burden. Additionally, an interactive website based on SCT was successful in preventing the typical decline in PA during pregnancy and simultaneously increased PA in previously sedentary women. The intervention also inadvertently increased energy intake among the BI-group. Thus, given the energy intake of the BI-group, the amount of MVPA performed was not sufficient to prevent excess GWG or improve maternal weight retention. Given the benefits associated with prenatal PA, previously sedentary women without contraindications to exercise should be encouraged to increase prenatal PA and may need additional dietary counseling to prevent excessive GWG.

CHAPTER 1: GENERAL INTRODUCTION

Introduction

Current and traditional medical management is focused on the treatment of chronic disease, including but not limited to obesity, diabetes mellitus, and cardiovascular disease (1). As of June 2013, obesity was formally recognized as a disease by the American Medical Association, endorsing the seriousness of this condition as global obesity statistics continue to rise (2). Obesity is the second largest modifiable cause of preventable death in the United States (3) and thus it is necessary for the current medical paradigm to shift towards a central focus of prevention to avert this problem from continuing to perpetuate chronic disease rates among future generations.

Pregnancy offers a unique opportunity to influence the health of future generations by modifying the lifestyle of one individual – the expectant mother. The Developmental Origins of Health and Disease (DOHaD) Theory, also originally known as the Barker Hypothesis, provides evidence to suggest the environment an individual is exposed to *in utero* causes permanent physiological and metabolic changes (4). One possible method to optimize future and maternal health is to promote adherence to the Institute of Medicine's gestational weight gain (GWG) recommendations (5). Excessive GWG has been linked to cesarean delivery (6), large-for-gestational age infants (LGA; (LGA; weight above the 90th percentile for gestational age) (7), macrosomia (birth weight greater than 4000 grams) (8), childhood obesity (9), and postpartum weight retention (10). If the woman is unable to successfully return to her pre-pregnancy weight prior to the next pregnancy, she will begin that pregnancy with a larger body mass index (BMI) increasing the likelihood for gestational diabetes (11), hypertensive disorders including pre-eclampsia (11,12), LGA infants (13), increased risk of cesarean section (11), and childhood obesity (14), perpetuating the cycle once more.

A series of studies at Iowa State University, collectively entitled The Blossom Project, aims to improve the lives of women and their children one pregnancy at a time. The initial studies included observational designs to assess typical physical activity (PA), dietary intake, and gestational weight gain among women in central Iowa. Findings of these studies demonstrated low adherence to prenatal physical activity recommendations (25% of participants) (15) and excessive GWG among 48% of participants (unpublished data), both

statistics that match national trends (16,17,18). Furthermore, the complications of assessing PA during pregnancy with currently available methodologies (including, but not limited to self-report questionnaires, pedometers, and waist-worn accelerometers) were revealed and the need for a valid PA assessment tool for use in pregnancy and not worn on the waist was established. Chapter three of this dissertation presents a manuscript addressing the problem of prenatal PA assessment, evaluating the validity of the SenseWear® armband to predict energy expenditure during pregnancy.

Pilot randomized-controlled trials (RCT) were the next step for The Blossom Project to further understand how to increase maternal exercise and prevent excessive GWG. The first of these trials was entitled 'Moms to Move' (M2M) and provided intervention participants with a treadmill to keep in their home during pregnancy to promote adherence to current PA guidelines and minimize common barriers to prenatal exercise. This intervention studied sedentary overweight and obese women and the results are reported in detail elsewhere (19). In summary, while a treadmill in the home effectively increased walking among intervention participants compared to the control group, no significant differences in GWG, maternal weight retention, or infant body composition were observed between groups. Therefore, two research questions remained: 1) How else can maternal exercise be increased among previously sedentary pregnant women? and 2) Will these methods be more successful in improving maternal and infant outcomes?

The first of these questions aims to develop more sustainable methods to increase maternal exercise since providing treadmills in the home is not a practical solution for most pregnant women. The second question expands upon the findings of M2M to promote optimal maternal and infant outcomes. Blossom Project investigators looked to social media and behavioral theory to answer these questions. Utilizing the Internet as a source of information during pregnancy is common and well-accepted (20-22). A survey of 293 women in the Midwest revealed 94% of the respondents used the Internet to retrieve pregnancy related information, while nearly half (44%) of the women used it for information regarding PA (23). Women reported an increased confidence to make decisions regarding prenatal PA and 26% reported increasing their PA as a result, while only 3.8% had decreased their PA. Similarly, behavioral theory provides a framework for understanding why individuals do or do not participate in a particular behavior, what motivates them to do or not

do a behavior, and what barriers challenge the adoption of a new behavior (24). While behavioral theory has been used extensively to promote behavior change in non-pregnant adults, its use in pregnancy is limited. A recent review on PA in pregnancy stated "Most prenatal PA intervention studies have not applied theoretically based strategies to promote PA behavior, thus limiting mechanistic insight to intervention success" (25). In support of these collective findings, The Blossom Project research team and several collaborating investigators developed a behaviorally-based website to increase maternal exercise and thereby prevent excessive GWG, reduce maternal weight retention, and improve infant body composition. The resulting RCT was entitled "The Blossom Project Online" and the findings of this study construct the fourth (efficacy of the website to increase intentional PA in sedentary pregnant women) and fifth chapters (impact of the RCT on GWG, and maternal weight retention), and an addendum (impact of the RCT on infant birth outcomes and body composition) of this dissertation. It was hypothesized that previously sedentary pregnant women would increase adherence to current prenatal PA recommendations when given access to an interactive behaviorally-based website and a greater proportion of these women would meet recommendations compared to women that did not receive access to the interactive website. Additionally, mothers would successfully achieve appropriate pregnancy weight gain relative to pre-pregnancy BMI when given access to an interactive behaviorally-based website; and infants born to mothers who received access to an interactive behaviorally-based website would have more favorable birth outcomes and body composition at 1-month of age compared to the babies born to mothers that did not receive access to the interactive website.

Dissertation Organization

This dissertation consists of six chapters beginning with a general introduction, a comprehensive review of the literature, three manuscripts, and a summary with overall conclusions. The first manuscript is found in Chapter 3 and is entitled "Validity of the SenseWear® armband to predict energy expenditure in pregnant women". It was submitted and accepted for publication to the American College of Sports Medicine's leading original research journal, *Medicine & Science in Sports & Exercise* (MSSE). The fourth chapter, "Efficacy of a behaviorally-based website to increase physical activity in previously sedentary pregnant women: a randomized controlled trial" will be submitted to the

International Journal of Behavioral Nutrition and Physical Activity. Chapter five, "Impact of a behaviorally-based randomized controlled trial on prevention of excessive gestational weight gain and maternal weight retention", will be submitted to the journal *Medicine & Science in Sports & Exercise*. The data discussing the impact of the intervention on infant outcomes can be found in an addendum at the end of this dissertation (Chapter six). The appendices of this dissertation include the recruitment documents and questionnaires used for the current study at enrollment, throughout pregnancy, and at 1-month postpartum. All study documents were approved by the Institutional Review Board at Iowa State University.

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CHAPTER 2: LITERATURE REVIEW

Obesity

Obesity statistics Pregnancy is commonly viewed as a stage in the life cycle to "eat for two", minimize volitional activity and allow the woman to put her feet up and relax. Over the past decade, considerable evidence has accumulated suggesting this could very well be contributing to many of the health concerns in society today, including the obesity epidemic (1). In June 2013, the American Medical Association formerly recognized obesity as a disease. According to the World Health Organization, over 200 million men and 300 million women are currently obese worldwide (2) and the prevalence continues to increase (3). Obesity is the second largest modifiable cause of preventable death in the United States (4) as it poses substantial risk for multiple other chronic diseases, including but not limited to Type 2 Diabetes Mellitus (5), cardiovascular disease (including coronary heart disease, stroke, and heart failure) (6,7), osteoarthritis (7) and cancer (6). Furthermore, the demographics of pregnant women have drastically changed over the past several years as more women are overweight or obese prior to becoming pregnant (8). According to the recent National Health and Nutrition Examination Survey (NHANES), more than one-third (35.8%) of women in the United States (US) are obese, more than half of pregnant women are classified as overweight or obese, and 8% of reproductive aged women are extremely obese (9,10). Maternal obesity is associated with gestational diabetes (11,12), hypertensive disorders including pre-eclampsia (11-13), large-for-gestational age infants (LGA; weight above the 90th percentile for gestational age) (11,14), increased risk of cesarean section (12), and childhood obesity (10). Similarly, excessive gestational weight gain has been linked to cesarean delivery (15), LGA infants (16), macrosomia (birth weight greater than 4000 grams) (8), and childhood obesity (17). If the woman is unable to successfully return to her pre-pregnancy weight prior to the next pregnancy, she will begin that pregnancy with a larger body mass index (BMI) and the cycle will perpetuate once more. Statistics demonstrate that the nation's next generation will likely struggle with even more health complications than their predecessors as the obesity rates are climbing among children and adolescents, with over 30% of the nation's children ages 2-19 years overweight or obese (6). A recent review of the evidence for the long-term effects of pregnancy on the risk of obesity in offspring

stated, “Based on the current data, maternal obesity is a critical factor exacerbating multigenerational obesity” (18).

Prevention of future obesity Treatment options for obesity in non-pregnant adults include lifestyle intervention, pharmacotherapy, or surgery. However, 50% of all healthcare patients do not follow long term medication regimens and greater than 80% do not follow health behavior change advice without additional counseling and follow-up (19,20). Thus, to ensure the health of future generations, we must look at different ways to approach obesity and its associated co-morbidities by using preventative medicine rather than curative treatment.

Why intervene during pregnancy?

Most women are in infrequent contact with their medical provider during the prenatal period (1,21), thus this period of the life cycle is an opportune time to initiate preventative medicine, influencing the future health of women and their children. While it is ideal to achieve a healthy weight before pregnancy, current statistics support the notion that women are entering pregnancy at a higher BMI rather than losing weight prior to conception (8). Additionally, overcoming stereotypes during pregnancy such as “eating for two” and relaxing and avoiding activity may be difficult societal norms to conquer. However, many women are concerned about the health of their babies and in turn may be motivated to change their lifestyle to provide the best opportunities for their child (1). Pregnancy has been coined as a “teachable moment,” (1) thus warranting investigation on promotion of lifestyle changes during this time. Furthermore, the Developmental Origins of Health and Disease (DOHaD) Theory suggests risk for chronic disease develops *in utero* and thus, the key to prevention is before the child is even born. Prenatal interventions promote preventative care rather than relying on curative treatment.

Developmental Origins of Health and Disease

The DOHaD Theory, also originally known as the Barker Hypothesis, was first suggested during the mid-1980’s. Geographical studies in England and Wales by David Barker and his colleagues led to the hypothesis that under-nutrition *in utero* causes permanent physiological and metabolic changes, leading to low birth weight in the infant and coronary heart disease and stroke as an adult (22). Additionally, data from the Dutch Famine during the winter of 1944-1945 presented compelling data on the impact the *in utero*

environment has on long-term health. The estimated dietary intake by each person during the famine was between 500-1100 kcals per day, causing thousands of women to experience under-nutrition during their pregnancy. Data on 300,000 adult male offspring of women exposed to the famine during the first half of pregnancy displayed higher obesity rates than the offspring of women exposed to the famine in late pregnancy (23). The adult offspring of women exposed to the famine during the last trimester of pregnancy had significantly lower rates of obesity, suggesting the timing of maternal exposure influences fetal development.

Since the mid-1980's multiple studies have reinforced these findings and extended the research to include other countries and outcomes for female offspring. In addition to coronary heart disease and stroke, low birth weight has additionally been linked with hyperlipidemia, hypertension, coronary artery disease, impaired neurodevelopment, insulin resistance, altered glucose and insulin metabolism, and Type 2 Diabetes Mellitus (24).

The mechanisms to which birth weight is associated with long term disease risk is poorly understood; however, the most commonly accepted belief is an alteration in the *in utero* environment at a critical developmental time period causes irreversible effects on development. The role of genetics and epigenetics on fetal development has garnered much attention in the last five years, and is described elsewhere (24,25).

Gestational weight gain

Weight gain recommendations In order to reduce risk for both low- and high-birth weights and optimize maternal and fetal outcomes, the Institute of Medicine (IOM) has published guidelines based on observational data regarding the appropriate amount of weight to gain during pregnancy. The most recent recommendations for women in the United States were published in 2009 (26) in response to increased obesity and chronic disease rates among reproductive age women and increased gestational weight gain (GWG) since the last update in 1990. The prevalence of pre-pregnancy obesity has increased 70% since the first recommendations in 1990 (27). Appropriate weight gain is classified according to pre-pregnancy BMI (see Table 1) and presented in a range to support the concept that positive outcomes are achieved within a range of weight gains rather than one specific ideal number.

Table 1. 2009 IOM Weight Gain Recommendations

Pre-pregnancy Body Mass Index	Total weight gain range, kg (lbs)	2nd & 3rd trimester rates of weight gain* Mean (range) in kg/week	Mean (range) in lbs/week
Underweight (< 18.5 kg·m^2)	12.5-18 (28-40)	0.51 (0.44-0.58)	1 (1-1.3)
Normal weight (18.5 – 24.9 kg·m^2)	11.5-16 (25-35)	0.42 (0.35-0.50)	1 (0.8-1)
Overweight (25.0 – 29.9 kg·m^2)	7-11.5 (15-25)	0.28 (0.23-0.33)	0.6 (0.5-0.7)
Obese (≥ 30 kg·m^2)	5-9 (11-20)	0.22 (0.17-0.27)	0.5 (0.4-0.6)

Adapted from (26). **Calculations assume a 0.5-2 kg (1.1-4.4 lbs) weight gain in the first trimester.*

The 2009 guidelines were based on the World Health Organization's (WHO) BMI cut-offs and also include a minimum weight gain recommendation for obese women, two factors that distinguish the 2009 from the 1990 recommendations (26). When the 2009 weight gain recommendations were published, sufficient evidence was not available to make specific recommendations for higher obesity classes II (BMI 35-39.9 kg·m^2) and III (BMI ≥ 40 kg·m^2). The weight gain recommendations must balance the risks associated with inadequate weight gain such as small-for-gestational age infants (SGA; weight less than the 10th percentile for gestational age), preterm birth, and perinatal mortality, with risks such as LGA infants, increased rates of cesarean section, gestational diabetes and hypertensive disorders with excessive weight gain (26).

Excessive GWG statistics The most recent reports from the Centers for Disease Control (CDC) from the Pregnancy Nutrition Surveillance System (PNSS) indicate 48% of low-income women gain in excess of the 2009 IOM recommendations. Among overweight and obese low-income women, these rates are increased to 59% and 56% respectively (28). Data from Iowa is slightly above the national average with 50% of low-income women gaining in excess, while 3% enter pregnancy underweight and 31% enter pregnancy overweight (28). Interestingly, epidemiological data from the PIN (Pregnancy, Infection, and Nutrition) 3 study demonstrated even greater excessive GWG; 59% of participants gained in excess of the 2009 IOM recommendations. Excessive GWG occurred in 50% of underweight women, 51.8% of normal weight, 84.1% of overweight, and 67.2% of obese women. Furthermore, 14% of women gained ≥ 200% of the recommendations (29). The majority of

participants in this study were white, 25-34 years of age at conception, married, college educated, non-smokers, and from high-income households. Other data support that predictors of excessive GWG include nulliparity (no previous births), being overweight prior to pregnancy (overweight women are the most likely to gain in excess followed by obese women), low-income, young maternal age (25-30 years of age at highest risk), smoking status (smoking currently or in the past), and lack of nausea in the first trimester (30-33). Likewise, evidence suggests women with a history of dieting or weight cycling before pregnancy gain more weight than those who do not have a history of these behaviors (34).

Maternal implications of excessive GWG Alarming data from Brown University was published in May 2013. Of 8,293 nulliparous women studied, 73% gained in excess of the 2009 IOM guidelines. Excessive gain among all pre-pregnancy BMI categories was associated with increased risk of hypertensive disorders (35). The National Longitudinal Survey of Youth reported 40% of women who gained excessively also retained greater than 2.5 kg from 12-24 months postpartum (36). Postpartum weight retention has been shown to be a strong predictor of maternal overweight and obesity even as long as a decade after the pregnancy (37). Similarly, the Stockholm Pregnancy and Women's Nutrition study followed 483 women 15-years postpartum (38). Results indicated the women who gained less than the 1990 IOM recommendations or achieved the recommendations weighed 6.2 kg and 6.7 kg more, respectively, than their pre-pregnancy weight. However, women who exceeded IOM recommendations weighed 10.0 kg ($P < 0.01$) more than their pre-pregnancy weight, resulting in an increased BMI of 0.72 $kg \cdot m^2$ compared to women who gained appropriately. The findings remained significant even after controlling for several confounders, including parity, suggesting the long term obesity risk for women exceeding GWG recommendations.

Infant implications of maternal excessive GWG Infants born to mothers who gain excessive weight face considerable risks at birth and in the future. PIN 3 data illustrated higher weight-for-age, length-for-age, and weight-for-length z-scores during early infancy that persisted to three years of age in children born to women with excessive gain compared to women with adequate GWG (29). Long-term follow-up studies demonstrate the likelihood of such children becoming obese toddlers (39), adolescents (40), and adults (30). Children and adolescents that continue on the obese trajectory commonly face several co-existing difficulties such as asthma, bone and joint problems, sleep disorders, high blood pressure,

Type 2 Diabetes Mellitus, early growth and puberty, bullying, and emotional disorders such as depression, anxiety, and lack of self-confidence (41-43).

Timing of GWG Until recently, the primary focus and concern has been on the total amount of weight gained during an individual pregnancy. With rising efforts to determine specifically how to achieve appropriate GWG, more attention has been devoted to the relationship between timing of weight gain and pregnancy outcomes. Drehmer et al. demonstrated an association between LGA infants and excessive GWG during the 2nd trimester (RR 1.64, 95% CI 1.16-2.31) while excessive gain independently in the 3rd trimester was associated with preterm birth (RR 1.70, 95% CI 1.08-2.70) and cesarean delivery (RR 1.21, 95% CI 1.03-1.44) (44). Conversely, insufficient weight gain during the 2nd trimester was associated with SGA infants (RR 1.72, 95% CI 1.26-2.33) while no associations were found between adverse outcomes and insufficient weight gain during the 3rd trimester. These findings further support the early Dutch famine data: inadequate weight gain during the first half of pregnancy results in increased rates of infant low birth weight and infants predisposed to adult obesity; conversely, offspring born to mothers exposed to famine in the third trimester experienced lower rates of adult obesity (23).

Excessive GWG early in pregnancy has also been linked with increased risk of gestational diabetes, LGA infants, and excessive infant body fat at birth. In a large sample of 7,985 women, excessive early GWG (defined as GWG greater than the upper range of 2009 IOM guidelines for each pre-pregnancy BMI category occurring prior to 19 weeks gestation) occurred in 47.5% of participants. Ninety-three percent of the women with excessive early GWG exceeded IOM guidelines for total GWG whereas 55% of women who did not gain excessively early on still exceeded guidelines for total GWG ($P < 0.001$) (45). After adjustment for maternal age, smoking, and race, excessive GWG early in pregnancy was associated with a 43% higher risk for developing gestational diabetes mellitus, a 40% increased risk for delivering a LGA infant, and a 51% higher risk for a macrosomic infant. Davenport et al. observed an increased risk for excessive infant body fat (> 14%) at birth in infants born to mothers who gained in excess during the first half of pregnancy (OR 2.64, 95% CI 1.35-5.17) compared to those who gained appropriately during this time period (OR 1.49, 95% CI 0.80-2.79) (46).

GWG counseling- What medical providers are recommending to patients Medical providers are an important source of information for pregnant women regarding GWG. The American College of Obstetricians and Gynecologists (ACOG; name current as of October 2013 via personal communication) recommends calculating pre-pregnancy BMI and communicating appropriate weight gain based on the IOM recommendations at the initial prenatal visit and periodically throughout pregnancy (8,10). However, this is often complicated by the absence of a pre-pregnancy weight on the patient's medical record (47), thus ACOG has approved the use of an early-pregnancy weight to calculate BMI to determine GWG recommendations (10). Despite ACOG's suggestion, there is strong evidence that obstetric medical providers are not providing guidance in line with the IOM recommendations (1,48,49), or furthermore, are not providing any weight gain advice to their patients at all (1,49). A national survey of 433 obstetric practitioners conducted by the Research Department within ACOG demonstrated that 80% of respondents had read the ACOG Committee Opinion, "Obesity in Pregnancy" (50) and 86% rated it as "helpful" or "very helpful" (48). However, less than two-thirds (63.4%) of respondents used pre-pregnancy BMI to assess appropriate GWG (48). Similarly, national data from the CDC's Division of Nutrition, Physical Activity, and Obesity reported nearly 30% of all patient survey respondents (n=2237) did not receive any medical advice regarding GWG (49). Evidence suggests women are more likely to gain within appropriate ranges if medical providers recommend how much weight to gain during pregnancy (49,51,52). A study by Cogswell et al. evaluated the association between medical provider advised weight gain and actual weight gain. Women that received advice to gain less than minimum range of the 1990 IOM GWG recommendations were three times more likely to actually gain less than the IOM recommendations (OR 3.6, 95% CI 2.3,5.5), compared to women that were advised to gain the appropriate amount of weight according to their pre-pregnancy BMI and did so (49). Similarly, the CDC findings also showed an association between receiving no advice and excessive GWG (49). Women that were given no advice about GWG were twice as likely (OR 2.0, 95% CI 1.5,2.7) to gain excessively, while women that were advised to gain more than the 1990 IOM GWG recommendations were more than three times likely to gain excessively (OR 3.6, 95% CI 2.4,5.5) (49).

Some of the dissociations between GWG recommendations and the advice obstetric medical providers are providing to their patients may be due in part to the training of health care professionals. For one, surveys of clinicians and obstetricians, demonstrate they often do not remember the BMI categories (47). Thus, it becomes difficult to counsel a patient on appropriate GWG according to pre-pregnancy BMI if the clinician is unable to appropriately categorize the patient's BMI. Secondly, traditional health care has been focused around the treatment of acute illness, managed by the physician. However, in today's society, most health care is related to chronic disease (e.g. diabetes mellitus, hypertension, cardiovascular disease, renal disease, etc.). Contrary to the treatment of acute illness, chronic disease is primarily managed by each individual patient via lifestyle and medications while the physician takes on more of a "coach" role. Regardless, the training of health care professionals is still based on the older paradigm of dealing with acute illness and therefore active patient participation is not as important (53). As an important source of medical information during pregnancy, the obstetric provider must fulfill the role of the GWG "coach" and provide patients with proper guidance to achieve healthy weight gain. However, limited time during clinical appointments, uncertainty regarding appropriate weight gain recommendations, and reluctant feelings towards discussing the sensitive topic of weight gain (1,47) often leaves this topic to be avoided. The practice of discussing weight gain during pregnancy is in alliance with the recent 2013 ACOG Committee Opinion on Obesity in Pregnancy, which promotes offering nutrition consultation to all overweight and obese women and the encouragement to follow an exercise program (10). ACOG's recent statement on weight gain during pregnancy suggests "It is important to discuss appropriate weight gain, diet, and exercise (with all patients) at the initial visit and periodically throughout the pregnancy" (8). Referral to specialty services such as dietitians and exercise professionals may minimize the time necessary to discuss such topics during the prenatal visits with the medical provider and optimize maternal and infant outcomes.

Previous interventions to prevent excess GWG Recommendations describing how to achieve appropriate weight gain during pregnancy are limited. Continual graphing of GWG against recommended ranges has shown some benefit (54,55) and was found to be a desirable educational tool that would be well-received by medical providers to counsel patients (47). Interestingly, in a study of current prenatal health care providers in the Boston

area, most practitioners (n=12/16) reported they would be more likely to actively manage excessive GWG earlier in pregnancy and refer for counseling services, such as nutrition assessment, if it was visibly obvious on an electronic medical chart that the patient was not gaining within the recommended range (47).

Multiple studies have focused on decreasing maternal weight gain and/or prevention of excessive GWG. Those that have been successful in preventing excessive GWG have varied in methodology and study design (see Table 2), with graphical GWG charts used as a common educational tool (54-58). All but 1 of the 13 studies utilized some sort of dietary intervention (59). Likewise, only one study did not incorporate a physical activity or exercise intervention (60). Several studies included multiple face-to-face or telephone dietary consultations (60-64) or at least one supervised exercise session per week (59,62-65) including aqua aerobics (66), walking (62,63), aerobic dance (59), and resistance training (59,64) with weekly weight monitoring (58,62,63). At-home newsletters were also utilized by three studies (54,55,57) to disseminate information about diet and exercise, and use it as an opportunity for participants to set indivdiualized behavior goals related to both topics (54). Thus, multiple forms of interventions have been utilized to achieve appropriate GWG, with 85% (n=11) including both a diet and physical activity intervention.

However, the intensity of the interventions varied drastically with differing amounts of program length and participant-researcher contact. Most studies began between 10-20 weeks gestation while one began earlier at 6-9 weeks (59) and another began later at 20-26 weeks gestation (65). Four studies did not specify the onset of the intervention, but stated first and/or second trimester (54,61) or “early pregnancy” (60,66). Mottola et al. (62) and Ruchat et al. (63) both identified excessive GWG in nearly half of all participants prior to the onset of the intervention at 16-20 weeks, however, prevented weekly excessive GWG throughout the intervention. Given the adverse outcomes associated with excessive early GWG, future studies should be initiated as early as possible in pregnancy to promote optimal GWG throughout the entire prenatal period.

Interestingly, the studies that demonstrated participants achieved appropriate GWG were not effective in all populations studied. Polley et al. (n=120) (55) and Phelan et al. (n=401) (57) both studied normal weight, overweight and obese women and effectively prevented excessive GWG in normal weight women only according to the 1990 IOM GWG

recommendations. In these two studies, excessive GWG was observed in 33% and 40.2% of the normal-weight intervention groups compared to 58% and 52.1% in the control groups, respectively. Olson and colleagues (54) were able to prevent excessive GWG in normal weight, overweight, and obese women but only in the low-income population (household income $\leq$ 185% of the federal poverty line compared to a high household income > 185% of the federal poverty line). Studies that had considerable impact on overweight and/or obese women included a higher frequency of monitored exercise sessions held at least once per week compared to interventions that did not work to prevent excess GWG, or weekly dietary and weight gain monitoring/counseling sessions (62,64,66). Dietary counseling included individualized energy requirements based on weight and PA level (64) and a focus on macronutrient distribution of 40-55% carbohydrate, 30% fat, and 20-30% protein with a monitored carbohydrate distribution throughout the day (62). Claessen et al. (66) offered aqua aerobics classes 1-2x/week designed specifically for obese women (albeit no mention of adherence or attendance to these classes were discussed) and weekly motivational sessions to provide support and discuss weight control. The approach by Claessen et al. significantly decreased total weight gain (7.52 ± 15.4 kg vs 9.78 ± 16.24, $P = 0.001$) and increased the percentage of obese women who gained less than 7 kg compared to a control group receiving routine prenatal care (20.5% vs 35.7%, $P = 0.003$). However, nearly 65% of intervention participants still exceeded the weight gain goal of less than 7 kg. On the contrary, Vinter et al. (64) did not achieve significant differences in excessive GWG between the intervention and control groups ($P = 0.058$), yet 64.6% and 53.4% of obese women achieved weight gain recommendations respectively (35.4% and 46.6% gained in excess). This is a considerably higher success rate than US and international prevalence of excessive GWG in 56-67.2% of obese women (28,29,67). Both the intervention and control groups received weight gain monitoring which is not standard care in Denmark (site of intervention), suggesting this alone may have served as an intervention for the control group. Future interventions should consider any possible data collection that may not be standard practice, such as weight gain monitoring, and thus when utilized may serve as an indirect intervention to both groups.

Table 2. Effective Interventions to Prevent Excessive Gestational Weight Gain

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
Polley et al, 2002	n=120 NW, OW, OB Clinical RCT Pittsburgh, USA	<20 weeks Control: Standard nutrition counseling from medical provider & WIC	Stressed modest exercise & discussed in biweekly newsletters	Stressed low-fat diet and discussed in biweekly newsletters	Personalized GWG graph sent after every clinic visit with feedback; additional counseling & goal-setting if weight gain outside of recommended range 1990 IOM	**Decreased EGWG in NW (33 vs 58%)	EGWG for OW/OB women (non-significant increased GWG)
Olson et al, 2004	n=179 NW, OW (no obese) Non-randomized, clinic New York, USA	First & second trimester (not specified) Control: Historical control (n=381)	5, 1-page newsletters sent via mail; opportunity to set behavioral goals with each newsletter and return via postcard	5, 1-page newsletters sent via mail; diet self-monitoring; opportunity to set behavioral goals with each newsletter and return via postcard	Plotting GWG by medical provider, additional counseling if weight gain outside of recommended range; self-monitoring GWG 1990 IOM	*Decreased EGWG in low-income women (33 vs 52%)	EGWG for high-income women
Claesson et al, 2008	n=348 OB Clinical, prospective case control Sweden	Early pregnancy (not specified) Control: Routine prenatal care	Aqua aerobics 1-2x/wk designed for obese women	Education from midwife on potential consequences of different behaviors associated with eating and food intake; written information provided as needed	One session with trained midwife early in pregnancy to motivate behavior change; Offered individual 30-min weekly motivational sessions to provide support and discuss weight control;	*Decreased GWG (8.7 vs 11.3 kg); *Increased % gain <7kg (35.7 vs 20.5%)	Birth weight, delivery mode

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
… Claesson et al.					Goal: <7kg (IOM rec then was at least 6.8kg) 1990 IOM		
Wolff et al, 2008	n=50, OB Clinical RCT Denmark	Early pregnancy (15 ± 3 wks) Control: No consults with RD and no restrictions on energy intake or weight gain; All participants received vitamin/ mineral supplement	None	10, 1-hr consultations with RD to achieve Danish macronutrient guidelines (fat ≤ 30%, protein 15-20%, carb 50-55%) and energy restriction calculated by: EER= BMR*1.4 (PAL factor of 1.2+0.2 added to cover energetic cost of fetal growth)	Goal: 6-7kg 1990 IOM	*Decreased GWG (6.6 vs 13.3kg); **rate of GWG; *weight retention at 4 weeks postpartum; *Limited energy intake, met macronutrient goals (no difference in CHO intake)	
Shirazian et al, 2010 #	n=21, OB Prospective historical matched control	First trimester Control: Matched for starting BMI, parity, SES (n=20)	Written education materials promoting walking as exercise, pedometer;	Written education materials on healthy eating, calorie counting; food diary; discuss nutrition & food label reading in seminars	Goal: ≤ 15 lbs (6.8 kg) 6 structured seminars to overcome barriers to healthy living; ≥ 5 1:1 counseling sessions or phone calls to monitor progress, at least 1 each trimester	*Decreased GWG (17.86 vs 34 lbs or 8.1 vs 15.5 kg)	% of women gained ≤ 15lbs (38 vs 15%, p=0.159);

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
… Shirazian et al.	New York City, USA		discuss exercise during pregnancy in seminars		1990 IOM		pre-eclampsia, GDM, c-sec, infant birth weight
Mottola et al, 2010	n=65, OW, OB Historical control, research center Canada	16-20 wks Control: Matched for pre-pg BMI, age, parity (n=260)	Walking 3-4x/wk at 30% heart rate reserve for 25 mins working up to 40 mins; $\geq$ 1 session/wk at research center; pedometer & exercise log for self-monitoring	Meeting with RD to discuss individualized meal plan of ~2000 kcal/day, 40-55% total energy from CHO, 30% fat (emphasize MUFA over trans- and saturated), 20-30% protein, snacks and CHO distribution throughout day; 1-day food log each week with feedback	Goal: $\leq$ 10.6 kg (weekly gain of 0.3-0.4 kg in 2nd & 3rd trimesters) Weekly weigh-ins at research center 1990 IOM criteria	Decreased EGWG during intervention; Achieved optimal weekly GWG; **Decreased kcals and CHO intake, increased protein intake from baseline	

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
Barakat et al, 2011	n=67 All BMI RCT	Began 6-9wks, end 38-39 wks Control: Not specified	35-45 mins/3x per week, light-moderate intensity (<70% maximum heart rate) of core work, walking, aerobic dance (1x/wk), stretching, very light resistance training (1 set, 10-12 reps, 3kg weight or bands)	None	None	**Decreased GWG (11.9kg vs 13.9), stated "normal" GWG for healthy pregnancy of 9-11 kg (Noted: 90% adherence to exercise group)	Mode of delivery, birth weight
Huang et al, 2011	n=189 All BMI Clinical RCT Taiwan	16 wks Control: Routine prenatal care, discussions with nurse on pregnancy concerns; written	Education from nurse at 16-weeks on how to develop an individualized physical activity plan, follow-up sessions (30-	Education from nurse at 16-weeks on how to develop an individualized diet plan, follow-up sessions (30-40 mins) at 28, 36-38 weeks; self-monitor diet & turn in at sessions;	Goal: 10-14 kg, each woman set own goal in this range; Personalized GWG graph sent after every clinic visit with feedback; additional counseling if weight gain outside of recommended range	*Decreased EGWG (average 14.02 vs 16.22 kg)	

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
… Huang et al.		information on nutrition and exercise during pregnancy	40 mins) at 28, 36-38 weeks; self-monitor PA & turn in at sessions; written information on energy expenditure for various exercises	written information on healthy and balanced diet, food categories, and calorie calculations	Dept of Health Taiwan recommendations for all pregnant women		
Phelan et al, 2011 (based off Polley, 2002)	n=401 NW, OW, OB RCT at research center Providence, Rhode Island, USA	10-16 wks Control: Standard nutrition counseling from medical provider & WIC; Bi-monthly newsletters on pregnancy issues	At initiation, discussed walk 30 min/most days; daily self-monitoring; provided pedometers; weekly postcards prompting exercise habits	At initiation, discussed calorie goals (20 kcal/kg), decrease high-fat foods; daily self-monitoring of eating; provided food records; weekly postcards prompting healthy eating; 3 brief phone calls from RD	At initiation, discussed GWG recommendations; Personalized GWG graph sent after every clinic visit with feedback; additional counseling & goal-setting if weight gain outside of recommended range 1990 IOM	*Decreased EGWG in NW (40.2 vs 52.1%); Reduced odds for maternal gestational hyper-tension**, c-section*, & macro-somia***	EGWG, hyper-tension, c-section, macro-somia for OW/OB women

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
Hui et al, 2012	n=190, All BMI Community -based RCT Canada	Begin 20-26wks, end 36 wks Control: Written information on PA & diet in pregnancy	Supervised 1x/wk & recommend 3-5x/wk, 30-45 mins mild-moderate exercise, provided exercise video to use in home; Self-monitoring in logs turned in to research staff	Interviews and individualized diet counseling by RD 2x: enroll & 2 mos later	Included with individualized diet counseling by RD based on diet interview, pregnancy week, & weight gain 2009 IOM	*Decreased kcal, fat, saturated fat, cholesterol intake; *Increased PA; *Decreased EGWG (35.3 vs 54.5%)	GDM, c-sec or birth weight
Vinter et al, 2012	n=304 OB Clinical RCT Denmark	10-14 wks Control: Dietary & physical activity in pregnancy advice, weight monitoring in both groups (not standard care in Denmark)	Supervised exercise classes 1x/wk (aerobic & resistance); Encouraged 30-60mins/ day MPA; provided pedometer & free gym membership for 6-mos	Counseling by RD 4x: 15, 20, 28, 35 weeks; Individual energy requirements based on weight & PA level;	Goal: limit GWG to 5kg	*Decreased GWG (7.0 vs 8.6 kg); ***Decreased EGWG (35.4 vs 46.6%); % gain ≤5kg (28 vs 20%, P=0.102)	GDM, c-sec, LGA, NICU admission, pre-eclampsia/ pregnancy induced hyper-tension

Table 2. Continued

Authors	Population/ Location & Design	Initiation of intervention/ Control	Exercise component	Diet component	GWG counseling	Effective results of intervention	Outcomes not effected
Rauh et al, 2013	n=250 NW, OW, OB Clinical Cluster-RCT Germany	20 wks Control: Routine prenatal care with written information on healthy lifestyle during pregnancy (no diet or weight gain advice)	Discussed physical activity recommend-dations and FITT principle at two counseling sessions (20 & 30 wks); provided feedback on 7-day PAQ; List of local prenatal exercise programs and encouraged participation; goal-setting	Discussed nutrition (decrease energy dense & high fat foods), macro- & micronutrient requirements during pregnancy at two counseling sessions (20 & 30 wks); provided feedback on 7-day diet record; goal-setting	Discussed GWG monitoring at two counseling sessions (20 & 30 wks); Weekly self-monitoring of weight on individualized weight gain chart; goal-setting 2009 IOM	**Decreased GWG (14.1 vs 15.6 kg); **Decreased EGWG (38 vs 60%)	GDM, birth weight, LGA, mode of delivery

*P $\leq$ 0.01; **P < 0.05; ***0.05 $\leq$ P < 0.06; Vinter non-significant difference in EGWG included under effective results because 35% EGWG is considerable improvement from typical statistics for obese women; #Shirazian et al. found to have the strongest effect in decreasing GWG in Streuling 2010 AJCN meta-analysis.

BMI: body mass index; BMR: basal metabolic rate; CHO: carbohydrate; EER: estimated energy requirement; EGWG: excessive gestational weight gain; FITT: frequency, intensity, time, type; GDM: gestational diabetes mellitus; GWG: gestational weight gain; IOM: Institute of Medicine; LGA: large-for-gestational age; MUFA: monounsaturated fatty acid; NICU: neonatal intensive care unit; NW: normal weight; OB: obese; OW: overweight; PA: physical activity; PAL: physical activity level; PAQ: physical activity questionnaire; RCT: randomized-controlled trial; RD: registered dietitian; SES: socioeconomic status; USA: United States of America; WIC: Women, Infants, & Children.

Prenatal physical activity

Benefits of maternal physical activity Evidence from the studies listed in Table 2 suggests physical activity (PA) and/or exercise and dietary interventions may be beneficial in preventing excessive GWG (68-71), yet the benefits extend well beyond this purpose and are well documented (72,73). These benefits include, but are not limited to: reduced back pain, insomnia, nausea, stress, fatigue, and anxiety, improved mood, and reduced risk of cesarean section, preterm birth and LGA infants (73-76).

Prevalence of prenatal physical activity Despite the extensive benefits, very few pregnant women participate in enough exercise to meet current prenatal PA recommendations (77-79). One possible reason for low participation in prenatal exercise may be the confusion concerning the topic, even among medical providers.

History of prenatal physical activity recommendations Historically, the benefits of an active pregnancy date as far back as the third century BC when Aristotle reported a relationship between a sedentary maternal lifestyle and a difficult childbirth (80). However, ACOG has not always supported this viewpoint. The first set of exercise guidelines published by ACOG in 1985 included several restrictions: exercise no more than 15 minutes at a time, keep the heart rate below 140 beats per minute, and do not start an exercise program when pregnant if not active prior to becoming pregnant (81). Due to the extensive literature published shortly thereafter on the benefits of maternal exercise (82), ACOG abolished the restrictions on heart rate and exercise duration in 1994 (83). Finally, in 2002, the terminology used by ACOG changed from "guidelines" to "recommendations" and moderate exercise for 30 minutes a day on most, if not all, days of the week was recommended for all women with a healthy pregnancy regardless if previously active or inactive (72). Unfortunately, many of the old guidelines are still readily communicated to pregnant women, leading to mixed messages about the safety and efficacy of prenatal exercise.

ACOG's 2002 recommendation was based on PA recommendations for non-pregnant adults at the time: "Every US adult should accumulate 30 minutes or more of moderate-intensity PA on most, preferably all, days of the week" (84), with "most days of the week" defined as five days per week (85). Recommendations for pregnant women were also included in the first ever Physical Activity Guidelines for Americans (PAGA) published by the Department of Health and Human Services (DHHS) in 2008 (86). The guidelines for

pregnant women are very similar to that of non-pregnant adults: to achieve at least 150 minutes of moderate aerobic activity per week, preferably spread throughout the week. A minimal duration of 10 minutes at a time is sufficient to produce similar results as longer bouts of activity (85). However, the specificity of bout duration is not included in the prenatal recommendations thus it remains unclear if a specific minimum bout of activity is more beneficial in pregnancy compared to total accumulated PA (82).

Another confusing facet of prenatal recommendations is the use of the terms *exercise* and *physical activity*. *Physical activity* is defined as "any bodily movement produced by skeletal muscle that results in energy expenditure" (84) while *exercise* is a subset of *physical activity*, defined as "planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness" (84). Despite each of these terms having their own distinct definitions, they are often interchanged, and used in the ACOG and PAGA recommendations respectively. It is likely both PA and exercise improve maternal and fetal outcomes, with the distinct independent benefits yet to be identified.

Several studies have evaluated the effectiveness of maternal exercise and PA on positive pregnancy and birth outcomes. However, the volume of exercise prescribed or activity recommendation provided has varied drastically. Relative to preventing excessive GWG, Mottola and colleagues have reported the effectiveness of walking 3-4x/week for 25-40 minutes at 30% heart rate reserve for women across all pre-pregnancy BMI categories (62,63). Among normal weight women, excessive GWG was prevented for 70% of women exercising at the 30% heart rate reserve intensity with a slightly greater improvement (77% achieved appropriate GWG) with an intensity of 70% heart rate reserve (63). Barakat et al. utilized a similar volume of exercise with 35-45 minutes 3x/week of light-moderate intensity (<70% age-adjusted maximum heart rate) aerobic training, while also incorporating stretching and very light resistance training (59). This alone (without any diet or weight gain counseling) significantly decreased total GWG between the exercise group (n=34) and a non-exercise control (n=33) (11.9 vs 13.9 kg, $P = 0.03$) and prevented excessive GWG (normal GWG defined 9-11 kg).

It is important to remember that prenatal recommendations set forth by ACOG and PAGA are based on the appropriate amount of activity necessary to achieve an aerobic benefit, improve cardiovascular fitness, and decrease chronic disease risk factors for non-

pregnant adults (82). This amount of activity is safe for healthy pregnant women with no contraindications to exercise. However, specific volumes of recommended activity (frequency, duration, and intensity) may vary relative to individual prenatal outcomes, such as prevention of excessive gestational weight gain, gestational diabetes, and pre-eclampsia.

Assessment of physical activity during pregnancy Surprisingly, several studies and review articles have not found a relationship between PA, or PA counseling, and prevention of excessive GWG (87-92). The inconsistencies among the literature regarding the effectiveness of maternal PA to prevent excessive GWG may also be influenced by the assessment of PA during pregnancy.

Both objective and subjective forms of PA assessment have been used extensively, each providing their own strengths and limitations. Subjective assessment, such as surveys and activity recall, is inexpensive and can be implemented with a large sample size across a large geographical area. It does, however, inherently rely on participant recall and truthful documentation of activity. A validation study evaluated validity and reliability of a one-week PA recall questionnaire against the ActiGraph in pregnant women from the PIN 3 study. Reported minutes of moderate-vigorous PA (MVPA) from the questionnaire were 85% higher than MVPA observed by the accelerometer (93). Objective assessment of PA in the free-living environment typically involves the use of accelerometers, which may introduce a greater financial burden or involve the use of extensive data analysis and interpretation. Regardless, a recent systematic review evaluating the effectiveness of interventions to prevent the decline of PA during pregnancy encouraged the use of objective monitoring in prenatal PA interventions for two reasons: 1) to avoid the inherent difficulty of blinding participants to their randomization assignment (e.g. exercise or usual care), and 2) to avoid the possible exaggeration of self-reported PA by participants in a randomized PA intervention.

The availability of validated objective PA assessment tools in pregnancy is very limited. Pedometers offer a simple assessment of total step count, but traditionally do not allow for prediction of energy expenditure, intensity of activity, or duration of activity. Typical placement of pedometers on the anterior waistline introduces a tilt angle that influences the accuracy of the step count as pregnancy progresses (94). Similarly, other accelerometers such as the ActiGraph, are commonly worn on the waist, a placement that has

also been shown to be uncomfortable and result in decreased user wear time or compliance (95). Many accelerometers, including the ActiGraph, rely on counts of acceleration and particular cut points to predict intensity of activity and estimate energy expenditure. For example, a common cut point used to define moderate intensity activity in non-pregnant adults is 760 counts·min^{-1} (96), but other cut-points for the same intensity range from 191 counts·min^{-1} (97) to 1952 counts·min^{-1} (98), providing very different amounts of PA. Furthermore, cut points have not been validated for use in pregnancy (93,99).

Pattern-recognition monitors offer similar data output as typical accelerometers (e.g. PA intensity and energy expenditure), but also incorporate heat sensors to improve the estimations of PA and energy expenditure. These monitors, such as the SenseWear® Pro and SenseWear® Mini armbands, have been shown to provide more accurate estimates of energy expenditure than traditional accelerometers such as an older version of the Actigraph, the MTI (100,101). The SenseWear® Mini is a smaller and more advanced model of the armband than the SenseWear® Pro models, and has been shown to be more accurate when both models were compared against doubly labeled water in non-pregnant adults (102). Average total energy expenditure estimates were within doubly labeled water estimates by 22 kcal·day^{-1} for the Mini and 112 kcal·day^{-1} for the Pro model (ICC 0.85, 95% CI = 0.92-0.76 vs ICC 0.80, 95% CI = 0.89-0.70). The SenseWear® armbands incorporate data from four heat sensors and an accelerometer into proprietary algorithms to predict energy expenditure (kcals) for each minute of wear time. The intensity of an activity is then estimated using metabolic equivalent of task (MET) values by the equation: METs = kcal·hour^{-1}·kg^{-1}. Activity intensities are categorized by the MET value into sedentary behavior (1.0-1.5 METs), light-intensity PA (1.6-2.9 METs), moderate-intensity PA (3.0-5.9 METs), and vigorous PA ($\geq$ 6.0 METs) (103). Overall, the availability of valid tools to objectively assess physical activity during pregnancy is very limited. The SenseWear® Mini may be a promising option to further investigate for use in pregnant women since it does not involve the use of cut-points to determine physical activity or energy expenditure and it is conveniently worn on the arm, rather than the waist.

Dietary intake during pregnancy

Dietary modifications are commonly utilized in addition to PA to prevent excessive GWG. Determining caloric intake and comparing to dietary recommendations is commonly

thought of as the first step to nutrition assessment in any population. Estimated energy requirements for pregnant women are frequently determined with the use of the Institute of Medicine's Dietary Reference Intakes (104). For non-pregnant women 19-50 years old, energy requirements are approximately 2403 calories per day. During pregnancy, an additional 340 and 452 calories per day are added during the second and third trimesters, respectively (2743 and 2855 calories total per day), to account for the increased metabolic demands of pregnancy including fetal and placental growth, increased maternal adiposity, and blood volume. Similarly, prediction equations to estimate energy needs during pregnancy were published in 2002 as part of the Dietary Reference Intakes (104). The equations were based upon energy expenditure data collected from the doubly labeled water method, including data from pregnant women with a variety of activity levels (104). However, previous reports have indicated a wide variability in maternal energy expenditure, energy deposition, gestational weight gain, and consequently energy costs during pregnancy (105).

Energy intake during pregnancy Pilot data collected from women 18 weeks pregnant living in central Iowa reported an average daily intake of 2,084 calories (median 2,035 calories) via a 3-day weighed diet record (Unpublished data, Campbell). This is similar to previous reports of national epidemiological data that utilized food frequency questionnaires and reported median daily intakes of 2,008 (106) and 2,478 calories (107). Interestingly, when categorized as under reporters, adequate reporters, and high intake reporters, the median (± IQR) daily intakes were 1,483 ± 451, 2,182 ± 583, and 3,801 ± 1,213 calories, respectively (106). In the same study of nearly 1,000 pregnant women (n=988), the median energy intake (EI) to estimated energy requirement (EER) ratio (EI:EER) was 0.85, demonstrating under-reporting of energy intake was common, particularly among obese women (49.8% of obese women under-reported energy intake) (106). Collectively, these data indicate two things. The first being that on average, pregnant women do not appear to be consuming an excessive number of calories during pregnancy relative to the Institute of Medicine's estimated energy requirements (~2,084 calories consumed vs ~2743 calories recommended). However, as previous research demonstrates, underreporting energy intake is particularly common during pregnancy, particularly among obese women (106). Thus, it is difficult to truly understand energy intake in this population, and furthermore, comprehend the role it plays in GWG.

Dietary quality Caloric intake, however, is not likely to be the only dietary contributor to GWG; diet quality should also be considered due to its robust relationship with perinatal outcomes (108,109). Inadequate maternal folate intake has long been attributed to neural tube defects, but recent reports also suggest an association between increasing maternal diet quality and reduced risks for cleft lip and palate (108). Data from the Project Viva cohort reported direct associations between maternal intake of total energy, dairy, and fried foods with excessive GWG. Meanwhile, percent of total calories from monounsaturated fats were inversely related to excessive GWG (110).

Currently, two primary methods exist to assess diet quality specifically during pregnancy in the United States, the Dietary Quality Index for Pregnancy (DQI-P) (111), and the Alternate Healthy Eating Index-Pregnancy (AHEI-P) (112). The DQI-P was developed by researchers with the PIN Study and based off of the current Dietary Guidelines for Americans at the time (2005) and the Food Guide Pyramid. It includes the following eight categories, each worth 10 points for a total maximum score of 80: daily servings of grains, vegetables, and fruits; folate, iron, calcium and total fat intake; and meal patterning (discerning between frequency of meals and snacks). While the frequency of meals and snacks are considered in the diet quality score, these are not defined by the authors of this methodology making it very difficult to implement this tool and score this aspect of the assessment. Additionally, the DQI-P does not distinguish between different types of fat, potentially influencing the qualitative score provided by this index since not all fats have been shown to equally contribute to maternal outcomes, such as GWG (110).

The Alternate Healthy Eating Index (113) was based on the Healthy Eating Index (HEI)-2005 developed by the United States Department of Agriculture after the publication of the Dietary Guidelines for Americans 2005 (114), and then further modified to include nutrition recommendations during pregnancy to create the AHEI-P (112). The AHEI-P measures diet quality on a 90-point scale via nine categories where each category has a maximum score of 10 points: vegetables; fruit; ratio of white to red meat; fiber; *trans* fat; ratio of polyunsaturated to saturated fatty acids; and folate, calcium, and iron from foods only (not including vitamins or supplements). A higher score indicates a higher diet quality, and has been associated with higher maternal age, lower blood glucose, and slightly reduced risk of pre-eclampsia (112). Mean AHEI-P scores of 1,777 women in the first trimester were 61 ±

10 (33-89) based on results from a food-frequency questionnaire. One important observation to consider is the lack of the AHEI-P to consider total energy intake in the index score. Thus, it is possible to achieve a high diet quality score on this index but simultaneously radically exceed recommended calorie intake.

Due to the limitations of the AHEI-P to consider total energy intake and the difficulties of defining meals and snacks to appropriately score a diet using the DQI-P, some researchers have chosen to use the HEI-2005 to assess diet quality during pregnancy (115,116). This tool, along with the most recent version of the HEI (HEI-2010), assess diet quality on a per calorie basis, thus no additional modifications are needed for pregnancy (117). The maximum score for the HEI-2005 is 100, with scores coming from 12 different categories worth either 5 points maximum (total fruit, whole fruits, total vegetables, dark green and orange vegetables, vegetables and legumes, total grains, and whole grains), 10 points maximum (milk, meat and beans, oils, saturated fat, and sodium), or 20 points maximum (solid fats, added sugars, and alcohol). An overall HEI score above 80 is considered 'good', while a score of 50-80 'needs improvement', and scores below 50 are considered poor (115,118). Data from 301 overweight and obese pregnant women in Australia indicated a significant decline in HEI scores across pregnancy: 56.7 ± 10.1 between 10-20 weeks gestation, 54.0 ± 10.3 at 28 weeks gestation (P <0.001), and 54.0 ± 9.7 at 36 weeks gestation. Decreasing scores came from decreases in milk, meat, and oils and increases in the proportion of energy from solid fats, alcohol, and added sugars ($P < 0.001$) (115). Tsigga et al. evaluated diet quality using the HEI-2005 among 100 pregnant women in Athens, Greece (119). The mean HEI score was 66.9 ±0.6 (n=9 first trimester, n=47 second trimester, n=44 third trimester). However, the HEI score during pregnancy differed by pre-pregnancy BMI with the HEI of normal weight women (n=62) significantly higher than that of overweight women (n=19) (67.1 ± 0.6 vs 66.6 ± 0.6, respectively, $P \leq 0.01$) but not of obese women (n=11; 67.1 ± 0.6 vs 66.7 ± 0.4). HEI was negatively associated with pre-pregnancy BMI (r = -0.298, $P \leq 0.003$) while protein intake as a percentage of total energy intake was positively associated with HEI score (r = 0.306, $P \leq 0.002$).

The impact maternal diet and diet quality have on GWG continues to garner more attention. A recent cross-sectional study using NHANES data from 490 women tested the hypothesis that diet quality during pregnancy (evaluated by the HEI-2005) is associated with

adequate GWG (defined by the 2009 IOM guidelines) at different stages of pregnancy (116). After adjusting for age, trimester of pregnancy, race/ethnicity, education, marital status, income, daily supplement use, PA, and pre-pregnancy BMI, HEI-2005 scores did not differ significantly (P = 0.15) across GWG groups (inadequate GWG, adequate GWG, excessive GWG). However, inadequate intake of total vegetables and oils were associated with excessive GWG (OR 2.8, CI 1.2-6.4, *P* = 0.02).

A recent systematic review of 12 observational studies concluded both energy intake and protein intake were significantly positively associated with GWG, while carbohydrates and a vegetarian diet were both associated with lower GWG (68). However, these findings are limited by the inherent inability for causal relationships due to the observational study designs. Similarly, the review lacked specificity and clarification regarding the type of association (positive or negative) between carbohydrate intake and GWG. A large meta-analysis of 44 randomized controlled trials by Thangaratinam et al. concluded dietary interventions were the most effective of the lifestyle interventions studied (diet, PA, GWG feedback, counseling, or a combination of some or all of these components) in reducing maternal GWG and improving obstetric outcomes, including reduced risk for gestational diabetes mellitus and pre-eclampsia (71). However, among the 34 trials included in the analysis on maternal weight gain, there was no significant difference between control and interventions groups in the effectiveness to promote adherence to the IOM weight gain recommendations (relative risk 0.85, 0.66 to 1.1). Furthermore, Skouteris et al. (120) and Ronnberg et al. (121) used many of the same studies in their systematic reviews, and concluded the evidence for the effectiveness of these interventions was not convincing.
A better understanding of the role of diet quality in GWG is warranted to further improve the effectiveness of interventions designed to prevent excess GWG. The recent publication of the HEI-2010 (117) provides an opportunity for diet quality to be evaluated according to the 2010 Dietary Guidelines for Americans (122). To date, no studies have evaluated diet quality in pregnancy using the HEI-2010.

Behavioral theory

The wide variability in success rates reported among interventions to prevent excessive GWG and promote adherence to the IOM weight gain recommendations may in part be explained by the inconsistent use of behavioral theory in the design of prenatal

interventions (99,123). Behavioral theory provides a framework for understanding why individuals do or do not participate in a particular behavior, what motivates them to do or not do the behavior, and what barriers challenge their adoption of a new behavior (124). The use of behavioral theory incorporates methods to overcome particular barriers to change, such as environmental influences, social support, and self-confidence. It individualizes the approach to explore what may and may not work to promote change for a particular person. Behavior modification is a fundamental characteristic of improved health yet it can be difficult to adopt and even more difficult to sustain as a lifestyle change. Counselors, dietitians, psychologists, and exercise and medical professionals frequently use learning theories to understand behavior, individualize the approach for each individual, and promote behavior change. Historically, information was commonly dispensed to patients and clientele without any effort to assist the individual in initiating a change in behavior. This practice is very similar to the standard obstetrical practice to distribute information on gestational weight gain, and prenatal diet and PA, without any counseling to achieve a healthy weight gain. During the 1990's, goal-setting became widely accepted as a client-centered counseling technique (125). More recently, a variety of behavioral theories (e.g. social learning or social cognitive theory, self-determination theory, motivational interviewing, transtheoretical model, etc.) are being incorporated into counseling and interventions alike (53,124) to understand the individual and the factors that influence behaviors socially, culturally, psychologically, and physiologically.

Social Cognitive Theory One behavioral theory that has played a dominant role in health education for many years is the social cognitive theory. This theory stemmed from the social learning theory, developed by Rotter and Bandura in the mid-twentieth century (126,127). The social learning theory was based on the ideal that learning occurs by observing others in the individual's environment. This theory was later renamed the social cognitive theory by Bandura in 1986 (126). The title, social cognitive theory, directs attention towards the social influences on behavior as recognized by the social learning theory, but also incorporates the cognitive contribution of the individual's thoughts, motivation and actions. The social cognitive theory (SCT) has widely been implemented as the foundation of many health education practices for many years (127), including dietary (128-131) and PA (131-134) interventions. Contrary to many theories focused on reinforcement as the primary

determinant of behavior, cognitive theories recognize the individual has expectations of the consequences of behavior change (e.g. if people are in a weight loss program and follow the program appropriately, they would expect to lose weight). These are termed *outcome expectations*. Similarly, *outcome expectancies* are the values that people place on an expected outcome (e.g. how important weight loss really is to them or not). *Outcome expectancies* and *outcome expectations* are two of the nine key constructs of SCT, in addition to reinforcement, behavioral capability, locus of control, reciprocal determinism, self-regulation (self-control), emotional coping response, and self-efficacy (127). This review will focus on the six constructs related to the current intervention discussed later in this document: self-efficacy, self-regulation, reciprocal determinism, behavioral capability, emotional-coping response, and reinforcement.

Key constructs of SCT: Self-efficacy Self-efficacy is defined as how competent an individual feels to do a task and how confident he/she is in his/her ability to overcome the barriers to performing the task or behavior (127,128). Self-efficacy is commonly referred to as the key construct of SCT that elicits behavior change, and has been recognized as the key determinant of healthy eating (129) and a predictor of PA in pregnancy (135). If individuals do not believe they will experience success, then they have little motivation to pursue a behavior change knowing they will experience many difficulties along the way (127). This mindset can be overcome by increasing self-efficacy in several ways: mastering the task themselves by actually doing the task (performance accomplishments), observing others doing the task (vicariously), being encouraged by others to do the task (verbal persuasion), dealing with emotions that surround the behavior (emotional arousal), self-regulation (monitoring the behavior), and social support (peer influence) (127,128). In order to increase self-efficacy, the focus must be on the positive outcomes of behavior change (e.g. the benefits of changing a particular behavior) rather than the negative (e.g. barriers an individual may experience along the way).

Key constructs of SCT: Self-regulation Self-regulation is another construct of SCT that directly relates to self-efficacy. Self-regulation is defined as gaining control over one's own behavior (127) by controlling the actions that pertain to the behavior (130). This can be done through monitoring and appropriately adjusting the behavior using self-regulating techniques such as goal-setting and behavior tracking. Self-regulation is used to increase self-

efficacy but likewise, improving self-efficacy can also increase self-regulation. For example, if an individual believes he/she will have success in participating in a particular behavior (self-efficacy), he/she will likely experience success in monitoring this behavior (self-regulation), leading to adoption and maintenance of behavior change (129). Conversely, if the individual is able to accomplish small goals along the way to accomplishing a larger goal (self-regulation), he/she may feel more confident in the ability to achieve the ultimate behavior change (self-efficacy). Research on obesity and weight management has widely incorporated the use of self-regulation as it relates to nutrition and PA. Self-regulation has been associated with healthier eating by promoting healthier intakes of fruits, vegetables, fiber, and fat in adults (129). In an intervention designed to explore how SCT constructs influenced nutrition behavior, self-regulation was the best predictor of overall nutrition (129). Planning to purchase healthier foods (more fruits and vegetables to increase fiber and decrease fat consumption) and tracking food intake led to lower intake of fat (β [total] = -0.45, P <0.01), higher consumption of fiber ((β [total] =0.61, P <0.001), and increased intake of fruits and vegetables ((β [total] =0.52, P <0.001).

Key constructs of SCT: Reciprocal determinism The construct of reciprocal determinism combines the cognitive influences of the individual with the social persuasions of the environment as they relate to behavior. As a result, there is an interaction among the individual, the environment, and the behavior. Perceived support from the social environment (e.g. social support from family, friends, co-workers, etc.) is an important determinant of behavior change as a pre-cursor to increase self-efficacy (129). While the early stages of behavior change may consist of the environment influencing the person, the later stages of change may also be defined by the person influencing the environment (127). Improvement in self-efficacy may render an individual to change his/her environment in order to increase the possibilities for behavior change to be sustained (or decrease the likelihood for relapse).

Key constructs of SCT: Behavioral capability In order for behavior change to occur, individuals must have the knowledge and skills necessary to perform the behavior. Like other constructs of SCT, behavioral capability is closely linked with self-efficacy: knowing how to do a certain task and having the skills to do so may increase an individual's confidence that the task can be accomplished (127).

Key constructs of SCT: Emotional-coping response People must be able to deal with the sources of anxiety that may surround a behavior in order to learn and adopt a new behavior (127). Strategies to help deal with an individual's emotions include, but are not limited to, problem-solving, social-support, and stress management.

Key constructs of SCT: Reinforcement Reinforcement is the response to behavior that may increase the change of reoccurrence. It can occur in three ways: directly (receiving verbal praise for a job well done), vicariously (seeing someone else being praised for a particular behavior, also known as observational learning), or through self-reinforcement (rewarding one's self when a behavior is performed) (127).

Use of SCT in research and practice Several interventions have incorporated the use of SCT to improve diet and PA in non-pregnant populations. Anderson et al. integrated self-efficacy, self-regulation, outcome expectations, and social support (reciprocal determinism) to determine how the SCT explains the food purchases and consumption of food among adults, primarily overweight or obese adults (79% of participants) (129). Shopping receipts and food-frequency questionnaires were used to collect quantitative data related to nutrition behavior while psychosocial questionnaires were used to collect qualitative data. The social cognitive variables were measured with the use of a commonly used survey to quantify social cognitive variables, known as the Food Beliefs Survey (129,130). The constructs of SCT assessed in this study explained up to 60% of the variance in the purchase and consumption of fat, fiber, fruits and vegetables. Results also indicated that characteristics such as age, gender, socioeconomic status, social support, self-efficacy, outcome expectations, and self-regulation also contributed to nutrition behavior. The results from this study suggest the pivotal role that self-efficacy, self-regulation, outcome expectations, and social support play in explaining healthy behaviors. Future interventions seeking behavioral change or adoption of healthier lifestyles, particularly related to nutrition, should implement strategies to positively influence these SCT constructs.

Grim et al. used the SCT as a foundation for the design of a web-based intervention to increase PA (132). Three groups of non-pregnant young adults were tested for ten weeks. The first group was not required to participate in exercise but received general health information in a traditional classroom setting three times per week at a collegiate institution. One lecture discussed the benefits of PA and recommendations for improving health and

fitness. The second group received the information in a traditional PA course at the same institution with one lecture and three guided exercise sessions each week. The third group was a web-based group and received the information via an online course and was required to participate in at least three exercise sessions per week on their own and log the activity. Weekly lessons in the web-based group focused on self-regulation via self-monitoring, goal-setting, exercise opportunities, and reinforcements; outcome expectancy value by discussing the benefits of exercise and reasons to exercise; self-efficacy by tailoring PA to their likes and needs, overcoming barriers, goal setting, self-reinforcement, and time management; and social support by assigning students to find a fitness buddy to exercise with at least once throughout the course. While one may predict the supervised activity group to be the most successful, the web-based group also significantly increased their PA from pre-post evaluations (pretest mean of 4.16 days per week of moderate-vigorous PA vs posttest mean of 6.05, $P < 0.01$). The PA among the general health group did not change over time. Furthermore, the web-based group and the PA course group were not significantly different in the amount of weekly moderate-vigorous PA post-intervention. The web-based group and PA course showed improvements in self-regulation, self-efficacy, and outcome expectancy value, demonstrating that an online course using social cognitive theory as the foundation of the intervention can be just as effective in promoting PA behavior change as a supervised in-person approach.

Use of behavioral theory & SCT during pregnancy While the use of behavioral theory has been widely employed in non-pregnant adults and children, its use is limited in prenatal interventions. A recent American College of Sports Medicine/American Diabetes Association Joint Position Statement stated, "efforts to promote physical activity should focus on developing self-efficacy and fostering social support" (136). Barriers to PA specific to pregnancy include fatigue, discomfort, perceived lack of time, and lack of social support (137). Previous research has demonstrated a pregnant woman's motivation to exercise most strongly predicts her exercise behavior in the second and third trimesters (138,139). As a result, researchers have suggested the use of goal-setting and the creation of a supportive social network to increase intention to exercise and ultimately the implementation of this behavior (138,140).

The vast majority of previous studies that focused on prevention of excessive GWG were not based on a behavioral theory (141). Of the 13 interventions that effectively prevented excessive GWG (Table 2), nine were either rooted in a behavioral theory (Social Learning Theory) (57) or incorporated behavior change techniques (54-58,62,63,65), such as self-monitoring of PA (56-58,62,63,65), diet (54,56-58,62,63,), and/or GWG (54,58,62,63), charting GWG with feedback (54-58), goal-setting (54-58), or problem-solving (56,61). Motivational interviewing techniques are another counseling approach used to elicit behavioral change and have been used to construct an interactive doctor on video to provide counseling to low-income pregnant women on nutrition, exercise, and GWG. Briefly, the interactive doctor on video asks demographic and behavioral assessment questions, delivers tailored counseling messages based on the patient's responses (e.g. BMI, eating and exercise habits, and readiness to change), and provides printed output for both the patient and the practitioner. While the multimedia feature was effective in significantly improving several components of dietary intake (fruits and vegetables +0.4 servings/day; whole grains +0.7 servings/day; fish, avocado, and nuts +0.7 servings/day; sugary foods -0.4 servings/day; white grains -0.5 servings/day; high fat meats -0.7 servings/day; fried foods -0.7 servings/day; solid fats -0.6 servings/day; and fast food -0.5 servings/day; each outcome P <0.05) and increasing weekly amounts of exercise (+28 minutes/week, $P < 0.05$), there were no significant differences in GWG or prevention of GWG compared to usual care (142). Similarly, the Problem Solving Treatment Theory for primary care provided the foundation for the New Life(style) randomized controlled trial in the Netherlands. This theory focuses on helping people gain control over their difficulties and allows the researcher or counselor to act as a coach for the individual (88). The New Life(style) study was aimed at preventing excessive GWG in nulliparous women but it too had no effect on preventing excessive GWG (OR = 0.92; 95% CI 0.48-1.77) while 71% (n = 145) of participants gained in excess of the 1990 IOM recommendations (88,143). While not statistically significant, overweight and obese women (n=47) in the intervention group gained 10.6 ± 5.2 kg compared to 12.1 ± 3.8 kg in the control group. Seventy-five percent of overweight and obese intervention participants gained excessively compared to 100% of the overweight and obese control women (88,143). However, in a process evaluation of the same intervention, the authors reported a low adherence (43.2%) to the use of this theory (144). Adherence was defined as

the inclusion of six required theory components at each session by each of the two counselors. An average of only one of the six theory components was implemented during all sessions, with one counselor scoring significantly higher using these components than the other counselor (mean difference = 0.28; $P < 0.001$). Data concerning adherence and compliance to the study protocol, whether by researchers or participants, provide important efficacy data that are commonly not reported for other interventions (144).

Despite the fact that SCT has provided the basis for many of the PA interventions in the literature (124) only three studies to date have used it during pregnancy. Chasan-Taber et al. used SCT in conjunction with another behavioral theory, the Transtheoretical Model in the B.A.B.Y. (Behaviors Affecting Baby and You) Study to increase exercise in a diverse sample of pregnant women at high risk for gestational diabetes (145). The Transtheoretical Model helps to understand how and when individuals make behavior change by recognizing individuals do so by moving through specific stages of change (145). Specific behavioral strategies included weekly PA goal setting, building social support, encouragement of self-monitoring of exercise, overcoming barriers to PA, and counseling by health educators to overcome barriers if PA goals were not achieved. Women in the exercise group experienced a significantly smaller decrease in total PA across pregnancy compared to the control (-1.0 MET-hrs/wk vs -10.0 MET-hrs/wk, $P = 0.03$) and a significantly larger increase in sports/exercise (0.9 MET hrs/wk intervention vs -0.01 MET-hrs/wk control, $P = 0.02$) (146). Secondly, Ferrara et al. conducted a pilot prenatal/postpartum intervention to modify diet and PA in women diagnosed with gestational diabetes to promote achieving postpartum weight loss goals (147). Similar to the B.A.B.Y. Study, Ferrara et al. also utilized constructs of both the SCT and Transtheoretical Model. The prenatal portion of the intervention included one in-person and two telephone counseling sessions by a registered dietitian to discuss gestational weight gain recommendations, encourage 150 minutes per week of moderate intensity PA, and dietary modifications such as low glycemic food choices, low-fat diet, and proper interpretation of food labels. A 7-day PA recall at baseline (following gestational diabetes diagnosis ~28 weeks) and 7-months postpartum revealed a non-significant increase in MVPA (mean difference between groups 25.3 minutes per week, $P = 0.91$) among intervention participants. However, since PA was not assessed a second time during

pregnancy, it is unknown if the intervention had any effect on increasing PA during pregnancy.

Finally, Smith et al. is currently conducting a 10-week community lifestyle program based on SCT to improve physical and psychological well-being of 400 obese pregnant women in England (148). Incorporated behavioral change techniques include self-efficacy, outcome expectations (develop realistic expectations about benefits of behavior change), feedback on behavior change from health care professionals, positive reinforcement from health care professionals and other women in the group, and social support. Outcomes of interest include maternal GWG, self-efficacy, well-being, goal attainment, PA, food intake, birth weight, mode of delivery, and method of infant feeding at hospital discharge (148). Therefore, the use of SCT to potentially influence positive behavioral modifications during pregnancy remains largely to be further explored.

Online source of health information during pregnancy

Utilizing the Internet as a source of information during pregnancy is common and well-accepted (149-151). Medical providers typically provide general information about pregnancy in paper handouts or books, but few women report using such sources (22.3% and 11.9%, respectively) (152). Thus, a few studies have evaluated the use of online sources for health-related information during pregnancy. A Swedish study interviewed 182 women during their time in the waiting room for prenatal appointments and discovered 91% had access to the Internet and nearly all of these women (84%) used the internet as a source of information while pregnant, most often during the early months of pregnancy. Most participants accessed the Internet at least once a month for this reason, while the median use among participants was four times per month during pregnancy (151). The most commonly researched topic was fetal development (59% of women) with childbirth (20%) and nutrition during pregnancy (18%) as the next two most popular searches. Women were asked to evaluate how reliable they perceived the information on the Internet and reported the two most important factors were if the information coincided with other sources and if references were available. While this study was not conducted in the United States, maternity care is available via the public-health system in Sweden and is free of charge. Thus, it is reasonable to believe the sample includes women across a range of socioeconomic status (151). Furthermore, 72.4% of homes in the US have Internet access (153) and thus similar usage of

the Internet during pregnancy has been reported in the US. A survey of 293 women in the Midwest revealed 94% of the respondents used the Internet to retrieve pregnancy related information, while nearly half (44%) of the women used it for information regarding PA (154). Women reported an increased confidence to make decisions regarding prenatal PA and 26% reported increasing their PA as a result, while only 3.8% had decreased their PA. Eighty-nine percent of women used the Internet at least "somewhat" for information related to foods eaten during pregnancy and 67% reported increasing fruit and vegetable consumption. Sixty-one percent changed their beverage of choice and reported drinking less sugar sweetened beverages, indicating that information retrieved on the internet during pregnancy influences maternal decisions on PA and dietary choices.

An international survey (placed on 23 websites) designed to deliver general information on pregnancy, collected responses from 613 women who were currently pregnant (61.8%), or had a baby in the past year (38.2%), and had used the Internet as a source of information during pregnancy (152). The purpose of the survey was to determine why and how pregnant women use the Internet as a source of health information and how this influences their decision-making. Respondents spanned 24 different countries including, but not limited to, the United Kingdom (34.4%), Australia (23.8%), US (16%), New Zealand (9.3%), Canada (9.1%), and Ireland (3.8%). Nearly all women had access to the Internet at home (96.6%) and used this as their main source of access when viewing web pages (84%). Most women (60.5%) had access at work but only 15% utilized this source; no participants accessed the Internet from a public source such as a library or Internet café. The purpose of using the Internet spanned a wide variety of responses, with most women using it to find information "on their own" (99.3%), to learn more about a topic provided by their medical provider (93.8%), or to explore particular symptoms (88.7%). Forty-nine percent used the Internet to clarify information from a medical provider that was not clear or unsatisfactory (48.6%), while 46.5% used it to seek information due to the lack of time to ask a medical provider a question during their appointment. Collectively, this data suggests there are multiple intentions of using the Internet as a source of information during pregnancy and the information retrieved from the Internet can influence maternal behavior.

Online interventions As a result of the popularity of the Internet, an increasing number of interventions have been delivered online (e.g. e-programs, e-interventions).

Reviews of the literature have reported similar improvements in outcomes from e-studies compared to face-to-face interventions involving a variety of populations and programs (132,155-158). Furthermore, web-based programs have been shown to be more cost-effective than traditional forms of interventions such as clinic, work-site, or phone delivery (159). Concerns faced by many online interventions include high attrition rates, user adherence (160), selective enrollment, and selective adherence (161).

Prenatal online interventions An online healthy prenatal lifestyle program was initiated in Amsterdam and concluded that higher-educated women were more likely to enroll in the program (47% of participants had obtained higher-education compared to 13% had not, $P = 0.01$) as well as more likely to continue to use the program after enrollment than those who had not completed higher-education degrees (63% vs 45%, $P = 0.02$) (161). Similarly, women with a healthier lifestyle were more likely to enroll in the e-program (not overweight, non-smoking before or during pregnancy, no use of alcohol during pregnancy, and use of supplemental folic acid), a finding replicated elsewhere in non-pregnant adults (162). The program was designed to promote a healthy pregnancy and provide links to reliable websites for information regarding nutrition, exercise, lifestyle, smoking, safety, and pregnancy. Monthly interactive quizzes were delivered via email to promote access of the information on the websites. Once an answer to the quiz question was selected, feedback was provided and a link was given to access a practical tip. Fifty-two percent (n=120/238) of the women continued to use the program throughout the pregnancy, with the use of the quizzes gradually declining across pregnancy (61% opened at week 16 of pregnancy vs 29% at week 40). The study reported among quizzes opened, 85% of lifestyle topics were accessed, but supplementary information (links to related websites) was accessed considerably less frequently (37% of practical tips and 12% of related websites accessed) and not accessed at all by most participants (71%). Nulliparous women were more likely to access a supplementary website than primiparous (39% vs 22%, $P = 0.002$). Considering the widespread use of the Internet among pregnant women, the demonstrated impact it has on changing maternal behavior, and the very limited use of the Internet to deliver interventions among this population thus far, future interventions should consider an online approach when working with pregnant women.

Conclusion

A resolution to the frightening obesity epidemic is necessitated for the health of future generations worldwide. Excessive gestational weight gain imparts a substantial risk for maternal postpartum obesity as well as childhood obesity. Pregnancy provides an opportune time for intervention; women are receiving frequent health care and are more inclined to make behavioral modifications to optimize the well-being of their unborn fetus. Obstetric medical providers are hard-pressed for time to discuss diet and exercise with their patients, and report concerns conversing about gestational weight gain, particularly with overweight and obese patients. Consequently, pregnant women turn to their peers for advice and social support, and frequently seek prenatal lifestyle information from the Internet. The National Physical Activity Plan published in 2010 supports the substantial influence of mass media on behavior. Specific strategies to increase PA in the United States within this plan include the encouragement of web-based PA interventions (Mass Media Strategy #7) (163). Pratt et al.'s review on the implications for technology and changes in PA provide insight into perhaps the best way to use technology: "few web-based physical activity trials have used program features specifically matched to theoretical constructs known to result in changes in physical activity behavior and likely to increase effectiveness" (164). Specifically in pregnancy, a recent demand for interventions with a behavioral framework has garnered much attention but resulted in little action and development of new studies (99,123). Furthermore, a recent systematic review of behavioral interventions designed to improve PA among pregnant women discovered that of the 777 publications identified in their search, only 9 interventions fit their search criteria: increase PA as the primary or secondary outcome, randomized-controlled trial (RCT), inclusion of PA measures at baseline and follow-up, and no use of mandatory exercise sessions to promote elective, non-mandatory PA among participants. Perhaps even more striking is the fact none of these 9 interventions included an objective measure of PA (165). The combination of these two calls to action, web-based PA trials using behavioral constructs, and prenatal PA interventions focused on a behavioral framework, and the lack of robust RCT interventions designed to increase PA in pregnancy lend themselves to a unique and warranted study design. The Blossom Project Online, an interactive behavioral theory-based website to promote maternal exercise and prevent

excessive gestational weight gain, may be a pivotal step towards preventing the multigenerational cycle of obesity.

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CHAPTER 3: VALIDITY OF THE SENSEWEAR® ARMBAND TO PREDICT ENERGY EXPENDITURE IN PREGNANT WOMEN

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Abstract

Few valid, objective methods exist to quantify physical activity and predict energy expenditure (EE) during pregnancy. **Purpose:** The purpose of this study was to evaluate the validity of the SenseWear® Mini armband monitor (SWA) to estimate EE in pregnant women. **Methods:** Thirty healthy pregnant women (22-24 weeks gestation) completed a series of activities of daily living (typing, laundry, sweeping, treadmill walking: 2.0, 2.5, 3.0 mph, 3.0 mph, 3% incline) while EE was estimated by the SWA and measured by indirect calorimetry (IC). The SWA data were processed using both the v2.2 algorithm and the newer v5.2 algorithm. The estimated EE values were compared to the measured EE values using a 3-3- way (Method x Algorithm x Activity) mixed model ANOVA. Least square means $\pm$ SE were estimated in the model. Significance was set at $P < 0.05$. **Results:** The analyses revealed a significant Method (IC vs SWA) x Algorithm (v5.2 vs v2.2) interaction with significantly smaller error (IC – SWA) for the newer v5.2 algorithm (-0.57 ± 0.06 kcal·min^{-1}) than the older v2.2 algorithm (-0.78 ± 0.06 kcal·min^{-1}). The SWA significantly overestimated EE for all activities, except inclined walking. The average mean absolute percent error was considerably lower for the new algorithm (22%) than the older algorithm (35%). The average individual correlation coefficients revealed good overall agreement between the SWA and the IC (v5.2: mean r = 0.93; v2.2: mean r = 0.87). **Conclusion:** Overall, the SWA correlated well with indirect calorimetry; however, EE was significantly overestimated during most activities. Future studies should develop pregnancy-specific algorithms and assess validity of the SWA at all stages of pregnancy to further improve prediction of EE in this population.
Key words: activity monitor, validation, pregnancy, physical activity, assessment

Introduction

Paragraph Number 1 Maternal pre-pregnancy weight status and excessive weight gain are independent risk factors for future maternal and childhood obesity, cardiovascular disease and diabetes mellitus (13,26). Utilizing physical activity for the management of healthy weight gain during pregnancy represents an important strategy to reduce the prevalence of chronic disease. The current American Congress of Obstetricians and Gynecologists' recommendations (3) state that all women without medical or obstetric complications accumulate at least 30 minutes of exercise on most, if not all, days of the week. To accurately assess physical activity and energy balance relative to maternal weight gain, valid tools are necessary to predict energy expenditure in pregnant women.

Paragraph Number 2 A few subjective questionnaires have been designed and validated specifically for use during pregnancy. Some of these include the Pregnancy Physical Activity Questionnaire (9), Physical Activity and Pregnancy Questionnaire (18), the Pregnancy Infection and Nutrition 3 (PIN3) physical activity questionnaire (16), and one by the Norwegian Mother and Child Cohort Study, MoBa (5). Additionally, the Kaiser Physical Activity Survey was designed for use in women (1) but has since been validated for use in pregnant women (36). These subjective tools provide a way to evaluate general levels of physical activity but they are not sufficient for detailed assessment of energy expenditure during pregnancy.

Paragraph Number 3 A variety of objective monitoring devices are available but each have inherent limitations. A number of studies have used pedometers in pregnancy-related studies (10,11,15,19,32) but they have been used mainly for self-monitoring applications. While they are well suited for these applications, they have limited use for monitoring intensity of activity or for studies evaluating weight gain and pregnancy outcomes. Accelerometry-based activity monitors have been tested and validated for use in different segments of the population but, surprisingly, little has been done to test their utility in pregnant women (19). A possible reason for this is that most commercially available monitors require detailed calibration processes that enable movement "counts" to be converted into estimates of energy expenditure. Typically, quantification of physical activity intensity is predicted from raw energy expenditure estimated by the monitor. However, the dynamic change in metabolism (6) and body composition during pregnancy makes this a

particularly challenging endeavor and pregnancy-specific equations or cut points have not been developed. Another limitation of many objective monitoring devices is that most are designed to be worn on the waist. Previous studies have reported decreased compliance in late pregnancy with placement on the waist (19,28). Improvements in physical activity assessment techniques are needed to advance the sophistication of research on pregnancy related outcomes.

Paragraph Number 3a A promising new activity monitor known as the SenseWear® Mini armband monitor (SWA) offers potential for overcoming limitations with current monitoring technologies. An advantage of the SWA is that it is worn on the upper arm which presents a convenient and comfortable location, particularly for pregnant women. The monitor is a multi-sensor device that combines data from three accelerometers with information from several heat-related channels to improve the precision of physical activity and energy expenditure (EE) estimates. Several recent studies have demonstrated that the SWA provides more accurate estimates of EE than traditional accelerometers for monitoring lifestyle activities (7,39). A recent study by Johannsen et al. (22) evaluated validity of the SWA to predict energy expenditure, reporting mean absolute error rates of approximately 8% against doubly labeled water. Due to the dynamic metabolic state of pregnancy, methods of assessing energy expenditure and physical activity need to be evaluated for validity specifically in pregnant women. The inclusion of heat related variables in the SWA offer similar potential for evaluating the metabolic effects associated with pregnancy but specific validation studies have not been done with this population.

Paragraph Number 4 Other studies have evaluated the prediction of energy expenditure in pregnant women and these studies have used uniaxial accelerometers (38), waist or wrist placement (14,25,39), or only included conditioning exercises without assessing any common activities of daily living (4). The present study will fill that gap by evaluating the validity of the SenseWear® Mini Armband, against indirect calorimetry in a controlled laboratory setting during a series of daily activities in mid-pregnancy. A unique advantage of the SenseWear® platform is that the pattern recognition algorithms are continually updated as refinements are made. Previous research has demonstrated that the various enhancements have continued to improve accuracy so a secondary goal of this study was to directly compare performance of the previous algorithm (version 2.2) with the newest

algorithm (version 5.2). This will make it possible to evaluate possible improvements in accuracy between these versions. It is hypothesized that the newer algorithm will more accurately estimate EE compared to the older algorithm.

Methods

Research participants

Paragraph Number 5 Forty-one healthy pregnant women (22-24 weeks gestation) were recruited between May 2010-May 2011 using campus-wide emails and advertisements online, in the community, and in local obstetric clinics. Gestational age was calculated based on date of last normal menstrual period. If this was not available, gestational age was calculated based on the due date determined by the clinical ultrasound and then self-reported by the participant to the research team. Six women withdrew from the study after enrollment and 5 additional women experienced pregnancy-related complications, including miscarriage; therefore, 30 women were included in this analysis. Inclusion criteria included a singleton pregnancy, maternal age between 18-45 years of age, and ability to walk on a treadmill at a light and moderate pace (maximum speed 3.0 mph with 3% incline) for approximately 30 minutes consecutively. Participants were excluded if they smoked during their pregnancy or had a history of chronic disease, including thyroid disorders. All qualification criteria were confirmed for each participant by their medical provider and each woman provided written informed consent. The study was approved by the university's Institutional Review Board.

Reference measure

Paragraph Number 6 Indirect calorimetry (IC) has been shown to correlate well with doubly-labeled water (23,31,33), the gold-standard method for determining EE in free-living persons. Expired gases (oxygen (O_2) and carbon dioxide (CO_2)) were analyzed at a known temperature by gas sensors within a single metabolic cart (ParvoMedics, Salt Lake City, UT) to measure O_2 consumption and CO_2 production in ml/min. These values were converted into kcals to predict EE. A primary gas standard (0.5% CO_2, 20.5% O_2, balanced N_2) was used for gas calibration before each measurement. Periodic alcohol burn experiments showed CO_2 and O_2 recoveries of $\geq$ 99%.

Pattern-recognition activity monitor

Paragraph Number 7 A SenseWear® Mini Armband (Model: MF-SW) (BodyMedia, Pittsburgh, PA) was configured for each participant and worn on the upper, posterior aspect of the left arm (per manufacturer instructions) throughout all activities. The SWA is a wireless, non-invasive monitor that houses 5 sensors: a tri-axial accelerometer and 4 heat sensors. Each sensor is sampled 32 times per second (BodyMedia, personal communication). Data from each sensor is then incorporated into proprietary algorithms to predict EE. If needed, the EE estimates can then be converted to metabolic equivalents (METs) and the percentage of time spent in different intensities of physical activity can be computed.

Study design

Paragraph Number 8 Participants were enrolled prior to week 15 of gestation. At this initial appointment the women completed the consent form and the medical history questionnaire and provided contact information for her medical provider. She then arrived at the research center between 22-24 weeks gestation having fasted overnight for a minimum of eight hours. The SWA was configured for each participant using her age, height, current weight, handedness, and sex and then placed on the participant. Each woman was allowed to consume a snack containing approximately 250 kcals in order to standardize the thermic effect of food for all participants. The total thermic effect of food was predicted to be approximately 25 kcals and thus have minimal impact on the EE during the remaining activities. These activities were completed following consumption of the snack and were sustained for seven minutes each with EE assessed via IC and SWA. Activities were selected to represent typical activities of daily living performed commonly by women and covered a variety of intensities. Activities included computer typing (seated while typing on a standard sized keyboard using a standardized script), folding laundry while standing (continuous stationary folding of clothing into a laundry basket), sweeping (sweeping a pile of Lego® blocks back and forth between two marked spots 3 meters apart on an uncarpeted floor), and walking on a calibrated treadmill (C956i, Precor Inc., Woodinville, WA) at treadmill settings of 2.0 mph, 2.5 mph, and 3.0 mph at 0% incline and 3.0 mph at 3% incline. Participants received two minutes of rest between each of the non-walking activities.

Anthropometric and demographic data

Paragraph Number 9 Height and weight were measured at both visits. Height was measured to the nearest 0.1 cm (Ayrton 226 Hite-Rite Precision Mechanical Stadiometer, Quick Medical GS, Snoqualmie, WA) while weight was measured to the nearest 0.1 kg (Detecto Model 6855 Cardinal Scale, Manufacturing Co., Webb City, MO). Weight at the first prenatal appointment (or at the study enrollment visit, whichever was earlier) and measured height was used to determine pre-pregnancy body mass index (BMI). At the time of enrollment participants reported their age, education level, marital status, parity and number of pregnancies (including the current pregnancy) on the medical history questionnaire. Participants were also asked to classify their ethnicity as American Indian or Alaska Native, African American, Caucasian, Asian, Hispanic, or other.

Data processing

Paragraph Number 10 Energy expenditure from the IC was observed as an average of 15-second epochs. Exact start and stop times of each activity were recorded in the IC to synchronize with the SWA estimates. Energy expenditure from the SWA was observed in 1-minute epochs and the timestamp feature of the armband was utilized to denote specific start and finish times for each activity. Data from the SWA was downloaded into the SenseWear® Software (version 7.0, algorithm version 2.2; SWA_{old}) and then exported into Microsoft Office Excel 2007 (Microsoft, Redmond, WA). The data were also processed using a new proprietary algorithm (version 5.2; SWA_{new}). These estimates were obtained by sending raw data files (.swd) to representatives from BodyMedia, Inc. If necessary, the indirect calorimeter mask was repositioned on participants during the two-minute transition period between non-walking activities. It is possible that the EE observed by the IC during this time would have been negatively impacted and could have influenced the agreement with the SWA. Thus, the transition minutes were not included in the analysis. Data from each method (IC and SWA) was summed to provide total EE over the entire 49-minute activity protocol and by individual activity. To facilitate interpretation, the data were reported in kcals per minute ($kcal \cdot min^{-1}$). Thus, total energy expenditure from each 7-minute activity was summed and divided by 7 to find the average $kcal \cdot min^{-1}$ expended by each individual. These values were then averaged for all participants to find the overall mean $kcal \cdot min^{-1}$. One

participant's sweeping data was removed due to a problem measuring EE by the IC during this particular activity.

Statistical analysis

Paragraph Number 11 Descriptive variables are presented as mean ± standard deviation (SD). A three-way mixed model ANOVA was used to detect differences in EE between methods. The models used the method (IC or SWA), algorithm (older or newer), and activity as fixed effects. Least square means and standard error were estimated within the model and overall effects were examined with standard *F*-tests (statistical significance was set at $P < 0.05$). The Method effect provides a global indication of agreement (regardless of algorithm), the Algorithm effect enables direct evaluation of the two algorithms, and the Activity effect reveals whether agreement varied across activities. Emphasis was placed on possible two and three way interactions and post hoc analyses using Tukey-Kramer comparisons were conducted to examine differences in EE agreement for specific comparisons. The mean absolute percent error was calculated for individual activities to reflect the true error in estimation. These calculations are based on the absolute value of the individual errors and provide the most appropriate indicator of overall error.

Paragraph Number 12 Additional analyses were conducted to further examine the agreement between the measures. Average individual correlation coefficients (Pearson Product Moment correlations) were computed to evaluate overall measurement agreement. Bland-Altman plots (2) were also used to examine agreement across the range of activities. The mean of two estimates (*x*-axis) is plotted against the difference of two estimates (*y*-axis) to detect if any systematic bias was present. Confidence intervals defining the limits of agreement were established as 1.96 SD from the overall mean difference. The primary statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC).

Results

Paragraph Number 13 The women in this study were predominantly Caucasian (93%, n=28) and married (93%, n=28). Almost all women (87%, n=26) had at least a bachelor's degree and an additional 10% (n=3) had attended college but did not receive a bachelor's degree. Average pre-pregnancy BMI was 24.1 ± 3.0 kg/m^2 with approximately

23% (n=7) overweight or obese (BMI $\geq$ 25 kg/m^2). Average age, number of pregnancies, and parity was 29.0 ± 4.3 years, 2.1 ± 1.7 pregnancies, and 0.8 ± 1.6 births, respectively.

Paragraph Number 14 Mixed-model analyses demonstrated a significant main effect by method (F = 158.99, P < 0.0001) and algorithm (F = 11.76, P = 0.0007). The overall differences in EE estimates were significant for both the older algorithm (difference = -0.78 $\pm$ 0.06 kcal·min^{-1}) and the newer algorithm (difference = -0.57 $\pm$ 0.06 kcal·min$^{-1;}$ P < 0.0001 for both). Additionally, the Method x Algorithm interaction was significant (P < 0.0001) showing that the difference in mean error between algorithms (~0.21 kcal·min^{-1}) was statistically significant. A significant main effect was also observed for activity (F = 353.26, P < 0.0001). *Post hoc* tests revealed significant differences between IC and SWA_{old} for all activities except for typing and inclined walking; no significant differences were found between IC and SWA_{new} for typing, sweeping, and inclined walking (all P < 0.0001) (see Table 1). The mean absolute percent error for the individual activities ranged from 9% to 65% for the older algorithm (mean = 35.6%) and from 8% to 45% for the newer algorithm (mean = 27.7%). The errors in EE estimates for both algorithms was largest for folding laundry and smallest for the inclined walking activity, but error was consistently smaller for the SWA_{new} compared with the SWA_{old} (see Figure 1).

Paragraph Number 15 The individual correlation coefficients for the entire 49-minute protocol between IC and SWA ranged from 0.08 to 0.99 for the SWA_{new} (mean = 0.87) and from 0.62 to 0.96 for the SWA_{old} algorithm (mean = 0.87). Bland-Altman plots in Figure 2 provided a view of the differences in measurement agreement between the methods. A tighter cluster of data points around the mean and less overall error are apparent for the SWA_{new} algorithm (see Figure 2a) compared to the SWA_{old} algorithm (see Figure 2b). The plots, however, revealed some anomalies with the new algorithm. Some clear outliers were evident in the EE estimates from the new algorithm; this pattern was not evident when the same data were processed with the older algorithm. Interestingly, the six specifically identified outlier values (means greater than two times the SD) were evident only for the folding laundry and sweeping activities. It is not clear why these data yielded the anomalous values but they influenced the overall results. When the four individual outliers were removed from the folding laundry activity, the mean absolute percent error value decreased from 45.1 % to 19.3%. When the two outliers were removed from sweeping, the mean

absolute percent error value decreased from 33.6% to 17.3%. Collectively, this reduced the average mean absolute percent error value from 28% to 22%.

Discussion

Paragraph Number 16 The purpose of this study was to evaluate the validity of the SWA to estimate EE during mid-pregnancy. Both SWA algorithms demonstrated strong overall agreement with IC with mean individual correlation coefficients of 0.87 for both algorithms. However, the estimates from the SWA were significantly higher than the criterion value (mean diff = 0.68 $\pm$ 0.05 kcal/min). The main effect is important to consider but the Method * Algorithm interaction demonstrated that the error was significantly lower with the new v5.2 algorithms than with the previous v2.2 algorithms. This is consistent with previous studies with the SWA (8) demonstrating that refinements in the pattern recognition algorithms can improve the accuracy of EE estimates.

Paragraph Number 17 The mixed model design made it possible to directly compare the validity of the two different algorithms as well as the accuracy of the SWA for each of the specific activities. We observed that the SWA overestimated the EE values for six of the seven activities. The only activity in which the SWA did not overestimate EE was inclined walking. However, this was due to the fact that the SWA reported nearly the same EE for inclined walking as level walking at the same speed (Table 1). In this case, the inability of the SWA to detect the increased EE of the activity countered the general tendency for overestimation and led to non-significant differences. Other studies have reported an underestimation of EE for inclined walking in non-pregnant individuals using the SWA (17,27) or other tri-axial accelerometers (20,24). The SWA incorporates heat related variables (e.g. heat flux) in addition to movement but it does not appear to be able to detect the increased EE cost associated with inclined walking.

Paragraph 17a It is possible that the overestimation of energy expenditure was also influenced by metabolic changes related to pregnancy. In this population, total body weight is comprised of a greater proportion of non-metabolically active tissue (such as water and fat mass), particularly as pregnancy progresses. If the SWA uses the participant's body weight in the proprietary algorithm, this may influence the estimation of energy expenditure. Incorporating body composition into algorithms designed for this population may improve the monitor's ability to predict energy expenditure during pregnancy.

Paragraph Number 18 Bland-Altman plots provided a way to examine the degree of bias as well as to detect outliers that may have influenced the relationships. The plots did not indicate any systematic bias as the distributions revealed the consistent overestimation. However, the plots revealed several outliers for two activities evaluated with the SWA_{new} algorithm (folding laundry and sweeping). When these cases were removed, the coefficient of variation dropped from 52.7 to 22.6 and 52.4 to 20 for folding laundry and sweeping, respectively. The average mean absolute percent error decreased from approximately 28% to 22% and the average individual correlation increased from 0.87 to 0.93, exceeding that of the SWA_{old} (0.87). While the relationships improved with removal of the outliers, the degree of overestimation is still considerable, suggesting the need for further refinement of the algorithms for this population.

Paragraph Number 19 To date, few studies have provided an objective reference measure to assess the validity of accelerometry for predicting EE during pregnancy (4,14,25,37,38,39). A number of studies have used accelerometers to measure physical activity in pregnant women; however, these studies have either only assessed step counts (11) or assessed physical activity without providing evidence of validity of the monitor in pregnant women (5,9,16,18,19,21,28,30,35,36). Berntsen et al. (4) used an older model of the SWA (SenseWear® Pro_2) to assess EE during a variety of free-living activities and compared the predicted EE from the SWA Pro_2 to that of a portable oxygen analyzer. The SWA Pro_2 underestimated EE by 9% (intraclass correlation coefficient 0.85, $P < 0.001$) but the study did not report mean absolute percent error as used in the present study. The version of the armband used in the present study (SenseWear® Mini Armband - Model Name: MF) is a smaller and more advanced device that has been shown to be more accurate than the SenseWear® Pro_3 under free-living conditions in non-pregnant populations (22). The Mini overestimated EE in the present study but it is not clear if the underestimation witnessed in the Berntsen et al. (4) study is due to the monitor, the different algorithm or the choice of activities in the protocol.

Paragraph Number 20 Many of the accelerometers used in the aforementioned studies required placement on the hip. The accuracy of the accelerometer may be sensitive to the specific orientation of the device but this placement can be problematic as pregnancy progresses (35,38). Some studies have also noted a decrease in participant-compliance when

using waist-worn accelerometers later in pregnancy (19,28). An advantage of the SWA is that it is worn on the arm rather than the waist or the hip and thus placement is not affected as pregnancy progresses. Another advantage of the SWA is that it employs pattern recognition algorithms that can be trained to provide more accurate estimates of EE. The SWA_{new} algorithm (v5.2) was not specifically trained to assess EE in pregnant women so it is likely that the accuracy could be improved with future refinements.

Paragraph Number 21 There were strengths and limitations of this study. A strength of the study is that we directly compared the accuracy of two different versions of SWA algorithms. The SWA monitor is unique in that the algorithms are continually updated. The study shows that the newer algorithm (v5.2) more accurately predicts EE during mid-pregnancy than the older algorithm (v2.2). The present study used a stationary metabolic cart to measure EE rather than a portable analyzer. This limited the range of activities to those that could be assessed within reach of the hose length on the metabolic cart. Portable analyzers offer some advantages but studies have demonstrated that portable devices overestimate EE when compared to the gold standard metabolic carts and Douglas bag method (4,12,29,34) - although improved accuracy has been noted in recent studies (34). While free living studies are clearly needed, the present study provided a comprehensive evaluation of the SWA in pregnant women using common activities of daily living. Future studies should evaluate the accuracy of the monitor with different activities and with stronger criterion measures such as doubly-labeled water in the free-living setting, similar to the 14-day evaluation of the SWA validity in non-pregnant populations by Johannsen et al. (22). Another limitation is that we studied participants only during mid-pregnancy. Our assessment occurred between 22-24 weeks gestation, a time when most women have surpassed excessive nausea and are most comfortable during physical activity. Future studies should assess individuals throughout the course of pregnancy to provide a more complete evaluation with this population.

Paragraph Number 22 Metabolic adaptations during pregnancy may complicate the ability to accurately predict energy expenditure during this critical phase of the lifecycle. Currently very few validated objective methods are available to assess physical activity in pregnant women (28). The results of the current study demonstrate the potential utility of the SenseWear® Mini Armband to predict energy expenditure in this population and

consequently improve assessment of physical activity during pregnancy; however, there is room for continued refinement of the algorithms. The proprietary algorithms used in the current study were not developed from data collected on pregnant women. Due to alterations in metabolic rate during pregnancy, SWA algorithms should be trained and validated for pregnant women and evaluated at all stages of pregnancy. With the development of pregnancy-specific algorithms, this pattern-recognition system may provide a valid, objective method to predict physical activity and energy expenditure in pregnant women.

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Conflict of Interest

While GJ Welk has collaborated with BodyMedia, Inc. in the past, no financial support for this study was obtained from BodyMedia, Inc. None of the other authors report any conflict of interest.

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TABLES

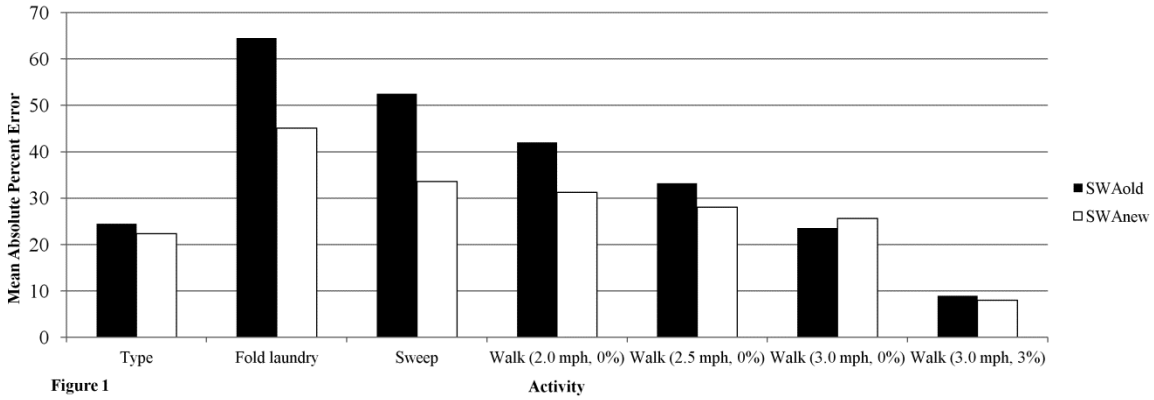
Table 1 – Mean (n=30) EE (kcal·min^{-1}) values for each activity (means ± SE), and differences (means ± SE) between methods (kcal·min^{-1}).

	IC	SWA_{new}	IC-SWA_{new}	P-value	SWA_{old}	IC-SWA_{old}	P-value
Type	1.31 ± 0.10	1.55 ± 0.12	-0.25 ± 0.16	0.1318	1.54 ± 0.12	-0.23 ± 0.16	0.1570
Fold laundry	1.79 ± 0.10	2.59 ± 0.12	-0.80 ± 0.16	<0.0001	2.93 ± 0.12	-1.14 ± 0.16	<0.0001
Sweep	2.10 ± 0.10	2.43 ± 0.12	-0.32 ± 0.17	0.0541	3.06 ± 0.12	-0.96 ± 0.17	<0.0001
Walk (2.0 mph, 0%)	3.03 ± 0.10	3.85 ± 0.12	-0.82 ± 0.16	<0.0001	4.28 ± 0.12	-1.25 ± 0.16	<0.0001
Walk (2.5 mph, 0%)	3.55 ± 0.10	4.46 ± 0.12	-0.90 ± 0.16	<0.0001	4.68 ± 0.12	-1.13 ± 0.16	<0.0001
Walk (3.0 mph, 0%)	4.09 ± 0.10	5.09 ± 0.12	-0.99 ± 0.16	<0.0001	5.00 ± 0.12	-0.91 ± 0.16	<0.0001
Walk (3.0 mph, 3%)	5.11 ± 0.10	5.01 ± 0.12	0.10 ± 0.16	0.5476	4.97 ± 0.12	0.14 ± 0.16	0.3956

The values are presented as the least square means + SE unless indicated otherwise. EE is measured by IC (metabolic cart). SWA_{new}, EE estimated by SWA algorithm 5.2; SWA_{old}, EE estimated by SWA algorithm 2.2.

FIGURES

Figure 1 – Mean absolute percent error of both SWA algorithms.



SWA_{old}, version 2.2 algorithm; SWA_{new}, version 5.2 algorithm. Mean absolute percent error (MAPE) is consistently higher with SWA_{old} than SWA_{new} for all activities except walking at 3.0 mph, 0% incline. The MAPE values in the figure include any outliers noted in the Bland-Altman plots.

Figure 2 – Bland-Altman plots between IC and SWA estimates of EE.

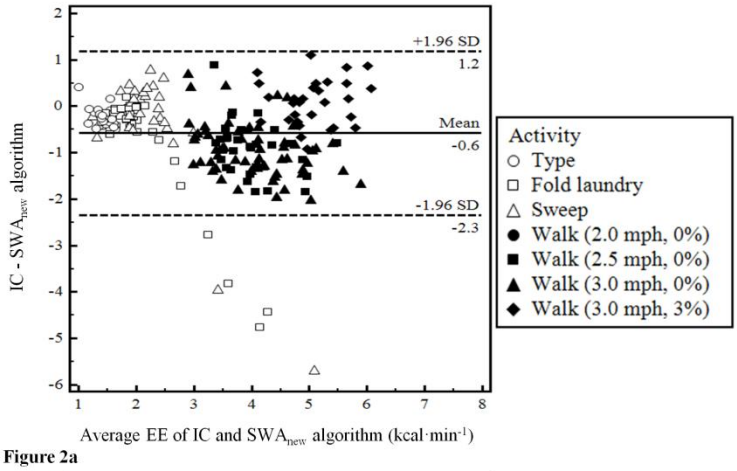


Figure 2a

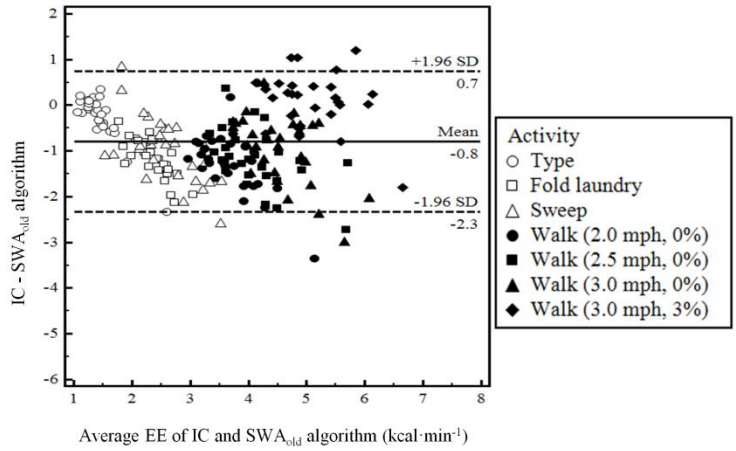


Figure 2b

EE, energy expenditure; IC, indirect calorimetry; SWA$_{new}$ algorithm, version 5.2; SWA$_{old}$ algorithm, version 2.2. The middle solid lines represent the mean difference between the methods:-0.57 and -0.78 kcal·min^{-1} for Figure 2a (IC vs. SWA$_{new}$) and Figure 2b (IC vs. SWA$_{old}$), respectively.

CHAPTER 4: EFFICACY OF A BEHAVIORALLY-BASED WEBSITE TO INCREASE PHYSICAL ACTIVITY IN PREVIOUSLY SEDENTARY PREGNANT WOMEN: A RANDOMIZED CONTROLLED TRIAL

A paper to be submitted to The International Journal of Behavioral Nutrition and Physical Activity

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Abstract

Background: Despite the numerous benefits of regular physical activity (PA) during pregnancy, consistent data demonstrate low participation and adherence to prenatal PA recommendations. Therefore, cost-effective interventions, such as interactive online resources, are warranted to promote maternal PA and thereby improve pregnancy outcomes. The purpose of this study was to evaluate the efficacy of an interactive website based on Social Cognitive Theory (SCT) to increase intentional PA in sedentary pregnant women. **Methods:** Forty-five sedentary pregnant women completed a pilot randomized-controlled trial. Participants were randomized to usual care (UC; n=21) or a behaviorally-based website intervention (BI-group; n=24) between 10-14 weeks of pregnancy. Usual care were asked to continue with their normal level of activity (previously sedentary) while the BI-group was encouraged to gradually increase moderate-vigorous PA (MVPA) to $\geq$ 150 mins/week by week 19 of pregnancy, sustain at least this amount of PA until delivery, and document all PA sessions on the website. Objective PA assessments were completed for all participants at baseline (prior to randomization) and between weeks 24-26 and 34-36 of pregnancy. Finally, all women were categorized into tertiles of website engagement to evaluate the efficacy of the website to increase PA. **Results:** Intentional PA self-reported by the BI-group on the website was 124 ± 44 minutes, a significant increase from baseline of 95 (67-130) mins/week ($P < 0.0001$). On average, 31.8% of women met the goal each week of $\geq$ 150 minutes. Objective MVPA assessment confirmed significantly more MVPA sustained in 20- and 30-minute bouts among BI-group compared to UC at weeks 24-26 of pregnancy ($P = 0.005$ and $P = 0.0008$, respectively). Similarly, highly-engaged website users completed more sustained

MVPA than their not-engaged counterparts (118 ± 102 vs 57 ± 63 minutes per week, $P < 0.05$). **Conclusions:** An interactive website based on SCT significantly increased self-reported intentional MVPA and objectively-assessed sustained MVPA in previously sedentary women. A behaviorally-based website may be a low-cost and sustainable method to increase PA in this population. **Trial registration:** Current Controlled Trials ISRCTN38498311

Keywords: Pregnancy, exercise, behavior, Social Cognitive Theory, web-based, sedentary

Background

The prenatal period has been viewed as a "window of opportunity" for promoting a healthy lifestyle and establishing long-term physical activity habits [1]. Many women are concerned about the health of their babies and in turn may be motivated to change their lifestyle to provide the best opportunities for their child [2]. The benefits of exercise during pregnancy are well documented and include, but are not limited to: reduced back pain [3], insomnia [4,5], nausea [6], stress [4,5], fatigue [4], depression [3-5], and anxiety [4-5], improved mood [4], and reduced risk of cesarean section [7,8], preterm birth [9,10] and large for gestational age infants [11]. Furthermore, regular moderate-intensity exercise of 30 minutes or more on most, if not all, days of the week is recommended by the American College of Obstetricians and Gynecologists in the absence of any complications or contraindications to exercise [12]. Similarly, the 2008 Department of Health and Human Services' Physical Activity Guidelines for Americans encourage at least 150 minutes of moderate-intensity aerobic activity spread throughout the week [13].

Despite the numerous benefits of regular exercise during pregnancy, consistent local [14], national [15,16], and international [3] reports demonstrate low participation and adherence to prenatal physical activity (PA) recommendations with 15-25% of pregnant women meeting minimum recommendations. Pregnant women encounter numerous barriers to participating in exercise [17] such as fatigue, discomfort, perceived lack of time, and lack of social support [18]. Behavioral theory-based interventions have been recommended to promote maternal PA and overcome barriers relevant to pregnancy, yet few prenatal PA interventions have used this approach [17,19]. Some studies [20-23] have focused on individual behavioral constructs such as self-efficacy, how competent an individual feels to

do a task and how confident she is in her ability to overcome the barriers to performing the task or behavior [24]. A recent systematic review evaluating the efficacy of behavioral theories to alter prenatal PA behavior concluded that interventions incorporating behavior change techniques help reduce the decline in PA during pregnancy [19]; however, another recent review of PA during pregnancy stressed the importance of interventions to be developed using a behavioral theoretical framework rather than just specific individual constructs [17].

Similar to the positive effect of behavioral theory on prenatal PA, information available on the Internet concerning PA during pregnancy has been shown to increase PA in this population. A survey of 293 women in the Midwest revealed 94% of the respondents used the Internet to retrieve pregnancy-related information; nearly half (44%) of the women used it for information regarding physical activity [25]. Women reported an increased confidence to make decisions regarding prenatal PA and 26% reported increasing their PA as a result, while only 3.8% decreased their PA. As a result of the popularity of the Internet, an increasing number of interventions have been delivered online as web-based programs (e.g. e-programs, e-interventions) for children and adults [26-29], including pregnant women [30]. Reviews of the literature have reported similar improvements in outcomes from web-based programs compared to face-to-face interventions involving a variety of populations [26,27,31-33]. Furthermore, web-based programs have been shown to be more cost-effective than traditional forms of interventions such as clinic, work-site, or phone delivery [34]. To our knowledge, no interventions developed using a behavioral theoretical framework and designed to increase physical activity during pregnancy in previously sedentary women have been delivered via an online website.

Behaviorally-based interventions incorporating methodologies utilized by pregnant women such as online resources are warranted to promote maternal PA and thereby improve pregnancy-related outcomes. The purpose of the current study was to evaluate the efficacy of a behaviorally-based website to change behavior (increase PA via primarily walking) in previously sedentary pregnant women. It was hypothesized that previously sedentary pregnant women would increase intentional PA when given access to an interactive behaviorally-based website compared to women that did not receive access to the website.

Additionally, women receiving access to the website would meet current prenatal PA recommendations.

Methods

Recruitment Fifty-one women between the ages of 18-45 years old with singleton pregnancies were recruited prior to 15 weeks gestation between January – September 2013. Fliers were posted online, in the community, and distributed in the local prenatal clinics and throughout a large partnering hospital network in a metropolitan area of nearly 600,000 people approximately 45 minutes away from the research university. Mass recruiting emails were also sent on campus. All women were sedentary for at least six months prior to pregnancy. At the time of recruitment, women answered two questions to determine initial eligibility: 1) *Do you currently participate in any physical activity outside of your normal daily activity?* and 2) *Did you participate in any physical activity outside of your normal daily activity during the last six months?* If the woman answered "yes" to either of these questions, they were asked to describe the type of PA, frequency, and duration. The criterion for defining "sedentary" was less than 3, 30-minute sessions per week since activity above this cut-off has previously been used to define "regular exercisers" during pregnancy [35-37]. The term "physical activity" was used during the screening process rather than "exercise" to encourage respondents to disclose all volitional activity. Exclusion criteria included smoking during pregnancy, underweight (body mass index, BMI < 18.5 $kg \cdot m^2$), a history of gestational diabetes, pre-eclampsia, or chronic disease (e.g. Type 1 Diabetes Mellitus, heart disease, renal disease), prevalence of a condition or use of a medication known to influence overall metabolism, and inability to communicate in the English language. Additionally, all participants had regular access to the Internet and stated they were willing, if asked to do so, to walk 30 minutes on most days of the week throughout their pregnancy. All qualification criteria were confirmed by each participant's medical provider with permission to participate. Six women withdrew from the study prior to completion for the following reasons: medical complications (n=2 usual care), lack of time (n=1 usual care), and loss to follow-up (n=2 intervention, 1 usual care). Thus, 45 women completed the entire study (see Figure A). The study was approved by the Institutional Review Board at both the affiliated university and partnering hospital. All participants provided written informed consent.

Study design The study was a pilot randomized-controlled trial (Current Controlled Trials ISRCTN38498311) to evaluate the efficacy of a behaviorally-based website to change maternal behavior (e.g. increase PA) in previously sedentary pregnant women. This study was conducted as part of The Blossom Project and entitled "The Blossom Project Online". The Blossom Project is a collection of research studies evaluating prenatal lifestyles, particularly maternal dietary intake and PA. Via lifestyle interventions, the overall goal of The Blossom Project is "to improve the lives of women and their children, one pregnancy at a time". Participants were recruited prior to 15 weeks gestation and visited the research center to provide written consent between 10-14 weeks of pregnancy. At this visit, all participants reported age, education level, race, marital status, number of previous pregnancies, parity, weekly moderate-vigorous physical activity (MVPA) prior to pregnancy, and weekly MVPA since becoming pregnant (prior to enroll). Additionally, height and weight were measured (without shoes, coats, sweatshirts, or heavy sweaters) to the nearest 0.1 cm and 0.1 kg, respectively (Ayrton 226 Hite-Rite Precision Mechanical Stadiometer, Quick Medical GS, Snoqualmie, WA, and Detecto Model 6855 Cardinal Scale, Manufacturing Co., Webb City, MO). All women self-reported their pre-pregnancy weight at this time and provided permission to obtain her weight from the first prenatal visit of the current pregnancy with the medical provider to identify any possible implausible self-reported weights. Gestational age was calculated by date of last normal menstrual period or ultrasound if completed by time of enrollment.

Baseline data collection-Visit 1 Following written informed consent and anthropometric measurement at the first visit (10-14 weeks gestation), all participants were provided verbal and written instructions regarding how to wear a PA monitor, the SenseWear® Mini armband. The PA monitor allowed for an objective comparison of PA between groups. Participants were instructed to wear the monitor for 24-hours/day for 8 consecutive days (to allow for a standardized wear time of 7, 24-hour periods for all participants) and to remove it when submerged in water (e.g. showering and swimming). Participants kept a PA record during the monitoring period to document daily activity and were instructed to keep their weekly routine and activity level as normal as possible.

Behaviorally-based website The social cognitive theory (SCT) by Bandura [38] was used as the theoretical framework for the behaviorally-based website. There are nine

behavioral constructs associated with the SCT including: self-efficacy (how competent an individual feels to do a task and how confident she is in her ability to overcome the barriers to performing the task or behavior), self-regulation (self-monitoring and goal-setting), behavioral capability (knowledge and skills necessary to perform a behavior), reinforcement (responses to behavior increasing the likelihood of recurrence), outcome expectancies (values placed on the expected outcome), outcome expectations (develop realistic expectations about benefits of behavior change), emotional coping response (strategies used to deal with emotions such as problem solving and stress management), locus of control (the extent to which individuals can control events that affect them), and reciprocal determinism (behavior change resulting from an interaction between the person and the social influences of the environment) [24]. Self-efficacy is commonly referred to as the key construct of SCT that elicits behavior change and can be increased by increasing self-regulation and social support [24]. The website in the current study used six of the SCT constructs to allow participants to gain the skills, knowledge, and confidence to elicit and sustain a successful behavior change of increasing PA. These behavioral constructs included self-efficacy, self-regulation (including self-monitoring and goal-setting), behavioral capability, reinforcement, emotional coping response, and reciprocal determinism (including social support) and were incorporated into the intervention website via the following features:

Blossom Tips (SCT construct: behavioral capability): Current prenatal PA guidelines and nutrition recommendations were provided to participants of both groups. This was the only feature of the website viewable by participants in the control group. This information was considered "usual care" as the information provided on the website was retrieved from the prenatal packets distributed to new obstetric patients at the local clinics.

Goal-setting (SCT construct: self-regulation): Following completion of the baseline data collection, intervention participants were encouraged to slowly work up to exercising at least 150 minutes per week by week 19 of pregnancy and sustain at least this amount of intentional PA until delivery. Participants were prompted to set individual long-term goals for the next 10 and 12 weeks at week 19 and week 28 of pregnancy, respectively. Five scripted goals of varying activity amounts (minimum 150 minutes per week) were available to choose from, or the woman could create her own goal. An example of an optional scripted goal included "The start to the finish line of a centennial ultra-marathon (100 miles): This

would involve about 2,000 minutes of walking over the next 10 weeks, or about 200 minutes per week on average. Thus, my long term goal is to walk 200 minutes per week the next 10 weeks." Automated emails were sent at weeks 19 and 28 of pregnancy to remind each woman to log in and set her PA goal for the upcoming 10-12 weeks.

Calendar (SCT construct: self-regulation): Daily intentional PA (type, duration, and intensity) was documented on a monthly calendar from the time of group randomization to delivery. Each participant would answer the question "Did you walk or exercise today?" by clicking "yes" or "no" on each calendar day. If the answer was "yes", she was further prompted to document the exercise type and duration. Exercise (intentional PA) was instructed to be done in at least 10-minute bouts, thus the minimum duration of exercise that could be reported on the calendar was 10 minutes.

Blossom Journal (SCT construct: self-efficacy): An online journal allowed women the option to privately document her thoughts and feelings. These entries were only viewable by the participant themselves and the research staff using an administrative password.

Blossom Community forum (SCT constructs: reinforcement, emotional coping response, and reciprocal determinism): A community forum provided a network of social support for participants in the intervention group. Each woman chose her own username when introduced to the website and was informed that this username would be viewable by other participants when she wrote on the community forum page, thus to ensure privacy of the individuals if they chose to remain anonymous. Women could utilize this feature by reading other participants' posts, posting her individual comments or thoughts to the forum page, or commenting on other participants' posts.

Problem-solving (SCT constructs: self-efficacy, behavioral capability, and emotional coping response): Participants of the intervention group were prompted to document barriers to exercise and brainstorm ways to overcome these barriers each week to achieve their exercise goals.

Activity resources (SCT construct: self-efficacy and behavioral capability): A page within the website was devoted to additional resources to encourage exercise among intervention participants. Other online resources such as "Map My Walk" (available at www.mapmywalk.com) were explained as well as a listing and location of local walking

trails including indoor mall walking hours to facilitate exercise during the extreme heat and humidity and local winter weather conditions.

Randomization Following the baseline data collection, participants returned the activity monitor to the research center and received their randomization assignment (see Figure A). A computer-generated random allocation was used to assign a randomization code to each participant at the time of enrollment. All research staff and participants were blinded to the group assignment of the randomization code until completion of the baseline data collection. Due to the nature of the study design, participants were not blinded once they were informed of their randomization. Upon return of the PA monitor and unveiling of the randomization assignment, each participant was given an orientation to the website and its applicable features pertaining to their group assignment. All participants logged in once using their own username and password to ensure it was working properly before leaving the research facility. Participants received further instruction based on their random group assignment to either usual care, or the behaviorally-based website intervention (BI-group).

Usual care Once logged-in, participants in this group could view current PA and nutrition recommendations during pregnancy (e.g. Blossom tips; see Figure B). This content was based on information collected from the local obstetric clinics and typically provided to each patient. This process ensured the information provided on the website and accessible by the control group was usual care throughout the local geographical area. Women in the usual care group were instructed to continue with their normal level of activity (previously sedentary) and appointments were scheduled to return to the research center for the remaining data collection periods between weeks 24-26 and 34-36 of pregnancy.

Intervention In addition to being able to view the same Blossom Tips information as the usual care group (see Figure B), intervention participants also had access to the behaviorally-based website features previously mentioned (see Figure C).

As part of her initial orientation to the behaviorally-based website, each woman in the intervention practiced documenting her exercise on the website with the study coordinator by entering one, 10-minute session of walking at a moderate pace prior to leaving the research facility. Additionally, every participant in this group also posted one introductory message (composed by each woman herself) to the community forum to alert other participants that a new woman had joined the program.

Finally, each woman in the intervention was provided a heart rate monitor (Polar FT1, Kempele, Finland)) to take home and utilize throughout her pregnancy. The purpose of this monitor was to ensure each woman was exercising at an appropriate intensity according to previously published target heart rate zones for pregnancy [39,40]. Currently, the American College of Sports Medicine recommends low-risk normal weight pregnant women exercise at a moderate intensity and for overweight or obese pregnant women, a light intensity [35]. Women were instructed on how to properly wear and use the monitor, and were provided with an individualized target heart rate zone based on her pre-pregnancy BMI, age, and fitness level [35,39,40]. The published target heart rate zones for normal weight pregnant women are further categorized for "fit" and "unfit" women. Thus, these participants were initially prescribed the target heart rate zone for their age and the "unfit" category, since all participants were sedentary prior to pregnancy. At the second data collection period (between weeks 24-26 of pregnancy), normal weight women were provided with the target heart rate zone for their age and the "fit" category [39], and encouraged to exercise within this zone as long as they did not experience any pain or other contraindications to prenatal exercise [12]. Similarly, the target heart rate zone was increased to an age-specific moderate intensity between weeks 24-26 of pregnancy as tolerated by overweight/obese women [40].

Data collection-visits 2 and 3 Between weeks 24-26 (visit 2) and 34-36 (visit 3) of pregnancy, each participant returned to the research center to begin wearing the activity monitor (SenseWear® Mini armband, SWA) for another 8 consecutive days, 24 hours per day except when submerged in water. The PA record was again used at both time points to document daily activity. Both written and verbal instruction was provided to all participants.

SenseWear® Mini armband The SWA (Model: MF-SW; BodyMedia, Pittsburgh, PA) is a pattern-recognition activity monitor incorporating data from multiple sensors and a tri-axial accelerometer to predict energy expenditure and PA intensity. The monitor has been described in detail elsewhere [41] and previously was shown to predict energy expenditure well using algorithm 5.2e ($R^2 = 0.86$) compared to indirect calorimetry in mid-pregnancy [42]. The most current version of the algorithm, 5.2h, has shown improved agreement and no systematic bias (unpublished data, Campbell). The monitor is worn on the posterior upper left arm over the triceps muscle and is placed in direct contact with the skin.

Data processing *SenseWear® Mini armband* SWA data from all participants at all three time points (baseline between 10-14 weeks, between 24-26 weeks, and 34-36 weeks gestation) were analyzed for 7-consecutive 24 hours. The participants wore the monitor for 8-days, thus the partial first day through 11:59pm was discarded as well as the partial last day after 12:00AM to yield 7-consecutive 24 hours starting at midnight on the second day of wear and ending at 11:59pm on the seventh day.

Minute-by-minute data from the SWA were downloaded into the manufacturer's software version 8.0 (algorithm 5.2h) and exported into Microsoft Office Excel. The following data were analyzed: moderate (3-5.9 METs)-vigorous ($\geq$ 6.0 METs) PA minutes sustained for at least 10-minutes, 20-minutes, and 30-minutes. Ten-minute bouts were defined as at least 8 minutes of MVPA within 10-consecutive minutes, thereby allowing for 2 minutes below the moderate intensity threshold as previously reported [43-44. Twenty- and 30-minute bouts were defined as sustained MVPA for at least 16 and 24 minutes respectively, with only 2 minutes below the moderate intensity threshold within any 10-minute period.

Participants were instructed to remove the activity monitor when submerged in water (e.g. showering, bathing, or swimming). Eight participants documented aquatic exercise in their PA record; these activities included water walking, freestyle lap swim, and water aerobics. The intensity of these activities were categorized using corresponding MET values from the 2011 Compendium of Physical Activities [45] and then accounted for in the analyses of sustained MVPA for at least 10-, 20-, and 30-minutes.

The SWA records wear time and thus provides the ability to assess when the monitor is not worn (e.g. nonwear time or off-body time). After accounting for aquatic activity, files with more than 500 minutes of nonwear time for the week were further evaluated using the PA record to determine the activities conducted during this time [41]. Five files exceeded 500 minutes of nonwear time, all of which occurred during sleep according to the PA record and would not influence MVPA. Files excluded from specific PA analyses are detailed in Figure A.

Website Participants in the intervention recorded exercise in at least 10-minute bouts on the study website calendar starting on the day they were randomized to this group (between 10-14 weeks gestation) until the day of infant delivery. Monthly email reminders

were sent to each woman in this group to log in on the last day of the month and update her exercise calendar if it was not currently up to date. Research staff logged into the website using an administrative password to download the calendar data into Microsoft Office Excel and sum weekly exercise recorded by each participant.

Adherence to PA guidelines Self-reported weekly exercise from the behaviorally-based website was used to evaluate the number of women in the BI-group meeting current prenatal PA guidelines ($\geq$ 150 minutes per week) [12,13]. MVPA in $\geq$ 10-minute bouts was used to assess adherence to PA guidelines.

Website engagement Participants' website usage was categorized into three groups: not engaged, low-engaged, and highly-engaged. Five criteria were established to define a highly-engaged participant: 1) number of website log-ins, 2) number of goal-setting modules completed, 3) number of problem-solving modules completed, 4) number of private journal entries made, and 5) number of posts made to the community forum. The participant received one point for every criterion she was among the top half of participants for that criteria (greater than the 50th percentile). Points were totaled as the final score. The final total scores were split into tertiles (0-25th percentile, 25-75th percentile, and $\geq$ 75th percentile) to establish the previously mentioned three groups and levels of engagement: *Not engaged*: 0 points; *low-engaged*: 1-3 points, and *highly-engaged*: $\geq$ 4 points.

Statistical analyses Values are shown as mean ± SD except where the Shapiro-Francia test revealed non-normally distributed data, in which case values are reported as medians and the 25th to the 75th percentiles for the interquartile range (IQR). To assess for any differences between the change in baseline exercise levels and average weekly exercise during pregnancy reported on the website among intervention participants a one-sample signed rank-sum test was conducted for non-normally distributed data. Objective PA including sustained MVPA minutes per week (10-, 20-, and 30-minute bouts) was compared between usual care and the BI-group at all three time points (baseline weeks 10-14, weeks 24-26, and weeks 34-36 of pregnancy) using Mann-Whitney tests for independent samples with a Bonferroni correction for multiple comparisons. Repeated measures ANOVA were used to evaluate any change across pregnancy in objective PA. One-way ANOVA analyses evaluated if any differences were present between tertiles of website engagement in average PA at weeks 24-26 and 34-36 of pregnancy and Tukey-Kramer post-hoc tests were used to

analyze pair-wise comparisons. Preliminary statistical analyses were conducted by a statistician who was blinded to the randomization assignment. Statistical significance prior to any adjustments for multiple comparisons (if applicable) was set at $P < 0.05$. Statistical analyses were conducted using MedCalc version 13.1 (MedCalc Software, Mariakerke, Belgium).

Results

Participants Descriptive characteristics of the participants are presented in Table 1. There were no significant differences in variables between groups. Most women identified themselves as Caucasian (88.9%, n=40), married (82.2%, n=37), and had either a 2-year degree (11.1%, n=5), 4-year degree (40%, n=18), or a graduate/professional degree (26.7%, n=12).

Exercise reported on website and adherence to PA guidelines Figure D depicts the weekly exercise among intervention participants self-reported on the website from the beginning of the intervention (post-baseline data collection) to delivery. The graph represents a moving average of five weeks to represent a smoother image of the data trends. Participants were encouraged to gradually increase weekly aerobic exercise (primarily walking) to at least 150 minutes per week from time of randomization to week 19 of pregnancy, and then continue at least that amount of exercise until delivery. The earliest delivery among intervention participants occurred during week 36 of pregnancy. Weekly exercise between 19-36 weeks of pregnancy was 124 ± 44 minutes; on average 31.8% of women (n=7) were adherent to PA guidelines and met the goal each week of $\geq$ 150 minutes of intentional PA.

Figure E displays the change from baseline (moving average of five weeks) in self-reported exercise minutes each week among intervention participants. Baseline exercise volume (typical weekly exercise during early pregnancy) was self-reported by all participants at enroll. Median (IQR) exercise per week between 19-36 weeks of pregnancy significantly increased from baseline by 95 (67-130) minutes ($P < 0.0001$).

Activity monitor MVPA While MVPA in 10-minute bouts was not significantly different between groups at any of the three time points, the BI-group appeared to do more sustained MVPA in 10-minute bouts between weeks 24-26 ($P = 0.065$; see Table 2). MVPA in 20-and 30-minute bouts was significantly greater among intervention participants compared to UC at week 24-26 of pregnancy ($P = 0.005$ and $P = 0.0008$, respectively). No

change was observed in any PA variables across pregnancy for usual care, while in the BI-group 20-minute bouts (61.3 ± 21.9 minutes) and 30-minute bouts (39.6 ± 14.8 minutes) significantly increased from baseline to weeks 24-26 ($P < 0.05$ for both).

Website engagement Average scores for each criterion used to define the tertiles of website engagement are available in Table 3. Highly-engaged participants accomplished significantly greater amounts of sustained MVPA in 20- and 30-minute bouts than not-engaged participants (P = 0.033 and 0.016, respectively) (see Table 4).

Discussion

The purpose of this pilot randomized-controlled trial was to evaluate the efficacy of a behaviorally-based website to increase PA in previously sedentary pregnant women. The results of this study demonstrate that highly-engaged participants utilizing the behavioral features of the website took part in significantly more sustained MVPA than their not-engaged counterparts. Additionally, participants receiving access to the behaviorally-based website significantly increased maternal exercise from baseline and this was continued for nearly the entire pregnancy. Significantly more MVPA in sustained bouts of at least 20- and 30-minutes was observed among intervention participants, with the increase in exercise and sustained MVPA supported by both subjective and objective data. Only two participants reported doing less exercise at some point during pregnancy compared to their regular weekly exercise prior to enrolling in the study, and this drop in exercise level did not occur until week 30 of pregnancy (see Figure E). These findings are notable for two reasons. First, pregnancy is a time during the lifecycle that typically results in decreased MVPA [46] and total PA [47]. This intervention was successfully able to increase intentional exercise and sustained MVPA among the BI-group. Secondly, all participants were sedentary individuals at the time of enrollment reporting an average of only 51 minutes of weekly MVPA prior to pregnancy and a median of zero minutes of MVPA during pregnancy prior to enrollment.

Weekly self-reported exercise increased to an average of 124 minutes per week among intervention participants between weeks 19-36 of pregnancy, resulting in 31.8% of intervention participants meeting current prenatal PA guidelines. While the majority of intervention participants were still not meeting PA guidelines, the number of women in the intervention meeting PA guidelines is clinically relevant since these women were previously sedentary. Additionally, this statistic is slightly greater than the national average (<25%) for

all pregnant women (including women exercising regularly prior to pregnancy) meeting PA guidelines [15,16]. Other randomized controlled trials reporting a significant increase in prenatal PA compared to controls indicated considerably smaller changes in PA than the current study: 8.6 MET minutes per week [48] and 0.77 minutes per week [49]. Huang et al. [50] evaluated frequency of PA according to a 4-point scale and witnessed a 2.45 point increase in frequency of PA. Furthermore, only one of these trials was behaviorally based with use of the Protection Motivation Theory [48] and none of the studies evaluated PA with an objective form of assessment.

Despite the fact that SCT has provided the basis for many of the PA interventions in the literature [35] only three studies to date have applied this theory during pregnancy. Chasan-Taber et al. utilized SCT in conjunction with the Transtheoretical Model in the B.A.B.Y. (Behaviors Affecting Baby and You) Study to increase exercise in a diverse sample of pregnant women at high risk for gestational diabetes [51]. Specific behavioral strategies included weekly PA goal setting, building social support, encouragement of self-monitoring of exercise, and overcoming barriers to PA. Counseling was provided by health educators to overcome barriers if PA goals were not achieved. The overall PA goal was to increase the time spent in moderate activity by 10% each week, and achieve 30 minutes of moderate-intensity PA (in at least 10-minute bouts) on 5 or more days per week by the end of the 12-week intervention (24-28 weeks of pregnancy). Based on data self-reported on the Pregnancy PA Questionnaire [52], women in the exercise group experienced a significantly smaller decrease in total PA across pregnancy compared to the control (-1.0 MET-hrs/wk vs -10.0 MET-hrs/wk, $P = 0.03$) and a significantly larger increase in sports/exercise (0.9 MET hrs/wk intervention vs -0.01 MET-hrs/wk control, $P = 0.02$) [53]. While a waist-worn accelerometer was also used to assess PA at baseline and follow-up, researchers reported low compliance to this method and thus objective data to support the findings were unavailable.

Secondly, Ferrara et al. used behavioral constructs of the SCT and transtheoretical model to assist women with gestational diabetes achieve their pre-pregnancy weight following delivery [54]. The prenatal portion of the intervention included one in-person and two telephone counseling sessions by a registered dietitian to discuss gestational weight gain recommendations, encourage 150 minutes per week of moderate intensity PA, and dietary modifications such as low glycemic food choices, low-fat diet, and proper interpretation of

food labels. Results indicated a greater proportion of women in the intervention group reaching their postpartum weight goal than usual care, although this was not statistically significant (37.5% vs 21.4%, $P = 0.07$). PA was assessed via a 7-day recall at baseline (following gestational diabetes diagnosis ~28 weeks) and 7-months postpartum. No differences were observed between groups in regards to increasing MVPA from baseline to postpartum (mean difference between groups 25.3 minutes per week, $P = 0.91$). Results of this study are difficult to compare to the current study for several reasons. In the Ferrara et al. study the participants were women diagnosed with gestational diabetes; thus, the intervention was not initiated until approximately 28 weeks of pregnancy compared to 10-14 weeks in the current study. Additionally, PA was not assessed during pregnancy after baseline measurements, thus it is unknown if the intervention had an effect on increasing PA specifically during pregnancy.

Finally, Smith et al. is currently conducting a 10-week community lifestyle program based on SCT to improve physical and psychological well-being of 400 obese pregnant women in England. Incorporated behavioral change techniques include self-efficacy, outcome expectations (develop realistic expectations about benefits of behavior change), feedback on behavior change from health care professionals, positive reinforcement from health care professionals and other women in the group, and social support. Outcomes of interest include maternal GWG, self-efficacy, well-being, goal attainment, PA, food intake, birth weight, mode of delivery, and method of infant feeding at hospital discharge [55]. Therefore, to our knowledge, the present study is the first randomized-controlled trial to demonstrate the use of a SCT-based intervention to influence positive behavioral modifications during pregnancy (e.g. increase maternal MVPA) supported by both subjective and objective measures of PA.

The current study is not without limitations. The study was part of a larger trial to prevent excessive gestational weight gain and thus was powered to find results pertaining to this outcome rather than PA. However, there were no differences in descriptive characteristics or PA variables between the groups at baseline. Therefore, the risk of any potential bias in the findings was minimal [56]. Secondly, the participants in this study were primarily Caucasian women with 78% having at least a two-year college degree and the effectiveness of the website to increase maternal exercise may not be generalized to all

pregnant women. Lastly, participants in the control group were not asked to self-report weekly exercise during their pregnancy as self-regulation or documentation of PA is one construct of the SCT known to influence behavior [24].

The current study had many strengths including the initiation of the intervention by 15 weeks in pregnancy. Many interventions are often initiated closer to 20 weeks [57-61] due to many discomforts experienced by women in early pregnancy and potential difficulties to recruit an adequate number of participants in the first trimester. We were fortunate to partner with a large metropolitan hospital and several local obstetric clinics to recruit participants at their first prenatal visit. This also enabled us to confirm qualification criteria and obtain consent to participate by medical providers, particularly important for the women in this study since they were all sedentary prior to pregnancy. Recruiting participants of this PA level allowed us to control for pre-pregnancy PA levels limiting the variability within the control group and minimizing the likelihood these participants would increase their exercise level on their own without an intervention. Likewise, the participants in the intervention group had to participate in elective, non-mandatory exercise on their own time. This approach may be a sustainable way to increase PA and more feasible for many pregnant women as it doesn't require the added expense of a gym membership or personal training and may be more flexible for women to fit into their own schedule since it does not require mandatory exercise sessions at a particular time. A recent systematic review evaluating the efficacy of behavioral interventions to increase PA during pregnancy only identified nine interventions that met the search criteria of randomized-controlled trials with non-mandatory exercise sessions and PA measurements at baseline and follow-up [56]. Furthermore, none of the nine studies meeting these criteria used objective forms of PA assessment, further defining the unique nature of the current study.

Conclusions

In conclusion, the use of a behaviorally-based website focused on a theoretical framework significantly increased prenatal exercise and sustained bouts of MVPA in previously sedentary women. Additionally, the amount of sustained MVPA accomplished by the intervention participants was significantly more than that of a control group matched for pre-pregnancy PA. The intervention was facilitated through the website without any additional counseling or encouragement from the research staff. Future studies aiming to

increase adherence to prenatal PA guidelines may want to consider the incorporation of additional counseling strategies since not all women in the current study met current PA guidelines. Regardless, a behaviorally-based website may be a sustainable method to successfully increase prenatal exercise and sustained MVPA in future interventions designed to improve maternal and infant health outcomes.

List of Abbreviations

ANOVA: analysis of variance

BI-group: behaviorally-based website intervention

IQR: interquartile range

MET: metabolic equivalent

MVPA: moderate-vigorous physical activity

PA: physical activity

SCT: social cognitive theory

SD: standard deviation

SWA: SenseWear® Mini armband

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

All authors contributed to the study design. KMS conducted the intervention under the direction of CGC and drafted the manuscript. LLF, ASW, GJW, and CGC reviewed the manuscript.

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TABLES

Table 1. Descriptive characteristics of study participants at baseline

Characteristic	All n = 45	Usual care n = 21	Intervention n = 24	P-value
Age (years)	29.6 ± 4.5	29.4 ± 4.9	29.7 ± 4.1	0.82
Pre-pregnancy BMI ($kg \cdot m^2$)	26.4 ± 4.6	25.4 ± 4.5	27.3 ± 4.6	0.18
No. of pregnancies (including current)	2.5 ± 1.4	2.5 ± 1.1	2.5 ± 1.6	0.97
Parity	1.2 ± 1.1	1.2 ± 1.0	1.2 ± 1.2	0.94
Weekly MVPA pre-pregnancy (minutes)	51 ± 59	66 ± 69	38 ± 45	0.12
*Weekly MVPA in pregnancy prior to enroll (minutes)	0 (0-70)	6 (0-79)	0 (0-58)	0.39

** All values are mean ± SD except where noted for non-parametric data presented as median (IQR). Weekly MVPA was self-reported at enroll.*

Table 2. Objective MVPA for both groups at three time points during pregnancy

	Baseline Weeks 10-14		Weeks 24-26		Weeks 34-36	
	Usual care n=21	Intervention n=24	Usual care n=20	Intervention n=22	Usual care n=18	Intervention n=20
MVPA 10-min bouts	71 (11-183)	72 (36-158)	71 (31-180)	141 (59-214)	47 (16-163)	88 (22-155)
MVPA 20-min bouts	0 (0-100)	32 (0-93)	28 (0-79)	79*# (51-161)	24 (0-75)	46 (0-127)
MVPA 30-min bouts	0 (0-31)	0 (0-46)	0 (0-30)	56*# (27-123)	0 (0-40)	25 (0-127)

**Significantly different between groups at P < 0.0167 after Bonferroni correction.*
#Significantly different within group from baseline at P < 0.05.
All values are median (IQR).

Table 3. Criteria to establish tertiles of website engagement

Criteria (maximum score possible)	Not-engaged n=21	Low-engaged n=8	Highly-engaged n=16
Number of log-ins (?)	1.6 ± 0.6	16 ± 7.2	43.8 ± 32.8
Number of goal setting modules completed (2)	0 ± 0	0.5 ± 0.9	1.6 ± 0.6
Number of problem solving modules completed (?)	0 ± 0	0.8 ± 0.5	4.4 ± 3.4
Number of private journal entries (?)	0 ± 0	0.4 ± 0.5	1.9 ± 2.6
Number of posts to the community forum (?)	0 ± 0	1.3 ± 1.8	3.4 ± 4.5
*Final score (5)	0 ± 0	2.5 ± 0.5	4.4 ± 0.5

*∞: No limit to the maximum score possible for this category. *The final score was the sum of the number of categories the participant met the criteria for being "highly-engaged". All values are mean ± SD.*

Table 4. Objective physical activity based on tertiles of website engagement

	Not-engaged n =21	Low-engaged n=8	Highly-engaged n=16	P-value
Minutes of MVPA per week in 10-min bouts	114 ± 96	85 ± 63	182 ± 164	0.13
Minutes of MVPA per week in 20-min bouts	*57 ± 63	47 ± 40	*118 ± 102	0.033
Minutes of MVPA per week in 30-min bouts	*27 ± 35	29 ± 34	*77 ± 75	0.016

*MVPA: Moderate-vigorous physical activity. Objective physical activity data averaged from weeks 24-26 and 34-36 of pregnancy. *Significantly different between tertiles, P < 0.05. All values are mean ± SD.*

FIGURES

Figure A. CONSORT Diagram of Recruitment and Enrollment

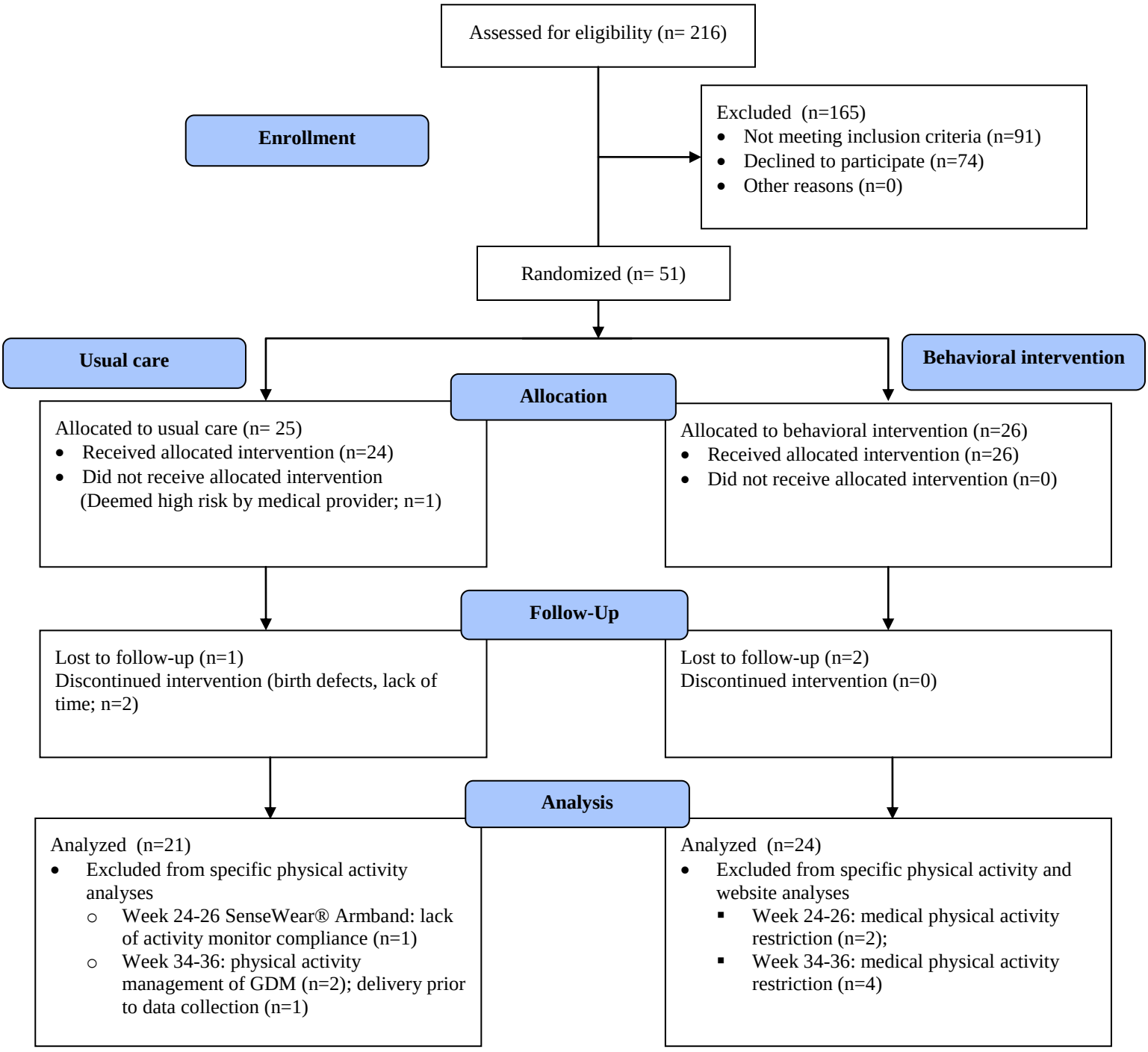
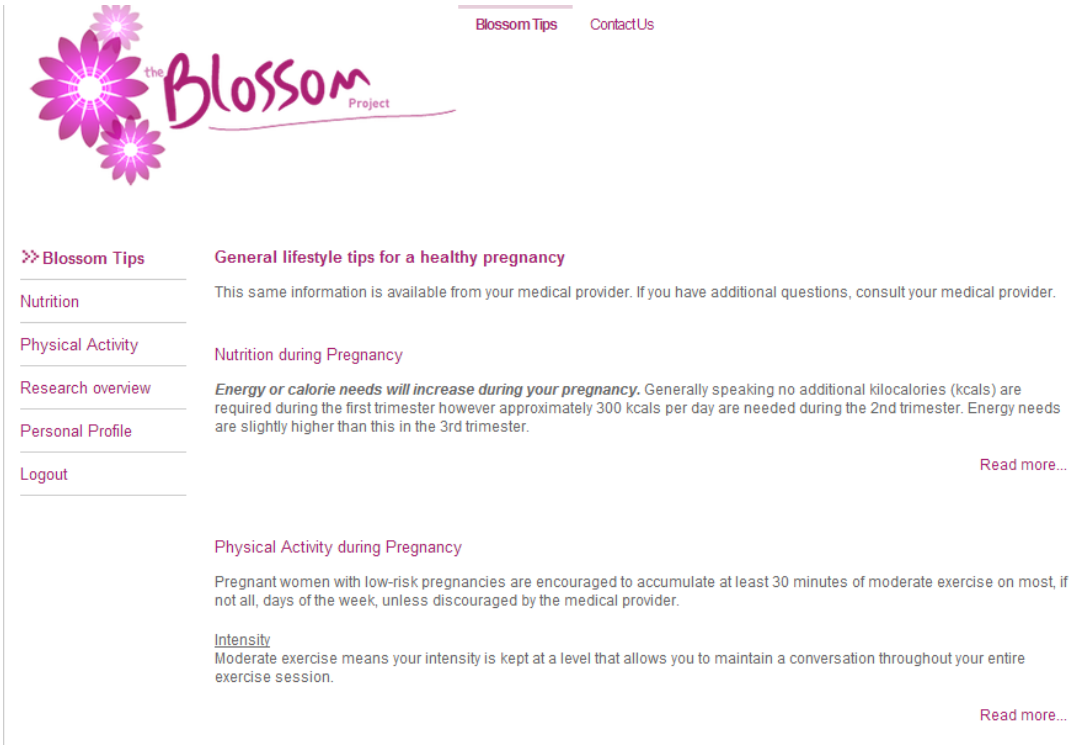
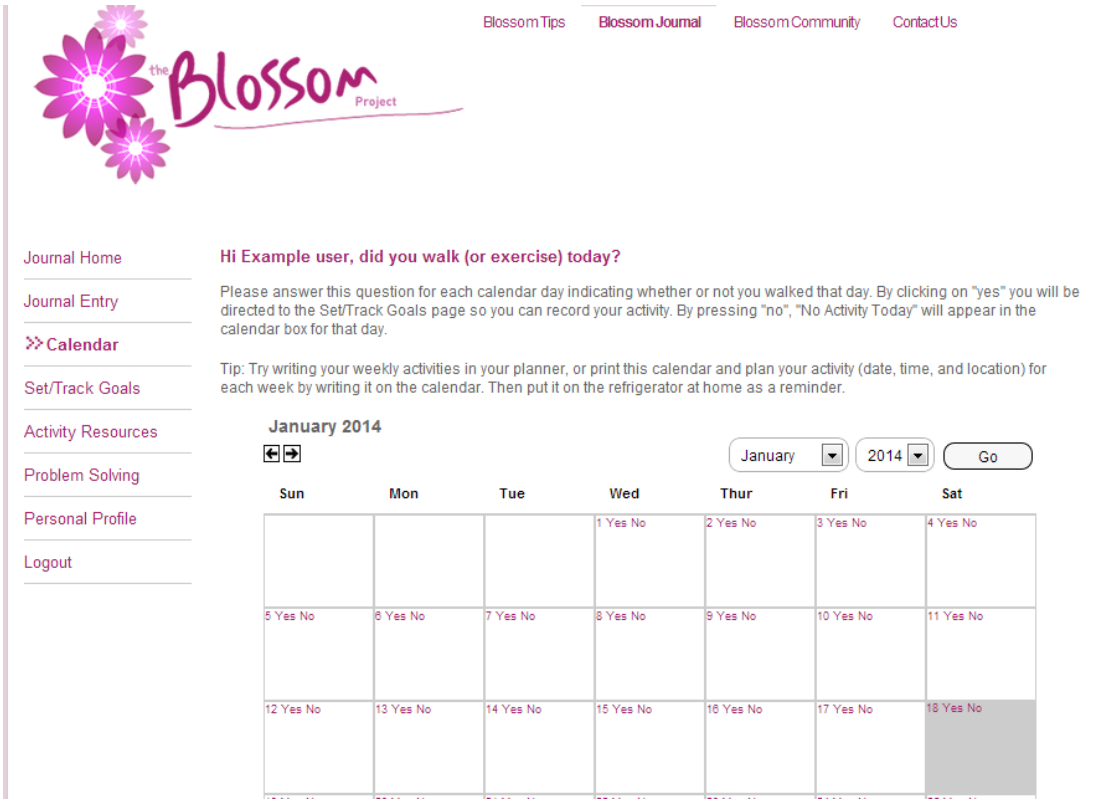


Figure B. Screen shot image of the usual care website



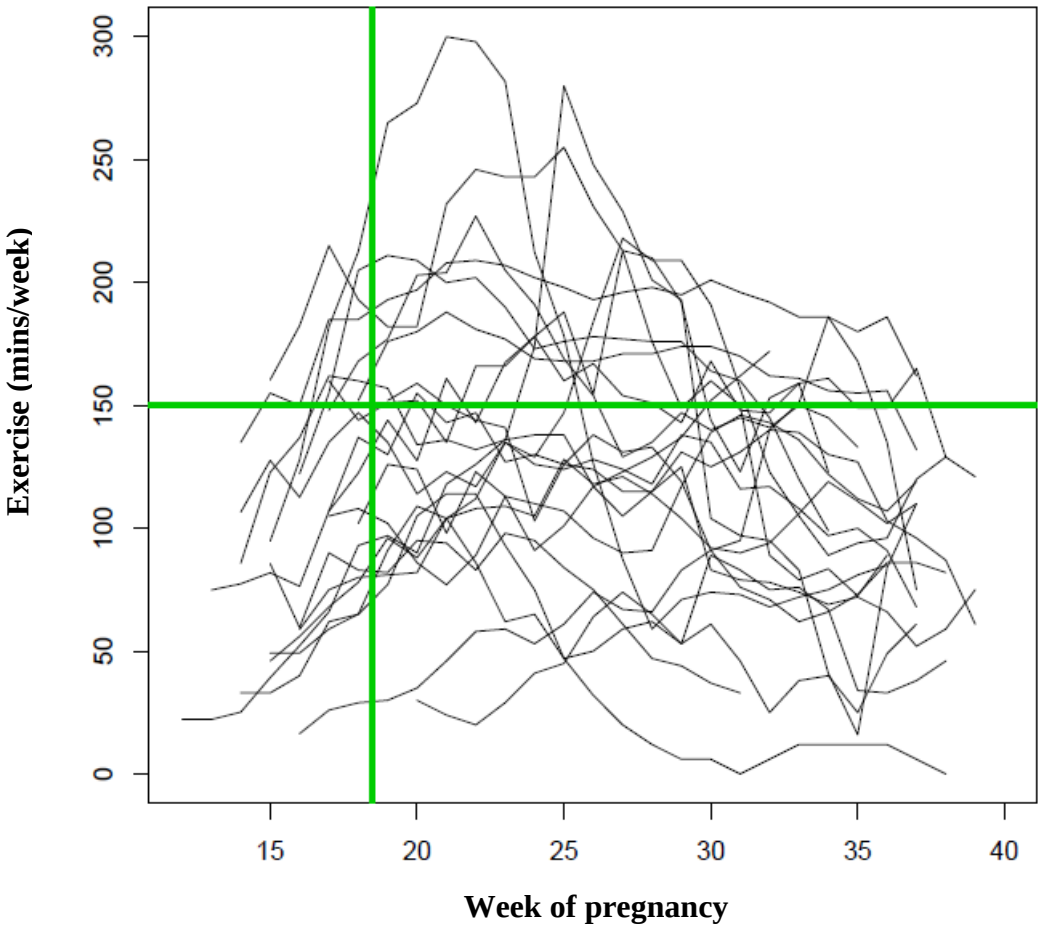
Participants in the usual care group received access to general nutrition and physical activity tips for a healthy pregnancy (termed Blossom Tips) on the study website. This information was also provided to women in the intervention group.

Figure C. Screen shot image of the intervention website



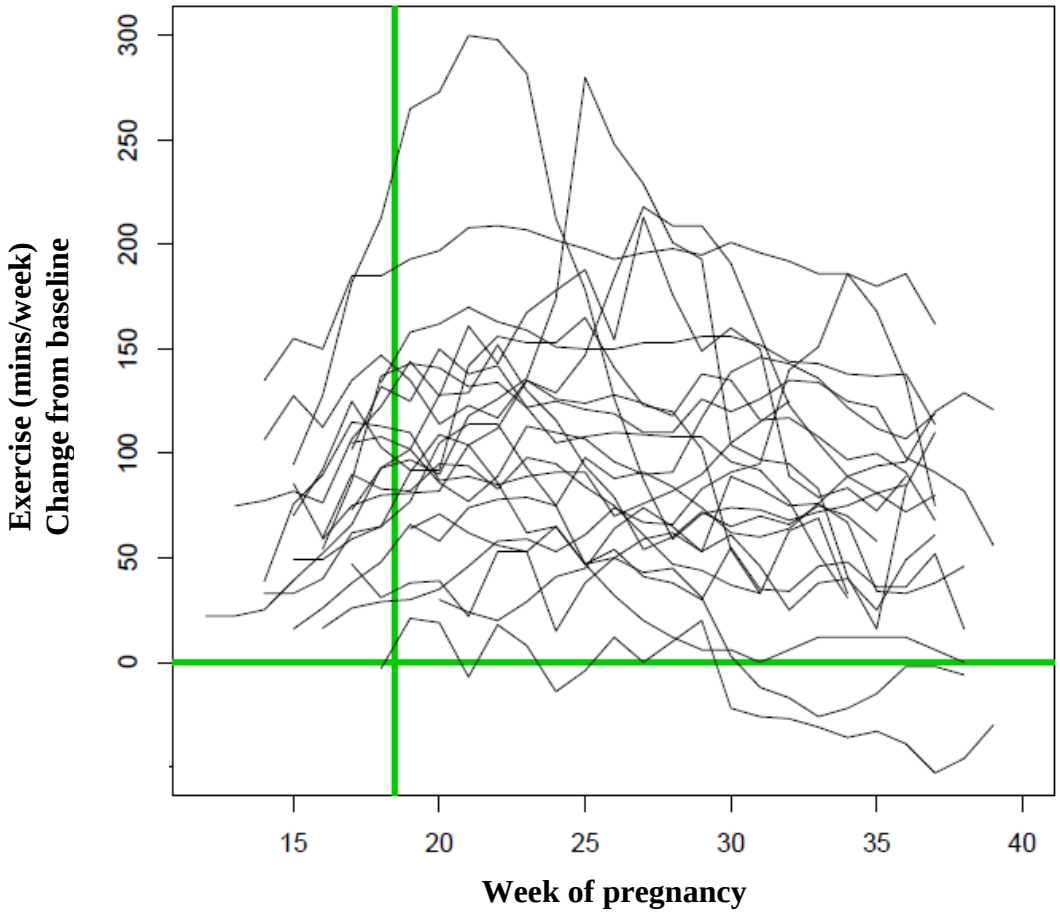
Women in the intervention had access to this exercise calendar as well as many additional website features beyond the general tips for a healthy pregnancy) received by the usual care group (Figure B). Figure C shows the calendar that women used to record their daily exercise throughout their pregnancy.

Figure D. Weekly exercise self-reported on website by intervention participants (n=22)



The dark horizontal line represents 150 minutes, the minimum weekly exercise goal for all participants from week 19 of pregnancy to delivery. The dark vertical line represents week 19 of pregnancy. Each data line represents one intervention participant's weekly exercise pattern throughout the study.

Figure E. Weekly change from baseline in self-reported exercise minutes per week by intervention participants (n=22)



Baseline exercise was self-reported at enroll as usual exercise minutes per week thus far in pregnancy. The dark horizontal line represents zero minutes in change of exercise from baseline, thus values along this line would indicate baseline and weekly exercise minutes were equivalent. The dark vertical line represents 19 weeks of pregnancy. Each data line represents one intervention participant's weekly change in exercise compared to her baseline exercise amount.

CHAPTER 5: IMPACT OF A BEHAVIORALLY-BASED RANDOMIZED CONTROLLED TRIAL ON PREVENTION OF EXCESSIVE GESTATIONAL WEIGHT GAIN AND MATERNAL WEIGHT RETENTION

A paper to be submitted to the journal Medicine & Science in Sports & Exercise

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Abstract

Objective: To determine if a web-based behavioral intervention can increase physical activity (PA) to prevent excessive gestational weight gain (GWG) and decrease postpartum weight retention. **Design and Methods:** Participants were randomized to usual care (UC; n=21) or behavioral intervention (BI-group; n=24) between 10-14 weeks gestation. GWG, PA and diet were assessed at baseline, 24-26 and 34-36 weeks; weight retention at 1-month postpartum. **Results:** Excessive GWG was 42.1%, 82.4%, and 66.7% for normal-weight, overweight, and obese women, respectively. No differences in GWG, adherence to GWG recommendations, or weight retention presented between groups. Week 24-26 BI-group PA was greater than UC (20-min bouts: 122 ± 106 vs 46 ± 48 mins/week, $P = 0.005$; 30-min bouts: 74 ± 70 vs 14 ± 24 mins/week, $P < 0.001$), and greater for BI-group at weeks 24-26 compared to baseline (20-min bouts: 61.3 ± 21.9; 30-min bouts: 39.6 ± 14.8, both $P < 0.05$). Conversely, at weeks 24-26 BI-group energy intake significantly increased (336 ± 127 kcals, $P = 0.04$) and was significantly greater than UC (2503 ± 703 vs 1894 ± 594, $P = 0.005$). **Conclusions:** A web-based behavioral intervention increased sustained PA. Sedentary pregnant women should increase PA but may need additional dietary counseling to prevent excessive GWG.

Introduction

Pregnancy has been referred to as a "teachable moment" for weight control and obesity prevention (1). Excessive gestational weight gain (GWG) has been shown to increase maternal (2) and infant (3,4) risk for obesity later in life. Physical activity (PA) during pregnancy has been repeatedly suggested as one plausible method to reduce excessive GWG thereby improving maternal and infant outcomes.

Several studies have focused on prevention of excessive GWG (4,6) with mixed results while the number of women in the United States exceeding GWG recommendations continues to rise (7). Therefore, a continued need to develop effective strategies to prevent excessive GWG and thereby improve prenatal outcomes remains. Recent awareness of using behavioral theory to elicit behavior change, such as increased PA, has resulted in a call for prenatal interventions to be based on theory to increase the probability of success (5). The social cognitive theory (SCT) is a behavior theory that has played a dominant role in health education for many years (8). This theory directs attention towards the social influences on behavior and incorporates the cognitive contribution of the individual's thoughts, motivation and actions. SCT web-based interventions conducted in non-pregnant adults have shown favorable weight-management results when incorporating the key strategies of self-efficacy and social support (9,10). Only a few studies to date have applied SCT in pregnancy interventions (11,12) however, none of these studies evaluated the effect of increasing prenatal PA to prevent excessive GWG. Furthermore, only one study has used a behavioral theory (social learning theory) to fully guide the development of a prenatal intervention (13). Excessive GWG significantly decreased in the intervention group compared to control (40.2 vs 52.1%, respectively; $P < 0.001$) in normal weight women, but not among overweight or obese women (13).

Given the need for behaviorally-focused prenatal interventions to prevent excessive GWG, the objective of the current randomized controlled trial (RCT) was two-fold: 1) Determine if previously sedentary women utilizing a web-based behavioral intervention designed to increase sustained PA would prevent excessive GWG (primary outcome); and 2) Evaluate the effect of the intervention on maternal weight retention at 1-month postpartum (secondary outcome). It was hypothesized that mothers receiving access to an interactive web-based behavioral intervention would achieve appropriate pregnancy weight gain and retain less weight 1-month postpartum.

Methods

Study participants Fifty-one women (Figure 1) 10-14 weeks pregnant were recruited and enrolled into a RCT (ISRCTN38498311) between January – September 2013. The sample size of at least 50 participants was based on GWG data from our previous observational studies with similar inclusion criteria. This sample size allowed for a

conservative attrition rate of 20% to yield an adequate sample (n=20) in both groups with 80% power to detect a difference between groups in total GWG of 4.0 kg. Participants were recruited by local prenatal clinics and a partnering hospital. Additional recruitment strategies included email list-services, advertisements online, and fliers posted within the community. At the time of recruitment (10-14 weeks gestation), women self-reported current PA and usual weekly PA for the last six months prior to conception. Only women with a history of participating in less than 3 sessions of exercise for 30 minutes or more per week (14) for at least six months prior to conception were enrolled. Additional inclusion criteria included 18-45 years old, English speaking, regular internet access, and willing to walk 30 minutes on most days of the week if asked to do so. Exclusion criteria was defined as a history of gestational diabetes mellitus (GDM), pre-eclampsia, or chronic disease (e.g. Type 1 Diabetes Mellitus, heart disease, renal disease), underweight (body mass index (BMI) < 18.5 $kg \cdot m^2$), smoking during pregnancy, and prevalence of a condition or use of a medication known to influence overall metabolism. Qualification criteria were confirmed by each participant's medical provider. All participants provided written informed consent and the study was approved by the local Institutional Review Boards.

Maternal anthropometric data Participants completed three, week-long data collection periods between 10-14 weeks (baseline), 24-26 weeks, and 34-36 weeks of pregnancy. At each timepoint, participants reported to the research center or partnering hospital and were weighed, with minimal clothing and without shoes, to the nearest 0.1 kg. Additionally, height was measured to the nearest 0.1 cm at the enrollment visit. Prior to randomization, participants self-reported pre-pregnancy weight, age, race, education level, marital status, number of previous pregnancies, and parity at enrollment (15). Therefore, any possible effect of misreporting pre-pregnancy weight should be equivalent in both groups. Gestational age was calculated by ultrasound if completed by time of enrollment, or date of last normal menstrual period.

Gestational weight gain Appropriate GWG was defined as the 2009 Institute of Medicine (IOM) total and weekly weight gain recommendations based on pre-pregnancy BMI (7). Total GWG was defined as the last weight measured by the research staff between 34-36 weeks gestation minus pre-pregnancy weight. Rates of GWG were calculated at each timepoint by subtracting pre-pregnancy weight from the measured weight at each data

collection period, using previously reported methodology (16). Expected GWG was calculated as follows: expected first trimester total GWG + ([gestational age at time of weight measurement] – 13 weeks 0 days] * weekly expected weight gain for 2nd & 3rd trimesters based on pre-pregnancy BMI). Appropriate GWG was calculated as a range using the minimum and maximum values of the weekly recommended weight gain range (7). Adequacy of GWG was then categorized by: inadequate (less than recommended range), adequate (within recommended range), or excessive (more than recommended range). Maternal weight retention was calculated by subtracting the woman's pre-pregnancy weight from her weight measured at the 1-month postpartum visit.

Physical activity assessment PA was objectively assessed for all participants wearing the SenseWear® Mini armband (Model: MF-SW) (BodyMedia, Pittsburgh, PA) for one week (7-consecutive 24-hour periods) at each data collection period (17,18). SenseWear® files were downloaded using version 8.0 of the BodyMedia software (algorithm 5.2h). A previous version of the SenseWear® algorithm (5.2e) has been shown to predict energy expenditure well (r=0.93) during mid-pregnancy (19). Further testing of the most currently available algorithm used in the present study has shown improved agreement and no systematic bias (unpublished data, Campbell).

Participants were instructed to wear the SenseWear® Mini armband 24-hours per day during each monitoring period except when showering or swimming. Activities performed when the monitor was not worn were documented in a PA record. PA records revealed eight women participated in aquatic exercise; PA for aquatic activity was filled in at an appropriate intensity specific to the activity (e.g. water walking, freestyle lap swim, or water aerobics) listed in the 2011 Compendium of Physical Activities (20). A unique feature of the SenseWear® Mini armband is its ability to detect when it is worn, allowing researchers to evaluate nonwear time. A valid week of armband use was considered less than 500 minutes of nonwear time per week as previously reported (21). After including aquatic activity, five participants exceeded 500 minutes of nonwear time, all of which occurred during sleep according to the PA record. Therefore, an equivalent amount of sedentary time was filled in to match activity conducted during nonwear time.

The following PA data were analyzed: total number of accumulated MET-minutes, sedentary ($\leq$ 1.5 METs), light (1.6-2.9 METs), and moderate -vigorous ($\geq$ 3.0 METs)

physical activity (MVPA) per week, and weekly number of minutes in MVPA performed in at least 10-, 20-, and 30-minute bouts. A code was written for Microsoft Office Excel to evaluate sustained bouts of PA. Interruptions of 1 or 2 minutes below the moderate threshold within a 10-minute bout were allowed (22).

Dietary intake assessment All participants completed a weighed 3-day diet record during each data collection period (two week-days and one weekend day). Dietary records were analyzed with Nutritionist Pro™ (Axxya Systems, Stafford, TX). Intake data from the three days were averaged to provide estimated daily intakes of total calories, carbohydrate, protein, and total fat. The Healthy Eating Index (HEI)-2010 (24) was used to assess diet quality according to the 2010 Dietary Guidelines for Americans (25). Furthermore, this tool assesses diet quality on a per calorie basis, thus is appropriate for use in pregnancy (24) when recommended caloric intake increases over time. The maximum score for the HEI-2010 is 100; an overall HEI score above 80 is considered 'good', while a score of 50-80 'needs improvement', and scores below 50 are considered poor (26). To identify individuals that may have reported implausible dietary intake data, a ratio of average daily energy intake to energy expenditure was calculated. A ratio of <0.80 was used to identify under-reporters as previously reported (27); these data were not used in the analyses (n=2) unless the woman gained less than the recommended GWG. In this case, her data was retained to help explain any possible dietary relationship to GWG (n=3).

Behaviorally-based intervention Participants were randomized (using computerized random numbers) to usual care or behavioral intervention following the completion of baseline data collection between 10-14 weeks gestation. Participants and research staff were blinded to the randomization assignment until the baseline data collection was completed. Due to the nature of the study design, participants were not blinded once they were informed of their randomization. Participants were then provided access to the SCT-based website with a username and password. Participants receiving usual care could only view general prenatal diet and PA recommendations while intervention participants had access to all of the website features including the diet and PA recommendations, exercise goal-setting modules, problem-solving modules, a journal, a calendar to track all exercise through delivery, and a community forum to interact with other participants in the behavioral intervention (social support). Intervention participants were instructed to gradually work up

to ≥ 150 minutes of moderate PA/week (in ≥ 10-minute bouts) by week 19 gestation and sustain at least this amount until delivery.

Statistical analyses Data are reported as mean ± SD and group comparisons were made by independent sample t-tests. All results were adjusted with a Bonferroni correction for multiple comparisons where applicable. Statistical significance was accepted at the level of $P < 0.05$. Stepwise and multiple regression were used to evaluate predictors of GWG and maternal weight retention. Group randomization assignment was forced into the models to explore if group assignment explained any variation in either outcome. Preliminary statistical analyses were conducted by a statistician who was blinded to the randomization assignment. Statistical analyses were conducted in MedCalc version 13.1 (MedCalc Software, Mariakerke, Belgium) and JMP Pro 11.0.0 (SAS Institute Inc., Cary, NC).

Results

Descriptive characteristics No differences in demographic characteristics were found between groups (Table 1). The majority of participants were married (82.2%, n=37), Caucasian (88.9%, n=40), and had at least a 2-year post-secondary degree (77.8%, n=35).

Diet and physical activity Diet and PA group comparisons are reported in Table 2. Intervention participants consumed a significantly greater number of calories at weeks 24-26 than usual care ($P = 0.005$). To further evaluate this finding, a repeated measures ANOVA was conducted to evaluate any change in caloric intake across pregnancy (overall F-statistic =4.72, $P = 0.014$). While average daily caloric intake did not change across pregnancy for usual care, a significant increase among intervention participants was present from baseline to weeks 24-26 (336 ± 127 kcals, $P = 0.04$). Diet quality scores ranged from 28.7-76.2 and 26.4-86 at baseline for usual care and intervention, respectively, while diet quality scores at weeks 24-26 ranged from 33-87.6 and 29.1-82 and weeks 34-36 from 40-82.4 and 28.8-71.6, respectively. No difference in diet quality was present between groups at any timepoint and HEI scores did not significantly change across pregnancy.

No differences between groups were evident for MET-minutes, sedentary, light, and MVPA minutes accumulated throughout the week, while sustained MVPA in bouts was greater among intervention participants (Table 2). Total accumulated MET-minutes significantly decreased among usual care from baseline to weeks 34-36 (1234 ± 372 MET-minutes, $P = 0.013$). No change was observed in any MVPA bouts across pregnancy for

usual care, while 20-minute bouts (61.3 ± 21.9 minutes) and 30-minute bouts (39.6 ± 14.8 minutes) significantly increased from baseline to weeks 24-26 in the intervention ($P < 0.05$ for both).

Gestational weight gain and weight retention Excessive total GWG occurred in 62.2% of all participants. Overweight women were most likely to exceed the IOM recommendations for GWG (82.4%), followed by obese women and normal weight women (66.7% and 42.1%, respectively). Rates of GWG, total GWG, and adherence to Institute of Medicine GWG recommendations were not significantly different between groups (Table 3).

No differences were observed between usual care and the behavioral intervention for weight retention (3.9 ± 5.4 vs 5.3 ± 5.7, $P = 0.67$) and percent of pre-pregnancy weight retained at 1-month postpartum (5.6 ± 6.9 vs 7.3 ± 7, $P = 0.42$).

During step-wise regression, group randomization assignment was forced into the model to explore if group assignment explained any variation in GWG ($P = 0.35$). Significant predictors of total GWG (percent of weight gained of total IOM recommendation at weeks 34-36) based on step-wise regression analyses were percent of IOM recommendation gained at week 24-26 ($P < 0.0001$), average energy intake per day between weeks 34-36 ($P = 0.02$), and accumulated MVPA at baseline ($P < 0.05$). MVPA sustained for at least 30-minutes at weeks 24-26 improved the model prediction and was included in the final model (final model $P < 0.0001$) (Table 4). Diet quality did not enter the model at any timepoint during the step-wise regression.

Group randomization assignment was also forced into a separate model to explore if group assignment explained any variation in weight retention ($P = 0.75$). Significant predictors of weight retention based on step-wise regression analyses included percent of weight gain of total IOM recommendation at weeks 34-36 ($P = 0.002$) and pre-pregnancy BMI ($P < 0.001$) (final model $P < 0.0001$; Table 4). PA or diet variables did not enter the model at any timepoint during the step-wise regression.

Discussion

Findings from this RCT supported that a web-based behavioral intervention significantly increased sustained PA, yet the amount of activity performed by women in this intervention was not sufficient to prevent excessive GWG or improve weight retention. Although more MVPA was conducted in sustained 20- and 30-minute bouts among

intervention participants (compared to control), total accumulated MVPA and accumulated MET-minutes (an indicator of total PA) did not change across pregnancy. Thus, it is unlikely that exercise-associated energy expenditure increased enough to prevent excessive GWG if overall PA was the same.

Additionally, a significant increase in caloric intake among women in the intervention may partially explain the greater GWG and thus postpartum weight retention in this group. It may be possible that women in the intervention experienced greater hunger due to increased MVPA and thus consumed more calories, or chose to eat more calories knowing they were doing more activity as a result of the intervention. Though the reason for increased caloric intake in the intervention group cannot be identified in the present study, these findings highlight the importance of maternal diet along with PA for optimal GWG.

These findings have several clinical implications for obstetric patient care and obesity prevention. It is important to note that GWG counseling was not provided in this intervention (e.g. no participants received GWG guidelines, individualized GWG charts, feedback on GWG, etc.). This approach was used to evaluate if a web-based behavioral intervention designed to increase intentional MVPA in previously sedentary pregnant women could also prevent excessive GWG, independent of additional counseling methods. While the website successfully and significantly increased sustained MVPA during pregnancy, additional strategies may need to be incorporated into clinical practice and communicated to pregnant women to promote favorable GWG, and prevent obesity for mother and child. Such strategies may include a higher volume of MVPA than performed in this study, dietary modifications, GWG counseling techniques as previously mentioned, or a combination of these strategies. It is plausible that such strategies could be effectively included as part of a multi-behavior web-based intervention, but further research would be needed to ascertain the effectiveness of such interventions for pregnant women.

In terms of behaviorally-based interventions, only one other study has developed its intervention on a behavioral theory (social learning theory) and reported significantly decreased excessive GWG between intervention and control (40.2 vs 52.1%, $P < 0.001$) (13). This study was only effective in normal weight women and GWG was based on the 1990 IOM recommendations. Relative to other PA interventions without dietary modifications or GWG counseling, Barakat et al. (28) reported a significant decrease in GWG between

exercise and control groups (11.9 kg vs 13.9 kg, $P = 0.03$). This study, conducted in Spain, made no reference to specific GWG recommendations beyond a notation that GWG in the exercise group was considered "normal for a healthy pregnancy". Several key differences exist between the study conducted by Barakat et al. and the current study. The exercise sessions in the Barakat study included walking, core work, stretching, and very light resistance training three times per week and were conducted in a hospital clinic in groups of 10-12 participants monitored by a fitness specialist and obstetrician. The current study was conducted via a website that required elective, non-monitored sustained PA and did not include any supplemental contact by research staff. While the website featured an interactive community to foster social support among intervention participants, women had the choice of whether or not to use this feature and thus the level of accountability may not have been equivalent to that of showing up to a group exercise session three times per week. Secondly, it is not clear if women in the Barakat study were participating in considerable amounts of PA prior to pregnancy. If so, women may have been more likely to participate in PA during pregnancy (29). All women in the current study were sedentary for at least six months prior to pregnancy and may have had additional barriers to overcome to regularly engage in sustained PA compared to the women in the Barakat study. One specifically unique feature to both studies was the early initiation and extended length of the interventions. Baraket et al. started between 6-9 weeks of pregnancy and continued through weeks 38-39 of pregnancy while the current study enrolled participants between 10-14 weeks of pregnancy and continued to delivery. Additionally, Barakat et al. reported 90% adherence to training among the exercise group. Collectively, these studies contribute valuable findings to inform future PA interventions designed to promote appropriate GWG.

Haakstad and Bo (30) also reported an interesting finding related to adherence during an exercise intervention. Their exercise program consisted of supervised aerobic dance and strength training for 60 minutes, at least twice per week for a minimum of 12 weeks, but did not result in significantly improved prevention of excessive GWG between groups. However, none of the women that attended all 24 exercise sessions exceeded the 2009 IOM GWG recommendations demonstrating that exercise and PA volume as well as adherence to PA intervention protocols are important factors to consider when determining effectiveness of PA to prevent excess GWG.

Haakstad and Bo's finding on prevention of excessive GWG and adherence to exercise sessions was also true for improved maternal weight retention. No differences in pregnancy weight retention were found overall between the exercise and control groups yet women in the exercise group that attended all 24 exercise sessions retained significantly less weight than controls (0.8 ± 1.7 kg vs 3.3 ± 4.1 kg, $P = 0.001$). Postpartum weight measurements were conducted between 6-12 weeks following delivery, compared to the current study measurements completed at 1-month postpartum, making it difficult to compare effectiveness between the studies relative to weight retention.

To our knowledge, this is the first study to report on the use of the HEI-2010 in pregnancy. Shin et al. used the HEI-2005 to conduct a cross-sectional study using NHANES data from 490 women and tested the hypothesis that diet quality during pregnancy is associated with adequate GWG (defined by the 2009 IOM guidelines) at different stages of pregnancy (31). After adjusting for age, trimester of pregnancy, race/ethnicity, education, marital status, income, daily supplement use, PA, and pre-pregnancy BMI, HEI-2005 scores did not differ significantly (P = 0.15) across GWG groups (inadequate, adequate, or excessive GWG). However, inadequate intake of total vegetables and oils were associated with excessive GWG (OR 2.8, CI 1.2-6.4, $P = 0.02$). Similarly, overall diet quality was not a significant predictor GWG in the current study.

There are many strengths to the current study. Only women with a history of a sedentary lifestyle for six months prior to pregnancy were enrolled to control for pre-pregnancy PA. Pre-pregnancy PA is a strong significant predictor of PA during pregnancy (29). This minimized the variation in PA between groups outside of the intervention itself. Secondly, while dietary modification was not an intent of this study, both groups completed 3-day weighed diet records at each time point to control for multiple variables in maternal diet. Some evidence suggests self-monitoring dietary intake may result in a change in dietary intake (32,33); however, the change would be expected to be similar in both groups. The current study observed a significant increase in caloric intake between baseline and weeks 24-26 among intervention participants. Coincidently, this is also the time point when MVPA in 20- and 30-minute bouts were significantly greater than baseline levels. The increase in caloric intake may partially explain the greater GWG present among intervention participants compared to usual care. In a study evaluating the effect of a low- and moderate intensity

exercise program on GWG in normal weight women, no differences were seen between groups in GWG or caloric intake (34). Both groups received the same meal plan and nutritional counseling to provide a nutritional control. No difference in GWG was surprising due to the increased energy expenditure among the moderate intensity exercise group yet similar total energy intake. Two possible explanations were provided: 1) a reduction in light and moderate activity beyond exercise (NEAT, non-exercise activity thermogenesis) in the higher intensity group; 2) An increased energy intake due to an increased exercise-induced energy deficit among moderate-intensity exercisers but underreporting of actual calories consumed. Several other prenatal PA interventions (without dietary modifications) that assessed GWG were either not successful in preventing excess GWG compared to controls (30,35,36) or did not assess GWG relative to recommendations (e.g. adequacy of GWG) (37-40). Therefore, the independent role of PA to prevent excess GWG has been poorly understood (41-43) but compliance with the PA program and lack of dietary assessment are likely to explain much of this variation (44). To our knowledge, the current study is the first to report an unintentional increase in caloric intake during a prenatal PA intervention designed to prevent excessive GWG. These findings may provide valuable insight as to why other studies evaluating only PA have not witnessed a favorable effect on GWG.

While a large hospital network within a metropolitan area was used to help recruit participants and increase sample diversity, it is important to recognize the limitations of the current study. The majority of the participants enrolled in the study were Caucasian, married, and had some form of post-secondary education. While the sample population was reflective of the general population where the study was conducted, the findings may not be representative of all pregnant women. The sample was also a convenience sample; it is possible there was an underlying motivation among all participants to make positive lifestyle modifications during pregnancy. This may have influenced the ability to detect differences between groups. To better control for this, baseline assessments were completed prior to randomization to evaluate if any changes were present in behavior (e.g. PA and diet) across pregnancy. Secondly, this study was powered to find a difference in GWG of 4.0 kg between groups. A larger sample size would have been necessary to detect a smaller difference in GWG between groups; however, the intervention group experienced greater GWG than usual care thus a larger sample size would only have increased the likelihood of finding a

significant difference in GWG in the opposite direction of the expected findings. We did not detect any differences in maternal weight retention between groups but the study was not powered to do so; therefore, the sample size may not have been appropriate to detect such a finding. Finally, while we did not use a block randomization design to assure equal BMI distribution in both groups, we did normalize GWG according to the IOM recommended weight specific to each woman's gestational length at the time weight was measured. Given that obese women were more likely to exceed IOM GWG recommendations than normal weight women, the distribution of excessive GWG among groups may have been influenced. Future study designs will incorporate the findings of this pilot study to develop a larger intervention appropriately powered to detect multiple outcomes and standardize BMI in each group.

In conclusion, the web-based behavioral RCT did not prevent excessive GWG despite a significant increase in intentional, sustained moderate-vigorous physical activity. Average caloric intake significantly increased in the intervention group. As a result, the amount of total activity performed by women in the intervention group was not sufficient to prevent excess gestational weight gain alone, possibly due to the significant increase in calorie consumption. Given the benefits of prenatal physical activity, this should be a regular topic of discussion between clinicians and pregnant women without contraindications to exercise, with referral to registered dietitian nutritionists for additional diet counseling.

Acknowledgements

All authors contributed to the study design. KMS conducted the intervention under the direction of CGC and drafted the manuscript. LLF, ASW, and CGC reviewed the manuscript. All authors read and approved the final version. The authors would like to thank Greg Welk for his contributions to the study design and Anna Peterson for her statistical assistance. KMS was supported by a predoctoral fellowship from the American Heart Association. Additional funding was provided by the Iowa State University College of Human Sciences and the Uelner Professorship (CGC). The authors have no competing interests.

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TABLES

Table 1. Demographic characteristics of participants at baseline

Characteristic	All n = 45	Usual care n = 21	Intervention n = 24	P-value
Age (years)	29.6 ± 4.5	29.4 ± 4.9	29.7 ± 4.1	0.82
Pre-pregnancy BMI ($kg \cdot m^2$)	26.4 ± 4.6	25.4 ± 4.5	27.3 ± 4.6	0.18
No. of pregnancies (including current)	2.5 ± 1.4	2.5 ± 1.1	2.5 ± 1.6	0.97
Parity	1.2 ± 1.1	1.2 ± 1.0	1.2 ± 1.2	0.94

Table 2. Diet and physical activity (PA) data for all participants

	Baseline Weeks 10-14		Weeks 24-26		Weeks 34-36	
	Usual care	Intervention	Usual care	Intervention	Usual care	Intervention
Kcal·day	1934 ± 678	2167 ± 556	1894 ± 594	2503 ± 703*	2016 ± 501	2264 ± 511
% Kcals carbohydrate	51.1 ± 8	50.9 ± 6	52.4 ± 5.8	52.2 ± 8	53 ±7.3	51.7 ± 7.6
% Kcals protein	16.5 ± 3.2	14.7 ± 2.7	16.3 ± 2.9	14.2 ± 2.5	16.1 ± 3.1	15.7 ± 3.1
% Kcals fat	34.1 ± 5.8	36.1 ± 4.7	33.3 ± 4.8	35.1 ± 7	33 ± 6.1	34.1 ± 6.1
Diet quality (HEI)	57 ± 12	52 ± 16	59 ± 15	52 ± 13	57 ± 13	52 ± 12
Total accumulated MET-minutes (minutes per week)	12386 ± 1429	12132 ± 1254	12180 ± 1388	12053 ± 1376	11312 ± 1306	11604 ± 1435
Total accumulated sedentary PA (minutes per week)	5417 ± 634	5506 ± 720	5421 ± 692	5455 ± 634	5406 ± 1086	5723 ± 609
Total accumulated light PA (minutes per week)	1309 ± 622	1229 ± 641	1289 ± 683	1196 ± 543	1117 ± 569	1024 ± 459
Total accumulated MVPA (minutes per week)	228 ± 149	240 ± 176	231 ± 142	313 ± 204	193 ± 169	289 ± 264
MVPA 10-min bouts (minutes per week)	105 ± 106	112 ± 120	104 ± 88	177 ± 155	98 ± 119	151 ± 176
MVPA 20-min bouts (minutes per week)	46 ± 67	57 ± 77	46 ± 48	122 ± 106*	51 ± 76	92 ± 119
MVPA 30-min bouts (minutes per week)	25 ± 46	31 ± 59	14 ± 24	74 ± 70*	29 ± 47	63 ± 89

*HEI: Healthy eating index-2010; MVPA: Moderate-vigorous PA. Values are presented as mean ± SD. *Significantly different between treatment groups, P < 0.01.*

Table 3. Rates and adequacy of gestational weight gain (GWG) across pregnancy

	Baseline Weeks 10-14		Weeks 24-26		Weeks 34-36	
	Usual care n=21	Intervention n=24	Usual care n=21	Intervention n=22	Usual care n=21	Intervention n=22
Total GWG (kg)	1.8 ± 2.3	2 ± 2.6	7 ± 3.1	7.6 ± 4	11.2 ± 5.1	13.6 ± 5.6
% gained of total IOM recommendation	84 ± 107	88 ± 112	109 ± 57	120 ± 79	106 ± 57	138 ± 73
Inadequate (%)	23.8	12.5	14.3	9.1	14.3	4.5
Adequate (%)	42.9	54.2	38.1	40.9	33.3	27.3
Excessive (%)	33.3	33.3	47.6	50	52.4	68.2

IOM recommendation: 2009 Institute of Medicine GWG recommendation. Total GWG = (current weight$_{measured\ at\ each\ timepoint}$ − self-reported pre-pregnancy weight). Values are presented as mean ± SD, or percentages as indicated.

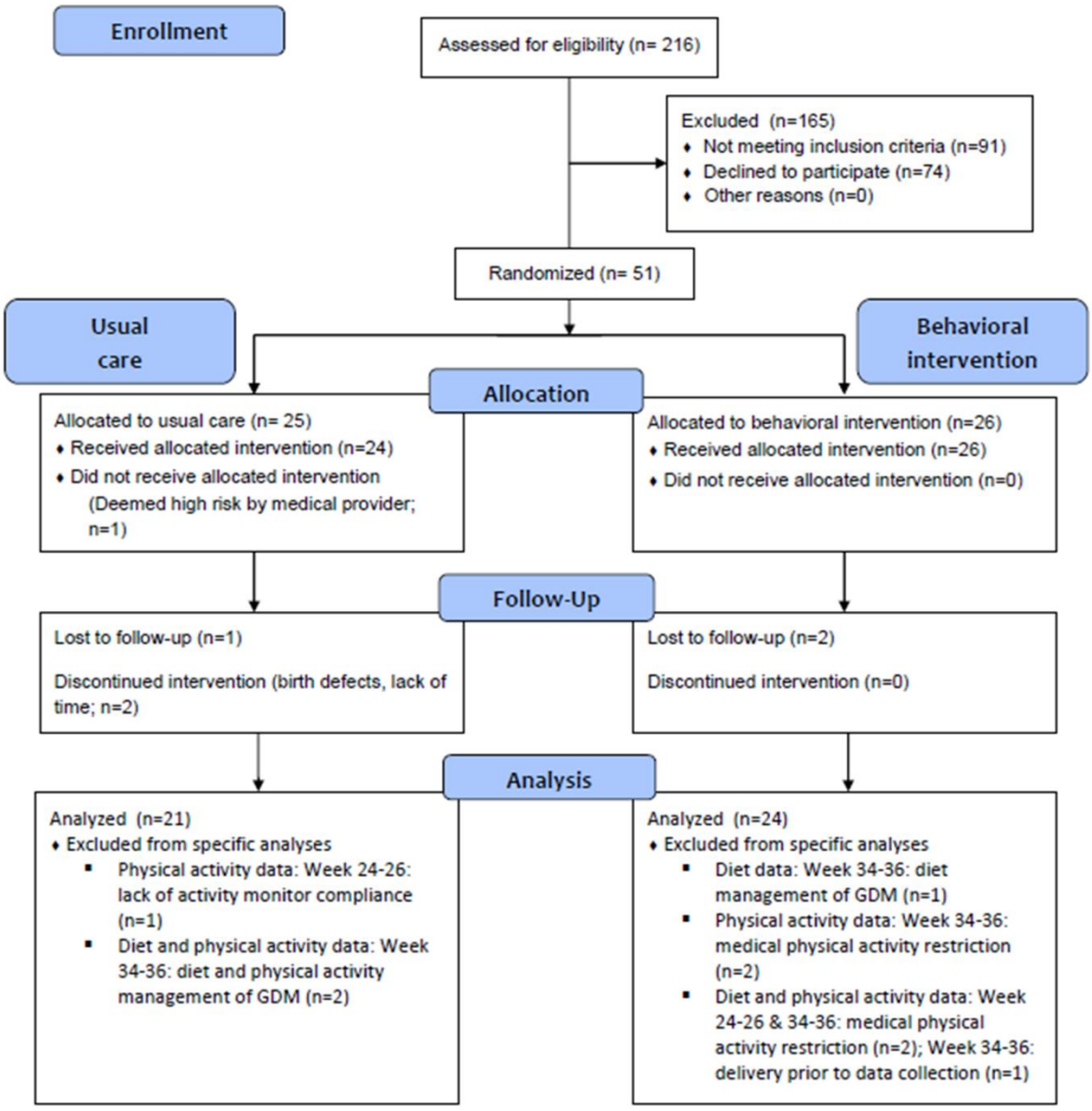
Table 4. Multiple regression predictors of gestational weight gain and weight-retention at 1-month postpartum

	Stepwise regression sequence				ANOVA for final model				
	Predictor	*P* -value	R^2	AIC	Source	DF	Sum of Squares	Mean Square	F-ratio
Outcome:	**Percent of IOM GWG at weeks 34-36 of pregnancy**				Model	5	59852.4	11971	20.55
	Group assignment*	0.35	0.026	384.2	Error	30	17479.6	582.6	Prob > F
	Percent of IOM recommended GWG at weeks 24-26	<0.0001	0.66	348.5	C. Total	35	77332		<0.0001
	Kcal·day, weeks 34-36	0.02	0.72	345					
	Accumulated MVPA, weeks 10-14	0.047	0.75	343.3					
	MVPA 30-min bouts, weeks 24-26	0.089	0.77	342.8					
						DF	Sum of Squares	Mean Square	F-ratio
Outcome:	**Maternal weight retention, 1-month postpartum**				Model	3	1499.37	499.79	44.01
	Group assignment*	0.75	0.003	234.2	Error	38	431.54	11.36	Prob > F
	Percent of IOM recommended GWG at weeks 34-36	0.0016	0.27	225.7	C. Total	41	1930.91		<0.0001
	Pre-pregnancy BMI	<0.0001	0.66	200.3					

Gestational weight gain; MVPA: Moderate-vigorous physical activity; AIC: Akaike information criterion. Values are presented as mean ± SD. P-values and R^2 values are cumulative and include outcomes previously listed in the model. For example, the model for predicting weight retention included group assignment, percent of IOM recommended GWG at weeks 34-36, and pre-pregnancy BMI, for an overall R^2 of 0.77 and AIC of 196.13. The final model includes all variables listed above from stepwise regression. P < 0.1 was used as the inclusion criterion for stepwise regression.

FIGURES

Figure 1. CONSORT diagram of participant flow



Flow chart shows recruitment, selection, and participation in study.

CHAPTER 6: ADDENDUM OF INFANT OUTCOMES

An addendum of the dissertation to be submitted to the journal Pediatrics.

Katie M Smith, Lorraine M Lanningham-Foster, Christina G Campbell

Hypothesis

Infants born to mothers who received access to an interactive behaviorally-based website will have more favorable birth outcomes and body composition at 1-month of age compared to the babies born to mothers that did not receive access to the interactive website.

Methods

Infant anthropometric data Birth outcome data (birth weight, birth length, head circumference, and APGAR scores at 1- and 5-minutes) were obtained from the infants' medical records.

Participants returned to the research center with their baby at 1-month postpartum. At this visit, maternal weight was measured as well as infant length (Seca 416 infantometer, Chino, CA), weight and body composition. Infant body composition was assessed via a method of air displacement plethysmography, the Pea Pod (Life Measurement Inc., Concord, CA). This system uses whole body densitometry to predict lean muscle mass (fat-free mass) and fat mass. The Pea Pod was calibrated each day prior to testing using a calibration cylinder with a known volume provided by the manufacturer. Similarly, a 2 kg weight was used to calibrate the system's scale for measuring infant body weight. No clothing or diapers were worn during the weight or body composition measurements. Weight was measured to the nearest 0.0001 kg. Baby oil was used to slick the infant's hair down and minimize any air volume trapped within the hair. The Pea Pod has been shown to be a valid tool to measure infant body fat with no differences between the Pea Pod and the gold standard four compartment model (16.9 ± 6.5% and 16.3 ± 7.2%, respectively) (1) or between the Pea Pod and deuterium (20.32 ± 6.87% and 20.39 ± 6.68%, respectively) (2).

Statistical analyses Data was assessed for normality by the Shapiro-Francia test prior to analyses. Means and standard deviations (normal distributions) and interquartile ranges (IQR) (skewed distributions) were calculated. Group comparisons were analyzed by independent sample t-tests (normal distributions) and Mann-Whitney tests for independent

samples (skewed distributions). Statistical significance was accepted at the level of $P < 0.05$. Stepwise regression was used to identify predictors for multiple regression analyses to predict infant body composition at 1-month postpartum.

Results

Infant outcome data No differences in birth outcomes (Table 1) or infant anthropometrics (Table 2) at 1-month of age were present between groups.

Predictors of infant body composition Group randomization assignment was forced into the model to explore if group assignment explained any variation in infant body composition ($P = 0.24$). Maternal moderate-vigorous physical activity (MVPA) between weeks 24-26 of pregnancy sustained for at least 30-minutes was the only significant predictor of infant body composition at 1-month of age ($P = 0.04$). Diet quality (HEI score) at weeks 24-26 improved the model by reducing the AIC but was not significant at $P < 0.05$ (Table 3).

Discussion

The current study demonstrates the potential role of maternal MVPA and diet quality in mid-pregnancy to predict and explain part of the variation in infant body composition at 1-month of age. Pre-pregnancy body mass index (BMI), adequacy of gestational weight gain (GWG), and percent gained of the 2009 Institute of Medicine (IOM) weight gain recommendations at baseline (weeks 10-14), weeks 24-26, and weeks 34-36 did not predict infant body composition. This was surprising considering the evidence to suggest pre-pregnancy BMI (3-5) and GWG (3) contribute to infant size and body fat at birth (including assessments of body composition with the same methodology as the current study), and the direct relationship between infant body fat and childhood body fat (6).

Davenport et al. evaluated the associations between GWG and infant body fat at birth (7). They reported greater birth weight and excessive body fat (> 14%) in neonates born to women who gained excessively in the first half of pregnancy (18.7 ± 3.3%) compared to women who gained appropriately (13.2 ± 4.1%, $P < 0.01$). Contrary to these findings, the current study did not find that percent rate of GWG predicted infant body composition. However, the current study measured body composition at 1-month of age versus at birth in the Davenport et al. study. Previous research has suggested infant body composition changes very rapidly in the first six weeks of life with body fat doubling during this time period (8).

As a result, body composition after 2-4 weeks of age is not indicative of measurements at birth and may explain the difference in findings between the two studies.

A key strength of the current study is the standardized time at which infant body composition was assessed (all measurements completed during the fourth week after birth). Due to the rapid changes in body composition early on, it is crucial to evaluate infants at the same age. This has been supported by data by Hull et al. (4) who found that infant age was the only significant predictor of body fat percentage during the first 35 days after birth. Secondly, the methodology of the Pea Pod used to assess infant body composition is a valid tool to measure infant body fat with no differences between the Pea Pod and the gold standard four compartment model (1). Utilizing the calibrated Pea Pod provides a standardized measurement to minimize potential error that may occur with other less expensive methods of infant body composition assessment such as the skinfold technique (9).

The current study is not without limitations. The analyses present in this manuscript are sub-analyses of a larger randomized-controlled trial (RCT) evaluating the effect of a behaviorally-based website to increase MVPA in sedentary pregnant women and evaluate the effect on maternal gestational weight gain. Thus, the sample size for the usual care and intervention groups were powered to detect a different between groups related to gestational weight gain and not infant body composition. It is possible a larger sample size is necessary to detect differences between groups. Additionally, the original RCT did not use a block randomized design to ensure an equal distribution of normal weight, overweight, and obese women in both groups. Previous research has demonstrated a greater percentage of infant body fat in obese women that gained appropriately according to 2009 IOM GWG recommendations compared to normal weight and overweight women that gained appropriately (10). Similarly, the same study discovered infants from overweight and obese mothers who gained excessively had greater percent body fat than normal weight mothers that gained excessively. The current study had seven obese women in the intervention group compared to only two obese women in usual care. Regardless, the primary outcomes of this pilot RCT were the ability of the behaviorally-based website to impact MVPA and GWG and secondarily evaluate any potential impact on infant outcomes. Future studies intending to evaluate infant body composition as a primary outcome should clearly provide power calculations based on preliminary infant data and also consider a block-randomized design to

minimize the variation in potential GWG among women of differing pre-pregnancy body mass index.

In conclusion, maternal sustained MVPA for at least 30-minutes and diet quality at mid-pregnancy may improve prediction of infant body composition at 1-month of age. Larger studies evaluating infant body composition may benefit from assessing maternal PA and dietary intake during pregnancy in addition to commonly used variables such as pre-pregnancy BMI and GWG.

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TABLES

Table 1. Birth outcomes by treatment group

	Usual care n=20	Intervention n=22
Weight (kg)	3.6 (3.3 - 3.8)	3.5 (3.3-4.1)
Length (cm)	50.8 (49.9-52.7)	51.4 (49.5-53.3)
Head circumference (cm)	34.7 (34-35.6)	35.8 (34.2-37.2)
Gestational age at birth (weeks)	39.5 (38.9-40.5)	39.5 (39.1-40.1)
APGAR 1-minute	8 (8-9)	8 (8-9)
APGAR 5-minute	9 (9-9)	9 (9-9)

Values are median (IQR). Significance was set at $P < 0.05$.

Table 2. Infant anthropometrics at 1-month of age by treatment group

	Usual care n=20	Intervention n=22
Weight (kg)	4.5 (4.3-4.8)	4.2 (4-4.9)
Length (cm)	54.1 (51.9-54.8)	54.3 (52.4-56.3)
Body fat (%)	17.6 ± 3.5	18.9 ± 4.3

Values are median (IQR) except for normally distributed data listed as mean ± SD. Significance was set at $P < 0.05$.

Table 3. Multiple regression predictors of infant body composition at 1-month of age

	Stepwise regression sequence				ANOVA for final model				
	Predictor	*P*-value	R^2	AIC	Source	DF	Sum of Squares	Mean Square	F-ratio
Outcome:	**Infant body composition**				Model	3	126.29	42.1	3.06
	Group assignment*	0.24	0.04	217.62	Error	36	495.34	13.76	Prob > F
	MVPA 30-min bouts, weeks 24-26	0.04	0.15	215.53	C. Total	39	621.64		0.04
	Diet quality (HEI), weeks 24-26	0.07	0.22	214.58					

MVPA: Moderate-vigorous physical activity; HEI: Healthy eating index; AIC: Akaike information criterion.

CHAPTER 7: GENERAL CONCLUSIONS

The intrauterine environment and prenatal period have garnered much attention as an opportunity to influence the health of future generations. Maternal pre-pregnancy and gestational weight status are associated with short- and long-term maternal and fetal health outcomes, and both can be influenced by maternal lifestyle behaviors, including physical activity and dietary intake. With evidence from epidemiological studies supporting a continual increase in the percentage of women exceeding gestational weight gain recommendations, it is crucial to explore new mechanisms to encourage a healthy maternal lifestyle and thereby improve maternal weight status.

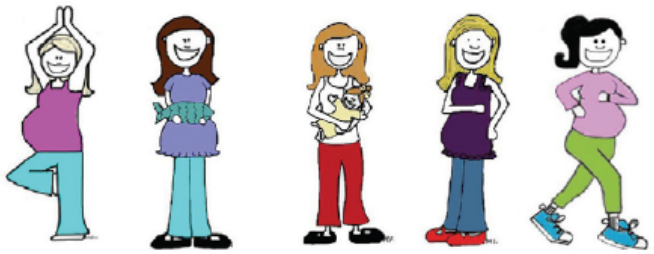
The previously presented project was focused on evaluating a potential tool to more accurately assess physical activity during pregnancy, and utilize a behaviorally-based website to increase maternal physical activity, promote adherence to gestational weight gain recommendations, and improve infant birth and anthropometric outcomes. The results of the project revealed the SenseWear® Mini Armband demonstrated good agreement with indirect calorimetry in its ability to predict energy expenditure during pregnancy. The randomized controlled trial, The Blossom Project Online, successfully increased self-reported intentional physical activity in previously sedentary pregnant women. Objective assessment of physical activity revealed significantly more moderate-vigorous physical activity was sustained in 20- and 30-minute bouts among the intervention participants compared to usual care. Similarly, when participants were categorized into tertiles of website engagement, highly-engaged website users completed significantly more sustained MVPA than their not-engaged counterparts.

No differences in GWG, adherence to GWG recommendations, or weight retention presented between groups. This may in part be due to the unintended significant increase in caloric consumption among intervention participants between baseline and week 24-26 of pregnancy. Birth outcome and anthropometric measurements at 1-month of age were not different between groups.

It is important to recognize that physical activity was facilitated by the intervention participants without any supervision from an exercise professional, group exercise class, or local gym. The behaviorally-based website provided several modules for women to utilize to encourage their participation in physical activity, but it was up to the individual to incorporate the activity into her weekly routine. Considering that physical activity typically declines during pregnancy and the population in this study included women that were all previously sedentary prior to becoming pregnant, the significant increase in PA observed as a result of the intervention is a considerable accomplishment. Given the benefits of prenatal physical activity, this should be a regular topic of discussion between clinicians and pregnant women without contraindications to exercise, with referral to registered dietitian nutritionists for additional diet counseling. Findings from this study provide a foundation for future work to explore if a behaviorally-based website could be incorporated into clinical obstetric care to increase the accountability of positive behavior change during pregnancy.

APPENDIX A. RECRUITMENT MATERIALS

ISU IRB # 1 11-286
Approved Date: 15 January 2013
Expiration Date: 18 July 2014



The Blossom Project

We are conducting a research study using an online website to promote physical activity in pregnant women.

QUALIFICATION CRITERIA INCLUDES:

- Must be pregnant (before week 15) and between the ages of 18-45
- Non-smoker
- Pregnant with only one baby
- No history of chronic disease (e.g. Type 1 diabetes, heart disease, renal disease, untreated thyroid condition)
- No condition or use of medication known to influence overall metabolism
- Low-active or sedentary lifestyle
- If asked, are willing to walk 30 minutes on most days of the week throughout your pregnancy
- Regular access to internet
- Able to communicate without language or mental status barriers
- Approval from your medical provider confirming you meet the qualification criteria will be required

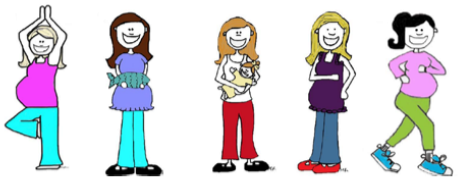
A maximum of 4 data collection periods required.
Eligible participants will be compensated. Participation is voluntary.

For further information:
Contact the Recruitment Team at blossomproject@iastate.edu or 515-294-8673

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

ISU IRB # 1 11-286
Approved Date: 15 January 2013
Expiration Date: 18 July 2014

Are you or is someone you know PREGNANT?



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IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

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PREGNANT WOMEN NEEDED!

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- No history of chronic disease
  (e.g. Type 1 diabetes, heart disease, renal disease, untreated thyroid condition)
- No condition or use of medication known to influence overall metabolism
- Low-active or sedentary lifestyle
- If asked, are willing to walk 30 minutes on most days of the week throughout your pregnancy
- Regular access to internet
- Able to communicate without language or mental status barriers
- Approval from your medical provider confirming you meet the qualification criteria will be required

A maximum of 4 data collection periods required.

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For further information:
Contact the Recruitment Team at blossomproject@iastate.edu or 515-294-8673

ISU IRB # 1 11-286
Approved Date: 15 January 2013
Expiration Date: 18 July 2014

The Blossom Project Online Recruiting Email

Thank you for your reply! You do indeed qualify for a study that we are currently conducting.

Here is more information about this study:

The purpose of this study is to evaluate the effect of an innovative, online website to promote physical activity and prevent excess weight gain in pregnant women. You will be randomized to one of two groups at the beginning of your participation in this study and you will be given access to an online website entitled: Blossom Online. Individuals in the first group will have access to helpful tips about healthy eating and lifestyle habits during pregnancy. The other group will use the website to record daily physical activity, create weekly goals regarding physical activity, be expected to meet current prenatal physical activity guidelines, and interact with other participants using a password-protected website. Individuals in both groups will fill out various questionnaires related to your medical history and/or pregnancy. At any time you are invited to discuss concerns that you have about the study protocol; however, the project staff will not make any physical activity recommendations beyond those provided on the website.

You will visit the research center at ISU for 4 data collection periods at weeks 10-14, 24-26, and 34-36 of your pregnancy; as well as 1-month postpartum.

During the first three data collection periods the following measurements will be taken or collected:

- Weight,
- Physical activity assessment via 2 activity monitors worn on your arm and thigh for 8-days,
- Dietary assessment by recording the food and beverage that you consume for 3-days,
- Body composition, and
- Various questionnaires regarding social support and your attitude, beliefs, and barriers regarding physical activity
- Between weeks 24-26 you will complete a 1-hour oral glucose tolerance test at our research facility

Additionally, the following data will be collected to assess birth outcomes:

- APGAR scores
- Birth weight
- Birth length
- Head circumference
- Gestational length at delivery
- Gender

At one-month postpartum the following data will be collected:

- Maternal weight

- Maternal body composition
- Questionnaires regarding physical activity and the intervention
- Length, weight, and body composition of the infant

To qualify for our study you must be:

- Pregnant (prior to 15th week of pregnancy);
- Between the ages of 18-45 years old
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of chronic disease (e.g. Type 1 diabetes, heart disease, renal disease, untreated thyroid condition);
- No condition or use of medication known to influence overall metabolism;
- Low-active or sedentary lifestyle;
- If asked, are willing to walk 30 minutes on most days of the week throughout your pregnancy;
- Regular access to internet; and
- Able to communicate without language or mental status barriers

For your participation, you will receive $200 following completion of the one-month follow-up visit and return of all equipment. An additional $15 for each of the first three data collection periods can be earned if the activity monitors are not off of the body for more than 90 minutes per day. Therefore, a maximum total of $245 compensation is possible.

I am attaching the consent form which provides more detailed information. I'll be happy to answer any more questions that you may have.

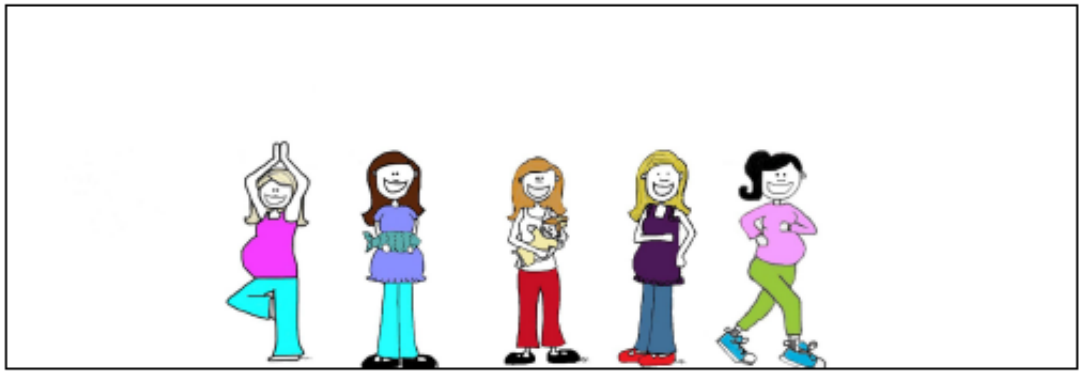
Please email me at katiel@iastate.edu if you have further questions. **Also, let me know whether you are or are not interested in participating. If you are interested, please provide me with your availability for a 30-45 minute appointment in the next [*time period to be specified depending upon what is applicable to the specific participant's current gestational length]*.**

I look forward to hearing from you soon!

Thanks!

Katie Smith
Blossom Project Online Study Coordinator
Iowa State University
515-294-8673
katiel@iastate.edu
blossomproject@iastate.edu

APPENDIX B. THE BLOSSOM PROJECT ONLINE STUDY TIMELINE



The Blossom Project Online

Weeks 6-14

- Recruit
- participants

Weeks 10-14

- Sign consent forms
- Medical history questionnaire
- Height, weight & body composition measured
- Armband activity monitor
- activPAL
- 8-day physical activity record
- 3-day diet record
- Questionnaires to assess physical activity, self-efficacy, and social support

Weeks 24-26

- Weight & body composition measured
- Armband activity monitor
- activPAL
- 8-day physical activity record
- 3-day diet record
- Oral glucose tolerance test
- Questionnaires to assess physical activity, self-efficacy, and social support

Weeks 34-36

- Weight & body composition measured
- Armband activity monitor
- activPAL
- 8-day physical activity record
- 3-day diet record
- Questionnaires to assess physical activity, self-efficacy, and social support

1-month post-partum

Birth Outcomes:

- Gender
- APGAR scores
- Birth weight
- Birth length
- Head circumference
- Gestational length at delivery

- Maternal weight
- Maternal body composition
- Questionnaires to assess physical activity, self-efficacy, social support, and evaluation of the intervention
- Infant length
- Infant weight
- Infant body composition

APPENDIX C. CONSENT FORM

ISU IRB # 1	11-286
Approved Date:	18 April 2013
Expiration Date:	18 July 2014

CONSENT FORM FOR:
THE BLOSSOM PROJECT ONLINE

This form describes a research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Who is conducting this study?

Christina Gayer Campbell, PhD, RD
Associate Professor, Nutrition
Department of Food Science and Nutrition
Mailing Address: 220 MacKay Hall
Physical Address: 1105 Human Nutrition Science Building
Iowa State University
Ames, IA 50011-1123

515-294-4260; ccampbel@iastate.edu.

What is the purpose of this study?
The purpose of this study is to evaluate the effect of an innovative, online website to promote physical activity and prevent excess weight gain in pregnant women. The physical activity intervention consists of 30 minutes of walking time per day on most days of the week.

Why am I invited to participate in this study?
You are being asked to take part in this study because you are a healthy woman living in the communities in and around Ames, IA who has shown interest in our study by responding to our recruiting efforts. You have been selected to participate based on several criteria including:

- Between 18-45 years of age;
- Pregnant prior to 15 weeks gestation;
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of gestational diabetes mellitus, pre-eclampsia, or chronic disease (e.g. Type 1 diabetes, heart disease, renal disease, untreated thyroid condition);
- No condition or use of medication known to influence overall metabolism;
- Low-active or sedentary lifestyle;
- If asked, are willing to walk 30 minutes on most days of the week throughout your pregnancy;
- Regular access to the internet;
- Not underweight prior to pregnancy (BMI < 18.5 kg/m^2)
- Able to communicate without language or mental status barriers.

What will I be asked to do?
If you agree to participate, you will be asked to do the following:

You will be required to receive confirmation from your medical provider that you are healthy enough to participate in this study. At your first visit, you will need to provide contact information (including name and phone number) for your medical provider. The attached consent letter will be sent by the principal investigator to your medical provider and returned via fax to a member of the project staff. This form will request your weight at your first prenatal appointment. After the delivery of your baby, a similar form will be sent to your medical provider to obtain your weight at the last prenatal appointment.

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Throughout your pregnancy

At the beginning of your participation in this study, you will be randomized to one of two groups; both groups will be given access to an online website entitled: Blossom Online. Individuals in Group 1 will have access to helpful tips about healthy eating and lifestyle habits during pregnancy, Group 2 will use an interactive portion of the website to record daily physical activity, create weekly goals regarding physical activity, and interact with other participants using a password-protected website. You will need to fill out various questionnaires related to your medical history and/or pregnancy. At any time, you are invited to discuss concerns that you have about the study protocol; however, the project staff will not make any physical activity recommendations beyond those provided on the website. If you are diagnosed with multiple fetuses, or miscarry after enrolling in the study, you will no longer be able to participate in the study.

At weeks 10-14, 24-26 & 34-36 of your pregnancy

Regardless of group assignment, your participation in this study may last up to 10 months (e.g. 10th week of pregnancy to 1 month post-partum). There will be 4 data collection periods and 2 visits required at each of the first 3 periods: 1) data initiation (described below) and 2) return of equipment. For each data collection period, you will be asked to meet with a member of the project staff at the Nutrition and Wellness Research Center (2325 N. Loop Drive #6146, Ames, Iowa) or the facility located on campus in the Human Nutritional Sciences Building (HNSB) rooms 2021, 2022, and 2023. For your convenience, please provide us with a contact number to facilitate scheduling. You will be asked to schedule approximately a 60 minute meeting to complete enrollment paperwork and receive instructions regarding the physical activity and diet data collection.

During the visit you will be given two activity monitors and the equipment needed to collect an 8-day physical activity record and a 3-day diet record. Your height and weight will be measured, body composition will be assessed, and you will be asked to complete questionnaires regarding self-efficacy and social support.

You will be provided with a **SenseWear® Mini physical activity armband** that is worn on the upper left arm over the triceps muscle. The activity monitors will be worn for 8 days, 24 hours a day to ensure the best possible data collection. The monitor is not water resistant and needs to be removed when showering and swimming. This activity monitor has been used in many studies at ISU with minimal complaints.

You will be provided with an **activPAL activity monitor** that is worn on the upper leg over the quadriceps muscle. The activPAL will be worn for 8 days, 24 hours a day, except when showering or swimming. This monitor is not waterproof so it should also be removed during water submersion. It will be attached to your leg using an adhesive pad.

The 8-day **physical activity record** requires you to record all of your daily activities into a log that will be provided for the same 8 consecutive days you wear the 2 activity monitors.

The **3-day food record** (3dDR) requires you to weigh and record all food and beverages consumed for 2 weekdays and 1 weekend day. You will be given detailed instructions on how to properly complete the forms and tips on accurately weighing food. You will be provided with a dietary scale, at no cost to you, for use during the study to facilitate the process. You may perceive this to be a tedious process; however it is the most accurate means of collecting dietary intake information. You will not be given a diet to follow; observations are made on what you typically choose to eat.

Your **body composition** (percent body fat) will also be measured using Bioelectrical Impedance Analysis (BIA). Four electrodes will be placed on you (foot, ankle, wrist, and finger) to measure the resistance to the current flow in your body. This is a very safe method and you will not feel anything throughout this process.

Your attitude, beliefs, and barriers regarding participation in physical activity during pregnancy will be measured using self-administered **self-efficacy questionnaires**. In a similar manner, you will complete questionnaires to assess your perceptions of social support.

You will need to arrange a time with a member of the project staff to turn in your data collection bag and all materials (all monitors, 3dDR, scale, etc.) at the end of the data collection period.

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Oral Glucose Tolerance Test: During weeks 24-26, your data collection will also include completion of an oral glucose tolerance test to assess insulin resistance. It is important that we conduct our own glucose tolerance test to collect consistent and reliable data since this protocol varies between clinics. The oral glucose tolerance test will consist of providing a fasted blood sample (following an overnight fast of 10-12 hours), consuming a 75g oral glucose solution and a blood sample at 60 minutes following consumption of the glucose solution. During this 1-hour period you will be asked to remain seated at the research facility. The blood draw will be conducted by a well-trained phlebotomist. Consenting to this study allows the investigators to use blood samples for further analysis of glucose and lipid metabolism.

Group 1: "Blossom Tips": If you are given access to this aspect of the website, you will be asked to continue your normal daily activity throughout your pregnancy.

Group 2: "Blossom Journal and Blossom Community" (Interactive portion of the website)
If you are given access to the interactive website, your participation will begin no later than week 15 and is expected to last until you deliver, provided no complications during your pregnancy occur. Participants in this group will be asked to walk 30 minutes per day on most, if not all, days of the week, as recommended by the American College of Obstetrics and Gynecologists, for a total of at least 150 minutes per week. The first three weeks of the program will allow for a gradual increase in walking time. The amount of walking will be increased by 10 minutes/day (week 15), followed by 20 minutes/day (week 16) and 30 minutes/day (week 17). By week 18, you should be at your walking goal, which is 30 minutes per day on most, if not all, days of the week.

You will have access to an online personal calendar through the website (available in the "Blossom Journal") to record the amount of exercise and how often you exercise. You will be asked to **use this calendar daily and set goals** as part of your physical activity assessment. This will be monitored by the study coordinator to document adherence to the walking program. Data collected within the website may be analyzed as part of the study. You will be provided a heart rate monitor to use during your pregnancy to monitor your heart rate during your exercise sessions. You will be provided with validated target heart rate zones published for use during pregnancy.

Birth outcome data
We will be collecting birth outcome data including gender, APGAR scores, birth weight, birth length, head circumference, and gestational length at delivery. This information will be obtained from the official medical record at your delivering hospital. You will be asked to fill out a Release of Medical Record form to allow us to contact the hospital and obtain this information after you have delivered. You will need to notify the Blossom Project research team of your delivery. Consent to participate in this study allows the investigators to contact you following your due date if we have not heard from you.

If you deliver at Mary Greeley Medical Center, Mercy Hospital in Des Moines, Methodist Hospital in Des Moines, or other hospitals in the area with similar medical release protocols: The research team will provide you with a medical release form and self-addressed stamped envelope at your week 34-36 appointment. You will return the completed form to the Blossom Project as soon as possible **AFTER** your delivery using the provided envelope. These hospitals require a medical release form be completed after you deliver because your child's information (name, date of birth) is required. Following these procedures fulfills your responsibility to notify the research team. If you are not comfortable with providing the researchers access to obtain this information on their own, you may retrieve a copy of the medical record yourself containing the requested information and provide it to the research team. After this information is obtained, your compensation form will be submitted to the accounting offices.

At 1-month post-partum
You will return to the research facility (Nutrition and Wellness Research Center in ISU Research Park) with your baby for a follow-up visit. At this visit your weight will be measured and body composition will be measured using BIA. You will be asked to fill out questionnaires regarding self-efficacy, social support, recommendations received from your medical provider regarding physical activity and weight gain, and your reactions to the website used in the current study. Your baby will also be weighed and his/her length and body

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composition will be measured. The infant's body composition will be assessed via air displacement plethysmography. This is a safe, non-invasive method called the PEA POD. Your baby will be placed in a temperature-controlled test chamber with a continuous outside air source for a brief amount of time (approximately one minute or less) while the measurement is taking place. This method has previously been used for infants in another study in our laboratory.

What are the possible risks and benefits of my participation?
Risks –There are no foreseeable risks to either you or your fetus by participating in this study. The armband used in this study has been used in other studies within our laboratory with minimal complaints. A few participants have noted a minor skin irritation but it has receded within a couple of days following discontinued use of the monitor. The activPAL is also currently being used in other studies in our laboratory with minimal complaints. You may experience discomfort from fasting overnight prior to the blood draw and momentary pain may occur during the blood draw. An experienced phlebotomist will conduct all blood draws under strict sanitary conditions to minimize pain and risk of infection.

Benefits – You may not receive any direct benefit from taking part in this study. If assigned to the interactive website, you may be encouraged to participate in more physical activity during your pregnancy. We hope that this research will benefit society by generating data that may contribute to further understanding the health benefits of physical activity during pregnancy.

How will the information I provide be used?
The findings of this study will be shared throughout the scientific community via oral and poster presentations at scientific meetings, and published research articles.

Will I incur any costs from participating or will I be compensated?
There are no direct costs involved with participating in this study, except your cost of transportation to and from the research facility (e.g. gas money, bus fare). You will be compensated for participating in this study. Upon return of all equipment, the proper communication notifying the research team that the baby was born, and completion of all data collection periods (wks 10-14, 24-26, 34-36, and 1-month follow-up), you will receive $200. An additional $15 for each of the first three data collection periods can be earned if the activity monitors are not off of the body for more than 90 minutes per day. Therefore, a maximum total of $245 compensation is possible. If you happen to deliver prior to the week 34-36 data collection period you will be compensated $50 ($65 if good monitor wear time) for each period completed. You will need to complete a form at your one-month post-partum visit to receive payment. This form will ask for your social-security number. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payment you receive. If, for any reason, a participant is unable to finish all data collection periods, she will be given the gifts appropriate for the monitoring periods that were completed.

What measures will be taken to ensure the confidentiality of the data or to protect my privacy?
Records identifying participants will be kept confidential to the extent allowed by applicable laws and regulations. Records will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the ISU Institutional Review Board (a committee that reviews and approves research studies with human subjects) may inspect and/or copy your records for quality assurance and analysis. These records may contain private information.

To ensure confidentiality to the extent allowed by law, the following measures will be taken: subjects will be assigned a unique code and letter that will be used on forms instead of their name. If the results are published, your identity will remain confidential. The data obtained from the study will be regarded as privileged and confidential. Your privacy will be maintained in any future analysis and/or presentation of the data with the use of coded identifications for each participant's data. All data will be stored in a locked file cabinet with access only by the principal investigator and project staff. Additionally, any data entered into the computer will be available with restricted password only. This data will be kept on hand until the results of the study have been published in a locked file in the PI's laboratory (HNSB 1109). Identifiers will be kept separate from the data.

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What are my rights as a human research participant?
Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. Your choice of whether or not to participate will have no impact on you as a student/employee in any way. You may skip any question during a questionnaire (e.g. medical history, physical activity or self-efficacy questionnaires). You may withdraw consent in person or by phone with the principal investigator, Christina Campbell at any time. Please feel free to ask any questions or express your concerns regarding this study. The investigator will attempt to answer all questions. Contact Dr. Christina Campbell at 515-294-4260. If by chance any aspect of the data (e.g. physical activity monitors, diet record, online calendar) are returned with compliance (e.g. wear time) deemed insufficient to the primary investigator, participation in the study may be terminated.

What if I am injured as a result of participating in this study?
Emergency treatment of any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity.

Whom can I call if I have questions or problems?
You are encouraged to ask questions at any time during this study.

- For further information about the study contact the principal investigator Christina Campbell at 515-294-4260.
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

Consent and Authorization Provisions

Your signature indicates that you voluntarily agree to participate in this study and allow your child to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your participation in the study.

Participant's Name (printed) _____

_____ _____
(Participant's Signature) (Date)

Investigator Statement

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

_____ _____
(Signature of Person Obtaining Consent) (Date)

APPENDIX D. MEDICAL HISTORY FORM

Medical History Questionnaire – Blossom Online

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

Subject ID: _____

Age: _____yrs_____mo Date of Birth:_____

Usual Pre-pregnancy weight:_____lbs Height:_____ft_____in

Have you experienced considerable weight gain/loss (5 lbs or more) in the past 6 months prior to pregnancy? Yes No If yes, please explain:

_____

_____

Handedness: Right OR Left

Is this your first pregnancy? Yes No

If no, number of pregnancies (including this one)_____

Number of live births_____

If number of pregnancies and number of live births are not equal to each other, please explain:

_____

Birth dates of children _____
mo/day/yr mo/day/yr mo/day/yr mo/day/yr mo/day/yr

Are you planning to breastfeed? Yes No Not sure

First day of last menstrual period:_____ Due Date:_____

What is your current due date based on? LNMP Ultrasound Other:_____

What is the first day of your next week of pregnancy (i.e. turnover day)? (circle)

Sunday Monday Tuesday Wednesday Thursday Friday Saturday

In what week of your pregnancy did you find out you were pregnant?_____

Prior to your pregnancy what was your average number of workouts per week?_____

Average duration of workout_____

Type of activity_____

Since you became pregnant what has been your average number of workouts per week?_____

Average duration of workout_____

Type of activity_____

Have you experienced any morning sickness that altered your activity level? Yes No

If yes, please describe_____

Are you following any guidelines regarding exercise during your pregnancy?_____

If yes, please describe_____
If yes, where did you receive the guidelines?_____

Has your medical provider discussed exercise during pregnancy with you? Yes No
If yes, please describe his/her recommendations: _____
_____

Has your medical provider discussed weight gain during pregnancy with you? Yes No
If yes, please describe his/her recommendations: _____
_____

Race (circle):
1. American Indian or Alaska Native
2. African American
3. Caucasian
4. Asian
5. Hispanic
6. Other (specify):_____

Marital Status (circle):
1. single
2. married
3. divorced/separated
4. widowed

Education Level
What is the highest degree in school that you received? Please circle:
1. GED
2. High School Diploma
3. Associate's Degree
4. Bachelor's Degree
5. Graduate or Professional Degree
6. Other (if none, please specify): _____

Employment:
What is your occupation?_____
If employed how many hours a week do you work?_____

How many adults, age 18 years and older, live in your household? Please include yourself. _____

How many children, age 17 years and younger, live in your household? _____

What was your total household income in the past year?

1. None	4. $20,001-$30,000	7. $50,001-$75,000
2. $1-$10,000	5. $30,001-$40,000	8. $75,001 or more
3. $10,001-$20,000	6. $40,001-$50,000	

Drug and Alcohol:

1. Do you currently take vitamin supplements on a regular basis? Yes No
   If yes, please specify_____
   Have you in the past? Yes No
   If yes, how long ago?_____
2. Do you currently take herbal supplements on a regular basis? Yes No
   If yes, please specify_____
   Have you in the past? Yes No
   If so, how long ago?_____
3. Do you currently take any medications on a regular basis? Yes No
   If yes, please specify_____
4. Have you taken medication regularly in the past? Yes No
   If yes, please specify_____
   How long ago was medication taken regularly?_____
5. During your pregnancy are you consuming alcohol? Yes No
   If yes, how many drinks each week?_____

Medical History (circle any, and give age at diagnosis):

	Age
1. Diabetes	____
2. Thyroid Disease	____
3. Cirrhosis	____
4. Hepatitis	____
5. Gall Stones	____
6. Kidney Stones	____
7. Nephritis	____
8. Cancer (specify)	____
9. High Blood Pressure	____
10. Angina	____
11. Allergies (specify)	____
12. Goiter	____
13. Cardiovascular Disease	____
14. Depression requiring medication	____
15. Insomnia requiring medication	____
16. Gestational Diabetes	____
17. Preeclampsia	____
18. Previous infant with low birth weight	____
19. Early delivery with previous pregnancy	____

If so, please explain: _____
_____

APPENDIX E. MEDICAL PROVIDER RELEASE FORM

ISU IRB # 1	11-286
Approved Date:	18 April 2013
Expiration Date:	18 July 2014

Online intervention to promote physical activity in pregnant women

Dear Medical Provider,

_____ has volunteered to participate in a research study using an online website to promote physical activity in pregnant women. If assigned to the treatment group, your patient will be asked to walk at least 150 minutes a week per the American College of Obstetrics and Gynecology. Participants in the control group will receive information regarding healthy eating and physical activity but are not expected to achieve any minimum recommendations. All participants will complete four data collection periods. At weeks 10-14, 24-26 and 34-36 of her pregnancy, your patient will wear a SenseWear® Mini physical activity armband and an accelerometer-based posture monitor known as the activPAL, and complete an 8-day physical activity record and a 3-day food record. She will also complete questionnaires to assess barrier & task self-efficacy and social support during the current trimester of pregnancy. Each participant will also be weighed at each time period and have her body composition assessed via Bioelectrical Impedance Analysis (BIA). Between weeks 24-26 of pregnancy, she will undergo a 1-hour, 75-gram oral glucose tolerance test to assess insulin sensitivity. At one-month post-partum, your patient will return to our research facility to have her weight and body composition measured and repeat the social support and self-efficacy questionnaires. Her child's weight, length, and body composition will be measured at this time. This study is approved by the Iowa State University Institutional Review Board.

We would like you to confirm that _____ meets the study criteria:

- Between the ages of 18-45;
- Pregnant with only one baby;
- Non-smoker;
- No history of gestational diabetes mellitus, pre-eclampsia, or chronic disease (e.g. Type 1 diabetes, heart disease, renal disease, untreated thyroid condition);
- No condition or use of medication known to influence overall metabolism;
- No physical restrictions to achieve current physical activity recommendations by walking; and
- Able to communicate without language or mental status barriers

Weight of patient at first prenatal appointment: _____**Date of appointment**: _____

Signature of Medical Provider_____

Print Name_____ Date_____

Please return this form via facsimile as soon as possible. Thank you for your help with this project.

Sincerely,
Christina Campbell, PhD, RD; Associate Professor, Nutrition; Iowa State University
Email: ccampbel@iastate.edu; Phone: 515-294-4260; Fax: 515-294-6193

Signature of research participant providing permission to contact physician & to receive her weight:

Signature:_____ Date: _____

APPENDIX F. ACTIVITY MONITOR AND PHYSICAL ACTIVITY RECORD INSTRUCTIONS

Directions for Activity Monitors

- The SenseWear® armband activity monitor should be placed on the back side (over your triceps muscle) of your **left arm** between the elbow and shoulder. Adjust the strap so if fits your arm comfortably. Ensure it is contact with your skin at all times and that the monitor is right side up on your arm (the words should not be upside down when viewed in a mirror).
    - There is no on/off button for the activity monitor. It will be collecting data when it is in direct contact with your skin.
    - When the monitor is correctly placed on your arm it will sound off "dee dee dee, dee dee".
    - If the monitor loses contact with your skin or becomes misplaced from the proper contact site it will sound off "dee dee dee." Readjust the monitor and listen for the "dee dee dee, dee dee" sound to ensure proper placement.
- The activPAL activity monitor should be placed on top center of the **right thigh** approximately 1/3 distance down from the hip bone to the top of the knee cap.
    - The head of the person on the front of the monitor should be right side up.
- Please record each activity as you do it in the physical activity log for 8 days
    - Enter the start and stop time for each activity
    - Include ALL activities throughout your day (showering, eating, driving, sitting at computer, watching tv, cooking dinner, walking to work, etc.)
- After 8 days have passed please be sure to make arrangements with a research investigator to return your materials.

The armband and activPAL are NOT waterproof! Please do not wear them while showering or swimming or submerge it in other liquid. Thank you.

****If you develop a skin irritation during the 8-day period, immediately contact a research investigator.**

Christina Campbell at 515-520-2326 OR Katie Smith at katiel@iastate.edu

For Official Use Only
Subject ID:

Physical Activity Log

Date___September 24 , 2011_____

Start Time	End Time	Activity	Description
7am	7:30am	Getting dressed/showering	Up and down stairs 2 to 4 times
7:30	8:00	Making and Eating Breakfast	
8:00	8:25	Drive to work	
8:25	8:30	Walk from car	Quick walk from parking lot up stairs, one flight, to office
8:30	12:00pm	Working	Mostly sitting at desk or computer
12:00	1:00	Eating Lunch	Ate lunch and read a magazine
1:00	5:00	Working	Mostly sitting at desk or computer
5:00	5:05	Walk to car	Walk to car in parking lot, down one flight of stairs
5:05	5:45	Errands	Walking around stores, and driving
5:45	6:30	Swimming	Lap swim mostly freestyle and backstroke about 1000 yards
6:30	7:30	Making and eating dinner	Standing in kitchen, sitting at table
7:30	8:00	Walking the dog	Stroll around block mostly flat

For Official Use Only
Subject ID:

Physical Activity Log

Date_____

Start Time	End Time	Activity	Description

APPENDIX G. THREE-DAY DIET RECORD INSTRUCTIONS

Directions for 3-Day Weighed Diet Record

- Please use the scale provided to weigh all food that you eat during your 3 day recording period.
- Keep your food record current. List all foods and supplements immediately after they are weighed. Do not wait until the end of the day to record entries.
- Please print all entries.
- Be as specific as possible when describing the food or beverage:
  - Include the method of preparation used (boiled, baked, broiled, fried, grilled, steamed, raw, etc); *example: pork chop, center cut, no bone, grilled*
  - Include a well detailed description of the food item (fresh, canned, packed in heavy or light syrup, packed in water or oil, skinless, boneless, cut of meat, brand name); *examples: peaches in heavy syrup, tuna in oil, broiled T-bone steak, microwave heated canned corn*
  - Include label with the nutritional information for any unusual items or if unsure how to record
- Categorize the food consumed by meal type. Indicate "B" for breakfast, "L" for lunch, "D" for dinner, or "S" for snack.
- Include the name of restaurant if eating out
- Report only the portion of food that was actually eaten*; example: T-bone steak, grilled -100g (do not include the weight of the bone)*

Example: 100g t-bone- 30 g bone=70g actual food consumed
1- 500 mg multivitamin

- Weigh food left on plate that you did not eat and subtract from original total
- Record amount in either grams or ounces (wt) –please be consistent
- Remember to record condiments (ketchup, soy sauce, mustard, ranch dressing, salt, etc) as well as any fats used in cooking (oils, butter, margarine, etc), it is acceptable to measure these (Tbsp, tsp etc)
- Please try not to alter your normal diet during the period that you keep this record …… **Thank you!!!!!!**
- If there are any questions please email:
  blossomproject@iastate.edu

For Official Use Only
Subject ID:

Date: Wednesday, March 21, 2007

B/L/D/S	Time	Food	Constituents	Description	Weight
B	9 am	Daily Supplements:	Multivitamin	One a Day multivitamin	1-500 mg capsule
B	9am	Grape Nuts		Post Brand	120g
B	9am	Sugar		White	3g
B	9am	Milk		1%	106g
S	9am	Blueberries		Frozen, unsweetened	50g
S	9am	Orange Juice		Tropicana, no pulp, calcium added	120g
S	11:30 am	Almonds		Raw, unsalted, Kirkland brand	60g
L	1:00pm	Sandwich	Bread	Whole Wheat, Wheat Montana	45g
L	1pm		Sprouts	alfalfa	5g
L	1pm		Cheese	Tillamook Sharp Cheddar	33g
L	1pm		Ham	Hillshire Farms Honey Ham	15g
S	1pm	Cottage Cheese		Low fat 2% small curd	55g
S	1pm	Apple Juice		From concentrate, Apple Tree brand, 100% juice	

For Official Use Only
Subject ID:

Date:_______:

B/L/D/S	Time	Food	Constituents	Description	Weight

APPENDIX H. SELF-EFFICACY QUESTIONNAIRES

HOW CONFIDENT ARE YOU THAT YOU WILL BE PHYSICALLY ACTIVE?

1. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **1 day per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

2. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **2 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

3. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **3 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

4. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **4 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

5. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **5 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

6. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **6 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

7. I feel confident that I will walk (for at least 30 minutes at my preferred pace) **7 days per week**

10% ▫▫▫ 20% ▫▫▫ 30% ▫▫▫ 40% ▫▫▫ 50% ▫▫▫ 60% ▫▫▫ 70% ▫▫▫ 80% ▫▫▫ 90% ▫▫▫ 100%

TOTAL SELF-EFFICACY SCORE:

Item 1 + Item 2 + Item 3 + Item 4 + Item 5 + Item 6 + Item 7 = Total Walking Self-Efficacy

▢ ▢ ▢ ▢ ▢ ▢ ▢ = ▢

Appendix C.6 – Barrier Self-efficacy Questionnaire

INSTURCTIONS. Barriers are defined as anything that may stop you from doing physical activity. Please list four barriers to physical activity relevant to you, which you anticipate will occur **in the next 6 WEEKS**. An example is provided.

EXAMPLE:

Barrier: Lack of sleep

How confident you are in overcoming this barrier in the next 6 WEEKS? Please check one:

☐ ☐ ☐ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

not at all confident — **somewhat confident** — **completely confident**

BARRIER #1: _____

How confident are you in overcoming this barrier in the next 6 WEEKS? Please check one:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

not at all confident — **somewhat confident** — **completely confident**

BARRIER #2: _____

How confident are you in overcoming this barrier in the next 6 WEEKS? Please check one:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

not at all confident — **somewhat confident** — **completely confident**

BARRIER #3: _____

How confident are you in overcoming this barrier in the next 6 WEEKS? Please check one:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

not at all confident — **somewhat confident** — **completely confident**

BARRIER #4: _____

How confident are you in overcoming this barrier in the next 6 WEEKS? Please check one:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

not at all confident — **somewhat confident** — **completely confident**

APPENDIX I. SOCIAL SUPPORT QUESTIONNAIRES

SOCIAL SUPPORT AND EATING HABITS SURVEY

Below is a list of things people might do or say to someone who is trying to improve their eating habits. We are interested in high fat and high salt (or high sodium) foods. If you are not trying to make any of these dietary changes, then some of the questions may not apply to you, but please read and give an answer to every question.

Please rate each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

SAMPLE:

	Family	Friends
A. If my family *rarely makes fun of the foods I eat, and my friends very often* do, I would answer like this:		
A. Made fun of the foods I eat	A. 2	A. 5

---

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	8

During the past three months, my family (or members of my household) or friends:

	Family	Friends
1. Encouraged me not to eat "unhealthy foods" (cake, salted chips) when I'm tempted to do so.	1.	1.
2. Discussed my eating habit. changes with me (asked me how I'm doing with my eating changes).	2.	2.
3. Reminded me not to eat high fat, high salt foods.	3.	3.
4. Complimented me on changing my eating habits ("Keep it up", "We are proud of you") .	4.	4.
5. Commented if I went back to my old eating habits.	5.	5.
6. Ate high fat or high salt foods in front of me.	6.	6.
7. Refused to eat the same foods I eat.	7.	7.
8. Brought home foods I'm trying not to eat.	8.	8.
9. Got angry when I encouraged them to eat low salt, low fat foods.	9.	9.
10. Offered me food I'm trying not to eat.	10.	10.

SOCIAL SUPPORT AND EXERCISE SURVEY

Below is a list of things people might do or say to someone who is trying to exercise regularly. If you are not trying to exercise, then some of the questions may not apply to you, but please read and give an answer to every question.

Please rate each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	8

During the past three months, my family (or members of my household) or friends:

		Family	Friends
11.	Exercised with me.	11.	11.
12.	Offered to exercise with me.	12.	12.
13.	Gave me helpful reminders to exercise ("Are you going to exercise tonight?").	13.	13.
14.	Gave me encouragement. to stick with my exercise program.	14.	14.
15.	Changed their schedule so we could exercise together.	15.	15.
16.	Discussed exercise with me.	16.	16.
17.	Complained about the time I spend exercising.	17.	17.
18.	Criticized me or made fun of me for exercising.	18.	18.
19.	Gave me rewards for exercising (bought me something or gave me something I like).	19.	19.
20.	Planned for exercise on recreational outings.	20.	20.
21.	Helped plan activities around my exercise.	21.	21.
22.	Asked me for ideas on how *they* can get more exercise.	22.	22.
23.	Talked about how much they like to exercise.	23.	23.

Office Use Only

☐1. English ☐ 2. Spanish Date: Entered ☐☐/☐☐/☐☐ Coder: ☐☐

September 26, 1986

APPENDIX J. USUAL CARE POSTPARTUM QUESTIONNAIRE

Postpartum Questionnaire – Group 1

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

PARTICIPANT INFORMATION

Subject ID: _____ Date (today):_____

Date of infant delivery: _____ Your due date was: _____

Are you currently breastfeeding? Yes No

If yes, what percentage of the feeding is breastmilk: _____% vs formula:_____%

If yes, for how long do you continue to breastfeed? _____

If no, did you breastfeed initially? Yes No

If yes, please list for how long you breastfed:_____

Please indicate what caused you to stop breastfeeding: _____

_____

RECOMMENDATIONS DURING PREGNANCY

During your pregnancy, did your medical provider ever discuss exercise or physical activity with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

_____

During your pregnancy, did your medical provider ever discuss weight gain during pregnancy with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

Has your medical provider discussed postpartum weight loss with you? Yes No

If yes, please describe_____

_____

Do you wish you would have received any additional information on any of these or other topics from your medical provider? Yes No

If yes, please describe_____

_____

_____

BLOSSOM ONLINE WEBSITE

Did you find the information regarding physical activity during pregnancy on the Blossom Online website helpful? Yes No

Did you find the information regarding nutrition during pregnancy on the Blossom Online website helpful? Yes No

If you answered "No" to either of the previous two questions, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

What additional topics would you have liked posted on this website?

_____

_____

MISCELLANEOUS

Would you be interested (either in future pregnancies or past pregnancies had it been available) in receiving prenatal counseling that involved individualized diet and physical activity recommendations? Yes No

If yes, in what form would you prefer this counseling to take place (please circle):

1. Online website
2. Face-to-face meeting
3. Email
4. Telephone
5. Other: _____

APPENDIX K. BEHAVIORAL INTERVENTION POSTPARTUM QUESTIONNAIRE

Postpartum Questionnaire – Group 2

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

PARTICIPANT INFORMATION

Subject ID: _____ Date (today):_____

Date of infant delivery: _____ Your due date was: _____

Are you currently breastfeeding? Yes No

If yes, what percentage of the feeding is breastmilk: _____% vs formula:_____%

If yes, for how long do you continue to breastfeed? _____

If no, did you breastfeed initially? Yes No

If yes, please list for how long you breastfed:_____

Please indicate what caused you to stop breastfeeding: _____

_____

RECOMMENDATIONS DURING PREGNANCY

During your pregnancy, did your medical provider ever discuss exercise or physical activity with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

_____

During your pregnancy, did your medical provider ever discuss weight gain during pregnancy with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

Has your medical provider discussed postpartum weight loss with you? Yes No

If yes, please describe_____

_____

Do you wish you would have received any additional information on any of these or other topics from your medical provider? Yes No

If yes, please describe_____

_____

_____

BLOSSOM ONLINE WEBSITE

Did you find the information regarding physical activity during pregnancy on the Blossom Online website helpful? Yes No

Did you find the information regarding nutrition during pregnancy on the Blossom Online website helpful? Yes No

If you answered "No" to either of the previous two questions, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

What additional topics would you have liked posted on this website?

_____

_____

Did you find the features of the interactive website to be helpful in increasing your physical activity during pregnancy? Yes No

If no, why not? _____

_____

What features of the website were most helpful? Please circle all that apply.

1. Blossom Tips (Information on physical activity during pregnancy)
2. Blossom Journal (journaling)
3. Blossom Community (interacting with other participants)
4. Goal Setting
5. Self-regulation (tracking of physical activity on the calendar)
6. Activity Resources
7. Other: _____

What aspects of the website could be improved? _____

_____

_____

MISCELLANEOUS

Would you be interested (either in future pregnancies or past pregnancies had it been available) in receiving prenatal counseling that involved individualized diet and physical activity recommendations? Yes No

If yes, in what form would you prefer this counseling to take place (please circle):

1. Online website
2. Face-to-face meeting
3. Email
4. Telephone
5. Other: _____

APPENDIX L. POSTPARTUM INTERVIEW

Blossom Online Postpartum Interview

Subject ID: _____ **Date:** _____

1) **Type of delivery:** Vaginal Cesarean

2) **Length of active labor** (active/quicker dilation, usually at least 4-5cm dilated; hrs, min):
_____

3) **Was your labor induced?** Yes No
If yes, what method was used:
- Pitocin
- "Broke my water"
- Other: _____

4) **Did you use any pain medications during labor?** Yes No
If yes, what type?
- Epidural
- Narcotics: Demerol Nubain Stadol Other: _____
- Local block
- Other: _____
- Not sure

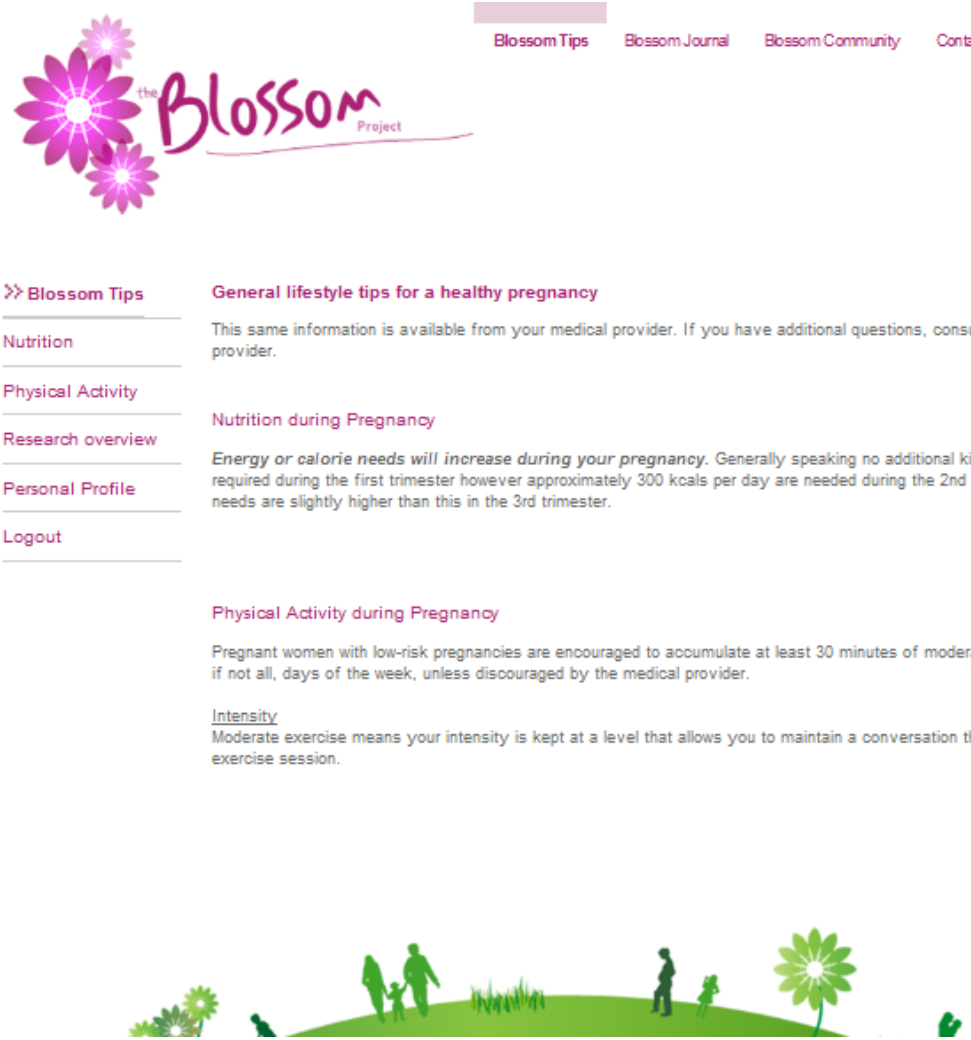
5) **Did you experience any complications during labor?** Yes No
If yes, what were your complications?
- Breech
- Unplanned cesarean Reason for c-sec:
- Stalled labor after 4cm dilation
- Difficulty pushing
- Other: _____

6) **Were you diagnosed with any of the following during your pregnancy?**
- Pregnancy-induced hypertension
- Pre-eclampsia or Eclampsia
- Gestational Diabetes Mellitus
- Thyroid condition: _____
- Other: _____

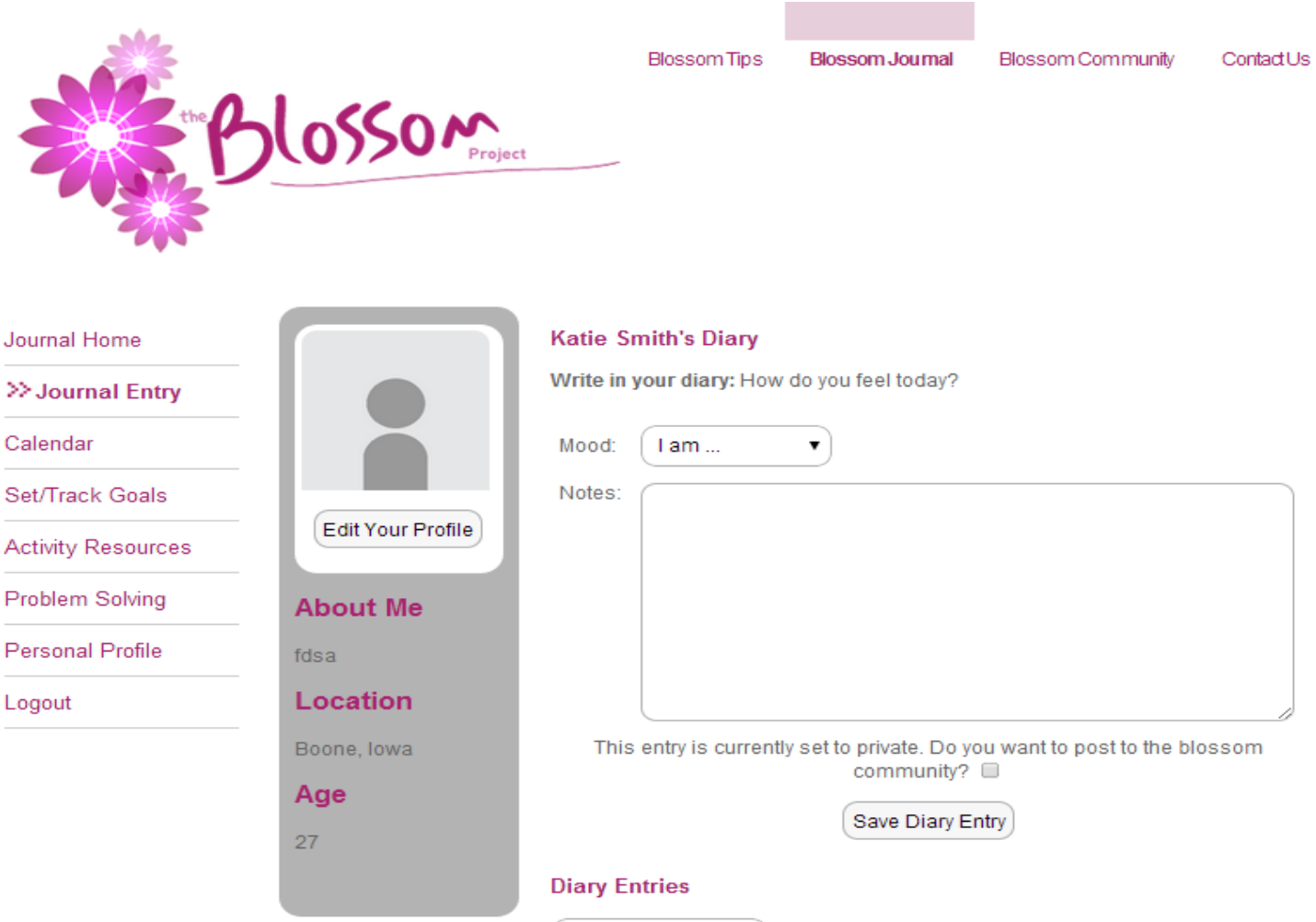
If yes, what treatment or medical plan was used/were you advised to follow, if any?
_____
_____
_____

APPENDIX M. SCREENSHOTS OF THE BLOSSOM PROJECT ONLINE WEBSITE

Blossom Tips



Blossom Journal



Entry from [redacted] 3 months ago (December 9th, 2013 at 9:25 AM)

I am feeling Good!

This cold has been a little harder in having the motivation to get out and walk. I am walking but I was hoping to be walking for longer periods of time than I am.

Entry from [redacted] 3 months ago (December 8th, 2013 at 11:55 PM)

I am feeling Tired.

I will be 39 weeks on Tuesday and really want this baby to arrive! I haven't done much walking or exercising for the past few months, so I've definitely not met my exercise goals. I haven't felt well since about 32 weeks - I feel out of breath and tired when I grocery shop for a half hour.

Entry from [redacted] 4 months ago (November 15th, 2013 at 10:44 AM)

I am feeling Content!

To the person who posted about half an hour ago: It won't let me respond to your post, so I'm going to this way instead. I just wanted to say not to feel too guilty and don't feel bad about not meeting every goal every week. I have not met the 150-minute goal some weeks, and I felt bad about it and sometimes still do, but at the same time, any exercise is better than none, and if you find you only have time or energy for 15 minutes of walking today or tomorrow, so be it. You may find, too, that once you dedicate yourself to 15 minutes of walking today (rather than focusing on the big 150), you may feel super energized and want to keep going. Be proud of what you HAVE accomplished! It means much more than what hasn't been reached. Chin up, mama! Just do what you can!

Entry from [redacted] 4 months ago (November 15th, 2013 at 10:13 AM)

I am feeling Guilty.

I am having a really difficult time motivating myself to workout. I havent done any exercise all week so it looks like a lot of exercise is in store this weekend. Hoping to get back some motivation to move

Blossom Online Exercise Calendar