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Samantha Langstaff, University of Western Ontario

Supervisor: Dr. Michelle Mottola, *The University of Western Ontario* A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Kinesiology © Samantha Langstaff 2015

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BRINGING AN EVIDENCE-BASED NUTRITION AND EXERCISE LIFESTYLE INTERVENTION PROGRAM (NELIP) FOR OBESE PREGNANT WOMEN INTO CLINICAL PRACTICE

by

Samantha Langstaff

Graduate Program in Kinesiology

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science

The School of Graduate and Postdoctoral Studies The University of Western Ontario London, Ontario, Canada

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Abstract

One purpose was to identify the need for specialized care (*My Clinic*) for women with a prepregnancy body mass index (BMI) of ≥ 35 kg/m². Women receiving *My Clinic* care were compared to a matched cohort control group (perinatal database, N=47). *My Clinic* care significantly reduced rates of macrosomia (5% vs 28%, p=0.02) and small birth weight babies (0% vs 6%, p=0.00) compared to perinatal database.

The second purpose was to test the efficacy of a Nutrition and Exercise Lifestyle Intervention Program (NELIP) in this clinical setting to prevent excessive weight gain, macrosmia, small birth weight babies and pregnancy complications. Twelve women with a BMI \geq 35 kg/m² were randomized between 12-20 weeks of pregnancy to Nutrition-only, Exercise-only, or full NELIP. Exercise-only intervention reduced rate of weight gain (0.15 ± 0.13 kg/week vs 0.61 ± 0.12 kg/week, p=0.01) compared to Nutrition-only. Combining a nutrition and exercise intervention appeared difficult for this population, as 100% of the women randomized to full NELIP did not complete the program.

Keywords

"Obesity, gestational weight gain, exercise and pregnancy, nutrition and pregnancy, gestational diabetes mellitus, macrosomia, small birth weight"

Co-Authorship Statement (for future publication)

Dr. Michelle Mottola - R. Samuel McLaughlin Foundation - Exercise & Pregnancy Laboratory, School of Kinesiology, Faculty of Health Sciences, The University of Western Ontario, London, ON; Department of Anatomy & Cell Biology, The University of Western Ontario, London, ON

Dr. Barbra de Vrijer – Obstetrician/Gynaecologist, Associate Scientist, Division of Maternal, Fetal & Newborn Health, Children's Health Research Institute Associate Professor, Maternal-Fetal Medicine Subspecialist, Department of Obstetrics & Gynaecology, The University of Western Ontario, London, ON

Dr. Debbie Penava – Obstetrician/Gynaecologist, Associate Scientist, Division of Maternal, Fetal & Newborn Health, Children's Health Research Institute Associate Professor, Department of Obstetrics & Gynaecology, The University of Western Ontario, London, ON

Dr. Maggie Sopper - R. Samuel McLaughlin Foundation - Exercise & Pregnancy Laboratory, School of Kinesiology, Faculty of Health Sciences, The University of Western Ontario, London, ON

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Chapter 1

1 Obesity

The following chapter will begin by discussing the prevalence of obesity in the nonpregnant individual. The chapter will review obesity management, psychosocial issues associated with obesity, physical activity and obesity, barriers and challenges of obesity and the role of health care practitioners in the treatment and prevention of obesity. The latter half of the chapter will focus on maternal obesity and discuss what has been learned from weight management issues in the non-pregnant obese population to assist in preventing excessive gestational weight gain in obese pregnant women. Increased pregnancy complications, childhood obesity risk and the risk of gestational diabetes mellitus as a result of obesity will also be discussed. Pregnancy weight gain guidelines will be examined, and physical activity during pregnancy will be discussed. Maternal obesity management and intervention strategies will be evaluated while considering the challenges and barriers to adopting a healthy lifestyle for an obese pregnant woman with a summary of factors that may relate to successful intervention strategies.

1.1 Prevalence of Obesity

Obesity is the second highest cause of preventable disability and death in the developed world (House of Commons Health Committee, 2004). Obesity is clinically defined by body mass index (BMI), which is calculated by dividing weight in kilograms by height in meters squared (kg/m²) (Gilmore, 1999). There are three classes of obesity outlined by the World Health Organization (WHO, 1997). A BMI of 30.0 to 34.9kg/m² constitutes Obese Class I (high risk of developing health problems), 35.0 to 39.9kg/m² constitutes Class II (very high risk), and ≥ 40.0 kg/m² constitutes Class III (extremely high risk) (see Table 1). The WHO estimates that 1.9 million people die annually as a result of physical inactivity, while 2.6 million people die as a direct result of being overweight and/or obese (Tunstall-Pedoe, 2006). The morbidity and mortality associated with obesity presents a huge economic burden on the Canadian health care system (Plourde, 2006). Over a

decade ago, in 2001, the cost of obesity was estimated at \$4.3 billion per year (Pirkola et al., 2010).

 Table 1: Body mass index (BMI) classification related to health risks for men and women

	BMI range	Risk of developing health problems
Underweight	<18.5	Increased
Normal weight	18.5 to 24.9	Least
Overweight	25.0 to 29.9	Increased
Obese Class I	30.0 to 34.9	High
Obese Class II	35.0 to 39.9	Very high
Obese Class III	≥40.0	Extremely high

Source: Davies et al., 2010

1.1.1 Obesity Management

The Canadian Obesity Network (2011) describes obesity as a chronic and often progressive condition that requires realistic and sustainable treatment strategies for successful weight and health management (Canadian Obesity Network, 2011). To best treat obesity the '5 A's of Obesity Management' were created for the non-pregnant population. Firstly, health care providers must *ask* for permission to discuss weight, as it is a sensitive issue that may evoke feelings of embarrassment, fear, blame and stigma. Secondly, all obesity related risks based on BMI classification and potential causes of weight gain should be *assessed*. Thirdly, health care providers should *advise* on obesity risks and discuss the benefits of weight loss and treatment plans. Emphasis should be placed on improving overall health and well-being rather than weight loss. Health care providers and patients should *agree* on realistic weight-loss expectations and initiate a SMART plan (specific, measurable, achievable, rewarding and timely goals). It is important to help patients set weight targets based on a weight that is sustainable while still enjoying life. Unrealistic weight-loss expectations can lead to disappointment and non-adherence. Lastly, providers should *assist* in addressing barriers, and offer education, resources, referrals and follow-up appointments as necessary. It is important to identify the 'root causes' of weight gain when considering the barriers to weight management. Weight gain may result from a reduction in metabolic rate, overeating, or reduced physical activity. However, these factors typically stem from psychological or socioeconomic issues (Canadian Obesity Network, 2011).

1.1.2 Psychosocial Issues of Obesity

Stress during childhood has been associated with increased risk for weight problems during adolescence and adulthood (Johnson et al., 2002). Eating disorders, anxiety and compulsive behaviours seen in adult obese patients are often associated with past or ongoing abuse (whether that be physical, sexual or emotional) (Grilo et al., 2006). Van der Waerden et al. (2013) found that exercise has both a preventative and therapeutic impact on mental health problems that occasionally underlie an obesity diagnosis. The study attempted to reduce stress and depressive symptoms in women with lowsocioeconomic status using a group-based program consisting of part physical exercise and part psycho-education (Van der Waerden et al., 2013). The psycho-education component involved a multi-component intervention developed to counter the negative effects of stressful events, reduce depressive symptoms and improve access to psychological resources (Van der Waerden et al., 2013). The intervention was nonstigmatizing, as it was presented and executed as a course rather than therapy. This was important in low SES groups as they are more likely to report stigma concerns for mental health issues, which may inhibit their use of mental health services (Grote et al., 2007). Literature typically suggests that a population of women with low-socioeconomic status is generally considered hard to reach for participation in prevention and research trials (Gadalla, 2008). However, it was found that exercise alone or in combination with psycho-education is a viable prevention option for disadvantaged women, especially those women with low-socioeconomic status who have been found to have higher rates of stress, depression and anxiety (Van der Waerden et al., 2013). It is recommended that health care professionals complete mental health screening, as deemed appropriate on obese adults (Lau et al., 2006).

Obesity prevalence is greater in lower socioeconomic groups (Mauro et al., 2008). This can be attributable to the greater number of fast-food restaurants in low-income neighbourhoods, the high cost of healthy food, safety concerns that prevent walking or outdoor activities, and greater social acceptance of excess body weight (Mauro et al., 2008). The affordability of gym memberships, commercial weight-loss programs and obesity medications may also be barriers for low-income individuals (Mauro et al., 2008).

1.1.3 Physical Activity and Obesity

Sedentary lifestyle contributes to the prevalence of overweight and obesity (Ball et al., 2000; National Audit Office, 2001). Increased exercise engagement should therefore be one tool to tackle the 'obesity epidemic' (Tunstall-Pedoe, 2006). Simple activities like walking, rather than vigorous exercise or competitive sports, is one strategy that should be targeted to obese individuals (Ball et al., 2000). The use of a pedometer as a tracking device and feedback tool is an effective way to increase physical activity (Tudor-Locke et al., 2002). Taking 10,000 steps per day is considered an active lifestyle; 3100-4000 steps taken are equivalent to 30 minutes of walking at a moderate intensity (Tudor-Locke et al., 2002). Promotion of regular physical activity will potentially deliver multiple health benefits at a population level through reducing the health effects associated with inactivity, overweight and obesity (Ball et al., 2000).

1.1.4 Barriers to Physical Activity in Obese Individuals

Little research has been conducted on exercise initiation and maintenance among obese individuals (Biddle & Fox, 1998). A significant proportion (22.6%) of obese participants report that being too fat is a barrier to increasing their level of physical activity, and many of these respondents were women (Ball et al., 2000). Other intrapersonal barriers reported include comorbidities (mental health, sleep, pain, cardiovascular (CV) disease, etc.), an injury or disability, too shy or embarrassed, not athletic, being generally unmotivated and lazy to initiate an exercise program, disproportionate focus on weight loss, and previous

negative experiences with exercise (Ball et al., 2000; Chambliss et al., 2004; Mauro et al., 2008). Environmental factors such as proximity to facilities, as well as personal factors such as time constraints and children, are common barriers frequently reported by both normal and overweight individuals (Chambliss et al., 2004). Further research is required to consider the intrapersonal factors that reinforce the initiation and maintenance of physical activity among the obese (Ball et al., 2000).

1.1.5 Challenges and Barriers of Obesity

One of the most successful and recent prevention interventions in public health was promoting smoking cessation (Volkow & Wise, 2005). The obesity epidemic offers a unique challenge, as food, unlike cigarettes, is necessary for survival. It is difficult for a society to implement regulations that will limit easy access to food that can lead to compulsive eating. Restricted access to high-fat high-calorie foods that are unnecessary for the maintenance of good health is required, particularly in public places (Volkow & Wise, 2005).

It is essential that health behaviour counseling is framed in a positive manner (emphasize the health benefits of increased physical activity and weight loss) rather than in a negative manner (emphasizing the detrimental effects of remaining obese) (Forman-Hoffman et al., 2006). Some clinicians believe that having obese patients complete questionnaires rating their readiness to change prior to the visit would be helpful (Forman-Hoffman et al., 2006). Further research is required to determine the effectiveness of this strategy.

Whether health care providers accept obesity as a chronic disease influences the way obese patients are counseled; 83% of clinicians who considered obesity a disease counseled their patients in a positive context, while only 50% of clinicians who did not consider obesity a disease counseled their patients in a positive context (Forman-Hoffman et al., 2006). Clinicians who believe obesity is a disease may be more compassionate towards obese patients versus those clinicians who believe obesity is a result of a character flaw or a lack of willpower (Forman-Hoffman et al., 2006). Research indicates that health care providers who are most likely to counsel patients on weight management practices initiated conversations by "medicalizing" the obesity (Kizer et al.,

2000). In a recent report, the American Heart Association (AHA) now considers obesity a disease (Jensen et al., 2013) and advocates weight loss in obese individuals to prevent heart disease and stroke, America's number one and number four killers, respectively (Jensen et al., 2013). The health problems and risk factors of obesity that are being passed down through the generations can no longer be ignored (Jensen et al., 2013). A collaborative effort between the AHA, the American College of Cardiology (ACC) and the National Heart, Lung, and Blood Institute (NHLBI) resulted in updated evidence-based guidelines designed for health care providers to help patients lose weight and keep it off (Jensen et al., 2013).

1.1.6 Obesity and Health Care Practitioners

Participation of the medical community will be required to initiate large-scale prevention and treatment programs for obesity (Volkow & Wise, 2005). There are various provider level barriers that influence the management of obesity in primary care. Primary care practitioners may have a perceived inability to change patient behaviours, negative attitudes toward obese patients, a belief that patients are not interested or ready for treatment, or a belief that obesity is the responsibility of the patient (Forman-Hoffman et al., 2006). Furthermore, practitioners commonly have a lack of formal training in nutrition, obesity and weight management counseling (Forman-Hoffman et al., 2006). Few clinicians (23.6%) report learning beneficial obesity management practices in medical school and residency training programs (Forman-Hoffman et al., 2006). Weight management education would be beneficial to make obesity a higher priority for health care providers (Forman-Hoffman et al., 2006). The engagement of obstetricians, pediatricians and family physicians will aid in the prevention of obesity for the next generation (Volkow & Wise, 2005). More formal training for physicians, nurses, psychologists and social workers is required for improved management and prevention of obesity (Volkow & Wise, 2005).

It is unknown whether health behaviour and dietary counseling led by practitioners actually motivates patient behaviour (Forman-Hoffman et al., 2006). Patients and clinicians alike express the need for increased ease of access to obesity educators, dieticians, physical therapists and behavioural counselors for a well-rounded approach to health and weight management (Forman-Hoffman et al., 2006). Research demonstrates that many primary care clinicians do not regularly counsel or refer obese patients to weight management services (Forman-Hoffman et al., 2006). In one study, personal dietary vigilance by clinicians impacted the likelihood of regularly calculating the BMI of obese patients, with more vigilant clinicians being more likely to calculate BMI (Forman-Hoffman et al., 2006). There is conflicting literature as to the effect of weight management counseling initiated by clinicians who have a personal history of obesity. One study found that these clinicians were more likely to provide obesity counseling to patients (Epstin & Ogden, 2005). On the contrary, another study concluded that patients were more receptive to health counseling provided by non-obese physicians (Epstin & Ogden, 2005).

More often than not, primary care practitioners are not properly trained in the management of obesity. A well-rounded team of formally trained physicians, nurses, psychologists, social workers and kinesiologists is ideal to initiate and manage obesity treatment and prevention programs.

1.2 Maternal Obesity in Pregnancy

There has been a significant rise in the incidence of obesity among pregnant women, consistent with the increasing number of obese individuals (Hillier et al., 2007; Hiramatsu et al., 2000; Katzmarzyk et al., 2008); about 50% of women of childbearing age (20 to 34 years) are overweight or obese (Nascimento et al., 2012). In Canada alone, the number of overweight and obese women of childbearing age has increased by 80,409 in a four-year span from 2008 to 2012 (Statistics Canada, CANSIM, 2013). Consequently, the occurrence of pediatric obesity (among infants 0-11 months) in Canada is increasing at a frightening rate (Plourde, 2006). An overweight or obese child has a predisposition towards obesity as an adult (Shankar et al., 2008; Vanasse et al., 2006), which is bound to have critical consequences on Canadian health care as a generation of these obese children mature. Healthy lifestyle interventions targeting school-aged children occur too late to prevent childhood obesity (Wardle et al., 2006). Clinical research, therefore, suggests that prevention of obesity be initiated as early as pregnancy (Plourde, 2006). The Institute of Medicine (IOM) has outlined a specific range of

recommended gestational weight gain for obese women, based on pre-pregnancy BMI, with both the welfare of the infant and health of the mother being priority (Institute of Medicine, 2009). The antenatal period provides an opportunity to manage weight to reduce both maternal and fetal complications associated with excessive weight gain and maternal obesity (Nascimento et al., 2012).

Maternal obesity in pregnancy can lead to a lifetime of unhealthy weight for mother and baby (Mottola et al., 2010). Excessive weight gain during pregnancy is often followed by maternal weight retention postpartum, and these are independent predictors of long-term weight gain and obesity (Phelan et al., 2011). The cycle of excessive gestational weight gain and postpartum weight retention continues with each pregnancy thereafter, causing BMI to increase with each new child born, thus increasing the health risks associated with obesity. Pregnancy presents a time of powerful emotional, social, identity and physical changes, as well as a new awareness that maternal behaviour may impact offspring health (Phelan et al., 2014). This new awareness during pregnancy may provide an incentive for women to adopt healthy nutrition and physical activity behaviours (Phelan et al., 2014). Aggressive preventative management is recommended for all overweight and obese women prior to pregnancy, during pregnancy and after delivery to reduce the risk of pregnancy complications and health issues for both mother and baby in the future (American College of Obstetricians & Gynecologists, 2005). The increasing prevalence of maternal obesity demands an even more rigorous intervention strategy carried out by a team of health care practitioners to properly manage treatment in an obese pregnant woman.

1.2.1 Maternal Obesity Increases Pregnancy Complications

There are numerous medical complications associated with maternal obesity that may arise during pregnancy. Depending on pre-pregnancy BMI, an increased risk of macrosomia (birth weight >4.0 kg), augmentation of labour, gestational hypertension and neonatal metabolic abnormalities can occur (Davies et al., 2010). With maternal obesity there is an increased rate of fetal anomalies, one being neural tube defects (Davies et al., 2010). One study reported a two-fold increase in neural tube defects in the offspring of obese women (Nuthalapaty & Rouse, 2004). A dose response was also noted, with heavier women having an even higher risk (Nuthalapaty & Rouse, 2004). Repeat ultrasounds may be required for women with a BMI above the 90th percentile and obstetricians should consider BMI when scheduling a fetal anatomic assessment in the 2nd trimester (Davies et al., 2010; Wolfe et al. 1990). Earlier ultrasounds may be optimal for high-risk, high BMI pregnancies to detect abnormalities sooner rather than later.

Further pregnancy complications include spontaneous abortion, more severe forms of preeclampsia, and gestational diabetes mellitus (GDM). The obese population is at an increased risk of recurrent early miscarriages (Lashen et al. 2004). The most prevalent risk factor for unexplained still birth is pre-pregnancy obesity (Fretts, 2005). Fetal and uterine monitoring are challenging intrapartum complications, due to the maternal pannus and difficulty transducing fetal heart rate and maternal contractions (Davies et al., 2010). Maternal obesity is associated with an increased rate of Caesarean sections due to macrosomia and the possibility of shoulder dystocia (Davies et al., 2010). Caesarean section rates were 14.3% for lean women (BMI<19.8kg/m²) and 42.6% for very obese women (BMI≥35.kg/m²) (Perlow & Morgan, 1994; Wall et al., 2003). Furthermore, obese women undergoing Caesarean section experience more complications, which may include blood loss >1000mL, increased operative time, increased postoperative wound infection and endometritis, and the need for vertical skin incision (Perlow & Morgan, 1994; Wall et al., 2003). Obstetric anesthesia complications and the risk of epidural failure are increased in obese women (Davies et al., 2010). Multiple attempts at catheter placement for anesthesia may also be required (Davies et al., 2010).

1.2.2 Maternal Obesity Increases Childhood Obesity Risk

Maternal obesity in early pregnancy may increase the risk of offspring obesity in childhood, adolescence, and adulthood (Laitenen et al., 2012). Maternal weight gain >7.0 kg during the first half of pregnancy is associated with a nearly 1.5-fold increased risk for a child to be overweight or obese in adolescence (Laitenen et al., 2012). Statistics indicate that children of obese mothers are twice as likely to be large for gestational age at birth, and are more likely to be obese at preschool age (Hiramatsu et al. 2000; Mottola et al., 2010). Moreover, research suggests that early exposure to certain diets during fetal life can influence the food preferences of an individual later in life (Mennella et al. 2004;

Volkow & Wise, 2005). Childhood obesity has repeatedly shown to be a strong predictor of adult obesity (Flynn et al., 2006; Plourde, 2006), particularly in those children who are overweight and experience adolescent obesity or have at least one parent who is obese (Flynn et al., 2006).

There is growing research demonstrating the *in utero* environment is a predictor of future neonatal, child and adult health risks (Simmons, 2008). Data consistently suggest that excessive maternal weight gain and pre-pregnancy BMI have been correlated with birth weight (Mottola, et al., 2010). Overweight and/or obese women are at an increased risk of giving birth to larger babies (>90th percentile), even after controlling for GDM (Nomura et al., 2012; Shankar et al., 2008). The odds of an infant weighing more than 4.0kg at birth was 1.7 times greater for obese mothers and 2.0 times greater for obese mothers of Class 2/3 (Bellver et al., 2003). Maternal obesity has been shown to be an independent risk factor for macrosomic infants (Artenisio, et al., 1999). Excessive gestational weight gain may also predict macrosomia as the majority of Canadian women (58%) who gained more weight than recommended gave birth to an infant weighing 4.0 kg or more (Lowell & Miller, 2010). Furthermore, a 1kg increment in birth weight in full-term infants was associated with an approximate increase of 50% in the risk of the child being overweight at ages 9-14 years (Gillman et al., 2003).

1.2.3 Maternal Obesity and Gestational Diabetes Mellitus (GDM) Risk

Excessive maternal weight gain is associated with a substantially higher risk of GDM (Chu et al., 2007), as an elevated BMI is a major risk factor for developing GDM (Davenport et al., 2010). A positive relationship exists between BMI and maternal glucose disorders. Davenport et al. (2010) noted that as pre-pregnancy BMI increased, the prevalence of maternal glucose disorders also increased. GDM diagnosis during pregnancy has been associated with increased Caesarean section deliveries due to the incidence of large for gestational age (LGA) babies, as well as gestational hypertension (Davenport et al., 2010). GDM affects 3-4% of Canadian pregnancies and this statistic is on the rise due to the obesity epidemic and decreasing physical activity (Canadian Diabetes Association, 2003; Catalano et al., 2009; Dempsey et al., 2004; Dempsey et al.,

2004A; Ferrara, 2007; Jovanovic & Pettitt, 2001). In London, Canada, the prevalence of GDM has increased by 52%, while the incidence of type 2 diabetes has increased by 206% between 2000 and 2009 (Davenport et al., 2010).

The diagnostic criteria for GDM remain controversial and the 2013 CDA guidelines differ from those of the American Diabetes Association (ADA, 2013; CDA, 2013). The 2013 CDA expert committee chose a preferred approach and an alternate approach to screening GDM. The preferred approach begins with a 50 mg glucose challenge test, and if appropriate, is followed up with a fasted 75 g oral glucose tolerance test (OGTT). GDM is diagnosed with \geq 1 abnormal value. The increased maternal and perinatal morbidity associated with GDM resulted in both the CDA and ADA guidelines outlining GDM screening as standard of care for all women, despite risk factors (CDA, 2013).

There is escalating evidence of long-term complications, such as obesity and diabetes, in children of women with maternal obesity and GDM (Hiramatsu et al., 2000). These long-term complications can include an increased risk of developing obesity, impaired glucose tolerance, type 2 diabetes and chronic disease (Dunger et al., 2007; Hillier et al., 2007). Emerging evidence suggests that maternal pre-pregnancy BMI is one of several key factors that influence childhood weight gain and adiposity (Baker et al., 2004; Catalano et al., 2009; Whitaker, 2004). Maternal pre-pregnancy BMI is significantly associated with abnormal fetal growth, and further, childhood overweight and obesity (Catalano et al., 2009). While maternal obesity is commonly linked to macrosomic infants, obese women with a BMI >30 kg/m² are also at risk for having a pregnancy complicated by a small birth weight infant (Leddy et al., 2008). The "catch-up growth" phenomenon links small birth weight infants to early onset obesity and the subsequent emergence of metabolic syndrome in those born small compared to appropriate for gestational age growth starting at puberty.

In a cohort of low income children, maternal obesity during pregnancy more than doubled the risk of obesity in children (Whitaker, 2004). Hyperglycemia during pregnancy, a consequence of GDM, is correlated with obesity in children aged 5-7 years (Hillier et al., 2007), while childhood obesity is associated with a dramatic increase in the prevalence of chronic disease (Flynn et al., 2006). Risk factors for chronic cardiovascular disease, specifically hypertension, as well as impaired glucose tolerance, dyslipidemia and hyperinsulemia have all been identified in obese children as young as 5 years (Csabi et al., 2000; Flynn et al., 2006). The combination of obesity and chronic disease are undeniably early risk factors for future morbidity in adulthood (Plourde, 2006). Maternal nutrition and physical activity are incredibly important during pregnancy as they impact the offspring risk of developing obesity and metabolic disease (Catalano et al., 2009). Physical activity during pregnancy in particular has been shown to significantly reduce the risk of GDM (Davies et al., 2010).

1.2.4 Physical Activity During Pregnancy in Non-Obese Women

Pregnant women seek medical care more readily and are often highly motivated to make healthy lifestyle changes (Artal et al., 2007). Not only does a lifestyle intervention program using nutrition and exercise reduce pregnancy weight gain, it also improves pregnancy outcomes and can have a significant impact on future behaviours (Artal et al., 2007). Pregnancy, therefore, provides an ideal time to make lasting lifestyle changes (Artal et al., 2007). Unfortunately, pregnancy has also been associated with a sharp decline in exercise and an increase in sedentary behaviour (Gaston and Cramp, 2011). Few pregnant women are meeting exercise guidelines due to a decrease in frequency and intensity from pre-pregnancy to pregnancy (Gaston and Cramp, 2011). For pregnancy specifically, a commonly cited barrier is fatigue (Gaston and Cramp, 2011).

A growing body of literature suggests women be encouraged to participate regularly in physical activity during pregnancy (Davies et al., 2003). Physical activity during pregnancy has numerous benefits in addition to the prevention of excessive weight gain, some of which include improved psychological well-being (Hartmann & Bung, 1999), improved response to a carbohydrate load (Jovanovic-Peterson & Peterson, 1996), decreased incidence of macrosomic babies resulting in delivery complications (Pivarnik, 1998) and quicker recovery following delivery (Giroux et al., 2006). Exercise during pregnancy is associated with higher cardiorespiratory fitness, prevention of low back pain, decreased symptoms of depression, and decreased insulin use for those with GDM (Nascimento et al., 2012). The literature consistently indicates that physically active pregnant women feel better and experience fewer symptoms (including shortness of breath, backaches, headaches, vomiting and hot flashes) associated with pregnancy (Gaston and Cramp, 2011).

1.2.5 Assessing Physical Activity Readiness During Pregnancy

The Canadian Society for Exercise Physiology has developed a Physical Activity Readiness Medical Examination for Pregnancy (PARmed-X) tool as a guideline for health screening prior to participation in prenatal exercise. PARmed-X for pregnancy is a convenient checklist for health care providers to evaluate patients and can be used for ongoing medical surveillance during pregnancy (PARmed-X for Pregnancy, CSEP, 2013). PARmed-X for pregnancy prescribes a prenatal fitness program based on the FITT principle (frequency, intensity, time and type of exercise). In terms of aerobic exercise, it is recommended that pregnant women exercise three to four times weekly at a moderate intensity (Davies et al., 2003; PARmed-X for Pregnancy, CSEP, 2013). Intensity of exercise should be monitored using a combination of a target heart rate range and a rating of perceived exertion (RPE) scale. Lower target heart rate zones are recommended for pregnant women with a pre-pregnancy BMI of $>25 \text{kg/m}^2$ with a target range of 102-124 beats per minute (bpm) for a maternal age of 20-29 years, and 101-120 bpm for a maternal age of 30-39 years (Davenport et al., 2008). Pregnant women should attempt to exercise for 15 minutes, even if it means reducing the intensity. Rest intervals may be incorporated. Non-weight bearing or low-impact endurance exercises using large muscle groups (e.g., walking, stationary cycling, swimming, aquatic exercises, low impact aerobics) is recommended, preceded by a brief warm up and followed by a short cool down (PARmed-X for Pregnancy, CSEP, 2013).

1.2.6 Pregnancy Weight Gain Guidelines

To improve maternal and child health outcomes, women should aim to remain within the projected pregnancy weight gain recommendations. The Institute of Medicine (2009) has issued pregnancy weight gain guidelines based on BMI (see Table 2). Underweight women ($<18.5 \text{ kg/m}^2$) are recommended to gain 12.7-18.1 kg during pregnancy at a rate

of 0.45 kg/week. Normal weight women (18.5-24.9 kg/m²) are recommended to gain 11.3-15.9 kg at a rate of 0.45 kg/week. Overweight women (25.0-29.9 kg/m²) are recommended to gain 6.8-11.3 kg at a rate of 0.32 kg/week. Lastly, obese women (\geq 30.0 kg/m²) are recommended to gain 5.0-9.0 kg at a rate of 0.27 kg/week (Institute of Medicine, 2009). These calculations assume a 0.5-2.0 kg weight gain in the first trimester (Institute of Medicine, 2009). A range of weight gain is necessary because a single number cannot accommodate factors such as age and race/ethnicity that may affect pregnancy outcomes.

 Table 2: Recommendations for total and rate of weight gain during pregnancy by

 pre-pregnancy body mass index (BMI)

Pre-pregnancy BMI	BMI	Total weight gain range (kg)	Rates of weight gain 2 nd and 3 rd trimester (maximum kg rate per week)
Underweight	<18.5	12.7-18.1	0.45
Normal weight	18.5-24.9	11.3-15.9	0.45
Overweight	25.0-29.9	6.8-11.3	0.32
Obese (includes all classes)	≥30.0	5.0-9.0	0.27

Source: IOM, 2009

Those who are obese at the time of conception are recommended to gain less pregnancy weight in total compared to a woman of normal weight (Institute of Medicine, 2009). A substantial number of pregnant women surpass these goals (Polley et al., 2002). In a study of over 4000 women from the University of California, 70% of overweight (BMI \geq 25 kg/m²) women exceeded the recommendations (Polley et al., 2002). In another study, 42% of women gained excessively according to the Institute of Medicine recommended

guidelines (Olson et al., 2003). Lastly, Pereira et al. (2007) found that 52.7% of women in all BMI categories had excessive gestational weight gain. Canadian statistics reveal similar findings. Women with a higher pre-pregnancy BMI were more likely than normal or underweight women to gain more weight than recommended during pregnancy (Lowell & Miller, 2010). Fifty-five % of overweight/obese pregnant women gained more than the IOM gestational weight gain guidelines, compared with 41% of those who were normal weight and 25% who were underweight (Lowell & Miller, 2010).

Few pregnant women report being counseled correctly regarding weight gain and the risks associated with excessive gestational weight gain by their health care practitioner despite the revised 2009 IOM guidelines. Only 28.5% of the women reported their health care provider made a recommendation about how much weight they should gain, while 25% reported being told the risks of inappropriate or excessive weight gain (McDonald et al., 2011). A mere 12% of the women achieved the recommended weight gain in accordance with the 2009 IOM guidelines (McDonald et al., 2011).

A significant number of patients (51.3%) reported that gestational weight gain was not discussed at all during their first prenatal appointment, while 44.8% of patients reported that exercise during pregnancy was not discussed (McDonald et al., 2011). Evidently, there is a need for better patient education to improve the knowledge deficit for many pregnant women regarding the recommended weight gain guidelines (McDonald et al., 2011). Tovar et al. (2010) found similar results while evaluating the knowledge about gestational weight gain in Hispanic women; a group typically found to have higher obesity rates. The majority of the overweight and obese women reported that they had not received any recommendations from physicians for weight gain during their pregnancy (Tovar et al., 2010). For those who received gestational weight gain education, pregnancy weight gain advice was not always consistent with IOM guidelines and was found to vary widely (Tovar et al., 2010).

1.2.7 New Literature in Pregnancy Weight Gain Guidelines

New research has just recently suggested that IOM weight gain guidelines are just that – recommendations that reserve the right to be individualized on a case by case basis,

taking into account known risk factors. This matter is complicated by the American Congress of Obstetrics and Gynecology committee, who recently suggested there may be potential benefits of gaining below guidelines for an obese woman, as long as the fetus is growing at a healthy rate (Kapadia et al., 2015). However, accurate clinical estimation of fetal growth using ultrasound is especially difficult in obese women and may not always be reliable.

Kapadia et al. (2015) aimed to determine the risk of adverse pregnancy outcomes with GWG below 2009 IOM guidelines and within the guidelines in obese women. Primary outcome measurements were preterm birth, small for gestational age (SGA) and large for gestational age (LGA). SGA was defined as birth weight less than 3rd and less than 5th percentile for sex and gestational age, while LGA was defined as birth weight >95th and >97th percentile for sex and gestational age. GWG below the guidelines had higher odds of preterm birth and SGA babies and lower odds of LGA than GWG within the guidelines.

Swank et al. (2014) conducted a retrospective cohort study where super obese women $(BMI \ge 50 \text{ kg/m}^2)$ were stratified to below, within and above IOM GWG guidelines. Weight gain below IOM guidelines was not associated with statistically significant increased odds of preterm birth or small babies, while LGA was significantly reduced for the super obese women. Excessive weight gain statistically increased odds of pregnancy induced hypertension and Cesearean delivery, while not reducing odds of small birth weight babies. Swank et al. (2014) suggested that minimal weight gain in this population is not detrimental to fetal growth, and may actually be protective against the development of macrosomia. In summary, the study found that women with BMI \ge 50 kg/m² may warrant individualized GWG recommendations.

As previously mentioned, it is recommended that obese women gain 5-9 kg during pregnancy. It is interesting to note that gaining the lower limit of this range would actually result in maternal weight loss following birth, since approximately 6 kg of weight gained during pregnancy can be attributed to additional extracellular fluids, blood, amniotic fluid, growth of the uterus and breast tissue, and the placenta (Kapadia et al.,

2015). It is difficult to recommend GWG below the 2009 IOM guidelines considering the lack of research as of late, as well as the increased risk of small birth weight and preterm birth. GWG should be monitored closely, taking into account IOM recommendations and individual risk factors.

1.2.8 Excessive Gestational Weight Gain and Weight Retention

For many women, obesity is initiated by an excessive weight gain during pregnancy (Clark and Odgen, 1999). Numerous studies have found that pre-pregnancy weight is a strong predictor of 12-month post-partum weight retention (Hartmann & Bung, 1999; Moher et al., 2012). Overweight and obese women retain more weight post-partum versus normal weight women (Harmann & Bung, 1999; Moher et al., 2012). A higher pre-pregnancy weight is also associated with exceeding weight gain goals in accordance with IOM recommendations (Nohr et al., 2008).

Women in the normal, overweight and obese BMI categories who gained excessively during pregnancy retained significantly more weight at one year post-partum (Olson et al., 2003). Statistics Canada reports that women who gained more weight than recommended during their pregnancy retained more weight (4.5 kg on average) than women who gained within (2.0 kg) or below the 2009 IOM recommendations (0.5 kg) (Lowell & Miller, 2010). Clark and Odgen (1999) reported that women who later went on to develop morbid obesity following pregnancy had already gained 4 kg more than the control women at a mere 6 weeks post-partum. Overweight and obese women may require more intensive lifestyle interventions to reduce excessive gestational weight gain and weight retention than normal weight women (Phelan et al., 2014). This is particularly true for obese women because of the more restricted recommended range of weight gain (Phelan et al., 2014).

1.2.9 Maternal Obesity Management

All pregnant women, including those who are obese, are advised to keep gestational weight gain within the IOM recommended parameters (classified by pre-pregnancy BMI) to improve the health and well-being of both mother and baby. The Canadian Obesity Network recently released a guide for practitioners titled the "5 A's of Healthy

Pregnancy Weight Gain," addressing how to manage obese pregnant women in particular. After weight gain recommendations have been established early in pregnancy, it is important to identify and discuss the "root causes" of obesity itself, as well as the myths and barriers associated with managing gestational weight gain. Barriers may include environmental, socioeconomical, emotional, medical or cultural factors, as well as physical barriers or physical discomfort (e.g. lack of sleep, mobility issues which may hinder participation in daily activities). Practitioners must understand a woman's cultural context to fully understand her behaviours and provide an effective intervention, as pregnancy-related health beliefs can be powerful influences on weight gain. Offering credible resources and education are essential to improve understanding and weight selfmanagement. Evidence supports an interdisciplinary team approach for successful weight management (Canadian Obesity Network, 2013). Depending on the identified complications of excessive weight gain and/or the barriers to weight management during pregnancy, providers may include general practitioner, obstetrician, midwife, nurse, dietician, exercise physiologist, psychologist and social worker. Given the prevalence of excessive weight gain and the subsequent high probability of post-partum weight retention, pregnancy is an ever more critical period for obese women.

1.2.10 Difficulty of Behaviour Change and Obesity

Various interventions combining physical activity, nutrition and healthy gestational weight gain guidelines have been implemented for normal weight women. A large number of these intervention studies were unfortunately not successful at reducing mean gestational weight gain and preventing excessive gestational weight gain based on IOM guidelines. One potential reason that gestational weight gain interventions may have success among normal weight women but not obese women is that overweight and obese pregnant women may have unique barriers that require a more intensive intervention. Many factors that may influence weight gain during an obese pregnancy in particular are related to behaviour (energy intake, physical activity), psychological factors (attitude, perceived control, intention), sociodemographic issues (age, parity) and physical factors (BMI) (Savage et al., 2014).

Renault et al. (2014) recently assessed gestational weight gain in obese pregnant women using a physical activity intervention with or without dietary intervention. There was no significant difference found between the two interventions, and the additive effect of the dietary intervention was not significant. Compliance was an issue in the study as a large part of the participants did not follow the dietary or physical activity advice. If only compliant participants were measured, the weight reduction of the intervention group may have been more pronounced. In a review by Pearce et al. (2013), only three interventions of the ten randomized control trials included reported statistically significant differences between the intervention and control groups. Unfortunately, compliance was not consistently reported in the review and it remains unknown if participants were adherent to the interventions. Findings suggest that there is little known about the efficacy of interventions for obese pregnant women.

Few interventions have had success specifically targeting gestational weight gain in overweight and obese pregnant women. Shirazian et al., (2010) developed a prenatal intervention for obese women consisting of six seminars and individual counseling sessions promoting healthy eating, walking and obesity education during pregnancy. Obese women in the intervention group gained less weight than those in the standard care group $(8.1 \pm 7.4 \text{ kg versus } 15.3 \pm 7.5 \text{ kg}, p=0.003)$ (Shirazian et al., 2010). A limitation of the study was that physical activity and eating habits were not reported. Shirazian et al. (2014) later conducted another intervention revolving around educational and individual counseling sessions focused on diet, exercise and weight goals. The free program began in the first trimester and consisted of six group seminars, one-on-one counseling and telephone calls. Fifty % completion of food diary and pedometer recordings were emphasized. The curriculum aimed to educate women on obesity and pregnancy, promote healthy eating and encourage walking as exercise. Barriers to a healthy lifestyle were addressed and all participants met with a dietician at least once during prenatal care. GWG was lower in participants versus control group, though not significant. The number of sessions attended was associated with a decrease in total weight gain, demonstrating participant attendance is key (Shirazian et al., 2014).

Nascimento et al. (2011) conducted weekly aerobic dance classes of moderate intensity, with recommendations about weekly physical activity and healthy gestational weight gain for both overweight and obese women. A lower mean gestational weight gain was seen in the intervention group $(10.0 \pm 1.7 \text{ kg})$ versus control $(16.4 \pm 3.9 \text{ kg}, \text{p}=0.001)$, but only for overweight women (Nascimento et al., 2011). Physical activity levels of women in the control group were not reported.

An intervention including only obese women implemented by Claesson et al. (2008) focused on behaviour change via motivational interviews and individual counseling sessions, and physical activity in the form of aqua aerobic classes 1-2 times per week. The intervention group gained less weight (8.7 ± 5.5 kg) compared to the control group (11.3 ± 5.8 , p <0.001) (Claesson et al., 2008). Seventy-eight % of intervention participants actively participated in the counseling sessions and aqua aerobic classes once per week.

McGiveron et al. (2014) developed an intensive health education program around diet and exercise, titled the Bumps and Beyond Intervention for obese pregnant women. The program offered one-to-one guidance and monitored dietary change while comparing 89 intervention women to 90 non-intervention women. The intervention group gained less weight than the non-intervention group (4.5 kg vs 10.3 kg, respectively). Twenty-one % of the intervention group lost weight during pregnancy. Women in the intervention group must have attended 7/8 sessions to be included in analysis. The researchers concluded that women must perceive the benefits of physical activity and healthy eating to ultimately change their lifestyles (increase level of physical activity and reduce unhealthy eating) (McGiveron et al., 2014).

Phelan et al. (2014) conducted behaviour interventions via telephone that targeted gestational weight gain, healthy eating and exercise. The intervention increased the percentage of women achieving pre-pregnancy weight at 12-months postpartum (35.4% vs 28.1%) and significantly reduced the weight retained (1.4 kg vs 3 kg) compared to the control group, respectively. Seventy-nine % of participants completed the study through 12 months postpartum.

In a review of physical activity (PA) and physical activity plus diet interventions in managing weight among overweight or obese pregnant women, Choi et al. (2013) concluded that PA plus diet interventions are most effective in managing weight regardless of body weight status in pregnant women. In addition, Phelan et al. (2011) concluded that the best weight control strategies for both non-pregnant and pregnant women appears to be the combination of PA and caloric management, with the addition of behavioural strategies including frequent self-monitoring of diet and body weight. Phelan et al. (2011) examined weight control literature of the past 30 years outside of pregnancy to identify the key components of effective programs to potentially apply the research to managing weight in the pregnant population. The researchers argue that effective weight control strategies outside of pregnancy may also promote better weight control and prevent excessive weight gain during pregnancy. The key components of effective programs included use of caloric restriction, daily diet self-monitoring, selfweighing, behaviour therapy and ongoing patient-provider contact. Phelan et al. (2011) reported that several clinical trials have found that structured meal plans, which simplifies food selection and shopping for patients, improves adherence to calorie goals and improves long-term weight loss outcomes. In terms of physical activity in the nonpregnant population, it was found that long-term results were better in home based exercise programs, including the use of pedometers, to improve adherence. Weight control literature in the non-pregnant population suggests that daily self-monitoring of diet and body weight improves adherence, accountability and motivation.

In a randomized trial in early pregnancy, Harrison et al. (2014) found regular selfweighing combined with a self-management intervention optimized weight gain at 28 weeks gestation ($5.66 \pm 2.6 \text{ kg vs } 7.03 \pm 3.56 \text{ kg}$) and reduced post-partum weight retention ($0.57 \pm 3.94 \text{ kg vs } 1.48 \pm 5.49 \text{ kg}$) compared with control participants. The selfmanagement intervention focused on self-directed changes to lifestyle behaviours, goal setting and problem solving skills. Intervention participants were encouraged to plot their GWG on a chart and self-weigh regularly.

Research continually suggests that pregnant overweight and obese women require more than advice; supervised and personalized programs and goals are needed to prevent excessive weight gain (Choi et al., 2013). Continued patient-provider contact (≥ 2 visits/month) seems to provide patients with the support and motivation required to continue to practice weight control behaviours (Phelan et al., 2011A).

A mild exercise (i.e., walking program) in obese patients is beneficial when used in combination with a nutritional program monitoring carbohydrate intake, to limit gestational weight gain (Artal et al., 2007). The inclusion of mild exercise is advantageous during pregnancy because dietary control alone may reduce not only fat mass but also fat-free mass (Mottola et al., 2010). A reduction in fat-free mass in combination with a lack of physical activity in obese women may lead to insulin resistance, impaired glucose tolerance and possibly GDM (Mottola et al., 2010). As a result, Mottola et al. (2010) devised a lifestyle intervention program incorporating both dietary control and physical activity to prevent excessive pregnancy weight gain in overweight and obese women. The Nutrition and Exercise Lifestyle Intervention Program (NELIP), designed at the Exercise and Pregnancy Lab, Western University, London, Canada, has since been posted as best practice on the portal website from the Public Health Agency of Canada; http://cbpp-pcpe.phac-aspc.gc.ca/interventions/nutritionexercise-lifestyle-intervention-program/. NELIP was implemented at 16-20 weeks gestation and reduced excessive weight gain with minimal weight retention at 2 months postpartum in overweight and obese women, with an 80% success rate (Mottola et al., 2010). It has been shown that pregnancy weight gain during the first 20 weeks of gestation is predictive of total weight gain (Polley et al., 2002). Therefore, it may be possible to identify women in early pregnancy that may be at risk for exceeding weight gain recommendations, allowing for early nutrition and exercise counseling and interventions (Polley et al., 2002). It would be advantageous to begin the intervention earlier in gestation (12-16 weeks rather than 16-20) to prevent excessive weight gain (Mottola et al., 2010).

Ultimately, there is limited research on gestational weight gain control in obese (class 2/3) women. Literature suggests that pregnant women of normal BMI are often highly motivated to make lifestyle changes, thus pregnancy provides an ideal time to initiate a lifestyle intervention program. It is unknown if this remains true for obese women.

Research supports a multidisciplinary team approach of health care providers to improve care for obese pregnant women, who have unique and challenging barriers. Behavioural, psychological and physical barriers discussed previously may require a more intensive intervention. Literature routinely suggests that the best weight control strategy for both nonpregnant and pregnant women alike is a combination of PA and a dietary intervention. However, as previously mentioned, Renault et al. (2014) found that the additive effect of a dietary intervention on top of a PA intervention was not significant in controlling excessive GWG in obese pregnant women, contrary to what one would expect. While dietary control and physical activity is an ideal combination to prevent excessive GWG, it may not be a practical solution for obese pregnant women. Perhaps pregnancy is not the ideal time to make intensive lifestyle changes in the obese population because of the unique barriers these women face. Obese women may have difficulty with two behaviour changes (healthy nutrition and increased exercise simultaneously) and may find one lifestyle change easier to achieve (either nutrition or exercise) than both of these behaviour changes at the same time. The current pilot study has been designed to investigate how to better manage GWG and pregnancy outcomes for class 2/3 obese pregnant women.

Objectives of the current pilot trial include assessing feasibility, exploring the practical application for a pivotal randomized controlled trial, and evaluating the logistics of the trial (Loscalzo, 2009). Results obtained may be used to optimize the design in subsequent studies, and may help guide the effective use of limited (financial and non-financial) resources essential for a successfully performed intervention in the future (Loscalzo, 2009).

Chapter 2

2 Purpose

The primary purpose of the current pilot study was to investigate the efficacy of an evidence-based laboratory program, known as the Nutrition and Exercise Lifestyle Intervention Program (NELIP), in the clinical setting. The specialized clinical setting chosen was "*My Clinic*" located at the London Health Sciences Centre (LHSC) that provides specialized care for those women with a pre-pregnancy BMI of \geq 35 kg/m² and who have an increased obstetric risk for complications. A secondary purpose was to determine if a specialized clinic improved outcomes for obese pregnant women in London, Ontario.

Advanced care at *My Clinic* includes twice monthly clinic visits, additional ultrasounds for fetal assessment and oral glucose tolerance tests at first visit (extra), 28 weeks (usually done between 24 and 28 weeks) and 34 (extra) weeks gestation. These extra visits, assessments and tests are not routinely done in standard care. *My Clinic* care uses a team approach offering patients specialized obstetrical care, social work, and the expertise of a dietician and a kinesiologist. Patients of *My Clinic* have regular meetings with a dietician on staff where they receive education on Canada's Food Guide and healthy eating tips. A social worker and kinesiologist are available for patients if deemed appropriate or beneficial.

To determine if *My Clinic* care improved pregnancy outcome measures in women with class 2/3 obesity, those receiving *My Clinic* standard care were compared to a sanitized (no personal information) perinatal database (receiving no specialized obstetric care) containing information on birth outcomes in the City of London. The perinatal database was analyzed to determine whether maternal obesity class 2 and 3 (pre-pregnancy BMI \geq 35 kg/m²) is an issue regarding perinatal outcomes compared to those women with a pre-pregnancy BMI < 35 kg/m² that may necessitate specialized obstetrical clinic care. Rates of obesity and birth outcomes for women who delivered a singleton baby in London were evaluated.

In order to examine the efficacy of the NELIP in the *My Clinic* clinical setting, women recruited from *My Clinic* were randomized into one of three groups: 1) Women who received the full NELIP; 2) Women who received only the nutrition component of NELIP; or 3) Women who received only the exercise component of NELIP. GWG and pregnancy outcomes were compared between the three groups and to those women receiving standard care from *My Clinic* who did not want to be randomized but were willing to provide their clinic data for analyses. Comparing these three randomized groups to standard care at *My Clinic* also justified if an additional intervention (either full NELIP, Nutrition only or Exercise only) was necessary in addition to standard care at the specialized clinic to help prevent excessive GWG and to assess the resultant pregnancy outcomes. Comparison of the three randomized groups determined if one behaviour change (Nutrition alone or Exercise alone) is more efficacious for obese pregnant women than two behaviour changes (full NELIP) in preventing excessive GWG.

2.1 Hypotheses

- It was hypothesized that women receiving standard care at *My Clinic* would have better outcome measures; decreased incidence of macrosomia (babies born >4.0 kg), small birth weight babies (<2.5 kg) and pregnancy complications than those not receiving specialized standard care at *My Clinic* (perinatal database).
 Pregnancy complication was defined by the number of Caesarean sections (yes or no).
- It was hypothesized that women receiving full NELIP at *My Clinic* would have better success in preventing excessive GWG, reduction in macrosomia, small birth weight babies, and pregnancy complications than those receiving Nutrition alone, Exercise alone, or standard care at *My Clinic*.

Chapter 3

3 Methodology

3.1 Perinatal Database

Ethics approval from the Human Research Ethics Boards for Health Sciences at Western University and the London Health Science Centre was obtained (Appendix A1) for analyzing the sanitized perinatal database from medical records containing maternal characteristics and perinatal outcomes for all singleton births in London, Canada between January 1 and December 31, 2011. Women with incomplete data (i.e., lacking height, or pre-pregnancy weight), smokers, drug users, and those who consumed alcohol were removed from the dataset. Women diagnosed with type 1 and type 2 diabetes prior to pregnancy, and those who developed GDM were also removed from the data set. The remaining women defined the perinatal database and were stratified by those with a pre-pregnancy BMI<35 and those with a BMI \geq 35 kg/m². Those women meeting study inclusion criteria with a BMI \geq 35 kg/m² were used as a matched cohort control group. Caesarean section (yes/no) and infant birth weight were recorded. However, maternal gestational weight gain was not available in the dataset.

3.2 Standard Care Procedure at My Clinic

Standard care *My Clinic* patients completed a self-reported Weight and Health History Questionnaire (Appendix A2) during their initial visit to the clinic. From this questionnaire, self-reported pre-pregnancy weight was recorded from the patient file. Height was measured and also recorded in the patient file. All women were medically pre-screened by their obstetrician for contraindications to physical activity using the PARmed-X for Pregnancy (2013; Appendix A3). The height and pre-pregnancy weight measurements were used to calculate pre-pregnancy BMI (kg/m)². *My Clinic* patients had appointments in the clinic every two weeks on average. Weight was charted at each visit to monitor rate of weight gain as well as total gestational weight gain. Patients received three fasted oral glucose tolerance tests (OGTT) throughout their pregnancy. All women who had no contraindications to physical activity were approached to participate in the randomized control trial (RCT; see below) and those women who did not wish to participate in the RCT (see below) signed informed consent (Appendix A4) to be considered as the *My Clinic* standard care group. Those in *My Clinic* standard care were offered Canada's Food guide and healthy eating tips but did not receive a structured meal plan from dietician. Those receiving *My Clinic* standard care were encouraged to exercise by their obstetrician but were not given a formal exercise program.

3.3 My Clinic Randomized Controlled Trial

Women were recruited for the pilot RCT from *My Clinic* standard care patients who met the above criteria. The Human Research Ethics Boards for Health Sciences at Western University and the London Health Science Centre approved the RCT protocol (Appendix A1), and all women gave informed written consent to participate in the RCT. This trial was registered at <u>www.clinicaltrials.gov</u>, NCT02155751.

3.3.1 Participants

Women over the age of 18 years, with a pre-pregnancy BMI of \geq 35 kg/m² (class 2 and 3 obese), between 12 and 20 weeks gestation were recruited to participate in the study through self-referrals and family physician referrals to *My Clinic*. In order to participate in the study, women had no contraindications to walking, did not have type 1, type 2 diabetes, or GDM at baseline, and were nonsmokers.

3.3.2 Randomization

CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed to generate the random allocation sequence using a random numbers table. CONSORT ensures proper design and execution of the RCT to avoid bias or exaggerated treatment effects (Moher et al., 2012). The SNOSE (sequentially numbered, opaque sealed envelopes) (Doig & Simpson, 2005) method was chosen for random allocation to the different treatment groups: full NELIP, Nutrition only or Exercise only.

3.3.3 Intervention Procedure at My Clinic

If patients did not have GDM at their initial fasted OGTT at 12-20 weeks gestation, they were eligible to participate in the study. Following consent, each participant completed a 3-day food intake record (Appendix A6) and a 7-day pedometer log (Appendix A7) for baseline measurements. The 3-day food intake records were analysed for nutritional information (total energy per day and daily macronutrient intake) using a nutrition program (ESHA Food Processor SQL software). Once the 3-day food intake record and the pedometer log sheets were collected, the women were assigned at random to one of the study groups (full NELIP, Nutrition-only, or Exercise-only).

Participants assigned to the <u>Nutrition-only</u> component of NELIP were taught a specific meal plan (Appendix A8) by the *My Clinic* dietician (trained in the NELIP protocol) to promote healthy eating habits, regulate blood sugar levels and control excessive GWG. The dietary program was similar to the gestational diabetic meal plan designed to: a) individualize total energy intake with a minimum of 2000 kcal/day (8360 kJ/day), taking into account the usual energy intake as indicated by each dietary assessment (including 3-day food intake record) with a restriction of not more than 33% total energy intake; b) adjust if necessary the total carbohydrate intake to 40-50% of total energy intake, distributing carbohydrate intake throughout the day with three balanced meals, and three snacks per day emphasizing complex carbohydrates and low glycemic index foods; c) adjust the total fat intake to 30% of total energy intake (substituting monounsaturated fatty acids for saturated and trans-fatty acids), with the remaining 30% dedicated to protein intake; and d) meet all micronutrient and fluid needs recommended during pregnancy (Mottola et al. 2010).

Participants in the <u>Nutrition-only</u> group recorded their 24-hour food and drink intake once per week and met with the dietician at each clinic visit to determine whether adjustments in the nutrition program were required as pregnancy progressed. These weekly food intake logs were handed in to the dietitian and analysed using the ESHA Food Processor SQL software. Women in this group were given no formal exercise advice, (except to be active as standard care for the women in *My Clinic*), no pedometer to record steps, and no exercise self-monitoring during the intervention. Participants assigned to the Exercise-only component of NELIP began a controlled walking program. Participants walked for 25 minutes per session, 3 to 4 times per week, adding 2 minutes each week to the session until 40 minutes was reached and then maintained until delivery (Mottola et al. 2010). Daily steps were recorded using a pedometer and log sheet (Appendix A7) to keep track of daily steps and to initiate self-monitoring behaviour. An easy and maintainable walking pace was encouraged to avoid becoming breathless. Participants had the option of attending the clinic once per week for a monitored walk with an exercise specialist, or completing walks at home (whether that be on a treadmill, an outdoor trail, in their neighbourhood, etc.). Pedometer log sheets were handed in to the exercise specialist at each clinic visit. As part of standard care at *My Clinic* the participants in the Exercise-only group met with the clinic dietitian at each scheduled *My Clinic* visit and were given information on Canada's Food Guide and healthy eating tips. These women did not receive the NELIP meal plan, nor did they complete or record (self-monitor) their food intake.

Participants assigned to the full Nutrition and Exercise Lifestyle Intervention Program (NELIP) were introduced to both the dietary and walking program, including the self-monitoring for both nutrition and exercise, described above.

All participated in the programs from 12-20 weeks until delivery and were weighed at each visit to the clinic, on average twice monthly, similar to standard care at *My Clinic*. Infant birth weight, APGAR scores and pregnancy and/or delivery complications were obtained from medical charts. Within 6-18 hours after birth (before the women left the hospital), a member of the research team visited the participant in hospital and measured the length of the newborn within 0.1 cm and recorded all other birth information from the chart.

3.4 Outcome Measurements

Maternal anthropometric measurements were taken from each patient's chart and included height (cm), pre-pregnancy weight (kg), and last measured weight prior to delivery (kg) to calculate gestational weight gain (weight prior to delivery (kg) – prepregnancy weight (kg)). Total gestational weight gain (kg) and rate of weight gain (calculated per week) were used to determine whether there was a significant difference between the three NELIP groups and those receiving standard care at *My Clinic*.

The incidence of macrosomia was assessed as the number of babies born >4.0 kg (Artal et al., 2007). Macrosomia incidence rates were compared between the three groups of NELIP women vs. *My Clinic* standard care women, and those not receiving *My Clinic* care (information from the London, ON perinatal database).

Pregnancy complications were also assessed between the three groups of NELIP women, *My Clinic* standard care, and the perinatal database. Pregnancy complication was defined as Caesarean section (yes/no).

3.5 Statistical Analyses

Participant characteristics were compared between the perinatal database, *My Clinic* specialized standard care, and *My Clinic* NELIP participants (that also received the *My Clinic* specialized standard care). Continuous data (i.e. maternal height, maternal prepregnancy weight, maternal pre-pregnancy BMI, maternal gestational weight gain, infant weight) were compared using an ANOVA. ANOVA and Student's t-tests were used to compare pedometer step-counts and nutrition data between the three randomized groups at baseline and to compare pre data to data collected while on the intervention for each individual group. Data were presented as mean \pm standard deviation. Categorical infant data (small birth weight (yes/no), macrosomia (yes/no), C-section rate (yes/no)) were compared using a chi-squared test. Statistical significance was set at p≤0.05.

Chapter 4

4 Results

4.1 Perinatal Database

A total of 4565 women were removed from the dataset due to incomplete data (i.e., lacking height, or pre-pregnancy weight), smokers (N=139), drug users (N=76), and those who consumed alcohol (N=25) and women diagnosed with type 1 and type 2 diabetes prior to pregnancy (N=8), leaving 834 women for the final analysis. A total of 39 women developed GDM during pregnancy (approximately 5%) (N=23 GDM diet controlled, N=13 GDM insulin controlled, N=3 no information how they controlled their GDM) and were also removed from the dataset for final analyses. Interestingly, the mean pre-pregnancy BMI for those that developed GDM was $31.3 \pm 6.6 \text{ kg/m}^2$. Twenty-six % of those that developed GDM had a BMI $\geq 35 \text{ kg/m}^2$ (N=10).

Average birth weight for all infants born to mothers of all BMI classifications in the perinatal database (N=834) was 3.4 ± 0.6 kg. Average gestational age was 38.6 ± 2.4 weeks. Macrosomia (>4.0 kg birth weight) incidence for mothers of all BMI classifications was 14% (N=117). Small birth weight (<2.5 kg) incidence was 8% (N=69). The Caesarean section rate for mothers of all BMI categories was 27.8% (N=232).

The remaining women (N=834) were stratified by BMI<35 (N=787) and \geq 35 kg/m² (N=47). The 47 women meeting study inclusion criteria with a BMI \geq 35 kg/m² were used as a matched control group to *My Clinic* participants.

The women in the matched control group were 30.9 ± 4.1 years old, 164 ± 6.6 cm tall, with a pre-pregnancy body mass of 106.5 ± 15.0 kg and a pre-pregnancy BMI of 39.2 ± 4.4 kg/m². Average infant birth weight was 3.5 ± 0.8 kg, while gestational age was 38.4 ± 2.5 weeks. Maternal gestational weight gain was unfortunately not included in the database. Macrosomia incidence was 27.7% (N=13). Small birth weight incidence was 6.4% (N=3).

Chi-square analysis revealed a difference in macrosomia incidence between the women in the perinatal database with a pre-pregnancy BMI of \geq 35 kg/m² (27.7%) and those women with a BMI of < 35 kg/m² (12.6%; p=0.03). The rate of small birth weight babies for women with a pre-pregnancy BMI of \geq 35 kg/m² (6.4%) did not differ from those women with a BMI of < 35 kg/m² (7.6%; p=0.58).

The Caesarean section rate for infants of mothers with a BMI \ge 35 kg/m² was 40.4% (N=19), while the Caesarean section rate for infants of mother's with a BMI <35 kg/m² was 22.4%; p=0.007. For those with a BMI \ge 35 kg/m² there were three cases of forceps deliveries (6%) and one vacuum delivery (2%). Five infants (10.6%) had fetal complications and were admitted to the Neonatal Intensive Care Unit (NICU). For those with a BMI <35 kg/m² there were 59 cases of forceps deliveries (7.5%) and 24 cases of vacuum deliveries (3%), and 114 (13.1%) had fetal complications and were admitted to the NICU.

4.2 My Clinic Standard Care vs Perinatal Database

Twenty-one women consented to be included as patients representing standard care for *My Clinic*. The women were 30.8 ± 7.1 years old, 165 ± 6.2 cm tall, with a pre-pregnancy body mass of 123.1 ± 23.2 kg and a pre-pregnancy BMI of 45.2 ± 7.3 kg/m². Average infant weight was 3.4 ± 0.5 kg, while gestational age was 38.7 ± 1.4 weeks. Average parity for this group was 0.9 ± 1.4 . Macrosomia incidence was 5.3% (N=1) and there were no cases of small birth weight infants.

Chi-square analysis revealed a difference in macrosomia incidence between *My Clinic* standard care (5.3%) and perinatal database women with a pre-pregnancy BMI \geq 35 kg/m² (27.7%; p=0.000), and standard care was not different than those women from the perinatal database with a BMI < 35kg/m² (12.6%; p=0.112). There was a significant difference in small birth weight babies between *My Clinic* standard care and the perinatal database (none vs 6.4%, respectively; p=0.000). The Caesarean section rate for infants born to mothers of *My Clinic* standard care was 38% (N=8), and was not significantly different than the Caesarean section rate of the women in the perinatal database with a pre-pregnancy BMI \geq 35 kg/m² (see Table 3).

Group	Birth Weight (kg)	Birth Length (cm)	C-section (#/%)	Macrosomia (#/%)	Small birth weight (#/%)
<i>My Clinic</i> Standard Care N=21	3.4 ± 0.5	N/A	8/38.1%	1/5.3%†	0/0%**
Perinatal Database N=47	3.5 ± 0.8	N/A	19/40.4%	13/27.7%	3/6.4%

Table 3 *My Clinic* standard care women compared to women in the Perinatal Database with a pre-pregnancy body mass index of \geq 35 kg/m²

Birth length was not available

† *My Clinic* standard care vs perinatal database \geq 35 kg/m², p=0.000

** My Clinic standard care vs perinatal database \geq 35 kg/m², p=0.000

Total gestational weight gain for the *My Clinic* standard care group was 7.6 ± 7.1 kg, within the IOM's 2009 recommendations for obese women (IOM, 2009). Weight gain prior to the first appointment at *My Clinic* was 1.8 ± 8.8 kg. Women received *My Clinic* standard care for 20.0 ± 8.8 weeks. Weight gain while attending the clinic was 6.4 ± 4.9 kg, while the rate of weight gain was 0.4 ± 0.4 kg/week. Fifty-five % of the women gained excessive weight while receiving *My Clinic* care (N=12). For four of these women (33%), excessive weight gain occurred prior to their first appointment at *My Clinic* at 18.1 ± 5.9 weeks gestation.

4.3 My Clinic Intervention (RCT)

A total of 26 women were recruited to participate in the RCT and signed consent (Appendix A5). Three women developed GDM prior to 20 weeks gestation, before randomization, and were removed from the study (exclusion criteria). Eleven women

withdrew from the study prior to randomization. Twelve women agreed to participate and met the inclusion criteria (see Figure 1). They were randomized into one of three groups. Four women were allocated to the nutrition only group, and one dropped due to the severity of her Crohn's disease flare ups with the meal plan. Five women were allocated to the exercise only group, and two dropped due to the required time commitments. Three women were allocated to the full NELIP and all withdrew due to a combination of factors, including pain when exercising, leaving *My Clinic* care for midwifery care, and the time commitments required, resulting in a drop out rate of 100%. Ultimately, only 6 women in total completed the program for the entire duration of pregnancy.

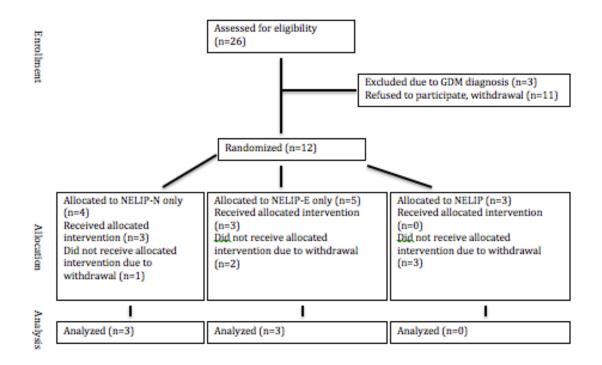


Figure 1: Randomization flow chart for My Clinic research patients

¹ GDM – gestational diabetes mellitus

Baseline data consisting of a three-day food intake record (Table 4) and seven-day pedometer log (Table 5) were collected for the RCT women. There was no statistical difference between the groups at baseline.

Group	Total						
	Energy	PRO	СНО		%	%	%
	(kcal)	(g)	(g)	Fat (g)	Protein	СНО	Fat
Participants							
(N=6)	$2535.6\pm$	$93.8 \pm$	321.0 ±	$102.2 \pm$	$14.6 \pm$	47.8 ±	$37.6 \pm$
	1286.5	36.3	159.5	70.4	3.7	9.7	9.1
Nutrition-							
only (N=3)	3385.5 ±	122.9 ±	411.25	148.45 ±	12.5 ±		$44.5 \pm$
	1871.7	45.4	± 185.1	112.1	0.7	43 ± 4.2	5.0
Exercise-							
only (N=3)	$1969 \pm$	74.5 ±	$260.9 \pm$	71.4 ±		51 ±	33 ±
	595.7	14.2	142.0	8.9	16 ± 4.4	11.8	8.7

 Table 4 Baseline data: Average daily three-day food intake record data for participants (N=6) prior to randomization.

PRO – protein

CHO - carbohydrate

No statistical difference between the groups at baseline

Table 5 Baseline data: Average daily step counts from seven-day pedometer recordfor participants prior to randomization.

Participants (N=6)	6340.1 ± 2443.7		
Nutrition-only (N=3)	7167.5 ± 4532.8		
Exercise-only (N=3)	5895.6 ± 628.9		

No statistical difference between the groups at baseline.

The six women who completed their respective intervention program were 31.3 ± 5.4 years old, 164.3 ± 5.9 cm tall, with a pre-pregnancy body mass of 123.3 ± 18.6 kg and a pre-pregnancy BMI of 44.1 ± 5.5 kg/m². Infant weight was 3.51 ± 0.55 kg, and infant length was 52.6 ± 4.8 cm, while gestational age was 38.8 ± 2.9 weeks. The incidence of macrosomia (>4.0 kg) for infants of *My Clinic* intervention participants was 15% (N=1). There were no cases of small birth weight infants (<2.5 kg). Two women had C-sections (33.3%), and one woman had a forceps delivery. One infant of an intervention participant (N-only) had fetal complications and as a result was admitted into NICU.

Average parity was 1.0 ± 2.4 . Total gestational weight gain for intervention participants was 7.5 ± 10.6 kg, within the IOM guidelines for obese women (IOM 2009). An average weight loss of 1.2 ± 5.5 kg occurred prior to beginning the intervention at 12-20 weeks gestation. Weight gain on the 20.6 ± 2.9 week long intervention was 7.5 ± 10.6 kg, while the rate of weight gain was 0.38 ± 0.27 kg/week. Fifty % of the women did not gain excessive weight (N= 3). Fifty % gained excessively (N=3), and for two of these women, excessive weight gain occurred prior to beginning the intervention at 16-20 weeks gestation. If excessive weight was not gained prior to the intervention the success rate would increase from 50% to 83%.

The 3 women who participated in the Nutrition-only intervention were 27.0 ± 3.0 years old with a pre-pregnancy body mass of 127.1 ± 26.5 kg and a pre-pregnancy BMI of 46.2 ± 7.4 kg/m². Infant birth weight was 3.64 ± 0.6 kg, infant length was 52.4 ± 4.0 cm, infant BMI was 13.2 ± 0.7 , and gestational age was 39.7 ± 1.2 weeks. Total gestational weight gain was 14.6 ± 5.7 kg, above the IOM guidelines for obese women (IOM 2009). The rate of weight gain during the intervention was 0.6 ± 0.1 kg/week. The drop-out rate for the Nutrition only intervention was 25% (1/4). The average nutritional data (Table 6) revealed a significant increase (p=0.04) in % of total energy intake from protein between baseline food intake records and records obtained during the ongoing Nutrition-only intervention. The % of calories from fat did not change while following the meal plan, however there appeared to be a reduction of 36% compared to baseline records (p=0.07).

	Total Energy (kcal)	PRO (g)	CHO (g)	Fat (g)	% Protein	% CHO	% Fat
Pre- intervention (baseline)	3385.5 ± 1871.7	122.9 ± 45.4	411.3 ± 185.1	148.5 ± 112.1	12.5 ± 0.7	43 ± 4.2	44.5 ± 5.0
Nutrition-only intervention	1769.9 ± 27.3	90.55 ± 1.3	232.2 ± 22.9	56.45 ± 13.7	20 ± 0*	51.5 ± 6.4	28.5 ± 6.4**
Effect size	0.52	0.45	0.56	0.49			

 Table 6 Average nutrition data at baseline compared to the Nutrition-only

 intervention at the end of the program

* Intervention different from baseline, p=0.04

** p=0.07

Medium effect size = 0.3 - 0.5

The three women who participated in the Exercise only intervention were 35.7 ± 2.9 years old with a pre-pregnancy body mass of 119.5 ± 10.8 kg and a pre-pregnancy BMI of 42.0 ± 3.0 kg/m². Infant birth weight was 3.4 ± 0.6 kg, infant length was 52.2 ± 5.7 cm, infant BMI was 12.4 ± 1.2 , and gestational age was 38.0 ± 3.6 weeks. Total gestational weight gain in the exercise only intervention was 0.4 ± 9.9 kg (within the IOM guidelines; IOM, 2009). The rate of weight gain during the intervention was 0.2 ± 0.1 kg/week. The drop-out rate for the exercise only intervention was 40% (2/5). Participants doubled their daily step counts (Table 7), though not significant (p=0.18).

 Table 7 Average daily step counts at baseline compared to Exercise-only

 intervention at the end of the program

Pre-intervention (baseline)	5895.6 ± 628.9		
Exercise-only intervention	11900.8 ± 2659.8		
Effect size	0.84		

No statistical difference between baseline and Exercise-only intervention

Large effect size = ≥ 6.0

Although there was no significant difference in average total weight gain between the groups (see Table 8), there was a difference trending towards significance (p=0.09) between the *My Clinic* Exercise-only group $(0.4 \pm 9.9 \text{ kg})$ compared to the Nutrition-only $(14.6 \pm 5.7 \text{ kg})$ group. The average rate of weight gain was significantly less in the Exercise-only group $(0.2 \pm 0.1 \text{ kg/week})$ compared to both *My Clinic* standard care $(0.4 \pm 0.4 \text{ kg/week}; p=0.04)$ and the Nutrition-only $(0.6 \pm 0.1; p=0.01)$ groups.

Birth weight was not different between the groups (see Table 9). Chi-square analysis failed to find a difference in C-section rates between patient groups from *My Clinic*.

Table 8 Characteristics of women receiving Standard Care at My Clinic comparedto women receiving the intervention (Exercise only; E-only, or Nutrition only; N-only)

Group	Pre- pregnancy weight (kg)	Pre- pregnancy BMI (kg/m ²)	Age (years)	Total Weight Gain (kg)	Rate of Weight Gain (kg/week)	Gestational Age (weeks)
My Clinic Standard Care N=21	123.1 ± 23.2	45.2 ± 7.3	30.8 ± 6.9	7.6 ± 7.1	0.42 ± 0.43‡	38.7 ± 1.4
My Clinic NELIP <u>E-only</u> N=3	119.5 ± 10.8	42.0 ± 3.0	35.7 ± 2.9.	0.42 ± 9.9**	0.2 ± 0.1*	38.0 ± 3.6
My Clinic NELIP <u>N-only</u> N=3	127.1 ± 26.5	46.2 ± 7.4	27.0 ± 3.0	14.6 ± 5.7	0.6 ± 0.1	39.7 ± 1.2

• E-only different from N-only, p=0.02

* E-only different from N-only, p=0.01; **p=0.09

‡ Standard Care different from E-only, p=0.04.

NELIP – Nutrition and Exercise Lifestyle Intervention Program

Group	Total Weight Gain (kg)	Rate of Weight Gain (kg/week)	C-section (#/%)	Macrosomia (#/%)	Small birth weight (#/%)
Perinatal Database N=47	N/A	N/A	19/40.4%	13/28%	3/6.4%+
My Clinic Standard Care N=21	7.6 ± 7.1	0.4 ± 0.4‡	8/38.1%	1/5.3%††	0/0%
My Clinic NELIP <u>E-only</u> N=3	0.4 ± 9.9**	0.2 ± 0.1*	1/33.3%	0/0%	0/0%
My Clinic NELIP <u>N-only</u> N=3	14.6 ± 5.7	0.6 ± 0.1	1/33.3%	1/33.3%	0/0%

 Table 9 Summary of weight gain between My Clinic groups and perinatal outcomes

 between all groups

* E-only different from N-only, p=0.01; **p=0.09

‡ Standard Care different from E-only, p=0.04

†† *My Clinic* standard care different from perinatal database \geq 35 kg/m², p=0.02

+ *My Clinic* standard care different from perinatal database \ge 35 kg/m² vs E-only vs N-only p=0.000

Chapter 5

5 Discussion

For women with a pre-pregnancy BMI of $\geq 35 \text{ kg/m}^2$ who were referred to a specialized clinic (*My Clinic*) an intervention consisting of exercise only was better at preventing excessive gestational weight gain than a nutrition intervention alone. Combining a nutrition and exercise intervention appeared difficult for this population as 100% of the women randomized to this group dropped out (although one woman changed to midwifery care). It may be that the combination of a nutrition and exercise program requiring two lifestyle behaviour changes (eating habits and physical activity) may be a burden for this specialized group of obese women. Changing one behaviour, specifically the addition of a walking program appeared to be best for this population group, as these women were able to prevent excessive gestational weight gain. Standard care at *My Clinic* appeared to reduce macrosomia rates and no babies were born small compared to women with similar BMIs matched from the perinatal database.

5.1 Is there a need for *My Clinic* care?

Literature indicates that both patients and health care practitioners express a need for a well-rounded approach to obesity and weight management (Forman-Hoffman et al., 2006). Increased ease of access to a multidisciplinary team of health care providers will benefit patients and physicians alike. Few primary care clinicians are regularly counseling obese patients on weight management, as many lack the proper training in the management of obesity as a whole, and more specifically, maternal obesity (Forman-Hoffman et al., 2006). McDonald et al., (2011) reported that few pregnant women were counseled by their primary care physician according to the 2009 IOM weight gain guidelines, and advised of the risks associated with excessive GWG. Only 28.5% of the women in the sample survey at prenatal clinics reported their health care provider made weight gain recommendations, while only 25% were made aware of the risks of inappropriate or excessive weight gain. Despite the 2009 publication of the GWG guidelines, only 12% of women reported being counseled correctly on weight gain according to the IOM recommendations (McDonald et al., 2011). These statistics reveal

an urgent need for improved patient care, especially in the obese population where the risks associated with excessive GWG are even greater. In recognition of this, the Canadian Obesity Network (2013) developed the '5 A's of Healthy Pregnancy Weight Gain' as an education tool for health care practitioners to better manage obese pregnant women. The program advises physicians to follow the 2009 IOM weight gain guideline recommendations, and identify and discuss the root cause(s) of the patient's obesity as well as the barriers associated with managing GWG. An essential element of the Canadian Obesity Network is patient education to improve self-management. The Canadian Obesity Network concludes that evidence supports a multidisciplinary team approach for successful weight management. Many of the recommendations from the '5 A's' have been purposefully adopted in *My Clinic* to better manage weight gain in the pregnant obese population.

The model of behavior change, known as the Stages of Change (SOC) model, states that individuals can be characterized as belonging to one of five 'stages' in respect to changing chronic behavior patterns (Prochaska & Di Clemente, 1985). In precontemplation the individual does not intend to change their behaviour in the next six months. An individual in the contemplation stage is strongly inclined to change behaviour in the next 6 months. Preparation is characterized by an individual's intention to act in the near future (generally the next month). In the action stage the behaviour has already been incorporated for at least six months. The individual incorporating the behaviour for more than six months characterizes the maintenance stage, where the likelihood of the old behaviour returning is low.

Literature supports interventions tailored to an individual's specific stage of change to improve effectiveness (Prochaska & Goldstein, 1991). *My Clinic* standard care aimed to assist and guide women through the stages of change by implementing the 5 A's of healthy pregnancy weight gain and obesity management into standard care (Canadian Obesity Network, 2013). The majority of women referred to *My Clinic* began in the precontemplation stage. In attempt to guide women into the contemplation stage obstetricians first asked for patient permission to discuss patient's current weight and healthy pregnancy weight gain. The risks associated with the patient's BMI and

pregnancy were then assessed and communicated (advised). The benefits of a healthy lifestyle were discussed with an emphasis on improving overall pregnancy outcomes for both mother and baby. If the patient was ready to transition into the preparation stage, realistic goals for appropriate pregnancy weight gain were discussed in a positive manner and agreed upon in attempt to avoid patient self-disappointment and non-adherence. The preparation stage also involved the obstetrician assisting the patient, which included but was not limited to a dietician referral, exercise specialist referral, more frequent follow-up appointments, educational resources, etc.

The lack of training among primary care practitioners combined with the increasing prevalence of maternal obesity justifies the need for *My Clinic* to better service obese pregnant women. A team approach used at *My Clinic* was shown to better manage obesity treatment and prevention than those not receiving the specialized *My Clinic* care (perinatal database).

Analysis of the perinatal database determined that maternal obesity is an issue in London, Canada, with an obesity rate of 18%. Six % of all pregnancies belonged to class 2/3 obese women, necessitating specialized obstetrical care. Moreover, this 6% did not include class 1 obese women nor class 2/3 obese women with GDM (as it was an exclusion criteria), which would increase the percentage of obese pregnant women. It is concerning that current evidence reveals that up to 72% of obese women have excessive GWG according to current IOM recommendations (Faucher and Barger, 2015). There was a marked difference between macrosomia incidence between the women in the perinatal database with a pre-pregnancy BMI of \geq 35 kg/m² (27.7%) and those women with a BMI of < 35 kg/m² (12.6%), further justifying the need for more intensive obstetrical care. Similarly, women in the perinatal database with a BMI \geq 35 kg/m² also had an increased Caesarean section rate (40%) compared to women with a BMI < 35 kg/m² (23%).

While *My Clinic* standard care did not impact Caesarean section rates compared to the perinatal database, rate of macrosomia (5.3% vs. 28%) and rate of small birth weight infants (0% vs 6.4%) were reduced. Evidence over the long term has demonstrated that macrosomia and small birth weight can lead to an increased risk of infants later

developing metabolic syndrome and childhood obesity (Guelinckx et al., 2008). If *My Clinic* care can decrease rates of macrosomia and small birth weight babies it may potentially slow down the vicious cycle of obesity, diabetes and metabolic syndrome over future generations. It is evident that *My Clinic* standard care played an important role in delivering healthier babies of class 2/3 obese pregnancies compared to women who did not receive the specialized obstetrical care (perinatal database).

5.2 NELIP – Did it work?

The second major objective of the present study was to determine if an evidenced-based Nutrition and Exercise Lifestyle Intervention Program (NELIP) was an effective addition to *My Clinic* standard care. Furthermore, the current study aimed to determine whether one behaviour change (Nutrition alone or Exercise alone) would be a more realistic intervention for class 2/3 obese pregnant women compared to two behaviour changes (full NELIP). Considering the drop-out rate for the full NELIP was 100%, even though NELIP is best practice, the full intervention may be too difficult for class 2/3 obese women in the clinical setting. Adhering to a meal plan and recording food intake while simultaneously incorporating and recording daily exercise may be too challenging and ultimately may have led to withdrawal from the full intervention. Although one woman switched to midwifery care, the other two women cited pain upon exercise and too great of a time commitment.

Campbell et al. (2011) conducted a review to explore the factors influencing the effectiveness of behaviour change interventions to prevent excessive gestational weight gain. The authors reported limited effectiveness of interventions during pregnancy aimed to prevent excessive weight gain, despite the interventions being personalized and tailored on a case-by-case basis. Cited barriers of the interventions included fear of harming the unborn baby, general physical discomfort, discouragement to undertake physical tasks by people around them, and positive encouragement toward over eating (Campbell et al. 2011). These factors were found to lead to a general decline in physical activity and an increased risk of excessive gestational weight gain (Campbell et al., 2011). General physical discomfort was often cited as a barrier to physical activity for *My Clinic* women, and one woman dropped out of NELIP because of it. It is also a

possibility, based on the high drop-out rates, that many participants were lacking the support network required for the intensive lifestyle modifications of NELIP. The majority of drop out participants cited the time commitment as the major barrier of the intervention, although it would be interesting to explore this further and discuss their individual support network (or lack thereof) in the future.

There was one significant difference in the recruitment process for the NELIP intervention between the women studied in the laboratory setting and those in *My Clinic*. Intervention participants in the laboratory NELIP were self-referred and contacted study investigators after viewing study participation posters in midwifery/physician's office and/or around the campus of Western University. On the basis of self-referrals, laboratory participants likely entered the study already in the contemplation stage of change. On the contrary, NELIP participants in the *My Clinic* setting were directly referred by their obstetrician and many remained in the pre-contemplation stage of change, which may have led to failure to comply with the intervention or the high dropout rates.

Compared to the participants previously studied in the lab, the women at My Clinic were specifically obese class 2 and 3. My Clinic women also experienced various psychological issues such as depression and anxiety, which were frequently charted, perhaps related to the lack of perceived control associated with pregnancy, vulnerability, fear or past traumatic experiences (Campbell et al., 2011). Recording food intake and daily pedometer steps, essential to compliance and self-monitoring, may have repeatedly increased anxiety levels in this group of women, and anxiety was cited as a secondary reason for withdrawal from the intervention on more than one occasion. Women attending My Clinic were typically of lower socioeconomic status (as indicated from their medical charts), many were unemployed or receiving social assistance (with a few exceptions), which may differentiate this group of women from those studied in the lab. Unfortunately, the combination of behavioural, physical, psychological and sociodemographic factors (which were not measured in the present study) may have led to the 100% drop out rate in the more intensive intervention (NELIP) group. Future analyses should include all of these co-founding variables to assist in overcoming potential barriers to lifestyle change in obese class 2 and 3 women.

The more successful interventions of the study were those involving only one behaviour change; either the nutrition or exercise only groups. The nutrition group had a drop-out rate of 25%, while the exercise group had a drop-out rate of 40%. The exercise intervention was most efficacious in reducing GWG and keeping weight gain within the IOM guidelines. This may indicate that walking as the exercise modality, and as a single behaviour change, may be the best intervention for obese class 2 and 3 women. A walking intervention is an inexpensive method for increasing daily PA and can be easily implemented into daily clinical practice. A mild exercise program is important because it is an easier adjustment for obese women who were previously sedentary. Furthermore, obese individuals may have difficulties with nutrition, thereby making exercise in the form of walking or increasing daily step counts as a more realistic intervention.

Haby et al. (2015) recently conducted a pilot study using prescribed physical activity, pedometers and walking poles to significantly reduce GWG in pregnant women with an average BMI of 33.1 kg/m² in a midwifery setting. Food advice was given and counseling via a dietician was offered but the dietary program was not mandatory. Compliance characteristics were low in this study, with only 34% of women participating in the food discussion group and 50% using pedometers. Nonetheless, GWG was significantly lower in the exercise intervention group.

Renault et al. (2014) had similar results to the current *My Clinic* study when assessing GWG in obese pregnant women using a physical activity intervention with or without dietary intervention. Renault et al. (2014) found no significant difference between the two interventions, concluding that the additive effect of the dietary program was not significant. Compliance was also an issue in the study as many participants did not follow the dietary advice.

Although the nutrition intervention used a modified GDM meal plan combined with walking and was shown to prevent excessive GWG in the laboratory setting (Mottola et al. 2010), the nutrition component alone was not as effective as exercise in preventing excessive GWG. While exercise was a simple addition to their daily lives, the nutrition program was much more difficult to achieve. Non-compliance to the nutrition program

and under reporting of what they ate may be issues that resulted in the 14.6 ± 5.7 kg weight gain. Nevertheless, obese pregnant women might still benefit from regular visits to a dietician in a specialized obesity clinic who would be familiar with the nutrition recommendations for obese pregnant women.

Research indicates maternal obesity is an independent risk factor for macrosomia (Artenisio et al., 1999). Class 2/3 obese women, specifically, have two times the odds of delivering an infant >4.0 kg compared to women of a normal BMI (Bellver et al., 2003). A 1.0 kg increment in infant birth weight was associated with a 50% increase in childhood overweight/obesity at 9-14 years of age (Gillman et al., 2003). However, literature has shown that a small decrease in maternal weight (one BMI unit) is enough to decrease the risk of macrosomia (Villamor and Cnattingius, 2006). Prevention of macrosomia is paramount in order to reduce the cycle of obesity for future generations.

Along with reducing GWG, the exercise intervention significantly reduced macrosomia compared to *My Clinic* standard care. Both intervention groups along with *My Clinic* standard care prevented small birth weight babies. Babies born small are at a greater risk for obesity later in life, perhaps due to a period of catch-up growth, as well as an increased cardiovascular risk later in life (Mottola et al., 2010). Reducing macrosomia and small birth weight infants may perhaps be one step in preventing future childhood obesity by providing a healthy fetal environment and pregnancy lifestyle change for obese women.

Despite being best practice, the full NELIP including both diet and physical activity was not a successful addition to *My Clinic* standard care. However, either component of the intervention as a single behaviour change (i.e. Nutrition-only or Exercise-only) was found to be beneficial in class 2/3 obese women at *My Clinic*. The exercise intervention was found to best limit GWG and keep weight gain within IOM guidelines, as well as significantly reduce the risk of macrosomia. Incorporating one behaviour change into their lifestyle, rather than two, seemed to be most efficacious for class 2/3 obese women at *My Clinic*.

5.3 Strengths/Limitations and Future Directions

One strength of the current study was that it was designed to use an evidence-based best practice intervention program for overweight and obese pregnant women known as NELIP. NELIP in the laboratory setting had an impressive 80% success rate in preventing excessive weight gain in overweight and obese women during pregnancy. The exercise intervention and use of pedometers provided an inexpensive method for increasing daily physical activity that was easy to implement in the clinical setting and the delivery of the modified GDM diet with a specified meal plan was implemented by a dietitian associated with the specialized clinic. Theoretically, the delivery of the evidence-based intervention should have been complementary to the clinic setting. However, there were several limitations to the current study. Several women from the clinic were excluded because they were diagnosed with GDM early at the first visit screen for standard care. This exclusion criteria was necessary but also decreased the eligibility pool and lowered the number of women who agreed to participate in the study. In addition, a homogenous population was used and all women were Caucasian, reducing the risk of bias but also lowering external validity. There was a very wide range of weight gain, indicating that participants likely did not adhere to the dietary and/or exercise advice. The probability of underreporting of food intake and over reporting of pedometer steps or frequency of exercise may have been high. Pre-pregnancy weight was selfreported, which may be slightly different than if it were directly measured. In addition, the final sample size in the current study was small. The 2011 perinatal database was used as a proxy for the women referred to My Clinic as the 2012/2013 databases were not available at the time of data collection. Unfortunately, the 2011 perinatal database did not adhere to the CDA guideline updates (2013), and it remains unknown if some of the women in the perinatal database would have been diagnosed with GDM according to the updated current criteria.

Another possible limitation of the current study was the lack of self-monitoring that occurred in both the nutrition and exercise groups. The Nutrition-only group self-monitored food intake, however they did not record step counts so it remains unknown how active these women were. In addition, the Exercise-only group completed the

exercise log with pedometer steps but did not monitor nutrition, although both groups had access to *My Clinic* standard care with nutrition and exercise advice. To avoid burdening the women they did not have to self-monitor both behaviours, as these results would have been seen in the full NELIP group. Unfortunately, 100% of the women receiving the full NELIP dropped out so the results of self-monitoring two behaviours remain unknown. Future direction may include additional measurement of nutrition and exercise behaviour without using self-monitoring of the behaviour not being changed. For example, in the Exercise-only group, perhaps a food frequency questionnaire could be used at the beginning and at the end of the study to capture change in nutrition behaviour and an exercise questionnaire such as the Kaiser questionnaire validated for pregnant women (Schmidt et al., 2006) could be used to capture change in exercise behaviour pre and post intervention in all groups. In addition, future studies should be based on theories of behaviour change specifically designed for obese class 2 and 3 pregnant women.

Many questions remain unanswered as to how to best approach multiple behaviour change. Research is inconclusive and both sequential and simultaneous behaviour change have shown success depending on the intervention and individual (Vandelanotte et al., 2008). Perhaps participants would benefit from a tailored, individualized intervention where they are able to choose how they wish to integrate the multiple behaviour changes into their lifestyle (either sequentially or simultaneously).

Pregnant women attending *My Clinic* may have mental health issues including depression and anxiety (personal observation). An integrative team approach to obstetrical care should be continued at *My Clinic*, however, additional support of a social worker, psychologist and/or psychiatrist could be beneficial in the antenatal treatment plan to assist these women with the unique barriers they face related to class 2 and 3 obesity. Literature reveals that individuals tend to engage in activities in which they believe they can succeed – without confidence in their success one will not be successful (Savage et al., 2014). Furthermore, research suggests individuals must perceive the benefits of physical activity and healthy nutrition to ultimately change their lifestyles and be compliant to an intervention (McGiveron et al., 2014). Unrealistic expectations regarding weight management in obese individuals can often lead to disappointment and nonadherence (Canadian Obesity Network, 2011). Future intervention studies at *My Clinic* may benefit from patient education workshops focusing on setting appropriate GWG goals, with the emphasis on prevention of excessive weight gain, and problem solving skills to overcome their unique barriers and time management skills. Workshops previously provided by *My Clinic* in the group setting were lacking in attendance. Perhaps this group of obese women may respond better to anonymity and may benefit from one-on-one goal setting and time management counseling sessions in the future.

In a randomized trial, Harrison et al. (2014) found that regular self-weighing combined with a self-management intervention optimized pregnancy weight gain compared to control participants. Intervention participants in the trial were encouraged to plot and track their weekly GWG on a chart. While *My Clinic* patients were weighed in the clinic at all appointments, self-weighing was not necessarily encouraged. It remains unknown if self-weighing would be efficacious for the *My Clinic* population and result in improved self-management of obesity.

Evidence suggests pregnancy presents a new maternal awareness of the ability to impact infant health (Phelan et al., 2014). Pregnant women are often highly motivated to make healthy lifestyle changes and many argue that pregnancy is an ideal time to provide an intervention to benefit both mother and infant (Artal et al., 2007). On the contrary, research indicates that many women also feel that pregnancy is an opportunity to not worry about their weight, which leads to increased caloric intake (Clark and Ogden, 1999). Both of these scenarios were indicated (personal observation) in the participants from *My Clinic* and should be explored further in an attempt to find common themes.

Despite the challenges related to integrating NELIP in the *My Clinic* setting, the unique intervention program should be continued for class 2/3 obese pregnant women at risk for excessive weight gain and macrosomic babies. The non-pregnant and pregnant literature concludes the best weight control strategies involve a combination of physical activity and nutritional management, with the possible addition of behavioural strategies (Phelan et al., 2011). However, obese class 2 and 3 pregnant women may have difficulty with two behaviour changes simultaneously. As a result, obese women may find one intensive

lifestyle change easier to achieve. These pilot results should be further pursued to explore the efficacy of lifestyle interventions for obese class 2 and 3 pregnant women in the clinical setting.

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Appendices

Appendix A1 Ethics Approval

	e of Human Participants - Ethics Approval Notice	
women into clinical practice Department & Institution:Schulich Schoo Sponsor:Children's Health Research Insti Ethics Approval Date:October 04, 2012 B	i Nutrition and Exercise Lifestyle Intervention Program (NEL I of Medicine and Dentistry\Obstetrics & Gynaecology,St. Jo ute Expiry Date:April 30, 2014	
Documents Reviewed & Approved & Do	cuments Received for Information:	Version
Document Name	Comments	Date
Revised Western University	Revised methodology, & clarification of	blood
Protocol	draw amounts	
Revised Letter of Information of Consent	&	2012/05/14
Other	Revised consent to participate as a control	ol
date noted above. The membership of this of the Food and Drug Regulations. The ethics approval for this study shall ren the HSREB's periodic requests for surveill time you must request it using the Univers Members of the HSREB who are named a discussion related to, nor vote on, such str	In granted approval to the above referenced revision(s) or an REB also complies with the membership requirements for F hain valid until the expiry date noted above assuming timely ance and monitoring information. If you require an updated a ty of Western Ontario Updated Approval Request Form. is investigators in research studies, or declare a conflict of in idies when they are presented to the HSREB. bert. The HSREB is registered with the U.S. Department of H 100940.	and acceptable responses to approval notice prior to that terest, do not participate in
11	Ethics Officer to Contact for Further Information	
Janice Sutherland	Grace Kelly (grace, kelly@uwo.ca) (swalcot@uwo	
(fsutherl@uwo.ca)		
This	s an official document. Please retain the original in your files.	

Appendix A2 Weight & Health History Questionnaire

Today's date: ____ Unique Identifier: ____ _____ 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: _____ (month, day, year) 1) What is your date of birth? 2) What is your ethnic background? O Caucasian **O** Hispanic O Aboriginal (please circle: First Nations, Métis, Inuit) O Asian O African American O Other, please specify 3) What is your height? ______ feet _____ inches, OR _____ centimeters 4) What education level did you complete? Please check all that apply. O High school O Elementary school O College O 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 did you gain 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 immediately before this pregnancy? _____ pounds, OR ______ kilograms

10) Were you actively trying to reduce your body weight in the year before this pregnancy?

1

	O No	O If Yes, how much we	ight did you lose?	pounds, OR	kilograms
11) What have	your eating habits been l	ike in the <u>year before</u> thi	s pregnancy? Check all that ap	oply.
	O one mea	l per day, specify when _			
	O two mea	als per day, specify when			
	O three me	eals per day			
	O snack(s)	every day, specify when			_
	O Special	diet, please specify name			

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

O Other nutrition plan, please specify

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

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

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

O No stress.

O Low stress level.

O Moderate stress level.

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

14) Was this your first pregnancy?

O No O Yes

Section C – Previous Pregnancies:

	Age you were	Body weight you were immediately before	Weight you gained during pregnancy	Weight retained <u>after</u> pregnancy	
	you were	pregnancy	<u>aaring</u> prognancy	(never really lost)	
1 st pregnancy		pounds,	pounds,	pounds,	
		ORkg	ORkg	ORkg	
2 nd pregnancy		pounds,	pounds,	pounds,	
		ORkg	ORkg	ORkg	
3rd pregnancy		pounds,	pounds,	pounds,	
		ORkg	ORkg	ORkg	
4 th pregnancy		pounds,	pounds,	pounds,	
		ORkg	ORkg	ORkg	
5 th pregnancy		pounds,	pounds,	pounds,	
		ORkg	ORkg	ORkg	

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
1 st baby	weeks		pounds	inches,
			ounces,	ORcm
			ORkg	
2 nd baby	weeks		pounds	inches,
			ounces,	ORcm
			ORkg	
3 rd baby	weeks		pounds	inches,
			ounces,	ORcm
			ORkg	
4 th baby	weeks		pounds	inches,
			ounces,	ORcm
			ORkg	
5 th baby	weeks		pounds	inches,
			ounces,	ORcm
			ORkg	

Other babies:

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

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

O stable (always about the same weight, only changing by a couple of pounds when I am not pregnant), please skip to question 28

O unstable and progressively increasing

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

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

O 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?

O Yes O If No, please skip to question 28

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

4

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

	you were 19 years old, how many times have you been actively trying to lose weight <u>and</u> at what ease explain.
<i>´</i>	ll the methods you have tried to lose weight.
O Vi	tamin/mineral supplement, please specify
O Di	etary changes or special diets, please specify
O Ph	ysical activity, please specify
O Pi	lls or herbal products, please describe
O Pr	escribed medication, please describe
O Su	rgery, please describe
ЭM	eetings with a health care professional(s), please indicate which professional(s)
O Ot	her, please describe
– 28) What did you u	was the maximum weight you ever lost , how long did it take you to lose that weight and what method se?
Ι	lost pounds, OR kilograms in months, using the following method
– 29) Have	

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

0	No

- **O** No, but I would like to.
- O Yes, and it was helpful. Explain _____
- O 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.

O Group meetings	O Individual support
O Short-term results	O Long-term results
O Minimum time commitment	• Follow-up support
• Education	O Learning healthier lifestyle choices
O Expert advice by registered dietitian	• Expert advice by physician
O Expert advice by exercise physiologist	O Cost
O Safety	O Help with stress management
O Other, please specify	

Section E – About Your Health:

32) Have you ever been diagnosed with:

Type 1 Diabetes Mellitus	O Yes	O No
Type 2 Diabetes Mellitus	O Yes	O No
Gestational Diabetes Mellitus	O Yes	O No
Pre-diabetes	O Yes	O No
Gestational hypertension	O Yes	O No
Polycystic Ovarian Syndrome	O Yes	O No

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

O No **O** If Yes, please describe

Section F – About Your Family:

34) How many siblings do you have?

____ Sister(s) _____ Brother(s)

O I do not know

6

35) How many of your sibling	gs are overweigh	t or obese?				
Sister(s)	Br	other(s)	O I do not know	w		
36) Is there a history of overv	veight or obesity	in the rest of y	our immediate fan	nily? (Check	all that aj	oply)
• Your mother	• Your father					
• Grandmother on year	our mother's side	• Grandfath	er on your mother'	s side		
• Grandmother on year	our father's side	• Grandfath	er on your father's	side		
O None	O I do not kno	OW	O Other(s), ple	ase		
specify:						
37) How many of your siblin	gs have diabetes?	,				
Sister(s)			• I do not know	W		
38) Is there a history of diabe	tes in the rest of y	your immediat	e family? (Check	all that apply)	
O Your mother	O Your father					
• Grandmother on year	our mother's side	• Grandfath	er on your mother'	s side		
• Grandmother on year	our father's side	OG	randfather on your	father's side		
O None	O I do not kno)W	O Other(s), ple	ase		
specify:						
39) What is the height and we	ight of the father	of your child	to be?			
Height	feet	_ inches, OR _		_ centimeters		
Weight	pounds, OR		kilograms			
40) What is the ethnic backgr	ound of the fathe	r of your child	to be?			
O Caucasian O Hi	spanic	O Aborigina	l (please circle: F	irst Nations,	Métis,	Inuit)
O Asian O A	frican American	O Other, ple	ase specify			
41) How many siblings does	the father of your	r child to be ha	ve?			
Sister(s)	B	srother(s) O I	do not know			
42) How many of the father's	s siblings are ove	rweight or ob	ese?			
Sister(s)	Br	other(s)	• I do not know	W		
43) How many of the father 's	s siblings have di	abetes?				
Sister(s)	Br	other(s)	O I do not know	W		

Appendix A3 PARmed-X for Pregnancy

Physical Activity Readiness Medical Examination for Pregnancy

PARmed-X for PREGNANCY MEDICAL ACTIVITY READINESS MEDICAL EXAMINATION

PARmed-X for PREGNANCY is a guideline for health screening prior to participation in a prenatal fitness class or other exercise.

Healthy women with uncomplicated pregnancies can integrate physical activity into their daily living and can participate without significant risks either to themselves or to their unborn child. Postulated benefits of such programs include improved archoic and muscular filtness, promotion of appropriate weight gain, and facilitation of labour. Regular exercise may also help to prevent gestational glucose intolerance and pregnancy-induced hypertension.

The safety of prenatal exercise programs depends on an adequate level of maternal-fetal physiological reserve. PARmed-X for PREGNANCY is a convenient checklist and prescription for use by health care providers to evaluate pregnant patients who want to enter a prenatal fitness program and for ongoing medical surveillance of exercising pregnant patients.

Instructions for use of the 4-page PARmed-X for PREGNANCY are the following:

- 1. The patient should fill out the section on PATIENT INFORMATION and the PRE-EXERCISE HEALTH CHECKLIST (PART 1, 2, 3, and 4 on p. 1) and give the form to the health care provider monitoring her pregnancy.
- 2. The health care provider should check the information provided by the patient for accuracy and fill out SECTION C on CONTRAINDICATIONS (p. 2) based on current medical information.
- 3. If no exercise contraindications exist, the HEALTH EVALUATION FORM (p. 3) should be completed, signed by the health care provider, and given by the patient to her prenatal fitness professional.

In addition to prudent medical care, participation in appropriate types, intensities and amounts of exercise is recommended to increase the likelihood of a beneficial pregnancy outcome. PARmed-X for PREGNANCY provides recommendations for individualized exercise prescription (p. 3) and program safety (p. 4). *NOTE:* Sections A and B should be completed by the patient before the appointment with the health care provider.

ADDRESS		HEALTH INSURANCE №.					
NAME OF							
PRENATAL FITNESS PROFESSIONAL		PRENATAL FITNESSPROFESSIONAL'S PHONE NUMBER					
B PRE-EXERCISE HEALTH CHE	CKL	IST	PART 3: ACTIVITY HABITS DURING THE PAST MC	ONTH			
PART 1: GENERAL HEALTH STATUS		1. List only regular fitness/recreational activities:					
In the past, have you experienced (check YES or NO):	YES	NO					
1. Miscarriage in an earlier pregnacy?			INTENSITY FREQUENCY TIME				
 Other pregnacy complications? 	0	<u> </u>	(times/week) (minutes/da				
 I have completed a PAR-Q within the last 30 days. 	0	ū	1-2 2-4 4 ⁺ <20 20-40	40*			
If you answered YES to guestion 1 or 2, please explain:		-	Medium				
			Light				
			2. Does your regular occupation (job/home) activity involve:				
Number of previous pregnancies?			YES				
			YES Heavy Lifting?				
Number of previous pregnancies? PART 2: STATUS OF CURRENT PREGNANC	СҮ		YES Heavy Lifting? Frequent walking/stair climbing?				
PART 2: STATUS OF CURRENT PREGNAN			YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)?				
PART 2: STATUS OF CURRENT PREGNAN			YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing?				
PART 2: STATUS OF CURRENT PREGNAN		 NO	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting?				
PART 2: STATUS OF CURRENT PREGNAN			YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity?				
PART 2: STATUS OF CURRENT PREGNANCE Due Date: During this pregnancy, have you experienced:	YES	NO	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?*				
PART 2: STATUS OF CURRENT PREGNANCE Due Date: During this pregnancy, have you experienced: 1. Marked fatigue?	YES	NO L	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?* 4. Do you consume alcohol?*				
PART 2: STATUS OF CURRENT PREGNANC Due Date: During this pregnancy, have you experienced: 1. Marked fatigue? 2. Bleeding from the vagina ("spotting")?	YES	NO L	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?*				
PART 2: STATUS OF CURRENT PREGNANCE Due Date:	YES	NO L	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?* 4. Do you consume alcohol?*				
PART 2: STATUS OF CURRENT PREGNAND Due Date: During this pregnancy, have you experienced: 1. Marked fatigue? 2. Bleeding from the vagina ("spotting")? 3. Unexplained faintness or dizziness? 4. Unexplained abdominal pain?	YES	NO L L L	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?* 4. Do you consume alcohol?* PART 4: PHYSICAL ACTIVITY INTENTIONS				
PART 2: STATUS OF CURRENT PREGNAND Due Date: During this pregnancy, have you experienced: 1. Marked fatigue? 2. Bleeding from the vagina ("spotting")? 3. Unexplained faintness or dizziness? 4. Unexplained abdominal pain? 5. Sudden swelling of ankles, hands or face?	YES	NO 	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?* 4. Do you consume alcohol?* PART 4: PHYSICAL ACTIVITY INTENTIONS What physical activity do you intend to do?				
PART 2: STATUS OF CURRENT PREGNAND Due Date: During this pregnancy, have you experienced: 1. Marked fatigue? 2. Bleeding from the vagina ("spotting")? 3. Unexplained faintness or dizziness? 4. Unexplained abdominal pain? 5. Sudden swelling of ankles, hands or face? 6. Persistent headaches or problems with headaches?	YES	NO 	YES Heavy Lifting? Frequent walking/stair climbing? Occasional walking (>once/hr)? Prolonged standing? Mainly sitting? Normal daily activity? 3. Do you currently smoke tobacco?* 4. Do you consume alcohol?* PART 4: PHYSICAL ACTIVITY INTENTIONS What physical activity do you intend to do?				

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PARmed-X for PREGNANCY MEDICAL ACTIVITY READINESS

C CONTRAINDICATIONS TO EXERCISE: to be completed by your health care provider **Absolute Contraindications Relative Contraindications** Does the patient have Does the patient have YES NO YES NO 1. History of spontaneous abortion or premature labour 1. Ruptured membranes, premature labour? in previous pregnancies? 2. Persistent second or third trimester \square \square 2. Mild/moderate cardiovascular or respiratory disease bleeding/placenta previa? (e.g., chronic hypertension, asthma)? 3. Pregnancy-induced hypertension or pre-eclampsia? 3. Anemia or iron deficiency? (Hb < 100 g/L)? \square \square 4. Incompetent cervix? 4. Malnutrition or eating disorder (anorexia, bulimia)? 5. Evidence of intrauterine growth restriction? 5. Twin pregnancy after 28th week? \square 6. High-order pregnancy (e.g., triplets)? \square 6. Other significant medical condition? 7. Uncontrolled Type I diabetes, hypertension or thyroid disease, other serious cardiovascular, Please specify: respiratory or systemic disorder? Risk may exceed benefits of regular physical activity. The decision to NOTE: be physically active or not should be made with qualified medical advice PHYSICAL ACTIVITY RECOMMENDATION: Recommended/Approved Contraindicated

Prescription for Aerobic Activity

RATE OF PROGRESSION: The best time to progress is during the second trimester since risks and discomforts of pregnancy are lowest at that time. Aerobic exercise should be increased gradually during the second trimester from a minimum of 15 minutes per session, 3 times per week (at the appropriate target heart rate or RPE to a maximum of approximately 30 minutes per session, 4 times per week (at the appropriate target heart rate or RPE).

WARM-UP/COOL-DOWN: Aerobic activity should be preceded by a brief (10-15 min.) warm-up and followed by a short (10-15 min.) cool-down. Low intensity calesthenics, stretching and relaxation exercises should be included in the warm-up/cool-down.

F TYPE FREQUENCY INTENSITY TIME Non weight-bearing Begin at 3 times Exercise within Attempt 15 or low-impact endurance an appropriate minutes, even per week and progress to RPE range if it means exercise using large four times and/or target reducing the muscle aroups (e.a., walking, stationary per week heart rate intensity. cycling, swimming, Rest intervals zone may be helpful aquatic exercises, low impact aerobics)

exertion (RPE)	-		_		RATING OF PERCEIVED	
HEART RATE RANGES FOR PREGNANT WOMEN					KERTION (RPE)	
MATERNAL AGE	FITNESS LEVEL or BMI	HEART RATE RANGE (beats/minute)		Check the accuracy of your heart rate targed zone by comparing in to the scale below. A range of about 12-14 (somewhat hard) is appropriate for most pregnant women.		
Less than 20	-	140-155				
20–29	Low Active Fit BMI>25 kg m ⁻²	129-144 135-150 145-160 102-124		6 7 8	Very, very light	
30–39	Low Active Fit BMI>25 kg m ⁻²	128-144 130-145 140-156 101-120		9 10 11 12	Somewhat light Fairly light	
exercise tests	ges were derived t in medically preso ere pregnant. (Mo al., 2008).	reened low-risk	;	13 14 15 16	Somewhat hard Hard	
	,,			17 18 19	Very hard Very, very hard	

20

PRESCRIPTION/MONITORING OF INTENSITY: The best way to prescribe

"TALK TEST" - A final check to avoid overexertion is to use the "talk test". The exercise intensity is excessive if you cannot carry on a verbal conversation while exercising.

The original PARmed-X for PREGNANCY was developed by L.A. Wolfe, Ph.D., Queen's University and updated by Dr. M.F. Mottola, Ph.D., University of Western Ontario.

No changes permitted. Translation and reproduction in its entirety is encouraged.

Disponible en français sous le titre «Examination medicale sur l'aptitude à l'activité physique pour les femmes enceintes (X-AAP pour les femmes enceintes)»

Additional copies of the PARmed-X for PREGNANCY, can be downloaded from

Canadian Society for Exercise Physiology www.csep.ca/forms

2

Physical Activity Readiness Medical Examination for Pregnancy

PARmed-X for PREGNANCY MEDICAL ACTIVITY READINESS MEDICAL EXAMINATION

Prescription for Muscular Conditioning

major muscle groups during both prenatal and postnatal periods.		CATEGORY	PURPOSE		EXAMPLE		
		Upper back	Promotion of good posture		Shoulder shrugs, shoulder blade pinch		
		Lower back	Promotion of good posture		Modified standing opposite leg & arm lifts		
WARM-UPS & COOL DOWN: Range of Motion: neck, shoul- der girdle, back, arms, hips,		Abdomen	Promotion of good posture, prevent low-back pain, prevent diastasis recti, strengthen muscles	of la	Abdominal tightening, abdominal curl-ups, head raises lying on side or standing positior abour		
knees, ankles, etc. Static Stretching: all ma	ior	Pelvic floor ("Kegels")	Promotion of good bladder control, prevention of urinary incontinence				
muscle groups		Upper body	Improve muscular support for breas	s	Shoulder rotations, modified push-ups against a wall		
(DO NOT OVER STRET	<u>CH!)</u>	Buttocks, lower limbs	Facilitation of weight-bearing, preven of varicose veins	ntion	Buttocks squeeze,standing leg lifts, heel raises		
	PRI	ECAUTIONS F	OR MUSCULAR CONDITION	ING	DURING PREGNANCY		
VARIABLE	EFFEC	TS OF PREGNAN	CY		EXERCISE MODIFICATIONS		
Body Position	may half c	the supine position (lying on the back), the enlarged uterus y either decrease the flow of blood returning from the lower if of the body as it presses on a major vein (inferior vena cava) it may decrease flow to a major artery (abdominal aorta)			 past 4 months of gestation, exercises normally done in the supine position should be altered such exercises should be done side lying or standing 		
Joint Laxity		ments become relaxed due to increasing hormone levels ts may be prone to injury			avoid rapid changes in direction and bouncing during exercises stretching should be performed with controlled movements		
Abdominal Muscles	midlin	esence of a rippling (bulging) of connective tissue along the dline of the pregnant abdomen (diastasis recti) may be seen ring abdominal exercise			 abdominal exercises are not recommended if diastasis recti develops 		
Posture	forwa the lo	asing weight of enlarged breasts and uterus may cause a rd shift in the centre of gravity and may increase the arch in wer back any also cause shoulders to slump forward			emphasis on correct posture and neutral pelvic alignment. Neutral pelvic alignment is found by bending the knees, feet shoulder width apart, and aligning the pelvis between accentuated lordosis and the posterior pelvic tilt position.		
Precautions for Resistance Exercise	 exhall Valsa shoul 	asis must be placed on continuous breathing throughout exe o on exertion, inhale on relaxation using high repetitions and va Manoevre (holding breath while working against a resista b be avoided exercise in supine position past 4 months gestation			weights		

(to be completed an	nancy - Health Evaluation Form ad given to the prenatal fitness professional ning medical clearance to exercise)
I, PLE activity during my current pregnancy with my health ca	ASE PRINT (patient's name), have discussed my plans to participate in physical are provider and I have obtained his/her approval to begin participation.
Signed:(patient's signature)	Date:
	HEALTH CARE PROVIDER'S COMMENTS:
Name of health care provider:	
Address:	
Telephone:	
· · · · ·	(health care provider's signature)

Physical Activity Readiness Medical Examination for Pregnancy

Advice for Active Living During Pregnancy

Pregnancy is a time when women can make beneficial changes in their health habits to protect and promote the healthy development of their unborn babies. These changes include adopting improved eating habits, abstinence from smoking and alcohol intake, and participating in regular moderate physical activity. Since all of these changes can be carried over into the postnatal period and beyond, pregnancy is a very good time to adopt healthy lifestyle habits that are permanent by integrating physical activity with enjoyable healthy eating and a positive self and body image.

Active Living:

Healthy Eating:

- see your doctor before increasing your activity level during pregnancy
 the need for calories is than before pregnancy
- exercise regularly but don't overexert
- exercise with a pregnant friend
- or join a prenatal exercise program
- follow FITT principles modified for pregnant women
- know safety considerations for exercise in pregnancy
- the need for calories is higher (about 300 more per day) than before pregnancy
- follow Canada's Food Guide to Healthy Eating and choose healthy foods from the following groups: whole grain or enriched bread or cereal, fruits and vegetables, milk and milk products, meat, fish, poultry and alternatives
- > drink 6-8 glasses of fluid, including water, each day
- > salt intake should not be restricted
- limit caffeine intake i.e., coffee, tea, chocolate, and cola drinks
- dieting to lose weight is not recommended during pregnancy

Positive Self and Body Image:

- remember that it is normal to gain weight during pregnancy
- accept that your body shape will change during pregnancy
- enjoy your pregnancy as a unique and meaningful experience

For more detailed information and advice about pre- and postnatal exercise, you may wish to obtain a copy of a booklet entitled *Active Living During Pregnancy: Physical Activity Guidelines for Mother and Baby* © 1999. Available from the Canadian Society for Exercise Physiology, www.csep.ca. Cost: \$11.95

Public Health Agency of Canada. The sensible guide to a healthy pregnancy. Minister of Health, 2012. Ottawa, Ontario K1A 0K9. http://www.phac-aspc. gc.ca/hp-gs/guide/assets/pdf/hpguide-eng.pdf. HC Pub.: 5830 Cat.: HP5-33/2012E. 1 800 O-Canada (1-800-622-6232) TTY: 1-800-926-9105.

Davenport MH. Charlesworth S. Vanderspank D. Sopper MM. Mottola MF. Development and validation of exercise target heart rate zones for overweight and obese pregnant women. Appl Physiol Nutr Metab. 2008; 33(5): 984-9.

Davies GAL. Wolfe LA. Mottola MF. MacKinnon C. Joint SOGC / CSEP Clinical Practice Guidelines: Exercise in Pregnancy and the Postpartum Period. Can J Appl Physiol. 2003; 28(3): 329-341.

Mottola MF, Davenport MH, Brun CR, Inglis SD, Charlesworth S, Sopper MM. VO peak prediction and exercise prescription for pregnant women. Med Sci Sports Exerc. 2006 Aug;38(8):1389-95.PMID: 16888450

SAFETY CONSIDERATIONS

- Avoid exercise in warm/humid environments, especially during the 1st trimester
- Avoid isometric exercise or straining while holding your breath
- Maintain adequate nutrition and hydration drink liquids before and after exercise
- Avoid exercise while lying on your back past the 4th month of pregnancy
- Avoid activities which involve physical contact or danger of falling
- Know your limits pregnancy is not a good time to train for athletic competition
- Know the reasons to stop exercise and consult a qualified health care provider immediately if they occur

REASONS TO STOP EXERCISE AND CONSULT YOUR HEALTH CARE PROVIDER

- Excessive shortness of breath
- Chest pain
- Painful uterine contractions (more than 6-8 per hour)
- Vaginal bleeding
- Any "gush" of fluid from vagina (suggesting premature rupture of the membranes)
- Dizziness or faintness

Appendix A4 Letter of Information and Consent to Participate as a Control



Letter of Information

Investigation Title:

Bringing an evidence-based Nutrition and Exercise Lifestyle Intervention Program (NELIP) for obese pregnant women into clinical practice.

Study Investigators:

- 1. Dr. Debbie Penava, MD, FRCSC, Department of Obstetrics & Gynecology;
- 2. Dr. Michelle Mottola, PhD, Exercise and Pregnancy Lab, UWO;
- 3. Dr. Barbra deVrijer, MD, FRCSC, Department of Obstetrics & Gynecology

The purpose of this letter of information is to provide you with the information you need to make an informed decision about participating in this study.

Introduction

You are being invited to participate in a research study looking at the effects of a nutrition and exercise lifestyle intervention program (NELIP) in the prevention of excessive pregnancy weight gain, and a reduction in the incidence of diabetes and cardiovascular disease risks, for mothers and their offspring, through an early initiation of healthy living.

Purpose of the Study

The main goal of the study is to prevent childhood obesity early through a lifestyle intervention aimed at at-risk pregnant women to prevent excessive weight gain during pregnancy and gestational diabetes. There will be a total of 30 program patients and 30 controls enrolled in this study.

Inclusion/Exclusion Criteria

In order to participate in this study, you **must** be a patient who has been referred to the specialized "My Clinic" at the London Health Sciences Centre. You **must** also be:

- At least 18 years old
- 12-16 weeks pregnant

In order to participate in this study, you must not:

- Have a medical reason that would keep you from walking regularly.
- Have existing type 2 diabetes.

If you are unsure about whether you are eligible to participate in this study, please discuss with your "My Clinic" physician.

Initials:

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South Street Hospital • University Hospital • Victoria Hospital and Children's Hospital

May 14, 2012

Study Procedures

Oral Glucose Tolerance Test

If you are interested in participating in this study, we ask that you inform us before you have your oral glucose tolerance test performed in the clinic. The oral glucose tolerance test performed as part of standard care is slightly different than the one used for the study:

- The standard oral glucose tolerance test for patients at "My Clinic": To prepare for this test you must eat no food or drink anything except water for 12 hours (overnight) before your visit. Once in the lab, we will draw 10mL of blood once you have been sitting quietly for 20 minutes. Two more blood samples will be withdrawn after we have given you a sweet liquid containing 75 g of glucose to drink. These samples will be taken at 60 and 120 minutes after you have taken the drink, while you are resting comfortably in a chair. The total blood withdrawn from your vein is approximately 20 mL (less than 2 tablespoons). The blood samples will be used to analyze the changes in your blood sugar over time in response to the glucose drink that we gave you.
- The study oral glucose tolerance test for patients in this research study: You prepare for the test the same way. An extra 5mL (for a total of 15mL extra) will be withdrawn at the same time points as above. The total blood withdrawn from your vein is approximately 35 mL (less than 3 tablespoons). The additional blood samples will be used to analyze the changes in your lipids (fat) and blood insulin (a hormone that responds to blood sugar) over time in response to the glucose drink that we gave you. This is not part of standard care.

Because participants in the study need a different test than non-participants, we will need to know if you are interested in participating before you complete your oral glucose tolerance test. Rarely, the results of your oral glucose tolerance test may show that you have a medical condition which means you cannot participate in the study. If this is the case, your physician will inform you.

Questionnaires/Diaries

At your first visit at My Clinic, you will be asked to fill out a Weight and Health History Questionnaire and the PARmed-X for Pregnancy. Completing these items is part of **standard care**; your doctor will ask you to complete them whether you enroll in the study or not. However, we will be using information from these questionnaires in the study.

If you agree to participate in this study, you will also be asked to complete a Physical Activity Survey at your initial visit. This is not part of standard care. Once you have completed the glucose tolerance test, you will be asked to complete a food diary for 3 consecutive days, including one weekend day. You will also be given a pedometer and a log sheet to record the number of daily steps you take.

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Group Assignment

Once you have completed these logs, you will be assigned at random, that is, by a method of chance (like the flip of a coin), to one of the study groups. There are three study groups you may be assigned to:

- The first group (10 participants) will be assigned to receive the full Nutrition & Exercise Lifestyle Intervention Program (NELIP) intervention. If you are assigned to this group, you will be introduced to a walking program at London Health Sciences Centre – Victoria Hospital, and will be encouraged to come to the hospital 3 to 4 times per week for walks ranging from 25-40 minutes throughout your pregnancy. You will be given a pedometer and log sheet in order to record your daily steps. You will also receive information on the dietary program you will be following throughout your pregnancy.
- The second group (10 participants) will be assigned to receive only the exercise component of the NELIP intervention. If you are assigned to this group, you will be introduced to the walking program and encouraged to come to LHSC for your walks, but you will not receive any dietary intervention.
- 3. The third group (10 participants) will be assigned to receive **only the nutrition component** of the NELIP intervention. You will not be involved in the walking program, but you will receive information on the dietary program you will be following throughout your pregnancy.

Alternatively, if you are not willing to be randomized to one of the three study groups, you can choose to be in the control group. These 30 control participants will be assigned to receive standard care; that is, they will not receive any of the NELIP intervention. However, we will still need your consent to be a control participant, as we will still be taking additional blood samples, having you complete additional questionnaires, and having you return to the clinic at 6 and 12 months post-partum.

Nutrition Program

If you are assigned to group 1 or group 3, you will receive the nutrition component of the NELIP. After completing the 3-day food diary, you will receive instructions on our nutrition program. The purpose of the controlled nutrition regime is to promote good eating habits, to control excessive weight gain and to regulate your blood sugar levels. Once per week throughout the program, you will be required to record for a 24-hour period everything you ate and drank during that time period. This will assist us in adjusting your nutrition program as your pregnancy progresses.

Controlled Walking Program

If you are assigned to group 1 or group 2, you will receive the exercise component of the NELIP, which consists of a walking program in which you will walk for 25 minutes, 3 to 4 times per week, adding 2 minutes each week, until 40 minutes is reached and then maintained until delivery. You will be given a pedometer and log sheet to keep track of daily steps. You should follow a walking pace that is easy for you to maintain without you becoming breathless. You will have the option of either walking an indoor track at My Clinic with supervision by a study volunteer, on a treadmill in your own gym, on an outdoor trail (weather permitting) or in your

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neighbourhood. We encourage you to come to the clinic for your walks.

Visits

If you agree to participate in this study as a program participant (groups 1-3), we will ask you to come to My Clinic every Friday to track weekly weight gain.

At 28 Weeks of pregnancy

As part of your standard care, your doctor will request a second oral glucose tolerance test. As at your initial test, if you choose to participate in this study, an additional <u>20mL</u> of blood will be drawn to assess changes in your lipids and blood insulin levels.

At 34 Weeks of pregnancy

As part of your standard care, your doctor will request a third oral glucose tolerance test. As at your initial test, if you choose to participate in this study, an additional <u>20mL</u> of blood will be drawn to assess changes in your lipids and blood insulin levels.

You will also be asked to complete the Physical Activity Survey again. You are under no obligation to complete this questionnaire, and you may refuse to answer any or all of the questions.

Delivery

After you deliver, one of our research staff will visit you and your new baby within 6 to 18 hours. We will collect your baby's length and birth weight and the weight of your placenta from your hospital chart. We will measure head size, chest size and abdomen size of your baby, using a cloth tape measure. We will record placental weight. We will record 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. 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.

Six Months Postpartum

At 6 months post delivery, we will ask you to return to the clinic for a follow-up visit. We will ask you to complete the Breastfeeding and Infant Feeding Questionnaire and the Physical Activity Survey. You are under no obligation to complete these questionnaires, and you may refuse to answer any or all of the questions.

As previously described, we will measure your infant's length, weight and head circumference, chest circumference, abdomen circumference, hip circumference, arm circumference, mid-thigh circumference and calf circumference. We will also measure 6 skinfold sites on your infant. 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. Infant circumferences will be taken using a

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soft cloth tape measure, and a special infant skinfold caliper will be used for the skinfold measurements. There are no known risks with this procedure. 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.

The total time for this visit will be one hour.

Twelve Months Postpartum

At 12 months post delivery, we will ask you to return to the clinic for a follow-up visit. We will ask you to complete the Breastfeeding and Infant Feeding Questionnaire and the Physical Activity Survey. You are under no obligation to complete these questionnaires, and you may refuse to answer any or all of the questions.

As previously described, we will measure your infant's length, weight and head circumference, chest circumference, abdomen circumference, hip circumference, arm circumference, mid-thigh circumference and calf circumference. We will also measure 6 skinfold sites on your infant. 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. Infant circumferences will be taken using a soft cloth tape measure, and a special infant skinfold caliper will be used for the skinfold measurements. There are no known risks with this procedure. 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.

The total time for this visit will be one hour.

Risks and Benefits to You if You Participate in This Study

There are no known risks to your participation in this study. If you are randomized to one of the groups receiving the exercise component and you have previously been inactive, you may experience muscle cramps and fatigue when you begin the exercise program.

Participation in this study may be of no direct benefit to you. The benefits to you and your family may include prevention of excessive weight gain during pregnancy and minimizing weight retention after the baby is born. You may also gain information about healthy eating and how to be active for you and your family that will last you a lifetime.

Other Information You Need to Know About Taking Part in This Study

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on your future care. If you withdraw from the study at any time, we may still use your data compiled up to that point.

If your medical condition changes throughout the course of the study, and your physician

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determines that continuation in the study would impair your health or that of your baby, you will be advised at that time to discontinue the program. We will still include you in the study and you will continue to receive ongoing medical care. If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

An alternative to the procedures described above is not to participate in the study and continue on just as you do now. There is no guarantee of a personal benefit by participating in the study. Regardless of your decision to participate you would still receive continuing medical care.

Biological Specimens

Any specimen(s) (e.g., blood) obtained for the purposes of this study will become the property of the researchers/sponsors and once you have provided the specimens you will not have access to them.

The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.

Compensation and Costs

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 Victoria Hospital for **those visits that are required only for this research study**. For study visits that occur with your clinical care, your parking will not be covered.

Specific Things You Should Know About Confidentiality

Your confidentiality will be respected. The information collected will be used for this current research project only. Your records will be kept locked in a cabinet in a secure office. You will be given a unique identification number and will not be personally identified in any way. However, it is important to note that the original signed research consent form and the data which will follow will be included in your health record. If the results of this study are published or presented to groups of other researchers or health care professionals, they will be presented as group data, and your name will not be associated with any specific result without your consent to the disclosure.

We will strive to ensure the confidentiality of your research–related records. Absolute confidentiality, however, cannot be guaranteed, as we may have to disclose certain information under certain laws. 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.

While we will do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your initials and your date of birth may allow someone to link the data

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and identify you.

Contact Information

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute, (519) 667-6649.

What You Need to Know About Signing the Consent Form

If during the course of this study new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the study investigators.

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.

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Bringing an evidence-based Nutrition and Exercise Lifestyle Intervention Program (NELIP) for obese pregnant women into clinical practice

Consent to Participate as a Control

I have read the letter of information, have had the nature of the study explained to me and I agree for myself and my child to participate **as controls**. All questions have been answered to my satisfaction.

While I do not wish to participate in this research study, I am willing to have my information used as a control participant. This involves:

- Having additional blood samples (<u>15-20mL total</u>) taken at oral glucose tolerance tests at intake, <u>28</u> weeks, and 34 weeks;
- · Completing additional questionnaires not required for clinical care; and
- Returning to the clinic at 6 and 12 months post-partum for study follow-up.

Control Participant Name (print)

Control Participant Signature

Date

Person conducting the informed consent process including administration and explanation of the form:

Printed name

Date

Signature

Appendix A5 Consent to Participate



Bringing an evidence-based Nutrition and Exercise Lifestyle Intervention Program (NELIP) for obese pregnant women into clinical practice

Consent to Participate

I have read the letter of information, have had the nature of the study explained to me and I agree for myself and my child to participate. All questions have been answered to my satisfaction.

Participant Name (print)

Participant Signature

Date

Person conducting the informed consent process including administration and explanation of the form:

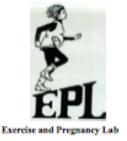
Printed name

Date

Signature

Nutrition & Exercise Lifestyle Intervention Program (NELIP)







Syrups, sauces and gravies

□ Condiments, e.g., ketchup,

soy sauce, mayo, etc.

Candy and soft drinks

EXERCISE AND PREGNANCY LABORATORY

3-DAY FOOD RECORD

Unique ID: Dates to record:

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



□ Spreads on toast, potatoes and vegetables

Sugar and cream or creamers in beverages

Salad dressings



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

snacks and beverages.

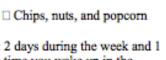
If in doubt, leave too much information! Thank you!





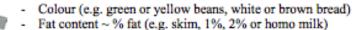


Exercise and Pregnancy Lab, 3M Centre, The University of Western Ontario London, N6A 3K7; Phone: 519-661-2111 X 88366; Fax: (519) 661-2008



What do I need to include?

- 1. List the food item and amount eaten
 - Product Name type of food eaten (ex. mushroom soup)
 - Brand Name- different ingredients may be used (ex. Campbell vs. Lipton)
 - Characteristics:





- ~ learness of meat (e.g. extra rear ground over)
- ~ fat claims (e.g. light, low fat, etc.) ~ Was it fresh, frozen, canned or dried?
- 2. Record the time and the place where the food was eaten.
- 3. For each item briefly describe how it was prepared:

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



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

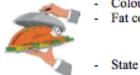
Give dimensions: e.g., 2 slices of roast beef – 5" x 3" x ¼" thick Give spoon or cup measurements: e.g., ¾ cup peas with ½ tsp butter Give ounces (oz): e.g., 4 oz of salmon or a 6 oz steak Give metric units: e.g., 250 mL of milk

For mixed dishes such as lasagna, casseroles and stews, record approximate amounts of the main ingredients.

> E.g., Lasagna - Were there vegetables in it? What kind? - Was it a meat and cheese lasagna?







How do I know what a serving size is?

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

Count the number of food items if practical.

E.g., 20 grapes

or 8 shrimps

- Use household measures to specify serving sizes.
 - E.g., 1 cup (c) = 250 mL 1 ounce (oz) = 30 g

1 tablespoon (Tbsp) = 15 mL 1 teaspoon (tsp) = 5 mL

- Use your hands to estimate serving sizes.
 - A palm is equal to 3 ounces (e.g., 3 ounces of meat, fish or poultry).
 - A fist is equivalent to a 1 cup measure (e.g., 1 cup of lettuce)

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

- 3 thumb tips are equal to 1 tablespoon (e.g., 1 Tbsp of salad dressing and peanut butter).
- Other objects that may help to estimate serving sizes.
 - A deck of cards is approximately 3-4 oz of meat.
 - A computer mouse is a serving of potato.
 - A baseball is equal to one cup or a serving of pasta.
 - A tennis ball is equal to a medium sized fruit.
 - A hockey puck is the serving size of a bagel.
 - A Ping-Pong ball is equal to 2 tablespoons.
 - A CD is the serving size of a pancake.
 - A chequebook is a 3 oz fillet of fish.
 - A floppy disk is a slice of processed cheese.
 - A pair of dice is 2 tsp of sugar.
 - A film canister is an ounce of nuts.
 - Three dominos is 3 oz of low fat hard cheese.













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

2880

Unique ID:

3-Day Food Record

Date:

Day 1

Time Place Food and Description and Amount Method of Preparation Total number of steps today: Time: Structured Activity: Place: Duration: Pre-exercise steps: Post-exercise steps:

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



Unique ID:

3-Day Food Record

Date:

Time	Place	Food and Description and Method of Preparation	Amount
Fotal num	ber of steps today:		
Structured	Activity:	Place:	Time:
Pre-exercis	se steps:	Post-exercise steps:	Duration:

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



Unique ID:

3-Day Food Record Day 3

Date:

Time	Place	Food and Description and Method of Preparation	Amount
Total num	ber of steps today:		
	l Activity:	Place:	Time:
Pre-exerci		Post-exercise steps:	Duration:

Appendix A7 Seven-Day Pedometer Log

PEDOMETER/ACCELEROMETER LOG

NELIP STUDY – UNIVERSITY OF WESTERN ONTARIO					
Unique ID #		Pedometer #		Accelerometer #	
DAY 1		DAY 2		DAY	3
PUT ON PEDOME	ETER A	AS SOON AS YO	U GET OUT OF	BED &	2 SET IT TO ZERO
Did you exercise? Y	N	Did you exercis	e?YN	Did y	ou exercise? Y N
IF YES: Steps Before:		IF YES: Steps I	Before:	IF YE	S: Steps Before:
Steps After:		Steps A	After:		Steps After:
ONCE IN BED, RECO	RD	ONCE IN BED	, RECORD		E IN BED, RECORD
Total Steps:		Total Steps:		Total Steps:	
DAY 4	DAY	5 DAY 6			Day 7
PUT ON PEDOME	ETER A	AS SOON AS YO	U GET OUT OF	BED &	2 SET IT TO ZERO
Did you exercise? Y	Did you exercise? Y Did you		ou exercise? Y Did you exercise		Did you exercise? Y
Ν	Ν		Ν		Ν
IF YES:	IF YE	ES:	IF YES:		IF YES:
Steps Before:	e: Steps Before:		Steps Before:		Steps Before:
Steps After: Steps		After:	Steps After:		Steps After:
				-	
ONCE IN BED,		E IN BED,	ONCE IN BED,		ONCE IN BED,
RECORD	RECO		RECORD		RECORD
Total Steps:	Total	Steps:	Total Steps:		Total Steps:

Appendix A8 NELIP Meal Plan

		1					
TIME	FOOD GROUP	CHOICES	ONE DAY SAMPLE MENU	ALTERNATIVES			
	Target = ~25 grams of carbohydrates						
BREAKFAST	Starch Foods	1	¹ / ₂ cup cereal (e.g. Shreddies) <u>or</u> ¹ / ₂ small multigrain bagel <u>or</u> 1 slice whole wheat bread				
	Protein Foods	1	1 egg <u>or</u> 1 ounce (~30 grams) low-fat cheese <u>or</u> 1 Tbsp (15 mL) peanut butter				
	Milk	2	1 cup (250 mL) skim milk or 1/4 cup (60 g) low-fat fruit yogurt				
_	Extra Vegetables	recommended	2 slices tomato or ½ cup mushrooms & green pepper (in omelette)				
			Target = ~25 grams of carbohydrates				
AM SNACK	Starch Foods	1	1⁄2 whole wheat English muffin <u>or</u> 1 small oat bran muffin <u>or</u> 5 multigrain crackers				
A N	Fats & Oils	1	1 tsp (5 mL) soft (e.g. Becel) margarine				
••	Vegetable & Fruit	1	1 cup vegetable juice or ½ medium apple or 1 small orange or 2 apricots				
			Target = ~35 grams of carbohydrates				
	Starch Foods	2	2 slices whole wheat or pumpernickel bread or 1 cup legumes				
Ξ	Protein Foods	3	3 ounces lean meat <u>or</u> skinless poultry e.g. 90 g <u>or</u> 1 medium roasted chicken breast				
LUNCH	Fats & Oils	2	1 tsp olive oil and ¼ avocado or 2 tsp regular salad dressing				
Ľ	Milk	1	$\frac{1}{2}$ cup (125 mL) skim milk or $\frac{1}{2}$ cup (125 mL) plain fortified soy beverage				
	Extra		1 slice tomato and 1 cup spinach salad (with avocado and oil				
	Extra Vegetables	recommended	above) <u>or</u> 2-3 slices cucumber <u>and</u> a celery stick <u>or</u> ½ cup sliced sweet peppers				
			Target = ~25 grams of carbohydrates				
PM SNACK	Starch Foods	1	5 whole wheat crackers \underline{or} 4 melba toasts \underline{or} 1 slice flax bread \underline{or} $\frac{1}{2}$ small multigrain bagel \underline{or} 1/3 cup legumes				
	Vegetable & Fruit	1	¹ / ₂ cup mixed raw vegetables <u>or</u> ½ cup grapes <u>or</u> 1 kiwi <u>or</u> 4 tsp raisins (small box) <u>or</u> ½ small banana				
	Fats & Oils	1	10 peanuts or 5 cashews or 1 Tbsp (15 mL) cream cheese				
			Target = ~45 grams of carbohydrates				
	Starch Foods	2	⅔ cup rice <u>or</u> baked beans <u>or</u> 1 cup pasta <u>or</u> 1 cup (250 mL) potato <u>or</u> corn <u>or</u> couscous				
₽	Fats & Oils	2	2 tsp (10 mL) oil <u>or</u> soft, non-hydrogenated margarine <u>or</u> 2 Tbsp (30 mL) low-fat sour cream				
DINNER	Vegetable & Fruit	1	1/2 cup (125 mL) cooked carrots or peas or mixed vegetables				
	Protein Foods	3	3 ounces lean meat <u>or</u> poultry or fish; <u>or</u> ½ cup legumes e.g. 90 g roast beef <u>or</u> a medium pork chop				
	Milk	1	¹ / ₂ cup (125 mL) skim milk or plain fortified soy beverage				
	Extra Vegetables	recommended	1/2 cup (125 mL) tossed salad <u>or</u> 1/2 cup (125 mL) broccoli <u>or</u> 1/2 cup (125 mL) cauliflower or 1/2 cup (125 mL) green beans				
		1	Target = ~25 grams of carbohydrates				
	Starch Foods	1	¹ / ₂ whole wheat pita or 3 cups (750 mL) plain popcorn				
۶Ľ	Fats & Oils	1	1 Tbsp (15 mL) low-fat mayo <u>or</u> 1 tsp (5 mL) margarine				
EVENING	Protein Foods	1	¹ ⁄ ₄ cup (60 mL) canned salmon <u>or</u> tuna <u>or</u> low-fat cottage cheese <u>or</u> 1 egg <u>or</u> 1 Tbsp (15 mL) peanut butter				
	Vegetable & Fruit	1	8 baby carrots <u>or</u> 1 cup celery <u>or</u> 1 peach <u>or</u> 1 kiwi <u>or</u> 1 small orange <u>or</u> ½ pear <u>or</u> ½ cup berries				
			Target = ~25 grams of carbohydrates	l			
BED SNACK	Starch Foods	1	1 fig Newton cookie <u>or</u> ³ / ₄ cup plain cheerios <u>or</u> ¹ / ₂ cup oat flakes <u>or</u> 2 rice cakes	May substitute with 1 cup of low-fat plain			
SN B	Milk	2	[→] ³ ⁄ ₄ cup (175 g) low-fat plain yogurt <u>or</u> 1 cup (250 mL) skim milk <u>or</u> 1 cup (250 mL) plain fortified soy beverage	chocolate, strawberry or vanilla ice cream.			
Nater (00000000	2	1 cup (250 mL) plain fortified soy beverage	or vanilla ice cre			

NELIP Suggested Meal Plan

FBBT 2009

Curriculum Vitae

Name:	Samantha Langstaff
Post-secondary Education and Degrees:	University of Windsor Windsor, Ontario, Canada 2009-2012 BHK
	The University of Western Ontario London, Ontario, Canada 2012-2015 MSc, Integrative Physiology, Kinesiology
Honours and Awards:	Western Graduate Research Scholarship 2012-2014
	Ontario Graduate Scholarship 2012-2014
Related Work Experience	Teaching Assistant The University of Western Ontario 2012-2014
	Research Assistant R. Samuel McLaughlin Exercise and Pregnancy Laboratory The University of Western Ontario 2012-2014

Scientific Presentations:

Langstaff, SE, Giroux, I, Sopper, MM, Mottola, MF. Efficacy of a Nutrition and Exercise Lifestyle Intervention Program (NELIP) for preventing excessive gestational weight gain in class 2 and 3 obese women. Canadian Society for Exercise Physiology (CSEP) Annual Conference, Toronto, ON.