BlossomUP (BUP): A pilot randomized control trial to assess strategies to reduce sedentary time during pregnancy

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BlossomUP (BUP): A pilot randomized control trial to assess strategies to reduce sedentary time during pregnancy

by

Caroline Lund McKinney

A thesis submitted to the graduate faculty in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

Major: Nutritional Sciences (Human Nutrition)

Program of Study Committee:
Christina Campbell, Major Professor
Laura Ellingson
Sarah L. Francis

Iowa State University
Ames, Iowa

2017

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ABSTRACT

A three-armed, six-week randomized controlled trial was conducted between 16-22 weeks gestation (baseline) and 24-28 weeks gestation (final). Previously sedentary women (n=11) were randomized to one of three groups following baseline: Group 1) Reduce sedentary time (ST) by interrupting prolonged sitting (n=5); Group 2) Reduce ST via walking 30 minutes most days of the week (n=3); or Group 3) Continue with daily routines (n=3). Participants (Groups 1 and 2) received Fitbit® monitors to promote physical activity (PA) behavior change.

Data was collected over a 7-day period during baseline and final. PA was assessed with activPAL™, Sensewear® armband, Fitbit®, and PA record. Measured weight was compared to the 2009 Institute of Medicine (IOM) recommended rate of weekly weight gain. Dietary intake was assessed using a 3-day weighed diet record. Participants underwent a 75-gram 2-hour oral glucose tolerance test (final).

No significant differences were found; descriptive results are as follows. One participant in each group decreased ST from baseline to final (-3.63%, -4.07%, -13.75%, per group, respectively). Groups 1 and 2 decreased ST in bouts ≥ 60 minutes (152.40 ± 103.34 minutes baseline, 133.18 ± 19.88 minutes final; 202.55 ± 60.51 minutes baseline, 175.02 ± 89.84 minutes final, respectively), whereas, Group 3 increased (203.95 ± 92.89 minutes baseline, 224.69 ± 132.18 minutes final). A moderate effect size was found for reducing prolonged ST between intervention groups and Group 3 (0.66). Group 1, decreased moderate vigorous physical activity (MVPA) from baseline (132 ± 96.16 minutes) to final (40.5 ± 34.64 minutes). Groups 2 (16.66 ± 22.30 minutes baseline;
53.66 ± 85.27 minutes final) and 3 (UC; 73.33 ± 62.26 minutes baseline; 84.33 ± 84.67 minutes final) increased. A small effect size was demonstrated between intervention groups and Group 3 (0.48). Groups 1 and 2 met the intervention goal 58.4-98.8% and 0-213% of the time, respectively. A positive relationship for increased ST, higher fasting, 60, 120-minute blood glucose levels and increased calorie consumption was found. Based on the IOM guidelines, one participant gained less, one met and six exceeded recommendations. Based on preliminary data, finding effective strategies to decrease ST during pregnancy remains important.
CHAPTER 1. INTRODUCTION

Introduction

Pregnancy is one of life’s most important stages, as the health of two human lives is influenced by the actions of one individual. Many researchers and healthcare workers have utilized this fact to encourage pregnant women to adopt healthier lifestyles by engaging in nutritious eating and physical activity (PA). Among the multitude of healthy factors women can engage in during pregnancy, PA has been identified as a contributor to a healthier pregnancy. PA is defined as any bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above a basal level, whereas exercise is defined as an activity that is planned, structured and repetitive with a final goal of maintaining or improving physical fitness.

According to the American College of Obstetricians and Gynecologists’ (ACOG) committee opinion, pregnant women should engage in an exercise program that leads to an eventual goal of moderate-intensity exercise for at least 20-30 minutes per day on most or all days of the week. In contrast to PA, more time spent sedentary, commonly referred to as sedentary behavior (SB) or sedentary time (ST), can have detrimental effects on health. The topics of PA and SB are independent of one another but frequently discussed concurrently. For example, an individual can be very physically active and spend little time in SB, be extremely inactive and spend the majority of the day sedentary or exist in any variation between the two extremes. The pregnant population spends nearly 75% of waking hours in SB and approximately only 16% of
pregnant women comply with current PA recommendations.\textsuperscript{8,9} Although not as intensely researched at this time, SB literature regarding pregnant populations is evolving, as research in the non-pregnant population demonstrates that SB has a negative effect on metabolic health parameters and overall well-being. To minimize SB and associated health consequences, present research in the non-pregnant population is focusing on interrupting time spent in prolonged SB bouts.\textsuperscript{10-12}

The purpose of the BlossomUP (BUP) study focus was to decrease ST in pregnant women with secondary outcomes addressing the evaluation of PA, adherence to 2009 IOM weight gain guidelines and glucose tolerance. It is our hypothesis that women instructed to break up their prolonged ST will better achieve the goal of decreasing their ST than women instructed to engage in a 30-minute walk on most days of the week.

\textbf{Thesis Organization}

This thesis includes an introduction, literature review, study methods, study findings and conclusion. Data/findings (Chapter 3) from this study, BUP, will be used as preliminary data for a grant to be submitted to the American Diabetes Association (ADA). Figures are embedded within the text and the appendices contain a table regarding relevant ST and pregnancy studies and documents utilized for enrollment and data collection.
CHAPTER 2. LITERATURE REVIEW

Physical Activity (PA) Components

In addition to ACOG recommendations of moderate-intensity activity for at least 20-30 minutes per day on most or all days of the week, the U.S. Department of Health and Human Services provides PA guidelines for women during pregnancy. Healthy women should engage in at least 150 minutes of moderate-intensity activity each week. These bouts of PA should be accumulated in at least 10 minutes and should be spread throughout the week for substantial health benefits. Examples of moderate intensity activities include brisk walking, recreational swimming and bicycling. Moderate intensity activities are given a metabolic equivalent of task (MET) value of 3.0-6.0 METs. Where one MET is defined as 1kcal/kg/hour and is equivalent to the energy expended by an individual sitting at rest. METs describe the energy cost of various physical activities on the body. Vigorous activity is assigned a MET value of greater than 6.0 METs and includes activities such as: paced swimming laps and jogging or running. Finally, the term, leisure activity refers to activities such as sports and exercise, but also household tasks such as gardening and cleaning.

In regards to pregnant women, as earlier stated, ACOG recommends women engage in an exercise program that leads to an eventual goal of moderate-intensity exercise for at least 20-30 minutes per day on most or all days of the week. Recommendations for safe activities during pregnancy include types such as walking, swimming and modified yoga.
Although there are benefits of PA during pregnancy, such as improved cardiovascular function, management of gestational diabetes (GDM) and limiting gestational weight gain, pregnant women are frequently not partaking in movement beyond their daily routine. The National Maternal and Infant Health Survey, encompassing 9,953 women from 48 states, the District of Columbia, and New York City reported that approximately 45% of women stated they did not exercise at least three times a week before or during pregnancy and 13% exercised before pregnancy but stopped after they found out they were pregnant. Further, in 2000, data from the Behavioral Risk Factor Surveillance System (BRFSS) demonstrated that 34% of pregnant women reported not engaging in any moderate or vigorous intensity leisure activity within the last month. With a concerning low number of women engaging in PA during pregnancy, one must consider the barriers to PA.

Evenson et al. investigated perceived barriers to PA during pregnancy utilizing data from two separate studies of pregnant women. Data from a cohort study (n=1,535 women), the Pregnancy, Infection, and Nutrition (PIN) Study, found the main barrier to PA to be intrapersonal and health-related (52.1%) followed by intrapersonal and non-health related (32.7%) reasons. Intrapersonal barriers refer to factors that originate within and the individual has control over, such as fatigue or lack of motivation. In a separate study, qualitative data utilizing focus groups with 58 pregnant women with a median age of 26 years old reveal the same two barriers at the top of the list. The main intrapersonal health-related barriers include: tiredness, musculoskeletal problems and shortness of breath, whereas, intrapersonal non-health related barriers include
examples such as: lack of time, childcare and enjoyment from PA.\textsuperscript{20} With pregnant women reporting barriers to exercise such as not enough time to engage in PA, musculoskeletal problems triggered by PA and the exhaustion caused by physical exertion, a solution is needed that will be perceived as easier, less time-consuming and enjoyable.

**SEDENTARY TIME (ST):**

**ST introduction**

The topic of ST has become a newly explored area within the last two decades with a lot of interest in the last five years.\textsuperscript{21} Appendix A highlights previous research carried out regarding ST in pregnancy within the last 11 years. Current PA guidelines for both pregnant and non-pregnant populations recommends only 30 minutes of PA activity per day on most days of the week, accounting for only 2.1% of an entire day\textsuperscript{7,19}, but it is important to consider what activity may or may not be taking place during the remaining 97.9% of the day.\textsuperscript{23} The word “sedentary” stems from the Latin word ‘sedere’, meaning, “to sit”.\textsuperscript{24} ST is defined as any waking activity characterized by an energy expenditure of ≤ 1.5 METs in a sitting or reclining posture, but does not include sleep.\textsuperscript{25} ST refers to MET activities requiring much less energy expenditure (<1.5 METs) than those of moderate or vigorous intensity activities (3-6 METs or >6 METs, respectively). Common sedentary activities include television viewing, working at a desk, eating a meal at a table and driving.\textsuperscript{25} This behavior is assessed via subjective measures (self- and proxy-report questionnaires) and/or objective measures such as accelerometers (e.g., ActiGraph, worn on the hip or the activPAL\textsuperscript{TM}, worn on the front of the thigh).\textsuperscript{26}\textsuperscript{27} The definition of “prolonged ST (or
SB)”, phrases commonly utilized in the sedentary literature, is not well defined; however Dunstan et al. describes this as “too much sitting” as distinct from “too little exercise”.  

**ST in non-pregnant adults**

Research suggests that non-pregnant adults spend the majority of days sedentary. Utilizing an Actigraph, data from the 2003–2004 National Health and Nutrition Examination Survey (NHANES) found that participants spent 7.7 hours per day (54.9% of waking time) in sedentary activities, with females engaging in more ST than males throughout youth and early adulthood. Similarly, a study on 528 adults (30-80 years of age) found that participants with newly diagnosed type 2 diabetes mellitus (T2DM) spent 61.7% of their waking time in ST.

The large percentage of hours spent sedentary throughout the day is concerning, as this idle time has been associated with negative health consequences. Increased prolonged bouts of ST have been independently associated with lower levels of PA energy expenditure, increased risk of weight gain, metabolic syndrome, diabetes and cardiovascular disease. Specifically, Wijndaele et al. found that ST (engagement in television watching and computer activities) was positively associated with metabolic syndrome risk in men (P<0.05) and women (P<0.01), irrespective of PA level. The risk scoring took into account: waist circumference, triglycerides, HDL cholesterol, blood pressure and fasting plasma glucose. Categorized by age, time spent in SB (hours/week) included: 14.6 ± 8.2 (men <45 years), 14.9 ± 8.1 (men ≥ 45 years), 11.1 ± 6.3 (women <45 years), 16.4 ± 8.8 (women ≥ 45 years). Furthermore, a prospective study of 73,743
women enrolled in the Women’s Health Initiative Study reported that women who spent a cumulative 16 or more hours per day sitting (assessed via detailed questionnaire) had an elevated relative risk of 1.68 (95% confidence interval, 1.07 to 2.64) for cardiovascular disease incidents (newly diagnosed case of coronary disease, stroke and first cardiovascular event) during a six year follow-up compared with women who spent less than 4 hours per day sitting. In addition, sitting while watching television, while driving, at work or away from the home and other sitting at home were all positively associated with incident T2DM during a six-year follow-up among 68,497 women from the Nurses’ Health Study. Incident rates were obtained by dividing the number of cases by person-years in each category of average time spent on each sedentary activity (i.e., television viewing). The nine categories included zero hours/week up to >90 hours/week of ST, reflective of greater than 53% of the day spent sedentary. Breaking this time up incrementally, each 2-hour block per day of TV watching was associated with a 23% increase in obesity and a 14% increase in diabetes risk. When this same increment of time was spent sitting at work, a 5% increase in obesity and 7% increase in diabetes was exhibited. Finally, when this time was spent standing or walking around the home (which most likely reflects household work) a 9% reduction in obesity and a 12% reduction in diabetes was shown.

Screen-time has become a major topic of research as it relates to ST, as a large amount of time in which people engage in sedentary activities is spent in front of the television. In 2007, a study examining the associations of television viewing time with blood draws at two different time points yielded interesting results in women. Blood
specimens were collected at fasting and at 2-hours post-glucose load and television viewing time was assessed via an interviewer-administered questionnaire. After adjusting for age, a significant positive association between television viewing and fasting plasma glucose (FPG) was found (P=0.002). Additionally, a positive, but non-significant association was observed between the television viewing and the 2-hour plasma glucose levels. Even more specific and interesting, in age-adjusted regression models, each 1-hour per day increase in television time accounted for a 0.04mmol/l increase in FPG and a 0.16mmol/l increase in 2-hour plasma glucose.\(^{37}\)

To further emphasize the detrimental effects ST has on glucose tolerance, Henson et al. utilized ActiGraph accelerometers to measure ST in 878 adults who were at high risk for T2DM (including variables such as: age, BMI, sex, additional factors [family history, CVD]). ST was defined as <25 counts per 15 second epochs and a break in ST was defined as a transition from sedentary (<25 counts per 15 seconds) to an active state (≥25 counts per 15 seconds). After adjusting for confounders, ST exhibited a significant detrimental association with 2-hour glucose levels (p<0.001), whereas breaks in ST were significantly inversely associated (p=0.046).\(^{38}\) In summary, studies examining ST in non-pregnant adults demonstrated the majority of days are spent in ST and this time is associated with negative health consequences such as metabolic syndrome, cardiovascular disease, diabetes and obesity.

**ST in pregnant population**

ST has been associated with negative health consequences in non-pregnant populations, but these health consequences have not been as thoroughly investigated
during pregnancy. Of importance, when women become pregnant they not only become less physically active but also more sedentary. When comparing ST amongst non-pregnant and pregnant women in a cross-sectional study, pregnant women spent 13% more time sedentary and had 44% lower total activity (counts/day), as assessed by Actiheart accelerometer data, than non-pregnant women.\(^{39}\)

Furthermore, current literature demonstrates that pregnant women spend a significant amount of their waking time in ST.\(^{40,41}\) In a longitudinal study evaluating ST, researchers found that pregnant women in their 2\(^{nd}\) and 3\(^{rd}\) trimester spend on average 75% of their waking time in SB, as assessed by the activPAL\(^ \text{TM}\). Further, women increased ST from mid-pregnancy (week 18) to late pregnancy (week 35) (P=0.07).\(^8\) Similarly, in a recent study examining objectively-measured PA and ST (<1.5 METs) via Fitbit\(^ \circledR\) monitors in pregnancy, researchers found that ST progressively increases throughout pregnancy with a rapid rate of increase toward the end of the nine months.\(^{42}\) Not only are women extremely sedentary throughout their days, but their volume of ST increases with the duration of pregnancy.

**ST in pregnancy health consequences**

Although not as thoroughly researched in the pregnant population, ST during pregnancy has also exhibited negative health effects, similar to those seen in non-pregnant adults. One can argue that this behavior may be of greater concern during pregnancy, as this behavior has repercussions for two people. ST during pregnancy is associated with adverse perinatal health outcomes including abnormal glucose
tolerance, increased risk of GDM, decreased insulin sensitivity, increased insulin secretion and excessive gestational weight gain.

A significant prenatal complication with negative consequences for mother and baby is the risk of developing GDM. GDM occurs when a woman without diabetes develops high blood glucose levels during pregnancy. More specifically, diagnosis occurs when one or more of these values from a 75-gram oral glucose tolerance test is equal or greater than the cut-off: fasting blood glucose: 92mg/dL, 1-hour: 180mg/dL, 2-hour: 153mg/dL. This test, commonly referred to as the one-step approach, is performed between 24-28 weeks gestation following an overnight fast and is currently recommended by the International Association of Diabetes in Pregnancy Study Groups (IADPSG) task force and the American Diabetes Association (ADA). In contrast, ACOG currently recommends pregnant women be screened for GDM following the two-step process. This includes a 50-gram, 1-hour glucose test. If the 50-gram test is positive, women perform a 100 gram, 3-hour oral glucose tolerance test for possible GDM diagnosis. Utilizing the one-step process, 16.1% of pregnancies result in GDM diagnosis, whereas, 7% of pregnancies results in GDM when the two-step process is utilized. In a 2014 analysis by the CDC including reported Pregnancy Risk Assessment Monitoring System (PRAMS) questionnaires and birth certificates, GDM was diagnosed utilizing a mix of diagnostic criteria including IADPSG National Diabetes Data Group and Carpenter and Coustan. This analysis yielded GDM diagnoses in up to 9.2% of pregnancies yearly in the United States. Its prevalence increasing among all ethnic groups since the early 1900s, parallel to the increase in T2DM.
GDM is of great concern as the condition increases the risk of fetal macrosomia, neonatal hypoglycemia, jaundice, polycythemia and hypocalcemia. Further GDM is associated with an increased frequency of maternal hypertensive disorders and cesarean delivery. Halting this vicious cycle is crucial not only for the short-term but also the long-term considerations for the mother and future newborn.

Regarding the topic of GDM, it is important to note that during pregnancy, a woman’s body undergoes many necessary adaptations in order to meet the energy demands of the growing fetus. These adaptations include: impaired insulin sensitivity, increased beta-cell response, increased blood glucose and changes in circulating nutrients. Impaired insulin sensitivity in pregnancy can lead to insulin resistance, which is similar to the insulin resistance observed in T2DM. This insulin resistance seen in the mother, is a physiological event favoring a necessary and adequate supply of glucose to the fetus. Gradmark et al. illustrates this difference in insulin resistance between pregnant and non-pregnant women. Results from a 2-hour OGGT demonstrated significantly higher insulin levels and a larger glucose area under the curve in pregnant women when compared to non-pregnant women indicating the presence of insulin resistance at 30, 60, 120 minutes post glucose load. Further, insulin sensitivity was found to be significantly lower in pregnant women (p=0.016) than their non-pregnant counterparts.

Despite insulin resistance in the mother, glucose homeostasis is maintained in normal pregnancies by a naturally occurring compensatory increase in insulin secretion. However, when beta-cell secretion is no longer sufficient to compensate for the insulin
resistance, high blood glucose develops and thus GDM is diagnosed.$^{55}$ Women who are diagnosed with GDM during their pregnancy have a 3-7 fold increased risk of developing T2DM within 5 to 10 years of delivery.$^{51,52}$ A systematic literature review of 28 studies published between 1965 and 2001 examined the relationship between GDM and T2DM after delivery. T2DM development in these participants ranged from 2.6% to over 70%. The variability in these numbers can be accounted for with the following reasons: T2DM follow-up taking place anywhere between 6 weeks to 28 years postpartum, the varied diagnostic criteria utilized for both GDM and T2DM and the variation of exclusion criteria applied to each study. T2DM diagnosis had an accelerated appearance during the first five years following delivery and appeared much slower after 10 years.$^{56}$

As mentioned earlier, the child of a mother diagnosed with GDM is also placed at risk for health complications including obesity, glucose intolerance and diabetes during late adolescence and young adulthood.$^{51,57}$ The long-term effects of GDM on the offspring of Pima Indian women who had and had not been diagnosed with GDM yielded interesting results. The mothers who were categorized as obese (30-34kg/m$^2$), their children at 5-9 years old exhibited the following outcomes: 12.9% of the offspring born to mothers who did not have GDM or were considered pre-diabetic were obese, whereas, 25% of the offspring born to mothers with GDM were obese (defined as at least 140% of desirable weight). At 10-14 years, mothers who did not have GDM but had prediabetes, only 25.7% of their offspring were obese, while 41.7% of the offspring were obese whose mothers were diagnosed with GDM. Finally, at 15-19 years of age, the comparison of obese offspring is vastly different--23.2% versus 57.1% of offspring
categorized as obese with the offspring of women without GDM and with GDM, respectively. This study demonstrates that children born to mothers who were obese and diagnosed with GDM during pregnancy were more likely to be obese than children born to mother who were obese but did not have GDM. In a similar study with Pima Indians, complications of pregnancy as a function of a 2-hour plasma glucose concentration following ingestion of a 75-gram glucose beverage was assessed. A total of 55.5% of women with a 2-hour plasma glucose of ≥200mg/dL experienced perinatal mortality or an infant who was large for gestational age, whereas only 18.1% of women with a glucose level of <140mg/dL experienced these two complications. Additionally, 44.4% of women with a glucose level of ≥200mg/dL experienced toxemia and/or a C-section, whereas only 23.6% of women experienced either or both of these complications when plasma glucose was <140mg/dL. According to the one-step approach, a 2-hour plasma glucose level of 200mg/dL exceeds the cut-off of 153mg/dL, indicative of GDM diagnosis, whereas, 140mg/dL is within normal limits.

As mentioned earlier, women diagnosed with GDM, are more likely to deliver macrosomic infants (>4000g). The growing fetus receives a greater amount of glucose which is stored as excess body fat, leading to fetal macrosomia. In a recent study following women into their third trimester, women were predicted to either deliver macrosomic (>4000g) infants or infants <4000g. Predictions were based on ultrasound measurement, abdominal palpations and if the woman had given birth to a previous macrosomic infant. Women who spent significantly more time (16.1 ± 2.8 hours) sedentary defined as ≤ 1 MET were more likely to deliver macrosomic infants as
compared to women who spent less time sedentary (13.8 ± 4.3 hours; p=.002). This is concerning, as fetal macrosomia is in turn associated with future increased risk of obesity and breast cancer in the offspring later in life.²³

The topic of ST and the development of glucose intolerance during pregnancy is becoming a newly researched area. A prospective cohort of 1,231 Latina women using a non-fasting 50-gram 1-hour OGTT, examined the associations between ST and glucose tolerance. Utilizing the Kaiser Physical Activity Survey, women who were categorized in the highest tertile of ST during mid-pregnancy, a variable taking into account TV watching, time spent sitting at work and no participation in sports/exercise experienced significantly higher glucose levels (3rd (most sedentary) vs. 1st tertile (least sedentary): $\beta=0.08$ (log scale), $P=.038$) at 1-hour than those who engaged in the lowest total ST. However, ST in pre-pregnancy and early pregnancy were not significantly associated with glucose levels.⁶⁰ Similarly, a cohort study utilizing PA questionnaire data from Project Viva demonstrates that a sedentary lifestyle, defined in this study as 2 or fewer weekly hours of total PA (time spent walking and light, moderate and vigorous activity) during pregnancy is associated with abnormal glucose tolerance (OR 1.71, 95% CI 1.07-2.73) and risk for GDM (OR 2.11, 95% CI 1.01-4.40).³ Abnormal glucose tolerance in this study was defined as those who failed the non-fasting 50-gram OGTT. The aforementioned studies exhibit the adverse health implications such as GDM and potential T2DM for mother and child and fetal macrosomia when time is spent sedentary during pregnancy.
In regards to overall health during pregnancy, the gestational weight a woman gains can have immediate and long-term consequences for the woman and her child. In 2009, the Institute of Medicine (IOM) published updated gestational weight gain (GWG) guidelines that are based on pre-pregnancy body mass index (BMI) ranges for underweight, normal weight, overweight and obese women that encompass both total and rate of weight gain during pregnancy. These recommendations provide a clinical basis for weight gain during pregnancy that physicians can utilize to provide individualized care to patients.

<table>
<thead>
<tr>
<th>Pre-pregnancy BMI</th>
<th>BMI (kg/m²) (WHO)</th>
<th>Total Weight Gain Range (lbs)</th>
<th>Rates of Weight Gain 2\textsuperscript{nd} and 3\textsuperscript{rd} Trimester (Mean Range in lbs/wk)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>28-40</td>
<td>1 (1-1.3)</td>
</tr>
<tr>
<td>Normal weight</td>
<td>18.5-24.9</td>
<td>25-35</td>
<td>1 (0.8-1)</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0-29.9</td>
<td>15-25</td>
<td>0.6 (0.5-0.7)</td>
</tr>
<tr>
<td>Obese (includes all classes)</td>
<td>≥30.0</td>
<td>11-20</td>
<td>0.5 (0.4-0.6)</td>
</tr>
</tbody>
</table>

*Calculations assume a 0.5-2kg (1.1-4.4 lbs) weight gain in the first trimester (based on Siega-Riz et al., 1994; Abrams et al., 1995; Carmichael et al., 1997)*

If a woman exceeds her targeted recommended range of total weight gain during pregnancy, the woman is said to have gained in excess, otherwise referred to as excessive gestational weight gain (EGWG). This also holds true for the rate of gain during the 2\textsuperscript{nd} and 3\textsuperscript{rd} trimesters of pregnancy. EGWG increases risk of macrosomia, postpartum weight retention, future maternal obesity and possibly future childhood obesity. In a study conducted by Deputy et al., 68% of the women enrolled,
A representative of 28 states from the Pregnancy Risk Assessment Monitoring System project, gained more than their recommended amount of weight set forth by the 2009 IOM guidelines, placing them in the “excessive” weight gain category. According to combined state-specific CDC data from 2013 and PRAMS data from 2012, only 32.1% (range = 26.2-39%) of women gained within the IOM recommendations, 12.6-25.5% gained inadequately, while the prevalence of EGWG ranged from 38.2-54.7%. Further, the prevalence of EGWG was >50% in 17 states. Simas et al. report similar findings—52.6% of all pregnant women gaining in excess with even more pronounced outcomes in women who are overweight or obese, with 68.9% and 59.8% gaining in excess, respectively.

The understanding of the relationship between time spent sedentary and the influence on weight gain during pregnancy is limited and requires further research. In a secondary data analysis evaluating the relationship of ST and GWG, no significant associations were found between the reduction of ST during pregnancy leading to a reduction of EGWG. However, the researchers note the findings from this study are new and the literature still young, confirming more studies with randomized designs should be carried out. Additionally, studies focusing on non-pregnant women and adolescent girls yield results demonstrating a relationship between ST and weight gain exist. In a recent review of 33 studies regarding the relationship between ST and health indicators in adolescent girls (12-18 years old), 17 out of 19 (89%) studies focusing on weight status found an overall positive association between screen-based ST and weight status, particularly when screen time exceeded 2 hours per day. As previously mentioned, a
A multitude of the sedentary literature is based on television viewing, as television viewing is considered a proxy for ST. The findings from this review are concerning because if ST during adolescence is associated with increased body weight, these habits are likely to track into adulthood. In contrast, two studies within the review reported the reduction of overall screen-based ST is associated with lower weight. Specifically, less than 4 hours of screen time per week reduced the risk of obesity by 40%.

In 2003, Hu et al. assessed exercise levels via questionnaire asking participants how much time they spent during the week in the following activities: walking, jogging, running, biking, aerobics, lap swimming, racquetball and tennis and their typical walking pace. Independent of exercise levels, ST, specifically television viewing was associated with a significant elevated risk of obesity. A 23% (95% CI, 17-30%) increase in obesity risk accompanied each 2-hour/day increase in time spent watching TV. In a multivariate analysis, participants who accumulated the least METs per week (assessed by participant report of amount of time spent in activity per week and walking pace per week) and were the most sedentary (>20 hours/week of television viewing) had a significant increased risk of obesity (RR, 1.90; 95% CI, 1.61-2.24) compared to those with the most METs per week and lowest television viewing time (<6 hours/week).

Overall, EGWG is considered a mounting issue and one that researchers and healthcare workers have increasingly strategized to combat. Although not heavily studied in the pregnant population, optimism is present that modest reductions in ST may also benefit this population.
Breaking up prolonged ST with walking

During pregnancy, total PA is positively associated with insulin sensitivity ($r=0.28$; 95% CI, -0.07-0.57). This suggests that increased movement and PA at any intensity, not just moderate-vigorous PA, including short, walking breaks to break up prolonged ST, may aid in controlling and maintaining glucose homeostasis during pregnancy.

In addition to the effects of total ST, the manner in which it is accumulated may also be important. Dunstan et al. examined overweight/obese adults’ plasma glucose and serum insulin levels following consumption of a 200 mL standardized test drink simulating a mixed meal (75-grams carbohydrate, 50-grams fat and 0-grams protein). Metabolic biomarkers were evaluated when participants remained seated, uninterrupted for 5 hours or seated with 2-minute bouts of light or moderate-intensity walking every 20 minutes. In this crossover study, participants who engaged in a light-intensity walk every 20 minutes experienced a 24.1% (P<0.01) lower glucose response than those who continually sat. A moderate-intensity walk every 20-minutes resulted in a glucose response that was 29.6% (P<0.0001) lower than uninterrupted sitting. Both walking groups displayed a 23% (P<0.0001) reduction in their insulin area under the curve (iAUC; incremental area under the curve) relative to the uninterrupted sitting group. These findings suggest that by including brief bouts of activity regardless of intensity during prolonged ST, plasma glucose concentrations and serum insulin response may be more tightly controlled.

To further demonstrate the beneficial effects on metabolic risk variables by interrupting prolonged ST, Healy et al. demonstrated in a cross-sectional study that
frequent breaks in ST were beneficially associated with a lower BMI (P=.026) and lower 75-gram, 2-hour plasma glucose levels (P=0.025). Participants in the highest quartile of ST breaks exhibited a 0.88 mmol/L lower 2-hour glucose level than those in the lowest quartile. Cut points for quartiles includes: 506, 612 and 673 total breaks. On average, breaks were less than five minutes in duration (4.50 ± 1.05 minutes) and categorized as light intensity (accelerometer; 514 ± 94 counts/min), suggesting that something as simple as getting up during television commercials or walking to the restroom at work can have beneficial metabolic health implications. Comparatively, another study conducted by Healy and colleagues found that walking breaks as short as one minute can result in lower waist circumferences and fasting plasma glucose levels. Individuals who ranked in the top quartile of breaks in ST, had a 4.1 cm smaller waist circumference and a 0.04 mmol/L reduction in fasting plasma glucose than those in the lowest quartile. (Quartile cut points for total breaks in ST: 470, 559 and 645).

In addition to walking breaks, research has examined the impact of standing breaks. A randomized cross-over trial conducted by Bailey et al. analyzed data from non-obese adults and the effects of three-treatment trials including: uninterrupted sitting; seated with 2 minute bouts of standing; or 2 minute bouts of light intensity walking every 20 minutes. Each trial lasted five hours and with at least six days between each treatment, ensuring no carry-over effects from the previous trial. All trials were conducted after the ingestion of test drinks (80.3-grams carbohydrate, 50-grams fat and 0-grams protein). In regards to glucose AUC, researchers found that sitting paired with 2-minute walking bouts every 20 minutes significantly lowered glucose response by
15.9% (20.0mmol L/5-h, p<0.001) as opposed to uninterrupted sitting (23.5 mmol L/5-h) and sitting with the 2-minute standing bouts which lowered glucose response by 16.7% (23.7mmol L/5-h). It should be noted that interrupting sitting time with short bouts of light-intensity activity assists in lowering postprandial glycemia in non-obese adults.\textsuperscript{10} Although short frequent bouts of standing had no significant effect on glucose response over a five-hour period.

In another randomized trial, researchers examined the effects of reducing workplace ST via utilization of a height-adjustable desk during the workday on postprandial glucose response in overweight/obese adults (BMI >25kg/m\textsuperscript{2}). Participants underwent two, five consecutive-day experimental conditions with a minimum of a week between each trial. The control consisted of participants performing usual workday activities in a seated posture for eight hours per day and only walked for restroom use. The intervention participants performed usual workday activities, however, they were instructed to alternate between a seated and standing position every 30 minutes of the eight total hours (equivalent to four cumulative hours of standing and four hours of sitting daily). A fasting venous blood sample was collected prior to consumption of a mixed test drink (75-grams carbohydrate, 50-grams fat, 0-grams protein) and initiation of the eight-hour work day each day for the five-day period. Blood samples were then collected at 60, 120, 180 and 240-minutes post meal ingestion. At the end of the 4-hour blood collection, participants were fed a lunch meal; all other meals for the five-day period were developed and prepared by a registered dietitian to minimize diet variability. A significant (P=0.007) 11.1% reduction in glucose
incremental area under the curve (iAUC) during the prolonged sitting with intermittent 30 minute standing was observed, however no significant differences were observed on serum insulin.\textsuperscript{71}

In regards to ST in pregnancy, Di Fabio et al. found the number of transitions between sedentary activity to upright activity increases significantly by 27\% (P=.002) from mid to late pregnancy suggesting that women increase interruptions in prolonged ST as pregnancy advances.\textsuperscript{41} Although engaging in PA and reducing ST may have different health implications, partaking in one may be better than nothing at all. Furthermore, towards the end of pregnancy, women are more likely to feel uncomfortable and increase the frequency of breaks from ST as pregnancy advances. Interventions that focus on reducing prolonged ST may be a more attainable and viable option compared to intentional PA participation. Future pregnancy interventions that aim to reduce prolonged ST may be more successful at improving maternal and fetal outcomes such as glucose tolerance, appropriate weight gain and increasing time spent moving more so than interventions targeted at increasing PA levels.\textsuperscript{20, 42, 72}

**PA and inactivity relationship**

With respect to decreasing ST, PA can almost be recognized as the antagonist. An individual who sleeps eight hours per day has a remaining 16 hours to carry out domestic and work duties. Depicting a typical day, this individual wakes up at 7am and immediately engages in 45 minutes of purposeful PA, fulfilling the current PA guidelines of 30 minutes per day on most days of the week.\textsuperscript{22} Following this exercise bout, the adult drives to work, works on the computer, eats lunch, continues to work, drives
home, eats dinner and then relaxes while watching TV—all of which are sedentary activities. Although it is evident that the majority of this individual’s time is spent sitting, he/she would classify him/herself as physically active, as current PA guidelines consider this adult “physically active”, yielding the phrase “active couch potato”. The active couch potato phenomenon is described as the coexistence of high ST and achievement of PA recommendations. This may lead to adverse thinking that since the daily PA requirement for the day was met, the rest of the day can be spent in sedentary activities.

The Blossom Project demonstrates this same phenomenon among pregnant women. A total of 44 women were randomized to either a walking intervention (n=23) to increase walking or a usual care group (n=21) that was asked to continue on with their normal daily routine. At mid-pregnancy (week 26), walking in more than 10 minute bouts (P=0.002) and intentional walking (P=<0.01), defined as ≥20 minutes, was greater in the intervention than in the usual care group. Unfortunately, the increased walking came with an unfavorable outcome, women who increased their intentional walking spent more of their day sedentary (70.9% total ST, P=0.026) and spent more time in sedentary activities for bouts greater than 30 minutes (371.8 ± 122.9 minutes per day in bouts > 30 minutes, P=0.024) than those who did not increase their intentional walking (65.33% total ST, 285.7 ± 90.6 minutes per day in bouts >30 minutes). This suggests that when women increased intentional walking, more time was spent sedentary and in bouts greater than 30 minutes.
When daily fulfillment of current PA guidelines is achieved, but the rest of the day is spent sedentary, can a desirable health status be maintained? Peddie et al. studied 70 healthy, normal weight adults in a randomized crossover study comparing the effects of prolonged sitting for nine hours versus a single 30-minute walk followed by prolonged sitting versus short (1 minute 40 second every 30 minutes) walks interrupting prolonged sitting on postprandial glycemia and insulinemia. Meal-replacement beverages (1.12-grams carbohydrate, 0.46-grams fat, 0.54-grams protein per kg body weight) were provided at the 1, 4 and 7-hour marks. Each participant provided 16 blood samples. A fasting venous sample, a sample from each hour between baseline and the nine-hour mark and six additional samples at 30 and 45-minutes post beverage consumption. Results of glucose and insulin iAUC are as follows, respectively: prolonged 9-hour sitting: 48.8mmol/L (95% CI, 40.7-57.0); 3337.0IU/L (95% CI, 2783.4-3890.6), continuous 30-minute walk: 47.2mmol/L (95% CI, 39.1-55.4); 3012.3IU/L (95% CI, 2460.5-3564.1), short activity breaks: 29.9mmol/L (95% CI, 21.8-38.0); 2470.3IU/L (95% CI, 1919.6-3021.0). With respect to the short activity breaks, glucose and insulin iAUC were significantly different (P<0.001) from the prolonged sitting and continuous 30-minute walk values (insulin iACU, P=0.003). These results support the idea that short activity breaks throughout the day may be more beneficial to health than a single continuous 30-minute bout of PA or continuous sitting for nine-hours, specifically at lowering postprandial glucose and insulin concentrations.75

The importance of PA cannot be overlooked. Accumulating evidence demonstrates the physiological responses of decreasing ST are different from the
responses of engaging in PA, and that both play an important role in determining metabolic health. In a study conducted by Dempsey et al. women who engaged in recreational PA during the first 20 weeks of pregnancy experienced a 48% reduced risk of GDM compared to women who were inactive during this early pregnancy period (OR=0.52; 95% CI 0.33-0.80). Similarly, Dempsey et al. via questionnaire interviews, reported women who spent >6.0 hours per week during pregnancy engaged in PA were 58% less likely than women who were inactive to develop GDM (RR=0.42, 95% CI: 0.19-0.97). In-person interviews were carried out when the mean gestational age of participants was 12.7 weeks. Similarly, Dye et al. reported that inactivity during pregnancy was associated with a 1.9-fold increased risk of GDM (OR=1.9; 95% CI 1.2-3.1).

Both PA and ST have important health implications. However, ST may be a more important indicator of health than moderate-vigorous physical activity (MVPA), since ST occupies the majority of the day, unlike MVPA. Based on these findings, it may be more beneficial to focus on the amount of ST and work to decrease this behavior as opposed to increasing PA time.

Conclusion

As outlined, limited data regarding relationships including ST associations with weight gain, PA and glucose intolerance have been addressed in the pregnancy literature. The extent of associated negative health outcomes and interventions focusing on breaking up prolonged ST need to be further addressed and more extensively. Studies in the non-pregnant population demonstrate that reducing ST has
the potential to reduce the detrimental health effects of this behavior. Future studies assessing this relationship during pregnancy are needed, as lifestyle choices have repercussions for two individuals including: EGWG, glucose intolerance and decreased insulin sensitivity leading to GDM with possible T2DM diagnosis for mother and baby in future years.

Research in non-pregnant populations demonstrate breaking up total ST with short bouts of walking or standing are helpful at decreasing total ST and thus negate the side effects associated with this behavior.10-12 As previously noted, pregnant women spend the majority of their waking hours sedentary, making strategies and best methods in which to decrease ST in pregnancy a research priority. The goal of BUP, the research study described in this thesis, was to determine the best method in which to decrease ST. While ST research continues to evolve, words by Henson and colleagues, should remain in the forefront, “when sitting, stand when possible; when standing, walk or employ purposeful movement where possible”.79
CHAPTER 3. METHODS

Study

The study described in this thesis was completed in The Blossom Project Lab. The overall goal of the Blossom Project at Iowa State University (ISU) is to improve the lives of pregnant women and their children through encouraging PA and healthful eating during pregnancy. As part of The Blossom Project’s goal and to contribute to filling the research gap regarding ST in pregnancy, BlossomUP, a component of the Blossom Project, was a three-armed, randomized controlled trial with the primary purpose of decreasing ST in previously inactive pregnant women with secondary outcomes addressing the evaluation of PA, calorie consumption, glucose tolerance and adherence to the 2009 IOM weight gain guidelines. Data collection occurred over a one-year period. The University’s institutional review board approved the study.

Participants

Healthy pregnant women living in the communities in and around Ames, Iowa were recruited to participate in BUP. Recruitment efforts included local obstetric clinic partnerships, posting fliers around the community, Craigslist and Facebook postings, and distributing campus-wide emails. Women were recruited for this study between weeks 16-22 gestation. Inclusion criteria included 18-45 years of age, low-active or sedentary lifestyle prior to pregnancy (defined as less than three, 30-minute intentional exercise sessions per week) and a BMI less than 40kg/m². Exclusion criteria included being pregnant with more than one baby, a smoker, and history of type 1 diabetes mellitus, heart disease or renal disease.
Study Design

The total length participants were enrolled in this study was six weeks; data was collected at weeks 16-22 gestation (baseline) and 24-28 of gestation (final) (Figure 1). Participants were randomized to one of three groups after baseline. These groups included: Group 1 (Idle) women were asked to decrease ST with the assistance of the Fitbit® Alta as a self-monitoring behavior change tool; Group 2 (Walk) women were asked to accumulate 150 minutes of moderate-vigorous PA per week, the current pregnancy PA recommendation, using the Fitbit® Charge to record the goal; Group 3 (Usual Care; UC) women were asked to continue with normal daily routines and received no form of intervention.
The Blossom Project “BlossomUP”

Randomize to group 1, 2 or 3

Intervention Period

Week 1; Weeks 16-22

Week 2

Week 3

Week 4

Week 5

Week 6; Weeks 24-28

Baseline Data Collection:
- Appropriate documentation
- Ht, wt
- PA assessment (activPAL™, Sensewear®, Fitbit®)
- 3 – day weighed day record

Fitbit® Wearing: Alta/Charge

Fitbit® Wearing: Alta/Charge

Fitbit® Wearing: Alta/Charge

Fitbit® Wearing: Alta/Charge

Final Data Collection:
- Wt
- PA assessment (activPAL™, Sensewear®, Fitbit®)
- Nutrition assessment
- 2-hr Oral Glucose tolerance test

Group 1: Idle; Decrease sedentary time via Fitbit®

Group 2: Walking; Meet current prenatal physical activity guidelines, utilizing Fitbit® Charge

Group 3: Usual care; continue with normal daily

Figure 1 - BUP Study Timeline
Abbreviations: Ht: height; Wt: Weight; PA: Physical Activity; 2-hr: Two-hour
Data Collection

At enrollment, each participant’s height (cm) and weight (kg) was measured, the consent form was signed and a medical history questionnaire was completed. Participants provided consent for Blossom Project staff to communicate with the participant’s obstetric provider to confirm eligibility requirements. In addition, participants provided consent for the research staff to request weight from the participant’s first prenatal appointment (obtained to calculate weight gain since the participant’s first obstetric appointment). These forms were faxed and completed by the obstetric provider and faxed back to the Blossom Project staff.

Data collection occurred prior to randomization (between weeks 16-22 gestation; baseline) and post-intervention (between weeks 24-28 gestation; final). During data collection, participants were provided verbal and written instructions as to how to wear two PA monitors (SenseWear® armband; SWA®, activPAL™; AP™) for a seven-day PA assessment. A Fitbit® tracker was also worn during data collection, but was not utilized as a PA monitoring assessment tool. A written PA record was also completed by participants during the seven-days of monitor wearing. Finally, instructions were provided regarding diet data collection (three-day weighed diet record) for three days of the seven-day PA assessment.

At final, weight was measured and the aforementioned instructions were repeated regarding the PA assessment and three-day weighed diet record. Additionally, a 2-hour, 75-gram oral glucose tolerance test was performed to assess glucose tolerance.
Intervention

Following the seven-day baseline data collection, participants were randomized to one of three groups. Randomization was done using Microsoft Excel. Participant codes were listed in column D and 1’s, 2’s and 3’s were written every other row in column C. The randomization function of excel (RAND()) was put into every A column’s cell. Column A values were then pasted into column B and both columns were highlighted. Utilizing the “sort and filter” feature from smallest to largest in column B and filling in column C cells with black, participants were then randomized. Following baseline data collection and prior to randomization, the participant’s group number (Group 1, 2 or 3) was revealed.

Group 1 (Idle) was asked to decrease ST, by walking 250 steps per hour for 12 hours per day. Participants in this group received a Fitbit® Alta activity tracker, worn on the non-dominant wrist for the entire intervention. The Alta is a fitness tracker designed to help individuals track their sedentary and PA behaviors when paired with an external device (e.g. iPhone, computer). Each participant had a Fitbit® account set up with a Blossom Project username code to ensure privacy of the participant's identity. Participants were asked to achieve a goal of 250 steps per hour for 12 hours per day for the duration of the four-week intervention. Participants could choose the 12 hours in which they wanted the Fitbit® to be activated (based on typical waking and sleeping times). Using the "reminder to move" function, if a participant had not reached the hourly step goal at 50 minutes, the Alta would vibrate, cueing the participant to walk (~2 minutes) to achieve her 250 steps before the next hour. If the hourly goal was met, on
the dashboard of the Fitbit® app, the gray circle would turn pink, indicating the goal was met for that hour. If the goal was not met, the gray circle would remain gray, indicating the goal was not met (Figure 2).

Figure 2 – Fitbit® Group 1 Idle Alert Sedentary Time App View

Group 2 (Walk) was asked to meet current prenatal PA recommendations of walking 30 minutes per day on most days of the week (defined as 5 days per week) to accumulate 150 minutes per week. Group 2 participants received a Fitbit® Charge activity tracker and were asked to record 30-minute walks under the “track exercise”
feature of the Fitbit® app. There is no "reminder to move" function on the Fitbit® Charge, ensuring participants randomized to this group were not influenced by a vibrating band. The Charge was worn on the non-dominant wrist for the entire intervention. It is a fitness tracker that tracks PA when paired with an external device. Group 2 participants had a Fitbit® account set up with a Blossom Project username code to ensure privacy of the participant's identity. Participants used the app to view "active minutes" (accumulated activities in at least 10 minutes at or above 3 METs) (Figure 3).

![Figure 3 – Fitbit® Group 2 Active Minutes App View](image-url)
Group 3 (Usual Care [UC]) participants were not provided with a Fitbit® Alta or Charge activity monitor; participants were simply asked to continue with normal daily routines. Group 3 did not receive any intervention for four weeks.

**Physical activity assessment overview**

As mentioned previously, at baseline and final, participants wore two PA monitors (SWA® and AP™) for the next seven days, 24 hours per day except when showering or swimming. These were not worn during the intervention. Data analysis was standardized to represent a full seven days, 24-hour periods beginning and ending at midnight on the 1st and 7th day of data collection, respectively.

**Fitbit® monitor**

The company, Fitbit®, produces wrist-worn PA monitors that track daily PA and SB and provide real-time feedback on the face of the monitor and/or when synced wirelessly to the participant’s phone, tablet, computer, etc. These monitors require charging every five days to ensure track-ability and are worn on the non-dominant wrist. To ensure activity levels were not influenced by the wearing of the monitor, at baseline and final, the monitor screen was blacked out using black electrical tape. Depending on which group participants were randomized to, for the duration of the intervention, the black electrical tape was removed and they were provided with a Fitbit® Alta (Group 1), a Fitbit® Charge (Group 2) or no Fitbit® (Group 3). Monitor utilization within each group is described in the intervention section above.
The BodyMedia SenseWear® armband (SWA®) measures both movement and physiological response to estimate energy expenditure. It is a multi-sensory device containing three sensors: accelerometer, heat flux and galvanic skin response that is worn over the participant’s left tricep for the duration of the seven-day data collection period. Data was downloaded using version 8.0 of the BodyMedia software (algorithm v5.2h). An excel code was written to categorize minute epochs into sleep, sedentary (≤1.5 METs; independent of nighttime sleep), light (1.6-2.9 METs), moderate (3-5.9 METs) and vigorous (>6 METs) activity to provide the estimates of total energy expenditure. Valid SWA® data included days with less than 90 minutes of off body time (OBT). For participants who did not meet this criterion on any given day, their PA record was utilized in order to fill in the OBT, if possible. If the OBT could be filled in, MET values from the 2011 Compendium of Physical Activity were used to help fill in the OBT in the excel spreadsheet containing the data. For example, if a woman was not wearing her SWA® for 95 minutes due to taking a bath (bathing-sitting), 1.5 METs was used to fill in this time. To do this, the METs (1.5) was multiplied by the amount of minutes the armband was off her body divided by 60 minutes and multiplied by the woman’s weight in kilograms. If the woman weighed 99kg, the equation would be as follows: 1.5METs*(95/60)*99kg for her energy expenditure. The amount of minutes, in this example, 95 minutes would be filled in the “sedentary” category as bathing-sitting has a MET value of 1.5METs and 142.5 total METs for this activity would be filled in for the “METs” category. Bouts of PA were also assessed using the SWA® data output.
When analyzing the excel spreadsheet output for each participant, a 10-minute bout of activity consisted of at least 8 minutes in MVPA, allowing a 2-minute gap in activity within those 10 consecutive minutes. A 20-minute bout consisted of at least 16 minutes in MVPA, allowing for no more than a 2-minute gap within a 10-minute period. Finally, a 30-minute bout consisted of at least 24 minutes in length with no more than a 2-minute gap within a 10-minute timeframe.

**activPAL™ monitor**

The activPAL™ (PALtechnologies, Scotland, UK) accelerometer monitor (software 7.1.18) provides insight into the postural positioning of participants throughout the seven days of data collection. This monitor classifies patterns of daily activity such as standing, stepping and lying down and provides objective assessment of a participant’s SB. Participants adhered this monitor onto the right quadriceps muscle for the duration of data collection utilizing AP™ stickies from the company, PALtechnologies. The women were also provided with surgical tape and could choose to use it in order to better keep the monitor in place. Valid AP™ days matched the days of the valid SWA® days to maintain consistency within the data. Utilizing the excel spreadsheet output, 15-second epochs were analyzed and any period of time greater than one second during which posture was maintained was considered a bout. The AP™ did not categorize sleep and SB individually. Therefore, the matched SWA® data was utilized to assess the time in which participants were awake, in order to view SB during awake time ranges. The output of the AP™ included: ST, length of sedentary bouts, upright time, length of upright bouts, ST to upright movements and upright to sedentary movements.
Physical Activity Record (PAR)

The PA record (PAR) was a log recorded by each participant at baseline and final for seven days, each. This subjective information was used to compliment the objective PA data provided by the aforementioned PA monitors. Participants were instructed to keep a record of daily activities, including the start and stop times of each activity in this log. All activities were included in this log, such as: showering, eating, driving, sitting at a computer, watching T.V., etc. This descriptive information allowed the OBT to be filled in within the SWA® excel spreadsheet, if feasible (described in the SWA® Activity Monitor section, above).

Three Day Diet Record (3DDR)

Participants collected diet record information for three of the seven days of the PA data collection. Participants were provided with a digital scale and instructed to keep track of everything they ate for two weekdays and one weekend day during this time period. Participants were asked to record the food in grams immediately after weighing and to be specific as possible when describing the foods and beverages consumed (e.g. Dole® diced peaches packed in 100% fruit juice). Diet records were analyzed for total calorie intake, macro and micronutrients utilizing NutritionistProTM Diet Analysis software (Axxya Systems, Stafford, Texas). The 2010 Healthy Eating Index was then used to determine average consumption of total fruit, whole fruit, total vegetables, dark green vegetables, beans, seafood, plant protein, dairy, grains, whole grains, sodium and empty calories. Under-reporting was calculated by taking the ratio of a participant’s
average daily energy intake (Nutritionist Pro™) to energy expenditure (SWA®). If the value was <.80 (80%), the participant was categorized as under-reporter.⁸⁴

**Oral Glucose Tolerance Test (OGTT)**

At final, between weeks 24-28 of pregnancy, participants completed a 75-gram, 2-hour OGTT to assess glucose tolerance and screen for GDM. The 75-gram 2-hour OGTT, also known as the one-step approach, is recommended by the American Diabetes Association.⁴⁶ Participants were asked to fast for at least 12 hours prior to the scheduled test. Upon arrival at the research center, participants had a fasted blood draw (7.5mL) taken by a trained phlebotomist. Participants consumed a 75-gram oral glucose beverage (McKesson, San Francisco, California) in five minutes. Venous puncture was repeated at 60 and 120 minutes. Plasma serum from all three time points were sent to Quest Diagnostics (Madison, New Jersey; headquarters) to clinically assess glucose tolerance. Table 2 outlines the threshold values used to assess GDM in pregnancy.

**Table 2. Threshold Values to Diagnosis Gestational Diabetes Mellitus in Pregnancy**

<table>
<thead>
<tr>
<th>Glucose Measure</th>
<th>mg/dL⁸</th>
<th>mmol/L⁹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Plasma Glucose</td>
<td>92</td>
<td>5.1</td>
</tr>
<tr>
<td>1-hour plasma glucose</td>
<td>180</td>
<td>10.0</td>
</tr>
<tr>
<td>2-hour plasma glucose</td>
<td>153</td>
<td>8.4</td>
</tr>
</tbody>
</table>

⁸One or more of these values from a 75-gram OGTT must be equaled or exceeded for the diagnosis of GDM.⁴⁶

Participants also signed documents allowing for Blossom Project staff to send OGTT results to their healthcare provider, if desired. These forms were then faxed to the appropriate provider.
Actiparse

Actiparse.RB can be utilized applying data from the AP™ PA monitor. In order to use Actiparse for each participant’s time point, an “awake range” file was created in excel that included the approximate time the woman woke up and went to sleep on each date at baseline and final. Time spent asleep was determined using the SWA® data file. Following creation of these awake ranges for seven days of the data collection period, the Actiparse.RB script was used to create an output. This output produces visual representation (bar graphs) of average minutes per hour on the y axis in ST in 60+ minutes, 50-60 minutes, 40-50 minutes, 30-40 minutes, 20-30 minutes, 10-20 minutes, 0-10 minutes and time spent stepping and standing and hour increments of the entire day of the x axis (i.e. 7-8am, 8-9am, etc.) (Figure 4).

Additionally, bar graphs representing average minutes/day spent sedentary, standing and stepping were produced. This time represents increments of 0-10, 10-20, 20-30, 30-40, 40-50 and 60+ minutes for each graph (Figure 5). Finally, a percent wear time in standing, stepping and ST was created indicating the amount of time spent in each activity (Figure 6).
Figure 4 – Example Actiparse Average Minutes/Hour Sedentary, Standing and Stepping Output

Figure 5 – Example Actiparse Sedentary, Standing, Stepping and Upright Time Output
Figure 6 – Example Actiparse Percent Wear Time in Stepping, Standing and Sedentary time Output

Analysis

To determine if a participant in Group 1 met the intervention goal, each hour per day the participant met the goal was added and totaled for one week (Fitbit® data). The amount of hours the participant met the goal divided by 84 hours per week (12 hours per day multiplied by seven days per week) was equivalent to the percentage in which the intervention goal was met each week for four weeks. To determine if a participant in Group 2 met the intervention goal, active minutes for each day were added and totaled for one week (Fitbit® data). The total minutes accumulated each week were then
divided by the goal of 150 minutes per week to obtain the percentage of time in which the goal each week for the four-week intervention was met.

Data was descriptively examined, as the sample size for this study was small (n=8) and no significant differences could be accurately detected. Data means, standard deviations and effect sizes were calculated. Effect sizes were calculated by taking the Group 3 mean minus the intervention mean (pooled together) and divided by the pooled standard deviations (standard deviations of the usual care plus standard deviation of the interventions) divided by two. Effect sizes of 0.2, 0.5 and 0.8 were categorized as small, moderate and large effects, respectively.85
CHAPTER 4. RESULTS

Participants

As part of BUP, participants (n=11) were randomized to one of three groups: Group 1 (n = 5), Group 2 (n = 3) and Group 3 (n = 3) (Figure 7). Three women were lost to follow-up (n=1 SenseWear® armband sensitivity issue; n=2 Jawbone PA monitor was initially utilized at the beginning of the study, but transitioned to Fitbit® band use for the remainder of the study), leaving eight women that completed the study. The PA monitor transition occurred as the Fitbit® provided more information regarding participant SB and had a reliable idle alert feature. Participants (n=8) were on average 32.9 ± 3.6 years old, married (89%), White (100%), and college educated (100%; bachelor’s degree, 50%, bachelors and graduate/professional degree, 50%). Participants on average had a pre-pregnancy body mass index (BMI) of 28.8kg/m² (overweight; BMI classifications: underweight: n=0; normal: n=3; overweight: n=1; obese I: n=3; obese class II: n=1). On average participants had 1.75 ± 1.2 live births while one participant was nulliparous.
Figure 7 – BUP Consort Diagram

SB

Average total SB, reported as data extracted from Actiparse, demonstrates that one participant in each group decreased SB from baseline to final. One participant in Group 1 spent an average of 781.63 ± 91.59 minutes per day at baseline and 753.24 ± 122 minutes per day at final data collection in SB resulting in a -3.63% change. A participant in Group 2 spent an average of 647.43 ± 88.20 minutes per day at baseline and 621.03 ± 136.05 minutes per day at final data collection in SB, resulting in a -4.07% change. Finally, a participant in Group 3 spent an average of 614.68 ± 120.24 minutes
per day at baseline and $530.10 \pm 138.54$ minutes per day at final data collection in SB, resulting in a $-13.75\%$ change (Figure 8). This data descriptively demonstrates that despite the group participants were randomized to, these three participants decreased time spent sedentary.

Figure 8 – Individual Participant Change in Sedentary Behavior From Baseline to Final Data Collection

Utilizing Actiparse, SB was also broken up into time spent sedentary in $\geq 60$ minute bouts. Data was analyzed in time spent in bouts $\geq 60$ minutes, as previously unpublished Blossom Project analysis demonstrated an association between prolonged bouts $\geq 60$ minutes and higher fasting blood glucose levels. By examining the data descriptively, when Group 1 was asked to break-up prolonged SB, this group, decreased time spent in bouts of $\geq 60$ minutes ($152.40 \pm 103.34$ minutes baseline, $133.18 \pm 19.88$ minutes final data collection). The same is true of Group 2 ($202.55 \pm 60.51$ minutes
baseline, $175.02 \pm 89.84$ minutes final data collection). However, Group 3 (UC) increased time spent in bouts $\geq$ 60 minutes ($203.95 \pm 92.89$ minutes baseline, $224.69 \pm 132.18$ minutes final data collection) (Figure 9). Additionally, when examining effect size of both interventions compared to usual care, a moderate effect size was demonstrated (0.66).

![Graph showing Prolonged Sedentary Behavior in ≥ 60 minute bouts](image)

**Figure 9 – Group Change in Prolonged Sedentary Behavior in ≥ 60 minute bouts**

MVPA minutes were analyzed, as the Department of Health and Human Services (DHHS) recommends 150 minutes of MVPA be accumulated per week during pregnancy. On average, Group 1 (Idle), decreased minutes of MVPA from baseline ($132 \pm 96.16$ minutes) to final ($40.5 \pm 34.64$ minutes) data collection. On average, participants collectively in Groups 2 (Walk; $16.66 \pm 22.30$ minutes baseline; $53.66 \pm 85.27$ minutes final) and 3 (UC; $73.33 \pm 62.26$ minutes baseline; $84.33 \pm 84.67$ minutes final) increased
PA of this intensity (Figure 10). Additionally, when comparing the intervention groups to the usual care group, a small effect size was detected (.48).

**Figure 10 – Group Change in minutes of MVPA**

**Goal attainment for group 1 and group 2 (Fitbit® self-regulation tool)**

Individuals in Group 1 (n=2) were asked to accumulate 250 steps per hour for 12 hours per day for 4 weeks of the intervention (84 total hours per week). Data collected from the participants’ assigned Fitbit® demonstrates that one participant met the goal ≥ 90.4% of the time during the four-week intervention. The second participant in Group 1, met the goal ≥ 58.4% of the time (Figure 11). Group 1’s variability for meeting the specified goal ranged from 58.4-98.8% (minimum; maximum, respectively).
Group 2 (n=3) was asked to meet current prenatal PA guidelines and accumulate 150 minutes per week for four weeks of the intervention. Data collected from the Fitbit® demonstrates that one participant in this group met the goal 68.6%, 14.6%, 0% and 0% during weeks 2-5, respectively. The second participant exceeded the goal each week evidenced by meeting the goal 172%, 213%, 138% and 168% during weeks 2-5, respectively. Finally, the third participant met the goal 43.3%, 34.6%, 23.3% and 57.3% of the time during weeks 2-5, respectively (Figure 12). Group 2 had a larger variability (minimum-maximum; 0-213%) in regards to meeting the specified goal during the four-week intervention.
Figure 12 - Group 2 Participant’s Ability to Meet the Goal

Blood glucose

Descriptively, there appears to be a positive relationship between increased SB and higher fasting, 60 and 120 minute blood glucose levels. (Figure 13-15). One participant did not pass the OGTT between 24-28 weeks gestation, whereas seven out of the eight participants did. Group 3 (UC) had the lowest fasted blood glucose levels (83 ± 4 mg/dL) followed by Group 1 (85 ± 3 mg/dL) and Group 2 (88 ± 11 mg/dL), respectively. However, at 60 and 120 minutes, respectively, Group 2 (128 ± 32 mg/dL; 107 ± 41 mg/dL) had the lowest blood glucose levels followed by Group 1 (138 ± 8 mg/dL; 116 ± 15 mg/dL) and Group 3 (150 ± 11 mg/dL; 123 ± 9 mg/dL).
Figure 13 – All Participants Fasted Blood Glucose Values and Sedentary Behavior

Figure 14 – All Participants 1-Hour Blood Glucose Values and Sedentary Behavior
Figure 15 – All Participants 2-hour Blood Glucose Values and Sedentary Behavior

Diet

Similar to blood glucose results, a positive relationship is present between participants that spent more time sedentary and increased calorie consumption (Figure 16). On average, participants in Group 2 (Walk) consumed the most calories (2150 ± 505 kcal) followed by Group 1 (Idle; 2077 ± 38 kcal) and Group 3 (UC; 1982 ± 1135 kcal) at final data collection.
Figure 16 – All Participants Calorie Intake and Sedentary Behavior

Gestational weight gain

According to the 2009 Institute to Medicine (IOM) weight gain guidelines, one participant was under the recommendation, one participant met the recommendation and six participants exceeded the weight gain recommendations at final data collection. By group (1, 2, 3) 1 out of 2, 3 out of 3, and 2 out of 3 participants exceeded specified IOM recommendations, respectively. When women were randomized to Group 2 (Walk), all of the participants (n=3) exceeded specified weight gain recommendations (Figure 17).
Figure 17 – Participants Weight Gain in Comparison to the 2009 Institute of Medicine Guidelines
CHAPTER 5. CONCLUSION

Pregnancy is a stage in life in which women have been encouraged to adopt healthier lifestyles for the benefit of both mother and baby.\textsuperscript{1,2} A variety of topics that may influence healthful behavior include: SB, PA, glucose tolerance, diet and gestational weight gain.\textsuperscript{3,4,43} The current, three-armed randomized controlled trial provided information on those aforementioned subjects.

Sedentary Behavior

The assessment of SB in pregnant women was the primary outcome of this study, as research shows this behavior is associated with negative health implications.\textsuperscript{3,43} Descriptive results from BUP demonstrate despite the group (group 1, 2, 3) participants were randomized to, a participant from each group was able to decrease SB. This yields the idea that the approach pregnant women take to decreasing sedentary activity is individualized and one method may not be equally attainable for all.

It appears that participants in both intervention groups were able to decrease prolonged SB in bouts > 60 minutes. Meanwhile, Group 3 (UC) increased prolonged SB in > 60 minutes, demonstrating that both interventions were successful at decreasing SB in prolonged bouts, while the participants that were left to self-manage, worsened this prolonged SB. This finding is also supported by the moderate effect size demonstrated between the interventions and usual care group. It is important to note that the UC group was not able to decrease the pattern of prolonged SB, as these participants would be less likely to reap the benefits associated with breaking up this behavior. As previously mentioned research with non-pregnant adults demonstrates breaks in SB
contribute to lower fasting blood glucose levels, reductions in insulin area under curve, lower BMI and waist circumference.\textsuperscript{10-12} BUP was the first pregnancy randomized controlled trial evaluating different strategies to decrease SB. In the non-pregnant population, research breaking up prolonged sedentary activity with short walking breaks and intentional walking have been carried out. Dunstan et al. found that when participants rose to complete 2-minute walking bouts of light or moderate intensity activity every 20 minutes, for 5 hours, participants had lower glucose responses and a reduction in iAUC, compared to when participants continually sat for 5 hours.\textsuperscript{11} Additionally, preliminary evidence from Healy et al. demonstrate that breaking up prolonged bouts of sitting is beneficially associated with various health markers (e.g. BMI, waist circumference, glucose tolerance and triglycerides). The authors call attention to the idea that benefits of breaking up prolonged SB go beyond the health implications found in the study; less time spent sedentary may mean more time spent in light and/or moderate-vigorous activity. Hypothetically, not only would individuals decrease time spent sedentary and reduce the negative health implications associated with SB, individuals would also increase PA and the associated health benefits.

**Physical Activity**

MVPA was evaluated, as the Department of Health and Human Services recommends 150 minutes of MVPA be achieved each week.\textsuperscript{22} In the evaluation of MVPA, a small effect size was demonstrated between the interventions and usual care group. Additionally, Group 1 participants decreased minutes spent in MVPA, whereas Group 2 and Group 3 increased this intensity and engagement of PA. Group 2’s increase
corresponds with the goal of walking 30 minutes on most days of the week and is positive, as 45% of pregnant women report not engaging in exercise at least three times per week during pregnancy.\textsuperscript{17} Regarding PA interventions in pregnancy, Smith et al. report a significant (P < 0.0001) increase in intentional walking when participants were randomized to a behaviorally-based online intervention and asked to walk at least 150 minutes per week. On average, 31.8% of the intervention group met the goal of accumulating at least 150 minutes of PA per week, as reported on the associated study website.\textsuperscript{86} Additionally, in the Behaviors Affecting Baby and You (BABY) Study, participants that were randomized to the 12-week exercise intervention (encouraging pregnant women to achieve at least 30 minutes of moderate-intensity activity most days of the week), had significantly greater increases in sports or exercise activity (P < 0.001) and were more likely to achieve guidelines for PA (odds ratio = 2.12; 95% CI = 1.45 – 3.10).\textsuperscript{87} Cumulatively, this research demonstrates that when participants are asked to increase intentional walking via PA interventions, participants have the ability to do so and follow through with the specified intervention.

\textbf{Goal attainment for group 1 and group 2 (Fitbit® self-regulation tool)}

Utilizing Fitbit® data, Group 1 (Idle), more easily met the set goal (250 steps per hour for 12 hours per day for the four-week intervention) than did the walking group (walking 150 minutes per week for the four-week intervention). This finding aligns with the perceived barriers to PA women face during pregnancy. Breaking up time spent in SB with short walks may seem like a more attainable goal to prevent prolonged sitting as it is likely to be perceived as a less taxing and intimidating activity such that a 30-
minute walk bears. Short bouts of walking avoid the reported PA barriers such as lack of time, enjoyment and feelings of exhaustion.\textsuperscript{19, 20} Additionally, insufficient activity was observed among women who had at least one child in the home, had a lack of child care and worked $\geq 45$ hours per week.\textsuperscript{88} To overcome these additional barriers to PA, pregnant mothers can utilize short walks to break up sedentary activity while at work and at home. Rather than taking a 20-30-minute walk away from children, simple activities such as getting up and walking during commercial breaks, getting up for frequent bathroom breaks and playing with children rather than watching TV may be more attainable ways to decrease SB when a time constraint exists and children are present.

**Blood glucose**

Group 3 (UC) had the lowest fasting blood glucose levels, however at 60 and 120 minutes, blood glucose levels were among the highest. Both interventions (Group 1 and 2) demonstrated the lowest blood glucose levels at 60 and 120 minutes. It is important to note the interventions may have assisted in lowering blood glucose levels at the 60- and 120-minute mark, as keeping blood glucose levels within targeted range wards of GDM. Similarly, when participants engaged in a non-fasting 50-gram OGTT as a part of Project Viva, a sedentary lifestyle was associated with abnormal glucose tolerance and thus increased risk for GDM.\textsuperscript{3} Additionally, Gollenberg et al. reports similar findings in pregnant Latina women; when participants engaged in high levels of SB, elevated glucose levels were present at mid-pregnancy (24-28 weeks gestation).\textsuperscript{60} If a GDM
diagnosis can be avoided during pregnancy, the vicious cycle of developing type two diabetes mellitus in mother and baby post-delivery can also be halted.\textsuperscript{89, 52, 57}

\textbf{Diet}

In regards to energy intake, participants in Group 3 (UC) consumed the least amount of calories and Group 2 (Walk) consumed the most calories. Women in the intervention groups consumed more calories than women randomized to the UC group. Group 2 was asked to meet current prenatal PA guidelines of walking 30 minutes per day on most days of the week. Similar to results from another Blossom Project study, the women who were asked to increase intentional walking (intervention group), also inadvertently increased calorie consumption.\textsuperscript{86} This information demonstrates that when interventions instruct women to increase intentional PA, a compensatory effect of increasing calorie consumption may occur.

Additionally, a review authored by Blair, et al. reports that individuals who are more physically active, have higher calorie intakes than inactive individuals.\textsuperscript{90} A crossover study conducted by Finlayson et al. had non-pregnant females engage in 50 minutes of high-intensity activity and no exercise at all at two different time points. Energy intake was measured among other subjective measures. Although not statistically significant, following exercise, energy consumption at the ad lib meal was higher (1128.2 ± 72.8 kcals) than when participants did not exercise (1018.1 ± 73.0 kcals).\textsuperscript{91} Although the reason for increased calorie consumption is not completely understood, it may be, that participants in these intervention groups felt they were engaging in more PA, leading them to believe they can/should consume more calories.
Limitations and future studies

Limitations of this study include a small sample size (n=8) and little diversity within the population (college educated, Caucasian and married). The intervention of this study was not performed during the final week of data collection (week 6), as participants were blinded to the self-monitoring assessment tool (Fitbit®). Therefore, the true effects of the intervention were not determined and instead, the assessment of whether or not the participants could continue with the specified intervention was evaluated. Finally, during baseline data collection, a participant in group 1 had the Fitbit® idle alert activated, therefore her baseline data may have been influenced. If this study were to be carried forward, to fully understand the effects of the two interventions (Idle and Walk), the idle alert feature of the Fitbit® should be completely deactivated during baseline data collection and participants should not be blinded to the self-monitoring assessment tool during final data collection (week 6). Additionally, a larger and more diverse population would be needed to better evaluate the most effective strategy to reduce SB during pregnancy.

For future studies, it would be important to understand why recruitment was difficult for BUP and how to make a similar study more attractive for potential participants. BUP’s recruitment may have been difficult as there were two studies being conducted at the same time in The Blossom Project Lab. One study captured women between 10-14 weeks gestation, therefore women that could/would have been interested in BUP were enrolled in a different study. It’s also been suggested that women dislike undergoing two OGTTs during the same pregnancy; one for the research
study, the other for clinical practice. If the participant’s provider did not accept BUP’s OGTT results, the woman typically needed to undergo an additional OGTT for her provider. Therefore, it may be more beneficial to The Blossom Project lab to accept the results of the physician; by doing this, the lab decreases costs and the study may become more attractive to potential participants. Finally, BUP was advertised as a study targeting PA. If the detrimental effects of SB were more heavily publicized and became an even larger public health concern, it may be beneficial to advertise future studies as SB interventions, instead of PA interventions, as more women may view an intervention working to decrease SB as beneficial for not only herself but her baby, as well.

**Conclusion**

Descriptive results from BUP suggest that when participants have high sedentary time, more calories were consumed and higher fasting, 60 and 120-minute blood glucose levels were demonstrated. This data indicates that when participants sat more, calorie consumption increased; a metabolic relationship was also present between increased SB and poorer blood glucose levels. Provided this information, future studies are needed to identify the best strategy to decrease SB in pregnant women. This study should be executed with a larger sample size to determine if breaking up prolonged SB is a more successful method for decreasing this behavior throughout the day than is meeting current prenatal PA guidelines. It may also be possible to explore utilizing motivational interviewing techniques to assist individuals with the goal of decreasing SB.

Motivational interviewing is a counseling style that assists in eliciting self-motivational statements from participants, with the idea that individuals themselves
find the best solution to facilitate a given behavior change.\textsuperscript{92} Regarding SB, motivational interviewing may yield a higher success rate than either or both of the proposed methods used in BUP as it uses the individual’s own self-motivation and ideas regarding how to successfully decrease SB.

The study described in this thesis, BlossomUP explored two methods as ways to decrease SB in pregnant women. This study helped continue to lay the foundation for the need of further research regarding pregnancy and SB. Both the use of continued randomized controlled trials and possible implementation of motivational interviewing will continue to provide insight, advance the scientific literature regarding this topic and has the opportunity to lead to healthier pregnancies and in turn, a healthier future.
REFERENCES


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86. Smith K. 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. Ames, Iowa: Food Science Human Nutrition, Iowa State University; 2014.


92. Enhancing Motivation for Change in Substance Abuse Treatment: Substance Abuse and Mental Health Services Administration (US); 1999.
## APPENDIX A. SEDENTARY BEHAVIOR AND PREGNANCY RESEARCH STUDIES

<table>
<thead>
<tr>
<th>Authors</th>
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<tr>
<td>Oken et al, 2006&lt;sup&gt;3&lt;/sup&gt;</td>
<td>n=1,805 Prospective cohort Eastern Massachusetts</td>
<td>Associations of PA and TV viewing with risk of GDM and abnormal glucose tolerance before and after pregnancy</td>
<td>At initial visit (average of 10.4 weeks gestation), questionnaire completed evaluating PA &amp; TV viewing habits over the last 12 months before pregnancy. At 26-28 weeks gestation the same questionnaire regarding the last 3 months was completed. Sedentary lifestyle was defined as 2 or fewer weekly hours of total PA</td>
<td>Sedentary lifestyle increased from 13% (before pregnancy) to 21% (during pregnancy). Non-sedentary lifestyle decreased from 87% (before pregnancy) to 79% (during pregnancy). Television viewing for &lt;13 hours and &gt;14 hours remained constant at 66% (before and during pregnancy) and 34% (before and during pregnancy), respectively. Sedentary lifestyle before and during pregnancy was associated with abnormal glucose tolerance and risk for GDM</td>
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<tr>
<td>Gollenberg et al, 2010&lt;sup&gt;60&lt;/sup&gt;</td>
<td>n=1231 Prospective cohort Western Massachusetts</td>
<td>Association between SB and glucose intolerance during pregnancy in Latina women</td>
<td>Interviewers utilized a modified version of the Kaiser PA Survey capturing pre-pregnancy (1 year before pregnancy), early pregnancy (since pregnancy onset) and mid-pregnancy (24-28 weeks gestation) behaviors</td>
<td>High total SB (high amounts of TV viewing, sitting at work, low amounts of exercise) associated with elevated glucose during mid-pregnancy (P=0.038). SB during pre-pregnancy and early pregnancy not significantly associated with glucose levels</td>
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<tr>
<td>Gradmark et al, 2011&lt;sup&gt;39&lt;/sup&gt;</td>
<td>n=108; 35 pregnant, 73 non-pregnant Cross-sectional Sweden</td>
<td>Evaluate insulin sensitivity/beta cell response in relationship to subcomponents of PA</td>
<td>Actiheart accelerometer worn 4 days (28-32 weeks gestation)</td>
<td>ST significantly higher in pregnant women (55.5% wear time) than non-pregnant women (49.2%) P=&lt;0.0001. Associations between SB, insulin sensitivity and beta cell response were not significantly different</td>
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<tr>
<td>Evenson et al, 2011^40</td>
<td>359</td>
<td>Cross-sectional United States; NHANES data</td>
<td>Examine PA and SB in pregnant women</td>
<td>Average of 57.1% of time spent in SB. Average sedentary minutes/day during first, second and third trimester: 422.7, 427.6 and 423.2, respectively</td>
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<td>Reid et al, 2014^23</td>
<td>100</td>
<td>Parallel-group cross-sectional Northern Ireland</td>
<td>Explore relationship between PA/SB and the risk of fetal macrosomia in uncomplicated pregnancies</td>
<td>ST in hours at ≤ 1MET was 16.1 and 13.8, for study (those predicted to birth infants &gt;4000g) and control groups (predicted to birth infants &lt;4000g), respectively. Macrosomic infants were born to women who spent significantly more time at ≤ 1METs than women who delivered infants &lt;4000g</td>
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<td>Ruifrock et al, 2014^56</td>
<td>111</td>
<td>Secondary analysis of data from two randomized controlled trial prospective studies Netherlands</td>
<td>Evaluate relationship between PA/SB and gestational weight gain and birth weight</td>
<td>Average SB min/day was 530 and 505 for 15 weeks and 32-35 weeks, respectively. No significant associations found between SB and GWG or birth weight</td>
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<td>Di Fabio et al, 2015^51</td>
<td>46</td>
<td>Prospective longitudinal Iowa</td>
<td>Quantify and evaluate SB and PA during 2nd and 3rd trimesters and evaluate activity habits for women</td>
<td>SB during 2nd and 3rd trimesters stayed relatively consistent at 52% and 54%, respectively. No significant differences at week 18 in ST between women who met PA guidelines and those that did not, however at week 35, women who met PA guidelines engaged in significantly less SB</td>
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<tr>
<td>Huberty et al, 2016&lt;sup&gt;42&lt;/sup&gt;</td>
<td>n=80</td>
<td>Observational study based on randomized controlled trial data Southwestern United States</td>
<td>Evaluate daily PA and SB in different weight statuses of pregnant women</td>
<td>Fitbit® worn 8-16 weeks gestation until 36-40 weeks gestation (or end of pregnancy)</td>
</tr>
</tbody>
</table>
The Blossom Project Recruiting Email

Hi

Thank you for your interest in The Blossom Project! My name is [INSERT NAME HERE] and I am the recruitment coordinator for The Blossom Project at Iowa State University. I am replying to you in regards to your inquiry about the project.

The overall objective of The Blossom Project is to assess dietary intake and physical activity during pregnancy. We currently have multiple research studies in process, each having their own qualification criteria. To help us better assess which research study you qualify for, there are a short series of questions that you will be asked to answer, taking less than five minutes to complete.

**What are the possible risks and benefits of answering these questions?**
There are no risks associated with answering these questions. By providing answers to the questions below, we are able to efficiently screen participants for the research studies and minimize the amount of visits you need to make to the research center.

**What measures will be taken to ensure the confidentiality of the responses or to protect my privacy?**
Your responses 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 (ISU), 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 responses may contain private information. To ensure confidentiality to the extent allowed by law, the following measures will be taken. Participant email responses will be stored in a specific email folder within the Blossom Project Iowa State University email account. This email account is only accessible by password to the Primary Investigator and the Recruitment Coordinator. The data obtained from the screening process will be regarded as privileged and confidential.

**What are my rights as a human research participant?**
Participating in this screening questionnaire is completely voluntary. Your choice of whether or not to participate will have no impact on you as a student/employee in any way (if applicable). You may skip any question during the questionnaire.

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

- For further information about the study contact the recruitment coordinator at blossomproject@iastate.edu or 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.

The following questions will allow us to more efficiently assess which study you qualify for. If you are interested in participating in a research study, could you please answer the following questions? By replying to this email, you consent to provide this information.

1) Are you between the ages of 18-45?
2) Are you currently a smoker?
3) Are you having multiples (ie. twins, etc)?
4) Do you have any history of chronic disease or blood clotting disorders (type 2 diabetes, thyroid disorders, heart disease, kidney disease, high blood pressure, etc)?
5) Prior to becoming pregnant, did you participate in any physical activity outside of your normal daily activity?
6) If so, please summarize your regular weekly activity routine and state how long you had been doing this amount of physical activity prior to pregnancy?
7) What is a phone number at which you could be reached?
8) How did you hear about The Blossom Project?
9) Where will you be delivering?
10) Height:
11) Pre-pregnancy weight:
12) Have you been diagnosed with Gestational Diabetes in a previous pregnancy?
13) Have you been diagnosed with Gestational Diabetes in your current pregnancy?
14) Have you been diagnosed with pre-eclampsia or eclampsia in a previous pregnancy?
15) What is your due date?

Thank you and we look forward to hearing from you!

[INSERT NAME HERE]
Blossom Project: Recruitment Coordinator
Iowa State University
blossomproject@iastate.edu
515-294-8673

ISU IRB #1 11-388
Approved Date: 22 September 2016
Expiration Date: 24 September 2017
We are currently recruiting pregnant women for several research studies. General qualification criteria include the following:

- 18-45 years old
- Pregnant with only one baby
- Non-smoking
- No history of chronic disease (e.g. DM1, CVD, CRF, Untreated thyroid condition)
- Able to communicate without language or mental status barriers

Participation is voluntary. Compensation is provided and varies based on the study. For further information contact the Recruitment Team at: blossomproject@iastate.edu or 515-294-8673.

ISU IRB #1: 11-388
Approved Date: 22 September 2016
Expiration date: 24 September 2017
**PREGNANT WOMEN NEEDED!**

*We are conducting a research study using physical activity to promote improved health outcomes in pregnant women.*

QUALIFICATION CRITERIA INCLUDES:
• Must be pregnant between 16 and 22 weeks of gestation and between the ages of 18-45
• Not a smoker
• BMI less than 40kg/m²
• Not pregnant with multiple babies (e.g. twins)
• No history of the following chronic diseases: Type 1 diabetes, heart disease or renal disease
• Low-active or sedentary lifestyle prior to pregnancy (<3 30-minute intentional exercise sessions)
• Able to comprehend the information shared during the informed consent process
• Approval from your medical provider confirming you meet the qualification criteria will be required

A maximum of 2 data collection periods required. If asked, participant willing to walk 30 minutes on most days of the week. Eligible participants will be compensated. Participation is voluntary.

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

A program to promote a physically active lifestyle in pregnant women

WHAT YOU MAY RECEIVE:

• A Fitbit Alta for the duration of the intervention

• Eligible participants may be compensated with $75.00 in the form of cash and giftcards

WHAT YOU WILL BE ASKED TO DO:

• Limit time spent sitting

• Meet current pregnancy physical activity recommendations

• Continue with normal daily routine

FOR FURTHER INFORMATION:

Contact the Recruitment Team at blossomproject@iastate.edu or at 515-294-8673
Are you or is someone you know PREGNANT?

The Blossom Project

“BlossomUP”

A program to promote a physically active lifestyle in pregnant women

WHAT YOU MAY RECEIVE:

• A Fitbit Alta for the duration of the intervention
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• Continue with normal daily routine

FOR FURTHER INFORMATION:
Contact the Recruitment Team at blossomproject@iastate.edu or at 515-294-8673
Be part of

The Blossom Project

Improving the lives of women and their babies...
one pregnancy at a time

If you or is someone you know is PREGNANT, contact us. We are currently recruiting for several research studies promoting physical activity and healthful eating. Eligible participants will be compensated. Recruitment is ongoing.
Participation is voluntary.

General Eligibility Criteria:
Less than 22 weeks pregnant and not pregnant with multiples (e.g. twins)

Not a smoker
Low level of activity prior to pregnancy (<3 30 minute exercise sessions per week)

For further information:
Email the Recruitment Team at blossomproject@iastate.edu
or call 515-294-8673
Be part of

The Blossom Project

Improving the lives of women and their babies...
one pregnancy at a time

If you or is someone you know is PREGNANT, contact us.
We are currently recruiting for several research studies promoting physical activity
and
healthful eating.
Eligible participants will be compensated. Recruitment is ongoing.
Participation is voluntary.

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Less than 22 weeks pregnant and not pregnant with multiples (e.g. twins)
Not a smoker
Low level of activity prior to pregnancy (<3 30 minute exercise sessions per week)

For further information:
Email the Recruitment Team at blossomproject@iastate.edu
or call 515-294-8673
The Blossom Project “BlossomUP” 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 increase physical activity. If you agree to participate in this study you will be randomized to one of three groups:

- Group 1: will be asked to limit time spent sitting
- Group 2: will be asked to meet current pregnancy physical activity recommendations
- Group 3: will be asked to continue their normal daily routine

During your time in the study you will also be given a Fitbit Alta activity monitor to help you keep track of your activity. This is provided to you at no cost.

Individuals in all three 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.

You will visit the research center at ISU for 2 data collection periods at the start of week one and week six.

During the two 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
- Between weeks 24-28 you will complete a 2-hour oral glucose tolerance test at our research facility

To qualify for our study you must be:

- Between 18-45 years of age;
- Pregnant between 16 and 22 weeks of gestation;
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of the following chronic diseases: Type 1 diabetes, heart disease or renal disease
- Low-active or sedentary lifestyle prior to pregnancy (< 3 30-minute intentional exercise sessions per week);
- BMI less than 40 kg/m²;
- Able to comprehend the information shared during the informed consent process.
For your participation, you will receive $75.00 in the form of cash and giftcards following completion of the study and return of all equipment.

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 clmck@iastate.edu if you have further questions. Let me know if you would like to participate or not. 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!

Caroline McKinney  
BlossomUP Study Coordinator  
Iowa State University  
515-294-8673  
clmck@iastate.edu  
blossomproject@iastate.edu
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 aim of our study is to increase physical activity in pregnant women. If you agree to participate in this study, you will be randomized to one of three groups after you have completed the first “baseline” data collection (described below). Group 1 will be asked to sit less each day; Group 2 will be asked to meet current physical activity recommendations for pregnant women; Group 3 will continue with their daily routine as this is the usual care group.

**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 between 16 and 22 weeks of gestation;
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of Type 1 diabetes, heart disease or renal disease
- Low-active or sedentary lifestyle prior to pregnancy (< 3 30-minute intentional exercise sessions per week);
- BMI less than 40 kg/m^2;
- Able to comprehend the information shared during the informed consent process.

**Regardless of group assignment, 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 that you are healthy enough to participate in this study from your medical provider. 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 before you begin any participation in the study.

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. If you have any known metal allergies or implanted electromagnetic devices you will not be able to participate in this study due to possible adverse effects when using the Sensewear® armband monitor.

**First week (week 1) and Last week (week 6) of the study:**

Your participation in this study will last no more than seven weeks. Baseline data collection occurs during week 1 of the study and the second data collection is during the last week of the study (week 6). Each data collection period (weeks 1 and 6) requires two visits (data initiation [described below] and return of equipment). A data collection period is for 8 days (see details below). 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. The initial meeting to receive instructions regarding the physical activity and diet data collection and complete the medical questionnaire will last 60-75 minutes; the subsequent data initiation meeting will last approximately 30 minutes.

During each data initiation visit (week 1 and week 6 of the study) you will be given two activity monitors and the equipment needed to collect a weighed 3-day diet record. Your height and weight will be measured.

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 monitor 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, including studies with pregnant women, with minimal complaints.

You will be provided with an **activPAL™ activity monitor** that is worn on the upper leg over the quadriceps muscle and will be attached to your leg using an adhesive pad. The activPAL will be worn for 8 days, 24 hours a day except when showering and swimming since it is not waterproof. We have previously used this activity monitor in Blossom Project studies with minimal complaints.

The 8-day **physical activity record** requires you to record all of your daily activities for 24 hours 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 verbal and
written 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, 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.

During both initiation visits, you will arrange a time with a project staff member to turn in your data collection bag and all materials (all monitors, 3dDR, scale, etc.) at the completion of both 8-day data collection period.

**Prenatal Weight**
Your weight will be measured at your first obstetric prenatal visit by your health care provider. Your weight will be recorded on a “Prenatal Weight” form that you will be asked to sign at the beginning of the study. Your medical provider will fax the “Prenatal Weight” form to the Blossom Project Staff. Additionally, your weight will be measured and recorded by a Blossom Project Staff member at week 1, the initial data collection period and week 6, at the end of the study.

**Six-Week Intervention**
During the six-week intervention, you will be provided with a wrist-worn activity monitor called a Fitbit Alta. You will be asked to wear this daily (remove when showering or swimming). A Blossom Project staff member will provide you with a Fitbit account and help you set up the application on your external device (e.g. iPhone or laptop) at the completion of week 1 baseline data collection and when randomized to a specific group.

Additionally, you will be responsible for charging your Fitbit Alta every five days. If you are having any difficulties with your monitor, please contact the Blossom Project staff immediately. You will be asked to return the monitor at the completion of the study (week 6).

**Between weeks 24-28 of your pregnancy:**
Oral Glucose Tolerance Test: Data collection will also include completion of an oral glucose tolerance test to assess how well your body can decrease sugar from your blood; this is a measure of insulin resistance. This is a test that is conducted during all pregnancies. Your medical provider may accept the results of our test instead of requiring you to complete another; you will need to confirm this with your provider. If you would like the Blossom Project Staff to send the results to your medical provider, you will need to sign the document, “Request for Oral Glucose Tolerance Test Results” and then the research staff can fax the test results to your medical provider. 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), and blood samples at 60 and 120 minutes following consumption of a 75g oral glucose solution. During this 2-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.

**If you are randomized to Group 1:**
The idle alert function of your Alta will be activated so you will feel your band vibrate every 50 minutes. You are being asked to accumulate 250 steps every hour for 12 hours
(times will be set based on your waking and bedtime).

**If you are randomized to Group 2:**
You are being asked to meet current pregnancy physical activity recommendations; walking 30 minutes on most days of the week for a total of 150 minutes per week. You will use the app to view your “active minutes”.

**If you are randomized to Group 3:**
You are being asked to continue with your normal daily routine.

**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. To avoid skin irritation with the Fitbit wrist-worn monitor keep the backside of the monitor and wristband clean. Use a cotton ball with rubbing alcohol and gently swipe the metal back of the monitor and the portion of the band that touches your skin. Do not immerse the monitor in water. Additionally, do not wear the monitor tightly; allow for space between your wrist and the monitor.

**Benefits** – You may increase your physical activity. We hope that this research will benefit society by generating data that may contribute to further understanding the health benefits of being physically active 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 and completion of all data collection (six week intervention), you will receive $75.00 in the form of cash and giftcards. If your doctor advises you to withdraw from the study following the completion of the first data collection period and prior to the final data collection period, you will receive $20.00 (if all records are complete).

**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.

**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 the medical history questionnaire. 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) 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, 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)
Dear Medical Provider,

_____________________________ has volunteered to participate in a research study that promotes a physically active lifestyle through decreasing sedentary time and increasing physical activity. If assigned to group 1, your patient will be asked to reduce sedentary time, specifically sitting time, by interrupting prolonged bouts of sitting, as monitored by the Fitbit Alta. Participants in group 2 will be asked to increase moderate physical activity by taking a 30 minute walk on most days of the week. Participants in group 3 will be asked to continue their normal daily routine. This is a 6-week intervention. At baseline (week 1) and at the end of the study (week 6), your patient will complete an 8-day data collection period. During each data collection period, your patient will be weighed, wear a SenseWear® Mini physical activity armband, an accelerometer-based posture monitor known as the activPAL and complete an 8-day physical activity record and a 3-day weighed food record. Between weeks 24-28 of pregnancy, she will undergo a 2-hour, 75 gram oral glucose tolerance test to assess insulin sensitivity. If your patient would like for us to send the results to you, after obtaining her permission, we will do so via fax.

We request you provide us with the participant’s weight at her first prenatal appointment. We will fax you an additional form to record the participant’s first prenatal appointment weight on and please return the fax to the Blossom Project at Iowa State University. 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;
• BMI less than 40 kg/m^2;
• Pregnant with only one baby;
• Non-smoker;
• No history of Type 1 diabetes, heart disease or renal disease
• No physical restrictions to engage in a 30 minute walk most days of the week;
• Able to comprehend the information shared during the informed consent process.

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
Dear Medical Provider,

_____________________________ has consented to participating in a study to observe total sedentary time and physical activity during their pregnancy. We are asking that you provide us with the participant’s weight at the first prenatal appointment, record it on this document and fax it to the Blossom Project at Iowa State University. This study is approved by the Iowa State University Institutional Review Board.

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
campbel@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:____________________
Medical History Questionnaire – Blossom Project: BlossomUP

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

Weight when you found out you were pregnant:________________________ lbs

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 this is not your first pregnancy and number of pregnancies and 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

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?____________________

Your average number of workouts per week (if any) prior to pregnancy?_____

Average duration of workout____________________

Type of activity

____________________________________________________

Your average number of workouts per week (if any) since becoming pregnant?____

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?_______________________________

Have you met or seen your medical provider since becoming pregnant? Yes No

If yes, please answer the following two questions: If no, do you have an appointment scheduled and if so, when?:
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 gross 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):

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:
BlossomUP Data Sheet

Subject ID: _______________________

DOB:

Due date: ________________________

Handedness:

Visit 1: Enrollment Wks 16-22
Date: ____________________________

Gestation length:

Height (cm): _____________________

Weight (kg):

Visit 2: Wks 24-28
Date: ____________________________

Gestation length:

Weight (kg): _____________________
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
<table>
<thead>
<tr>
<th>B/L/D/S</th>
<th>Time</th>
<th>Food</th>
<th>Constituents</th>
<th>Description</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>9 am</td>
<td>Daily Supplements:</td>
<td>Multivitamin</td>
<td>One a Day multivitamin</td>
<td>1-500 mg capsule</td>
</tr>
<tr>
<td>B</td>
<td>9am</td>
<td>Grape Nuts</td>
<td></td>
<td>Post Brand</td>
<td>120g</td>
</tr>
<tr>
<td>B</td>
<td>9am</td>
<td>Sugar</td>
<td></td>
<td>White</td>
<td>3g</td>
</tr>
<tr>
<td>B</td>
<td>9am</td>
<td>Milk</td>
<td>1%</td>
<td></td>
<td>106g</td>
</tr>
<tr>
<td>S</td>
<td>9am</td>
<td>Blueberries</td>
<td></td>
<td>Frozen, unsweetened</td>
<td>50g</td>
</tr>
<tr>
<td>S</td>
<td>9am</td>
<td>Orange Juice</td>
<td></td>
<td>Tropicana, no pulp, calcium added</td>
<td>120g</td>
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<tr>
<td>S</td>
<td>11:30 am</td>
<td>Almonds</td>
<td>Raw, unsalted, Kirkland brand</td>
<td>60g</td>
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<tr>
<td>L</td>
<td>1:00pm</td>
<td>Sandwich</td>
<td>Bread</td>
<td>Whole Wheat, Wheat Montana</td>
<td>45g</td>
</tr>
<tr>
<td>L</td>
<td>1pm</td>
<td>Sprouts</td>
<td>alfalfa</td>
<td></td>
<td>5g</td>
</tr>
<tr>
<td>L</td>
<td>1pm</td>
<td>Cheese</td>
<td>Tillamook Sharp Cheddar</td>
<td>33g</td>
<td></td>
</tr>
<tr>
<td>L</td>
<td>1pm</td>
<td>Ham</td>
<td>Hillshire Farms Honey Ham</td>
<td>15g</td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>1pm</td>
<td>Cottage Cheese</td>
<td>Low fat 2% small curd</td>
<td>55g</td>
<td></td>
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<tr>
<td>B/L/D/S</td>
<td>Time</td>
<td>Food</td>
<td>Constituents</td>
<td>Description</td>
<td>Weight</td>
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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 it fits your arm comfortably. Ensure it is in 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 Fitbit Alta is a wrist-worn fitness tracker that should be worn on the non-dominant wrist.
  - The monitor will need to be charged once every 4 days during the six week intervention.
  - You are provided with a USB charging cord that connects to a computer.

- 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 7 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 7 days have passed in week one and week six please be sure to make arrangements with a research investigator to return your materials. The armband, Fitbit monitor, 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 7 day period, immediately contact a research investigator.**
Christina Campbell at 515-520-2326 OR Caroline McKinney at clmdsm@gmail.com
<table>
<thead>
<tr>
<th>Start Time</th>
<th>End Time</th>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7am</td>
<td>7:30am</td>
<td>Getting dressed/showering</td>
<td>Up and down stairs 2 to 4 times</td>
</tr>
<tr>
<td>7:30</td>
<td>8:00</td>
<td>Making and Eating Breakfast</td>
<td></td>
</tr>
<tr>
<td>8:00</td>
<td>8:25</td>
<td>Drive to work</td>
<td></td>
</tr>
<tr>
<td>8:25</td>
<td>8:30</td>
<td>Walk from car</td>
<td>Quick walk from parking lot up stairs, one flight, to office</td>
</tr>
<tr>
<td>8:30</td>
<td>12:00pm</td>
<td>Working</td>
<td>Mostly sitting at desk or computer</td>
</tr>
<tr>
<td>12:00</td>
<td>1:00</td>
<td>Eating Lunch</td>
<td>Ate lunch and read a magazine</td>
</tr>
<tr>
<td>1:00</td>
<td>5:00</td>
<td>Working</td>
<td>Mostly sitting at desk or computer</td>
</tr>
<tr>
<td>5:00</td>
<td>5:05</td>
<td>Walk to car</td>
<td>Walk to car in parking lot, down one flight of stairs</td>
</tr>
<tr>
<td>5:05</td>
<td>5:45</td>
<td>Errands</td>
<td>Walking around stores, and driving</td>
</tr>
<tr>
<td>5:45</td>
<td>6:30</td>
<td>Swimming</td>
<td>Lap swim mostly freestyle and backstroke about 1000 yards</td>
</tr>
<tr>
<td>6:30</td>
<td>7:30</td>
<td>Making and eating dinner</td>
<td>Standing in kitchen, sitting at table</td>
</tr>
</tbody>
</table>
APPENDIX E. INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Date: 2/1/2016
To: Dr. Christina Campbell
220 MacKay Hall

From: Office for Responsible Research

Title: The Blossom Project: "BUT UP"

IRB ID: 15-749

Approval Date: 1/29/2016

Date for Continuing Review: 1/4/2017

Submission Type: Now

Review Type: Full Committee

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- Use only the approved study materials in your research, including the recruitment materials and informed consent documents that have the IRB approval stamp.

- Retain signed informed consent documents for 3 years after the close of the study, when documented consent is required.

- Obtain IRB approval prior to implementing any changes to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.

- Immediately inform the IRB of (1) all serious and/or unexpected adverse experiences involving risks to subjects or others; and (2) any other unanticipated problems involving risks to subjects or others.

- Stop all research activity if IRB approval is revoked, unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.

- Complete a new continuing review form at least three to four weeks prior to the date for continuing review as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. Approval from other entities may also be needed. For example, access to data from private records (e.g., student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. IRB approval in no way implies or guarantees that permission from these other entities will be granted.

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1136 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.