8-19-2019 10:00 AM

Nutrition and exercise interventions during pregnancy: How important is adherence?

Taniya S. Nagpal, *The University of Western Ontario*

Supervisor: Mottola, Michelle F., *The University of Western Ontario*
Co-Supervisor: Prapavessis, Harry., *The University of Western Ontario*
A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Kinesiology

Abstract

Lifestyle interventions (nutrition and exercise) offered during pregnancy may prevent excessive gestational weight gain (EGWG) and improve pregnancy outcomes. The efficacy of previous interventions has been inconsistent as some studies ‘successfully’ achieve their health outcome goals while others have had a null effect. A common limitation reported among ‘unsuccessful’ studies is low adherence. The objective of this dissertation was to execute three independent yet interrelated studies to determine if adherence is a key factor in determining the success of a lifestyle intervention during pregnancy. Study 1 compared adherence to ‘successful’ and ‘unsuccessful’ lifestyle interventions during pregnancy using a systematic review. Results showed that adherence is significantly higher among ‘successful’ health outcome studies than ‘unsuccessful’ ones. Study 2 aimed to determine if adherence remains a key factor in determining program ‘success’ among women with a pre-pregnancy body mass index $\geq$25.0 kg/m^2 who may have experienced weight fluctuations prior to pregnancy. Results revealed that high adherence to nutrition and exercise goals during pregnancy is a significant predictor of appropriate gestational weight gain. Study 3 aimed to determine a strategy to improve program adherence by comparing adherence to the sequential introduction of nutrition and exercise behaviors to the simultaneous approach. Results showed that the sequential introduction of exercise followed by nutrition improves adherence and may also improve health outcomes including promotion of appropriate gestational weight gain. By improving adherence to prenatal nutrition and exercise goals, more women may have a healthy pregnancy and this improves health outcomes for mother and child.

Keywords

Adherence, pregnancy, exercise, nutrition, behavior change, obesity

Lay Summary

Adherence is defined as the degree to which an individual follows the recommendations of a healthcare provider. Among pregnant women, previous authors have reported low adherence as a limitation of nutrition and exercise programs. Low adherence is problematic because it means that the participants are not actually performing the required goals of a program and therefore this can reduce their likelihood of achieving positive health outcomes. Examples of health outcomes include preventing excessive weight gain during pregnancy, macrosomia (large babies, birthweight >4000g) and low birth weight (small babies, birthweight <2500g). Women who exceed weight gain recommendations during pregnancy and babies born too small or large are at an increased risk for later life diseases. Providing women with a nutrition and exercise program can help them gain an appropriate amount of weight and promote a healthy baby birthweight. This thesis aims to determine if adherence plays an important role in the success of lifestyle programs (nutrition and exercise) during pregnancy. The first study measured adherence to 'successful' and 'unsuccessful' programs and found that studies that met their health outcome goals (successful) had higher adherence than studies that did not (unsuccessful). The second study measured adherence to a nutrition and exercise program among women who entered pregnancy with an overweight body mass index and may have experienced weight loss before pregnancy. Study two found that adherence is still higher among women who successfully achieved the health outcome (prevention of excessive weight gain), even if they experienced weight loss before pregnancy.

Finally, the third study tested adherence strategies including offering nutrition and exercise at the same time compared to offering the behaviors one at a time. Results showed that when exercise is offered first followed by nutrition, adherence improves. Additionally, the group that received exercise first also reported positive health outcomes including prevention of excessive weight gain. This thesis provides evidence that adherence is a key factor for the success of nutrition and exercise programs during pregnancy. By improving adherence, more women can have a healthy pregnancy and this can improve the health and well-being of both mom and baby.

Co-Authorship Statement

Chapters 2, 3 and 4 were co-authored by Drs. Christina Campbell and Barbra de Vrijer (thesis committee members, assisted with the design of the study and editing the manuscripts). Chapters 2 and 4 were co-authored by Dr. Roberta Bgeginski and Mollie Manley (assisted with data collection). Chapter 2 was co-authored by Dr. Marina Vargas-Terrones (assisted with data collection). Chapter 3 was co-authored by Dr. Isabelle Giroux (developed the questionnaire used). Chapter 4 was co-authored by Karishma Hosein and Stephanie Paplinskie (assisted with data collection).

All chapters were reviewed and edited by thesis supervisors, Drs. Michelle Mottola and Harry Prapavessis.

Acknowledgments

Thank you to Dr. Michelle Mottola for giving me the chance of a lifetime to pursue graduate studies and countless learning opportunities with continuous support and encouragement to open as many doors as I can.

Thank you to Dr. Harry Prapavessis for his guidance, kindness, wisdom and encouragement to always be curious and continue learning.

Thank you to my committee members, Dr. Christina Campbell and Dr. Barbra de Vrijer, for their support with my thesis studies and for supporting my overall learning and growth throughout graduate studies.

Thank you to my lab-mates, past and present, from both the Exercise and Pregnancy Laboratory and Exercise and Health Psychology Laboratory for their support with the completion of my thesis studies and friendship. Thank you to Dr. Maggi Sopper for welcoming me to graduate studies and supporting me throughout the process. Thank you to the team of mentors I got to work with as a part of the *2019 Physical Activity Throughout Pregnancy Guidelines,* which was a unique and very important part of my graduate experience.

Thank you to my friends, colleagues and mentors around the world for broadening my perspective, exploring new places with me and for beautiful friendships; Dr. Ruben Barakat, Dr. Roberta Bgeginski, Dr. Marina Vargas-Terrones, Dr. Karina Kasawara, Dr. Ana Cardona Garcia.

Thank you to my friends, mentors and colleagues from Exercise is Medicine Canada, Obesity Canada, Canadian Cancer Society, Retired Research Association and The Society of Graduate Students for being a pleasure to work with and making ideas into a reality with me. Thank you to Dr. Lorraine Davies (SGPS) for her support with extra-curricular activities and guidance. Thank you to Dr. Lyndsay Fitzgeorge (Fanshawe College) for giving me the chance to pursue and fall in love with teaching and for her guidance with my graduate work.

Thank you to the many faculty members and administrative staff at the School of Kinesiology and Health Studies for making graduate school easier to navigate and for creating many learning opportunities.

Thank you to my graduate family from Write Café and Tea Time for your friendship and unforgettable memories.

Thank you to all of the research participants for wonderful walks, conversations and for contributing to this work. And thank you to all of the babies, for contributing to research even before birth.

Thank you to my dear friends who have supported me through all the good and tough times over the last 10 years; Shaathaka Nandakumar, Samantha Fernandes, Sahar Nagal, Priynka Patil and Meera Manicks.

Thank you to Munish Mehta for his love, for always being there for me and for encouraging me to work hard, do more and be more.

Thank you to my family for believing in me and always encouraging me to do my best. My best friend, Buddy, for being my number one fan and the greatest study buddy. My pal, Domi, for always making me laugh. My brother bear, Tanish Nagpal, for being the reminder in my life to take it easy and enjoy the process. My parents, Paramjit Nagpal and Gurmit Nagpal, for their unconditional love, strength and encouragement to always dream big...this one’s for you.

Table of Contents

List of Tables

List of Figures

List of Appendices

Chapter 1

Introduction

This chapter will first provide an overview on the prevalence of excessive gestational weight gain and the associated health consequences, including the risk for chronic conditions such as obesity. Next, this chapter will provide information on existing lifestyle interventions that have addressed health outcomes during pregnancy, such as prevention of excessive gestational weight gain, to reduce the risk of later life obesity. The effectiveness of previous lifestyle interventions (nutrition and exercise) has been inconsistent, with some studies achieving their health outcome goals while others have had a null effect. Low adherence to previous lifestyle interventions will be discussed as a limitation that contributes to null results, followed by the rationale to further examine adherence as a potential key factor for determining the 'success' of nutrition and exercise interventions during pregnancy. Based on the theory of self-control and self-regulation, this chapter will rationalize further exploration of the sequential introduction of nutrition and exercise behaviors as a way to improve program adherence in comparison to the simultaneous approach. Finally, this chapter will conclude with a summary of studies 1-3 included in this thesis.

1.1 Excessive gestational weight gain

The risk for pregnancy complications, including gestational diabetes, gestational hypertension and preeclampsia, will increase if an excessive amount of weight is gained during pregnancy (1, 2). Excessive gestational weight gain

(EGWG) has been defined by the Institute of Medicine (2009) as gaining above 9.0 kg, 11.5 kg and 16.0 kg for women with a pre-pregnancy body mass index (BMI) of obese (BMI ≥30.0 kg/m^2), overweight (BMI ≥25.0-29.9 kg/m^2) and normal weight (BMI ≥18.0-24.9 kg/m^2), respectively (3). It is recommended that women gain 2.0 kg in the first trimester (0 to 12 weeks gestation) regardless of pre-pregnancy BMI (3). After the first trimester, women are expected to gain no more than 0.29 kg, 0.33 kg and 0.50 kg per week for an obese, overweight and normal weight pre-pregnancy BMI, respectively (3). Approximately 50% of Canadian women gain excessively during pregnancy, with a higher prevalence seen in women who have a pre-pregnancy BMI ≥25.0kg/m^2 (4).

Gaining above these guidelines (regardless of pre-pregnancy BMI) has been shown to significantly increase the risk for pregnancy complications (1, 2). Additionally, EGWG can increase the risk for later life obesity that can affect both mother and growing fetus (5-7).

1.2 Cycle of obesity

Women who gain weight excessively during pregnancy are at greater risk for delivering babies with a birthweight >4000g (macrosomia) (1, 8, 9) and having a large for gestational age baby (10, 11). A recent meta-analysis including individual patient data from 162,129 mothers reported that EGWG, large for gestational age babies and macrosomia were positively correlated with childhood obesity (7). Babies born large for gestational age have higher levels of adipocytes which increases fat storage and therefore puts them at risk for both childhood and adult obesity (12).This may suggest that EGWG can perpetuate a cycle of obesity (13, 14).

If a woman enters pregnancy with obesity, she is at greater risk of gaining excessively, and having a large for gestational age baby who is more likely to have obesity as an adult (13). If the baby is female, she may then enter pregnancy as an adult with obesity, and if she gains weight excessively when pregnant, the obesity cycle can continue (13). Further, women who gain excessively during pregnancy are more likely to retain the extra weight in the postpartum period which may be difficult to lose and therefore increases her risk of carrying extra weight potentially into subsequent pregnancies (13). Women with a normal weight can potentially enter the cycle of obesity by gaining excessively during pregnancy and retaining that extra weight post-delivery and into future pregnancies (13). The link between exposures, such as EGWG, that occur during pregnancy and later life chronic disease risks, including obesity, is explained by the Developmental Origins of Health and Disease (DOHaD) theory.

1.3 Brief Introduction to the Developmental Origins of Health and Disease: Obesity

The origin of the DOHaD theory stems from coronary heart disease related research (15) conducted in England and Wales. Barker (2007) examined a large cohort of birthweight data that showed infants born small for gestational age (SGA) were more likely to develop and die from cardiovascular disease later in life in comparison to babies born at an appropriate birthweight (15). This was linked to early exposures to famine while *in utero*, which may have led to under-nutrition during pregnancy and babies born SGA (15). Potential mechanisms that led to babies being born SGA include poor organ development and placental dysfunction (16). It has been proposed that under-nutrition can potentially lead to reduced angiogenesis which affects the transfer of blood and nutrients across the placenta, leading to intrauterine growth restriction and consequently low birthweight (17). Babies may not be able to grow to their full potential and this increases their risk for later life chronic diseases (17).

The potential programming of obesity has also been extensively studied (6, 18, 19). One study measured the BMI of adults at age 50 who were born during a period of famine in Amsterdam (born between 1943 and1947) (20). Similar to the results found on cardiovascular disease, most babies born in the period of famine in Amsterdam were also born SGA (20). Interestingly, when followed into the future, the infants born small were more likely to have an obese BMI in their teenage years and at age 50 compared to the babies that were born at an appropriate birthweight (20).This may be because of a mismatch experienced between the adaptation of the growing fetus to the exposed environment *in utero* compared to the environment expected after birth (21). *In utero*, the fetus was programmed to expect famine (low nutrient intake) and therefore was programmed to store nutrients, but post-birth if exposed to an environment with greater availability of nutrients, rapid catch-up growth and fat storage occurs, which increases the risk for later life obesity (21). On the opposite end, research has also shown that over-nutrition experienced *in utero* increases the risk for macrosomia (birthweight >4000g) and this is also positively correlated with childhood and adult obesity (18-20).

Overall, the results of large cohort studies suggest that birthweight on either end of the spectrum (low birth weight and macrosomia) increases the risk for later life obesity (18-20). Therefore, there is evidence to show that environmental exposures during pregnancy may increase the risk for later life chronic disease development, including obesity.

1.4 Prevalence of Obesity

The prevalence of obesity continues to increase, with recent statistics suggesting that over 5 million Canadian adults have a body mass index (BMI) $\geq$30 kg/m^2 and one in four adults have a BMI $\geq$25 kg/m^2 (22, 23). If current *status quo* healthcare practices remain, it is projected that obesity rates will continue to increase for Canadian adults for at least the next two decades (23). In addition to adults, the prevalence of childhood obesity in Canada has doubled over the last four decades, with recent statistics suggesting that one in seven children and youth (<18 years) has a BMI $\geq$30 kg/m^2 (24). Projected trends for childhood obesity suggest that the prevalence will remain as it has been over the last ten years, especially if no changes are made on how the Canadian healthcare system manages and prevents childhood obesity (24).

The operational definition of obesity for adults is having a BMI $\geq$30 kg/m^2 taking into account the ratio between height and weight (25-29). The medical definition of obesity as a disease goes beyond just BMI. In 2015 the Canadian

Medical Association officially recognized obesity as a disease defined as a condition characterized by abnormal or excess fat accumulation (26). Body mass index remains the most common way to measure obesity, and although it has been criticized for not being the best source of measurement in all populations (e.g. athletes), it remains effective and accurate in the general population (25, 27, 29). By defining obesity as a disease specifically characterized by excess body fat, it means that individuals with Class I obesity (30.0 – 34.9 kg/m^2; low-risk obesity) do not have a severe level of obesity but are at risk of developing Class II (35.0 - 39.9 kg/m^2, moderate-risk obesity) or Class III (≥40.0 kg/m^2, high-risk obesity) (30). Class I obesity may not require medical intervention and can potentially be managed and prevented with lifestyle behavior change, including nutrition and exercise (30). Classes II and III obesity may require further medical intervention, such as medication or surgery (30). Overall, obesity was recognized as a disease because of its progressive nature, symptomology which is similar to that of other diseases (e.g. increased risk of insulin resistance) and its association to significantly increasing the risk for other chronic conditions (31).

In a recent report card released by Obesity Canada, it was highlighted that across Canada not a single province or territory has effectively implemented strategies to reduce the prevalence of obesity (32). As a result, it is estimated that the annual healthcare cost associated with obesity in Canada is $5 billion (32). Based on the increasing trends of obesity for all population groups in Canada, it is important to develop both preventative and treatment strategies.

As the prevalence of obesity increases, more women of child bearing age are entering pregnancy with an elevated BMI and this can increase the risk for a number of pregnancy complications. Specifically, 24% and 21% of women 20 to 44 years of age have a BMI ≥25.0-29.9 kg/m^2 and ≥30.0 kg/m^2, respectively (5).

1.5 Obesity and pregnancy complications

Obesity is a risk factor for infertility (33). Increased body fat can dysregulate menstrual cycles and as a result conception may be difficult (33). As well, an elevated BMI significantly increases the risk for polycystic ovarian syndrome which has a negative effect on fertility (34). Statistics from *in vitro* fertilization clinics have shown that the majority of the women who need assisted reproductive technology have a BMI ≥25.0 kg/m^2 (35) and as fat percentage increases the success rate of assisted reproductive technology decreases (36). It has been recommended by healthcare providers that women with obesity seeking pre-conception counselling should also be offered weight loss support (4, 37).

For those women with an elevated pre-pregnancy BMI that do conceive, there are a number of pregnancy complications that can impact both the mother and growing fetus including gestational diabetes (38-40), gestational hypertension and preeclampsia (41), preterm delivery (37, 42), macrosomia (37, 43) and caesarean sections (44). These conditions may increase the risk for later life chronic conditions, including type 2 diabetes and cardiovascular disease, for both mother and offspring (38, 45). Two conditions that will be discussed in further detail are gestational diabetes and hypertension as they are positively correlated with two highly prevalent chronic conditions in Canada, type 2 diabetes and cardiovascular disease (46, 47).

Gestational diabetes is the onset of diabetes that is first diagnosed during pregnancy (48). During pregnancy women experience a natural increase in insulin resistance in order to allow for increased concentrations of blood glucose for fetal growth and development (48-50). If elevated blood glucose concentrations continue to progress beyond normal values during pregnancy, women may develop gestational diabetes (49). To manage gestational diabetes, women are given a specific nutrition plan to follow that focuses on a low glycemic index, and if this fails they will be prescribed insulin (51). Developing gestational diabetes may increase the risk for type 2 diabetes later in life (38).

Women with an elevated BMI are at greater risk of entering pregnancy with increased insulin resistance and therefore may be more likely to develop gestational diabetes (52). Babies born to women who developed gestational diabetes are also at greater risk for early onset of type 2 diabetes (39, 53). One longitudinal study assessed the effects of maternal obesity and maternal obesity in combination with gestational diabetes on the incidence of type 2 diabetes in the offspring (54). Results showed that gestational diabetes was a predictor for insulin resistance in the offspring up to eleven years of age, suggesting a greater risk of developing early type 2 diabetes (54).

In addition to a natural increase in insulin resistance, pregnant women experience an increase in cardiac output, including higher blood and stroke volume and heart rate (55, 56). An increase in plasma volume and stroke volume in combination with a decrease in peripheral vascular resistance allows women to maintain blood pressure at normal or lower values, however if women do develop high blood pressure (≥140/90 mmhg) after 20 weeks of pregnancy they are diagnosed with gestational hypertension (56). If high blood pressure persists for a long period of time, the condition may progress to preeclampsia (onset of hypertension and proteinuria during the second half of pregnancy) and eclampsia (onset of seizures during pregnancy with a diagnosis of pre-eclampsia) (57-61).

Women with an elevated BMI are at greater risk of entering pregnancy with high blood pressure and are vulnerable for developing gestational hypertension and preeclampsia (10, 62). A population-based cohort study including over 6000 pregnant women, found that women with obesity had greater odds of developing preeclampsia (Odds Ratio [OR] 3.61, 95% Confidence Intervals [CI] 2.04, 6.39) and gestational hypertension (OR 6.31, 95% CI 4.30, 9.26) than women with a normal weight BMI (41). Women who experience preeclampsia are at a 2.16 times greater risk of experiencing heart disease later in life (63).

A modifiable risk factor that can prevent pregnancy complications, including gestational hypertension and diabetes, is the prevention of EGWG (14). Regardless of pre-pregnancy BMI, gaining appropriately during pregnancy can reduce the risk of pregnancy complications (2, 40). Previous studies have shown that a lifestyle intervention, including nutrition and exercise, may prevent EGWG for all women (14, 64, 65).

1.6 Prevention of excessive gestational weight gain

Excessive gestational weight gain (EGWG) is known as a modifiable risk factor (14, 64, 65). Results from systematic reviews and meta-analyses have mostly shown that a lifestyle intervention (nutrition and exercise) can promote appropriate gestational weight gain (66, 67).

Streuling et al. (2011) conducted a meta-analysis that included twelve exercise interventions delivered during pregnancy to prevent EGWG (68). Results suggested that exercise may have a positive effect on reducing total gestational weight gain, as seven included studies showed significance favoring the intervention group compared to a standard care control group (68). However, the remaining five studies favored the control group suggesting no effect of an exercise intervention for prevention of EGWG (68). As a result, the authors concluded further research is required to determine the effects of prenatal exercise and prevention of EGWG (68). Oteng-Nitim et al. (2012) assessed the effects of nutrition and/or exercise interventions during pregnancy on gestational weight gain (69). Similar to results shared by Streuling et al. (2011) (68), the more recent review showed a small reduction in gestational weight gain with a lifestyle intervention (-2.86 kg to -1.59 kg), however authors reported that all included studies were of low to medium quality and therefore the results should be interpreted with caution (69). More recently a study combined individual patient data from various randomized controlled trials that offered exercise interventions during pregnancy and reported a slight statistically significant decrease in gestational weight gain among women randomized to the exercise condition versus a standard care control group (an average decrease of 0.70 kg) (70). The authors discussed that 0.70 kg as an average difference is not clinically significant, however a limitation of the study was the high levels of heterogeneity among interventions and the fact that some included trials did not actually provide independent patient data (70). When the included interventions were evaluated independently, there was evidence to show that nutrition and exercise interventions have a clinically meaningful impact on total gestational weight gain and increased the likelihood of women meeting the Institute of Medicine (2009) weight gain recommendations (70). Finally, a recent meta-analysis assessing physical activity interventions reported that exercise during pregnancy reduced the odds of EGWG by approximately 32% (67).

A few meta-analyses have also compared the effects of a nutrition only, exercise only or both nutrition and exercise interventions offered during pregnancy and the effect on gestational weight gain. Thangarintrim et al. (2012) assessed 88 randomized controlled trials and observational studies that included a nutrition and/or exercise intervention for pregnant women to reduce total gestational weight gain (71). Results showed that dietary interventions may be the most effective in reducing gestational weight gain (on average 3.48 kg reduction) followed by a combination of both nutrition and exercise (on average 1.42 kg reduction) (71). Another meta-analysis that also assessed the impact of exercise only, nutrition only or both on multiple pregnancy outcomes, reported that all three approaches significantly reduced gestational weight gain in comparison to standard care control groups and one approach does not appear to be more superior than the other (72). Authors reported that a lifestyle intervention reduces the risk of EGWG by 20% in comparison to a standard care control group (72). A more recent meta-analysis comparing the effects of nutrition only, exercise only and both nutrition and exercise interventions on gestational weight gain for women with an overweight BMI reported that nutrition interventions hold the most promise in this population group, however similar to previous results, any lifestyle intervention compared to standard care only was effective in preventing EGWG (73). There are unique benefits for both a healthy diet and exercise during pregnancy. A balanced diet during pregnancy provides many health benefits for both mom and baby including improved digestion and availability of blood glucose which is required for fetal growth and development (70, 71). Prenatal exercise also has many unique benefits including improved cardiovascular fitness, blood flow, and protection against the loss of muscle mass which has an effect on increasing insulin resistance and consequently gestational diabetes risk (13, 14). Taken together, both a nutrition and exercise lifestyle intervention would be optimal for maternal and fetal health, but perhaps it is more challenging to address two behaviors at the same time compared to just one.

1.7 Multiple Health Behavior Change Research

Multiple Health Behavior Change (MHBC) is a research area that has garnered more attention over the years. Research has shown that for most chronic diseases (e.g. obesity, cardiovascular disease, cancer) more than one health behavior change would be required for the most optimal results for prevention, management or treatment (74). For example, a systematic review found that research on prevention/treatment of lung cancer often focuses on preventing smoking, however individuals who smoke are more likely to also engage in other modifiable health behaviors that can increase cancer risk such as physical inactivity and an unhealthy diet (75). The review concluded that the most effective interventions for the prevention of cancer focus on more than one health behavior change (75). Another review discussed the importance of MHBC interventions to prevent and treat obesity (76). Authors reported that 'obesogenic behaviors' are multi-faceted (e.g. increased sedentary behavior is also related to not meeting physical activity guidelines or a poor diet may also be linked to poor sleeping habits) and therefore the most optimal results for obesity prevention and treatment, are interventions that target more than just one health behavior (76).

Changing just one lifestyle behavior is challenging. For example in Canada approximately 15% of the general population 'successfully' achieves 150 minutes of moderate intensity physical activity every week, and interestingly only 10% indicate being aware of this guideline (77). Similarly, less than 15% of North American pregnant women report meeting physical activity guidelines during pregnancy and this number significantly decreases as pregnancy progresses

(78). Additionally, most Canadians did not meet the guidelines for the previous Canadian Food Guide with only 26% of the population meeting the minimum requirement for each food group (79). One study reported that most Canadian pregnant women report having an “unhealthy diet” compared to a “healthy diet” during pregnancy (80). These low statistics are evidence that Canadians, including pregnant women, find it challenging to meet physical activity and nutrition recommendations individually. It may be challenging to adhere to two behavior changes (nutrition and exercise) simultaneously.

1.8 Definition of adherence

Adherence is defined as the degree to which an individual follows recommendations given by a healthcare provider (81). According to this definition, adherence is a continuous variable and can be graded on a spectrum (0% to 100%) (81). Majority of literature surrounding adherence has focused on medication intake and overall, there is consensus that greater adherence to prescriptions will increase the likelihood of improving health outcomes (81).

The concept of adherence can also be translated to lifestyle behavior change. Vitolins et al. (2000) suggested that lifestyle interventions reporting low levels of adherence showed null effects because the intervention and control group were actually performing similarly (81). If participants are not engaging in the lifestyle behaviors being prescribed within an intervention, then results will not correctly reflect the effectiveness of the intervention on the health outcome being studied. Currently, it is not mandatory for authors to measure and report adherence to nutrition and exercise interventions during pregnancy. Additionally, there is no gold standard measurement tool to measure and report adherence to nutrition and exercise behaviors and as a result most investigators will use adherence measurement methods that best fit their study design (81). For example, with exercise interventions, the most commonly used adherence measurement tools include home exercise logs, attendance to classes, and the use of a pedometer or accelerometer (81). For nutrition interventions, the most commonly used adherence measurement tools include food intake records and questionnaires to summarize previous dietary habits (81). Vitolins et al. (2000) suggested that regardless of the tool being used to measure adherence, all lifestyle interventions should have clear goals for participants to meet and therefore the selected measurement tool should measure whether the participants are achieving the goals or not (81).

1.9 Lifestyle interventions during pregnancy and adherence

Adherence to nutrition and exercise interventions during pregnancy have varied. A common theme observed is that when authors do not achieve their primary health outcome or do not show that the intervention was more favorable than a standard care control group, low adherence was reported as a study limitation (82-85). For example, a dietary counselling intervention designed to prevent EGWG found no difference between the intervention and control group, however authors reported that there were significantly low levels of attendance to the counselling sessions (82). If the key difference between the intervention and control group was receiving counselling sessions, then low levels of attendance may explain why the intervention group performed similarly to a control group. Another example is a nutrition and exercise program that included weekly group fitness classes and nutrition information for a healthy diet during pregnancy (85). Results showed no difference between the intervention and control group for total gestational weight gain, however authors reported less than 20% attendance to group fitness classes and they did not measure adherence to nutrition (85).

On the opposite end, studies that do 'successfully' meet their health outcome report adherence as a strength of their intervention (86-88). For example, Barakat et al., (2016) reported 80% adherence to a supervised exercise intervention and results showed that the exercise group had a lower prevalence of macrosomia (86). A recent meta-analysis assessed the difference between 'successful' and 'unsuccessful' exercise interventions during pregnancy to prevent EGWG and authors reported that adherence was higher among 'successful' studies (89). Adherence may be related to specific characteristics that make lifestyle interventions more 'successful' than others during pregnancy.

Abraham and Michie (2008) proposed a taxonomy of behavior change techniques that are used in nutrition and exercise interventions for the general population (90). Currie et al. (2013) applied these taxonomies specifically for lifestyle interventions during pregnancy (91). The authors wanted to determine which behavior change techniques were used in studies that 'successfully' increased physical activity levels among pregnant women (91). Fourteen studies were included in the review and overall, interventions that 'successfully' increased physical activity levels among pregnant women included goal setting, feedback and repetition of behaviors (91). Additionally authors reported that a common characteristic among all ‘successful’ studies was having face to face meetings with participants and this was suggested to be an effective technique for increasing adherence to the intervention (91). Similar findings were reported by Walker et al., (2018) in their systematic review that assessed different characteristics between lifestyle interventions that ‘successfully’ prevented EGWG to those that did not (92). Eighty-nine RCTs were included in this review and the authors reported that between ‘successful’ and ‘unsuccessful’ studies a key difference was the inclusion of more face to face visits within ‘successful’ studies (92). Face to face appears to be an effective approach to delivering a lifestyle intervention during pregnancy suggesting that in person meetings may increase accountability and motivation to meet the goals of the program (91, 92). Increasing accountability to the intervention may have a positive effect on adherence.

Additionally, theory-driven research is recommended when designing behavior change programs that include nutrition and exercise (93). Common theories used within pregnant and non-pregnant research related to improving lifestyle behaviors is the self-determination theory, theory of planned behavior, protection motivation theory and the theory of self-control and self-regulation (93-95). A recommended theory for multiple behavior change programs is the theory of self-control and self-regulation (93, 96) which states that everyone has a certain level of self-control resources, and if that supply becomes depleted there will be a negative effect on subsequent health behaviors (94). Self-control resources are described as the ability to manage thoughts and emotions that would affect behaviors and decisions (94). Self-control includes the ability to manage and refrain from giving into immediate needs or desires (94). The ability to exert control requires self-regulation (reduce the frequency of impulses) and previous authors have suggested that successful self-regulation will result in goal-directed behavior (96).

A recent study evaluated multiple behavior change theories among pregnant women to determine which theory may predict an increase in physical activity (95). Participants completed an initial survey before starting a weekly exercise program during pregnancy (95). This questionnaire included information about intrinsic motivation to exercise stemming from the self-determination theory, constructs from the theory of planned behavior change and information about perception of self-control using the self-control theory (95). Results showed that all three behavior change theories had a positive correlation with exercise and specifically perceived self-control was the strongest predictor for motivation to be physically active (95). The ability to self-regulate successfully may be related to self-efficacy, because if women do not feel as though they can engage in lifestyle behaviors this may significantly affect their motivation to try and meet nutrition and/or physical activity goals and consequently adherence may be low. Perhaps multiple behavior changes are challenging because asking to change more than one factor at the same time has a negative effect on self-control resources.

1.10 Strategy to protect/promote self-control and self-regulatory resources

A strategy that has been proposed to protect self-control resources when trying to address more than one lifestyle behavior may be the sequential introduction of multiple behaviors instead of introducing behaviors simultaneously (96). Introducing one behavior (exercise first or nutrition first) followed by the second may allow time to master one set of goals before adding the second and therefore self-control resources will be protected (96). One behavior change may act as a gateway to a second set of behavior change goals.

Limited research among non-pregnant adults has suggested that exercise can act as a gateway to nutrition (97, 98). One study found that non-pregnant women who reported being in later stages of physical activity behavior change also had an increase in fruit and vegetable intake (99). Similarly, another study among non-pregnant women found that women who expressed feeling confident in their physical activity behaviors also had higher levels of motivation to pursue a healthy diet (100). This may mean when individuals master one behavior (exercise) they may experience a greater sense of self-control. This may then act as a motivator to pursue an additional health behavior, such as improving nutrition.

To date the sequential versus simultaneous introduction of nutrition and exercise behaviors have not been assessed in the pregnant population. Additionally, research in non-pregnant populations has only considered adherence as retention to the strategy and overall there has not been a difference in drop-out rate if multiple lifestyle behaviors were introduced simultaneously or sequentially and both approaches have had positive health outcomes (97, 98). This suggests that some behavior change is superior to no behavior change and perhaps a more comprehensive approach to measuring adherence, such as measuring adherence to the goals of the intervention, is required. Perhaps both the sequential and simultaneous approach are beneficial in improving health outcomes but adherence may be the differentiating factor, as one approach may result in higher adherence to the goals of the intervention than the other and this will increase the likelihood of achieving positive health outcomes.

1.11 What is "high" adherence?

Currently there is no value that is considered "high" adherence to nutrition and/or exercise interventions during pregnancy. Among studies that have reported adherence as a limitation there has not been a consensus of a value that depicts adherence as "low". For example low adherence has been reported as ≤ 45% (85, 101-103) and ≥ 60% (104, 105). Interestingly, there are also studies that have reported adherence as a strength but values were as low as 55% (106-108) suggesting that the participants only adhered to about half of the intervention. Therefore there appears to be no consensus on the values placed on adherence that would indicate adherence as a strength or limitation of a study.

A systematic review that assessed the difference between ‘successful’ and ‘unsuccessful’ studies for preventing EGWG reported most studies that achieved statistical significance favoring the intervention group had at least 70% adherence (89). Similarly, a study that scored women on meeting the goals of a nutrition and exercise program found that women who were >68% adherent to the intervention were more likely to prevent EGWG (109). It may appear that by observation of existing literature, 70% adherence is a goal for interventions to prevent EGWG, however this has not been statistically confirmed. Furthermore, previous literature has suggested that women who have a pre-pregnancy BMI ≥25 kg/m^2 are less likely to prevent EGWG despite being on a lifestyle program, in comparison to women with a normal weight BMI (68). Low adherence has been suggested as the reason for the lack of ‘success’ among this population group (68).

1.12 Factors that may influence EGWG among women with a BMI ≥25.0 kg/m^2

Pregnancy has been described as a “teachable moment” to promote lifestyle behavior change (65). This is because women may be more motivated to lead a healthy lifestyle as they are now concerned for the well-being of the growing fetus (14, 65). Research has shown that women report being aware that improving nutrition intake and engaging in physical activity during pregnancy will improve health outcomes (110, 111). Although there is research to support the effectiveness of nutrition and exercise interventions during pregnancy, the efficacy of lifestyle behavior change remains unclear as some studies do not succeed in preventing EGWG. Specifically, interventions for women with a pre-pregnancy BMI ≥25 kg/m^2 seem to have less success in preventing EGWG than among normal weight women (68, 112). Women with an elevated BMI are at greater risk of gaining excessively and having a large for gestational age baby therefore, it is important to determine if adherence remains the key factor in the success of lifestyle interventions in this group or whether there are other factors that may require further attention.

A key factor that may be different between women with a normal weight BMI and women with a BMI ≥25 kg/m^2 may be previous weight loss attempts. Women with an elevated BMI are more likely to have engaged in weight loss programs prior to pregnancy compared to normal weight women (113). Research in non-pregnant populations has shown that a higher number of weight loss attempts may predict shorter commitment to future attempts, meaning that as weight loss attempts increase the motivation to adhere to each future attempt may continuously decrease (114, 115). The differentiating factor between the success of a nutrition and exercise intervention between normal weight and overweight/obese BMI may be the fact that women with an elevated BMI have been attempting to lose weight prior to pregnancy and this has an effect on gestational weight gain.

Women with an elevated BMI are more likely to seek pre-conception counselling than normal weight women and this may include being informed by healthcare providers to lose weight (115). Weight loss is recommended to women with a BMI ≥25.0 kg/m^2 to increase their chances of conception and also to decrease the risk for complications when pregnant (4). Research does support weight loss as an effective way to improve fertility (115) and weight loss prior to pregnancy decreases the risk for complications including reduced chances of developing gestational diabetes and preeclampsia (4). As an effort to improve pregnancy outcomes, women with an elevated BMI may be trying to lose weight quickly. One study showed that women who are trying to lose weight specifically to increase their chances of conceiving will often use unhealthy weight loss methods (e.g. juice based diets, yo-yo dieting, meal restriction, excessive exercise) (113). Weight loss immediately before pregnancy and the effect on gestational weight gain has not been assessed.

It may be possible that weight fluctuations prior to pregnancy lead to gaining excessively during pregnancy despite participating in a nutrition and exercise intervention. In addition to adherence, it is important to address and determine if other factors such as weight fluctuations prior to pregnancy influence EGWG among women with a BMI ≥25.0 kg/m^2.

1.13 Summary

Overall, there is literature to support providing women with a nutrition and exercise intervention during pregnancy reduces the risk of EGWG and this may have a positive downstream effect on preventing the future risk of obesity for both mom and baby. The effectiveness of previous interventions has been inconsistent as some studies ‘successfully’ achieve their health outcome goals while others have had a null effect. A common limitation reported among ‘unsuccessful’ studies is low adherence. Furthermore, adherence to nutrition and exercise interventions during pregnancy have varied with no adherence goal value to predict intervention success. The objective of this dissertation was to execute three independent yet interrelated studies to determine if adherence is a key factor in determining the success of a lifestyle intervention during pregnancy. Study 1 will determine if adherence is a key factor in determining the effectiveness of a lifestyle intervention during pregnancy, and if so, what value for adherence would lead to intervention success.

The effectiveness of nutrition and exercise interventions has been particularly questioned among women with a BMI ≥25 kg/m^2. It must be acknowledged that previous behaviors including weight loss attempts and weight fluctuations prior to pregnancy may impact pregnancy outcomes including EGWG. Therefore, Study 2 will test the effects of pre-pregnancy weight loss on EGWG and whether or not this may have a greater influence on gestational weight gain in comparison to program adherence among women with a pre-pregnancy BMI ≥25 kg/m^2.

Finally, if adherence is indeed a key factor in determining the success of a lifestyle intervention for prevention of EGWG, then effective strategies to improve program adherence during pregnancy need to be investigated. One such strategy may be the sequential introduction of nutrition and exercise behaviors in comparison to introducing both behaviors simultaneously. Referring to the self-control and self-regulatory theories, Study 3 will evaluate adherence to the introduction of nutrition and exercise behaviors sequentially compared to simultaneously.

1.14 Chapter 1 References

1. Yang W, Han F, Gao X, Chen Y, Ji L, Cai X. Relationship Between Gestational Weight Gain and Pregnancy Complications or Delivery Outcome. *Sci Rep.* 2017;7(1):12531.

2. Santos S, Voerman E, Amiano P et al. Impact of maternal body mass index and gestational weight gain on pregnancy complications: an individual participant data meta-analysis of European, North American, and Australian cohorts. *BJOG.* 2019;126(8):984-995.

3. Institute of Medicine. *Weight during pregnancy: reexamining the guidelines.* Washington (DC): National Academy Press, National Academy of Science; 2009.

4. Davies GAL, Maxwell C, McLeod L. Obesity in pregnancy. *JOGC.* 2010;32(2):165-73.

5. Cohen AK, Chaffee BW, Rehkopf DH, Coyle JR, Abrams B. Excessive gestational weight gain over multiple pregnancies and the prevalence of obesity at age 40. *Int J Obes (Lond).* 2014;38(5):714-8.

6. Oken E, Rifas-Shiman SL, Field AE, Frazier AL, Gillman MW. Maternal gestational weight gain and offspring weight in adolescence. *Obstetrics and Gynecology.* 2008;112(5):999-1006.

7. Voerman E, Santos S, Patro Golab B, et al. Maternal body mass index, gestational weight gain, and the risk of overweight and obesity across childhood: An individual participant data meta-analysis. *PLoS Medicine.* 2019;16(2):e1002744-e.

8. Ferraro ZM, Barrowman N, Prud'homme D, et al. Excessive gestational weight gain predicts large for gestational age neonates independent of maternal body mass index. *J Matern Fetal Neonatal Med.* 2012;25(5):538-42.

9. Goldstein RF, Abell SK, Ranasinha S, et al. Gestational weight gain across continents and ethnicity: systematic review and meta-analysis of maternal and infant outcomes in more than one million women. *BMC Med.* 2018;16(1):153.

10. Shin D, Song WO. Prepregnancy body mass index is an independent risk factor for gestational hypertension, gestational diabetes, preterm labor, and small- and large-for-gestational-age infants*. J Matern Fetal Neonatal Med.* 2015;28(14):1679-86.

11. Davenport MH, Ruchat SM, Giroux I, Sopper MM, Mottola MF. Timing of excessive pregnancy-related weight gain and offspring adiposity at birth. *Obstet Gynecol.* 2013;122(2 Pt 1):255-61.

12. Desai M, Beall M, Ross MG. Developmental origins of obesity: programmed adipogenesis. *Current Diabetes Reports.* 2013;13(1):27-33.

13. Mottola MF. Pregnancy, Physical Activity and Weight Control to Prevent Obesity and Future Chronic Disease Risk in Both Mother and Child. *Current Women's Health Reviews.* 2015;11(1):31-40.

14. Ruchat SM, Mottola MF. Preventing long-term risk of obesity for two generations: prenatal physical activity is part of the puzzle. *J Pregnancy.* 2012;2012:470247.

15. Barker DJ. The origins of the developmental origins theory. *Journal of Internal Medicine.* 2007;261(5):412-7.

16. Henry A, Alphonse J, Tynan D, Welsh AW. Fetal myocardial performance index in assessment and management of small-for-gestational-age fetus: a cohort and nested case-control study. *Ultrasound in obstetrics & gynecology.* 2018;51(2):225-35.

17. Henry SL, Barzel B, Wood-Bradley RJ, Burke SL, Head GA, Armitage JA. Developmental origins of obesity-related hypertension. *Clinical and Experimental Pharmacology & Physiology.* 2012;39(9):799-806.

18. Wells JC, Chomtho S, Fewtrell MS. Programming of body composition by early growth and nutrition. *The Proceedings of the Nutrition Society.* 2007;66(3):423-34.

19. Wilding S, Ziauddeen N, Smith D, Roderick P, Alwan NA. Maternal and early-life area-level characteristics and childhood adiposity: A systematic review. *Obes Revs.* 2019;1-13.

20. Ravelli AC, van Der Meulen JH, Osmond C, Barker DJ, Bleker OP. Obesity at the age of 50 y in men and women exposed to famine prenatally. *The American Journal of Clinical Nutrition.* 1999;70(5):811-6.

21. Berends LM, Fernandez-Twinn DS, Martin-Gronert MS, Cripps RL, Ozanne SE. Catch-up growth following intra-uterine growth-restriction programmes an insulin-resistant phenotype in adipose tissue. *Int J Obes (Lond).* 2013;37(8):1051-7.

22. Statistics Canada. "Canadian Health Measures Survey Cycle 4 2014-2015". https://www.statcan.gc.ca/eng/about/pia/chmsc4. Accessed May 14 2019.

23.Bancej C, Jayabalasingham B, Wall RW, et al. Evidence Brief--Trends and projections of obesity among Canadians. *Health Promot Chronic Dis Prev Can.* 2015;35(7):109-12.

24. Rao DP, Kropac E, Do MT, Roberts KC, Jayaraman GC. Childhood overweight and obesity trends in Canada. *Health Promot Chronic Dis Prev Can.* 2016;36(9):194-8.

25. Apovian CM. Obesity: definition, comorbidities, causes, and burden. *Am J Manage Care.* 2016;22(7 Suppl):s176-85.

26. Canadian Medical Association. "Obesity as a disease." https://www.cma.ca/En/Pages/cma-recognizes-obesity-as-a-disease.aspx. Accessed March 5 2019.

27. Bell JA, Carslake D, O'Keeffe LM, et al. Associations of Body Mass and Fat Indexes With Cardiometabolic Traits. *J Am Coll Cardiol.* 2018;72(24):3142-54.

28. Obesity Canada. “Obesity in Canada”. https://obesitycanada.ca/obesity-in-canada/. Accessed April 15 2019.

29. Hall DMB, Cole TJ. What use is the BMI? *Archives of disease in childhood.* 2006;91(4):283-6.

30. Erlanger SR, Henson EA. Classification and pharmacological management of obesity. *P & T : A peer-reviewed journal for formulary management.* 2008;33(12):724-8.

31. Allison DB, Downey M, Atkinson RL, et al. Obesity as a disease: a white paper on evidence and arguments commissioned by the Council of the Obesity Society. *Obesity (Silver Spring).* 2008;16(6):1161-77.

32. Canadian Obesity Network. “Report Card on Access to Obesity Treatment for Adults in Canada 2019.” https://obesitycanada.ca/resources/report-card/. Accessed April 28 2019.

33. Mustaqeem M, Sadullah S, Waqar W, Farooq MZ, Khan A, Fraz TR. Obesity with irregular menstrual cycle in young girls. *Mymensingh Medical Journal*. 2015;24(1):161-7.

34. El Hayek S, Bitar L, Hamdar LH, Mirza FG, Daoud G. Poly Cystic Ovarian Syndrome: An Updated Overview. *Frontiers in Physiology.* 2016;7:124.

35. Turner-McGrievy GM, Grant BL. Prevalence of body mass index and body weight cut-off points for in vitro fertilization treatment at U.S. clinics and current clinic weight loss strategy recommendations. *Human Fertility (Cambridge, England).* 2015;18(3):215-9.

36. Sermondade N, Huberlant S, Bourhis-Lefebvre V, et al. Female obesity is negatively associated with live birth rate following IVF: a systematic review and meta-analysis. *Human Reproduction Update.* 2019;DMZ011.

37. Marchi J, Berg M, Dencker A, Olander EK, Begley C. Risks associated with obesity in pregnancy, for the mother and baby: a systematic review of reviews. *Obesity Revs.* 2015;16(8):621-38.

38. Durnwald C. Gestational diabetes: Linking epidemiology, excessive gestational weight gain, adverse pregnancy outcomes, and future metabolic syndrome. *Semin Perinatol.* 2015;39(4):254-8.

39. Ruchat SM, Hivert MF, Bouchard L. Epigenetic programming of obesity and diabetes by in utero exposure to gestational diabetes mellitus. *Nutr Rev*. 2013;71(Suppl 1):S88-94.

40. Mottola MF. Exercise prescription for overweight and obese women: pregnancy and postpartum. *Obstet Gynecol Clin North Am.* 2009;36(2):301-16.

41. Gaillard R, Durmus B, Hofman A, et al. Risk factors and outcomes of maternal obesity and excessive weight gain during pregnancy. *Obesity (Silver Spring).* 2013;21(5):1046-55.

42. Cnattingius S, Villamor E, Johansson S, et al. Maternal obesity and risk of preterm delivery. *JAMA.* 2013;309(22):2362-70.

43. Catalano PM, Shankar K. Obesity and pregnancy: mechanisms of short term and long term adverse consequences for mother and child. *BMJ.* 2017;356:j1.

44. Crane JM, Murphy P, Burrage L, Hutchens D. Maternal and perinatal outcomes of extreme obesity in pregnancy. *JOGC.* 2013;35(7):606-11.

45. Charlton F, Tooher J, Rye KA, Hennessy A. Cardiovascular risk, lipids and pregnancy: preeclampsia and the risk of later life cardiovascular disease. *Heart Lung Circ.* 2014;23(3):203-12.

46. Padwal RS, Bienek A, McAlister FA, Campbell NR. Epidemiology of Hypertension in Canada: An Update. *The Canadian Journal of Cardiology*. 2016;32(5):687-94.

47. Leiter LA, Berard L, Bowering CK, et al. Type 2 diabetes mellitus management in Canada: is it improving? *Canadian Journal of Diabetes.* 2013;37(2):82-9.

48. Catalano PM, Roman-Drago NM, Amini SB, Sims EA. Longitudinal changes in body composition and energy balance in lean women with normal and abnormal glucose tolerance during pregnancy. *Am J Obstet Gynecol.* 1998;179(1):156-65.

49. Dahlgren J. Pregnancy and insulin resistance. *Metab Syndr Relat Disord.* 2006;4(2):149-52.

50. Sonagra AD, Biradar SM, KD, Murthy DSJ. Normal pregnancy- a state of insulin resistance. *JCDR.* 2014;8(11):CC01-CC3.

51. Buchanan TA, Xiang AH, Page KA. Gestational diabetes mellitus: risks and management during and after pregnancy. *Nature reviews Endocrinology.* 2012;8(11):639-49.

52. Chu SY, Callaghan WM, Kim SY, et al. Maternal obesity and risk of gestational diabetes mellitus. *Diabetes Care.* 2007;30(8):2070-6.

53. Ma RC, Tutino GE, Lillycrop KA, Hanson MA, Tam WH. Maternal diabetes, gestational diabetes and the role of epigenetics in their long term effects on offspring. *Prog Biophys Mol Biol.* 2015;118(1-2):55-68.

54. Boney CM, Verma A, Tucker R, Vohr BR. Metabolic syndrome in childhood: association with birth weight, maternal obesity, and gestational diabetes mellitus. *Pediatrics.* 2005;115(3):e290-6.

55.Ouzounian JG, Elkayam U. Physiologic changes during normal pregnancy and delivery. *Cardiol Clin.* 2012;30(3):317-29.

56. Soma-Pillay P, Nelson-Piercy C, Tolppanen H, Mebazaa A. Physiological changes in pregnancy. *Cardiovascular Journal of Africa.* 2016;27(2):89-94.

57. Steegers EA, von Dadelszen P, Duvekot JJ, Pijnenborg R. Pre-eclampsia. *Lancet.* 2010;376(9741):631-44.

58. Weissgerber TL, Mudd LM. Preeclampsia and diabetes. *Curr Diab Rep.* 2015;15(3):9.

59. Weissgerber TL, Wolfe LA, Davies GA, Mottola MF. Exercise in the prevention and treatment of maternal-fetal disease: a review of the literature. *Applied Physiology, Nutrition, and Metabolism*. 2006;31(6):661-74.

60. von Dadelszen P, Menzies J, Magee LA. The complications of hypertension in pregnancy. *Minerva Med.* 2005;96(4):287-302.

61. Peracoli JC, Borges VTM, Ramos JGL, et al. Pre-eclampsia/Eclampsia. *Revista brasileira de ginecologia e obstetricia : revista da Federacao Brasileira das Sociedades de Ginecologia e Obstetricia.* 2019;41(5):318-32.

62. Mission JF, Marshall NE, Caughey AB. Pregnancy risks associated with obesity. *Obstet Gynecol Clin North Am.* 2015;42(2):335-53.

63. Bellamy L, Casas JP, Hingorani AD, Williams DJ. Pre-eclampsia and risk of cardiovascular disease and cancer in later life: systematic review and meta-analysis. *BMJ.* 2007;335(7627):974.

64. Kominiarek MA, Peaceman AM. Gestational weight gain. *Am J Obstet Gynecol.* 2017;216(6):642-51.

65. Phelan S. Pregnancy: a "teachable moment" for weight control and obesity prevention. *Am J Obstet Gynecol.* 2010;202(2):135.e1-8.

66. Farpour-Lambert NJ, Ells LJ, Martinez de Tejada B, Scott C. Obesity and Weight Gain in Pregnancy and Postpartum: an Evidence Review of Lifestyle Interventions to Inform Maternal and Child Health Policies. *Frontiers in Endocrinology.* 2018;9:546.

67. Ruchat SM, Mottola MF, Skow RJ, et al. Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: a systematic review and meta-analysis. *BJSM.* 2018;52(21):1347-56.

68. Streuling I, Beyerlein A, Rosenfeld E, Hofmann H, Schulz T, von Kries R. Physical activity and gestational weight gain: a meta-analysis of intervention trials. *BJOG.* 2011;118(3):278-84.

69. Oteng-Ntim E, Varma R, Croker H, Poston L, Doyle P. Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome: systematic review and meta-analysis. *BMC Med.* 2012;10:47.

70. Rogozinska E, Marlin N, Jackson L, et al. Effects of antenatal diet and physical activity on maternal and fetal outcomes: individual patient data meta-analysis and health economic evaluation. *Health Technology Assessment (Winchester, England).* 2017;21(41):1-158.

71. Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ*. 2012;344:e2088.

72. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *The Cochrane Database of Systematic Reviews.* 2015(6):Cd007145.

73. Craemer KA, Sampene E, Safdar N, Antony KM, Wautlet CK. Nutrition and Exercise Strategies to Prevent Excessive Pregnancy Weight Gain: A Meta-analysis. *AJP Reports.* 2019;9(1):e92-e120.

74. Geller K, Lippke S, Nigg CR. Future directions of multiple behavior change research. *Journal of Behavioral Medicine.* 2017;40(1):194-202.

75. Green AC, Hayman LL, Cooley ME. Multiple health behavior change in adults with or at risk for cancer: a systematic review. *American Journal of Health Behavior.* 2015;39(3):380-94.
76. Rennie LJ, Uskul AK. Encouraging bigger-picture thinking in an intervention to target multiple obesogenic health behaviors. *Appetite.* 2017;118:144-8.

77. LeBlanc AG, Berry T, Deshpande S, Duggan M, et al. Knowledge and awareness of Canadian Physical Activity and Sedentary Behavior Guidelines: a synthesis of existing evidence. *Applied physiology, nutrition, and metabolism.* 2015;40(7):716-24.

78. Borodulin KM, Evenson KR, Wen F, Herring AH, Benson AM. Physical activity patterns during pregnancy. *Medicine and Science in Sports and Exercise.* 2008;40(11):1901-8.

79. Black JL, Billette JM. Do Canadians meet Canada's Food Guide's recommendations for fruits and vegetables? *Applied Physiology, Nutrition, and Metabolism*. 2013;38(3):234-42.

80. Jarman M, Bell RC, Nerenberg K, Robson PJ. Adherence to Canada's Food Guide Recommendations during Pregnancy: Nutritional Epidemiology and Public Health. *Current Developments in Nutrition.* 2017;1(7):e000356.

81. Vitolins MZ, Rand CS, Rapp SR, Ribisl PM, Sevick MA. Measuring adherence to behavioral and medical interventions. *Controlled Clinical Trials.* 2000;21(5 Suppl):188s-94s.

82. Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling: a randomized controlled trial. *Obstet Gynecol.* 2009;113(2 pt 1):305-12.

83. Nascimento SL, Surita FG, Parpinelli MA, Siani S, Pinto e Silva JL. The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial. *BJOG.* 2011;118(12):1455-63.

84. Guelinckx I, Devlieger R, Mullie P, Vansant G. Effect of lifestyle intervention on dietary habits, physical activity, and gestational weight gain in obese pregnant women: a randomized controlled trial. *Am J Clin Nutr.* 2010;91(2):373-80.

85. Oostdam N, van Poppel MN, Wouters MG, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial. *BJOG*. 2012;119(9):1098-107.

86. Barakat R, Pelaez M, Cordero Y, et al. Exercise during pregnancy protects against hypertension and macrosomia: randomized clinical trial. *Am J Obstet Gynecol.* 2016;214(5):649 e1-8.

87. Barakat R, Pelaez M, Lopez C, Montejo R, Coteron J. Exercise during pregnancy reduces the rate of cesarean and instrumental deliveries: results of a randomized controlled trial. *J Matern Fetal Neonatal Med.* 2012;25(11):2372-6.

88. Vargas-Terrones M, Barakat R, Santacruz B, Fernandez-Buhigas I, Mottola MF. Physical exercise programme during pregnancy decreases perinatal depression risk: a randomised controlled trial. *BJSM.* 2018;53(6):348-53.

89. McDonald SM, Liu J, Wilcox S, Lau EY, Archer E. Does dose matter in reducing gestational weight gain in exercise interventions? A systematic review of literature. *Journal of Science and Medicine in Sport.* 2016;19(4):323-35.

90. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychology.* 2008;27(3):379-87.

91. Currie S, Sinclair M, Murphy MH, Madden E, Dunwoody L, Liddle D. Reducing the decline in physical activity during pregnancy: a systematic review of behavior change interventions. *PloS One.* 2013;8(6):e66385.

92. Walker RA-O, Bennett C, Blumfield M, et al. Attenuating Pregnancy Weight Gain-What Works and Why: A Systematic Review and Meta-Analysis. *Nutrients.* 2018;10(7):E944.

93. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology.* 2009;28(6):690-701.

94. Baumeister RF, Exline JJ. Virtue, personality, and social relations: self-control as the moral muscle. *J Pers.* 1999;67(6):1165-94.

95. Hamilton K, Fleig L, Henderson J, Hagger MS. Being active in pregnancy: Theory-based factors associated with physical activity among pregnant women. *Women & Health.* 2018:1-16.

96. Baumeister RF, DeWall CN, Ciarocco NJ, Twenge JM. Social exclusion impairs self-regulation. *J Pers Soc Psychol*. 2005;88(4):589-604.

97. Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Archives of Internal Medicine.* 2007;167(11):1152-8.

98. James E, Freund M, Booth A, et al. Comparative efficacy of simultaneous versus sequential multiple health behavior change interventions among adults: A systematic review of randomised trials. *Prev Med.* 2016;89:211-23.

99. Dutton GR, Napolitano MA, Whiteley JA, Marcus BH. Is physical activity a gateway behavior for diet? Findings from a physical activity trial. *Prev Med.* 2008;46(3):216-21.

100. Mata J, Silva MN, Vieira PN, et al. Motivational "spill-over" during weight control: increased self-determination and exercise intrinsic motivation predict eating self-regulation. *Health Psychology*. 2009;28(6):709-16.

101. Nobles C, Marcus BH, Stanek EJ 3rd, et al. Effect of an exercise intervention on gestational diabetes mellitus: a randomized controlled trial. *Obstet Gynecol.* 2015;125(5):1195-204.

102. Olson CM, Groth SW, Graham ML, Reschke JE, Strawderman MS, Fernandez ID. The effectiveness of an online intervention in preventing excessive gestational weight gain: the e-moms roc randomized controlled trial. *BMC Pregnancy Childbirth.* 2018;18(1):148.

103. Seneviratne SN, Jiang Y, Derraik J, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. *BJOG.* 2016;123(4):588-97.

104. Bo K, Haakstad LA. Is pelvic floor muscle training effective when taught in a general fitness class in pregnancy? A randomised controlled trial. *Physiotherapy.* 2011;97(3):190-5.

105. Sagedal LRS, Overby NC, Bere E, et al. The effect of prenatal lifestyle intervention on weight retention 12 months postpartum: Results of the Norwegian Fit for Delivery randomised controlled trial. *BJOG*. 2017;124(1):111-21.

106. Bruno R, Petrella E, Bertarini V, Pedrielli G, Neri I, Facchinetti F. Adherence to a lifestyle programme in overweight/obese pregnant women and effect on gestational diabetes mellitus: a randomized controlled trial. *Matern Child Nutr.* 2017;13(3).

107. Stafne SN, Salvesen KA, Romundstad PR, Torjusen IH, Morkved S. Does regular exercise including pelvic floor muscle training prevent urinary and anal incontinence during pregnancy? A randomised controlled trial. *BJOG*. 2012;119(10):1270-80.

108. Reilly ETCF, Waterfield MR, Waterfield AE, Steggles P, Pedlar F. Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: A randomised controlled trial of antenatal pelvic floor exercises. *International Journal of Obstetrics and Gynaecology.* 2002;109:68-76.

109. Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? *Behavior Analysis in Practice.* 2017;10(4):347-54.

110. Forbes LE, Graham JE, Berglund C, Bell RC. Dietary Change during Pregnancy and Women's Reasons for Change. *Nutrients.* 2018;10(8).

111. Vanstone M, Kandasamy S, Giacomini M, DeJean D, McDonald SD. Pregnant women's perceptions of gestational weight gain: A systematic review and meta-synthesis of qualitative research. *Matern Child Nutr.* 2017;13(4).

112. Choi J, Fukuoka Y, Lee JH. The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum: a systematic review and meta-analysis of randomized controlled trials. *Prev Med.* 2013;56(6):351-64.

113. Sim KA, Partridge SR, Sainsbury A. Does weight loss in overweight or obese women improve fertility treatment outcomes? A systematic review. *Obes Rev.* 2014;15(10):839-50.

114. Ismail TATA-Ohoo, Jalil RA, Wan Ishak WR, et al. Understanding Dieting and Previous Weight Loss Attempts among Overweight and Obese Participants: Insights into My Body Is Fit and Fabulous at Work Program. *Korean J Fam Med.* 2018;39(1):15-22.

115. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and 'successful' weight management in women*. Int J Obes Relat Metab Disord.* 2004;28(9):1124-33.

Chapter 2

Study 1: Is adherence a key factor in determining the success of a nutrition and/or exercise intervention during pregnancy? A systematic review.

2.1 Introduction

Many studies have investigated the effects of nutrition and exercise interventions during pregnancy on a number of different health outcomes. Overall, results summarized in systematic reviews and meta-analyses have been mixed, with some studies showing positive results while others have had a null effect (1-5). Inconsistencies in the literature may be due to the varying levels of adherence reported in nutrition and/or exercise intervention studies. Adherence in the domain of health research is defined as the degree to which participants follow the recommendations given by healthcare providers or investigators (6).

Studies with a null effect on the primary pregnancy health outcome often report low adherence or suggest a limitation of the study was low adherence to the program (4, 7). For instance, McDonald et al., (2016) conducted a systematic review with a meta-analysis to determine characteristics between studies that were 'successful' and 'unsuccessful' in attenuating excessive gestational weight gain (7). Authors reported that a key difference was that adherence was higher in 'successful' studies than 'unsuccessful' studies (7). In a more recent observational study where adherence was the primary variable of interest, authors assessed the effect of high versus low adherence on the prevention of excessive gestational weight gain (8). It was found that women who met gestational weight gain recommendations had higher adherence to the goals of the nutrition and exercise program than women who gained excessively (8). Taken together, there is evidence to suggest that adherence may be a key factor in the success of a lifestyle intervention with respect to gestational weight gain. Although previous meta-analyses have indicated that adherence may contribute to positive health outcomes (3, 4, 9), no systematic review to date has examined the influence of lifestyle interventions during pregnancy for health outcomes and none with adherence as the primary outcome of interest of the review. Additionally, adherence has not been statistically compared between ‘successful’ and ‘unsuccessful’ interventions to determine if there is a significant difference.

Furthermore, before conclusions can be drawn regarding adherence as a salient factor in determining the success of lifestyle interventions during pregnancy, a careful examination of key moderators that would influence adherence seems warranted. The method of intervention delivery, for instance, was examined for interventions for pregnant women and results showed that many ‘successful’ studies have face to face meetings with participants throughout the intervention to improve outcomes (10). Face to face meetings may increase accountability and therefore adherence to the intervention (10). Abraham and Michie (2008) suggested a taxonomy of behavior change techniques that are used in lifestyle-based interventions for all populations (11). The authors determined which technique is often used in lifestyle-based studies that have reported improving exercise and nutrition habits (12). A meta-regression of lifestyle-based interventions in non-pregnant populations showed that studies including self-monitoring of nutrition and/or exercise behaviors were more likely to be ‘successful’ (12). Another behavior change approach that has been studied in non-pregnant population groups is the delivery of simultaneous multiple behaviors versus sequential single behavior changes (13). The results showed no difference when using either the simultaneous or sequential approach, however it was suggested that interventions that attempt to address multiple behavior changes at once may be more challenging resulting in lower adherence (13). Through extension, it may be possible that studies that provide only a nutrition or exercise intervention versus both, may have higher adherence. Finally, the length of the intervention may also influence adherence. Studies that have assessed physical activity levels throughout pregnancy have shown that participation in exercise decreases in the third trimester (14, 15). This may mean that studies that are longer and span across the entire pregnancy may have lower program adherence than studies that are shorter in length.

With the above issues in mind, the primary purpose of the current study was to determine if adherence statistically differs between studies that showed statistically significant health outcome effects favoring nutrition and/or exercise interventions during pregnancy to those studies that reported null effects. To do this, a systematic review of lifestyle interventions (nutrition and/or exercise) during pregnancy that reported on any health outcome and provided program adherence information was conducted. Potential adherence moderators were also compared between studies that met or failed to meet their health outcomes. These moderators included: method of intervention delivery (i.e., face-to-face);

behavior change technique used (i.e., self-monitoring); number of behavior changes expected (i.e., multiple vs single); and length of the intervention (i.e., number of weeks). It was hypothesized that studies that met their health outcome (statistically favored the intervention) during pregnancy would have higher adherence than studies that did not meet their health outcome (statistically did not favor the intervention). It also was hypothesized that studies with higher adherence will likely have used behavior change techniques that improved adherence to the program including face-to-face delivery of the intervention, self-monitoring tools, one behavior change instead of two, and a shorter overall duration of the program compared to studies that had lower adherence.

2.2 Methods

Search Strategy and Study Selection

The present study was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and was registered *a-priori* on PROSPERO [CRD42017072716; Appendix A] (16). An electronic search of nutrition and exercise interventions during pregnancy that included information on program adherence up until August 2018 was conducted in the following databases: MEDLINE, EMBASE, Web of Science, Scopus, Trials, and SportDiscus. The participants, interventions, comparisons, outcomes and study design (PICOS) framework was used to determine the search strategy and guide the current review (17). The population of interest was pregnant women, the intervention was any lifestyle program (nutrition and/or exercise) assessing the impact on a health outcome, the comparator was no lifestyle intervention and the outcome was adherence to the intervention. A search strategy was developed focused on four main groups of terms: “pregnancy”, “nutrition” and/or “exercise”, and “adherence” (see search strategy in Appendix B).

We included studies that reported adherence to a nutrition and/or exercise intervention during pregnancy. Studies were included if they were written in English, published in peer-reviewed journals, included pregnant women without any contraindication for participating in exercise during pregnancy (18), provided a nutrition and/or exercise intervention during pregnancy, and the primary outcome of the included study was not measuring nutrition and/or exercise behavior change specifically (i.e. studies that had a primary outcome as measuring activity levels or nutrition content were not accepted). Additionally, studies had to report a quantitative value for adherence to the lifestyle intervention with no restriction on how adherence was measured. Both randomized controlled trials (RCT) and observational studies (OBS) were included. Any sample size and duration of intervention were accepted. Pre-clinical studies, protocols, systematic reviews and meta-analyses, case studies, letters, commentaries, editorials, other literature (i.e. magazines or newspaper articles) and conference proceedings were excluded (referred to as “Studies Not of Interest”).

Data Extraction

Stage 1 screening of titles and abstracts was completed by two independent reviewers. Stage 2 screening involved the full text review of all articles accepted from Stage 1; each article was independently reviewed by two authors. Four reviewers independently extracted data from included studies. TSN was the consistent reviewer across all studies. At any stage, if there was a discrepancy between reviewers, a third reviewer provided the final decision. Corresponding authors of studies were contacted if further information was required beyond what was available in the published article.

Using a standardized data extraction sheet on Excel™, the following data were extracted: 1. Study Information (Type of study, location of study, sample size, study duration, method of delivery); 2. Population Characteristics (Maternal age, gestational age at the start and end of the intervention, pre-pregnancy BMI); 3. Adherence (adherence value, measurement tool used); 4. Health Outcome (as defined by authors). Means and standard deviations were extracted for all applicable data.

Additionally, four potential study moderators that may influence adherence were identified and the following data were extracted: Method of intervention delivery (including face-to-face visits, online, telephone calls, informational resources such as pamphlets, text messages), self-monitoring tools used (if any), classifying interventions as nutrition only (N Only), exercise only (E Only) or both nutrition and exercise (N+E), and gestational age when the program started and ended to calculate total number of weeks for each intervention during pregnancy only.

Data Analysis

Studies were classified as ‘successful’ or ‘unsuccessful’ based on statistical significance favoring the intervention. ‘Successful’ studies showed a statistically significant difference between the intervention and control group favoring the intervention (RCTs) or a positive change pre- and post-assessment (OBS) for the health outcome being evaluated. ‘Unsuccessful’ studies showed no difference between the intervention and control group or favored the control group (RCTs) and no change observed pre- and post-assessments or a negative change (OBS) for the health outcome being evaluated. Therefore, classifications of studies as ‘successful’ or ‘unsuccessful’ was determined by the results presented in each individual study. Adherence values reported in each study were then averaged to provide mean adherence for both ‘successful’ and ‘unsuccessful’ studies. A *Student’s T-Test* was performed to compare adherence between ‘successful’ and ‘unsuccessful’ studies. The moderators used in ‘successful’ and ‘unsuccessful’ studies were described and compared using a Chi-Square analysis and *Student’s T-Test*, with significance accepted at $p<0.05$ (SPSS Version 23). Reported effect sizes followed Cohen’s (1988, 1992) criteria (Cohen’s *d* for Student’s T-test: small = 0.20, medium = 0.50, large = 0.80, Cramer’s V for Chi Square Analysis: small = 0.10, medium = 0.30, large = 0.50).

2.3 Results

We identified 45 studies from fourteen countries for inclusion. A PRISMA diagram of the search results and screening process are shown in Figure 2.1. Of the 45 studies, 38 were RCTs (19-56) and seven were OBS (57-63). Most studies used one to two methods of tracking adherence to the intervention including attendance, submitting nutrition and exercise logs, responses on questionnaires, number of times online resources were accessed, completion of program and adherence measurement tools designed specifically for that study. Study characteristics are reported in Table 2.1.

Figure 2.1 PRISMA flow diagram for study selection. Studies classified as “Not of Interest” included pre-clinical studies, systematic reviews and meta-analyses, case studies, letters, commentaries, editorials, and conference proceedings.

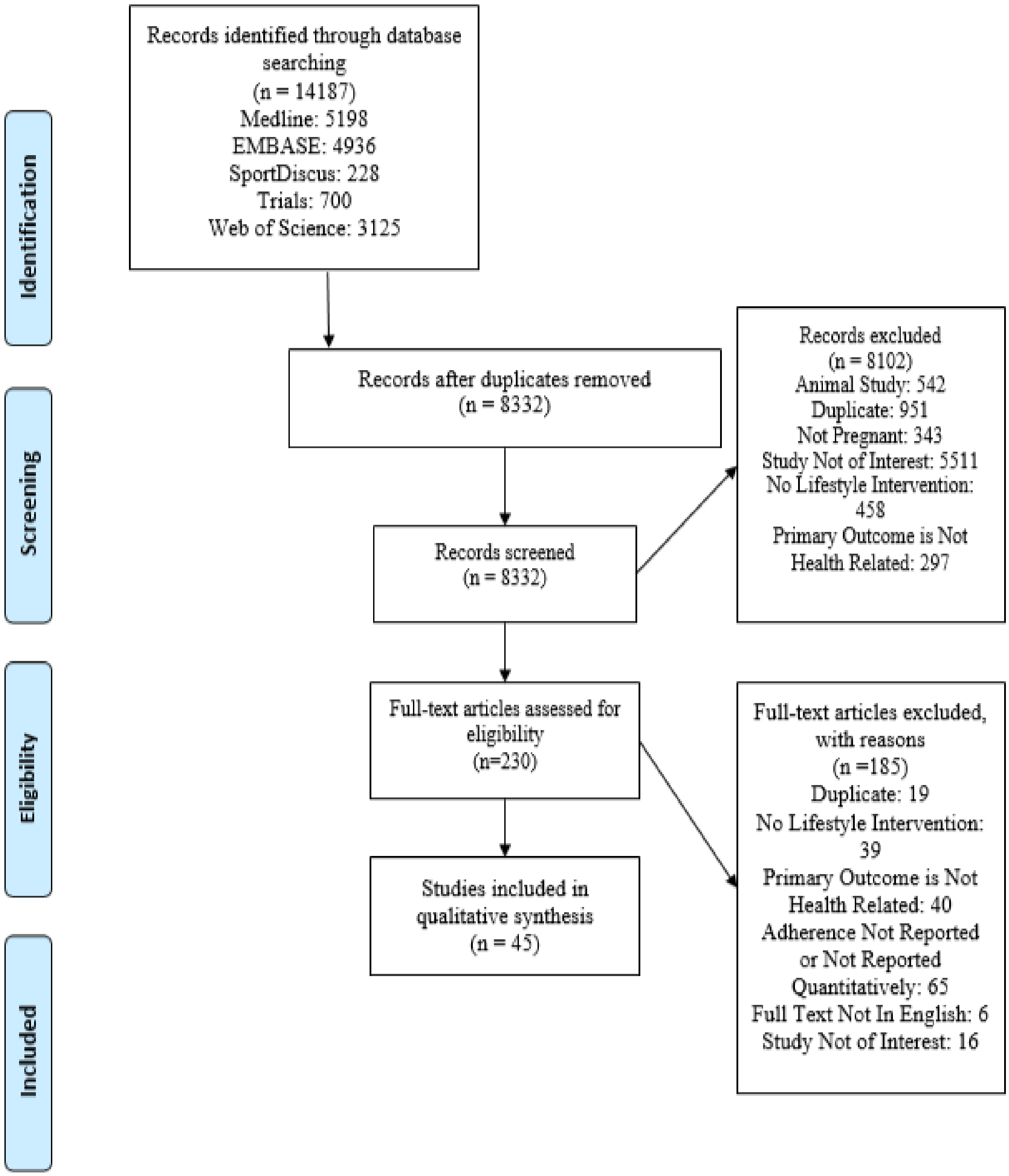


Table 2.1 Study characteristics.

Study	Study Design	Intervention	Sample Size (n)	Age (yrs±sd, or range)	Gestational Age (wks)	BMI (kg/m^2±sd)	Primary Outcome and Results
Althuizen et al., 2012 (Netherlands)	RCT N+E	I: Counselling sessions about weight gain, physical activity, and a healthy diet during pregnancy C: Standard care	I: 106 C: 113	I: 29.2±3.8 C: 30.4±4.0	Entry: 15 End: 36	I: 24.0±4.2 C: 23.5±3.8	Total GWG, prevention of EGWG and PPWR – Intervention did not have a statistically significant effect on primary outcomes
Barakat et al., 2012 (Spain)	RCT E Only	I: Aerobic group fitness classes three times per week, two out of three classes were aquatic sessions C: Standard care	I: 40 C: 43	I: 31.4±3.2 C: 31.7±4.5	Entry: 6-9 End: 38-39	I: 22.7±2.8 C: 23.0±2.9	Glucose tolerance – Intervention group had a significantly greater improvement in glucose tolerance levels compared to the control group
Barakat et al., 2012 (Spain)	RCT E Only	I: Group resistance exercise training session for 40-45	I: 138 C: 152	I: 31.4±3.2 C: 31.7±4.5	Entry: 6-9 End: 38-39	I: 24.0±4.3 C: 23.6±4	Method of delivery – Prevalence of caesarean

		minutes three days per week C: Standard care					sections was significantly less in the intervention group compared to the control group
Barakat et al., 2016 (Spain)	RCT E Only	I: Aerobic and strength conditioning group fitness classes including dance and light resistance training three times per week C: Standard care	I: 382 C: 383	I: 31.6±4.2 C: 31.8±4.5	Entry: 9-11 End: 38-39	I: 23.6±3.8 C: 23.4±4.2	Incidence of gestational hypertension – Significantly fewer women in the intervention group developed gestational hypertension compared to the control group
Bo et al., 2011 (Norway)	RCT E Only	I: Two group fitness classes per week including pelvic floor muscle training C: Standard care	I: 52 C: 53	I: 31.2±3.7 C: 30.3±4.4	Entry: 12-24 End: 36-38	I: 23.8±3.8 C: 23.9±4.7	Prevalence of urinary incontinence – No effect was found for the intervention group and on urinary incontinence before and after childbirth

Bruno et al., 2016 (Italy)	RCT N+E	I: Given individual counselling and pamphlets for a hypocaloric, low glycemic, and saturated fat diet and information on the ACOG physical activity guidelines (30 minutes of moderate activity at least 3 times per week) C: Given standard lifestyle advice	I: 69 C: 62	I: 31.5±5 C: 30.8±5.5	Entry: 9-12 End: 36	I: 33.3±6 C: 33.4±5.5	Prevalence of GDM – Fewer women in the intervention group were diagnosed with GDM compared to the control group
da Silva et al., 2017 (Brazil)	RCT E Only	I: Participated in individual supervised exercise sessions according to the ACOG Guidelines three times per week C: Standard care	I: 213 C: 426	I: 27.2±5.3 C: 27.1±5.7	Entry: 16-20 End: 32-36	I: 25.1±3.9 C: 25.2±4.1	Prevalence of preterm birth and preeclampsia – There was no difference between the intervention and control group for the number of preterm deliveries or number of

							women diagnosed with preeclampsia
Della et al., 2011 (Brazil)	OBS N Only	At least four sessions with a dietitian which included information about nutrient requirements during pregnancy and individual suggestions based on total energy intake, macro and micro nutrient requirements, personal habits, and food preference	208	27.3±4.8	Entry: <16 End: NR	NR	Total GWG – Those who adhered to the recommendations were more likely to meet the Institute of Medicine GWG recommendations
Dias et al., 2017 (Brazil)	RCT E Only	I: Two Pilates classes per week including pelvic floor muscle conditioning exercises C: Walked for ten minutes followed	I: 25 C: 25	I: 29.0±3.9 C: 29.8±3.0	Entry: 14-16 End: 32-34	I: 23.0±2.7 C: 23.8±3.2	Pelvic floor muscle strength – No significant differences were observed between the intervention and control group for pelvic floor muscle strength

		by resistance exercises using an elastic band and body weight twice per week					
Eggen et al., 2012 (Norway)	RCT E Only	I: Group fitness class once per week and at home exercise sessions. Sessions included walking or light jogging, balance exercises, body weight resistance exercise and pelvic floor muscle conditioning C: Standard care	I: 129 C: 128	I: 30.6±4.8 C: 30.0±4.8	Entry: <20 End: 36	I: 24.9±5.4 C: 23.6±4.2	Prevalence and severity of lower back and pelvic girdle pain – The intervention did not have an effect on reducing or preventing lower back and pelvic girdle pain in comparison to the control group
Garnes et al., 2016 (Norway)	RCT E Only	I: Group exercise sessions offered three times per week in accordance to the ACOG guidelines. Additionally, women were encouraged to	I: 46 C: 45	I: 31.3±3.8 C: 31.4±4.7	Entry: 12-18 End: 34-37	I: 33.9±3.8 C: 35.1±4.6	Total GWG and prevention of EGWG – There was no difference in total GWG and prevalence of EGWG between the intervention and control group

		exercise at least once per week at home including 35 minutes of endurance training, 15 minutes of strength exercises and pelvic floor conditioning C: Standard care					
Gesell et al., 2015 (USA)	RCT N+E	I: 90 minute group prenatal exercise classes once per week C: Standard care	I: 68 C: 67	I: 27.5±5.8 C: 25.8±5.9	Entry: 10-28 End: 22-40	NR	Total GWG and prevention of EGWG – More women in the exercise group met the Institute of Medicine GWG guidelines than the control group but there was no difference in total GWG between the two groups
Haakstad et al., 2011 (Norway)	RCT E Only	I: Group aerobic dance classes two times per week for 60 minutes	I: 52 C: 53	I: 31.2±3.7 C: 30.3±4.4	Entry: 12-24 End: 36-38	I: 23.8±3.8 C: 23.9±4.7	Total GWG and prevention of EGWG – Only women in the

		C: Standard care					intervention group who attended 24 sessions and exercised at a moderate intensity in their second and third trimester had lower total GWG when compared to the control group.
Haakstad et al., 2016 (Norway)	RCT E Only	I: Group fitness classes following the ACOG guidelines offered two times per week C: Standard care	I: 52 C: 53	I: 31.2±3.7 C: 30.3±4.4	Entry: 12-24 End: 36-38	I: 23.8±3.8 C: 23.9±4.7	Psychological well-being – Women who had high adherence to the program saw an improvement in psychological well-being
Haby et al., 2018 (Sweden)	OBS N+E	I: Midwives provided at least two individual counselling sessions to motivate healthy eating and physical activity during pregnancy. All	I: 459 C: 895	I: 30.9±2.5 C: 30.7±5.1	3-20 (I), 5-18 (C)	I: 34.7±4 C: 33.7±3.2	Total GWG – The number of visits attended and adherence to recommendations as reported on food and activity logs correlated with a decrease in

		women had the option to attend these sessions C: Standard care, women who chose not to attend the additional sessions					GWG suggesting that lifestyle advice may help control weight gain during pregnancy
Halse et al., 2015 (Australia)	RCT E Only	I: Three supervised at home exercise sessions on a cycle ergometer and two additional sessions at home on their own C: Standard care	I: 20 C: 20	I: 34.0±5 C: 32.0±3	I: 28.8 C: 34.6	I: 25.2±6.7 C: 26.4±7.1	Improvement in overall health and fitness – Results suggested that the intervention group improved their overall aerobic fitness whereas there was no change in the control group
Herring et al., 2016 (USA)	RCT E+N	I: All participants had individualized behavior change goals for nutrition and physical activity and received self-monitoring text messages, bi-	I: 33 C: 33	I: 25.0±5.7 C: 25.9±4.9	Entry: <20 End: 36	I: 33.5±5.8 C: 32.3±5.4	Total GWG and prevention of EGWG – Significantly fewer women in the intervention group exceeded GWG recommendations

		weekly calls from a health coach, and skills training support on social media C: Standard care					than the control group
Mason et al., 2010 (England)	RCT E Only	I: Received four training sessions for pelvic floor exercise and then encouraged to repeat the exercises twice daily C: Standard care. Some women did receive instruction about pelvic floor exercises through pamphlets, from an instructor or an occasional reminder from other sources	I: 141 C: 145	I: 28.3 C: 28.2	Entry: 20 End: 36	NR	Prevention of urinary incontinence – There was no difference between the intervention and control group for episodes of urinary incontinence and symptoms of incontinence in the postpartum
McGowan et al., 2013	RCT	I: Women attended a dietary education	I: 235	I: 32.0±3.8	Entry: 12.8	I: 26.4±4.4	Total GWG and prevention of

(Ireland)	N Only	session in group of 2-6 following their first antenatal visit. They received information about having a healthy diet during pregnancy focusing on a low glycemic index C: Standard care	C: 285	C: 31.7±4.2	End: 34	C: 26.3±4.2	EGWG – GWG in the intervention group was significantly less than the control group and women in the intervention group were more likely to meet IOM GWG guidelines
Moses et al., 2014 (Australia)	RCT N Only	I: Women were given information by telephone and email about low glycemic index alternatives and were given personalized dietary goals C: Women were given standard information for healthy eating during pregnancy as noted in	I: 296 C: 280	I: 29.9±0.3 C: 29.9±0.3	Entry: 16.5 (I), 16.2 (C) End: 36.4 (I), 36.3 (C)	I: 24.3±0.3 C: 24.7±0.3	Birth weight – There was statistical difference observed for birth weight between the intervention and control group

		Australia's Guide to Healthy Eating					
Ney et al., 1982 (USA)	RCT N Only	I: Pregnant women with GDM and T1D were provided in person counselling sessions at least eight times throughout pregnancy to discuss personalized goals for a high carb, high fibre diet low in fat C: Provided general information about healthy eating during pregnancy	I: 11 C: 9	I: 32.2±2.1 (GDM) 26.6±1.4 (T1D) C: NR	Entry: 10-30 End: 12 weeks postpartum	I: 34.5±2.1 (GDM) 21.8±0.8 (T1D) C: NR	Diabetes management – Women in the intervention group required lower amounts of insulin than the control group, otherwise similar diabetic control was observed in both groups
Nobles et al., 2015 (USA)	RCT E Only	I: Offered information and motivations specifically for increasing physical activity during pregnancy to meet	I: 143 C: 147	NR	Entry: 18.2 End: 39.2	NR	Prevalence of GDM – There was no difference between the intervention and control group for

		the ACOG guidelines C: Provided general information about being healthy during pregnancy without a specific focus on physical activity					the prevalence of GDM
Nobles et al., 2018 (USA)	RCT E Only	I: Individually tailored motivation program to encourage compliance with the ACOG guidelines C: Provided general information about being health during pregnancy without specific focus on physical activity	I: 118 C: 123	NR	Entry: 11.8 End: NR	NR	Total GWG – There was no statistically significant difference for GWG and prevalence of EGWG between the intervention and control group
Nyrnes et al., 2018 (Norway)	RCT E Only	I: Offered supervised moderate intensity	I: 27 C: 27	I: 31.1±3 C: 31.3±4.6	Entry: 11-14 End: NR	I: 33.4±3.4 C: 34.9±3.9	Newborn cardiac function – The intervention did

		exercise training three times per week and encouraged to exercise at least once more at home C: Standard care. A normal weight only group was also compared		31.2±4.1 (NW)		21±2.3 (NW)	not have a statistically significant effect on cardiac function of newborns
Olson et al., 2018 (USA)	RCT N+E	I: Given a weight gain tracker, a diet and physical activity goal setting and monitoring tool, educational resources, a blogging tool and an appointment reminder C: Given the same online resources as the intervention group but did not have access to information about	I: 1126 C: 563	I: 18-35 C: 18-35	Entry: NR End: NR	I: NR C: NR	Prevention of EGWG – There was no difference between the two groups for the number of women who exceeded weight gain recommendations

		diet and physical activity and were not given a weight gain tracker					
Oostdam et al., 2012 (Netherlands)	RCT E Only	I: Supervised group fitness classes including aerobic exercise and strength conditioning, two times per week for 60 minutes C: Standard care	I: 40 C: 45	I: 30.8±5.2 C: 30.1±4.5	Entry: 15 End: 39.6 (I) 39.4 (C)	I: 33±3.7 C: 33.9±5.6	Fasting blood glucose levels – Results suggested that the intervention did not have an effect on fasting blood glucose levels
Pelaez et al., 2014 (Spain)	RCT E Only	I: Group fitness classes in accordance to the ACOG guidelines, including a stretching and pelvic floor muscle condition session at the end of every class C: Standard care	I: 63 C: 89	I: 29.9±3.3 C: 29.1±4.5	Entry: 10-14 End: 36-40	I: 23.6±4.3 C: 22.7±3.8	Prevention of urinary incontinence – The intervention group reported significantly fewer incidences of urinary incontinence compared to the control group

Ramirez-Velez et al., 2011 (Colombia)	RCT E Only	I: Supervised group fitness classes including aerobic exercises, strength training and stretching offered three times per week C: Standard care	I: 24 C: 26	19.5±2.3	Entry: 16-20 End: 30-34	NR	Endothelium-dependent vasodilatation – The intervention group had significantly greater flow mediated dilation in comparison to the control group
Ramirez-Velez et al., 2017 (Colombia)	RCT E Only	I: Three supervised moderate-vigorous group fitness classes including aerobic exercise, resistance training, and relaxation C: Standard care	I: 25 C: 26	I: 19.0±3.0 C: 20.0±3.0	Entry: 16-20 End: 28-32	I: 21.8±2.4 C: 23.5±3.1	Maternal lipid concentration – The intervention group had significantly lower total glycerides and low-density lipid concentration in comparison to the control group
Reilly et al., 2002 (England)	RCT E Only	I: Participants were instructed to perform pelvic floor muscle conditioning exercises twice daily with specific	I: 120 C: 110	I: 17-42 C: 16-47	Entry: 20 End: NR	I:24.9±4.2 C: 24.1±4.3	Postpartum stress urinary incontinence – Participants who performed the exercises for 28 days or more were

		goals for repetitions, time and contractions C: General advice to perform pelvic floor muscle conditioning exercises					less likely to have stress urinary incontinence postpartum in comparison to the control group
Robertson et al., 2018 (Australia)	OBS N Only	All participants had a one-hour consultation with a dietitian focusing on nutrition requirements during pregnancy based on the Australian Guide to Healthy Eating. Participants were given a nutrition handout and were encouraged to return every 4-6 weeks for follow up	174	29.1±4.8	5-34	40.6±4.3	Total GWG – Individual nutrition counselling was an effective method for controlling GWG
Sagedal et al., 2017	RCT N+E	I: Participants were given individual dietary counselling	I: 203 C: 188	I: 28.0±4.0 I: 28.5±4.2	Entry: 15.4 (I), 15.7 (C)	I: 23.6±4.0 C: 23.4±3.3	PPWR – There was no difference between the

(Norway)		sessions over the phone. Two group fitness classes were available every week for 60 minutes C: Standard care					intervention and control group for PPWR 12 months after delivery. Those with higher compliance reported lower levels of PPWR
Senevirante et al., 2015 (Australia)	RCT E Only	I: Structured home exercise at a moderate intensity on stationary bicycles three to five times per week for 15-30 minutes. Participants were also given a heart rate monitor C: Participants were not given an exercise program or heart rate monitors	I: 37 C: 37	18-40	Entry: 20 End: 35	NR	Birth weight – There was no difference in birth weight between the intervention and control group
Shirazian et al., 2009 (USA)	OBS N+E	I: Participants received written information about nutrition and	I: 21 C: 20	I: 29.0±5.0 C: 24.3±5.6	Entry: Trimester 1 End: NR	I: 36.2±5.2 C: 34.2±5.3	Total GWG – The participants in the intervention group gained

		exercise, a food diary, and a pedometer. Participants attended six education sessions and had one follow-up phone call C: Matched control group that did not receive the intervention					significantly less weight than the control group
Shirazian et al., 2016 (USA)	OBS N+E	I: Participants received written information about nutrition and exercise, a food diary, and a pedometer. Participants attended six education sessions and had one follow-up phone call	I: 60 C: 60	I: 28.1±5.4 C: 26.8±5.8	Entry: Trimester 1 End: NR	I: 36.2±4.6 C: 35.9±5.1	Total GWG – There was no significant difference in gestational weight gain between the intervention and control group

		C: Matched control group that did not receive the intervention					
Stafne et al., 2012 (Norway)	RCT E Only	I: Group fitness class including aerobic, pelvic floor and strength exercises offered once per week for 60 minutes C: Standard care	I: 396 C: 365	I: 30.5±4.4 C: 30.4±4.3	Entry: 18-22 End: 32-36	I: 24.7±3 C: 25±3.4	Urinary and anal incontinence – Fewer women in the intervention group reported weekly incidences of urinary incontinence and faecal incontinence
Stafne et al., 2012 (Norway)	RCT E Only	I: Group fitness class offered once per week including moderate aerobic exercises, strength training and stretching. Additionally, women were encouraged to exercise at least once per week at	I: 379 C: 327	I: 30.5±4.4 C: 30.4±4.3	Entry: 18-22 End: 32-36	I: 24.7±3 C: 25±3.4	GDM and insulin resistance – There was no significant difference between the intervention and control group for insulin resistance and prevalence of GDM

		home for 45 minutes C: Women received written information about pelvic floor muscle exercises, diet and pregnancy related lumbo-pelvic pain					
Ussher et al., 2015 (England)	RCT E Only	I: Fourteen sessions of supervised exercise were offered over eight weeks; twice a week for six weeks then weekly for two weeks. At each session the participants walked at a moderate intensity on a treadmill for up to 30 minutes. Additionally, before each session participant received	I: 391 C: 393	I: 27.2±6.1 C: 27.8±6.5	Entry: 10-24 End: NR	I: 25.6±5.0 C: 26.6±5.6	Smoking cessation – Add physical activity to a behavioral counselling program did not increase smoking cessation during pregnancy

		behavioral counselling C: Six weekly sessions of behavioral counselling only					
Vargas-Terrones et al., 2018 (Spain)	RCT E Only	I: Moderate intensity group fitness classes including aerobic, strength and stretching exercises offered at least three times per week C: Standard care	I: 70 C: 47	I: 33.3±2.9 C: 32.3±5	Entry: 12-16 End: 38	I: 23.0±3.7 C: 23.9±5.0	Perinatal depression – Depression scored were significantly less in the intervention group than the control group. Fewer women in the intervention group were at risk for depression than in the control group post-intervention
Vestgaard et al., 2017 (Denmark)	OBS N Only	I: Women with GDM were offered sessions with a dietitian to receive personalized dietary advice	I: 128 (high adherence), 238 (low adherence) C: 70	I: 32.0±5.0 (high adherence), 31.0±5.0 (low adherence)	NR	NR	Birth weight – Women who received the nutrition advice had significantly lower birth weight

		C: Women who received standard care and did not meet with a dietitian		C: 31.0±5.0			than women who did not receive this
Wang et al., 2017 (China)	RCT E Only	I: Supervised moderate intensity cycling sessions C: Standard care	I: 112 C: 114	I: 32.1±4.5 C: 32.5±4.9	Entry: 10 End: 39	I: 26.7±2.7 C: 26.8±2.7	GDM – The incidence of GDM was significantly less in the intervention group than the control group
Vinter et al., 2011 (Denmark)	RCT N+E	I: Four dietary counselling sessions with a dietitian to provide individual nutrition recommendations. Participants were also encouraged to be active during pregnancy, were given a pedometer and free membership to a fitness facility with supervised training	I: 150 C: 154	29.0	Entry: 10-14 End: 35	I: 33.4 C: 33.3	Total GWG – The intervention group gained significantly less weight than the control group

		sessions. Additionally, women attended a group session to learn about integrating physical activity in daily life C: Received information only on being physically activity and eating well during pregnancy					
Ward-Ritacco et al., 2016 (USA)	OBS E Only	Individual 45-minute supervised exercise sessions including treadmill walking, seated strength exercises and stretching	24	29.7±4.7	Entry: 21-25 End: 33-37	NR	Energy and fatigue levels – For most of the women there was an improvement in energy levels and a decrease in fatigue
Yeo et al., 2000 (USA)	RCT E Only	I: Individual sessions of treadmill walking and stationary cycling	I: 8 C: 8	30±5.4.0	Entry: 18 End: 28	NR	Resting blood pressure – There was a decrease in blood pressure in the intervention group

		C: No intervention					
Youngwanichsetha et al., 2014 (Thailand)	RCT N+E	I: Women with GDM were trained to practice mindful eating and yoga exercises following a 50-minute video at home. They were asked to follow nutrition and exercise recommendations at least 5 times per week for 8 weeks C: Standard care	I: 85 C: 85	I: 32.5±5.0 C: 31.2±4.5	NR	I: 27±3.5 C: 27±4	Capillary fasting and postprandial blood glucose and hemoglobin A1c – Women in the intervention group had significantly lower fasting, postprandial blood glucose, and hemoglobin A1c than those in the control group

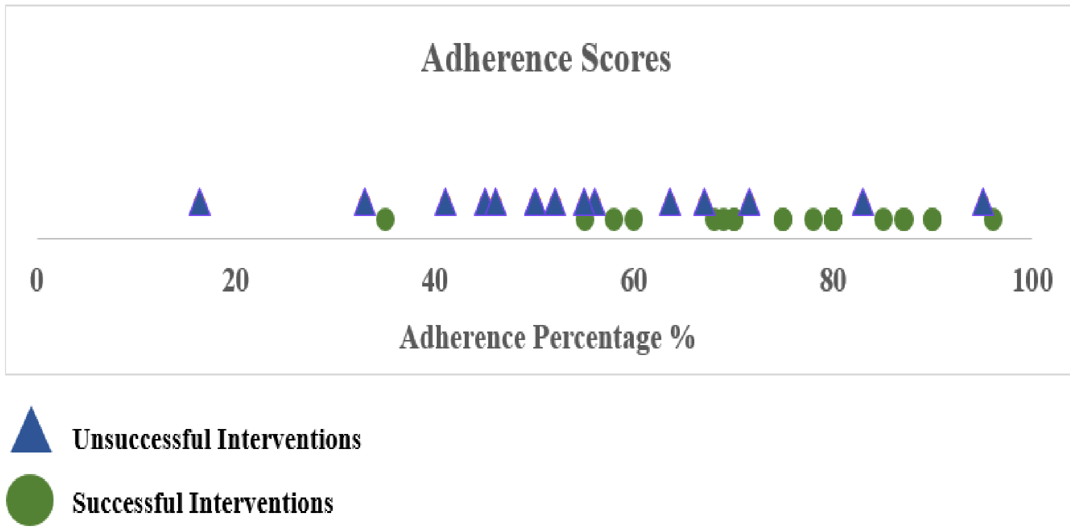
ACOG: American Congress of Obstetrics and Gynaecology; BMI: Body Mass Index; C: Control group; E: Exercise intervention; EGWG: Excessive Gestational Weight Gain; GDM: Gestational Diabetes Mellitus; GWG: Gestational Weight Gain; I: Intervention group; IOM: Institute of Medicine; N: Nutrition intervention; N+E: Nutrition + Exercise intervention; NR: Not Reported; NW: Normal Weight; OBS: Observational study; PPWR: Postpartum Weight Retention; RCT: Randomized Controlled Trial; T1D: Type 1 Diabetes

Twenty-four studies (19 RCTs, 5 OBS) reported meeting statistical significance favoring the intervention for the primary health outcome and were grouped as ‘successful’ (20-22, 24, 29, 32, 33, 35, 37, 43-46, 49, 52-57, 59, 61-63). Eighteen studies (17 RCTs, 1 OBS) did not report statistical significance favoring the intervention and were grouped as ‘unsuccessful’ (19, 23, 25-28, 34, 36, 38-42, 47-49, 51, 60). At post-data collection, a third category was developed as ‘unclear’ for three studies (2 RCTs, 1 OBS) because the reported data included only those with high adherence to the intervention instead of the full sample assessed (30, 31, 58).

Mean adherence for all studies that met their reported health outcome goal was 74.6% (±14.2, 95% Confidence Intervals [CI], 68.5, 80.7). The adherence average for ‘successful’ interventions was calculated with eighteen RCTs (as one RCT did not provide mean adherence to the intervention and therefore was not included in this calculation (46)) and 3 observational (OBS) studies (one study provided mean attendance but the number of total sessions required to attend was not a set goal for the study, and one study did not provide mean adherence to the intervention and therefore was not included in this calculation; (59, 62)). Mean adherence for all studies that did not meet their health outcome goal was 54.9% (±19.4, 95% [CI] 45.1, 64.7). The average adherence for ‘unsuccessful’ interventions was calculated with fourteen RCTs (two studies only provided median adherence and one study did not provide adherence for all participants; (27, 34, 47)) and one OBS study. Mean adherence for ‘successful’ studies was significantly higher than ‘unsuccessful’ studies

($t(34)=3.52$, $p=0.003$, Cohen's $d=0.24$). Adherence averages are reported in Table 2.2. Figure 2.2 visually represents adherence for each individual intervention. As seen in Figure 2.2, 'successful' studies are more clustered around approximately 70% adherence, whereas 'unsuccessful' studies are represented mostly below 60%.

Figure 2.2 Visual representation of individual study adherence scores.



'Successful' interventions on average had 74% adherence (±14.2).

'Unsuccessful' interventions on average had 54% adherence (±19.4).

Table 2.2 Study Characteristics

Study	Adherence	'Successful' (S) or 'Unsuccessful' (US)?	Number and Type of Behavior Changes	Self-Monitoring Behaviors	Primary Delivery of Intervention	Length (Max Weeks)
Barakat et al, 2012 (Spain)	85% - measured by attendance to group fitness classes	S	1 Exercise	None	Face to face for exercise sessions	33
Barakat et al, 2012 (Spain)	87% - measured by attendance to group fitness classes	S	1 Exercise	None	Face to face for exercise sessions	33
Barakat et al, 2016 (Spain)	80% - measured by attendance to group fitness classes	S	1 Exercise	None	Face to face for exercise sessions	30
Bruno et al, 2016 (Italy)	57.9% - measured by a scoring system based on meeting nutrition criteria	S	2 Nutrition + Exercise	Pedometer	Face to face for information only	27
Della et al, 2011 (Brazil)	70% were classified as having good adherence by their second visit - measured	S	1 Nutrition	None	Face to face for information only	24

	by a classification system based on self-reported nutrition intake. On average women attended 4.12 sessions with a dietitian.					
Gesell et al, 2015 (USA)	35% - measured by attendance to fitness classes	S	2 Nutrition + Exercise	None	Face to face for exercise sessions	12
Halse et al, 2015 (Australia)	96% - measured by attendance to exercise sessions	S	1 Exercise	Exercise log	Face to face for exercise sessions	5
Herring et al, 2016 (USA)	70% considered adherent - responded to >50% of text messages	S	2 Nutrition + Exercise	Online exercise and food logs	Online	24
McGowan et al, 2013 (Ireland)	68% said following the diet was easy – measured by an acceptability questionnaire suggesting that if participants rank the behavior as easy, they have adopted the behavior	S	1 Nutrition	Food logs	Face to face for information only one time	20

Ney et al, 1982 (USA)	78% - measured by an acceptability questionnaire where participants indicated how well they followed recommendations	S	1 Nutrition	None	Face to face for sessions	16
Pelaez et al, 2014 (Spain)	80% - measured by attendance to fitness classes	S	1 Exercise	None	Face to face for exercise sessions	30
Ramirez-Velez et al, 2011 (Colombia)	75% - measured by attendance to fitness classes	S	1 Exercise	None	Face to face for exercise sessions	16
Ramirez-Velez et al, 2017 (Colombia)	80% - measured by attendance to fitness classes	S	1 Exercise	None	Face to face for exercise sessions	12
Reilly et al, 2002 (England)	52 women did not submit records, 13 women exercised <28 days, 55 women exercised >28 days – measured by home exercise diaries	S	1 Exercise	Exercise logs	Face to face for information only	20

Robertson et al, 2018 (Australia)	47 women attended 3 or more nutrition sessions – measured by attendance to voluntary sessions with a dietitian	S	1 Nutrition	None	Face to face to for information and follow up every 4-6 weeks, follow up was not mandatory	20
Shirazian et al, 2010 (USA)	75% - measured by attendance to required sessions and submission of records	S	2 Nutrition + Exercise	Food logs and pedometers	Telephone and face to face	Varied
Stafne et al , 2012 (Norway)	55% - measured by attendance to group fitness classes	S	1 Exercise	Exercise logs	Face to face for exercise sessions	12
Vargas-Terrones et al, 2018 (Spain)	69% - measured by attendance to group fitness classes	S	1 Exercise	None	Face to face for exercise sessions	16
Vestgaard et al, 2017 (Denmark)	37% high, 39% medium, 24% low – measured as meeting Danish Obstetric Guidelines	S	1 Nutrition	Food log	Face to face for optional counselling sessions	Varied
Wang et al, 2017 (China)	80% - measured by attendance to	S	1 Exercise	None	Face to face for	12

	exercise sessions				exercise sessions	
Vinter et al , 2011 (Denmark)	92% completed diet assessment, 52% attendance to fitness classes. Overall 60% - calculated as attendance to four dietary sessions and at least 20 classes	S	2 Nutrition + Exercise	None	Face to face for information sessions and exercise sessions	14
Ward-Ritacco et al, 2016 (USA)	87.1% - measured by attendance to exercise sessions	S	1 Exercise	None	Face to face for exercise sessions	12
Yeo et al, 2000 (USA)	90% - measured by attendance to exercise sessions	S	1 Exercise	Exercise logs	Face to face for exercise sessions	10
Youngwanichsetha et al, 2014 (Thailand)	100% for mindful eating and 80% for at home sessions (90%) – measured by home exercise logs and attendance to counselling sessions	S	2 Nutrition + Exercise	None	Face to face for information only, followed home video for exercises	8

SUMMARY	Average Adherence: RCTS: 74% (n=18) OBS: 77% (n=13)	Total: 24	75% One behavior (18/24) 13 Exercise 5 Nutrition 6 Both	38% Used self-monitoring (9/24)	Primarily face to face 71% (17/24) Face to face for information or follow-up 33% (8/24)	Average: 18 weeks (5-33 weeks)
Althuizen et al, 2012 (Netherlands)	67% - measured by attendance to counselling sessions	US	2 Nutrition + Exercise	None	Face to face for information only	21
Bo et al, 2011 (Norway)	71.6% - measured by attendance to group fitness classes	US	1 Exercise	None	Face to face for exercise sessions	12
da Silva et al, 2017 (Brazil)	56% - measured by attendance to sessions and an exercise diary	US	1 Exercise	Personal training diary	Face to face for exercise sessions	16
Dias et al, 2018 (Brazil)	95% - measured by attendance to fitness classes	US	1 Exercise	None	Face to face for exercise sessions	18
Eggen et al, 2012 (Norway)	Median classes attended was 11 – measured by attendance	US	1 Exercise	Exercise log	Face to face for exercise sessions	20

	to group fitness classes					
Garnes et al, 2016 (Norway)	50% - measured by attendance to group fitness classes and exercise diaries	US	1 Exercise	Exercise log	Face to face for exercise sessions	25
Mason et al, 2010 (England)	64.5% attended at least ¼ sessions – measured by attendance to counselling sessions and three-day exercise diaries	US	1 Exercise	Exercise logs	Face to face counselling and instructions	16
Moses et al, 2014 (Australia)	53% adherence to the low glycemic index diet – measured by an acceptability questionnaire where participants indicated how well they followed recommendatio ns	US	1 Nutrition	Food logs	Telephone and email	20
Nobles et al, 2015 (USA)	41% - measured by exercise logs and questionnaire	US	1 Exercise	Exercise logs	Face to face for information only	12

	about physical activity habits					
Nobles et al, 2018 (USA)	63.6% - measured by exercise logs and questionnaire about physical activity habits	US	1 Exercise	Exercise logs	Face to face for information only	12
Nyrnes et al, 2018 (Norway)	52% - measured by attendance to exercise sessions	US	1 Exercise	Exercise logs	Face to face for exercise sessions	26
Olson et al, 2018 (USA)	46.1% - measured by website logins and overall online engagement	US	2 Nutrition + Exercise	Online exercise and food logs	Online resources and information only	20
Oostdam et al, 2012 (Netherlands)	16.3% attended at least half of the sessions – measured by attendance to fitness classes	US	1 Exercise	None	Face to face for exercise sessions	18
Sagedal et al, 2017 (Norway)	92.6% attended at least one class, the median attended was 14 classes – measured by attendance to	US	2 Nutrition + Exercise	None	Telephone and face to face exercise sessions	20

	group fitness classes					
Senevirante et al, 2015 (Australia)	33% - measured by at home exercise logs	US	1 Exercise	Heart rate monitor and exercise logs	Home exercises	15
Shirazian et al, 2016 (USA)	50% - measured by attendance to required sessions and submission of records	US	2 Nutrition + Exercise	Food and exercise logs	Face to face and telephone sessions for information and follow up only	Varied
Stafne et al, 2012 (Norway)	55% - measured by attendance to group fitness classes	US	1 Exercise	Exercise logs	Face to face for exercise sessions	12
Ussher et al, 2015 (England)	5.25 sessions attended on average (38%) – measured by attendance to planned exercise and counselling sessions	US	1 Exercise	Exercise logs	Face to face for exercise sessions	6

SUMMARY:	Average Adherence: RCTs: 55% (n=14) OBS: 50% (n=1)	Total: 18	78% One behavior (14/18) 13 Exercise 1 Nutrition 4 Both	72% Used self-monitoring (13/18)	Primarily face to face 50% (9/18) Face to face for information or follow-up 28% (5/18)	17 weeks (6 to 26 weeks)
Haakstad et al, 2011 (Norway)	70% - measured by attendance to fitness classes	Unclear	1 Exercise	Exercise log	Face to face for exercise sessions	12
Haakstad et al, 2016 (Norway)	Low, 19 women attended all sessions and 21 attended at least 80% of sessions – measured by attendance to fitness classes and exercise diaries	Unclear	1 Exercise	Exercise log	Face to face for exercise sessions	12
Haby et al, 2018 (Sweden)	50% - measured by evaluating food and activity logs based on personalized recommendations	Unclear	2 Nutrition + Exercise	Food log	Face to face for two counselling sessions that were optional	12

Summary:	Average Adherence: RCT: 60% (n=2)	Total: 3	67% One behavior change (2/3) 2 Exercise 1 Both	100% Used self-monitoring (3/3)	Primarily face to face 67% (2/3) Face to face for information or follow-up 33% (1/3)	12 weeks

Moderators of Adherence

There was no difference between 'successful' and 'unsuccessful' studies for the number of studies delivered face to face [χ^2 (1, N=42) = 1.89, *p*=0.15, Cramer's V=0.21]. The 'successful' studies (17/24, 71%) primarily delivered the intervention face to face (20-22, 29, 32, 37, 43-45, 49, 52-55, 59, 61, 63). Some 'successful' studies included face to face time for information only and participants carried out intervention behaviors on their own primarily (24, 35, 46, 53, 56, 57, 62). Half of the 'unsuccessful' studies (9/18, 50%) were delivered face to face (23, 25-28, 40, 42, 50, 51) or included limited face to face time for information and/or follow up (19, 34, 38, 39, 60).

There was no difference for the number of studies that included self-monitoring between 'successful' and 'unsuccessful' studies [χ^2 (1, N=42) = 3.88, *p*=0.05, Cramer's V=0.30]. Thirty-eight percent (9/24, 38%) of the 'successful' studies used some form of self-monitoring primarily including nutrition and/or exercise logs (24, 32, 33, 35, 49, 55, 61, 62). Seventy-two percent (13/18) of the 'unsuccessful' studies also used some form of self-monitoring (25, 27, 28, 34, 36, 38-41, 48, 50, 51, 60).

There was no difference between the 'successful' and 'unsuccessful' categories for the number of one behavior change interventions in comparison to multiple behavior change interventions included [χ^2 (1, N=42) = 0.04, *p*=0.57, Cramer's V=0.03]. Seventy-five percent of the 'successful' studies included only one behavior change (18/24) (20-22, 32, 35, 37, 43-46, 49, 52, 54, 55, 57, 59, 62, 63) and 25% (6/24) included two behaviors in the intervention (24, 29, 33, 53, 56, 61). Seventy-eight percent of the ‘unsuccessful’ studies (14/18) included only one behavior change (23, 25-28, 34, 36, 38-40, 42, 48, 50, 51) and 22% (4/18) included two behaviors (19, 41, 47, 60).

On average ‘successful’ interventions were 18 weeks long (±8.3, 95% [CI] 14.9, 21.9) whereas ‘unsuccessful’ interventions were 17 weeks long (±5.2, 95% [CI] 14.5, 19.5; $t(35.6)=0.67$, $p=0.51$; Cohen’s $d=0.01$). Adherence averages and moderator information are presented in Table 2.2.

2.4 Discussion

The results of the current study suggest that interventions that achieve statistical significance favoring the intervention group have higher program adherence (on average approximately ≥70%) than studies that do not (on average approximately ≤55% adherence, $p<0.05$), indicating that adherence is a key factor in determining the success of a lifestyle intervention during pregnancy. There was no difference among ‘successful’ and ‘unsuccessful’ studies for potential moderators of adherence including the method of delivery for the intervention, the use of self-monitoring tools, the number of behavior changes required, and the total length of the intervention.

Authors reporting results of lifestyle interventions that statistically favor the intervention and show a positive effect on the primary health outcome often report adherence as a strength (19-21, 24, 26, 37, 43, 45, 46, 52, 54). On the contrary, authors that do not meet their primary health outcome often suggest that adherence to the intervention may be a contributing factor and adherence is reported as a limitation (23, 25, 29-31, 34, 35, 38, 39, 41, 42, 47, 48, 50, 59, 60). Measuring and reporting program adherence is not a requirement for intervention based studies and this may be why the results vary in the literature in terms of the effectiveness of lifestyle interventions on health outcomes during pregnancy.

It should be noted that some ‘unsuccessful’ studies did achieve 70% or more adherence to the intervention in the present review. Bo et al, (2011) and Dias et al., (2017) reported >70% attendance to group fitness classes including pelvic floor muscle training, to prevent urinary incontinence (23, 26). The authors identified that the inability to assess if muscle contractions were correctly occurring is a limitation of the study. This may suggest that attendance only is not an appropriate measurement tool for adherence for interventions including pelvic floor muscle training to prevent urinary incontinence. Similarly, Ussher et al, (2015) reported >70% attendance to exercise sessions but the intervention did not affect smoking cessation rates. A limitation reported was the expectation to continue exercise behaviors at home which was self-reported (51). Attendance was the most common method to measure adherence, however it may not always be the most appropriate measurement tool because it does not capture nutrition and/or exercise behaviors taking place outside of the research setting.

On the opposite end, there were also ‘successful’ studies that reported adherence levels below 70%. Bruno et al., (2016) provided women with nutrition and exercise information to prevent gestational diabetes and although the overall group adherence was low, authors did report that those women who were adherent to the program had the most improved health outcomes (24). Stafne et al, (2012) also reported below 70% attendance to group fitness classes to prevent urinary incontinence, but still found that more women in the intervention group reported fewer incidences of urinary leakage (49). Authors reported that although attendance was low, the clear instructions for performing pelvic floor muscle training was a strength, and perhaps women performed these exercises more often than just during the class. Finally, three studies assessed the impact of a lifestyle intervention on gestational weight gain and reported low adherence (29, 35, 53). Interestingly both Gesell et al, (2015) and Vinter et al, (2011) included both nutrition and exercise, yet adherence was not measured for nutrition specifically (29, 53). McGowan et al, (2013) conducted a nutrition only study and developed their own acceptability questionnaire to assess adherence (35). Measuring nutrition adherence is challenging and relies heavily on self-reported data, therefore women may have been adherent to nutrition recommendations but this was not correctly captured in the adherence measurement.

Although not statistically significant, more 'successful' studies reported in the present investigation were delivered face to face with a large effect size, and this is in line with the findings of Currie et al, (2013) who suggested that supervised sessions may be more effective (10). Interestingly, new research has focused on reducing face to face time and increasing delivery of interventions via online methods (64). Although this may be an effective approach to reach a larger population and potentially more cost effective, future research should consider incorporating face to face time or a similar component within online interventions.

Contrary to previous findings that suggest self-monitoring can improve adherence (10), although not significant, more ‘unsuccessful’ interventions included self-monitoring than ‘successful’ studies with a moderate effect size. The current study however did not evaluate the type of self-monitoring resource used or how well or often it was used, therefore the effectiveness of self-monitoring on program adherence needs to be further evaluated. Finally, both ‘successful’ and ‘unsuccessful’ studies were similar in length (18 weeks for ‘successful’ studies, 17 week for ‘unsuccessful’ studies). It is unclear what duration of intervention would be most effective for behavior change during pregnancy. A longer intervention may allow for frequent follow up and more time to adjust to the required behavior change. For example, during the ‘Healthy Eating and Lifestyle Pregnancy (HELP)’ intervention for pregnancy, women reported that a facilitator for adherence to the intervention was the frequent support from study investigators especially for long term behavior change (65). Participants reported that it was a challenge to maintain behaviors over a longer period of time, however it also assisted them in having time to acquire knowledge and develop skills to sustain behaviors (65).

There is no gold standard to measuring and reporting adherence to nutrition and exercise interventions and therefore authors will use methods that best fit their study design (6). The current study builds on the work by McDonald et al, (2016) and Nagpal et al, (2017) by statistically evaluating the difference in adherence between ‘successful’ and ‘unsuccessful’ lifestyle interventions on any health outcome during pregnancy (7, 8). As suggested by McDonald et al, (2016) and confirmed by the results of the current study, adherence may provide valuable information for interpreting study results and future research should consider determining effective ways to measure and report full program adherence (7).

This is the first systematic review where the primary outcome was adherence instead of a specific health outcome, allowing for results to be generalized. This also assured that the search specifically sought to find lifestyle interventions that provide an adherence value. This may however also be seen as a limitation, as the search term ‘adherence’ may not capture all studies for each health outcome. The results of the current study provide evidence that further research investigating the effect of adherence on individual outcomes is warranted. Although the primary outcome of the current review was adherence, it was not possible to complete a meta-analysis as adherence data cannot be entered in a traditional forest plot meta-analysis to differentiate favorable versus unfavorable effects. Future meta-analyses should be completed for each health outcome and report individual study adherence to evaluate whether studies with low adherence are potentially contributing the greatest weight to the meta-analysis as this may negatively influence the overall effect. Additionally the *a priori* inclusion criteria stated that adherence must be reported quantitatively which led to the inclusion of studies that only provided median or selected adherence scores for study participants, and therefore the values could not be included in the average calculation. Future studies should aim to provide an appropriate adherence report for the full intervention as it can significantly affect how results are interpreted. Moreover, future studies should aim to further define potential moderators of adherence and statistically assess the impact of each one on program adherence. As adherence and the effect of moderators may vary on an individual level, independent patient data meta-analysis with adherence as the primary outcome may be an effective way to determine the required adherence to meet a health outcome and may reduce the high heterogeneity seen in previous meta-analyses (3). Furthermore, as a large effect size was found for face to face delivery of interventions and therefore this moderator may need to be further defined and explored. For example, majority of the studies were delivered in a group setting (20-22, 26-28, 30, 31, 34, 38, 39, 42-45, 47-56) and perhaps this has an influence on program adherence and overall ‘success’. Perhaps studies delivered in a group setting, compared to one on one or using an online modality had different adherence and this may have contributed to the results of the study.

2.5 Conclusion

In conclusion, it is suggested through this study that at least 70% adherence is recommended for lifestyle interventions (nutrition and/or exercise) during pregnancy to achieve statistical significance favoring the intervention for health outcomes. There is limited evidence at this time to suggest that the method of intervention delivery (i.e., face-to-face), use of self-monitoring resources, number of behavior changes, and length of intervention moderate adherence levels of ‘successful’ versus ‘unsuccessful’ interventions. Future studies should aim to measure and report adherence levels as well as assess potential adherence moderators in order to further evaluate the role adherence has in the success of lifestyle interventions during pregnancy.

2.6 Study 1 Key Points:

- Authors of previous studies have often stated that a limitation of the intervention was low adherence that may have led to a null effect
- Study 1 determined that adherence is a key factor in the success of a lifestyle intervention during pregnancy as authors who reported that interventions successfully achieved the health outcome goal had significantly higher adherence than interventions that were ‘unsuccessful’
- At least 70% adherence is observed among lifestyle interventions that successfully achieve health outcome goals during pregnancy
- Although not significant, a potential moderator that may increase adherence includes delivering the lifestyle intervention face to face. The use of self-monitoring tools, the number of behavior changes required and the length of the intervention as adherence moderators remain unclear

Important points to consider moving from Study 1 to Study 2:

- The results of study 1 provide evidence that adherence is a key factor in determining the success of a lifestyle intervention during pregnancy
- Previous research, however, has specifically identified women with a BMI ≥25 kg/m^2 as a population that is more likely to report low adherence to

nutrition and exercise during pregnancy compared to women with a normal weight BMI status

- Women who have an overweight or obese BMI may have been trying to to lose weight in the past and may have experienced weight fluctuations prior to pregnancy and this may influence gestational weight gain
- The influence that program adherence and weight fluctuations have on EGWG among women with an overweight or obese BMI remains unknown

2.7 Chapter 2 References

1. Dodd JM, Grivell RM, Crowther CA, Robinson JS. Antenatal interventions for overweight or obese pregnant women: a systematic review of randomised trials. *BJOG.* 2010;117(11):1316-26.

2. Ferraro ZM, Gaudet L, Adamo KB. The potential impact of physical activity during pregnancy on maternal and neonatal outcomes. *Obstetrical & Gynecological Survey.* 2012;67(2):99-110.

3. Rogozinska E, Marlin N, Jackson L, et al. Effects of antenatal diet and physical activity on maternal and fetal outcomes: individual patient data meta-analysis and health economic evaluation. *Health Technology Assessment (Winchester, England).* 2017;21(41):1-158.

4. Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ (Clinical research ed).* 2012;344:e2088.

5. Weissgerber TL, Wolfe LA, Davies GA, Mottola MF. Exercise in the prevention and treatment of maternal-fetal disease: a review of the literature. *Applied Physiology, Nutrition, and Metabolism.* 2006;31(6):661-74.

6. Vitolins MZ, Rand CS, Rapp SR, Ribisl PM, Sevick MA. Measuring adherence to behavioral and medical interventions. *Controlled Clinical Trials.* 2000;21(5 Suppl):188s-94s.

7. McDonald SM, Liu J, Wilcox S, Lau EY, Archer E. Does dose matter in reducing gestational weight gain in exercise interventions? A systematic review of literature. *Journal of Science and Medicine in Sport.* 2016;19(4):323-35.

8. Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? *Behavior Analysis in Practice.* 2017;10(4):347-54.

9. Streuling I, Beyerlein A, von Kries R. Can gestational weight gain be modified by increasing physical activity and diet counseling? A meta-analysis of interventional trials. *The American Journal of Clinical Nutrition.* 2010;92(4):678-87.

10. Currie S, Sinclair M, Murphy MH, Madden E, Dunwoody L, Liddle D. Reducing the decline in physical activity during pregnancy: a systematic review of behavior change interventions. *PloS One.* 2013;8(6):e66385.

11. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychology.* 2008;27(3):379-87.

12. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology.* 2009;28(6):690-701.

13. Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Archives of Internal Medicine.* 2007;167(11):1152-8.

14. Borodulin KM, Evenson KR, Wen F, Herring AH, Benson AM. Physical activity patterns during pregnancy. *Medicine and Science in Sports and Exercise.* 2008;40(11):1901-8.

15. Di Fabio DR, Blomme CK, Smith KM, Welk GJ, Campbell CG. Adherence to physical activity guidelines in mid-pregnancy does not reduce sedentary time: an

observational study. *The International Journal of Behavioral Nutrition and Physical Activity.* 2015;12:27.

16. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Journal of Clinical Epidemiology.* 2009;62(10):e1-34.

17. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews.* 2015;4:1.

18. Mottola MF, Davenport MH, Ruchat SM, et al. 2019 Canadian guideline for physical activity throughout pregnancy. *BJSM.* 2018;52(21):1339-46.

19. Althuizen E, van der Wijden CL, van Mechelen W, Seidell JC, van Poppel MN. The effect of a counselling intervention on weight changes during and after pregnancy: a randomised trial. *BJOG.* 2013;120(1):92-9.

20. Barakat R, Cordero Y, Coteron J, Luaces M, Montejo R. Exercise during pregnancy improves maternal glucose screen at 24-28 weeks: a randomised controlled trial. *BJSM.* 2012;46(9):656-61.

21. Barakat R, Pelaez M, Cordero Y, et al. Exercise during pregnancy protects against hypertension and macrosomia: randomized clinical trial. *Am J Obstet Gynecol.* 2016;214(5):649 e1-8.

22. Barakat R, Pelaez M, Lopez C, Montejo R, Coteron J. Exercise during pregnancy reduces the rate of cesarean and instrumental deliveries: results of a randomized controlled trial. *J Matern Fetal Neonatal Med.* 2012;25(11):2372-6.

23.Bo K, Haakstad LA. Is pelvic floor muscle training effective when taught in a general fitness class in pregnancy? A randomised controlled trial. *Physiotherapy.* 2011;97(3):190-5.

24. Bruno R, Petrella E, Bertarini V, Pedrielli G, Neri I, Facchinetti F. Adherence to a lifestyle programme in overweight/obese pregnant women and effect on gestational diabetes mellitus: a randomized controlled trial. *Matern Child Nutr.* 2017;13(3).

25. da Silva SG, Hallal PC, Domingues MR, et al. A randomized controlled trial of exercise during pregnancy on maternal and neonatal outcomes: results from the PAMELA study. *The International Journal of Behavioral Nutrition and Physical Activity.* 2017;14(1):175.

26. Dias NT, Ferreira LR, Fernandes MG, Resende APM, Pereira-Baldon VS. A Pilates exercise program with pelvic floor muscle contraction: Is it effective for pregnant women? A randomized controlled trial. *Neurourol Urodyn.* 2018;37(1):379-84.

27. Eggen MHS, Mowinckel P, Jensen KS, Hagen KB. Can supervised group exercises including ergonomic advice reduce the prevalence and severity of low back pain and pelvic girdle pain in pregnancy? A randomized controlled trial. *Physical Therapy.* 2012;92(6):781-90.

28. Garnaes KK, Morkved S, Salvesen O, Moholdt T. Exercise Training and Weight Gain in Obese Pregnant Women: A Randomized Controlled Trial (ETIP Trial). *PLoS Med.* 2016;13(7):e1002079.

29. Gesell SB, Katula JA, Strickland C, Vitolins MZ. Feasibility and Initial Efficacy Evaluation of a Community-Based Cognitive-Behavioral Lifestyle Intervention to

Prevent Excessive Weight Gain During Pregnancy in Latina Women. *Matern Child Health J.* 2015;19(8):1842-52.

30. Haakstad LA, Bo K. Effect of regular exercise on prevention of excessive weight gain in pregnancy: a randomised controlled trial. *Eur J Contracept Reprod Health Care.* 2011;16(2):116-25.

31. Haakstad LA, Torset B, Bo K. What is the effect of regular group exercise on maternal psychological outcomes and common pregnancy complaints? An assessor blinded RCT. *Midwifery.* 2016;32:81-6.

32. Halse RE, Wallman KE, Dimmock JA, Newnham JP, Guelfi KJ. Home-Based Exercise Improves Fitness and Exercise Attitude and Intention in Women with GDM. *Medicine and science in sports and exercise.* 2015;47(8):1698-704.

33. Herring SJ, Cruice JF, Bennett GG, Rose MZ, Davey A, Foster GD. Preventing excessive gestational weight gain among African American women: A randomized clinical trial. *Obesity (Silver Spring).* 2016;24(1):30-6.

34. Mason L, Roe B, Wong H, Davies J, Bamber J. The role of antenatal pelvic floor muscle exercises in prevention of postpartum stress incontinence: a randomised controlled trial. *J Clin Nurs.* 2010;19(19-20):2777-86.

35. McGowan CAW, Byrne H, Curran S, McAuliffe FM. The influence of a low glycemic index dietary intervention on maternal dietary intake, glycemic index and gestational wieght gain during pregnancy: A randomized controlled trial. *Nutrition Journal.* 2013;12(140):1-9.

36. Moses RG, Casey SA, Quinn EG, et al. Pregnancy and Glycemic Index Outcomes study: effects of low glycemic index compared with conventional

dietary advice on selected pregnancy outcomes. *The American journal of clinical nutrition.* 2014;99(3):517-23.

37. Ney DH, Cousins, L. Decreased insulin requirement and improved control of diabetes in pregnant women given a high-carbohydrate, high fiber, low-fat diet. *Diabetes Care.* 1982;5(5):529-33.

38. Nobles C, Marcus BH, Stanek EJ 3rd, et al. The Effect of an Exercise Intervention on Gestational Weight Gain: The Behaviors Affecting Baby and You (B.A.B.Y.) Study: A Randomized Controlled Trial. *Am J Health Promot.* 2018;32(3):736-44.

39. Nobles C, Marcus BH, Stanek EJ, 3rd et al. Effect of an exercise intervention on gestational diabetes mellitus: a randomized controlled trial. *Obstet Gynecol.* 2015;125(5):1195-204.

40. Nyrnes SA, Garnaes KK, Salvesen O, Timilsina AS, Moholdt T, Ingul CB. Cardiac function in newborns of obese women and the effect of exercise during pregnancy. A randomized controlled trial. *PloS One.* 2018;13(6):e0197334.

41. Olson CM, Groth SW, Graham ML, Reschke JE, Strawderman MS, Fernandez ID. The effectiveness of an online intervention in preventing excessive gestational weight gain: the e-moms roc randomized controlled trial. *BMC Pregnancy Childbirth.* 2018;18(1):148.

42. Oostdam N, van Poppel MN, Wouters MG, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial. *BJOG*. 2012;119(9):1098-107.

43. Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. Pelvic floor muscle training included in a pregnancy exercise program is effective in primary prevention of urinary incontinence: a randomized controlled trial. *Neurourol Urodyn.* 2014;33(1):67-71.

44. Ramirez-Velez R, Aguilar de Plata AC, Escudero MM, et al. Influence of regular aerobic exercise on endothelium-dependent vasodilation and cardiorespiratory fitness in pregnant women. *J Obstet Gynaecol Res.* 2011;37(11):1601-8.

45. Ramirez-Velez R, Lobelo F, Aguilar-de Plata AC, Izquierdo M, Garcia-Hermoso A. Exercise during pregnancy on maternal lipids: a secondary analysis of randomized controlled trial. *BMC Pregnancy Childbirth.* 2017;17(1):396.

46. Reilly ETCF, Waterfield MR, Waterfield AE, Steggles P, Pedlar F. Prevention of postpartum stress incontinence in primigravidae with increased bladder neck mobility: A randomised controlled trial of antenatal pelvic floor exercises. *International Journal of Obstetrics and Gynaecology.* 2002;109:68-76.

47. Sagedal LRS, Overby NC, Bere E, et al. The effect of prenatal lifestyle intervention on weight retention 12 months postpartum: Results of the Norwegian Fit for Delivery randomised controlled trial. *BJOG.* 2017;124(1):111-21.

48.Seneviratne SN, Jiang Y, Derraik J, et al. Effects of antenatal exercise in overweight and obese pregnant women on maternal and perinatal outcomes: a randomised controlled trial. *BJOG*. 2016;123(4):588-97.

49. Stafne SN, Salvesen KA, Romundstad PR, Torjusen IH, Morkved S. Does regular exercise including pelvic floor muscle training prevent urinary and anal incontinence during pregnancy? A randomised controlled trial. *BJOG*. 2012;119(10):1270-80.

50. Stafne SN, Salvesen KA, Romundstad PR, Eggebo TM, Carlsen SM, Morkved S. Regular exercise during pregnancy to prevent gestational diabetes: a randomized controlled trial. *Obstet Gynecol.* 2012;119(1):29-36.

51. Ussher M, Lewis S, Aveyard P, et al. Physical activity for smoking cessation in pregnancy: randomised controlled trial*. BMJ (Clinical research ed).* 2015;350:h2145.

52. Vargas-Terrones M, Barakat R, Santacruz B, Fernandez-Buhigas I, Mottola MF. Physical exercise programme during pregnancy decreases perinatal depression risk: a randomised controlled trial. *BJSM.* 2018;53(6):348-53.

53. Vinter CA, Jensen DM, Ovesen P, Beck-Nielsen H, Jorgensen JS. The LiP (Lifestyle in Pregnancy) study: a randomized controlled trial of lifestyle intervention in 360 obese pregnant women. *Diabetes Care.* 2011;34(12):2502-7.

54. Wang C, Wei Y, Zhang X, et al. A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women*. Am J Obstet Gynecol.* 2017;216(4):340-51.

55. Yeo SS, Chang M, Leclaire SM, Ronis DL, Hayashi R. Effect of exercise on blood pressure in pregnant women with a high risk of gestational hypertensive disorder. *The Journal of Reproductive Medicine.* 2000:293-8.

56. Youngwanichsetha S, Phumdoung S, Ingkathawornwong T. The effects of mindfulness eating and yoga exercise on blood sugar levels of pregnant women with gestational diabetes mellitus. *Appl Nurs Res.* 2014;27(4):227-30.

57. Della Líbera BRB, de Souza Santos MMA, Padilha P, Dutra Alves P, Saunders C. Adherence of pregnant women to deitary counseling and adequacy of total gestational weight gain. *Nutr Hosp.* 2011;26(1):79-85.

58. Haby K, Berg M, Gyllensten H, Hanas R, Premberg A. Mighty Mums - a lifestyle intervention at primary care level reduces gestational weight gain in women with obesity. *BMC Obes.* 2018;5:16.

59. Robertson N, Ladlow B. Effect of individual dietetic intervention on gestational weight gain and associated complications in obese pregnant women. *Aust N Z J Obstet Gynaecol.* 2018;58(3):274-7.

60. Shirazian T, Faris BS, Fox NS, Friedman F, Jr., Rebarber A. The lifestyle modification project: limiting pregnancy weight gain in obese women. *J Matern Fetal Neonatal Med.* 2016;29(1):80-4.

61. Shirazian T, Monteith S, Friedman F, Rebarber A. Lifestyle modification program decreases pregnancy weight gain in obese women. *Am J Perinatol.* 2010;27(5):411-4.

62. Vestgaard M, Christensen AS, Viggers L, Lauszus FF. Birth weight and its relation with medical nutrition therapy in gestational diabetes. *Arch Gynecol Obstet.* 2017;296(1):35-41.

63. Ward-Ritacco C, Poudevigne MS, O'Connor PJ. Muscle strengthening exercises during pregnancy are associated with increased energy and reduced fatigue. *J Psychosom Obstet Gynaecol.* 2016;37(2):68-72.

64. Sherifali D, Nerenberg KA, Wilson S, et al. The Effectiveness of eHealth Technologies on Weight Management in Pregnant and Postpartum Women:

Systematic Review and Meta-Analysis. *Journal of medical Internet research.* 2017;19(10):e337.

65. Cassidy D, John E, Copeland L, Simpson SA. Weight management in Pregnancy: Participants' experiences of 'Healthy Eating and Lifestyle in Pregnancy (HELP)', a maternity care intervention for obese pregnant women. *Pregnancy Hypertension.* 2014;4(3):233.

Chapter 3

Study 2: Do pre-pregnancy weight fluctuations and adherence to nutrition and exercise programs during pregnancy predict excessive gestational weight gain?

3.1 Introduction

As the prevalence of obesity continues to increase globally, more women are entering pregnancy with an overweight (pre-pregnancy body mass index (BMI) ≥25.0-29.9 kg/m^2) or obese (BMI ≥30.0 kg/m^2) BMI (1). A pre-pregnancy BMI ≥25.0 kg/m^2 increases the risk of pregnancy complications and the future risk for chronic diseases that can impact both the mother and child (2-4). Risks for chronic diseases, including obesity and diabetes, are further increased if the mother gains excessive weight during her pregnancy (5, 6). Excessive gestational weight gain (EGWG) is defined by the Institute of Medicine (IOM; 2009) according to pre-pregnancy BMI, with weight gain above 16.0kg, 11.5kg and 9.0kg considered excessive for women of normal weight, overweight and obese BMI categories, respectively (7). Women who are overweight or obese pre-pregnancy are more likely to gain weight excessively during pregnancy and have higher postpartum weight retention compared to women with a normal weight BMI (8).

EGWG is a modifiable risk factor for pregnancy and postpartum complications (9). Research suggests that pregnant women with a BMI ≥25.0

kg/m^2 can prevent excess weight gain by engaging in a lifestyle intervention during pregnancy that includes both nutrition and exercise components (10-12). Two recent meta-analyses showed that women who participated in an exercise only intervention, including women with a pre-pregnancy BMI ≥25.0 kg/m^2, gained significantly less weight than standard care control group participants (11, 13).

Despite the evidence to suggest that exercise and/or nutrition interventions can prevent EGWG, literature has suggested that pregnant women who have an elevated BMI may have low adherence to program recommendations and this may result in a null effect of the intervention (14, 15). Interventions that have been ‘unsuccessful’ in preventing EGWG among pregnant women with an overweight or obese BMI do not report adherence or report low adherence levels for their program (16, 17).

In non-pregnant populations, having previously failed weight loss programs may predict low adherence to nutrition and exercise recommendations in the future (18, 19). This may translate to the pregnant population, suggesting that women who have experienced previous weight loss attempts are less likely to adhere to another lifestyle intervention during pregnancy. Additionally, obesity is associated with an increased risk for infertility (20) and women may be told by their health care provider to lose weight to increase their chances of conceiving (21). Current research on weight loss prior to pregnancy has primarily focused on conception rates (21, 22) however the impact of previous weight loss on weight gain during pregnancy remains to be determined.

The purpose of the current study was to evaluate if a difference exists in weight loss history (i.e., information about weight fluctuations, previous weight loss attempts and weight loss prior to the current pregnancy) and adherence to the Nutrition and Exercise Lifestyle Intervention Program (NELIP) (23) among women with a pre-pregnancy BMI ≥25.0 kg/m^2 who gained excessively during pregnancy compared to women who did not gain excessively. It is hypothesized that women who met gestational weight gain guidelines will have fewer weight loss attempts and weight fluctuations prior to the current pregnancy compared to women who gained excessively. Additionally, program adherence will be higher among women who gained appropriately than excessively.

3.2 Methods

This was a cross-sectional study evaluating participants who were a part of the Nutrition and Exercise Lifestyle Intervention Program (NELIP) during their pregnancy (23). The NELIP was a single-arm intervention and is described in detail in a previous publication (23). Briefly, pregnant women without any contraindications to exercise were recruited between 16-20 weeks gestation from 2008-2012 in London, Ontario. The NELIP included both a nutrition and exercise intervention. The nutrition component included following a modified gestational diabetic diet designed to prevent gestational diabetes and promote appropriate weight gain (23). The exercise component included a mild intensity walking program with one supervised walk per week and encouragement to walk 2-3 additional times on their own per week (23). The walks began at 25 minutes and progressed by 2 minutes every week, until 40 minutes was achieved and maintained until the end of the program at 36 weeks gestation (23).

Weight Gain

Total weight gain on the NELIP was calculated as: weight at the end of the program (GA 36 weeks) - weight at the start of the program (GA 16-20 weeks). Women were stratified as gained excessively or not excessively using the 2009 IOM gestational weight gain guidelines (7). Following this, women with a BMI classified as overweight or obese are expected to gain between 0.23-0.33 kg/week and 0.17-0.27 kg/week, respectively (7). For an overweight BMI, EGWG on the NELIP was defined as gaining greater than the following: total number of weeks on the program*0.33. For an obese BMI, EGWG on the NELIP was defined as gaining greater than the following: total number of weeks on the program*0.27 (7). Women were stratified based on gaining excessively or not for a total of two groups to compare.

Weight Change and Weight Loss Attempts

Pre-pregnancy weight changes and weight loss attempts were assessed by the Weight and Health History Questionnaire (WHQ; Questions 2-5, 8-10, 23, 26, 27) (24). Women completed the WHQ at baseline before they entered into the NELIP (n=100). The program began at 16 to 20 weeks' gestational age (GA) and continued until 36 weeks of pregnancy. Women were weighed every week throughout the program.

Measuring Adherence to the NELIP

The nutrition component of the NELIP promoted a well-balanced meal plan during pregnancy and included three goals: 1. Submit a weekly food intake record; 2. Have an average intake of approximately 1800-2200 kcal per day and; 3. Have an average intake of 200-250g (40-55% of total caloric intake) of carbohydrates per day. The exercise component included a walking program that began at 25 minutes and progressed by 2 minutes each week until 40 minutes of walking was achieved which was then maintained until the end of the pregnancy. Additionally, the women were asked to walk at least two to three more times on their own each week which was then recorded in an exercise log. Adherence to the program was assessed using a previously developed measurement tool that scored women on meeting the goals of the NELIP (25). Women were given a score out of six for meeting the six nutrition and exercise goals on a weekly basis. An average score out of six for each woman was calculated and compared between women who gained weight excessively and those who did not gain weight excessively.

Statistical Analyses

A Mann-Whitney U Test and Chi-Square Analysis were used to compare responses reported on the WHQ. A Mann-Whitney U Test and Chi Square Analysis were performed to compare demographic data including age, pre-pregnancy BMI, ethnicity and previous number of pregnancies. Table 1 includes the list of questions on the WHQ used to determine if there was a difference in the weight history of women who gained excessively or not excessively. A Mann-Whitney U Test was also performed to compare weight gain on the NELIP between the two groups. Additionally, to compare potential contributors to weight gain during pregnancy including weight fluctuations prior to pregnancy (weight change from usual body weight to immediately before the pregnancy and weight loss (if attempting) immediately before the current pregnancy), and program adherence scores a Mann-Whitney U Test was performed. Finally, contributors were then assessed using a logistic regression model to determine the effect on gaining excessively during pregnancy. Statistical significance was accepted at $p<0.05$. Reported effect sizes followed Cohen's (1988, 1992) (26, 27) criteria (Cramer's V for Chi-Square Analysis: small = 0.10, medium = 0.30, large = 0.50, r for Mann Whitney-U Test: small = 0.10, medium = 0.30, large = 0.50). All statistical analyses were performed with SPSS version 23. The questions evaluated on the Weight and Health History Questionnaire are listed in Table 3.1 and the questionnaire is included in Appendix C.

Table 3.1 Questions from the Weight History Questionnaire (WHQ) used to compare women who gained excessive weight and those who did not during pregnancy.

Questions
Demographic Questions:
1. Age (at the beginning of the NELIP)
2. Ethnicity
3. Height and weight immediately before pregnancy (used to calculate pre-pregnancy BMI)
4. Number of previous deliveries
Weight Loss Attempts:
1. Have you ever tried to lose weight?
2. Were you trying to lose weight before the current pregnancy (within a year)?
If yes, how much weight did you lose?
3. Have you used the following methods to lose weight?
Prescribed medication
Diet
Physical Activity
Meeting with a Health Care Professional
Surgery
Herbal Products
Other
4. Total number of times you have attempted weight loss

BMI – Body Mass Index; NELIP – Nutrition and Exercise Lifestyle Intervention Program

3.3 Results

NELIP Weight Gain

One hundred participants from the NELIP who completed the WHQ and participated until the end of the intervention at 36 weeks' gestation were included. Fifty-three participants did not gain excessively (including 2 participants that gained below the weight gain recommendations) and 47 participants gained excessively during the NELIP. There was no difference between the excessive and not excessive groups for demographic characteristics (Table 3.2).

Table 3.2 Maternal demographic characteristics stratified by those who gained excessive weight compared to those women who did not during the Nutrition and Exercise Lifestyle Intervention Program.

	Excessive Gestational Weight Gain **N=47**	**Did Not Gain Excessive Weight** **N=53**
Age (yrs)	31.3±4.2	32.6±4.3
Ethnicity (n)		
Caucasian	41	44
Asian	2	1
African American	1	2
Aboriginal	1	2
Hispanic	1	2
Middle Eastern	1	2
Number of previous deliveries (mean, range)	1.1, 0-6	1.1, 0-4
Pre-Pregnancy BMI (kg/m^2)	31.5±5.6	33.3±6.7

All data presented as mean±sd unless otherwise stated.

BMI – Body Mass Index

Weight Fluctuations

There was no significant difference in reported weight fluctuations from usual adult body weight to weight reported before pregnancy between the two groups (gained excessively and did not gain excessively; U=1082.50, p=0.32). However, more women who gained excessively said that they were actively trying to lose weight a year before the current pregnancy (61%) than women who did not gain excessively (39%; χ^2 (1, N=100) = 4.86, p=0.022, Cramer's V=0.22, Table 3). Among the women who had attempted to lose weight a year prior to pregnancy, women who gained excessively during pregnancy had lost more weight than women who did not exceed weight gain guidelines (U=829.0, p=0.003). Among women who had previous pregnancies, there were no differences between the groups for total weight retention prior to the current pregnancy (U=1220.0, p=0.97; Table 3.3).

Table 3.3 Weight fluctuations prior to the current pregnancy stratified by those who gained excessively and those who did not during the Nutrition and Exercise Lifestyle Intervention Program.

	Excessive Gestational Weight Gain **N=47**	**Did Not Gain Excessive Weight** **N=53**	**Effect Size**
Weight change from usual adult body weight to immediately before the current pregnancy	-3.9±9.5 [-6.7, -1.1]	-5.2±6.5 [-7.0, -3.4]	-0.09
Actively trying to lose weight before the current pregnancy (n, %)	29, 61	21, 39*	0.22
If yes, weight lost before the current pregnancy	-6.7±10.2 [-9.7, -3.7]	-2.1±3.8* [-3.2, -1.1]	**-0.30**
Weight retention from previous pregnancies	3.5±5.5 [2.0, 5.1]	3.5±5.5 [2.0, 5.1]	0.04
Tried to lose weight in the past (n, %)	43, 91	47, 88	0.22
Total number of active weight loss attempts	3.8±2.3* [3.2, 4.6]	2.8±1.8 [2.2, 3.2]	**-0.26**

All data presented as Mean±sd [95% Confidence Intervals] in kgs unless otherwise stated.

Difference between women who gained excessively and those who did not,

$p<0.05$*

Large and moderate effect sizes are depicted in **bold.** Reported effect sizes followed Cohen's (1988, 1992) criteria with: (Cramer's V for Chi-Square Analysis: small = 0.10, medium = 0.30, large = 0.50, r for Mann Whitney-U Test: small = 0.10, medium = 0.30, large = 0.50).

Previous Weight Loss Attempts

Most of the women reported they tried to lose weight at least once in the past (Table 3), however women who gained weight excessively during the index pregnancy had a higher number of total weight loss attempts compared to women who did not gain excessively (U=871.5, p=0.009).

Adherence

Adherence scores were higher in the group of women who did not gain excessively (Total adherence: 73%) compared to those women who gained excessively (Total adherence: 55%; U=488, p<0.001). Individually, adherence was higher for nutrition only (70%) and exercise only (77%) among women who did not gain excessively compared to women who did gain excessively (nutrition only: 56%, U=751.0, p<0.001; exercise only: 53%, U=843.0, p=0.005). (Table 3.4).

Table 3.4 Weight gain on the Nutrition and Exercise Lifestyle Program (NELIP) and adherence scores.

	Excessive Gestational Weight Gain N=47	**Did Not Gain Excessive Weight N=53**	**Effect Size**
Weight gained during the NELIP (kg)	11.0±3.2 [10.1, 12.0]	4.1±3.0* [3.3, 5.0]	**-0.76**
Adherence Scores			
Exercise only (/3, %)	1.6±0.81; 53 [1.4, 1.9]	2.1±0.76; 70* [1.9, 2.3]	**-0.38**
Nutrition only (/3, %)	1.7±0.87; 56 [1.5, 2.0]	2.3±0.20; 77 * [2.1, 2.5]	**-0.28**
Total Score (/6, %)	3.3±0.84; 55 [3.1, 3.6]	4.4±0.95; 73 * [4.2, 4.7]	**-0.56**

All data presented as mean±sd [95% Confidence Intervals] unless otherwise indicated.

*$p<0.05$

Large and moderate effect sizes are depicted in **bold.** Reported effect sizes followed Cohen's (1988, 1992) criteria with: (Cramer's V for Chi-Square Analysis: small = 0.10, medium = 0.30, large = 0.50, r for Mann Whitney-U Test: small = 0.10, medium = 0.30, large = 0.50).

Predicting Excessive Weight Gain

The logistic regression model was statistically significant χ^2 (3)=38.54, p<0.001. The model explained 32% (Cox and Snell R Square) to 42% (Nagelkerke R Square) of the variance in gestational weight gain categories (excessive or not) and correctly classified 74% of the cases (sensitivity=72%; specificity=76%). Adherence was the most significant contributor; as adherence decreased (B=-1.362), the likelihood of gaining excessively increased by 0.25 times (95% confidence intervals [CI] 0.13, 0.47; p<0.001). Additionally, weight lost immediately before the current pregnancy was a significant finding; as the amount of weight lost immediately before pregnancy increased (B=0.109), the likelihood of gaining excessively increased by 1.1 times (95% CI 1.0, 1.2; p=0.03). Weight change from usual body weight to immediately before pregnancy was not a statistically significant contributor to excessive gestational weight gain (p=0.604).

3.4 Discussion

The results of the current study suggest that weight loss immediately before the current pregnancy and program adherence are significant contributing factors for excessive gestational weight gain. Additionally, frequent weight loss attempts prior to pregnancy are higher among women who gain excessively during pregnancy. This is an important finding as many women with obesity are advised to attempt weight loss pre-conception to improve fertility (21). Current literature on preconception weight loss has focused on identifying effective weight loss programs to improve fertility, including bariatric surgery and very low-energy diet programs (28, 29). It may be possible that in order to lose weight quickly, women may choose unhealthy (including restrictive and/or compulsive) methods of dieting. A large cross sectional study (n=1711) assessed the nutrition and weight management habits of women with a low-income background attending reproductive health clinics and found that the women who were actively trying to conceive participated in more weight loss attempts in the previous year than women who were not, including potentially dangerous avenues such as dieting pills and 24-hour fasting (30). Encouraging women to attempt weight loss for fertility or in an attempt to start pregnancy as healthy as possible may therefore have unintended consequences that increase the risk for EGWG.

In the non-pregnant population, weight loss has been associated with weight regain if a maintenance program is not provided (31). Research suggests that obesity alters and reduces the hypothalamic response to insulin and leptin, and this can cause an increase in appetite as well as an increased risk for fat storage and type 2 diabetes (32). In non-pregnant individuals, insulin sensitivity improves and fat storage decreases following weight loss, however, in order for this benefit to be maintained a continuous low energy and low fat diet is recommended (33). This, however, is impossible when the dietary intervention is more extreme, as a low caloric diet is unsustainable, for instance, a very low energy diet of 800 kcal/day (34). A similar process may be at play for pregnancy. During pregnancy there is a natural increase in insulin resistance to allow for higher levels of circulating glucose for fetal development (35). Additionally, in the first trimester of pregnancy there is an increase in leptin which will increase fat storage (35). As pregnant women should not participate in a very low-energy diet program and they are naturally experiencing an increase in insulin and leptin resistance, this may contribute to weight regain following weight loss prior to pregnancy and therefore EGWG.

Interestingly, when we examined weight changes from usual adult body weight (length of time was interpreted by the individual and therefore could be any length of time) to immediately before pregnancy, although not statistically significant, women who did not gain excessively lost more weight than women who gained excessively. The logistic regression model did not show a significant effect of weight change from usual body weight to immediately before pregnancy. This may suggest that losing weight quickly in the year before pregnancy may lead to EGWG whereas losing weight slowly over a longer period of time is not a contributing factor. This evidence suggests that a healthy lifestyle, which may include weight loss among women who have obesity, should be encouraged over time rather than waiting until the period immediately before pregnancy.

Program adherence during pregnancy was a stronger predictor for excessive gestational weight gain than weight loss immediately before pregnancy. The current study offered a lifestyle intervention to all participants, but women who gained excessive pregnancy weight had significantly lower adherence to the program than the women who did not gain excessively. Pregnancy is known as a teachable moment as many women are aware of health behaviors such as quitting smoking, reducing caffeine intake, not consuming alcohol and even including eating well and being active (36). This may explain why women join a lifestyle intervention during pregnancy such as the NELIP, but it may be possible that they do not adhere to the goals due to past experience with nutrition and exercise programs. In fact, research in non-pregnant populations suggests that the number of weight loss attempts predicts how long an individual may commit to a future method (19, 37) and this relates to the current study as women who gained excessively had tried more methods of weight loss prior to pregnancy compared to women who gained within guidelines. Furthermore, a qualitative study among pregnant women with a pre-pregnancy BMI ≥25.0 kg/m^2 found that motivation to participate in nutrition and exercise programs contributed to wanting to control gestational weight gain. However, they stated that women were more likely to prefer to wait until the postnatal period to try to lose weight rather than controlling weight gain during pregnancy as a way to prevent postpartum weight retention (38). This may explain why women made the initial decision to join a program such as the NELIP, but perhaps as the program progressed their adherence decreased.

Excessive gestational weight gain is a modifiable risk factor for pregnancy complications and research supports nutrition and exercise interventions as effective ways to promote healthy and gradual weight gain during pregnancy (9-13, 39). However, the efficacy of programs for pregnant women entering pregnancy with a BMI ≥25 kg/m^2 has been questioned (40). The present study suggests that weight loss experiences prior to pregnancy can predict weight gain during pregnancy. Additionally, program adherence is a significantly important contributor to preventing EGWG. Future studies should consider discussing previous weight loss and weight loss attempts with pregnant participants and implement strategies to improve commitment to the goals of the program during pregnancy to improve adherence and subsequently decrease the likelihood of gaining excessively. Furthermore, research supports weight loss to improve fertility however, the unintended consequence of rapid weight loss prior to pregnancy may be a rapid regain when pregnancy is achieved, resulting in EGWG. Future studies should aim to identify effective strategies to improve and maintain adherence to lifestyle recommendations before and during pregnancy to prevent excess weight gain.

To our knowledge, this is the first study to provide evidence that weight fluctuations and weight loss attempts prior to pregnancy and program adherence influence gestational weight gain. Strengths of the current study include using a large convenience sample of women with a pre-pregnancy BMI ≥25 kg/m^2, who participated in a nutrition and exercise program to prevent EGWG and associated-pregnancy complications. Additionally, we used an adherence measurement method (25) to provide an objective measure of adherence to both nutrition and exercise recommendations during pregnancy. Limitations of the current study include self-reported information on the WHQ. It is difficult to avoid using self-reported measurement tools to learn about previous weight-loss attempts, but perhaps future larger trials can begin following women during their pre-conception weight loss stage into pregnancy, reducing variability and recall bias. This could be done by following women in fertility clinics or women who seek pre-conception counselling who may also be attempting to lose weight prior to pregnancy. By doing this, pre-conception behaviors, including weight loss attempts, may also be correlated with program adherence. Furthermore, the type of method used to achieve weight loss before pregnancy and the impact this may have on gestational weight gain should be assessed. There were also two women who gained below gestational weight gain recommendations. Research suggests that inadequate gestational weight gain may also lead to maternal and fetal complications (41), however it is possible that women with a high BMI who are participating in a lifestyle intervention may actually lose excess fat because they are engaging in healthier behaviors (42). A larger sample size is required to adequately assess the weight history and adherence levels to nutrition and exercise programs for women who gain below recommendations with a follow-up on pregnancy outcomes. Future research should also aim to determine effective strategies to improve adherence to nutrition and exercise recommendations during pregnancy for women who have experienced recent weight loss and previous weight loss attempts.

3.5 Conclusion

Weight fluctuations prior to pregnancy and adherence to nutrition and exercise recommendations during pregnancy may predict EGWG. As adherence to nutrition and exercise recommendations during pregnancy decreases, the likelihood of gaining excessively during pregnancy significantly increases. Additionally, women who gained excessive weight during pregnancy had a higher number of weight loss attempts prior to pregnancy and were more likely to attempt to lose weight a year before the current pregnancy compared to women who did not gain excessively. Of those women attempting weight loss, women who gained weight excessively lost significantly more weight before the current pregnancy than women who did not exceed weight gain recommendations.

3.6 Study 2 Key Points

- Adherence to nutrition and exercise recommendations during pregnancy and weight loss a year before pregnancy are predictive factors for excessive gestational weight gain among women who enter pregnancy with a BMI ≥25 kg/m^2
- As adherence lowers, the risk for excessive gestational weight gain increases (negative correlation). As the amount of weight lost a year before pregnancy increases, the risk of excessive gestational weight gain also increases (positive correlation)
- Gradual weight loss from usual adult body weight to immediately before pregnancy does not appear to have an effect on gestational weight gain
- Adherence to nutrition and exercise recommendations during pregnancy predicts excessive gestational weight gain more than weight loss prior to pregnancy
- Adherence to a lifestyle intervention can effectively prevent excessive gestational weight gain in pregnant women with an overweight/obese pre-pregnancy BMI. Additionally, women who may have experienced weight loss prior to pregnancy can still benefit from a nutrition and exercise program during pregnancy to prevent excessive gestational weight gain

Important points to consider moving from Study 2 to Study 3:

- Similar to Study 1, Study 2 also provided evidence that adherence is a key factor in predicting the 'success' of a lifestyle intervention during pregnancy
- Study 2 provides evidence that a lifestyle intervention with high adherence can be 'successful' among women with a BMI ≥25 kg/m^2
- Study 2 suggests greater adherence is required to increase the number of women who 'successfully' achieve the desired health outcome of lifestyle interventions during pregnancy such as prevention of excessive gestational weight gain
- Effective strategies are required to increase program adherence to a multiple behavior change program (nutrition AND exercise) during pregnancy
- A strategy to enhance adherence that has been suggested for multiple behavior change programs is the introduction of nutrition and exercise behaviors sequentially rather than simultaneously
- The sequential approach of introducing behaviors has only been tested among non-pregnant adults and the primary outcome of interest has also been health-related. Both approaches are superior in comparison to a standard care control group for improving a health outcome. However, formal assessment of adherence other than retention, has not been conducted

- Only by examining adherence as a primary outcome, can conclusions be drawn on whether the sequential approach leads to superior adherence than the simultaneous approach, which in turn leads to improved health outcomes
- In the non-pregnant population there is some evidence that exercise may be a gateway behavior to nutrition. This implies that it may be advantageous to introduce exercise before nutrition
- Study 3 will test and compare adherence to introducing nutrition and exercise behaviors sequentially compared to simultaneously during pregnancy

3.7 Chapter 3 References

1. Heslehurst N, Sattar N, Rajasingam D, et al. Existing maternal obesity guidelines may increase inequalities between ethnic groups: a national epidemiological study of 502,474 births in England. *BMC Pregnancy and Childbirth.* 2012;18(12):156.

2. Patro Golab B, Santos S, Voerman E, Lawlor DA, Jaddoe VWV, Gaillard R. Influence of maternal obesity on the association between common pregnancy complications and risk of childhood obesity: an individual participant data meta-analysis. *Lancet Child Adolesc Health.* 2018;2(11):812-21.

3. Segovia SA, Vickers MH, Gray CA-O, Reynolds CM. Maternal obesity, inflammation, and developmental programming. *Biomed Res Int.* 2014;418975.

4. Kawasaki M, Arata NA-O, Miyazaki C, et al. Obesity and abnormal glucose tolerance in offspring of diabetic mothers: A systematic review and meta-analysis. *PLoS One.* 2018;13(1):e0190676.

5. Ferraro ZM, Barrowman N, Prud'homme D, et al. Excessive gestational weight gain predicts large for gestational age neonates independent of maternal body mass index. *J Matern Fetal Neonatal Med.* 2012;25(5):538-42.

6. Gaillard R, Durmus B, Hofman A, et al. Risk factors and outcomes of maternal obesity and excessive weight gain during pregnancy. *Obesity (Silver Spring).* 2013;21(5):1046-55.

7. Institute of Medicine. *Weight during pregnancy: reexamining the guidelines.* Washington (DC): National Academy Press, National Academy of Science; 2009.

8. Deputy NP, Sharma AJ, Kim SY, Hinkle SN. Prevalence and characteristics associated with gestational weight gain adequacy. *Obstet Gynecol.* 2015;125(4):773-81.

9. Ruchat SM, Mottola MF. Preventing long-term risk of obesity for two generations: prenatal physical activity is part of the puzzle. *J Pregnancy.* 2012;2012:470247.

10. Choi J, Fukuoka Y, Lee JH. The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum: a systematic review and meta-analysis of randomized controlled trials. *Prev Med.* 2013;56(6):351-64.

11. Peaceman AM, Clifton RG, Phelan S, et al. Lifestyle Interventions Limit Gestational Weight Gain in Women with Overweight or Obesity: LIFE-Moms Prospective Meta-Analysis. *Obesity (Silver Spring).* 2018;26(9):1396-404.

12. Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ.* 2012;16(344):e2088.

13. Ruchat SM, Mottola MF, Skow RJ, et al. Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: a systematic review and meta-analysis. *BJSM.* 2018;52(21):1347-56.

14. McDonald SM, Liu J, Wilcox S, Lau EY, Archer E. Does dose matter in reducing gestational weight gain in exercise interventions? A systematic review of literature*. J Sci Med Sport*. 2016;19(4):323-35.

15. Skouteris H, Hartley-Clark L, McCabe M, et al. Preventing excessive gestational weight gain: a systematic review of interventions. *Obes Rev.* 2010;11(11):757-68.

16. Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling: a randomized controlled trial*. Obstet Gynecol.* 2009;113(2 pt 1):305-12.

17. Oostdam N, van Poppel MN, Wouters MGAJ, et al. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial. *BJOG.* 2012;119(9):1098-107.

18. Ismail TATA-Ohoo, Jalil RA, Wan Ishak WR, et al. Understanding Dieting and Previous Weight Loss Attempts among Overweight and Obese Participants: Insights into My Body Is Fit and Fabulous at Work Program. *Korean J Fam Med.* 2018;39(1):15-22.

19. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and 'successful' weight management in women. *Int J Obes Relat Metab Disord.* 2004;28(9):1124-33.

20. Talmor A, Dunphy B. Female obesity and infertility. *Best Pract Res Clin Obstet Gynaecol.* 2015;29(4):498-506.

21. Sim KA, Partridge SR, Sainsbury A. Does weight loss in overweight or obese women improve fertility treatment outcomes? A systematic review. *Obes Rev.* 2014;15(10):839-50.
22. Moran L, Tsagareli V, Norman R, Noakes M. Diet and IVF pilot study: short-term weight loss improves pregnancy rates in overweight/obese women undertaking IVF. *Aust N Z J Obstet Gynaecol.* 2011;51(5):455-9.

23. Mottola MF, Giroux I, Gratton R et al. Nutrition and exercise prevent excess weight gain in overweight pregnant women. *Med Sci Sports Exerc.* 2010;42(2):265-72.

24. Giroux I, Lander S, Charlesworth S, Mottola MF. Weight history of overweight pregnant women. *Can J Diet Pract Res.* 2009;70(3):127-34.

25. Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? *Behav Anal Pract.* 2017;10(4):347-54.

26. Cohen J. A power primer. *Psychol Bull.* 1992;112(1):155-9.

27. Cohen J. Statistical Power Analysis for Behavioral Science: Lawrence Erlbaum Associates; 1988.

28. Edison E, Whyte M, van Vlymen J, et al. Bariatric Surgery in Obese Women of Reproductive Age Improves Conditions That Underlie Fertility and Pregnancy Outcomes: Retrospective Cohort Study of UK National Bariatric Surgery Registry (NBSR). *Obes Surg.* 2016;26(12):2837-42.

29. Sim KA, Dezarnaulds G, Denyer G, Skilton MR, Caterson ID. Weight loss improves reproductive outcomes in obese women undergoing fertility treatment: a randomized controlled trial. *Clin Obes.* 2014;61-68.

30. Berenson AB, Pohlmeier AM, Rahman M, McGrath CJ. Nutritional and weight management behaviors in low-income women trying to conceive. *Obstet Gynecol.* 2014;124(3):579-84.

31. Anderson JW, Konz E, Frederich R, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. *Am J Clin Nutr.* 2001;74(5):579-84.

32. Davis JF, Choi Dl, Benoit SC. Insulin, leptin and reward. *TEM.* 2010;21(2):68-74.

33. Leser MS, Yanovski SZ, Yanovski JA. A low-fat intake and greater activity level are associated with lower weight regain 3 years after completing a very-low-calorie diet. *J Am Diet Assoc*. 2002;102(9):1252-6.

34. Greenway FL. Physiological adaptations to weight loss and factors favoring weight regain. *Int J Obes (Lond).* 2015;39(8):1186-96.

35. Walsh JM, Byrne J, Mahony RM, Foley ME, McAuliffe FM. Leptin, fetal growth and insulin resistance in non-diabetic pregnancies. *Early Hum Dev.* 2014;90(6):271-4.

36. Phelan S. Pregnancy: a “teachable moment” for weight control and obesity prevention. *Am J Obstet Gynecol.* 2010;202(2):135.e1-8.

37. Dalle Grave R, Calugi S, Molinari E, et al. Weight loss expectations in obese patients and treatment attrition: an observational multicenter study. *Obes Res.* 2005;13(11):1961-9.

38. Weir Z, Bush J, Robson SC, McParlin C, Rankin J, Bell R. Physical activity in pregnancy: a qualitative study of the beliefs of overweight and obese pregnant women. *BMC pregnancy and childbirth.* 2010;10:18.

39. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev.* 2015(6):CD007145.

40. Dodd JM, Crowther CA, Robinson JS. Dietary and lifestyle interventions to limit weight gain during pregnancy for obese or overweight women: a systematic review. *Acta Obstet Gynecol Scand.* 2008;87(7):702-6.

41. Kapadia MZ, Park CK, Beyene J, Giglia L, Maxwell C, McDonald SD. Weight Loss Instead of Weight Gain within the Guidelines in Obese Women during Pregnancy: A Systematic Review and Meta-Analyses of Maternal and Infant Outcomes. *PloS One.* 2015;10(7):e0132650.

42. Davies GAL, Maxwell C, McLeod L. Obesity in pregnancy. *JOGC.* 2010;32(2):165-73.

Chapter 4

Study 3: Sequential or simultaneous introduction of nutrition and exercise behaviors during pregnancy – Which strategy improves program adherence? A randomized controlled trial.

4.1 Introduction

Excessive gestational weight gain (EGWG) significantly increases the risk for pregnancy complications that may impact both the mother and baby, including later life obesity (1-3). Women who gain excessively during pregnancy are at an increased risk for delivering babies with a birthweight >4000g (macrosomia) and <2500g (low birth weight; LBW), which are both positively correlated with childhood and adult obesity (4, 5). In North America, more than 50% of women gain excessively during pregnancy (6). The Institute of Medicine (IOM) defines EGWG as gaining above 16.0kg, 11.5kg, and 9.0kg for women with a pre-pregnancy body mass index (BMI) in normal weight (≥18.0-24.9 kg/m^2), overweight (≥25.0-29.9 kg/m^2) and obese (≥30.0 kg/m^2) categories respectively (7).

Excessive gestational weight gain is a modifiable risk factor for pregnancy complications and may be prevented by providing women with a lifestyle intervention that includes both nutrition and exercise (8, 9). However, results of individual studies have been inconsistent, with some studies successfully achieving statistical significance favoring the intervention group while others having a null effect (10, 11). A common limitation mentioned in many lifestyle interventions is low program adherence (12-15). Adherence is defined as the degree to which individuals follow recommendations of healthcare providers, including lifestyle behavior change goals (16). It has been suggested that lifestyle interventions with low adherence are more likely to have a null effect on the primary health outcome being investigated, as both the intervention and control group may be performing similarly (16).

One potential strategy that may increase adherence to lifestyle interventions during pregnancy, is the introduction of nutrition and exercise behavior changes sequentially rather than simultaneously. Sequential introduction may allow a period of time to master one set of behavior change goals before adding the second (17, 18). Adherence to nutrition and exercise constitute prime examples of behaviors that require the exertion of self-control (i.e., ability to abstain from gratifying immediate needs and desires, inhibiting strong impulses) and self-regulation (reducing the frequency and intensity of strong impulses) (19). Researchers have identified lapses in self-regulation as a key mediator of lifestyle change interventions (20). The ability to exert control over oneself (i.e., self-regulate) has been shown to delay gratification from immediate unhealthy needs and desires and engage in goal-directed behavior to instigate long-term positive outcomes (21, 22). Research into self-regulation and failure to control strong impulses has often adopted social cognitive models in which self-regulation is viewed as a function of expectations, attitudes, efficacious beliefs and intentions (23-25). It is reasonable to assume that changing multiple behaviors together (nutrition and exercise), are likely to tax self-control resources and lead to self-regulatory failure more so than changing sequential single behaviors (nutrition or exercise) (19).

Authors investigating non-pregnant adults reported that sequential and simultaneous approaches of introducing behaviors improved health outcomes equally compared to a standard care control group (18, 26). It is important to note however that these studies have only evaluated adherence as retention (drop-out rate), with no differences found between the simultaneous and sequential approaches (18, 26). Furthermore, evidence from the non-pregnant literature shows that exercise may be a gateway to nutrition behavior change. For example, one study among older adults found that participants who reported meeting exercise goals also showed an improvement in nutrition intake (27). Similarly, a physical activity intervention among non-pregnant women reported that women who met recommended physical activity goals also increased their fruit and vegetable intake (28). This suggests that there may be an optimal sequence to introducing multiple behavior changes (i.e., nutrition before exercise or exercise before nutrition). The simultaneous versus sequential approach of behavior change requires further investigation in terms of program adherence, and to date has not been assessed among pregnant women for nutrition and exercise behavior change.

As both nutrition and exercise have health benefits during pregnancy, the purpose of the current study was to determine whether there is greater adherence (primary outcome) to the goals of a lifestyle intervention (nutrition and exercise) if the introduction of behaviors are sequential rather than simultaneous.

Secondary outcomes included examining health outcomes of interest and determining if the group with the highest adherence also reported lower gestational weight gain on the program and prevalence of EGWG, birthweight, macrosomia and LBW. It was hypothesized that greater adherence would be found with the sequential introduction of nutrition or exercise compared to presenting both behaviors simultaneously. Additionally, based on findings among non-pregnant studies, higher adherence will be found in the group where exercise is introduced first compared to first introducing nutrition behavior change.

4.2 Methods

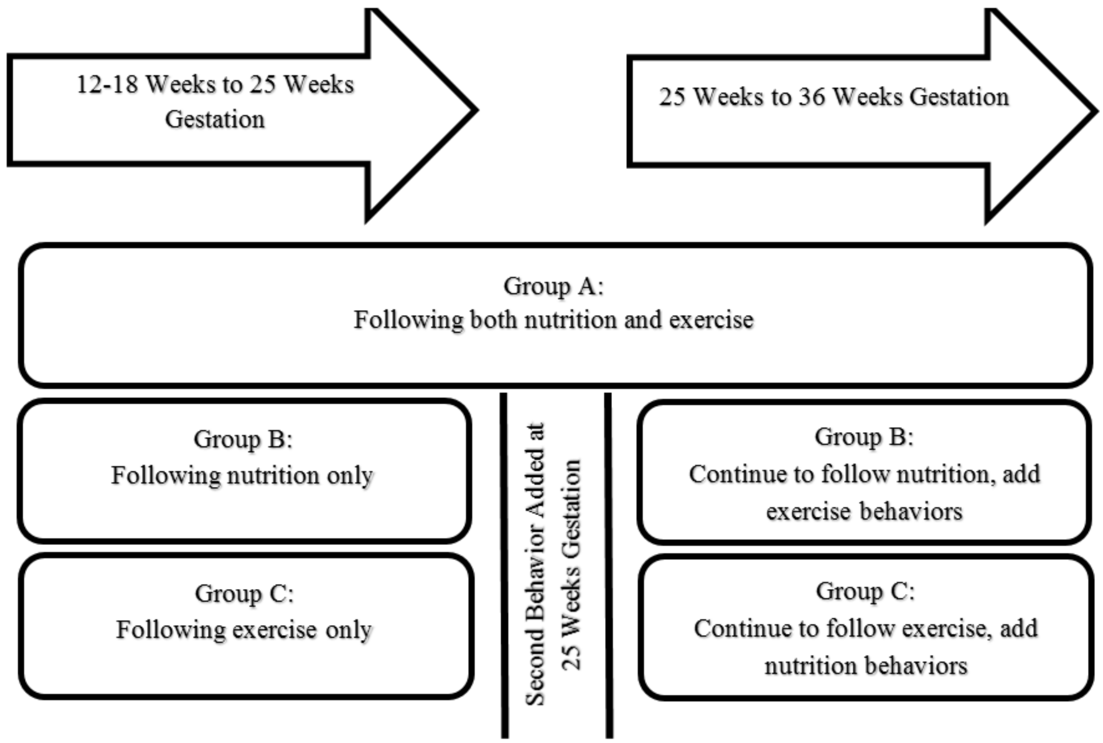
The current study was part of a larger superiority stratified randomized controlled trial (RCT; ClinicalTrials.gov Identifier: NCT02804061; Appendix D) including three strategies and was completed following CONSORT guidelines for a RCT (29). The research protocol was reviewed and approved by the Western University Human Research Ethics Board (Appendix E). Healthy pregnant women between 12-18 weeks gestation were recruited to participate through social media, community advertisements and posters in physician and midwifery clinics in London, Ontario, Canada. Participants were recruited from August 2016 to August 2018. All women provided written informed consent (Appendix F and G). Before beginning the program, women were medically prescreened using the PARMed-X for pregnancy (30) to assure that they were able to participate in a physical activity intervention. Women were excluded if they had any contraindications for exercise during pregnancy (31), were >18 weeks gestation,

≤18 years of age, were not pregnant with a singleton, had diabetes during or before pregnancy, smoked during pregnancy, were exceeding physical activity guidelines during pregnancy as indicated on the PARMed-X for pregnancy (30, 31), or had any other chronic condition. Study participants and investigators were not blinded to group assignment. Individuals checking data were blinded to group.

Intervention Strategies

The current RCT had three intervention arms and was based on a simultaneous approach previously examined in our lab (Nutrition and Exercise Lifestyle Intervention Program; NELIP) (32, 33). The NELIP includes both a nutrition and exercise component and has been successful in preventing EGWG among women who have a normal weight (32) and overweight (33) pre-pregnancy BMI when participants had high adherence to the program (34). Therefore, the current study is testing three strategies (Figure 4.1) including nutrition and exercise components introduced together (simultaneous introduction; Group A), nutrition first followed by exercise added at 25 weeks gestation (sequential introduction; Group B) and exercise first followed by nutrition added at 25 weeks gestation (sequential introduction; Group C) for the effect on program adherence. Adherence to the program was measured until 36 weeks gestation (final assessment), however all women were encouraged to followed nutrition and exercise goals until delivery.

Figure 4.1 Diagram describing three strategies for timing of introducing the nutrition and exercise components of a multiple behavior change program during pregnancy.



Nutrition Component: The meal plan was a modified gestational diabetic diet that was designed to prevent gestational diabetes and allow for appropriate gestational weight gain [33]. The meal plan included aiming for a total energy intake of approximately 1800-2200 kcal/day, complex carbohydrates with an overall goal of 200-250 g/day and eating three balanced meals with 3-4 snacks per day (33).

Participants submitted a one-day food intake record and met with study investigators once a week. During their weekly face to face visit, participants were weighed and provided with individualized nutrition counselling including ideas for snacks, discussions on how to improve meals, and opportunities for asking additional questions. Food records were analyzed using Nutritionist Pro™ to determine total calorie and carbohydrate intake. To track their food intake, women were given the options of using paper food logs, email logs, or an application of their choice.

Exercise Component: The exercise component was a self-paced mild intensity walking program (31). Participants submitted a weekly home exercise log and met with study investigators once a week. During their weekly face to face visit, participants were weighed and had a supervised walking session with the study investigator. Walks began at 25 minutes with 2 minutes added each week until a walk of 40 minutes was achieved and maintained until the end of the intervention. Additionally, women were asked to walk at least two more times on their own for a total of at least three walking sessions per week (33).

To monitor the intensity of the walks, the 'talk test' (can maintain a conversation while exercising, can converse but not sing) was used as it is a non-intrusive and is an easily accessible option that women could follow on their own, without the need of additional equipment (35). To track their walking sessions outside of the laboratory setting, women were given the option of submitting a weekly paper exercise log, email log, or using another application of their choice.

Measurements

Demographic Characteristics: At baseline (12-18 weeks gestation), women completed a weight and health history questionnaire (36). This questionnaire included the following information: age, parity, education, ethnicity and weight immediately before the current pregnancy. Height was measured using a standard stadiometer.

Program Adherence (Primary Outcome): Adherence was measured on a weekly basis by scoring the participants on meeting the goals of the nutrition and/or exercise program using a previously developed system (34). There were six goals in total, three goals for nutrition and three for exercise (total adherence score out of 6). The adherence goals and measurement are described in Table 4.1. For the two sequential groups, until the second intervention was added, they were scored out of three (three goals for nutrition or exercise) on a weekly basis. All adherence scores were converted to a percentage. Average adherence was calculated for each participant for the full program, from the beginning of the intervention until 25 weeks gestation and from 25 weeks gestation (second behavior was added for the two sequential groups at this time) until 36 weeks gestation (Figure 4.1). Additionally, we considered retention to the program (evaluated drop-out rate) as a secondary measure of adherence to the intervention strategies in order to determine if perhaps one method of introducing the nutrition and exercise interventions resulted in an increased likelihood of completing the program.

Table 4.1. Weekly adherence scoring based on the goals of the nutrition and exercise components of the three strategies.

WEEKLY PROGRAM GOALS				TOTAL
Nutrition Goals	Submit a one day food intake record *(0.5 point);* attend face to face nutrition counselling session *(0.5 point)*	Daily energy intake of 1800-2200 kcals *(0.5 point);* three balanced meals and 3-4 snacks per day *(0.5 point)*	Daily carbohydrate intake of 200-250 g *(1 point)*	*Total:* *3 (%) points per week*
Exercise Goals	Submit a weekly exercise record *(0.5 point);* Attend one face to face supervised walking session *(0.5 point)*	Complete one additional walk on their own that week for the allocated time *(1 point)*	Complete a second additional walk on their own that week for the allocated time *(1 point)*	*Total:* *3 (%) points per week*
				Total Adherence: **6 goals=6 points per week**

Adherence for Groups B (Nutrition introduced at 12-18 weeks followed by sequential introduction of exercise at 25 weeks gestation) and C (Exercise introduced at 12-18 weeks followed by sequential introduction of nutrition at 25 weeks gestation) was scored as a percentage of 3 until 25 weeks gestation (when the second behavior was added).

All scores were converted to a percent value.

Exit Survey: An exit survey was completed at the end of the intervention to further inform program adherence by evaluating preference of the sequential or simultaneous introduction of interventions and difficulty of the nutrition and exercise goals. This survey asked participants to rank the difficulty level of the nutrition and exercise goals on a Likert scale (1=Very Difficult; 2=Difficult; 3=Neutral; 4=Easy; 5=Very Easy). Additionally, participants were asked to indicate if they preferred the group they were assigned or not.

Secondary Health Outcomes (Gestational weight gain on the program, EGWG, birthweight, macrosomia and LBW): Using self-reported pre-pregnancy weight and measured height, pre-pregnancy BMI was calculated. Gestational weight gain on the program was measured as subtracting their weight from program entry until their final visit on the program (36 weeks or if women continued to come in past 36 weeks the last available weight measurement was used). Excessive gestational weight gain was defined using the 2009 Institute of Medicine guidelines (7). Regardless of pre-pregnancy BMI women are expected to gain 2.0 kg in the first trimester (7). Following this, weekly gestational weight gain is recommended to be no more than 0.50 kg, 0.33 kg and 0.27 kg for women with a normal weight, overweight and obese pre-pregnancy BMI, respectively (7). Therefore, EGWG on the program was individually determined as gaining above the following equation: expected rate of weight gain according to pre-pregnancy BMI (kg) X number of weeks on the program. Birthweight was retrieved from an in-hospital visit within 6 to 18 hours after delivery. Macrosomia and LBW were defined as birthweight >4000g and <2500g, respectively.

All study visits were delivered by one investigator (TSN) who was trained by an exercise physiologist and nutritionist to provide both the exercise and nutrition components. All measurements were completed by the same investigator.

Sample Size Calculation:

To our knowledge this is the first RCT where the primary outcome of interest is program adherence for a nutrition and exercise intervention during pregnancy, and an *a priori* sample size calculation was not completed. A post-hoc power analysis was completed for all outcomes and observed power is reported.

Randomization:

Stratified randomization was conducted, controlling for pre-pregnancy BMI categories (normal weight, overweight and obese). Randomization occurred in blocks of three (Groups A, B and C) for each pre-pregnancy BMI group. An independent person not involved with administering or assessing the intervention assigned participants to each group using sequentially numbered concealed opaque envelopes.

Statistical Analysis:

An intent to treat approach was not followed in the current study for the following reasons. Frist, for participants who completed the program there was no item-level response missing data for program adherence (primary outcome) as they were followed and scored on a weekly basis. Therefore using recommended intent to treat analysis approaches to handle missing data (i.e., multiple imputation) was not necessary (37). Furthermore, we might expect differential loss (retention) across treatment conditions, which is another form of adherence. Imputation of unit-level response missing data that are not at random requires strong assumptions that may be hard to justify (38). Birth weight and exit survey data were not available for 3 women, representing less than 10% of the data. It has been recommended that imputation of missing data this low is not required (39). For these reasons, all subsequent analyses included observed data only.

One-Way ANOVA and Student's T-Test were performed to compare percent mean adherence to the full program and to nutrition and exercise goals individually (overall program adherence; adherence from beginning of the program to 25 weeks gestation; adherence from 25 weeks to 36 weeks gestation). One-Way ANOVA was performed to compare gestational weight gain on the program and birthweight between the three groups. Chi Square Analysis was performed to compare the number of women who gained excessively while on the program, prevalence of macrosomia and LBW between groups. One-Way ANOVA was performed to compare demographic characteristics between groups, including maternal age, parity and pre-pregnancy BMI. Other demographic characteristics compared between groups including education and ethnicity were assessed using Chi Square Analysis. Exit survey responses for each group were compared using both One-Way ANOVA and Chi Square

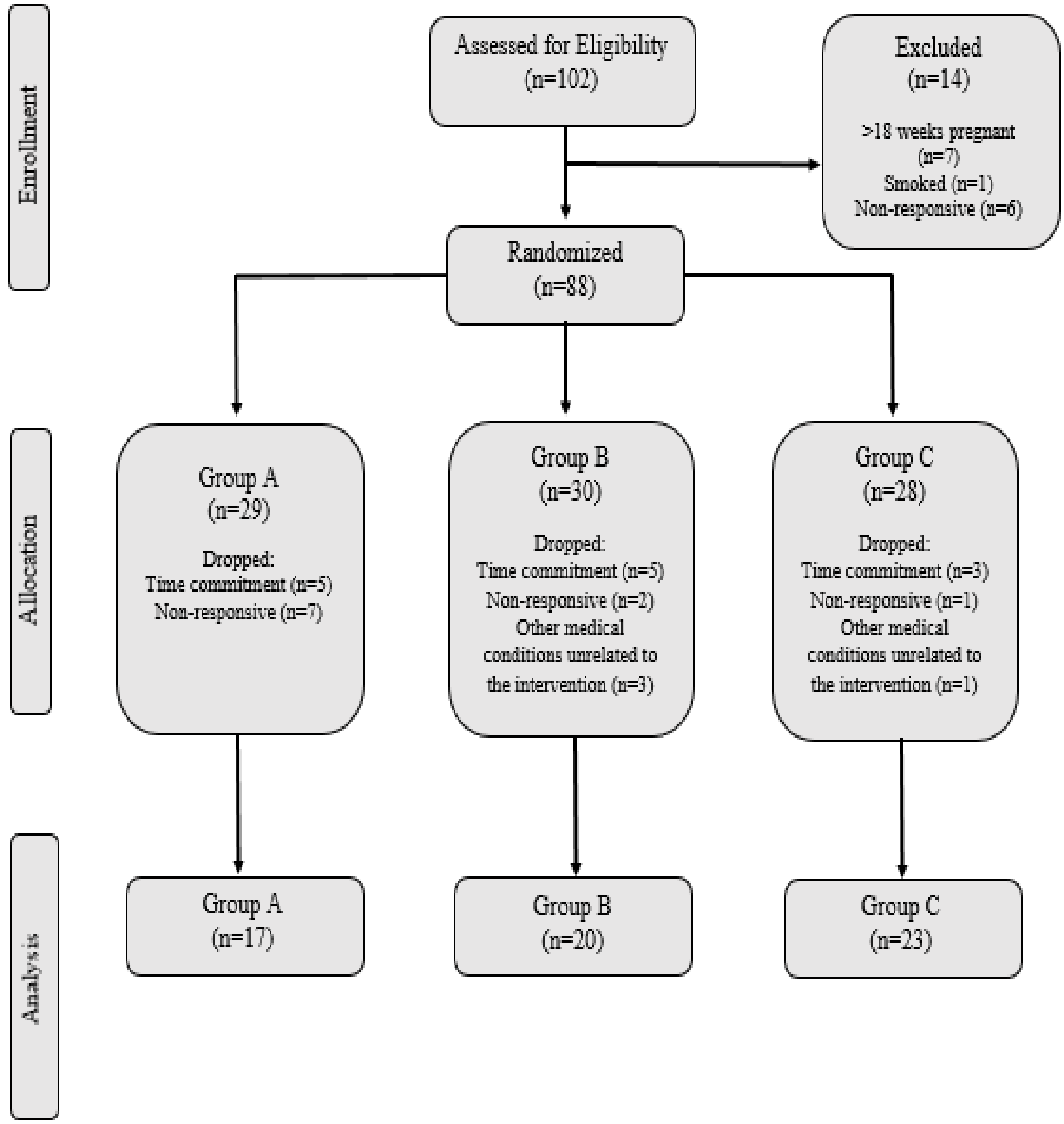
Analysis. Effect sizes were calculated following Cohen's (1988, 1992) criteria (40, 41): Cohen's d for Student's T-Test: small = 0.20, medium = 0.50, large = 0.80; Cramer's V for Chi-Square Analysis: small = 0.10, medium = 0.30, large = 0.50; and partial eta squared for One-Way ANOVA: small = 0.01, medium = 0.06, large = 0.14. Additionally, 95% confidence intervals and power were reported for all analyses. All statistical analyses were performed in SPSS Version 23.

4.3 Results:

Recruitment

One hundred and two pregnant women were assessed for eligibility, of which 88 met the criteria and were randomized. Women who completed the study were included in the final analysis: 17 women in Group A, 20 women in Group B, 23 women in Group C. A participant flow diagram, including reasons for drop-out is presented in Figure 4.2.

Figure 4.2 CONSORT flow diagram of three study groups.



Group A: Both nutrition and exercise delivered simultaneously
Group B: Nutrition introduced first followed by exercise added at 25 weeks gestation
Group C: Exercise introduced first followed by nutrition added at 25 weeks gestation

All women followed both behavior changes until the end of the program.
Non-responsive means that the participant did not attend scheduled visit and could not be contacted further

Demographics

There were no significant differences between the three groups for demographic characteristics including pre-pregnancy BMI, age, education, ethnicity and parity. Demographic characteristics are presented in Table 4.2. There were no significant differences in demographic data between the women who dropped out of the interventions and those who completed the program and were included in the analysis.

Table 4.2. Demographic characteristics of all participants in each strategy. All data presented as mean±sd unless otherwise indicated.

	Group A (Simultaneous) N=17	Group B (Nutrition first) N=20	Group C (Exercise first) N=23
Age (years)	32.6±4.3	31.7±3.1	32.3±3.3
Parity	0.4±0.7	0.3±0.6	0.3±0.8
Pre-Pregnancy BMI (kg/m^2)	27.0±3.5	25.3±5.3	26.7±5.8
Pre-Pregnancy BMI Category (n; %)			
Normal Weight	6; 35	11; 55	12; 53
Overweight	8; 47	6; 30	7; 30
Obese	3; 18	3; 15	4; 17
Ethnicity (n; %)			
Caucasian	15; 88	20; 100	21; 91
Asian	1; 6	0; 0	1; 4.5
Hispanic	1; 6	0; 0	0; 0
African American	0; 0	0; 0	1; 4.5
Education (n; %)			
College	2; 12	3; 15	1; 4.5
Bachelors	5; 29	7; 35	13; 57
Masters	9; 53	7; 35	7; 30
Doctorate	1; 6	3; 15	2; 8.5
Gestational Age at Program Entry (weeks)	16.1±2.3	16.4±2.3	15.7±2.5

Group A – Both nutrition and exercise introduced simultaneously; Group B - Nutrition introduced first followed by sequential introduction of exercise at 25 weeks gestation; Group C Exercise introduced first followed by sequential introduction of nutrition at 25 weeks gestation. All women followed both behavior changes until the end of the program.

BMI – Body mass index

Adherence Scores and Retention (Drop-out)

Average total adherence to the full program was statistically different (F (2, 57) = 7.51, p=0.001, η_p^2=0.21, observed power=0.93) as adherence to Group C (80.2±14.7%) was significantly higher than adherence in both Groups A (60.9±17.9%, p=0.001) and B (66.8±16.7%; p=0.028). Average adherence was statistically different from 25 weeks until 36 weeks gestation (F (2, 57) = 6.06, p=0.004, η_p^2=0.18, observed power=0.87) as Group C had higher adherence (74.3±17.9%) than Group A (53.2±21.8%, p=0.03). For nutrition goals only, there was no statistical differences found between Groups A and B from the beginning of the program to 25 weeks gestation (t(35)=-0.81, p=0.42, Cohen's d=0.02). From 25 weeks to 36 weeks there was a statistical difference for adherence to nutrition only (F (2, 57) = 3.74, p=0.03, η_p^2=0.12, observed power=0.66), with higher adherence to the nutrition goals in Group C (75.1±22.3%) than Group A (56.6±21.4%, p=0.03), however not Group B (66.7±19.1, p=0.60). Although trending towards significance, adherence to exercise goals only was not statistically different between Groups A (76.1±18.2%) and C (86.1±15.0%) from the beginning of the program to 25 weeks gestation (t(38)=-1.91, p=0.06, Cohen's d=0.09). There was no statistical difference for adherence to the exercise goals only from 25 weeks to 36 weeks gestation (F (2, 57) = 1.47, p=0.24, η_p^2=0.05, observed power=0.30). Although not significant, fewer women dropped out of Group C (n=6, 21%) than Groups A (n=12, 41%) and B (n=10, 33%; χ^2 (2, N=88) = 2.91, p=0.23, Cramer's V=0.18). Adherence data are presented in Table 4.3.

Table 4.3. Program adherence and responses to exit survey for each strategy completed at the end of the intervention. All data presented as mean±sd [95% Confidence Intervals] unless otherwise indicated.

	Group A (Simultaneous) N=17	Group B (Nutrition first) N=20	Group C (Exercise first) N=23	Effect Size
Full program adherence (%)	60.9±17.9 [51.6, 70.1]	66.8±16.7 [58.9, 74.6]	80.2±14.7* [73.8, 86.5]	**0.21**
Adherence from beginning of program to 25 weeks gestation (%)	68.8±17.0 [60.1, 77.6]			
Adherence to Nutrition Only	67.6±16.3 [59.2, 76.0]	72.6±20.9 [62.9, 82.5]		0.02
Adherence to Exercise Only	76.1±18.2 [66.7, 85.4]		86.1±15.0* [79.6, 92.6]	0.09
Program adherence from 25 weeks to 36 weeks gestation (%)	53.2±21.8 [42.0, 64.5]	63.0±17.7 [54.8, 71.3]	74.3±17.9* [66.5, 82.0]	**0.18**
Adherence to Nutrition Only	56.6±21.4 [45.6, 67.6]	66.7±19.1 [57.8, 75.6]	75.1±22.3$^+$ [65.3, 84.9]	**0.13**
Adherence to Exercise Only	62.6±29.6 [47.4, 77.8]	65.8±21.3 [55.9, 75.8]	74.5±19.0 [66.3, 82.7]	**0.05**
Nutrition Difficulty (/5)	3.0±0.7 [2.7, 3.4]	3.3±1.1 [2.7, 3.8]	3.5±0.9 [3.2, 4.0]	**0.05**
Exercise Difficulty (/5)	3.4±1.2 [2.7, 4.0]	3.7±0.8 [3.3, 4.1]	3.9±0.9 [3.5, 4.3]	**0.05**
Preferred the order received? (n;%)	11; 65	4; 21	12; 55	**0.28**

Group A Both nutrition and exercise introduced simultaneously; Group B Nutrition introduced first followed by sequential introduction of exercise at 25 weeks gestation; Group C Exercise introduced first followed by sequential introduction of nutrition at 25 weeks gestation. All women followed both behavior changes until the end of the program.

Nutrition and exercise difficulty scored on a scale of 5 where 1=Very Difficult, 2=Difficult, 3=Neutral, 4=Easy, 5=Very Easy

Adherence from the beginning of the program to 25 weeks for Group B is nutrition data only, for Group C is exercise data only and Group A includes both nutrition and exercise

*$p<0.05$ comparing Group C to Group A and Group B

$^{+}p<0.05$ comparing Group C to Group A

Large and medium effect sizes are depicted in **bold** referring to Cohen's (1988, 1992) criteria: Cohen's d for Student's T-Test: small = 0.20, medium = 0.50, large = 0.80; Cramer's V for Chi-Square analysis: small = 0.10, medium = 0.30, large = 0.50; and partial eta squared for One-Way ANOVA: small = 0.01, medium = 0.06, large = 0.14.

Exit Survey Results

Overall, there was no difference between groups when asked to rank the difficulty level of both nutrition and exercise (*F* (2, 55) = 1.56, *p*=0.22, η_p^2=0.05, observed power=0.32). Twenty-nine percent, (n=5), 40% (n=8) and 65% (n=15) indicated that nutrition was “easy” or “very easy” in Group A, Group B and Group C, respectively. Fifty-three percent (n=9), 70% (n=11) and 73% (n=17) indicated that exercise was “easy” or “very easy” in Group A, Group B and Group C, respectively. Although not significant, more women in Group A (n=11, 65%) and Group C (n=12, 55%) indicated that they received the order of the intervention they would have preferred than women in Group B (n=4, 21%; χ^2 (4, N=58) = 8.86, *p*=0.06, Cramer’s V=0.27). Table 4.3 includes data from the exit survey.

Health Outcomes (Gestational weight gain on the program, EGWG, Birthweight, Macrosomia, LBW)

There was a significant difference in gestational weight gain from program entry to delivery (*F* (2, 57) = 3.22, *p*=0.04, η_p^2=0.10, observed power=0.59) as Group C gained significantly less weight (7.7±2.2 kg) than Group B (9.8±2.8 kg, *p*=0.04) but not Group A (9.1±3.5 kg, p=0.35) while engaged in the intervention strategies. There was no significant difference between the three groups for the number of women who exceeded gestational weight gain guidelines (χ^2 (2, N=60) = 0.95, *p*=0.62, Cramer’s V=0.13). From program entry to 25 weeks gestation there was no significant differences observed for gestational weight gain (*F* (2, 57) = 1.15, p=0.33, η_p^2=0.04, observed power=0.24) and the number of women who exceeded gestational weight gain recommendations (χ^2 (2, N=60) = 1.25, *p*=0.53, Cramer's V=0.15). There was no significant difference in birthweight among the three groups (*F* (2, 57) = 2.17, *p*=0.12, η_p^2=0.07, observed power=0.43). There was no significant difference in the incidence of macrosomia between the three groups (χ^2 (2, N=57) = 4.92, *p*=0.09, Cramer's V=0.29) and there were no cases of LBW in all groups. All babies were born at term (>37 weeks gestation). Gestational weight gain and birthweight data are presented in Table 4.4.

Table 4.4. Health Outcomes: gestational weight gain on the program and birthweight for all strategies. All data presented as mean±sd [95% Confidence Intervals], unless otherwise indicated.

	Group A (Simultaneous) N=17	Group B (Nutrition first) N=20	Group C (Exercise first) N=23	Effect Size
Weight gain from program entry to delivery (kg)	9.1±3.5 [7.4, 11.0]	9.8±2.8 [8.5, 11.2]	7.7±2.2* [6.8, 8.7]	**0.10**
Gestational weight gain above recommendations (n, %)	4; 24	6; 30	4; 17	**0.13**
Weight gain from program entry to 25 weeks gestation (kg)	4.2±1.9 [3.2, 5.2]	3.8±1.6 [3.1, 4.6]	3.4±1.6 [2.9, 3.9]	0.04
Gestational weight gain above recommendations (n, %)	6; 35	9; 45	8; 35	**0.15**
Birthweight (g)	3539±540 [3261, 3817]	3392±311 [3246, 3538]	3262±394 [3091, 3432]	**0.07**
Macrosomia (n, %)	3; 18	0; 0	1; 4	**0.29**
Low Birth Weight (n, %)	0; 0	0; 0	0; 0	

Group A – Both nutrition and exercise introduced simultaneously; Group B - Nutrition introduced first followed by sequential introduction of exercise at 25 weeks gestation; Group C - Exercise introduced first followed by sequential introduction of nutrition at 25 weeks gestation. All women followed both behavior changes until the end of the program.

Macrosomia was defined as birthweight >4000g; Low birth weight was defined as birthweight <2500g

*p<0.05 comparing Group C to B

Large and medium effect sizes are depicted in **bold** referring to Cohen's (1988, 1992) criteria: Cohen's d for Student's T-Test: small = 0.20, medium = 0.50, large = 0.80; Cramer's V for Chi-Square analysis: small = 0.10, medium = 0.30, large 0.50; and partial eta squared for One-Way ANOVA: small = 0.01, medium = 0.06, large = 0.14.

4.4 Discussion

The results of the current study suggested that sequential introduction of exercise first followed by nutrition was associated with a significant increase in adherence to program recommendations during pregnancy. Nutrition may potentially be a more challenging intervention than exercise. Compared to exercise, fewer women ranked nutrition as “easy” or “very easy” on the exit survey and fewer women indicated that they preferred to be in the nutrition first group. It has been suggested that performing exercise first can be a gateway to nutrition interventions (27, 28). Perhaps mastering one change (exercise) improves motivation to then also complete the second intervention (nutrition), which results in overall improved adherence to a multiple behavior change program. In the current study we saw that all groups had a decline in their adherence as the program progressed from the beginning of the intervention to 25 weeks and from 25 weeks to 36 weeks gestation, however overall adherence for Group C remained higher in comparison to both Groups A and B even when the nutrition behavior change goals were added.

The current study also found a significant difference in weight gain that favored Group C over Groups B and A. These results are supported by McDonald et al., (2016) as they found that studies with higher adherence were more likely to show a significant difference favoring the intervention group for gestational weight gain than studies that had lower adherence (42). Additionally, there were non-significant small effects that favored group C for the prevention of EGWG, suggesting that the sequential approach may be superior to the simultaneous behavior change approach for improving health outcomes during pregnancy. This is in line with findings from a recent meta-analysis that used individual patient data as they found a small positive effect of exercise interventions during pregnancy on preventing EGWG (43). The overall prevalence of excessive gestational weight gain from program entry to the end of the intervention was 23%, whereas approximately 50% of the general pregnant population gains excessively (4). This is evidence that a nutrition and exercise intervention during pregnancy can promote appropriate gestational weight gain. Our findings suggest that the sequential approach with exercise introduced first, can increase program adherence and as a result more women will be likely to achieve desired health outcomes including controlling gestational weight gain.

There is no gold standard for measuring adherence to lifestyle interventions (16). A commonly used adherence measurement method, used often in medical trials, is evaluating program completion and attrition (16). In the current study, although not statistically significant, fewer women dropped out of Group C than both A and B, suggesting adherence was higher in Group C with more women able to continue to commit to the program. Therefore, if adherence was viewed in terms of drop-out rate, the results of the current study would still favor Group C.

To our knowledge this is the first study to assess the sequential versus simultaneous approach to introducing a lifestyle intervention during pregnancy with program adherence as the primary outcome. We used an adherence measurement tool that incorporated both the nutrition and exercise goals of the intervention, and our study was adequately powered to detect a difference between the three groups for full program adherence (primary outcome). In addition, all participants were followed and scored for adherence on a weekly basis which led to having complete data for program adherence. Adherence was also considered and measured as retention to the behavior change strategies. Additional strengths include the incorporation of an exit survey on participant preference and perceived difficulty of the interventions as factors that may influence adherence. Another strength is that all three groups had the same number of face to face visits with study investigators. Limitations of the current study included the use of self-reported measurement tools (nutrition and exercise logs) and the exit survey was not validated. Additionally, the current study was not powered to detect significant differences for the health outcomes evaluated. Future interventions can use the results from the current study to determine an adequate sample size to test the effectiveness of the simultaneous or sequential approaches on specific health outcomes with the assessment of program adherence. Additionally, the demographic of women included were mostly Caucasian, had received higher education and had self-selected to participate in a lifestyle intervention before randomization, therefore the results may not be generalizable to all diverse pregnant populations. Finally, as women were recruited between 12-18 weeks gestation it was possible that some participants engaged in the first behavior longer than others before the second behavior was added at 25 weeks gestation. A range was selected to improve recruitment and perhaps with a larger sample size it may be valuable to assess if the potential additional weeks on the intervention had an effect on program adherence.

4.5 Conclusion

In conclusion, adherence to intervention goals during pregnancy was improved by introducing exercise first followed by nutrition. Improving adherence to nutrition and exercise interventions during pregnancy may promote positive health outcomes. Future studies should aim to encompass a more diverse sample and adherence should be measured and reported in all lifestyle interventions during pregnancy. By increasing adherence to nutrition and exercise goals during pregnancy the efficacy of interventions may improve and increase overall achievement of positive health outcomes for both mom and baby.

4.6 Study 3 Key Points:

- Introducing nutrition and exercise behaviors sequentially, with exercise first followed by nutrition, can increase adherence to intervention goals during pregnancy
- There is some evidence that the sequential approach of exercise followed by nutrition leads to better health outcomes (i.e., less gestational weight gain and EGWG throughout the program)
- Introducing exercise first followed by nutrition will increase program adherence and therefore more women may be able to achieve the desired weight health outcomes

4.7 Chapter 4 References

1. Santos S, Voerman E, Amiano P et al. Impact of maternal body mass index and gestational weight gain on pregnancy complications: an individual participant data meta-analysis of European, North American, and Australian cohorts. *BJOG.* 2019;126(8):984-995.

2. Ren M, Li H, Cai W et al. Excessive gestational weight gain in accordance with the IOM criteria and the risk of hypertensive disorders of pregnancy: a meta-analysis. *BMC Pregnancy Childbirth.* 2018;18(1): p. 281.

3. Ruchat SM, Mottola MF. Preventing long-term risk of obesity for two generations: prenatal physical activity is part of the puzzle. *J Pregnancy.* 2012;420427.

4. McDowell M, Cain MA, Brumley J. Excessive Gestational Weight Gain. *J Midwifery Womens Health.* 2019;64(1)46-54.

5. Li N, Liu E, Guo J et al. Maternal prepregnancy body mass index and gestational weight gain on pregnancy outcomes. *PLoS One.* 2013;8(12):e82310.

6. Public Health Agency of Canada. "Effect of maternal weight on pregnancy outcomes." https://www.canada.ca/en/public-health/services/publications/healthy-living/effect-maternal-weight-pregnancy-outcomes.html. Accessed June 28 2019.

7. Institute of Medicine. *Weight during pregnancy: reexamining the guidelines.* Washington (DC): National Academy Press, National Academy of Science; 2009.

8. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev.* 2015;6:CD007145.

9. Ruchat SM, Mottola MF, Skow RJ et al. Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: a systematic review and meta-analysis. *Br J Sports Med.* 2018;52(21):1347-1356.

10. Choi J, Fukuoka Y, Lee JH. The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum: a systematic review and meta-analysis of randomized controlled trials. *Prev Med.* 2013;56(6):351-64.

11. Farpour-Lambert NJ, Ells LJ, Martinez de Tejada B, Scott C. Obesity and Weight Gain in Pregnancy and Postpartum: an Evidence Review of Lifestyle Interventions to Inform Maternal and Child Health Policies. *Front Endocrinol.* 2018;9:546.

12. Polley BA, Wing RR, Sims CJ. Randomized controlled trial to prevent excessive weight gain in pregnant women. *Int J Obes Relat Metab Disord.* 2002;26(11):494-502.

13. Althuizen E, van der Wijden CL, van Mechelen W, Seidell JC, van Poppel MN. The effect of a counselling intervention on weight changes during and after pregnancy: a randomised trial. *BJOG.* 2013;120(1):92-9.

14. Nascimento SL, Surita FG, Parpinelli MA, Siani S, Pinto e Silva JL. The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial. *BJOG.* 2011;118(12):1455-63.

15. Oostdam N, van Poppel MN, Wouters MG. No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial. *BJOG.* 2012;119(9):1098-107.

16. Vitolins MZ, Rand CS, Rapp SR, Ribisl PM, Sevick MA. Measuring adherence to behavioral and medical interventions. *Control Clin Trials,* 2000;21(5 Suppl):188S-94S.

17. Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Arch Intern Med.* 2007;167(11):1152-8.

18. James E, Freund M, Booth A et al. Comparative efficacy of simultaneous versus sequential multiple health behavior change interventions among

adults: A systematic review of randomised trials. *Prev Med.* 2016;89:211-223.

19. Baumeister RF, Exline JJ. Virtue, personality, and social relations: self-control as the moral muscle. *J Pers.* 1999;67(6):1165-94.

20. Teixeira PJ, Carraça EV, Marques MM. Successful behavior change in obesity interventions in adults: a systematic review of self-regulation mediators. *BMC Med.* 2015;**13**:84.

21. Baumeister RF, DeWall CN, Ciarocco NJ, Twenge JM. Social exclusion impairs self-regulation. *J Pers Soc Psychol.* 2005;88(4):589-604.

22. Metcalfe J, Mischel W. A hot/cool-system analysis of delay of gratification: dynamics of willpower. *Psychol Rev.* 1999;106(1):3-19.

23. Schifter DE, Ajzen I. Intention, perceived control, and weight loss: an application of the theory of planned behavior. *J Pers Soc Psychol.* 1985;49(3):843-51.

24. Bandura A. Comments on the crusade against the causal efficacy of human thought. *J Behav Ther Exp Psychiatry.* 1995;26(3):179-90.

25. Sansone C, Smith JL. The" how" of goal pursuit: Interest and self-regulation. *Psychological Inquiry.* 2000;41:306-309.

26. Schulz DN, Kremers SP, Vandelanotte C et al. Effects of a web-based tailored multiple-lifestyle intervention for adults: a two-year randomized controlled trial comparing sequential and simultaneous delivery modes. *J Med Internet Res.* 2014;16(1):e26.

27. Tucker M, Reicks M. Exercise as a gateway behavior for healthful eating among older adults: an exploratory study. *J Nutr Educ Behav.* 2002;34(1):S14-9.

28. Dutton GR, Napolitano MA, Whiteley JA, Marcus BH. Is physical activity a gateway behavior for diet? Findings from a physical activity trial. *Prev Med.* 2008;46(3):216-21.

29. Moher D. CONSORT: An evolving tool to help improve the quality of reports of randomized controlled trials. Consolidated standards of reporting trials. *JAMA.* 1998;279:1489-91.

30. Canadian Society for Exercise Physiology. “2019 Canadian Guideline for Physical Activity throughout Pregnancy - Resources” https://csepguidelines.ca/guidelines-for-pregnancy/. Accessed June 28 2019.

31. Mottola MF, Davenport MH, Ruchat SM et al. 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med.* 2018;52(21):1339-1346.

32. Ruchat SM, Davenport MH, Giroux I. Nutrition and exercise reduce excessive weight gain in normal-weight pregnant women. *Med Sci Sports Exerc.* 2012;44(8):1419-26.

33. Mottola MF, Giroux I, Gratton R et al. Nutrition and exercise prevent excess weight gain in overweight pregnant women. *Med Sci Sports Exerc.* 2010;42(2):265-72.

34. Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? *Behav Anal Pract,* 2017;10(4):347-354.

35. Mottola, MF. Exercise prescription for overweight and obese women: pregnancy and postpartum. *Obstet Gynecol Clin North Am.* 2009;36(2):301-16.

36. Giroux I, Lander S, Charlesworth S, Mottola MF. Weight history of overweight pregnant women. *Can J Diet Pract Res.* 2009;70(3):127-34.

37. Jakobsen JC, Gluud C, Wetterslec J, Winkel P. When and how should multiple imputation be used for handling missing data in randmised clinical trials - A practical guide with flowcharts. *BMC Med Res Methodol.* 2017;17:162.

38. Altman DG. Missing outcomes in randomized trials: Addressing the dillema. *Open Med.* 2009;3(2):e51-e53.

39. Dong Y, Peng CJ. Principled missing data methods for researchers. *SpringerPlus.* 2013;2:222.

40. Cohen J. Statistical Power Analysis for Behavioral Science. New York, NY: Lawrence Erlbaum Associates, 1988.

41. Cohen J. A power primer. *Psychol Bull.* 1992;112(1):155-159.

42. Rogozińska E, Marlin N, Betrán AP et al. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. *BMJ.* 2017;358:j3119.

43. McDonald SM, Liu J, Wilcox S, Lau EY, Archer E. Does dose matter in reducing gestational weight gain in exercise interventions? A systematic review of literature*. J Sci Med Sport.* 2016;19(4):323-35.

Chapter 5

Discussion

Overall, the findings of this dissertation provide evidence that adherence is a key factor in determining the success of a nutrition and exercise intervention during pregnancy. Study 1 assessed lifestyle interventions during pregnancy and determined that interventions that ‘successfully’ achieve the *a priori* decided upon health outcome showed significantly higher participant adherence than studies that had a null effect. Study 2 explored the potential of other factors (weight fluctuations prior to pregnancy) in addition to program adherence that may contribute to the success or failure of a lifestyle intervention during pregnancy among women with a pre-pregnancy BMI ≥25 kg/m^2. Results of study 2 showed that low adherence had a stronger effect on increasing the risk of excessive gestational weight gain than weight fluctuations before pregnancy. Therefore, Study 2 also provides evidence that program adherence is a strong predictive factor for the success of lifestyle interventions during pregnancy for women with a BMI ≥25 kg/m^2. Finally, Study 3 tested potential strategies to improve program adherence. Study 3 tested adherence to nutrition and exercise goals when behavior changes were introduced sequentially compared to simultaneous introduction. Results of Study 3 showed that the sequential introduction of exercise first followed by nutrition leads to higher adherence, compared to nutrition being introduced first and the simultaneous approach. There was also some evidence that this sequential approach led to better pregnancy weight health outcomes. Taken together, the three studies in this dissertation provided evidence to support the need to measure, report and increase adherence to nutrition and exercise recommendations during pregnancy to improve health outcomes.

Study 1 builds upon previous systematic reviews and meta-analyses that have explored the effectiveness of nutrition and exercise interventions during pregnancy with adherence as a key limitation reported among included studies (1-4). Study 1 determined that adherence was significantly higher among interventions that successfully met primary health outcomes versus studies that favored a control group or had a null effect. Study 1 provides the key application message which is, in order for the results of a study to be interpreted correctly lifestyle interventions should measure and report adherence. Furthermore, it was statistically determined that at least 70% adherence was required for a 'successful' pregnancy lifestyle intervention.

Previous research has suggested that women with a pre-pregnancy BMI ≥25 kg/m^2 are more likely to report lower adherence to nutrition and exercise recommendations during pregnancy than women with a normal weight BMI (4-6). Women with a BMI ≥25 kg/m^2 may be told by their healthcare provider to lose weight in order to improve chances of fertility and pregnancy outcomes (7). Results of Study 2 suggested that weight loss in the year before pregnancy does in fact predict excessive gestational weight gain, however low adherence to nutrition and exercise recommendations was a stronger predictor. Furthermore, rapid weight loss immediately before pregnancy was more likely to increase the risk for excessive gestational weight gain than gradual weight loss over a longer period of time. Potential application of Study 2 may be emphasizing caution for healthcare providers who suggest weight loss pre-conception and increase promotion for nutrition and exercise recommendations during pregnancy. Gradual weight loss before pregnancy, with high adherence to a healthy lifestyle approach during pregnancy may prevent excessive gestational weight gain. Both Studies 1 and 2 highlighted adherence as a key factor in predicting the success of a lifestyle intervention and therefore effective strategies are needed to improve adherence to nutrition and exercise recommendations.

An effective strategy to potentially protect/enhance self-control and self-regulatory resources when initiating multiple behavior change in an intervention may be the sequential introduction of nutrition and exercise behaviors (8). Results from Study 3 showed that women who received exercise first followed by nutrition had significantly higher adherence to the intervention compared to those women who received nutrition first or both behaviors simultaneously. Some evidence, albeit less conclusive, also was found that this sequential approach led to better weight related health outcomes (i.e., less weight gain and EGWG throughout the program). The key application message from Study 3 is that introducing exercise first followed by nutrition may be an effective way to increase program adherence and as a result more women may be able to meet nutrition and exercise goals during pregnancy, and in turn reduce their risk of excessive gestational weight gain. Through extension, by increasing the number of women who ‘successfully’ adhere to nutrition and exercise recommendations during pregnancy, future chronic diseases, including obesity, may be prevented in both mom and baby.

5.1 Future Work

Measure, evaluate and report adherence to all lifestyle-based interventions

Researchers developing lifestyle interventions should measure and report adherence. In the current dissertation the population of interest was pregnant women, however the concept of measuring and reporting adherence can be applied to all population groups and lifestyle interventions. By measuring adherence, investigators will be certain that the participants in the intervention are performing the required goals and therefore the observed results are a direct reflection of the intervention. Although the current dissertation provides evidence that adherence may be a key factor in determining the ‘success’ of lifestyle interventions, further investigation is required including measuring the potential mediation effect adherence may have. Overall, through this work it has been suggested that high adherence is needed to improve the ‘success’ of an intervention and although this may be true in many interventions, all levels of adherence provide valuable information to interpret the results of an intervention. For example, a study that has low adherence and results still favor the intervention group may be evidence that further investigation is required into potential co-variates that are influencing the results. Adherence may also be high yet results do not favor the intervention. This may suggest that the design of the intervention was not adequate to achieve the desired outcomes. Finally, low adherence and a lack of favorability towards the intervention may perpetuate further research to determine and address potential barriers that are preventing participants from adhering to the intervention. To determine if adherence (low or high) is contributing the results of the intervention, the mediation effect should be tested. Measuring, evaluating and reporting adherence to lifestyle interventions will further inform the success of future studies.

A gold standard method for measuring adherence to nutrition and exercise recommendations does not exist. Common methods to measure adherence include attendance to sessions, submission of exercise or nutrition logs, pedometers or accelerometers and completion of a program (9). Regardless of the measurement tools being used, all lifestyle interventions have goals that participants should ideally be meeting (for example: attending a certain number of exercise sessions, achieving a specific length of time for exercise, eating a recommended number of calories). It is recommended that the selected adherence measurement system should adequately capture whether participants are meeting the goals of the intervention or not (9).

Building on this, perhaps a universal method to measure and evaluate adherence to nutrition and exercise recommendations would include scoring participants on achieving the goals of an intervention. Study investigators should state the goals of their lifestyle intervention *a priori*, identify effective adherence measurement tools that will be used to evaluate if participants achieve these goals, or not, and finally, provide an adherence score at the end of the intervention indicating the degree to which participants achieved the study goals.

This method was used in Study 3. This adherence measurement method can be used universally because the goals of the intervention direct the evaluation and scoring system. Authors can modify and personalize all lifestyle interventions using this adherence measurement evaluation system accordingly.

Determine effective strategies to increase program adherence

The current dissertation tested the simultaneous versus sequential approach to improve adherence to a multiple behavior change program (nutrition and exercise) during pregnancy. The delivery method of the behavior change program should be examined further. For example, face to face delivery of lifestyle interventions has a positive effect on program adherence (11). Study 1 reiterated this finding. Futures studies should test the effectiveness of face to face delivery of lifestyle interventions in comparison to other approaches, such as online or smart phone messaging, to further evaluate delivery methods. As current research is trending towards the online delivery of lifestyle interventions (12), it would be important to determine what effect online delivery may have on program adherence or perhaps combining face to face time within an online intervention.

Self-monitoring resources increase adherence to program recommendations (11). Study 1 showed that the use of self-monitoring was not related to adherence, which was a surprising finding based on the literature. Future studies should evaluate self-monitoring as an adherence strategy by considering the type of self-monitoring tool, and how often and how well participants use self-monitoring resources.

Additionally, an effective adherence strategy should consider behaviors prior to pregnancy in those women with a pre-pregnancy BMI ≥25 kg/m^2 who lost weight before their pregnancy to assure women maintain adherence to nutrition and exercise recommendations during pregnancy. Pregnant women who have experienced recent weight loss may require additional support to maintain adherence to nutrition and exercise recommendations, especially for women with a pre-pregnancy BMI of obese, as they may be told by healthcare providers to lose weight prior to pregnancy to improve health outcomes and chances of fertility.

Finally, an additional strategy to test to improve adherence would be delivering interventions in a group setting in comparison to one on one. According to group dynamics theory, adherence to an intervention may increase when two or more individuals come together for a common goal (13). In a group setting there may be an increase in accountability and therefore attendance to face to face sessions may improve (13). Research in the post-partum has shown that group fitness classes are well received especially as women enjoy socializing with other mothers (14). Future research should compare adherence to a program delivered in a group setting or one on one.

Applying lifestyle behavior change within clinical settings

Pregnancy is known as a ‘teachable moment’ as women are considering their own health and also the health of the growing fetus (15). During pregnancy, the point of contact with healthcare providers increases as women have more appointments (15). This may mean that healthcare providers have more opportunities to discuss lifestyle behavior change and therefore they may be key agents for promoting healthy behaviors during pregnancy.

Research among non-pregnant individuals has shown that when healthcare providers prescribe nutrition and/or exercise behavior change, participants are more likely to engage in these health behaviors (16). Perhaps future research should advocate for the inclusion of lifestyle prescription during prenatal care. The results of this dissertation provide evidence that greater adherence to nutrition and exercise recommendations during pregnancy can improve health outcomes, therefore by engaging healthcare providers perhaps more women will adhere to lifestyle behaviors during pregnancy. Future research should test the clinical application of these research findings by evaluating adherence to nutrition and exercise recommendations during pregnancy when prescribed by a healthcare provider.

Continue to conduct superiority randomized controlled trials for lifestyle behavior change during pregnancy

It is especially challenging to move away from the standard randomized controlled trial design (intervention and standard care control group) because randomized controlled trials are recognized as the gold standard for research. Randomized controlled trials are indeed important and effective methods of research. For lifestyle interventions during pregnancy where there are many health benefits of exercise (17) and nutrition (18), randomized controlled trials are important but consideration should also be given to going beyond a standard care control group that does not include any lifestyle behaviors as this may mean women are being denied important health benefits. Instead, more research is required to determine effective strategies to improve interventions for all women. With the negative effects related to inactivity and poor nutrition during pregnancy, standard care itself should include some form of nutrition and exercise.

Across all three studies a common theme observed was that a lifestyle intervention including nutrition and exercise during pregnancy had a positive effect on health outcomes. This may mean that women who are randomized to a standard care control group are being denied the potential opportunity to engage in lifestyle behaviors that may improve pregnancy outcomes for both mom and baby. Therefore the next step may be to change standard care to incorporate lifestyle prescription. Furthermore, if standard care did include lifestyle related prescriptions such as nutrition and exercise, the next step for research studies may be to determine how to strengthen interventions by increasing program adherence to assure more women are having a healthy pregnancy, rather than testing the difference between a lifestyle intervention and no intervention at all. According to the results of this dissertation, a lifestyle intervention can be effective for all women if they adhere to the goals of the intervention.

Long term effect of program adherence

According to the Developmental Origins of Health Disease theory, exposures during pregnancy may program chronic disease risk including later life obesity (19). Trials with high levels of adherence are required to adequately assess the effect of nutrition and exercise interventions during pregnancy on long term outcomes in the postpartum period. Women who ‘successfully’ adhere to lifestyle behaviors during pregnancy may be more likely to maintain healthy practices in the postpartum period. Furthermore, improving nutrition and exercise behaviors may also have an effect on healthy behaviors for families. By supporting women during pregnancy with maintaining adherence to nutrition and exercise goals they will be equipped with the knowledge, motivation and resources to promote an active lifestyle and appropriate nutrition behaviors within their family. This may increase physical activity levels and healthy eating habits among children and have a positive effect on reducing both childhood and adult obesity.

5.2 Strengths and Limitations

This is the first lifestyle-based dissertation that has focused on measuring adherence as the primary outcome for nutrition and exercise intervention strategies during pregnancy. Previous research on nutrition and exercise programs during pregnancy has focused on measuring behavior change and/or the effect of lifestyle behavior change on specific health outcomes. By focusing on adherence and using the results of this dissertation as a template, all health outcomes and other population groups can be examined (For example: compare adherence to ‘successful’ and ‘unsuccessful’ lifestyle interventions in a specific population group [study 1]; determining if adherence can predict a specific health outcome [study 2]; and measuring and comparing adherence to the sequential and simultaneous introduction of nutrition and exercise behaviors in a population group for specific health behaviors [study 3]). The overall findings of this dissertation appear to be generalizable and applicable to lifestyle behavior change research at large.

All participants are self-selected and that may contribute to limitations of the current dissertation. For Study 1, all included studies in the systematic review had women who chose to participate in a lifestyle intervention during pregnancy. Similarly, in both Studies 2 and 3, women self-selected to join the lifestyle intervention. This may mean that adherence was higher because women were motivated to participate in a lifestyle program and perhaps results would vary in a clinical setting. Future research is required to assess the effect of adherence on nutrition and exercise prescriptions during pregnancy in a clinical environment.

The theoretical framework (self-control and self-regulation theories) used in Study 3 also has limitations. Recent reports have criticized self-control and self-regulation theories mainly for the inability to replicate previous results and because it is difficult to demonstrate the depletion of self-control and regulation resources within a laboratory setting (20). For example, Carter et al. (20) completed a meta-analysis to evaluate the effect of ego depletion and overall the results were non-conclusive. Results showed only a small effect size supporting the depletion of self-control and regulation resources influencing behaviors (20). Furthermore, previous studies that have attempted to deplete self-control and regulation resources have done so using a variety of different methods and only in short bouts (20). For example previous studies have asked individuals to complete difficult cognitive tasks and then refrain from indulging in unhealthy foods such as freshly baked cookies (21). Overall, the task used to deplete self-control and regulation resources have not represented the subsequent behavior change task that requires self-control and/or regulation (21). Study 3 however, may represent a more valid way of depleting self-control and regulation resources as participants were asked to carry out nutrition and exercise behaviors over a longer period of time and outside of a laboratory setting. However Study 3 did not include any measurement methods in order to determine if there was a depletion effect.

Furthermore, Study 3 did not include a method to determine the mechanism contributing to low or high adherence to each individual strategy. One mechanism that has been proposed to explain successful behavior change is self-efficacy (innate confidence to complete a task or behavior; 22). It may be possible that all participants had a high level of self-efficacy for lifestyle behavior change at the beginning of the program which may explain why they self-selected to participate in a lifestyle intervention. However, perhaps the group introduced to exercise first was able to maintain their level of self-efficacy and therefore their adherence was high from the beginning to the end of the program, even when the additional nutrition behavior change component was added.

Whereas the group introduced to both nutrition and exercise simultaneously and nutrition only, may have experienced a decrease in self-efficacy and consequently had low program adherence. To improve Study 3, perhaps questionnaires for evaluating self-control and regulation resources and the level of self-efficacy should be added at the beginning, at 25 weeks gestation (when the second behavior was added) and at the end of intervention.

An additional limitation is the homogeneity of the population in all three studies. The majority of the studies (in Studies 1-3) included Caucasian women with higher education. As well, the average BMI across all three studies was in the normal weight up to Class I obesity category (≥18.0-35.0 kg/m^2). As the North American population continues to become more diverse and the prevalence of obesity is increasing, perhaps different adherence strategies are required based on characteristics such as culture, beliefs and values, education, socio-economic status and for women who enter pregnancy with Class II or III obesity.

Finally, this dissertation viewed adherence as the degree to which patient behaviors coincide with the recommendations of a healthcare provider (9). This definition and measurement method has mostly been used when evaluating adherence to medical regimens (9). This definition can also be applied to lifestyle behaviors as it takes into account the fact that participants may not be fully adherent to the goals of a program, but can have partial adherence (0% - 100% adherence; 9). Other definitions of adherence have included viewing adherence as a feasibility measure and completion of a program (23-26). As a feasibility measure, if participants cannot adhere to a program then this is evidence for low feasibility (23). When adherence is viewed as completion of a program, individuals who drop out of an intervention are considered non-adherent (25). Although Study 3 also assessed adherence as a measure of drop-out, the overall dissertation did not assess other measures of adherence besides viewing adherence on a gradient from 0 to 100 percent. To further investigate the role of adherence in program 'success', adherence should be tested in multiple ways including the degree of following recommendations, feasibility and program completion.

5.3 Conclusion:

It has been shown through this dissertation that adherence is a key factor in determining the success of a nutrition and exercise intervention during pregnancy for improving health outcomes, including prevention of excessive gestational weight gain. Specifically, this dissertation determined that at least 70% adherence to lifestyle interventions is recommended in order to improve health outcomes during pregnancy. Adherence remains the strongest predictor for intervention success among women with a BMI ≥25 kg/m^2, who may have experienced weight fluctuations prior to pregnancy. Therefore in order to increase the number of women who are having a healthy pregnancy, effective adherence strategies are required. One such strategy may be introducing multiple behaviors sequentially rather than simultaneously. This dissertation found that introducing exercise first followed by nutrition will increase adherence to the goals of the intervention. By increasing adherence to nutrition and exercise interventions during pregnancy, and adopting a successful approach into standard care, more women will have a healthy pregnancy and this may reduce the risk for excessive gestational weight gain and later life chronic diseases, including obesity.

5.4 Chapter 5 References

1. Rogozinska E, Marlin N, Jackson L, et al. Effects of antenatal diet and physical activity on maternal and fetal outcomes: individual patient data meta-analysis and health economic evaluation. *Health Technology Assessment (Winchester, England).* 2017;21(41):1-158.

2. Thangaratinam S, Rogozinska E Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ.* 2012;16(344):e2088.

3. Choi J, Fukuoka Y, Lee JH. The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum: a systematic review and meta-analysis of randomized controlled trials. *Prev Med.* 2013;56(6):351-64.

4. Streuling I, Beyerlein A, Rosenfeld E, Hofmann H, Schulz T, von Kries R. Physical activity and gestational weight gain: a meta-analysis of intervention trials. *BJOG.* 2011;118(3):278-84.

5. Dodd JM, Crowther CA, Robinson JS. Dietary and lifestyle interventions to limit weight gain during pregnancy for obese or overweight women: a systematic review. *Acta Obstet Gynecol Scand.* 2008;87(7):702-6.

6. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev.* 2015(6):CD007145.

7. Davies GAL, Maxwell C, McLeod L. Obesity in pregnancy. *JOGC.* 2010;32(2):165-73.

8.Hyman DJ, Pavlik VN, Taylor WC, Goodrick GK, Moye L. Simultaneous vs sequential counseling for multiple behavior change. *Arch Intern Med.* 2007;167(11):1152-8.

9. Vitolins MZ, Rand CS, Rapp SR, Ribisl PM, Sevick MA. Measuring adherence to behavioral and medical interventions. *Control Clin Trials.* 2000;21(5 Suppl):188S-94S.

10. Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? *Behav Anal Pract.* 2017;10(4):347-54.

11. Currie S, Sinclair M, Murphy MH, Madden E, Dunwoody L, Liddle D. Reducing the decline in physical activity during pregnancy: a systematic review of behavior change interventions. *PloS One.* 2013;8(6):e66385.

12. Sherifali D, Nerenberg KA, Wilson S, Semeniuk K, Ali MU, Redman LM, et al. The Effectiveness of eHealth Technologies on Weight Management in Pregnant and Postpartum Women: Systematic Review and Meta-Analysis. *Journal of Medical Internet Research.* 2017;19(10):e337.

13. Harden SM, Burke SM, Haile AM, Estabrooks PA. Generalizing the finding from group dynamics-based physical activity research to practice settings: What do we know? *Eval Health Prof.* 2015;38(1):3-14.

14. Lim S, Dunbar JA, Versave VL et al. Comparing a telephone- and a group-delivered diabetes prevention program: Characteristics of engaged and non-engaged postpartum mothers with a history of gestational diabetes. *Diabetes Res Clin Pract.* 2017;126:254-262.

15. Phelan S. Pregnancy: a "teachable moment" for weight control and obesity prevention. *Am J Obstet Gynecol.* 2010;202(2):135.e1-8.

16. Thornton JS, Fremont P, Khan K, Poirier P, Fowles J, Wells GD, et al. Physical Activity Prescription: A Critical Opportunity to Address a Modifiable Risk Factor for the Prevention and Management of Chronic Disease: A Position Statement by the Canadian Academy of Sport and Exercise Medicine. *Clinical journal of sport medicine.* 2016;26(4):259-65.

17. Mottola MF, Davenport MH, Ruchat SM, et al. 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med.* 2018;52(21):1339-46.

18. Farpour-Lambert NJ, Ells LJ, Martinez de Tejada B, Scott C. Obesity and Weight Gain in Pregnancy and Postpartum: an Evidence Review of Lifestyle Interventions to Inform Maternal and Child Health Policies. *Frontiers in Endocrinology.* 2018;9:546.

19. Barker DJ. The origins of the developmental origins theory. *Journal of Internal Medicine.* 2007;261(5):412-7.

20. Carter EC, Kofler LM, Forster DE, McCullough ME. A series of meta-analysis tests of the depletion effects: Self-control does not seem to rely on a limited resource. *Journal of Experimental Psychology.* 2015;144(4):796-815.

21. Evans DR, Boggero IA, Segerstrom SC. The nature of self-regulatory fatigue and “ego depletion”: Lessons from physical fatigue. *Personality and Social Psychology Review.* 2016;20(4):291-310.

22. Bandura A. Social cognitive theory of self-regulation. *Organizational Behavior and Human Decision Processes.* 1991;50:248-287.

23. Modi AC, Guilfoyle SM, Rausch J. Preliminary feasibility, acceptability and efficacy of an innovative adherence intervention for children with newly diagnosed epilepsy. *Journal of Pediatric Psychology.* 2013;38(6):605-616.

24. Lentferink AJ, Oldenhuis HKE, de Groot M, Polstra L, Velthuijsen H, van Gemert-Pijnen JEW. Key componennts in eHealth interventions combing self-tracking and persuasive eCoaching to promote a healthier lifestyle: A scoping review. *J Med Internet Res.* 2017;19(8):e277.

25. Eysenbach G. The law of attrition. *J Med Internet Res.* 2005;7(1):e11.

25. Jahangiry L, Shojaeizadeh D, Montazeri A, Najafi M, Mohammed K, Yaseri M. Adherence and attrition in a web-based lifestyle intervention for people with metabolic syndrome. *Iran J Public Health.* 2014;43(9):1248-58.

Appendices

Appendix A: PROSPERO Registration for Study 1.

PROSPERO
International prospective register of systematic reviews

National Institute for Health Research

Does adherence to intervention goals predict the success of a lifestyle program during pregnancy?

Taniya Nagpal, Michelle Mottola, Roberta Bgeginski, Marina Vargas, Harry Prapavessis, Barbra deVrijer, Christina Campbell, Mollie Manley

Citation

Taniya Nagpal, Michelle Mottola, Roberta Bgeginski, Marina Vargas, Harry Prapavessis, Barbra deVrijer, Christina Campbell, Mollie Manley. Does adherence to intervention goals predict the success of a lifestyle program during pregnancy?. PROSPERO 2017 CRD42017072716 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017072716

Review question

Does adherence to intervention goals predict the success of a lifestyle program during pregnancy?

Searches

The research will be conducted using MEDLINE, Scopus, Embase, SPORTDiscus, ISI Web of Knowledge, the Cochrane Central Register of Controlled Trials (CENTRAL), SciELO and PEDro databases.
Search term categories: Intervention, Pregnant, Adherence/compliance.
Articles published in English will be eligible for inclusion.
Studies will be restricted to those conducted on humans.

Types of study to be included

English language;Any design – any follow-up length is allowed; no sample size limits;In-press publications (collaborators nominated).

Condition or domain being studied

Any lifestyle intervention (nutrition and/or exercise) during pregnancy.

Participants/population

Pregnant women without contradictions (absolute or relative) to exercise.
Absolute contraindications is defined as the ACOG guidelines (ACOG Committee Opinion No. 650: Physical activity and exercise during pregnancy and the postpartum period. Obstet Gynecol. 2015 Dec;126(6):e135-42) and include:
Hemodynamically significant heart disease;
Restrictive lung disease;
Incompetent cervix or cerclage;
Multiple gestation at risk of premature labor;
Persistent second- or third-trimester bleeding;
Placenta previa after 26 weeks of gestation;
Premature labor during the current pregnancy;
Ruptured membranes;
Preeclampsia or pregnancy-induced hypertension;
Severe anemia.

Intervention(s), exposure(s)

Lifestyle intervention is defined as including a physical activity only, nutrition only or both a physical activity and nutrition behaviour change in order to achieve a maternal and/or fetal health outcome. The nutrition behavior change should be planned, structured and include some form of reporting to evaluate whether participants are adhering to the recommendations or not. Exercise is defined as physical activity consisting of planned, structured, and repetitive bodily movements done to improve one or more components of physical fitness and must include some form of reporting to evaluate whether participants are adhering to the recommendations or not. Inclusion criteria for exercise are as follows: F (frequency) – all occasions of exercise, I (intensity) – any level of exercise intensity, T (time) – any length of time for all gestational ages, T (type) – any modality of exercise;
Human participants;

English language;
Any design – any follow-up length is allowed; no sample size limits;
In-press publications (collaborators nominated);
Presence of an adherence/compliance measurement (as defined by authors; e.g. food intake records; attendance, step count goals, exercise diaries).
Maternal and/or fetal primary health outcome (as defined by authors) values before and after the intervention.
Exclusion criteria:
Not original research;
Review articles;
Case studies;
Research protocol studies;
Book chapters;
No adherence/compliance;
Study goals not indicated

Comparator(s)/control

No prenatal behaviour change intervention (exercise and/or nutrition).

Context

Main outcome(s)

Program adherence/compliance (reported by authors to indicate meeting program goals or not).

Additional outcome(s)

Sub-analysis will include type of intervention (exercise only, nutrition only, both exercise and nutrition). Additionally the following potential adherence moderators will be extracted and discussed for all studies: length of intervention, mode of intervention delivery, number of behaviour changes and self-monitoring techniques used.

Data extraction (selection and coding)

Stage 1: Review of abstracts and titles (completed by two independent investigators)
Stage 2: Full text review (completed by two independent investigators)
Stage 3: Data extraction (completed by two independent investigators)

At any stage if there are any discrepancies a third investigator will be consulted.

All data will be extracted onto an Excel spreadsheet.

The following data will be extracted:

1. Participant characteristics - age, pre-pregnancy BMI, gestational age at the start and end of the intervention

2. Study characteristics - country, type of study, sample size, intervention details (FITT) or description, successful or unsuccessful as defined by authors and reported statistical significance for meeting health outcome

3. Adherence data - method to measure, reported value, considered strength or weakness

5. Health outcome - as reported by authors.

Risk of bias (quality) assessment

The risk of bias in each included study will be assessed by using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions.

Strategy for data synthesis

A meta-analysis will be conducted if possible.

Analysis of subgroups or subsets
Type of intervention (physical activity only, nutrition only, physical activity and nutrition)

Contact details for further information
Taniya Nagpal
[redacted]

Organisational affiliation of the review
University of Western Ontario
http://www.uwo.ca/fhs/EPL/

Review team members and their organisational affiliations
Miss Taniya Nagpal. University of Western Ontario
Dr Michelle Mottola. University of Western Ontario
Dr Roberta Bgeginski. Universidade Federal do Rio Grande do Sul
Dr Marina Vargas. Technical University of Madrid
Dr Harry Prapavessis. University of Western Ontario
Dr Barbra deVrijer. London Health Science Centre; The University of Western Ontario
Dr Christina Campbell. Iowa State University
Mollie Manley. University of Western Ontario

Type and method of review
Systematic review

Anticipated or actual start date
01 August 2017

Anticipated completion date
31 March 2019

Funding sources/sponsors
None

Conflicts of interest
None known

Language
English

Country
Canada

Stage of review
Review Completed not published

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Achievement; Female; Goals; Humans; Life Style; Pregnancy

Date of registration in PROSPERO
21 July 2017

Date of publication of this version
27 March 2019

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

Versions

21 July 2017
12 February 2019
27 March 2019

Appendix B: Search strategy for Medline for Study 1.

POPULATION:

Search ((((Pregnancy) OR Gestational) OR "pregnant"[All Fields]) OR Pregnancies) OR Maternal OR Prenatal OR Fetal OR Fetus OR Foetal OR Foetus OR Perinatal OR Prepartum

INTERVENTION:

(exercise) OR "Physical Exercise") OR "Isometric Exercise") OR "Aerobic Exercise") OR "Resistance Exercise") OR "Strength Training") OR "Plyometric Exercise") OR "Stretching Exercises") OR "Weight Bearing") OR Weightbearing) OR Pilates) OR "Motor Activity") OR "training"[All Fields]) OR “Fitness Training”) OR “Yoga Exercises” OR Yoga OR “Abdominal exercise” OR “Moderate to Vigorous Physical Activity” OR “Leisure Time Physical Activity” OR “Physical Fitness” OR “Physical Endurance” OR “Strenuous Activity” OR “Exercise Movement Techniques” OR “Physical Exertion” OR Sports OR “Sedentary Lifestyle” OR “Aerobic capacity” OR “Aerobic exercise” OR “Muscle Strength”

OR

(nutrition) OR diet OR “dietary habits” OR meal OR “meal plan” OR food OR “food intake”

OUTCOMES:

(adherence) OR compliance OR attendance OR goals OR accomplish OR “patient adherence” OR achievement

Appendix C: Weight and Health History Questionnaire used in Study 2.

Unique Identifier:

Today's date:

Postal Code:

Weight & Health History Questionnaire

Please answer the following questions to the best of your ability. All of the answers gained through this survey will be held in the strictest of confidence.

Section A – Background Information:

1) What is your **date of birth**? ____________________ (day, month, year)

2) What is your **ethnic** background?

☐ Caucasian ☐ Hispanic ☐ Aboriginal (please circle: First Nations, Métis, Inuit) ☐ Asian ☐ African American ☐ Other, please specify ________________

3) What is your **height**? ____________ feet ____________ inches, OR ____________ centimeters

4) What **education level** did you complete? Please check all that apply.

☐ Elementary school ☐ High school ☐ College

☐ University (please circle: certificate, bachelor, master, doctorate)

☐ Other, please specify________________

Section B – Current Pregnancy:

5) What has been your **usual adult body weight**? ____________ pounds, OR ____________ kilograms

6) How much **weight** did you **plan to gain** during this pregnancy?

____________ pounds, OR ____________ kilograms

7) How much **weight** have you gained so far during this pregnancy?

____________ pounds, OR ____________ kilograms

8) What was your **body weight <u>one year before</u> this pregnancy**?

____________ pounds, OR ____________ kilograms

9) What was your **body weight <u>immediately before</u> this pregnancy**?

____________ pounds, OR ____________ kilograms

10) Were you actively trying to reduce your body weight in the **<u>year before</u> this pregnancy**?

□ No □ If Yes, how much weight did you lose? ____________ pounds, OR ____________ kilograms

11) What have your **eating habits** been like in the **<u>year before</u> this pregnancy**? Check all that apply.

□ one meal per day, specify when ____________________________________

□ two meals per day, specify when ______________________________________

□ three meals per day

□ snack(s) every day, specify when ____

□ Special diet, please specify name ____

□ Trying to follow Canada's Food Guide to Healthy Eating

□ Other nutrition plan, please specify

____

12) What has your pattern of **physical activity** been like in the **year before this pregnancy**?

Type of Physical Activity	**Frequency**	Average **Duration** of your exercise sessions	**Intensity** (low, medium, high)	**Location** (home, outdoors, gym, etc.)
	________ time(s) per week	________ minutes		
	________ time(s) per week	________ minutes		
	________ time(s) per week	________ minutes		
	________ time(s) per week	________ minutes		

13) How would you qualify your **current level of stress** on most days?

□ No stress.

☐ Low stress level.

☐ Moderate stress level.

☐ High stress level. You perceive it as a problem.

14) Is this your **first pregnancy**?

☐ No ☐ Yes

Section C – Previous Pregnancies:

15) Please fill the following chart.

	Age you were	**Body weight** you were immediately **before** pregnancy	**Weight** you **gained** **during** pregnancy	**Weight retained** **after** pregnancy (never really lost)
1st pregnancy		__________pounds, OR ___________kg	__________pounds, OR ___________kg	__________pounds, OR ___________kg
2nd pregnancy		__________pounds, OR ___________kg	__________pounds, OR ___________kg	__________pounds, OR ___________kg
3rd pregnancy		__________pounds, OR ___________kg	__________pounds, OR ___________kg	__________pounds, OR ___________kg
4th pregnancy		__________pounds, OR ___________kg	__________pounds, OR ___________kg	__________pounds, OR ___________kg
5th pregnancy		__________pounds, OR ___________kg	__________pounds, OR ___________kg	__________pounds, OR ___________kg

Other pregnancies:

____

______

16) For each pregnancy, what were the gestational age, gender and approximate birth weight and length?

	Gestational Age	**Gender**	Birth **weight**	Birth **Length**
1st baby	__________ weeks		__________pounds ____________ounces, OR ___________kg	__________inches, OR ___________cm
2nd baby	__________ weeks		__________pounds ____________ounces, OR ___________kg	__________inches, OR ___________cm
3rd baby	__________ weeks		__________pounds ____________ounces, OR ___________kg	__________inches, OR ___________cm
4th baby	__________ weeks		__________pounds ____________ounces, OR ___________kg	__________inches, OR ___________cm
5th baby	__________ weeks		__________pounds ____________ounces, OR ___________kg	__________inches, OR ___________cm

Other babies:

____

____

17) Please indicate how you fed your baby(ies).

	Breastfeeding started	Duration of breastfeeding only	Age breastfeeding was stopped	Age at introduction of first solid foods
1st baby	____ Yes, ____ No	__________ months	__________ months	__________ months
2nd baby	____ Yes, ____ No	__________ months	__________ months	__________ months
3rd baby	____ Yes, ____ No	__________ months	__________ months	__________ months
4th baby	____ Yes, ____ No	__________ months	__________ months	__________ months
5th baby	____ Yes, ____ No	__________ months	__________ months	__________ months

Other babies:

____

Section D – Weight History:

18) What was **your birth weight**? _____________ pounds ______________ ounces, OR _____________ kilograms

19) What was **your birth length**? ____________ inches, OR ____________ centimeters

20) How has your **body weight** been **since** you were **19** years of age?

□ stable (always about the same weight, only changing by a couple of pounds when I am not pregnant),

please skip to question 28

□ unstable and progressively increasing

□ unstable, because it has been going up and down often

□ unstable, I feel I have been gaining weight with each pregnancy

□ Other, please describe

____

21) By how many pounds or kilograms does your body weight tend to fluctuate (or change) per year?

In average about ____________ pounds, OR ____________ kilograms per year.

22) What do you think causes your body weight to be unstable? Please explain.

____

____

____

____

____

23) Have you ever actively tried to lose weight?

□ Yes □ If No, please skip to question 28

24) How old were you when you first actively tried to lose weight?

____

25) What method did you use when you first actively tried to lose weight?

____

____

26) Since you were 19 years old, **how many times** have you been **actively trying to lose weight** <u>and</u> **at what ages**? Please explain.

____

____

____

27) List all the methods you have tried to lose weight.

☐ Vitamin/mineral supplement, please specify

____

☐ Dietary changes or special diets, please specify

____

____

☐ Physical activity, please specify

____

____

____

☐ Pills or herbal products, please describe

____

____

____

☐ Prescribed medication, please describe

____

____

____

☐ Surgery, please describe

____

____

____

☐ Meetings with a health care professional(s), please indicate which professional(s)

____

____

☐ Other, please describe

____

____

____

28) What was the **maximum** weight you ever **lost**, **how long** did it take you to lose that weight and what **method** did you use?

I lost ________ pounds, OR _________ kilograms in ___________ months, using the following method

____

____

29) Have you ever consulted a physician about weight issues or for weight management purposes?

- ☐ No
- ☐ No, but I would like to.
- ☐ Yes, and it was helpful. Explain

  ____

- ☐ Yes, but it was not helpful. Explain

  ____

30) Have you ever consulted a registered dietitian about weight issues or for weight management purposes?

- ☐ No
- ☐ No, but I would like to.
- ☐ Yes, and it was helpful. Explain

  ____

- ☐ Yes, but it was not helpful. Explain

  ____

31) If you choose a method to lose weight in the future, what will you be looking for as important characteristics? Check the **three (3) most important factors** for you.

☐ Group meetings
☐ Individual support

☐ Short-term results
☐ Long-term results

☐ Minimum time commitment
☐ Follow-up support

☐ Education
☐ Learning healthier lifestyle choices

☐ Expert advice by registered dietitian
☐ Expert advice by physician

☐ Expert advice by exercise physiologist
☐ Cost

☐ Safety
☐ Help with stress management

☐ Other, please specify

____

Section E – About Your Health:

32) Have you ever been diagnosed with:

Type 1 Diabetes Mellitus	☐ Yes	☐ No
Type 2 Diabetes Mellitus	☐ Yes	☐ No
Gestational Diabetes Mellitus	☐ Yes	☐ No

Pre-diabetes ☐ Yes ☐ No

Gestational hypertension ☐ Yes ☐ No

Polycystic Ovarian Syndrome ☐ Yes ☐ No

33) Do you currently, or have you ever taken medication for diabetes or pre-diabetes:

☐ No ☐ If Yes, please describe

____

Section F – About Your Family:

34) How many **siblings** do you have?

_________ Sister(s) _________ Brother(s) ☐ I do not know

35) How many of your **siblings** are **overweight or obese**?

_________ Sister(s) _________ Brother(s) ☐ I do not know

36) Is there a history of **overweight or obesity** in the rest of your **immediate family**? (Check all that apply)

☐ Your mother ☐ Your father

☐ Grandmother on your mother's side ☐ Grandfather on your mother's side

☐ Grandmother on your father's side ☐ Grandfather on your father's side

☐ None ☐ I do not know ☐ Other(s), please specify:_____________________________

37) How many of your **siblings** have **diabetes**?

_________ Sister(s) _________ Brother(s) ☐ I do not know

38) Is there a history of **diabetes** in the rest of your **immediate family**? (Check all that apply)

☐ Your mother ☐ Your father

☐ Grandmother on your mother's side ☐ Grandfather on your mother's side

☐ Grandmother on your father's side ☐ Grandfather on your father's side

☐ None ☐ I do not know ☐ Other(s), please specify:______________________________

39) What is the height and weight of the **father** of your child to be?

Height ___________ feet ___________ inches, OR _________________ centimeters

Weight ___________ pounds, OR _______________ kilograms

40) What is the **ethnic** background of the **father** of your child to be?

☐ Caucasian ☐ Hispanic ☐ Aboriginal (please circle: First Nations, Métis, Inuit) ☐ Asian ☐ African American ☐ Other, please specify _________________

41) How many **siblings** does the **father** of your child to be have?

_________ Sister(s) _________ Brother(s) ☐ I do not know

42) How many of the **father's siblings** are **overweight or obese**?

_________ Sister(s) _________ Brother(s) ☐ I do not know

43) How many of the **father's siblings** have **diabetes**?

_________ Sister(s) _________ Brother(s) ☐ I do not know

Thank you for taking the time to complete this questionnaire.

Appendix D: Clinical Trials Registration for Study 3.

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 3, 2019

ClinicalTrials.gov ID: NCT02804061

Study Identification

Unique Protocol ID: 108080

Brief Title: Early Prevention of Excessive Gestational Weight Gain Using Lifestyle Change (NELIP)

Official Title: Strategizing the Best Approach to Prevent Early Excessive Gestational Weight Gain Using a Nutrition and Exercise Lifestyle Intervention Program (NELIP)

Secondary IDs:

Study Status

Record Verification: July 2019

Overall Status: Recruiting

Study Start: July 2016 [Actual]

Primary Completion: August 31, 2020 [Anticipated]

Study Completion: September 30, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor: University of Western Ontario, Canada

Responsible Party: Principal Investigator
Investigator: Michelle Mottola [mmottola]
Official Title: Professor
Affiliation: University of Western Ontario, Canada

Collaborators: Iowa State University

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: 108080
Board Name: Health Sciences Research Ethics Board
Board Affiliation: The University of Western Ontario
Phone [redacted]
Email: [redacted]
Address:

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Nutrition and exercise behaviour change programs can prevent excessive gestational weight gain (EGWG). The Nutrition and Exercise Lifestyle Intervention Program (NELIP) is a previously published two-behaviour change program which was successful in preventing EGWG across normal weight, overweight and obese pre-pregnancy body mass index (BMI) categories (Ruchat et al. 2012; Mottola et al. 2010), however some women found it difficult to adhere to two lifestyle behaviour changes throughout pregnancy. The proposed pilot randomized controlled trial will address the issue of adherence by identifying the best way to offer a two-behaviour change program (NELIP) to pregnant women to increase the effectiveness of preventing early and total EGWG. Participants will begin the program at <18 weeks gestation and will be randomized to one of three groups: A) Receive both behaviour changes (Nutrition AND Exercise) simultaneously at entrance to the study; B) Receive the nutrition component first followed sequentially by the introduction of exercise at 25 weeks gestation (Nutrition FOLLOWED by Exercise); C) Receive the exercise component first followed sequentially by the introduction of the nutrition component at 25 weeks gestation (Exercise FOLLOWED by Nutrition).

Detailed Description: A randomized parallel groups design will be used as a pilot project. Each participant will be medically pre-screened using the PARmed-X for Pregnancy (2015) in early pregnancy (<18 weeks), stratified by pre-pregnancy BMI status (normal weight [18.5-24.9 kg/m2]; overweight [25.0-29.9 kg/m2], obese [=>30.0 kg/m2]) and randomized into one of 3 groups: Group A) NELIP (full intervention); Group B) Nutrition intervention given at study entry followed sequentially by the exercise intervention starting immediately after 24 week mid-way visit (N+E); or Group C) Exercise intervention started at study entry followed sequentially by the nutrition intervention starting immediately after 24 week mid-way visit (E+N). Infant sex, body weight, length, complications will be recorded at birth and the last known maternal body weight. Neonatal morphometrics will be assessed with diaper only (6 skinfold sites from umbilical, suprailiac, biceps, triceps, subscapular, and anterior thigh; circumferences from the head, chest, abdomen, hips, thigh, leg, arm, and arm, forearm, thigh and leg length measured to the nearest mm) and will be measured within 6–18 hours of delivery by a member of the research team visiting the woman either at hospital or home. Each maternal-infant pair will be asked to return to the lab at 2, 6 and 12 months post-delivery for follow-up and assessment of chronic disease risk.

Conditions

Conditions: Excessive Weight Gain in Pregnancy, First Trimester
Excessive Weight Gain in Pregnancy With Baby Delivered
Birth Weight

Keywords: nutrition
exercise
behavior change
adherence

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 141 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Full NELIP This group will receive the full Nutrition and Exercise Lifestyle Intervention Program (two behavior changes) from enrollment until birth and serves as the comparator control (Group A).	Behavioral: NELIP Other Names: • Nutrition and Exercise Lifestyle Intervention Program
Experimental: Nutrition followed by Exercise (N+E) Intervention - Nutrition component only (one behaviour) until 24 week assessment, then the addition of the second behavior change (Exercise component) at 25 weeks, with both behaviours followed until birth (Group B).	Behavioral: NELIP Other Names: • Nutrition and Exercise Lifestyle Intervention Program
Experimental: Exercise followed by Nutrition (E+N) Intervention - Exercise component only (one behaviour) until 24 week assessment, after which there will be the addition of the second behaviour change (Nutrition component), with both behaviours followed until birth (Group C).	Behavioral: NELIP Other Names: • Nutrition and Exercise Lifestyle Intervention Program

Outcome Measures

Primary Outcome Measure:

1. Prevention of early excessive gestational weight gain
   Calculations based on the Institute of Medicine (2009) weight gain guidelines

   [Time Frame: Up to 24 weeks gestation]

Secondary Outcome Measure:

2. Prevention of total excessive gestational weight gain
   Calculations based on the Institute of Medicine (2009)

   [Time Frame: Up to 38 weeks of pregnancy or last known pregnancy weight]
3. Birth weight
   Taken from medical records

   [Time Frame: At Birth]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: Female

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- single pregnancy (no twins);
- < 18 weeks, 0 days pregnant at time of entry to study;
- low-risk pregnancy, as determined by medical pre-screening via PARmed-X for Pregnancy by their health care provider;
- > 18 years of age;
- low physical activity defined as less than 3 intentional bouts of 30 minutes of moderately intense physical activity per week;
- non smokers.

Exclusion Criteria:

- multiple pregnancy (twins, etc);
- contraindication to exercise (includes chronic diseases such as cardiovascular diseases, thyroid diseases, uncontrolled Type 2 diabetes, peripheral vascular disease, hypertension);
- > 18 weeks, 0 days pregnant at time of entrance to study;
- <18 years of age;
- high physical activity defined as more than 3 intentional bouts of 30 minutes of moderately intense physical activity per week;
- smokers.

Contacts/Locations

Central Contact Person: Michelle F Mottola, PhD
[redacted]

Central Contact Backup:

Study Officials: Michelle F Mottola, PhD
Study Principal Investigator
University of Western Ontario, Canada

Locations: **Canada, Ontario**
[redacted]
Contact: [redacted]
Principal Investigator: Michelle F Mottola, PhD
Sub-Investigator: Harry Prapavessis, PhD

IPDSharing

Plan to Share IPD: No

References

Citations:

Ruchat SM, Davenport MH, Giroux I, Hillier M, Batada A, Sopper MM, Hammond JM, Mottola MF. Nutrition and exercise reduce excessive weight gain in normal-weight pregnant women. Med Sci Sports Exerc. 2012 Aug;44(8):1419-26. doi: 10.1249/MSS.0b013e31825365f1. PubMed 22453250

Mottola MF, Giroux I, Gratton R, Hammond JA, Hanley A, Harris S, McManus R, Davenport MH, Sopper MM. Nutrition and exercise prevent excess weight gain in overweight pregnant women. Med Sci Sports Exerc. 2010 Feb;42(2):265-72. doi: 10.1249/MSS.0b013e3181b5419a. PubMed 20083959

Davenport MH, Ruchat SM, Giroux I, Sopper MM, Mottola MF. Timing of excessive pregnancy-related weight gain and offspring adiposity at birth. Obstet Gynecol. 2013 Aug;122(2 Pt 1):255-61. doi: 10.1097/AOG.0b013e31829a3b86. PubMed 23969792

Nagpal TS, Prapavessis H, Campbell C, Mottola MF. Measuring Adherence to a Nutrition and Exercise Lifestyle Intervention: Is Program Adherence Related to Excessive Gestational Weight Gain? Behav Anal Pract. 2017 May 17;10(4):347-354. doi: 10.1007/s40617-017-0189-5. eCollection 2017 Dec. PubMed 29214130

Links:

Available IPD/Information:

Appendix E: Western University Human Research Ethics Board – Ethics Approval for Study 3.

Western Research

Date: 29 June 2018

To: Michelle Mottola

Project ID: 108080

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

Application Type: Continuing Ethics Review (CER) Form

Review Type: Delegated

REB Meeting Date: 17/Jul/2018

Date Approval Issued: 29/Jun/2018

REB Approval Expiry Date: 05/Jul/2019

Dear Michelle Mottola,

The Western University Research Ethics Board has reviewed the application. This study, including all currently approved documents, has been re-approved until the expiry date noted above.

REB members involved in the research project do not participate in the review, discussion or decision.

Western University REB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The REB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Daniel Wyzynski, Research Ethics Coordinator, on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Appendix F: Letter of Information for Study 3.

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)

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.

<u>If you are randomized into having the Nutrition strategy introduced first:</u>

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.

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.

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

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.

<u>If you are randomized into having both Nutrition and Exercise strategies introduced first:</u>

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.

Appendix G: Consent form for Study 3.

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 ________________________________

Curriculum Vitae

Name: Taniya Singh Nagpal

Post-secondary Education and Degrees: The University of Western Ontario
London, Ontario, Canada
2010-2014, BHSc

Honours and Awards: Province of Ontario Graduate Scholarship
2016-2017, 2017-2018 (Nicolaas and Regina Veenboer Foundation) 2018-2019 (Arthur and Sonia Labatt)

Canadian Institute of Research, Summer Travel Award 2019

PSAC 610 Community Involvement Graduate Award, 2018

Western Graduate Teaching Award, 2018

Western Kinesiology Research and Service Award, 2018

2018 Western 3 Minute Thesis Competition – 2nd place

Western Global Opportunities Award, 2018

Joint Student Research Grant for Student Led Conference Organization
2018, 2017

Student Summit Travel Award Canadian Obesity Network, 2017

Oral Presentation Award Western Kinesiology Graduate Symposium
2016, 2017

Outstanding Youth Leadership Award Recipient Canadian Cancer Society, 2016

1st Place Oral Presentation University of Toronto Bodies of Knowledge Conference, 2015

Related Work Experience	Teaching Assistant The University of Western Ontario 2014-2019
	Literature Review Specialist – Society of Obstetricians and Gynecologists of Canada 2019 –
	Fanshawe College – Course Instructor (Health Promotion, Sociology of Health) 2018-2019
	Research Institute of the McGill University Health Centre – Summer Student 2018

Publications:

1. M.J. Fagan., **T.S. Nagpal.,** L. Fitzgeorge., W.J. Smith., J. Rosaasen., H. Prapavessis. (2019). Smoking zones versus smoke-free zones on Canadian post-secondary campuses: Which zone is more effective, adhered to and preferred? *Tobacco Prevention and Cessation*, 5, DOI: 10.18332/tpc

2. M. Vargas & **T.S. Nagpal.,** R. Barakat. (2018). Impact of exercise during pregnancy on birthweight: An overview. *Brazilian Journal of Physical Therapy,* DOI: 10.1016/j.bjpt.2018.11.01

3. M.F. Mottola., M.H. Davenport., S.M. Ruchat., G.A. Davies., V.J. Poitras., C.E. Gray., A.J. Garcia., N. Barrowman., K.B. Adamo., M. Duggan., R. Barakat., P. Chilibeck., K. Fleming., M. Forte., J. Korolnek., **T. Nagpal.,** L.G. Slater., D. Stirling., L. Zehr. (2018). 2019 Canadian guideline for physical activity throughout pregnancy. *Br J Sports Med, 52*(21), 1339-1346.

4. S.M. Ruchat., M.F. Mottola., R.J. Skow., **T.S. Nagpal.,** V.L. Meah., M. James., L. Riske., F. Sobierajski., A.J. Kathol., A. Marchand., M. Nuspl., A. Weeks., C.E. Gray., V.J., Poitras., A.J. Garcia., N. Barrowman., L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., M.H. Davenport. (2018). Effectiveness of exercise interventions in the prevention of excessive gestational weight gain and postpartum weight retention: A systematic review and meta-analysis. *Br J Sports Med, 52*(21), 1346-1356.

5. M.H. Davenport., F. Sobierajski., M.F. Mottola., R.J. Skow., V.L. Meah., V.J. Poitras., C.E. Gray., A.J. Garcia., N. Barrowman., L. Riske., M. James., **T.S.**

Nagpal., A. Marchand., L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., S.M. Ruchat. (2018). Glucose response to acute and chronic exercise during pregnancy: A systematic review and meta-analysis. *Br J Sports Med, 52*(21), 1357-1366.

6. M.H. Davenport., S.M. Ruchat., V.J. Poitras., A.J. Garcia., C.E. Gray., N. Barrowman., R.J. Skow., V.L. Meah., L. Riske., F. Sobierajski., M. James., A.J. Kathol., M. Nuspl., A. Marchand., **T.S. Nagpal.,** L.G. Slater., A. Weeks., K.B. Adamo., G.A. Davies., R. Barakat., M.F. Mottola. (2018). Prenatal exercise for the prevention of gestational diabetes mellitus and hypertensive disorders of pregnancy: a systematic review and meta-analysis *Br J Sports Med, 52*(21), 1367-1375.

7. M.H. Davenport., A.P. McCurdy., M.F. Mottola., R.J. Skow., V.L. Meah., V.J. Poitras., A.J. Garcia., C.E. Gray., N. Barrowman., L. Riske., F. Sobierajski., M. James., **T.S. Nagpal.,** A. Marchand., M. Nuspl., L.G. Slater., R. Barakat., K.B. Adamo., G.A. Davies., S.M. Ruchat. (2018). Impact of prenatal exercise on both prenatal and postnatal anxiety and depressive symptoms: A systematic review and meta-analysis. *Br J Sports Med, 52*(21), 1376-1385.

8. M.H. Davenport., V.L. Meah., S.M. Ruchat., G.A. Davies., R.J. Skow., N. Barrowman., K.B. Adamo., V.J. Poitras., C.E. Gray., A.J. Garcia., F. Sobierajski., L. Riske., M. James., A.J. Kathol., M. Nuspl., A. Marchand., **T.S. Nagpal.,** L.G. Slater., A. Weeks., R. Barakat., M.F. Mottola. (2018). Impact of prenatal exercise on neonatal and childhood outcomes: A systematic review and meta-analysis. *Br J Sports Med, 52*(21), 1386-1396.

9. M.H. Davenport., **T.S. Nagpal.,** M.F. Mottola., R.J. Skow., L. Riske., V.J Poitras., A.J. Garcia., C.E. Gray., N. Barrowman., V.L. Meah., F. Sobierajski., M. James., M. Nuspl., A. Weeks., A. Marchand., L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., S.M. Ruchat. (2018). Prenatal exercise (including but not limited to pelvic floor muscle training) and urinary incontinence during and following pregnancy: A systematic review and meta-analysis. *Br J Sports Med, 52*(21), 1397-1404.

10. M.H. Davenport., S.M. Ruchat., M.F. Mottola., G.A. Davies., V.J., Poitras., C.E. Gray., A.J. Garcia., N. Barrowman., K.B. Adamo., M. Duggan., R. Barakat., P. Chilibeck., K. Fleming., M. Forte., J. Korolnek., **T. Nagpal.,** L.G. Slater., D. Stirling., L. Zehr. (2018). 2019 Canadian guidelines for physical activity throughout pregnancy: Methodology. *J Obstet Gynaecol Can,* doi.org/10.1016/j.jogc.2018.09.004

11. M.H. Davenport., A.J. Kathol., M.F. Mottola., R.J. Skow., V.L. Meah., V.J. Poitras., A.J. Garcia., C.E. Gray., N. Barrowman., L. Riske., F. Sobierajski., M. James., **T. Nagpal.,** A. Marchand., L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., S.M. Ruchat. (2018). Prenatal exercise is not associated with fetal

mortality: a systematic review and meta-analysis. *Br J Sports Med,* doi: 10.1136/bjsports-2018-099773

12. M.H. Davenport., A. Marchand., M.F. Mottola., V.J. Poitras., C.E. Gray., A.J Garcia., N. Barrowman., F. Sobierajski., M. James., V.L. Meah., R.J. Skow., L. Riske., M. Nuspl., **T.S. Nagpal.,** A. Courbalay., L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., S. Ruchat. (2018). Exercise for the prevention and treatment of low back, pelvic girdle and lumbopelvic pain during pregnancy: a systematic review and meta-analysis. *Br J Sports Med,* doi: 10.1136/bjsports-2018-099400

13. M.F. Mottola., **T.S. Nagpal.,** R. Bgeginski., M.H. Davenport., V.J. Poitras., C.E. Gray., G.A. Davies., K.B. Adamo., L.G. Slater., N. Barrowman., R. Barakat., S.M. Ruchat. (2018). Is supine exercise associated with adverse maternal and fetal outcomes? A systematic review. *Br J Sports Med,* doi: 10.1136/bjsports-2018-099919

14. M.H. Davenport., C. Yoo., M.F. Mottola., V.J. Poitras., A.J. Garcia., C.E. Gray., N. Barrowman., G.A. Davies., A. Kathol., R.J. Skow., V.L. Meah., L. Riske., F. Sobierajski., M. James., **T.S. Nagpal.,** A. Marchand., L.G. Slater., K.B. Adamo., R. Barakat., S.M. Ruchat. (2018). Effects of prenatal exercise on incidence of congenital anomalies and hyperthermia: a systematic review and meta-analysis. *Br J Sports Med,* doi: 10.1136/bjsports-2018-099653

15. M.H. Davenport., S.M. Ruchat., F. Sobierajski., V.J. Poitras., C.E. Gray., C. Yoo., R.J. Skow., A.J. Garcia., N. Barrowman., V.L. Meah., **T.S. Nagpal.,** L. Riske., M. James., M. Nuspl., A. Weeks., A. Marchand., .L.G. Slater., K.B. Adamo., G.A. Davies., R. Barakat., M.F. Mottola. (2018). Impact of prenatal exercise on maternal harms, labour and delivery outcomes: a systematic review and meta-analysis. *Br J Sports Med,* doi: 10.1136/bjsports-2018-099821

16. S. Rollo, L. Crutchlow, **T.S. Nagpal**, W. Sui, H. Prapavessis. The effects of classroom-based dynamic seating interventions on academic outcomes in youth: A systematic review. (2018). *Learning Environments Research, 16*(2), doi: 10.1007/s10984-018-9271-3

17. L. Fitzgeorge, M.J. Fagan, **T.S. Nagpal,** H. Prapavessis, M. Tritter. Informing population-specific smoking policy development for college campuses: An observational study. (2018). *Tobacco Prevention and Cessation*, *4(26),* doi: 10.18332/tpc/92482

18. **T.S. Nagpal,** L. Stathokostas, H. Prapavessis, & M.F. Mottola. (2017). Call to action: Enhancing 'Exercise is Medicine' from the perspective of fitness professionals. *International Journal of Sports and Exercise Medicine, 3*(4), doi: 10.23937/2469-5718/1510070

19. **T.S. Nagpal,** M. Fagan, & H. Prapavessis. (2017). Treatment options for

smoking cessation in pregnant women: A narrative review. *Medical Research Archives, 5(7),* doi: 10.18103/mra.v5i7.141

20. **T.S. Nagpal,** H. Prapavessis, C. Campbell, & M.F. Mottola. (2017). Measuring adherence to a nutrition and exercise lifestyle intervention: Is program adherence related to excessive gestational weight gain? *Behavior Analysis in Practice, 10,* 347-354.

Book Chapter

1. M. Perales, **T.S. Nagpal**, & R. Barakat. (2018). Physiological changes during pregnancy. Main adaptations and discomforts and implications for physical activity and exercise. In R. Santos-Rocha (ed.), Exercise and Sporting Activity During Pregnancy, ch 3.

Published Conference Abstracts

1. **Nagpal, T.S.,** Vargas-Terrones, M., Perales, M., Prapavessis, H., Barakat, R., Mottola, M.F. (2019). Structured exercise as a potential treatment option for prenatal depression. *Medicine and Science in Sports and Exercise, 51,* 476.

2. Bgeginski, R., **Nagpal, T.S.,** Mottola, M.F. (2019). Maternal water exercise and its effects on weight gain and fetal outcomes: A meta-analysis. *Medicine and Science in Sports and Exercise, 51,* 859.

3. **Nagpal, T.S.,** Vaikuntharajan, P., de Vrijer, B., Prapavessis, H., Penava, D., & Mottola, M.F. (2018). Patient experience on weight management advice prior to pregnancy from physicians and dietitians. *Medicine and Science in Sports and Exercise, 50*, 467.

4. **Nagpal, T.S.,** Stathokostas, L., Prapavessis, H., & Mottola, M.F. (2017). Evaluation of Exercise is Medicine From The Perspective Of Fitness Professionals. *Medicine and Science in Sports and Exercise, 49*(5S), 297.

5. **Nagpal, T.S.,** Mottola, M.F., Mcmanus, R.M. (2017). Families Defeating Diabetes (FDD): Focus Group Analysis of a Postpartum Healthy Living Intervention for Women with Gestational Diabetes (GDM). *Diabetes, 66*, A645.

6. **Nagpal T.S.**, Prapavessis, H., Campbell, C., & Mottola, M.F. (2016). Preventing excessive gestational weight gain in pregnant women with obesity: Does adherence to nutrition and exercise behaviour change programs improve with adding a family based component? *Journal of Exercise, Movement and Sport, 48*(1), 204.

7. **Nagpal T.S.**, Prapavessis, H., Campbell, C., & Mottola, M.F. (2016). Measuring adherence to nutrition and exercise behaviour changes to prevent

excessive gestational weight gain. *Applied Physiology, Nutrition and Metabolism, 41*(9), S375. DOI: 10.1139/apnm-2016-0366

8. Ramos, J.G.R., Bgeginski, R., **Nagpal, T.S.**, & Mottola, M.F. (2016). Exercise effects on inflammation during pregnancy: A systematic review. *Pregnancy Hypertension: An International Journal of Women's Cardiovascular Health, 6*(3), 203. DOI: 10.1016/j.preghy.2016.08.137