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Behaviour Change Intervention Strategies to Prevent Excessive Gestational Weight Gain in Pregnant Women Using a Nutrition and Exercise Lifestyle Intervention Program (NELIP)

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Abstract

Maternal obesity and excessive gestational weight gain (EGWG) are associated with adverse maternal and fetal outcomes. To evaluate the effectiveness of different behaviour change intervention strategies, it was hypothesized that the introduction of a single behaviour change, followed by a second, would be more effective at preventing early and total EGWG in pregnant women compared to the early simultaneous introduction of both behaviour changes. Eighteen pregnant women were block randomized into one of 3 Nutrition and Exercise Lifestyle Intervention Program (NELIP) strategies (full NELIP, Nutrition followed by Exercise N+E, Exercise followed by Nutrition E+N) and were followed at weekly face-to-face meetings with an investigator for the duration of their pregnancy. The women were assessed for weight gain at 24-25 and 36-38 weeks gestation. Following delivery, birth outcome assessment was performed within 6-18 hours. The rates of EGWG were 70% for full NELIP, 89% for N+E and 50% for E+N. The full NELIP and E+N groups had increased physical activity as pregnancy progressed. No difference in dietary habits was observed between groups at each time point during pregnancy. The E+N group had the highest adherence to both the nutrition and exercise components of the NELIP, which may suggest that the E+N strategy is most effective at preventing EGWG in women who are normal weight, overweight and obese.

Keywords

"Excessive gestational weight gain, gestational weight gain, nutrition and pregnancy, exercise and pregnancy, healthy lifestyle intervention, adherence, macrosomia"

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Chapter 1

1. Weight gain during pregnancy

The following chapter will begin by discussing the difference between appropriate and excessive gestational weight gain (EGWG) during pregnancy and the risks associated with EGWG. The chapter will review pregnancy weight gain guidelines, potential pregnancy complications due to EGWG, long-term effects of EGWG on the mother and child, and the cycle of obesity. The latter half of the chapter will focus on obesity management and intervention strategies to prevent EGWG, as well as successful behaviour change strategies from previous interventions. Maternal adherence to prescribed lifestyle change programs will be evaluated, while also considering barriers to healthy lifestyle adoption and a summary of factors that may be incorporated into successful intervention strategies.

1.1 Pregnancy weight gain guidelines for all BMI categories

It has been estimated that 42 to 52.7% of women gain excessive weight during pregnancy (Olson et al., 2003; Pereira et al., 2007). Ensuring appropriate weight gain during pregnancy is important to the health of all pregnant women, particularly because EGWG during pregnancy places women at higher risk for adverse events during pregnancy, including obesity (Rooney et al., 2005), gestational diabetes, hypertension, preeclampsia and caesarean section (Davies et al., 2010). Maternal weight gain during pregnancy, or gestational weight gain, is the weight of the fetus, uterus, amniotic fluid, placenta, increased maternal blood volume, fat mass and lean mass (Cordero et al., 2015a). Anything over and above the required weight gain is gained as fat in the mother (maternal body fat), and termed EGWG. EGWG, defined by the Institute of Medicine (IOM; 2009) as weight that is gained outside of the recommended ranges depending on pre-

pregnancy body mass index (BMI, kg/m^2, a measure of body fat based on weight and height), has been associated with an increased incidence of adverse maternal and fetal outcomes. Regardless of pre-pregnancy BMI, all women are recommended to gain 0.5-2.0 kg in the first trimester (from conception to 12 weeks gestation). Weight gain recommendations in the second (13 to 27 weeks gestation) and third (28 to 40 weeks gestation) trimesters in normal weight women (BMI ≥ 18.5-24.9 kg/m^2) are 0.29-0.45 kg/week, for a total weight gain of 11.5-16.0 kg. Overweight women (BMI ≥ 25.0-29.9 kg/m^2) are expected to gain 0.23-0.32 kg/week, for a total weight gain of 7.0-11.5 kg. Finally, obese women (BMI ≥ 30.0 kg/m^2) are expected to gain 0.17-0.27 kg/week, for a total weight gain of 5.0-9.0 kg (Institute of Medicine, 2009). Gaining within these guidelines has been associated with prevention of adverse maternal and neonatal outcomes (Polley et al., 2002).

1.2 EGWG can lead to pregnancy complications for normal weight, overweight and obese women

Women gaining above the guidelines are more likely to require obstetric intervention due to increasing risk of pregnancy complications such as large for gestational age (LGA) infants (Margerison et al., 2010), increased non-elective caesarean section (Durie et al., 2011), preeclampsia and gestational hypertension (Chung et al., 2013; Margerison et al., 2010). Limiting EGWG, especially in obese women, has been associated with improved pregnancy outcomes (Durie et al., 2011; Chung et al., 2013). Furthermore, EGWG has been reported to be a contributing factor to the obesity epidemic in women (Margerison et al., 2010; Ramussen et al., 2009) and may contribute to long-term obesity in women who start pregnancy normal weight, and will exacerbate obesity for those who start pregnancy overweight or obese (Chung et al., 2013).

A greater percentage of women are entering pregnancy overweight or obese, and many tend to gain too much weight during pregnancy. The risk of adverse outcomes due to EGWG is higher as pre-pregnancy BMI increases (Flick et al., 2010). In fact, overweight and obese women are more likely to gain more than the IOM (2009) weight gain recommendations than normal weight women (Cedergren, 2006). In a study of 1950 women, EGWG was observed in 84% (n=476) of overweight women and 80% of obese women (n=248), compared to 55% (n=1074) of normal weight women (Chung et al., 2013). Increased maternal BMI often results in heavier infants who are inherently at risk for obesity and other long-term complications (Lim et al., 2015; Chung et al., 2013; Cordero et al., 2015b). In fact, maternal weight gain in overweight women of more than 11.5 kg and obese women of more than 9.0 kg can lead to increased incidence of several adverse outcomes for the mother, such as preeclampsia and non-elective cesarean section, and the infant, including fetal macrosomia (infants born > 4.0 kg), preterm birth or still birth (Chung et al., 2013; Mottola et al., 2010; Davies et al., 2010), as well as long-term chronic diseases like type-2 diabetes, cardiovascular disease and obesity (Mottola & Artal, 2016) for both mother and child. In cases of maternal obesity, even fetal monitoring can become a challenge due to the maternal pannus and difficulty transducing fetal heart rate and maternal contractions (Davies et al., 2010).

1.3 Maternal obesity creates long-term complications for mother and child

Maternal weight gain and prepregnancy BMI have been positively correlated to birth weight, showing that EGWG can influence increased infant birthweight (Mottola et al., 2010; Cordero et al., 2015b; Chung et al., 2013). Several studies have shown that EGWG is associated with adverse neonatal outcomes such as fetal macrosomia (Chung et al., 2013), neonatal

metabolic abnormalities, lower Apgar scores (Lim et al., 2015) and admission to the neonatal intensive care unit (Davies et al., 2010), the risks of which are heightened as pre-pregnancy BMI increases (Flick et al., 2010).

Maternal overweight and obesity are strongly associated with increased risk of gestational hypertensive disorders, gestational diabetes and Cesarean section (Mottola, 2008; Gaillard et al., 2013). According to Statistics Canada (2016), the most recent measurements of obesity rates show that 33% of women aged 20 to 34 and 43.2% of women aged 35 to 44 are obese, suggesting that the number of women entering pregnancy in an overweight or obese state is likely to be high. Women with overweight or obese BMI status may have increased risk potential for short and long term health complications, but all BMI categories have the potential to gain EGWG and therefore be at risk of adverse health outcomes. Obesity during pregnancy caused either by entering pregnancy obese or by entering pregnancy normal weight and gaining EGWG to become obese, can cause physiological adaptations that create metabolic issues. For example, in normal pregnancy with appropriate weight gain, low-grade inflammation starts during early pregnancy, but with maternal obesity, this response is exacerbated and pro-inflammation signals are heightened, leading to insulin resistance and insulin insensitivity in the mother, putting her at risk for developing preeclampsia, gestational hypertension or gestational diabetes mellitus (Tanvig, 2014; Mottola et al., 2010; Kiel et al., 2007). Furthermore, EGWG is often followed by maternal weight retention post-partum, which is an independent predictor of long-term weight gain and obesity (Phelan et al., 2011). The cycle of EGWG and post-partum weigh retention continues with subsequent pregnancies, causing BMI to increase with each child born, thus increasing the health risks associated with obesity.

Maternal obesity and EGWG may also increase the risk of offspring obesity in childhood, adolescence and adulthood (Laitinen et al., 2012), with a nearly 1.5-fold increased risk of overweight or obesity in adolescence (Laitinen et al., 2012). The children of obese mothers are nearly twice as likely to be LGA at birth (Mottola et al., 2010), and often accompanied by difficulties with delivery (Tanvig, 2014). Macrosomic babies (>4.0 kg at birth) are more likely to be delivered by cesarean section, suffer from shoulder dystocia, nerve injury, infant adiposity and lethargy (Tanvig, 2014). The short- and long-term effects of maternal obesity are especially evident in the case of gestational diabetes, during which excess maternal glucose passes across the placenta to the fetus, but maternal insulin does not. As such, the fetus exists in an environment of heightened blood glucose with insufficient insulin response, thus causing the fetal pancreas to respond to the glucose overload with increased insulin production (Oken & Gillman, 2003; Hales & Barker, 1992). Insulin acts as a fetal growth promoter in addition to its metabolic effects (Oken & Gillman, 2003). This contributes to macrosomic and large for gestational age babies (Mottola et al., 2010). Furthermore, this puts the baby at risk for obesity, diabetes and cardiovascular issues, even into childhood, adolescence and adult life (Lim et al., 2015; Mottola et al., 2010; Cordero et al., 2015b), thus contributing to a multigenerational cycle of obesity.

It has been proposed, most prominently by Barker (2004), that long-term health outcomes have origins in the fetal environment. This environment can be affected by EGWG and maternal obesity, which may impact the uterine environment and ultimately affect the growing fetus (Barker, 2004). Barker (2004) proposed the concepts of developmental plasticity, the

"phenomenon by which one genotype can give rise to a range of different physiological or morphological states in response to different environmental conditions during development," and fetal programming (Hales & Barker, 1992), defined as "permanent or long-term change in the structure or function of an organ resulting from a stimulus or insult at a critical period of early life" (Hales &Barker, 1992). Collectively, these concepts may explain how maternal obesity and EGWG may cause adverse downstream effects to the short- and long-term health of the infant (Tanvig, 2014). According to Barker (2004), developmental plasticity will allow the fetus to prepare for the extrauterine environment. For example, blood pressure and metabolism of the fetus are very sensitive during pregnancy, and can make short-term modifications to ensure the longevity of the infant into the environment after birth (Barker, 2004). In terms of fetal programming, the environment that the fetus experiences can have epigenetic effects that carry over into adult life as later increased risk for adult chronic disease, including cardiovascular disease, cancer, osteoporosis, diabetes, neuropsychiatric outcomes and respiratory diseases (Oken & Gillman, 2003). Essentially, the data overwhelmingly suggest that EGWG and pre-pregnancy BMI are correlated with offspring birth weight (Oken & Gillman, 2003; Tanvig, 2014). Maternal obesity may act as a stimulus at a critical period of fetal development that triggers metabolic changes and has lasting effects over the life course (Oken &Gillman, 2003).

1.4 Cycle of obesity – maternal and infant

EGWG can lead to a lifetime of unhealthy weight for mother and baby (Mottola et al., 2010), with the cycle of obesity perpetuating for many generations. In a study of 180 obese pregnant women with BMI >40 kg/m^2, the reported incidence of LGA neonates was 31% (Kumari, 2001). Another study found that offspring born to mothers who gained excessive

weight during pregnancy had elevated risks of overweight or obesity (27% to 73%) compared to offspring whose mothers gained adequate weight (Luo et al., 2014). These macrosomic infants may experience obesity throughout childhood and into adulthood, with higher risks for developing diabetes, cardiovascular disease or other metabolic diseases (Davenport et al., 2013).

For normal weight and overweight women, obesity can be initiated by EGWG (Clark & Ogden, 1999) and weight retention so that women begin subsequent pregnancies at a higher pre-pregnancy weight (Mottola, 2008). Although women with higher pre-pregnancy BMI are more likely than normal weight women to gain more than recommended (Lowell & Miller, 2010) the risk of EGWG and weight retention is present for all women. According to Statistics Canada, women who gained more weight than recommended during pregnancy retained more weight (average 4.5 kg retained) than women who gained within (average 2.0 kg retained) or below (average 0.5 kg retained) the IOM (2009) guidelines (Lowell & Miller, 2010). If no intervention is made, this obesity cycle is likely to continue to affect future generations. However, this cycle can be changed with the use of a healthy lifestyle intervention (Mottola & Artal, 2016).

1.5 Maternal obesity management and intervention

The 2006 Maternity Experiences survey showed that 56% of Canadian pregnant women gained more weight than recommended and subsequently gave birth to macrosomic infants (Lowell & Miller, 2010). Additionally, 55% of women with high pre-pregnancy BMI gained excessively, compared to 41% of women with normal BMI and 25% who were underweight (Lowell & Miller, 2010). In fact, one study found that without an exercise intervention during pregnancy, women were 3 times more likely to develop hypertension, 1.5 times more likely to

gain excessive weight and 2.5 times more likely to give birth to a macrosomic infant (Barakat et al., 2015). Despite these known risks, few pregnant women report receiving advice or guidance from their health care practitioner regarding healthy, appropriate weight gain during pregnancy or the risks associated with excessive weight gain. In a 2011 study of 310 women, only 28.5% of women reported that their health care provider recommended a certain range of weight gain and only 12% reported that they were advised to gain within the recommended IOM (2009) guidelines (McDonald et al., 2011). A startling 51.3% reported that weight gain was not discussed at all and 44.8% reported that exercise was not discussed (McDonald et al., 2011). There is undoubtedly an urgent need for better patient education for weight gain success, as only 12% of women gained within the recommended IOM (2009) guidelines (McDonald et al., 2011).

Current studies examining the promotion of healthy lifestyles to prevent EGWG and maternal obesity have examined lifestyle interventions (Stuebe et al., 2009; Ruchat et al., 2012b; Choi et al., 2013) that incorporate effective nutrition and exercise behaviour change programs to help support women in meeting the IOM (2009) guidelines for gestational weight gain and preventing EGWG, thus improving health outcomes for mother and baby. However, there have been inconsistencies in the efficacy of implementation of these intervention programs with women of all BMI categories, but especially overweight and obese women. Specifically, obese women are less successful than normal weight women at preventing EGWG when following a supervised physical activity plus nutrition intervention (multiple behaviour changes; Choi et al., 2013).

1.6 Difficulties with behaviour change in obesity and strategies for preventing EGWG

Research has suggested that compared to normal weight women, obese women require additional assistance when following a multiple behaviour change program to successfully prevent EGWG (Choi et al., 2013; Hui et al., 2014). These programs can be more successful for obese pregnant women if they are tailored to include supervised and individualized nutrition and exercise goals (Choi et al., 2013; Phelan et al., 2011). For example, a successful intervention called the Nutrition and Exercise Lifestyle Intervention Program (NELIP; Mottola et al., 2010) involved individualized nutrition goals that were based on the guidelines of the gestational diabetic diet, as well as nutritional counselling and exercise sessions. The NELIP program introduced both nutrition and exercise behaviour change programs simultaneously in mid pregnancy (16-20 weeks). This intervention style was effective, as 80% of the overweight and obese participants and 70% of the normal weight participants were successful in preventing EGWG (Mottola et al., 2010).

Literature has suggested that obese pregnant women may need more specific guidance for appropriate gestational weight gain than women in the normal or overweight BMI categories due to unique barriers that require more intensive intervention (Hui et al., 2014). One study (Claesson et al., 2008) reported that motivating obese women to achieve a goal of gaining 6 to 7 kg of weight during pregnancy required considerable investment in individualized motivational counseling and specifically tailored exercise. Obese women were recruited to attend several extra visits with a specially trained midwife who facilitated motivational interviews with the participants, with the aim of motivating the obese pregnant woman to change her behaviour and to obtain individual counseling (Claesson et al., 2008). It was found that women in this

motivational interviewing group gained less weight (8.7 ± 5.5kg) during pregnancy than the control group (11.3 ± 5.8kg, $p<0.001$) and had a lower BMI ($p<0.001$) at the post-natal check-up compared with the control group ($p<0.086$) (Claesson et al., 2008). Claesson and colleagues postulate that more frequent visits to a midwife or health care provider may facilitate weight gain control in obese women (Claesson et al., 2008).

In addition to multiple behaviour change programs, there are interventions applying only one behaviour change (nutrition or exercise) that have been successful in preventing EGWG in obese pregnant women. Barakat and colleagues (2015) suggested that an exercise program alone may be sufficient at reducing the risk of hypertension, excessive maternal weight gain and incidence of macrosomic infants in women of all BMI categories. These findings, however, were not specific to obese pregnant women who have higher-risk pregnancies than their normal weight counterparts. A recent meta-analysis looking at multiple (exercise AND nutrition) and single (nutrition OR exercise) behaviour changes found that dietary interventions were most successful in preventing EGWG by 4.0 kg in obese women (Thangaratinam et al., 2012). This could be because while on a controlled nutrition program, participants are calorie controlled and on a structured meal plan, which are both effective ways to promote weight control and are behaviours that this population is not likely to follow outside of a supervised intervention (Phelan et al., 2011). However, other literature (Ruchat et al., 2012a) identified successful prenatal lifestyle change programs as including both nutrition and exercise components. Exercise – specifically, walking – is an important weight-bearing aerobic activity for pregnant women, and, due to the apparent beneficial effects on mother and fetus, should not be excluded from the design of a lifestyle intervention for women with low-risk pregnancies (Ruchat et al., 2012a).

1.7 Intervention strategies

Current studies examining the prevention of EGWG to promote healthy pregnancies have developed lifestyle interventions for women to follow (Stuebe et al., 2009; Ruchat et al., 2012b; Choi et al., 2013) based on the idea that EGWG can be altered through advice to pregnant women (Olson et al., 2003). Studies that have been most successful in preventing EGWG include multiple behaviour change programs with nutrition and exercise counselling components (Streuling et al., 2010). A recent review comparing diet and exercise, or both, interventions found that overall, the use of an intervention will result in an average risk reduction of EGWG of 20%, with the largest reduction occurring with supervised combined diet and exercise interventions (Muktabhant et al., 2015). These researchers, along with others, (Thangaratinam et al., 2012; Muktabhant et al., 2015) reported favourable outcomes for pregnancy weight gain with the use of an intervention.

Another factor to consider when prescribing lifestyle interventions is the introduction of the intervention and its subsequent effects on the timing of weight gain during pregnancy. Excessive weight gained early in pregnancy (during the first half of pregnancy) could lead to the development of chronic health conditions like diabetes, obesity and cardiovascular disease in the mother and child (Davenport et al., 2013). Recent research (Hivert et al., 2016) suggests that EGWG early in pregnancy is strongly related to childhood obesity, particularly in obese women. Furthermore, Davenport and colleagues (2013) suggested that the time of initiation of healthy lifestyle interventions during pregnancy should be early pregnancy (approximately 12-16 weeks gestation) to confer the greatest benefits to a woman and her infant. Their findings report that the neonates of women who gained excessively in the first half of pregnancy (early pregnancy) had

increased risk of elevated body fatness at birth, compared to neonates whose mothers gained excessively overall (Davenport et al., 2013). Considering the difficulties associated with multiple behaviour change, successful implementation may require tailored supervision and additional assistance in pregnant populations (Choi et al., 2013), as demonstrated in the NELIP study which ensured an intervention of at least 18 weeks in duration that was successful in preventing gestational diabetes mellitus, EGWG and excessive weight retention in 80% of overweight and obese participants (Mottola et al., 2010) and 70% of normal weight participants (Ruchat et al., 2012a). The design of the NELIP involves a structured meal plan based on the Gestational Diabetic Diet, supervised weekly physical activity, and weekly face-to-face meetings. Furthermore, the NELIP is a unique intervention strategy program that represents two behavior changes, nutrition and exercise, which can be delivered simultaneously or split up and delivered individually. To improve the implementation of the intervention and make the program easier to adapt, the behavior changes can be introduced sequentially so that the program's goals appear more feasible and easier to attain, compared to simultaneous introduction of behaviour changes which may be more overwhelming and cause individuals to feel over-burdened (James et al., 2016).

Moreover, the use of effective behaviour change strategies may help to increase adherence to a prescribed exercise program. Based on the findings of the NELIP (Mottola et al., 2010), Nagpal et al. (2017) found that, in all BMI categories, adherence scores were significantly greater for those women who met the gestational weight gain guidelines versus those who gained excessively, thus suggesting that regardless of pre-pregnancy BMI, adherence to the nutrition and exercise goals of a program can prevent EGWG. Furthermore, they concluded that women

with a pre-pregnancy BMI of obese require on average 80% adherence to the full behaviour change program, while overweight women require 67% and normal weight women require 77% adherence to prevent EGWG (Nagpal et al., 2017). Improving adherence to nutrition and exercise goals may ultimately increase prevention of EGWG, regardless of pre-pregnancy BMI (Nagpal et al., 2017). Strategies can be developed to improve adherence to the Canadian guidelines for exercise during pregnancy (Davies et al., 2003), outlined in the PARmed-X for pregnancy (Wolfe & Mottola, 2002), which state that women with low obstetric risks who have been exercising prior to pregnancy may continue to exercise throughout pregnancy, and previously sedentary women should begin an aerobic exercise program starting with 15 minutes of continuous exercise three times a week, increasing gradually to 30-minute sessions four times a week. Given the high rate of women entering pregnancy with a BMI of obese or overweight and the high rate of EGWG during pregnancy in women of all pre-pregnancy BMI categories, literature suggests that it is unlikely that the Canadian exercise guidelines are being met or adhered to (McDonald et al., 2011). As such, delivering nutrition and exercise behavior change programs sequentially, rather than simultaneously, may be more manageable for women to adapt and adhere to as pregnancy progresses.

Incorporating theories of behaviour change such as the Transtheoretical Model of Change (TTM) and the Social Cognitive Theory (SCT; Merkx et al., 2017) are also critical to the design of a successful EGWG prevention program. Voluntary behaviour change requires motivation, ability and the opportunity to change (Brug et al., 2005). For nutrition and physical activity behaviours, the TTM provides a distinction between the motivational and volitional phases in behaviour change (Brug et al., 2005). Understanding these distinct phases can help to create

interventions that bridge the intention-behaviour gap (Brug et al., 2005; Metkx et al., 2017). Such techniques as providing various strategies for action initiation and pursuit, goal setting and feedback, action planning and self-monitoring of behaviour can be employed to aid in the efficacy of interventions (Brug et al., 2005). The SCT can also be used to map an intervention strategy (Merkx et al., 2017) to further bridge the intention-behaviour gap by increasing environmental opportunities for healthy nutrition and physical activity behaviours (Brug et al., 2005). In addition, with the introduction of multiple health behaviour changes, the self-control strength model can be used to explain efforts in one domain (ex. using self-control to resist over-eating) depleting one's capacity to self-regulate in other domains (ex. walking for 40 mins, 3 times per week; James et al., 2016).

Ultimately, EGWG can lead to negative health outcomes, but nutrition, exercise, and nutrition and exercise intervention programs have been able to prevent EGWG in adherent participants. The current pilot study will further investigate this idea by strategically delivering each intervention component to maximize adherence for all pre-pregnancy BMI categories. Following the framework of Mottola et al. (2010), the current study will deliver both nutrition and exercise as part of the intervention program, but will present the behaviour change strategies in succession and concurrently to determine which strategy is most manageable for pregnant women with different pre-pregnancy BMI categories.

Objectives of the current trial include assessing the strategies for implementing lifestyle behaviour changes during pregnancy and exploring the success of strategies for different pre-

pregnancy BMI categories. The next chapter will outline the purpose, rationale and hypotheses of the current pilot study.

Chapter 2

2. Purpose and rationale

Based on the current literature, performing a randomized controlled trial involving the use of single and dual behaviour change intervention strategies may help to determine the best practice for preventing EGWG in women of all pre-pregnancy BMI categories. Furthermore, this information would be valuable for the development of more effective self-monitoring techniques and tools for monitoring and measuring adherence that can be applied to future studies involving pregnant populations.

The purpose of the present study was to evaluate the effectiveness of the timing of initiation of different behaviour change intervention strategies on weight management in pregnant women. This was accomplished by randomizing dual behaviour change strategies started early in pregnancy (12-18 weeks gestation), which are as follows: nutrition and exercise given at the same time (Group A, NELIP; Mottola et al., 2010), nutrition first until 24 weeks gestation (mid pregnancy) followed sequentially by introducing exercise at 25 weeks gestation (Group B), and exercise first until 24 weeks gestation followed sequentially by introducing nutrition at 25 weeks gestation (Group C; see methods below). Both behaviour changes, nutrition and exercise, were maintained from 25 weeks gestation until delivery in all groups. The primary aim was to determine which behaviour change intervention was most successful at preventing early and total EGWG. The secondary objectives were to evaluate the downstream effects of preventing early and total EGWG on infant outcomes. This was measured by evaluating the

infant at birth for health outcomes represented by body weight and body fatness, and related to excessive weight gain in the mother.

2.1 Hypotheses

It was hypothesized that the introduction of a single behaviour change sequentially followed by a second (regardless of which was introduced first – nutrition OR exercise), would be more effective at preventing early and total excessive gestational weight gain in women, compared to the early simultaneous introduction of both behaviour changes (nutrition AND exercise; NELIP) at the beginning of the study.

It was also hypothesized that prevention of EGWG would result in prevention of macrosomic (>4.0 kg) or small (<2.5 kg) babies born to women of all BMI categories, with infant morphometric outcomes that fall within the expected healthy ranges for body fat (BF) composition (13-14% BF; Catalano et al., 1995).

Chapter 3

3. Methods

The present study is a pilot prospective randomized controlled trial that was approved by the Health Sciences Research Ethics Board at Western University (see Appendix A1) and registered at clinicaltrials.gov as NCT0280406. All volunteers provided written informed consent and received medical clearance for study participation from their health care provider (see Appendix A2 and A3).

3.1 Participants

Pregnant women with a pre-pregnancy BMI $\geq$ 18.5 kg/m^2, were recruited from the London, Ontario area through posters, advertisements in local Facebook groups, London Health Sciences Center E-Cast and on the online advertising service Kijiji.ca. Specific exclusion criteria were the incidence of smoking, diabetes, gestational age greater than 18 weeks, multiple pregnancy (twins), chronic disease and contraindications to exercise, and a high level of physical activity defined as more than 3 intentional bouts of 30 minutes of moderately intense physical activity per week (Mottola et al., 2010; Davenport et al., 2013). To participate in the study, women had a single pregnancy (no twins), were < 18 weeks, 0 days pregnant at time of entry to study, had a low-risk pregnancy as determined by medical prescreening via the modified PARmed-X for Pregnancy (Wolfe & Mottola, 2002; Appendix A3) by their health care provider, were > 18 years of age, had a level of low physical activity defined as less than 3 intentional bouts of 30 minutes of moderately intense physical activity per week, and were non-smokers. If women met the inclusion criteria, they were invited to participate in the study.

3.2 Baseline Visit

At the first baseline visit, all participants self-reported pre-pregnancy weight. Height (to the nearest 0.1cm) and pregnancy weight (to the nearest 0.1kg) were measured and recorded, and pre-pregnancy BMI was calculated from the measured height and self-reported pre-pregnancy weight. Participants were given the modified PARmed-X for Pregnancy (Wolfe & Mottola, 2002; see Appendix A3) during this visit, to be signed by their healthcare provider to ensure no contraindication to exercise and returned upon the next visit to the lab.

3.3 Self-monitoring Techniques

Each participant was offered a choice for self-monitoring of food intake – either electronically record food intake and email records to the research team, or record food intake on paper as a log sheet. No personal information was used for identification purposes; each participant was assigned a unique identifier number (NELIP###). The participant was given instructions on how to complete a consecutive 3-day food intake record (including one weekend day) using their preferred recording method. Participants' 3-day dietary records (see Appendix A4) were analysed using Nutritionist Pro (NPROC; Axxya, Redmond, WA) to represent habitual food intake at baseline.

Participants were also given a Fitbit activity tracker, worn on the wrist, or a pedometer, worn at the waist, to be used during the same 3 days of food intake recording to log baseline physical activity. Participants were required to record their daily step counts on a provided exercise tracking sheet. All research participants were given the choice of using a mobile-health technology-based self-monitoring tool –the Fitbit activity tracker application – or using e-mail or

paper sheets to log step counts. The Fitbit activity tracker was used by participants as a step counter, and the corresponding app was available to be accessed via a smartphone by the participant to view progress and receive in-app feedback and encouragement. Although mobile-health technology-based interventions have been used in health behaviour change studies (Free et al., 2013), there have been few studies using smart phone applications. In the present study, the goal of using smart-phone applications, emails or paper records to track food intake and physical activity was to promote adherence and accessibility to the prescribed behaviour change intervention programs and to facilitate an instant feedback system for participants to view their diet and exercise progress. Presenting the participants with different choices of self-monitoring implements an element of patient-centered care that increases accommodation for the needs of a participant.

3.4 Randomization Process

A randomized parallel groups design was used. CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed to generate the random allocation sequence using a random numbers table (Schulz et al., 2010). The SNOSE (sequentially numbered, opaque sealed envelopes (Doig & Simpson, 2005)) method was chosen for block randomization allocation to the different treatment groups: full NELIP (Group A), Nutrition first (Group B) or Exercise first (Group C). See section 3.7, below.

- Group A) NELIP (full intervention of nutrition and exercise given simultaneously),
- Group B) Nutrition intervention given at study entry followed sequentially by the exercise intervention starting one week after a 24 week mid-way visit (N+E), or

- Group C) Exercise intervention given at study entry followed sequentially by the nutrition intervention starting one week after a 24 week mid-way visit (E+N).

Each block of 6 contained two Group A, two Group B and two Group C allocations. In order to maintain allocation concealment, an external person retrieved envelopes from a locked cabinet and opened them upon randomization of each subsequent participant.

3.5 Second Baseline Visit

Upon return of baseline records, women were given their group allocation. Participants and the researchers were blinded to group allocation until all baseline data were collected at the second baseline visit. Following group assignment, the participant was introduced to the program – either nutrition, exercise or both. If the participant was allocated to an exercise group, they would begin the walking portion of the program at this visit.

3.6 Monitoring Visits

Regardless of group assignment, all participants were followed at weekly visits to track weight, thus allowing "face-to-face" interaction for all research participants. Participants were weighed each week to track weight gain during the program. Additionally, this time was used for nutrition counseling and walking in the lab, as per group assignment.

All women had a choice of which self-monitoring techniques they preferred to use, and all women continued in their allocated intervention group until delivery.

3.6.1 Visits at 24 and 36-38 weeks gestation

At the 24 and 36-38 week visits, all participants again completed a 3-day food intake record and physical activity tracking, and skinfold measurement, regardless of randomized group allocation. An exit interview was given at the 36-38 week visit to record participants' feedback, including feelings of ease or difficulty, on the program they received.

3.7 Intervention Groups

Group A – *Full Nutrition and Exercise Lifestyle Intervention Program (NELIP)*

Group A received the full NELIP (based on Mottola et al., 2010). Two simultaneous behaviour changes (nutrition and exercise; see below) were started at the second baseline visit and continued until delivery. Group A served as the comparator control. After randomization into Group A, information regarding NELIP (Mottola et al., 2010) was given.

1. *Nutrition Component of NELIP*

At the second baseline meeting, women were introduced to the NELIP nutrition component. The specific nutrition meal plan was modified for the gestational diabetic diet (as used in NELIP; Mottola et al., 2010) that is given to women who have been diagnosed with gestational diabetes mellitus as a means of medical nutrition therapy (Catalano, 2007). A modified gestational diabetic meal plan was used to promote healthy eating during pregnancy, achieved through the consumption of a balanced diet, to prevent excessive gestational weight gain. The specific goals of the meal plan ensured that the nutrition program: 1) included an individualized total energy intake with a minimum of 2000 kcal/day (8360 kJ/day), taking into account the usual energy intake as indicated by each dietary assessment (including baseline 3-day food intake records)

with a restriction of no more than 33% total energy intake, 2) adjusted, if necessary, the total carbohydrate intake to 40-50% of total energy intake throughout the day with three balanced meals and two to three snacks per day, emphasizing complex carbohydrates and low glycemic index foods, 3) adjusted the total fat intake to 30% of total energy intake (substituting monounsaturated fatty acids for saturated and trans-fatty acids), with the remaining 30% of dietary intake dedicated to protein intake, and 4) met all micronutrient and fluid needs as recommended during pregnancy. The program was individualized to the nutritional needs of each woman and her BMI status, with emphasis on healthy eating. A member of the research team met with each participant at face-to-face weekly meetings to modify dietary needs accordingly. Using their preferred method of self-monitoring, participants completed a one-day dietary record on a weekly basis.

2. Exercise Component of NELIP

The exercise component consisted of walking sessions. Each participant was given a Fitbit activity tracker or pedometer to wear during the walking sessions. Each participant began the walking program for 25 minutes. Each subsequent exercise session increased in duration by 2 minutes/week, up to a maximum of 40 minutes per session. This exercise duration was maintained until birth (Mottola et al., 2010). During weekly face-to-face weigh-in sessions in the lab, participants in the exercise program had the option to walk at the laboratory or outside. In addition, they completed 2 to 3 walking sessions per week on their own, outside of the laboratory, either at their preferred fitness centre, shopping mall, outside or at home. The goal of the walking program intervention was to increase the participants' daily step counts to 10,000 steps (Tudor-Locke & Bassett, 2004).

During the walking exercise sessions, both at the lab and on their own, participants wore the Fitbit on the wrist or a pedometer at the waist. The Fitbit automatically records step counts and monitors activity, and the pedometer automatically records step counts. Participants wore the Fitbit or pedometer to monitor activity for the duration of enrollment in the exercise program component of the study to encourage self-monitoring and to assist in goal setting. Data collected by the Fitbit or pedometer was recorded by the participant on weekly exercise log sheets that were handed in every week and reviewed by a member of the research team. No personal information or identifiers were linked with the Fitbit account.

Group B – *Nutrition first Intervention followed by Exercise*

Group B received the nutrition component (one behaviour), starting at the second baseline visit. Following the 24-week mid-way assessment, the second behaviour change (exercise component) was added, with both behaviours followed from 25 weeks gestation until birth (N+E). Each participant randomized to this group was given the same nutritional information as Group A and came to the lab for weekly weigh-ins. Participants were given a choice for their preferred method of food tracking – either by email, electronic meal log or paper meal log. After the 24-week assessment, the participant was given the exercise component of NELIP and a Fitbit activity tracker or pedometer to track daily step counts, as per the NELIP intervention. The participant began with 25 minutes of walking and increased the exercise session by 2 minutes/per week to a maximum of 40 minutes per exercise session, maintained until delivery. The participant was given the NELIP exercise guidelines and their choice of

exercise self-monitoring at 24 weeks gestation, prior to starting with the exercise component at 25 weeks.

Group C – *Exercise first Intervention followed by Nutrition*

Group C received the exercise component (one behaviour) starting at the second baseline visit. Following the 24-week mid-way assessment, the second behaviour change (nutrition component) was added, with both behaviours followed from 25 weeks gestation until birth (E+N). Each participant randomized to this group was given the same exercise information as Group A and came to the lab for weekly weigh-ins and walking exercise sessions. Participants had access to the exercise component of NELIP and a Fitbit activity tracker or pedometer to track daily step counts. After the 24-week assessment, the participant was given the nutrition component of NELIP and access to their choice of nutrition self-monitoring at 25 weeks.

3.8 Outcome Measurements

To measure the birth outcome of the intervention strategies, infant sex, body weight (kg), length (cm), delivery complications, gestational age at delivery, and the last known maternal body weight (kg) prior to delivery (to measure total gestational weight gain, defined as pre-pregnancy weight subtracted from last known maternal body weight) were recorded within 6 to 18 hours after delivery. Total gestational weight gain (kg) and early gestational weight gain (kg, defined as pre-pregnancy weight subtracted from weight at 24-25 weeks gestation) were recorded for all participants. Early pregnancy expected weight gain was calculated assuming 2 kg was gained from start of pregnancy to 12 weeks, and maximum recommended rate of weight (as determined by IOM guidelines, 2009) was gained from 12 weeks to 24-25 weeks gestation. Late pregnancy expected weight gain was calculated assuming maximum recommended rate of

weight (as determined by IOM guidelines, 2009) was gained from 24-25 weeks gestation to 36-38 weeks gestation.

Neonatal morphometrics were assessed with a clean diaper only (6 skinfold sites: umbilical, suprailiac, biceps, triceps, subscapular and anterior thigh using a Lange caliper; Davenport et al., 2013), either at the hospital or at the participant's home, by a member of the research team within 6 to 18 hours of delivery. Using the Catalano et al. (1995) equation, neonatal percent body fat was calculated as 100/fat mass/birth weight, and body fat greater than 14% was considered excessive (Catalano et al., 1995). The Catalano equation used was 0.54657 + 0.39055 * Birth weight (g) + 0.0453*Flank Skinfold (mm) – 0.03237*Length (cm) (Catalano et al., 1995). The incidence of macrosomia was assessed as the number of babies born >4.0 kg, and the rate of macrosomia were compared across the intervention groups, as well as the incidence of babies born <2.5 kg. Infant weight and length at delivery, APGAR scores and birth complications were taken from medical records.

3.9 Statistical Analysis

Independent and paired samples t-tests were conducted to compare age at study entry, pre-pregnancy weight, height, pre-pregnancy BMI, gestational age at study entry, weight at study entry, average nutritional intake and step counts of groups at baseline, as well as comparison of average nutritional intake and step counts of groups 24-25 weeks and 36-38 weeks gestation. Independent and paired samples t-tests were also used to compare predicted and actual weight gained at 24-25 weeks and at 36-38 weeks gestation. Data are presented as means ±standard deviation. All tests were two-sided with a significance level of $p<0.05$. To determine the strength

of association, effect sizes were calculated using Cohen's *d* with 0.2 representing a small effect size, 0.5 representing a moderate effect size, and 0.8 representing a large effect size (Cohen, 1988).

3.10 Determination of Sample Size

The desired power was 0.80 and significance level was alpha = 0.05. The size of difference regarded as clinically significant was 5 kg, and the predicted population standard deviation was 3 kg. The multiplier for the chosen alpha and power values is 7.9.

$n = [\ 2((\text{multiplier})^2 \text{population variance}^2)]/\text{size difference regarded as significant}^2$
$n = [2(7.9*9)]/25$
$n = 5.6$
$n = 6$

Add 40% for long-term follow up attrition.

n = 9 [in each intervention strategy group (Group A, B and C) per BMI stratification]

Sample size per intervention strategy group, n = 27.

Chapter 4

4. Results

Of the 33 women who contacted the lab, 5 did not respond to booking appointments and 28 completed baseline assessment. Nine women dropped out of the study post-randomization due to too much time commitment (n=3), medical complications unrelated to the study (n=2), no interest in the program offered (n=1) or lack of follow-up response (n=3), leaving 19 women who completed the program until delivery. One woman was excluded from the final analysis due to incomplete data, leaving 18 women in the final analysis (see Figure 1). Drop-out rate for Group A was 33% (n=3, 1NW, 2OB), Group B was 44% (n=4, 2 NW, 2OW) and Group C was 22% (n=2, 2NW).

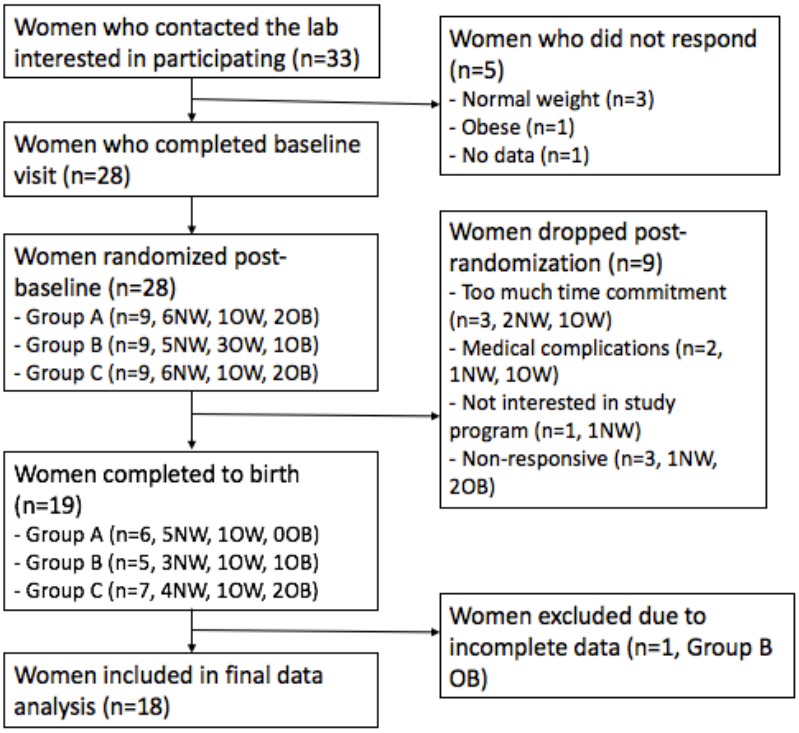

Figure 1 – CONSORT recruitment flowchart. Normal weight, NW. Overweight, OW. Obese, OB.

Average pre-pregnancy weight for all included women (n=18) was 66.86 ±14.33 kg and average height was 1.65 ±0.05 m. Mean pre-pregnancy BMI for all participants was 24.71 ±4.88 kg/m^2. Following the baseline assessment, women were randomized into Group A (n=6), Group B (n=5) or Group C (n=7). Pre-pregnancy BMI of Group C (27.31 ±5.94 kg/m^2) was higher at baseline than that of Group A (21.77 ±2.36 kg/m^2; p=0.052; see Table 1). Across all other baseline characteristics, the groups were similar.

Table 1 - Baseline characteristics of participants included in final analyses.

Baseline Characteristics	Group A (n=6)	Group B (n=5)	Group C (n=7)
Age (years)	30.4 ±3.43	32.75 ±5.03	32.5 ±2.88
Pre-pregnancy weight (kg)	59.56 ±7.39	67.73 ±18.23	73.30 ±17.38
Height (m)	1.65 ±0.05	1.64 ±0.04	1.64 ±0.06
Pre-pregnancy BMI (kg/m2)	21.77 ±2.36	25.07 ±6.35	27.31 ±5.94*
Gestational age at study entry (weeks)	17.3 ±3.90	17.2 ±2.39	17.1 ±4.22
Weight at study entry (kg)	63.92 ±7.48	71.62 ±17.86	75.90 ±16.50
Baseline daily energy (kcal)	2010.71 ±672.49	2086.59 ±501.96	2059.56 ±544.32
Baseline daily steps	8123.67 ±3560.72	5948.00 ±3070.72	7409.43 ±473.49
BMI category (n/%)			
Normal weight	5/83	3/60	4/57
Overweight	1/17	1/20	1/14
Obese	0/0	1/20	2/29

Significance set at p<0.05. *Group C pre-pregnancy BMI (p=0.052) significantly higher than Group A pre-pregnancy BMI.

At baseline, all three groups were similar for mean daily energy, carbohydrate, protein and fat consumed over a three-day period (see Table 2). At 24-25 weeks gestation, Group A and B were following the meal plan. By 36-38 weeks gestation, all three groups were following the

meal plan. There were no statistical changes between groups at 24-25 weeks gestation. At 36-38 weeks gestation, Group C consumed an average of 2280 ±193.12 kcal/day, which, compared to Group B 1814.59 ±206.24 kcal/day (p=0.0012, Cohen's *d*=2.33; see Table 2), was statistically higher with a large effect size. Also at 36-38 weeks gestation, average carbohydrate consumption was statistically different between Group A and Group B (p=0.029) and between Group B and Group C (p=0.036). Percent protein and fat consumption were similar at each time point for all groups (see Table 3). The macronutrient targets for the prescribed nutrition plan were 40-55% carbohydrate, 30% fat and 20-23% protein per day. The energy goals of the meal plan were 2000 kcal/day and 200-250 g/CHO/day. The women in each group were, on average, able to meet the nutrition goals for carbohydrate, but mean fat consumed was in excess of the nutrient goal and mean protein consumed was lower than the nutrient goal (see Table 3).

There were no significant differences between the nutrient percentages for each group and time point, but the magnitude of the difference between percent carbohydrate at 24-25 weeks gestation of Group A compared to Group C was small (Cohen's *d*=0.11) and Group B compared to Group C was large (Cohen's *d*=0.84). At 36-38 weeks gestation, there was a moderate effect size between the percent carbohydrate of Group A (Cohen's *d*=0.41) and very large effect size of the percent carbohydrate of Group B (Cohen's *d*=1.75) compared to Group C (see Table 3), but no statistically significant differences.

Table 2 - Average daily energy consumed over a 3-day period at baseline, 24-25 weeks and 36-38 weeks gestation.

	Baseline				24-25 weeks gestation				36-38 weeks gestation			
	Calories (kcal)	**Carbohydrate (g)**	**Protein (g)**	**Fat(g)**	**Calories (kcal)**	**Carbohydrate (g)**	**Protein (g)**	**Fat (g)**	**Calories (kcal)**	**Carbohydrate (g)**	**Protein (g)**	**Fat (g)**
Group A (n=6)	2010.71 ±672.49	227.86 ±73.90	87.88 ±33.20	89.12 ±37.97	2218.23 ±394.60	293.64 ±48.87	99.22 ±22.74	76.55 ±26.30	2292.59 ±394.45	305.30 ±61.35	98.94 ±15.73	81.47 ±18.98
Group B (n=5)	2086.59 ±501.96	233.19 ±55.62	89.64 ±20.92	75.25 ±54.72	2146.64 ±430.52	229.93 ±76.88	93.50 ±8.45	96.85 ±14.84	1814.59 ±206.24	207.18 ±41.06	85.32 ±4.59	72.48 ±21.54
Group C (n=7)	2059.56 ±544.32	237.85 ±64.81	97.38 ±20.49	84.33 ±30.01	2466.09 ±574.12	302.06 ±95.17	106.76 ±35.29	100.21 ±21.22	2280.44* ±193.12	282.96 ±45.61	102.90 ±14.85	86.99 ±17.98

Food intake recorded for three consecutive days (two weekdays and one weekend day) during the week before starting the program, the 24th week of gestation, and between the 36th and 38th weeks of gestation. Analysis of nutrients performed using Nutritionist Pro Diet Analysis and Nutrition Food Labelling Software. Values presented are averages of the three days recorded. Significance set at $p<0.05$. *Average calories at 36-38 weeks were significantly higher in Group C than in Group B ($p=0.0012$). The nutrition goals were to consume 2000 kcal/day and 200-250 g/CHO/day.

Table 3 – Average macronutrient percentage of total daily calorie intake consumed over a 3-day period at baseline, 24-25 weeks gestation and 36-38 weeks gestation.

	Baseline			24-25 weeks gestation			36-38 weeks gestation		
	% CHO	**% PRO**	**% Fat**	**% CHO**	**% PRO**	**% Fat**	**%CHO**	**% PRO**	**% Fat**
Group A (n=6)	45.32 ±43.95	17.48 ±19.75	39.9 ±50.82	52.5 ±49.54	17.90 ±23.10	31.30 ±60.0	53.27 ±62.21	17.30 ±15.96	31.99 ±43.31
Group B (n=5)	44.7 ±44.35	17.2 ±16.70	31.16 ±98.11	42.84 ±71.43	17.42 ±7.85	40.6 ±31.02	44.5 ±79.64	18.33 ±8.90	35.03 ±94.0
Group C (n=7)	46.19 ±47.63	18.91 ±15.06	36.85 ±49.62	49.00 ±66.61	17.32 ±24.59	36.57 ±33.26	49.63 ±94.47	18.05 ±30.76	34.33 ±83.8

CHO = Carbohydrate. PRO = Protein. Food intake recorded for three consecutive days (two weekdays and one weekend day) during the week before starting the program, the 24th week of gestation, and between the 36th and 38th weeks of gestation. Macronutrient percentages calculated assuming PRO/CHO = 4 kcal/gram and FAT = 9 kcal/gram. Significance set at $p<0.05$. The goals of the program were total daily calorie intake off 2000 kcal consisting of 40-55% carbohydrate, 30% fat and 20-23% protein.

Average daily step counts for all groups are shown in Table 4 and are presented as steps taken on exercise days and steps taken on non-exercise days. Theoretically, the steps taken on exercise days should be close to 10,000 steps/day by 36-38 weeks gestation in all groups. At baseline, there was no difference in the number of steps taken across groups. By 24-25 weeks gestation, only Groups A and C recorded steps for the exercise program. Group A had significantly more steps taken on exercise days than on non-exercise days at 24-25 weeks gestation (p=0.004, Cohen's *d*=2.09; see Table 4). Group C, given only the exercise program from baseline to 24-25 weeks, also had significantly more steps taken on exercise days than on non-exercise days at 24-25 weeks (p=0.019, Cohen's *d=1.39*; see Table 4). At 36-38 weeks gestation, Group A and C showed a similar pattern, with the number of steps taken on exercise days exceeding the number of steps taken on non-exercise days (Group A, p=0.0012; Group C, p=0.001; Cohen's *d*=2.29; see Table 4). Interestingly, in Group C the magnitude of difference between average number of steps taken on non-exercise days at 24-25 weeks to 36-38 weeks was medium (Cohen's *d=0.5*; see Table 4), potentially suggesting that being on the exercise program influenced activity levels even on non-exercise days. Group B saw no change in average daily step counts from the introduction of the exercise program at 24-25 weeks to 36-38 weeks gestation (see Table 4). Frequency of exercise is also shown in Table 3, and is similar at all time points for all groups once exercise was initiated.

Table 4 – Average daily steps taken over a 3-day period at baseline, for 1 week at 24-25 weeks and 1 week at 36-38 weeks gestation.

		Steps taken on Exercise Days		Steps taken on Non-Exercise Days		Frequency of Exercise	
	Baseline Steps	**24-25 weeks gestation**	**36-38 weeks gestation**	**24-25 weeks gestation**	**36-38 weeks gestation**	**24-25 weeks gestation**	**36-38 weeks gestation**
Group A (n=6)	8123.67 ±3560.72	10678 ±1643	9737 ±1108	6912 ±2123	6682 ±1044†	3 ±2	4 ±1
Group B (n=5)	8123.67 ±3560.72	-	10738 ±2999	5942 ±1214	7305 ±1654	-	3 ±2
Group C (n=7)	7409.43 ±473.49	10205 ±1088	10205 ±2349	6245 ±3157	7767±2868*	4 ±1	4 ±1

Baseline steps recorded for three consecutive days; no exercise recorded. Steps at 24-25 weeks and 36-38 weeks gestation were recorded for one week and included exercise (completing an intentional walk for a set duration of time) and non-exercise days. Frequency of exercise indicates how many times exercise was completed over the course of the tracking period. *Significant difference between exercise and non-exercise steps at 24-25 weeks and 36-38 weeks for Group A and Group C.

Of the women who participated in the intervention, twelve had a normal weight pre-pregnancy BMI (18.5-24.9 kg/m^2), three were overweight (25.0-29.9 kg/m^2) and three were obese (≥30.0 kg/m^2). Of the normal weight women, 33% (n=4) gained excessively, two from Group A and two from Group B. One hundred percent of the overweight women gained excessively from Group A (n=1) and B (n=1), and 100% of the obese women gained excessively from Group B (n=1). Fifty percent (n=1) of the obese women gained excessively from Group C (see Table 5). In all groups, there was no difference between early expected and actual weight gain. For late weight gain, Group C had a significantly lower actual weight gain (3.5 ±0 kg) compared to expected (3.38 ±0.19; p=0.036; see Table 5). Also for late pregnancy weight gain, Group C gained significantly less weight than Group A (p=0.014) and Group B (p=0.00042).

Adherence to each part of the intervention program is presented in Table 5, as adherence to the first (study entry to 24-25 weeks) and second (24-25 weeks to 36-38 weeks) parts of the intervention program. After averaging the adherence scores for each BMI category of each group, Group C had the highest adherence to the first part of the program (94%) and Group A had the lowest (74%) and Group B had 80% adherence. For the second part of the program, after averaging the adherence scores for each BMI category of each group, adherence scores decreased for Group B to 64% and Group C to 83%, while Group A had an adherence of 73%. Across BMI categories, Group B had the highest incidence of EGWG, with 89% of Group B participants experiencing EGWG. Seventy percent of Group A participants and 50% of Group C participants experienced EGWG.

Table 5 - Early (start of pregnancy to 24-25 weeks gestation) and late (24-25 weeks to 36-38 weeks gestation) gestational weight gain and percent gained excessive overall by pre-pregnancy BMI category and intervention group allocation, with adherence scores.

	Early Pregnancy			Late Pregnancy			
BMI	**Expected WG (kg)**	**Actual WG (kg)**	**Adherence Score (%)**	**Expected WG (kg)**	**Actual WG (kg)**	**Adherence Score (%)**	**Percent gained excessive (%)**
NW							
Group A (n=5)	7.76 ±0.20	7.31 ±1.86	83	5.04 ±0.20	4.8 ±1.83	85	40
Group B (n=3)	7.70 ±0.26	7.78 ±2.78	82	5.4 ±0.45	6.43 ±1.17	53	66
Group C (n=4)	7.85 ±1.54	6.97 ±2.55	92	4.95 ±0	3.38 ±0.51	89	0
OW							
Group A (n=1)	5.84 ±0	7.40 ±0	64	4.16 ±0	9.00 ±0	60	100
Group B (n=1)	6.16 ±0	7.40 ±0	96	3.52 ±0	2.5 ±0	71	100
Group C (n=1)	5.84 ±0	4.80 ±0	87	3.84 ±0	3.8 ±0	77	0
OB							
Group A	-	-	-	-	-	-	-
Group B (n=1)	5.93 ±0	6.1 ±0	63	3.52 ±0	5.2 ±0	67	100
Group C (n=2)	5.38 ±0.19	3.94 ±4.04	100	3.38 ±0.19	3.5 ±0	83	50

WG = Weight gain. Early pregnancy expected weight gain is calculated assuming 2 kg was gained from start of pregnancy to 12 weeks, and maximum recommended rate of weight (as determined by IOM guidelines, 2009) was gained from 12 weeks to 24-25 weeks. Late pregnancy expected weight gain is calculated assuming maximum recommended rate of weight (as determined by IOM guidelines, 2009) was gained from 24-25 weeks to 36-38 weeks.

Of the normal weight women in Group A (n=2) who gained excessively, their babies were, on average, 14% over the normal neonatal body fat (13-14% body fat) percentage based on the Catalano equation (see Table 6). However, the infant born to the overweight participant in Group

A (n=1) fell within the range of normal neonatal body fatness (11.05 ±0 %BF; see Table 7). Surprisingly, one overweight woman in Group C who did not gain excessively during pregnancy gave birth to an infant with 23.07 ±0 %BF, far exceeding the normal range of infant body fatness (see Table 6). There were no significant differences found between birth weight, body fatness at birth and suprailiac skin fold measurements at birth for babies born to women of all groups (see Table 6). The average infant body weight at birth for Group A, B and C was 3132.49 kg, 3344.17 kg, and 3381.14 kg, respectively (see Table 6). One baby was born macrosomic, at 4186.76 grams, to a normal weight woman in Group A (see Table 6), who was 90% adherent to the intervention program and gained within the weight gain guidelines. Table 7 shows infant size compared to maternal weight gain. Mean infant body fat percentage born to women in Group A had a large magnitude of difference from that of infants born to women in Group B for normal weight and overweight (Cohen's *d*=1.24; see Table 7). Percent of EGWG was significantly greater in Group B than in Group C (p=0.02) for all BMI categories (see Table 7). The magnitude of difference between percentage of infant body fat of infants born to mothers in Group C and Group A was small (Cohen's d=0.32) and between Group C and Group B was large (Cohen's d=0.85; see Table 7).

Table 6 - Infant morphometrics, taken 6-18 hours after birth.

Maternal pre-pregnancy BMI - NW	GA at delivery (weeks)	Infant body weight (g)	Length at birth (cm)	Suprailiac SF (mm)	Total body fat at birth (g)	Total body fat percentage at birth (%)
Group A (n=5)	40.25 ±0.5	3446.97 ±736.76	50.8 ±1.90	4.67 ±1.53	516.64 ±359.55	13.71 ±6.06
Group B (n=3)	39.33 ±1.53	3512.10 ±461.87	51.17 ±2.62	8.00 ±5.66	687.41 ±150.36	19.43 ±7.16
Group C (n=4)	40.25 ±1.25	3243.14 ±325.86	49.37 ±3.68	5.25 ±1.5	452.90 ±144.79	13.93 ±4.28
BMI - OW						
Group A (n=1)	40.00 ±0	2818.2 ±0	48.26 ±0	5.00 ±0	311.54 ±0	11.05 ±0
Group B (n=1)	39.00 ±0	3316.9 ±0	45.72 ±0	6.00 ±0	633.83 ±0	19.11 ±0
Group C (n=1)	39.00 ±0	3545.45 ±0	46.99 ±0	9.00 ±0	817.88 ±0	23.07 ±0
BMI - OB						
Group A	-	-	-	-	-	-
Group B (n=1)	40.00 ±0	3203.5 ±0	53.00 ±0	-	-	-
Group C (n=2)	38.50 ±2.12	3351.82 ±761.11	50.80 ±0.1	5.00 ±1.41	437.89 ±332.25	12.25 ±7.13

GA = gestational age. CH = crown to heel length. SF = skinfold. Dash (-) indicates no data available.

Table 7 – Relationship between EGWG and baby fatness by BMI category and group.

BMI	Percent gained excessive (%)	Infant body weight (g)	Total infant body fat at birth (g)	Total infant body fat percentage at birth (%)
NW				
Group A (n=5)	25	3446.97 ±736.76	516.64 ±359.55	13.71 ±6.06†
Group B (n=3)	66*	3512.10 ±461.87	687.41 ±150.36	19.43 ±7.16
Group C (n=4)	0	3243.14 ±325.86	452.90 ±144.79	13.93 ±4.28
OW				
Group A (n=1)	100	2818.2 ±0	311.54 ±0	11.05 ±0†
Group B (n=1)	100*	3316.9 ±0	633.83 ±0	19.11 ±0
Group C (n=1)	0	3545.45 ±0	817.88 ±0	23.07 ±0
OB				
Group A	-	-	-	-
Group B (n=1)	100*	3203.5 ±0	-	-
Group C (n=2)	50	3351.82 ±761.11	437.89 ±332.25	12.25 ±7.13

GA = gestational age. Dash (-) indicates no data available. *%EGWG significantly greater in Group B than in Group C for all BMI categories (p=0.02). †Group A infant body fat % at birth significantly lower than that of Group B for NW and OW (p=0.03).

Chapter 5

5. Discussion

For women who were adherent to the prescribed nutrition and exercise programs throughout the course of their pregnancy, it seems, based on the potential data trends, that an exercise intervention started early in pregnancy (12-18 weeks gestation), followed sequentially by an nutrition intervention (introduced at 24-25 weeks gestation), is most effective at preventing early and total EGWG regardless of pre-pregnancy BMI. Normal weight and overweight women had the highest adherence and program success in Group C, and obese women who completed the study were all in Group C. Of the three intervention groups, normal weight women in Group B were the least successful at preventing EGWG, but also had low adherence to the program. It may be that the combination of a nutrition and exercise lifestyle intervention program is challenging for pregnant women, especially those who are overweight or obese prior to beginning pregnancy. As hypothesized, changing one behaviour at a time seemed to be more manageable for participants, especially if the exercise behaviour change (increasing physical activity through a low-intensity walking program) is introduced before the nutrition behaviour change (following a prescribed gestational diabetic diet). The results suggest that exercise may be a "gateway" (Werle et al., 2015) for success in following a nutrition program, which may lead to reduction of EGWG.

5.1 Which strategy worked best?

The major objective of this study was to determine which intervention strategy for an evidence-based Nutrition and Exercise Lifestyle Intervention Program (NELIP) would be more effective at preventing EGWG – the full program given all at once, or the nutrition and exercise components split up and given sequentially throughout the course of pregnancy. The rates of

EGWG were 70% for Group A, 89% for Group B and 50% for Group C. Considering that the drop-out rates for Group A was 33%, Group B was 44%, and Group C was 22%, it seems that the full NELIP program, though best-practice, and nutrition-first programs might be too challenging for pregnant women to successfully implement. Perhaps adhering to a meal plan and recording food intake while also incorporating and recording daily exercise might be overwhelming to women and could be improved if the intervention components were split up and given sequentially. However, women who were randomized to Group B, the nutrition first, exercise added later group, also seemed to struggle with a higher drop-out rate and low program adherence (80% for nutrition component, 64% for exercise component; see Table 5). Nonetheless, prescribing the nutrition program first, followed sequentially by exercise added at 24-25 weeks gestation, also seemed to be challenging for the overweight and obese women participating in the study. The most well-received program for all BMI categories appeared to be the Group C strategy – exercise given first, followed sequentially by nutrition added at 24-25 weeks gestation. Group C had the best overall adherence to the program, with 94% for exercise and 83% for nutrition, as well as the lowest rate of EGWG with only one participant gaining excessively. At the completion of the program, Group C also showed significant improvement in the number of daily average steps taken on non-exercise days (Table 4), which may demonstrate the potential for the exercise program to influence lifestyle choices to add more physical activity into daily living.

Group C also had the lowest incidence of EGWG, with Group B having a significantly higher incidence of EGWG across BMI categories (Table 7). Furthermore, the body fat percentage of babies born to women in Group C were not statistically different from babies in Groups A and B,

but a large effect size was present (Table 7), suggesting that an increase in sample size may reveal a significant result.

A potential explanation for the success of the Group C intervention strategy (exercise first, nutrition added later) may be the way that the intervention was divided. Evidence has shown that exercise-alone interventions may be successful at preventing EGWG (Ruiz et al., 2013; Haby et al., 2015). One such study, performed by Ruiz and colleagues (2013), found that when given a light-to-moderate intensity exercise program, normal weight women had a 1.4 kg reduction of gestational weight gain. In their trials, there was no significant change to weight gain for overweight and obese women, but they had a decreased incidence of infant macrosomia. Haby et al. (2015) conducted a pilot study using prescribed physical activity with optional nutritional information counseling. The exercise program involved the use of walking poles and pedometers, and was found to significantly reduce EGWG in women with an average BMI of 33.1 kg/m^2 in a midwifery setting. Importantly, both studies cite that adherence to the intervention program is key to ensuring success of preventing EGWG (Ruiz et al., 2013; Haby et al., 2015). During pregnancy, most women tend to reduce physical activity (Pereira et al., 2007), but the literature stresses that it is of paramount importance to encourage women to continue or increase their activity within the guidelines during pregnancy to prevent EGWG (Stuebe et al., 2009). Perhaps an exercise program alone is simple to incorporate into daily life because walking might be an extension of activity in which she is already participating, even though most women lead increasingly sedentary lifestyles (Ruchat & Mottola, 2012).

However, exercise alone may not be enough to influence a healthy lifestyle change. In two studies by Barakat et al. (2009, 2012), it was found that women in resistance and aerobic exercise intervention groups and control groups had similar gestational weight gain. Similarly, another study found that a moderate intensity walking group had similar mean gestational weight gain compared to women who participated in light stretching sessions (Yeo, 2009). Based on these studies, perhaps a prenatal lifestyle intervention promoting healthy eating and physical activity habits would be more successful at decreasing EGWG compared to interventions involving an exercise component alone (Ruchat & Mottola, 2012). In fact, the success rate of combined nutrition and exercise interventions is 66%, whereas exercise-alone interventions have a success rate of just 33% (Ruchat & Mottola, 2012). Clearly, nutrition is also an important factor in preventing EGWG. The NELIP (Mottola et al., 2010) combined a modified gestational diabetic diet with walking and was shown to prevent EGWG in the laboratory setting. Ruchat et al. (2012a) also used a modified gestational diabetic diet paired with a walking program of low or vigorous intensity and found that participating in a walking program during pregnancy is an important component of a healthy pregnancy that also increased submaximal aerobic capacity. This success was due in part to the pairing of exercise with the dietary program to ensure proper intake of fluids, macronutrients and micronutrients (Ruchat et al., 2012a).

Though a single behaviour change may be more manageable, using a dual behaviour change strategy, like the NELIP (Mottola et al., 2010), could be the key to preventing EGWG. However, to ensure program adherence and to make the lifestyle changes as manageable as possible, splitting the components of the program so that a single behaviour change is introduced at a time might be more efficacious. Group C received the exercise component of the

intervention first, and, after having time to master it, were given the nutrition intervention, which is often perceived to be more difficult to adapt (Werle et al., 2014). Nonetheless, the adherence to the nutrition program was quite high for Group C, and this is seen in the overall prevention or attenuation of EGWG for this group.

5.2 Targeted intervention strategies for different BMI categories

In the present study, it seemed that overweight and obese women experienced the most difficulty with adapting to the intervention program when randomised into either Group A or Group B. This is based on the number of drop-outs, who were all from Group A and B, the adherence to each strategy and the rate of EGWG for these groups. A recent study (Tamborrino et al., 2016) found that overweight and obese women who were given a prescribed lifestyle intervention consisting of individualized counseling by a dietician struggled with low adherence and unsuccessful adoption of healthier eating habits. Despite this, recent reviews suggest that diet or physical activity or both are effective at preventing EGWG in this population, and point out that dietary interventions are particularly important for reducing obstetric complications like gestational hypertension and preeclampsia (Thangaratinam et al., 2012). It seems that both exercise and nutrition components are required for successful prevention of EGWG, but "one size does not fit all" when creating an effective intervention program. As BMI increases, perhaps the best way to prescribe a lifestyle intervention is to introduce the "easier" behaviour change first, like a low-intensity walking program, and then, once the exercise program has been mastered, introduce the nutrition component. Group C had the lowest rate of drop out across the groups, and, at final analysis, contained women of all BMI categories. Furthermore, Group C had the highest rate of adherence to the program. There may be potential for an exercise first,

nutrition added later intervention to be successful for women, especially those who are overweight or obese prior to their pregnancy. Normal weight women tend to be successful even with exercise alone interventions (Barakat et al., 2009), and the results of the current pilot study suggest that normal weight women may succeed with any of the three intervention strategies, but sequential introduction of behaviour change may be the best for overweight and obese women. Nevertheless, research in non-pregnant populations shows that no definitive conclusion can be drawn from reviews comparing the success of simultaneous versus sequential behaviour change introduction, as both appear to be equally efficacious in changing behaviour (James et al., 2016).

5.3 Strengths and limitations

One strength of the current study was its use of an evidence-based best practice intervention program for women of all BMI categories known as NELIP (Mottola et al., 2010). The program was originally designed to map strategies suggested by theories of behaviour change. The program included self-monitoring, the creation of reasonable goals and frequent feedback, and various opportunities for action (Brug et al., 2005). The NELIP used pedometers and smartphone fitness tracking applications that were inexpensive and an accessible way for women to participate and to increase daily physical activity via increased step counts, as well as a tool to be used for self-monitoring and instant feedback. Furthermore, the modified gestational diabetic diet was introduced with one-on-one weekly nutritional counselling. These factors contributed to the relatively high levels of adherence to the study program (>60% adherence). However, there were several limitations to the implementation of NELIP. The small sample size (n=18) is a limitation because a larger sample size would also increase the number of women from each pre-pregnancy BMI category, particularly overweight and obese women, which would

account for the higher dropout rate. A larger sample size may also result in statistical significance to be seen in study outcomes where there are currently large effect sizes. Another limitation to this study is the positional reliability of the Fitbit activity tracker compared to the pedometer. Though both instruments have been research validated, the Fitbit tracker is not consistently accurate in step count recording when the wrist that it is worn on is held in a fixed position while moving (for example, pushing a baby stroller and walking).

Another limitation was the use of a one-day self-report for activity and dietary intake tracking. Although this is a commonly used method of tracking, the one day of dietary recording may not represent nutrition behaviours over the course of 7 days. Similarly, with activity tracking, social desirability may have resulted in women exaggerating their self-reported physical activity to please the researchers (Currie et al., 2013). In the future, qualitative analysis can be added to the study to assess whether the food intake logs are an accurate portrayal of the food intake habits of the week, which could be performed via counselling interview at the weekly face-to-face meeting. The increased use of objective measures of physical activity, like pedometers and Fitbit trackers, are recommended for accurate recording of data in future research.

5.4 Summary and future research

The present pilot study suggests that the components of the NELIP program, nutrition and exercise, when delivered exercise first followed sequentially by nutrition, may be more effective at preventing EGWG in women of all BMI categories than the other strategies. Given the importance of preventing EGWG, presenting options of intervention strategies may be

beneficial for sustaining adherence throughout pregnancy, especially in overweight and obese women.

Future research could present a choice of strategy implementation, either nutrition or exercise first. The use of choice might make adapting the program seem easier and could improve adherence to the program. Additionally, a behaviour readiness questionnaire could be used to assess the participant willingness to make lifestyle changes, which, when paired with the applicable behaviour change theories, may be an effective tool to spur lifestyle change. On a larger scale, lifestyle change intervention programs can be introduced to health promoting hospitals (HPH; Graham et al., 2014) to improve the health of the vast population of pregnant women by using patient-centered health promotion strategies and advocating for healthier communities. However, barriers to this venture may exist due to Canadian resources of HPH being used towards illness care rather than healthy lifestyle promotion and prevention of potential illness (Graham et al., 2014). As such, future directions could look towards implementing cost-effective strategies, like electronic or mobile health applications, that will help to reduce the financial strain of implementing lifestyle programs for pregnant women in the community. Stressing the cost versus the benefits to the healthcare system may be important when introducing this program on a larger scale, as the current costs of prenatal care, including routine obstetric and midwife visits, screening for birth defects and pregnancy-related diseases, labour, delivery and extended hospital stay, and neonatal care in the hospital and community are mounting (Canadian Institute for Health Information, 2006). The current study represents a unique program that can be delivered at low cost to all pregnant women to help ensure a healthy pregnancy and subsequently lessen the financial strain on pregnancy-related healthcare costs in the Canadian system.

Overall, this pilot study adds to existing literature on healthy lifestyle programs during pregnancy, shows the benefits of including both nutrition and exercise components of a lifestyle program, and creates opportunities for future research.

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Appendices

Appendix A1: Research Ethics Board Approval Notice

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Annual Continuing Ethics Approval Notice

Date: June 14, 2017
Principal Investigator: Dr. Michelle Mottola
Department & Institution: Health Sciences\Kinesiology,Western University

Review Type: Full Board
HSREB File Number: 108080
Study Title: Strategizing the best approach to prevent early excessive gestational weight gain using a Nutrition and Exercise Lifestyle Intervention Program (NELIP).

HSREB Renewal Due Date & HSREB Expiry Date:
Renewal Due -2018/06/30
Expiry Date -2018/07/05

The Western University Health Science Research Ethics Board (HSREB) has reviewed the Continuing Ethics Review (CER) Form and is re-issuing approval for the above noted study.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH E6 R1), the Ontario Freedom of Information and Protection of Privacy Act (FIPPA, 1990), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940

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Appendix A2: Letter of Information and Consent

LETTER OF INFORMATION AND CONSENT

Strategizing the best approach to prevent early excessive gestational weight gain using a Nutrition and Exercise Lifestyle Intervention Program (NELIP)

Principal Investigator
Dr. Michelle Mottola, PhD FACSM, Director – Exercise and Pregnancy Lab,
School of Kinesiology,

Local Study Investigators
1. Dr. Harry Prapavessis, PhD, School of Kinesiology, UWO
2. Karishma Hosein, BScKin, Exercise and Pregnancy Lab, UWO
3. Taniya Nagpal, BHSc, Exercise and Pregnancy Lab, UWO
4. Dr. Barb de Vrijer, MD, Dept. Obstetrics and Gynecology
5. Dr. Karina Kasawara, PhD, Postdoctoral Fellow, University of Campinas, Brazil

Conflict of Interest
There are no conflicts of interest to declare related to this study.

Invitation to Participate in Research
You are being invited to participate in this research study about health in pregnancy because, you are 12 to 18 weeks pregnant and are eligible to participate. Your participation is voluntary, so choosing not to participate will have no negative consequences or effect on the care that you receive at your primary health care clinic or place of delivery.

Why is this study being done?
Although weight gain is expected during pregnancy, excessive weight gain may put mothers at risk of health problems like diabetes and high blood pressure. Excessive gestational weight gain is defined by the 2009 Institute of Medicine weight gain guidelines as > 16 kg if you are normal weight, > 11.5 kg if you are overweight and > 9 kg if you are obese. Babies of women who gain above these guidelines may also be at risk of being born too large and developing future health problems. We are interested in helping women to gain a healthy amount of weight during pregnancy to prevent problems associated with gaining excessive weight during pregnancy. A total of 81 pregnant women will be participating in this study. The results of this study will allow us to design future programs and guidelines for pregnant women so that mothers may have the

healthiest pregnancy possible. Because this is a smaller pilot study, we may use these findings to guide the future direction of a larger study.

The purpose of this study is to evaluate the success of starting a program of healthy eating first followed by starting exercise by 25 weeks of pregnancy, or starting a program of exercise first, followed by starting a healthy eating program by 25 weeks or starting both programs together. We will monitor your weight gain to see which strategy works best at preventing early and total excessive weight gain during pregnancy.

What will happen during the study?
The program will begin between 12 to 18 weeks of pregnancy. If you decide to participate, you will be randomly assigned (like the flip of a coin) to one of the intervention strategies. You will have a 1 in 3 chance of being placed in any group. Neither you, the study staff, nor the study investigators can choose which group you will be in.

Your participation involves the following:

First Visit: Tour of the facility, information session and pre-screening
Before you are randomized into your specific group or strategy, we will have you sign the consent form (attached). Once consent is signed, we will have you complete a medical screening questionnaire (PARmed-X for Pregnancy). All women will receive usual care and advice from their primary health care provider and he/she must sign the PARmed-X form to confirm you have a low-risk pregnancy before your participation in the study begins. Study participation will begin at 12-18 weeks of pregnancy and continue until the birth of your baby, with follow-up when your baby is 2, 6 and 12 months old. You will be asked to complete the Weight and Health History questionnaire about your general health, the Kaiser Physical Activity Survey and the Pregnancy Physical Activity Questionnaire, that will give us information about your activity levels during pregnancy. You will be given a Food Frequency Questionnaire and also asked about what you ate yesterday (24 hour recall) in order to see what your food intake profile looks like. In addition, you will be given a questionnaire about your current level of anxiety and stress. Also at the first visit, you will be asked if you have a smart phone (Android or iPhone). The purpose of this is to see if you want to track your food intake (everything you eat and drink) using a smart phone app. You will be given the option to track your food using either a paper log, email or smart phone application for 3 days in a row, including 1 weekend day (For example, Thursday, Friday and Saturday or Sunday, Monday and Tuesday). We ask that you be as honest as possible and not change your eating habits while you are recording your food intake over these three assigned days. We will use this information to help make a nutrition meal plan that is suited to you. If you do not have a smart phone we will provide you with a 3-day food intake record in paper form that you will fill out in the same way. You will also be given a Fitbit activity tracker that you will wear on your wrist that will track how active you are over these same three days. We will provide you with a personalized user name and password to protect your privacy online. The Fitbit tracker and your food intake record will allow us to monitor your nutrition and activity before you start the program. We will make an appointment for you to return to the lab the following week to find out which group you have been randomized into. The total time for this first visit will be approximately 60 to 90 minutes.

At the next visit, you will return your Fitbit and we will measure and record your height and your weight. At this time we will also measure your skinfolds. This is a measure of your fat just under the skin at 4 specific sites: at the front and back of your arm, between your shoulder blades, and just above your hip bone. We want to monitor how the fat at these sites will change over the course of your pregnancy. At these sites, your skin and fat underneath will be gently pinched between a caliper or tweezers. The sensation you will feel is just like when you "pinch an inch" on your body and you may feel the calipers as a tickle against your skin. Once this is complete, we will then randomize you into one of three strategies. If you are in the group that receives exercise first or both nutrition and exercise as your initial strategy, you will continue using the Fitbit to track your activity levels for the duration of the program. If you are in the group that receives the nutrition program first or both nutrition and exercise, you will be given a specialized meal plan and you will continue to record your food intake for a 24-hour period once per week using your choice of recording method (paper log, email or smart phone) for the duration of the program.

If you are randomized into having the Nutrition strategy introduced first:

The purpose of the controlled nutrition meal plan is to promote good eating habits, to control excessive weight gain and to help prevent gestational diabetes. This strategy will take into account your 3-day food intake record. It will allow you to have three balanced meals and two to three snacks per day, emphasizing high fiber and low sugar content foods and having healthy portion sizes. Once per week throughout the program, you will be required to record for a 24-hour period everything you eat and drink during that time period using eithera pen and paper food log, email or smart phone application. This will assist us in adjusting your nutrition program as your pregnancy progresses and to promote good eating habits and prevent excessive weight gain. We will make a weekly scheduled appointment to the lab at your convenience for a "weigh-in" and to discuss any nutrition concerns you may have. These weekly visits will take approximately 30 minutes, and will continue until you reach 24-weeks gestation. At 24-weeks gestation, during your weekly visit, we will give you the Kaiser Physical Activity Survey to complete again, we will repeat your skinfold measurements and record your weight. We will ask you to repeat the 3-day food intake record using your choice of recording method like you did at the beginning of the study. In addition, we will give you a Fitbit tracker to also record your activity levels like you did at the beginning of the study. At your following weekly visit (approximately 25-weeks gestation), you will begin the exercise strategy (please see below) while continuing the nutrition strategy, and will continue to come to the lab for your weekly scheduled "weight-ins," walking and discussion of nutritional concerns.

If you are randomized into having the Exercise (Walking Program) strategy introduced first:

The purpose of the exercise strategy is to promote an active lifestyle, to prevent excessive gestational weight gain and to help prevent gestational diabetes. This strategy will take into account your previous physical activity habits. You will begin the walking program at a walking pace that is easy for you to maintain without becoming breathless (out of breath) for 25 minutes. We recommend that you complete 3 to 4 total (2 to 3 on your own) exercise sessions per week until delivery. For each subsequent week, the exercise time will increase by 2 mins up to a

maximum of 40 mins per walking session, which will be maintained until delivery. We will make a weekly scheduled appointment to the lab at your convenience for a "weigh-in" and for you to walk with us. These weekly visits will take approximately 45 to 60 minutes, and will continue until you reach 24-weeks gestation. At 24 weeks gestation, during your weekly visit, we will give you the Kaiser Physical Activity Survey to complete again, we will repeat your skinfold measurements and record your weight. We will ask you to repeat the 3-day food intake record using your choice of recording method like you did at the beginning of the study. In addition, you will use your Fitbit tracker to also record your activity levels like you did at the beginning of the study. At your following weekly visit (approximately 25 weeks gestation), you will begin the nutrition strategy (please see above) while continuing the exercise strategy, and will continue to come to the lab for your weekly scheduled "weight-ins," walking and discussion of nutritional concerns.

If you are randomized into having both Nutrition and Exercise strategies introduced first:

You will be given both strategies at the same time (see above) and will continue these strategies until delivery. At 24-weeks gestation, during your weekly visit, we will give you the Kaiser Physical Activity Survey to complete again, we will repeat your skinfold measurements and record your weight. We will ask you to repeat the 3-day food intake record using your choice of recording method) like you did at the beginning of the study. In addition, you will use your Fitbit tracker to also record your activity levels like you did at the beginning of the study. At your following weekly visit (approximately 25-weeks gestation), you will continue your nutrition and exercise strategies as you did before.

Regardless of strategy assignment, at 36 to 38 weeks of pregnancy, we will give you the same questionnaire plus one exit questionnaire about your experience in the program, we will measure your skinfolds and record your weight just like we did when you were 24-weeks gestation. At this visit you will be required to return your Fitbit. Regardless of strategy assignment, we ask that you or your partner contact us as soon as possible after the birth of your baby. We will contact you within 6 to 18 hours after you deliver. One of our research staff will visit you and your new baby and, with your help, we will measure the length, head size, chest size and abdomen size of your baby, length of limbs and limb girths, using a cloth tape measure. We will record the birth weight of your baby, any complications which may have occurred during delivery, and the APGAR scores. These are numbers that refer to your baby's colour, breathing and reflexes at 1 minute and 5 minutes after birth. Finally, we will measure 6 skin fold sites on your baby using a special infant skinfold caliper. The sites that we will measure are: the front and back of the arm, between the shoulder blades, the front of one thigh, the front of the belly by the belly-button, and just above the hip bone. There are no known risks with this procedure. We will also ask you what your last known body weight was before delivery.

You and your baby will return to the lab at 2, 6 and 12 months post-delivery for follow-up. You will complete the same questionnaires that you filled in from your last pregnancy visit along with two additional questionnaires about breastfeeding and solid foods. In addition, we will ask you what you ate and drank in the last 24 hours before your visit. We will measure your infant's length, weight and head, chest, abdomen, hip, arm, mid-thigh and calf circumference using a cloth tape measure like we did at birth. We will measure the same 6 skinfold sites on your infant

as we measured at birth. The front and back of the arm, between the shoulder blades, the front of the thigh, the front of the belly by the belly-button and just above the hip bone. You will be weighed and we will also measure your waist (at the area of your belly-button) and hips (at the widest part of your hips) using a soft cloth tape and repeat the skinfold measurements that we did when you were pregnant.
The total time for each of these visits will be approximately 60 to 90 minutes.

Voluntary Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or to withdraw from the study at any time with no effect on your future care.

Withdrawal from Study

You may change your mind about participating in the study and withdraw (stop taking part in the study) at any time. If you do withdraw, we will still use your information that has been collected up to that point. If, during the course of the study, your physician determines that continuation of the study would worsen your health, or the health of your baby, you will be advised to discontinue the study. When you discontinue, we will still use your information that has been collected up to that point to help answer the research question. No new information will be collected without your permission. **We must insist that you return our Fitbit to us immediately following your decision to withdraw.**

An alternative to the study procedures described above is to not participate in the study and just continue on as you do now. There is no guarantee of personal benefit from participating in the study.

If you withdraw from the study prior to completion we will contact you by phone to record your final weight before delivery and birth information (birth weight, length, head circumference, APGAR scores and any problems with labour and birth).

Are there any risks to participating in this study?

The risks involved with participating in this study are minimal. When you first begin the exercise walking program, you may experience some soreness in your muscles, but this will go away within a few days.

Are there any benefits to participating in this study?

Participating in this study may help you to learn more about health in pregnancy – specifically, exercise and nutrition – and may prevent excessive gestational weight gain.

How will your information be kept confidential?

Your confidentiality will be respected. The information collected from you will be used for this current research project only. Your record will be kept locked in a cabinet in a secure office.

Your name, address, telephone number and email address will be collected in order to contact you. You will be given a unique identification number and any personal or health information collected from you will not be personally identifiable in any way. Your records will be kept in a secure and confidential location for a minimum of 15 years and then destroyed.

Your unique Fitbit username will not include any personal identifiers. Only members of the research team will know your username and password.

When the results of this study are published, reported or presented to other health care professionals and researchers, your name (or the names of any other participant) will not be associated with any specific result without your consent to the disclosure.

All information collected for this study (including personal health information) will be kept confidential and will not be shared with anyone outside the study unless required by law. Absolute confidentiality, however, cannot be guaranteed, as representatives of the University of Western Ontario Health Sciences Research Ethics Board may require access to your study-related records or may need to follow-up with you to monitor the conduct of this research.

Will there be any cost to me?
No. Your participation in this research will not involve any additional costs to you or your health care insurer, and you will not be compensated for your participation in the study. We will arrange for you to park free of charge at UWO.

What are your rights as a participant?
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

You do not waive any legal rights by signing the consent form. You will be given a copy of this letter of information and consent form once it is signed.

Questions about the Study
If you have any questions about this study or your treatment, please contact the principal study investigator, Dr. Michelle Mottola (Department of Anatomy and Cell Biology, Schulich School of Medicine and Dentistry; School of Kinesiology, Faculty of Health Sciences) of the University of Western Ontario,

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics

Consent form

Strategizing the best approach to prevent early excessive gestational weight gain using a Nutrition and Exercise Lifestyle Intervention Program (NELIP)

I have read the letter of information. This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree for myself and my child to participate.

Please check the appropriate box below and initial:
____ I agree to be contacted for future research studies
____ I do NOT agree to be contacted for future research studies

_____ _____ _____
Your Name (PLEASE PRINT) Your Signature Date (DD-MM-YYYY)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_____ _____
Name of Person obtaining consent Signature

Appendix A3: Modified PARmed-X for Pregnancy

PHYSICAL ACTIVITY READINESS EXAMINATION FORM (PARmed-X for pregnancy)
R. SAMUEL McLAUGHLIN FOUNDATION -EXERCISE AND PREGNANCY LABORATORY, 3M CENTRE
SCHOOL OF KINESIOLOGY-FACULTY OF HEALTH SCIENCES

Name: _____ **Physician/Midwife Name:** _____
Address: _____ **Phone #:** _____
Phone #: (W): _____
(H): _____ **Birth Date:** _____

Healthy women with uncomplicated pregnancies can participate in properly designed physical fitness programs without significant risk to themselves or their unborn child. Postulated benefits of such programs include improved aerobic and muscular fitness, promotion of appropriate weight gain, improved mood state and body image. Regular exercise may also help to prevent gestational glucose intolerance and pregnancy-induced hypertension. The safety of prenatal exercise programs depends on an adequate level of maternal-fetal physiological reserve. PARmed-X for Pregnancy is a convenient checklist for use by physicians and midwives to evaluate pregnant patients who want to enter a prenatal fitness program and for ongoing medical surveillance of exercising patients. **If the patients health status changes as pregnancy progresses, the physician or midwife is encouraged (if appropriate) to withdraw clearance to exercise by calling the Exercise and Pregnancy Laboratory**

PRE-EXERCISE HEALTH CHECKLIST
(TO BE COMPLETED BY PARTICIPANT)

PART A: GENERAL HEALTH
In the past, have you experienced:
(**Circle** #)
1. Miscarriage in an earlier pregnancy?
2. Other pregnancy complications?
3. Heart trouble?
4. Chest pain or palpitations?
5. Breathing problems? (e.g. Asthma, bronchitis)
6. Dizziness/fainting?
7. High blood pressure?
8. Diabetes?
9. Arthritis or other problems with joints?
10. Other health problems which might affect your ability to exercise?

If you **circled** any of the above, please explain:_____
_____
_____
_____
_____

11. Number of previous pregnancies:_____

PART B: CURRENT STATUS
Due Date:_____
Date of last menstrual period:
_____
During this pregnancy have you experienced: (**Circle #**)
1. Marked fatigue?
2. Bloody discharge from the vagina (e.g. spotting)?
3. Unexplained fainting or dizziness?
4. Unexplained abdominal pain?
5. Sudden swelling of ankles, hands or face?
6. Persistent headaches or problems with headaches?
7. Swelling, pain or redness in the calf of one leg?

8. Absence of fetal movement after the fourth month?
9. Failure to gain weight after the fourth month?

If you **circled** any of the above, please explain:_____
_____
_____
_____

PART C: HEALTH HABITS (past month)
1. Are you presently exercising? If **circled,** please list any fitness/recreational activities:
_____

If **N0,** go to question #**3**.
2. Please check off your workout-type:

Intensity	Frequency (#/ week)			Time (min./day)		
	1-2	**3-4**	**4+**	**<20**	**20-40**	**+40**
Heavy						
Medium						
Light						

3. Does your regular occupation involve:
(**Circle** any that apply to your job/home)
a. Heavy lifting **b**. Mainly sitting
c. Normal daily activity **d**. Prolonged standing
e. Frequent walking/stair climbing
f. Occasional walking (< once/hr)

4. Do you smoke cigarettes? If **circled:**
**Number of years smoked_____
** Number smoked per day_____
5. Do you consume alcohol? If **circled:**
**Number consumed per day_____
****Note:** *Pregnant women are strongly advised not to consume alcohol or to smoke during pregnancy.*

(PLEASE TURN OVER)

Version 1: 18-05-2016

CONTRAINDICATIONS
(TO BE COMPLETED BY ATTENDING HEALTH CARE PROVIDER)

ABSOLUTE CONTRAINDICATIONS
Permanent or temporary restriction until condition is treated, stable and/or past acute phase. Please **circle** any that pertain to your patient:

1. Clinically significant valvular or ischemic heart disease?
2. Uncontrolled Type I diabetes mellitus, peripheral vascular disease, thyroid disease, hypertension, or other systemic disorders (hepatitis, mononucleosis, etc.)
3. An incompetent cervix (multigravid patients)?
4. A history of two or more spontaneous abortions?
5. Persistent 2nd or 3rd trimester bleeding/ placenta previa?
6. Ruptured membranes or premature labour?
7. Toxemia or pre-eclampsia (current pregnancy)?
8. Evidence of fetal growth restriction (current pregnancy)?
9. A multiple pregnancy (eg. Triplets)?

RELATIVE CONTRAINDICATIONS
Risks may exceed benefits of fitness conditioning. Decision to exercise or not should be made with qualified medical advice. Please **circle** any that pertain to your patient:

1. History in previous pregnancies of premature labour and/or spontaneous abortion?
2. Anaemia or iron deficiency (Hb.<1 0 g/dl)
3. Clinically significant pulmonary disease (e.g. COPD)?
4. Mild valvular or ischemic heart or respiratory disease, eg. Chronic hypertension, asthma
5. Very low physical fitness prior to pregnancy?
6. A prescription of drugs which can alter cardiac output or blood flow distribution?
7. Obesity and/or 'Type II' diabetes prior to pregnancy?
8. Very low % of body fatness, eating disorders (i.e. anorexia or bulimia)?

I, _____ (*Participant's name*) have discussed my plans to participate in exercise testing and/or exercise sessions during my current pregnancy and I have obtained approval from_____(*Physician/Midwife name*) to begin participation.

_____	_____	_____	_____
Participant's signature	Date	Attending Physician/Midwife's Signature	Date

COMMENTS FROM THE ATTENDING HEALTH CARE PROVIDER ARE WELCOMED BELOW.

(Taken from: Wolfe, L and Mottola, MF. 2002. PARmed-X for Pregnancy. Available from the Canadian Society of Exercise Physiology. www.csep.ca)

Appendix A4: Three-day Food Intake Record Log Sheet

Nutrition & Exercise Lifestyle Intervention Program (NELIP)

Western
The University of Western Ontario

EPL
Exercise and Pregnancy Lab

Brescia University College

EXERCISE AND PREGNANCY LABORATORY

3-DAY FOOD RECORD

Unique ID: _____ Dates to record: _____

Checklist Before you return your food record, make sure you included:

☐ Spreads on toast, potatoes and vegetables

☐ Sugar and cream or creamers in beverages

☐ Salad dressings

☐ Syrups, sauces and gravies

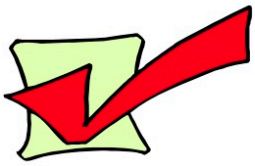
☐ Condiments, e.g., ketchup, soy sauce, mayo, etc.

☐ Candy and soft drinks

☐ Chips, nuts, and popcorn

Please keep a record of everything you eat and drink for 3 days: 2 days during the week and 1 day on the weekend. Keep track of everything you eat from the time you wake up in the morning until the time you go to bed at night. Do not forget to include all snacks and beverages.

If in doubt, leave too much information! **Thank you!**



What do I need to include?

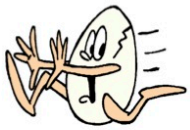
1. List the food item and amount eaten

   - Product Name – type of food eaten (ex. mushroom soup)
   - Brand Name- different ingredients may be used (ex. Campbell vs. Lipton)
   - Characteristics:

   - Colour (e.g. green or yellow beans, white or brown bread)
   - Fat content ~ % fat (e.g. skim, 1%, 2% or homo milk)
     ~ leanness of meat (e.g. extra lean ground beef)
     ~ fat claims (e.g. light, low fat, etc.)
   - State ~ Was it fresh, frozen, canned or dried?

2. Record the time and the place where the food was eaten.

3. For each item briefly describe how it was prepared:



   Was your meat fried, baked, broiled or barbecued?
   Were vegetables eaten raw or were they boiled steamed or sautéed?
   Did you trim the visible fat off of the steak? Was the chicken skinless?
   Did you fry the food in butter, oil or margarine?

4. Please measure and describe the amount of food eaten as best as possible:

   Give dimensions: e.g., 2 slices of roast beef – 5" x 3" x ¼'' thick
   Give spoon or cup measurements: e.g., ¾ cup peas with ½ tsp butter
   Give ounces (oz): e.g., 4 oz of salmon or a 6 oz steak
   Give metric units: e.g., 250 mL of milk

5. For mixed dishes such as lasagna, casseroles and stews, record approximate amounts of the main ingredients.
   E.g., Lasagna - Were there vegetables in it? What kind?
   - Was it a meat and cheese lasagna?

How do I know what a serving size is?

To help identify serving sizes, the following guidelines may come in handy:

- Count the number of food items if practical.

  E.g., 20 grapes or 8 shrimps

- Use household measures to specify serving sizes.

  E.g., 1 cup (c) = 250 mL 1 tablespoon (Tbsp) = 15 mL
  1 ounce (oz) = 30 g 1 teaspoon (tsp) = 5 mL

- Use your hands to estimate serving sizes.

  - A palm is equal to 3 ounces (e.g., 3 ounces of meat, fish or poultry).

  - A fist is equivalent to a 1 cup measure (e.g., 1 cup of lettuce).

  - A thumb tip is equal to 1 teaspoon (e.g., 1 tsp of margarine).

  - 3 thumb tips are equal to 1 tablespoon (e.g., 1 Tbsp of salad dressing and peanut butter).

- Other objects that may help to estimate serving sizes.

  - A deck of cards is approximately 3-4 oz of meat.
  - A computer mouse is a serving of potato.
  - A baseball is equal to one cup or a serving of pasta.
  - A tennis ball is equal to a medium sized fruit.

  - A hockey puck is the serving size of a bagel.
  - A Ping-Pong ball is equal to 2 tablespoons.
  - A CD is the serving size of a pancake.
  - A chequebook is a 3 oz fillet of fish.
  - A floppy disk is a slice of processed cheese.
  - A pair of dice is 2 tsp of sugar.
  - A film canister is an ounce of nuts.
  - Three dominos is 3 oz of low fat hard cheese.

When filling out the daily food record, remember to write down everything that you eat and drink from the time you wake up until the time you go to sleep. Please accurately record as much information as possible. This will assist the dietitian. Thank you!

Unique ID: _____

3-Day Food Record **Day 1** Date: _____

Time	Place	Food and Description and Method of Preparation	Amount

When filling out the daily food record, remember to write down everything that you eat and drink from the time you wake up until the time you go to sleep. Please accurately record as much information as possible. This will assist the dietitian. Thank you!

Unique ID: _____

3-Day Food Record **Day 2** Date: _____

Time	Place	Food and Description and Method of Preparation	Amount

When filling out the daily food record, remember to write down everything that you eat and drink from the time you wake up until the time you go to sleep. Please accurately record as much information as possible. This will assist the dietitian. Thank you!

Unique ID: _____

3-Day Food Record **Day 3**

Date: _____

Time	Place	Food and Description and Method of Preparation	Amount

Appendix A5: Baseline Step Count Log Sheet

Exercise and Pregnancy Lab – NELIP+: Baseline Step Count Tracking Sheet

Unique I.D. _____

Select 3 consecutive days (2 weekdays, 1 weekend) to record your steps.
****Please record your step counts before midnight (12:00am)****

	DATE (d/m/y)	Daily Total Step
Sunday		
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		

Appendix A6: Weekly Exercise Tracking Sheet

Exercise and Pregnancy Lab – NELIP+: Weekly Exercise Log Sheet

Unique I.D. _____
Week on Program: **Week Recording:**
Gestational Age:

****Please record your step counts before midnight (12:00am)****

	DATE (d/m/y)	Daily Total Step	Comments (Please list any additional walks, anytime you forgot to wear your FitBit/GG)
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Appendix A7: Modified Gestational Diabetic Meal Plan

NELIP Suggested Meal Plan

TIME	FOOD GROUP	CHOICES	ONE DAY SAMPLE MENU	ALTERNATIVES
BREAKFAST	Target = ~25 grams of carbohydrates			
	Starch Foods	1	½ cup cereal (e.g. Shreddies) or ½ small multigrain bagel or 1 slice whole wheat bread	
	Protein Foods	1	1 egg or 1 ounce (~30 grams) low-fat cheese or 1 Tbsp (15 mL) peanut butter	
	Milk	2	1 cup (250 mL) skim milk or ¼ cup (60 g) low-fat fruit yogurt	
	Extra Vegetables	recommended	2 slices tomato or ½ cup mushrooms & green pepper (in omelette)	
AM SNACK	Target = ~25 grams of carbohydrates			
	Starch Foods	1	½ whole wheat English muffin or 1 small oat bran muffin or 5 multigrain crackers	
	Fats & Oils	1	1 tsp (5 mL) soft (e.g. Becel) margarine	
	Vegetable & Fruit	1	1 cup vegetable juice or ½ medium apple or 1 small orange or 2 apricots	
LUNCH	Target = ~35 grams of carbohydrates			
	Starch Foods	2	2 slices whole wheat or pumpernickel bread or 1 cup legumes	
	Protein Foods	3	3 ounces lean meat or skinless poultry e.g. 90 g or 1 medium roasted chicken breast	
	Fats & Oils	2	1 tsp olive oil and ¼ avocado or 2 tsp regular salad dressing	
	Milk	1	½ cup (125 mL) skim milk or ½ cup (125 mL) plain fortified soy beverage	
	Extra Vegetables	recommended	1 slice tomato and 1 cup spinach salad (with avocado and oil above) or 2-3 slices cucumber and a celery stick or ½ cup sliced sweet peppers	
PM SNACK	Target = ~25 grams of carbohydrates			
	Starch Foods	1	5 whole wheat crackers or 4 melba toasts or 1 slice flax bread or ½ small multigrain bagel or 1/3 cup legumes	
	Vegetable & Fruit	1	**½ cup mixed raw vegetables** or ½ cup grapes or 1 kiwi or 4 tsp raisins (small box) or ½ small banana	
	Fats & Oils	1	10 peanuts or 5 cashews or 1 Tbsp (15 mL) cream cheese	
DINNER	Target = ~45 grams of carbohydrates			
	Starch Foods	2	⅔ cup rice or baked beans or 1 cup pasta or 1 cup (250 mL) potato or corn or couscous	
	Fats & Oils	2	2 tsp (10 mL) oil or soft, non-hydrogenated margarine or 2 Tbsp (30 mL) low-fat sour cream	
	Vegetable & Fruit	1	½ cup (125 mL) cooked carrots or peas or mixed vegetables	
	Protein Foods	3	3 ounces lean meat or poultry or fish; or ½ cup legumes e.g. 90 g roast beef or a medium pork chop	
	Milk	1	½ cup (125 mL) skim milk or plain fortified soy beverage	

	Extra Vegetables	recommended	½ cup (125 mL) tossed salad or ½ cup (125 mL) broccoli or ½ cup (125 mL) cauliflower or ½ cup (125 mL) green beans	
EVENING SNACK	Target = ~25 grams of carbohydrates			
	Starch Foods	1	½ whole wheat pita or 3 cups (750 mL) plain popcorn	
	Fats & Oils	1	1 Tbsp (15 mL) low-fat mayo or 1 tsp (5 mL) margarine	
	Protein Foods	1	¼ cup (60 mL) canned salmon or tuna or low-fat cottage cheese or 1 egg or 1 Tbsp (15 mL) peanut butter	
	Vegetable & Fruit	1	8 baby carrots or 1 cup celery or 1 peach or 1 kiwi or 1 small orange or ½ pear or ½ cup berries	
BED SNACK	**Target = ~25 grams of carbohydrates**			
	Starch Foods	1	1 fig Newton cookie or ¾ cup plain cheerios or ½ cup oat flakes or 2 rice cakes	May substitute with 1 cup of low-fat plain chocolate, strawberry, or vanilla ice cream.
	Milk	2	¾ cup (175 g) low-fat plain yogurt or 1 cup (250 mL) skim milk or 1 cup (250 mL) plain fortified soy beverage	

Curriculum Vitae

Name:	Karishma Hosein
Post-secondary Education and Degrees:	Western University London, Ontario, Canada 2011-2015 Honors BSc Kinesiology 2015-2017 MSc, Integrative Biosciences, Kinesiology
Honors and Awards:	Dean's Honor List 2014-2015 Western Scholarship of Distinction 2011
Related Work and Volunteer Experience:	Teaching Assistant Western University – School of Kinesiolgy 2015-2017 Research Assistant R. Samuel McLaughlin Exercise and Pregnancy Laboratory 2016-2017 Volunteer Research Assistant London Health Sciences Centre - Department of Respirology 2014-2017 Speaker and Public Education Chair Osteoporosis Canada – London Thames Valley Chapter 2014-2017

Scientific Presentations:

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Behaviour change intervention strategies to prevent excessive gestational weight gain in pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Exercise is Medicine National Student Research Conference, London, Ontario, 2017.

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Behaviour change intervention strategies to prevent excessive gestational weight gain in pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Kinesiology Graduate Student Association Research Symposium, London, Ontario, 2017.

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Behaviour change intervention strategies to prevent excessive gestational weight gain in pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Bodies of Knowledge Graduate Student Research Conference, Toronto, Ontario, 2017.

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Proposal: Behaviour change intervention strategies to prevent excessive gestational weight gain in obese pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Exercise is Medicine Ontario Student Research Conference, London, Ontario, 2017.

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Proposal: Behaviour change intervention strategies to prevent excessive gestational weight gain in obese pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Kinesiology Graduate Student Association Research Symposium, London, Ontario, 2016.

Hosein, K.S., Nagpal, T.S., Prapavessis, H., Campbell, C., Mottola, M.F. Proposal: Behaviour change intervention strategies to prevent excessive gestational weight gain in obese pregnant women using a Nutrition and Exercise Lifestyle Intervention Program (NELIP). Presented at Bodies of Knowledge Graduate Student Research Conference, Toronto, Ontario, 2016.