The Impact of a Lifestyle Intervention Program to Help Prevent Type 2 Diabetes in Rural Adults with Prediabetes in Southwestern Ontario

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ABSTRACT

Objective: To determine if a prediabetes lifestyle intervention program, tailored to rural adults from Southwestern Ontario, could decrease the risk of Type 2 Diabetes (T2D) development through positive lifestyle changes.

Methods: Forty-nine intervention participants and 34 controls partook in the study. At baseline, individuals diagnosed with prediabetes chose the lifestyle intervention group (6 sessions) or control group (1 session). Intervention participants were provided with tailored education which promoted positive lifestyle changes known to help prevent or delay the development of T2D.

Results: Lifestyle changes and long-term improvement of T2D modifiable risk factors were achieved by the intervention participants from baseline to post-program, unlike their control counterparts, such as increasing their average daily intake of vegetables and fruit servings ($p<0.001$) and reducing their fasting glycemia ($p=0.003$).

Conclusion: Positive lifestyle changes through this 6-month tailored community-based intervention was successful in helping many rural adults with prediabetes prevent the development of T2D.

Keywords: Prediabetes, Rural Adults, Lifestyle Changes, Intervention Program

RÉSUMÉ

Objectif: Déterminer si un programme d'intervention, adapté aux adultes avec prédiabète de régions rurales du sud-ouest ontarien, pourrait réduire le risque de diabète de type 2 (DT2) avec des changements au mode de vie.

Méthodes: Quarante-neuf adultes du groupe d'intervention et 34 contrôles ont participé. Des adultes ayant reçu un diagnostic de prédiabète ont choisi de participer au groupe d'intervention ou au groupe contrôle. Les participants à l'intervention ont reçu de l'éducation favorisant des changements de mode de vie pour aider à prévenir le DT2.

Résultats: Les participants à l'intervention ont réalisé des changements de mode de vie positifs, comme augmenter leurs portions de fruits et légumes ($p<0,001$), et amélioré des facteurs de risque de DT2, dont leur glycémie à jeun ($p=0,003$).

Conclusion: Des changements positifs au mode de vie ont aidé plusieurs adultes ruraux avec prédiabète à prévenir le DT2 grâce à cette intervention communautaire de six mois.

Mots-clés: Prédiabète, adultes ruraux, changements de style de vie, programme d'intervention

PREFACE

This thesis by article is submitted to the Master's degree of Interdisciplinary Health Sciences at the University of Ottawa. The research presented in this thesis was conducted under the supervision of Dr Isabelle Giroux at the Faculty of Health Sciences at the University of Ottawa. I was the graduate student of the study, responsible for data collection and analysis, as well as manuscript composition.

The research project, of which this thesis is a part, received research ethics approval from the University of Ottawa Office of Research Ethics and Integrity (REB: H10-12-10) and the Public Health Agency of Canada Research Ethics Board (REB: 2010-0072). This work was supported and funded by the Public Health Agency of Canada: Canadian Diabetes Strategy [grant number 6262-06-2010/0690496].

Abstracts regarding this research projects were presented at the Canadian Diabetes Association (CDA) conference in November 2016, at the International Diabetes Federation (IDF) conference in October 2016, at the Dietitians of Canada (DC) conference in June 2016, at the International Congress of Dietetics (ICD) conference in September 2016, at the DC conference in June 2015, and at the Canadian Obesity Summit (COS) conference in April 2015.

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LIST OF ABBREVIATIONS

A1C: Glycated Hemoglobin

BP: Blood Pressure

CDA: Canadian Diabetes Association

CDC: Center for Disease Control

CFG: Canada Food Guide

CSEP: Canadian Society of Exercise Physiology

CVD: Cardiovascular Disease

DPP: Diabetes Prevention Program

FPG: Fasting Blood Glucose

HDL-C: High-density Lipoprotein Cholesterol

IDF: International Diabetes Federation

IGF: Impaired Fasting Glucose

IGT: Impaired Glucose Tolerance

LDL-C: Low-density Lipoprotein Cholesterol

LHIN: North East Local Health Integration Network

NEFA: Non-Esterified Fatty Acids

OGTT: Oral Glucose Tolerance Test

PA: Physical Activity

PHAC: Public Health Agency of Canada

SCT: Social Cognitive Theory

T1D: Type 1 Diabetes

T2D: Type 2 Diabetes

TC : Total Cholesterol

TG: Triglycerides

WHO: World Health Organisation

CHAPTER 1: Introduction to The Study

This chapter breaks down the thesis by chapters and gives background information about Type 2 Diabetes.

1.1. Thesis Organisation

This thesis explores findings of a 6-month community-based intervention program targeting rural adults with prediabetes. The program took place at the STAR Family Health Team (FHT) in Stratford and Tavistock, situated in Southwestern Ontario. The study included a mixed method approach, where both quantitative and qualitative data were collected. It is written in an article format.

Chapter 1 provides background information on the importance of the thesis subject. Chapter 2 elaborates on the subject as indicated by the literature. Chapter 3 identifies the hypothesis and objectives of the study while justifying its pertinence. Chapter 4 describes the program's methodology and timeline.

Chapters 5 to 8 are in article format. Chapter 5 describes the characteristics of the participants of the program and answers the second secondary objective of the program. Chapter 6 answers the primary objective of the program and evaluates awareness, knowledge, self-efficacy, and behaviours of the intervention participants before and after the completion of the prediabetes program. Chapter 6 answers secondary objectives two and four. This chapter evaluates the effect of lifestyle changes at multiple time points throughout the program and at 6-month follow up. Chapter 8, also the third secondary objective, is the qualitative component of the program and evaluates the program based on practicality, feasibility, and acceptability.

Chapter 9 concludes the thesis with a general discussion highlighting the findings of the program, the limitations and strengths, the implications for professional practice and policy, the

directions for future research, and ends with a general conclusion. Chapter 10 is the bibliography and chapter 11 is the appendix which contains the materials used as part of the study.

1.2. Background

Humankind has always been threatened by hunger. This makes it unsurprising that the human body attempts to store all excess energy intake in adipose tissues [1]. This adaptive mechanism has become troublesome due to increased food availability in developed countries, such as Canada [2]. As a result, recent decades have seen a dramatic rise in the incidence and prevalence of not only obesity but also in comorbidities such as metabolic syndrome and type 2 diabetes (T2D) throughout the world [3]. T2D is the most prevalent form of diabetes and it is defined as a chronic condition that affects the way your body metabolizes glucose. This form of diabetes was previously referred to as "non-insulin-dependent diabetes mellitus" or "adult-onset diabetes"; however, it is now also diagnosed in overweight teenagers and children [4]. It is linked with physical inactivity, family history of T2D, age, and obesity [3,5]. Over time, uncontrolled T2D can lead to serious health complications such as heart disease, stroke, hypertension, blindness, kidney disease, and amputations. Some of these conditions can be life-threatening if they remain untreated [6].

Consequently, T2D has become a global pandemic. Whereas 30 million people lived with this disease in 1980, it is anticipated by the International Diabetes Federation (IDF) that more than 693 million people worldwide will have the disease by 2045 [4]. Rates of prediabetes have also been increasing [4]. Prediabetes is a precursor to the development of T2D, it refers to when blood glucose is higher than normal but not high enough to be diagnosed as T2D [7].

CHAPTER 2: Literature Review

This chapter is the literature review which talks about the pathophysiology of Type 2 Diabetes, its comorbidities, risk factors, and the importance of prevention through lifestyle changes using a behaviour change model. Our target population and its built environment is also investigated.

2.1. Type 2 Diabetes Pathophysiology

T2D is a metabolic disorder and a chronic disease that manifests when the body is unable to sufficiently produce and/or use insulin adequately [8]. Insulin is an endocrine hormone that binds to cells and allows the influx of glucose, which is crucial for cellular process. The signs and symptoms of uncontrolled T2D include frequent urination, excessive thirst, weight loss, and blurred vision [6]. Genetic and environmental factors play a role in the development and progression of T2D. While the onset of T2D typically occurs in adults over the age of 40, it can also be seen in children and youth [6]. The number of people with T2D is growing rapidly in both Canada and worldwide [9]. In 2016, 29% of Canada's population was estimated to have either T2D or prediabetes, and this number is expected to increase to 33% by 2026 [10]. Additionally$_y$, it's also believed that many more are likely undiagnosed [10,11].

The specific mechanisms of T2D is complex. It is a multisystem disorder, with multiple associated comorbidities, such as metabolic symptom [8,12]. Prior to the development of T2D, glucose levels increase into the prediabetes states characterized by impaired glucose tolerance (IGT) and/or impaired fasting glucose (IFG) [13]. IGT occurs when the insulin produced does not action properly, known as insulin resistance [14]. Insulin resistance is defined as a cell's suboptimal response to insulin and is recognized as an underlying component to the development of prediabetes, T2D, and metabolic syndrome [13–15]. IFG occurs when there is beta cell dysfunction, which decreases insulin secretion [13]. The beta cells are found in the pancreas and are responsible for the production of insulin [8]. This dysfunction causes hyperglycemia, defined by elevated blood glucose concentration, which can also cause an increase in insulin resistance [14]. Additional contributors to the development of T2D could include the liver, muscular

system, kidneys, elevated blood concentrations of non-esterified fatty acids (NEFA), central nervous system, gastrointestinal tract, as well as various hormones and even factors such as systemic inflammation, genetics, and the environment [8].

2.2. Type 2 Diabetes Comorbidities

If left uncontrolled, T2D results in consistent hyperglycemia. Over time, this can damage blood vessels, nerves, and organs such as the kidneys, eyes, and heart. Subsequently, the damage caused by hyperglycemia results in significant macrovascular and microvascular complications, decreasing quality of life [16,17]. These complications translate in the following co-morbidities of T2D:

Macrovascular complications:

- Cardiovascular diseases (CVD), which are conditions that can affect the heart's muscle, rhythm, or valve. Insulin resistance contributes to vasoconstriction, thrombosis, and inflammation which can progress into heart failure, myocardial infarction, and stroke [18,19]. In Ontario, T2D contributes to 30% of strokes and 40% of heart attacks [20]. In addition, individuals with T2D are over three times more likely to be hospitalized with CVD complications [21].
- Dyslipidemia, which affects 55% of individuals with T2D, is an abnormal amount of lipids in the blood, can either include elevated total cholesterol (TC), triglycerides (TG) or low-density lipoprotein cholesterol (LDL-C) concentrations, or can include reduced high-density lipoprotein cholesterol (HDL-C) concentrations [12]. This places individuals with T2D at a much higher risk of developing atherosclerosis and subsequent heart disease [22,23].

- Hypertension, which affects approximately 1 in 4 individuals with T2D, is abnormally high BP related to the vasoconstriction that follows insulin resistance and obesity [23]. In consequence, this increases individuals' risk of developing CVD complications [24].

Microvascular complications:

- Diabetic nephropathy, the leading cause of chronic kidney disease in Canada, is a progressive disease caused by damage to the kidney's filtration system [25,26].
- Neuropathy, a condition that is characterized by peripheral nerve damage causing numbness or weakness. As a result, foot ulcerations are common, affecting approximately 23% of individuals with T2D [27,28].
- Retinopathy, the leading cause of non-congenital blindness in Canada, is a disease of the retina that results in visual impairment and eventual blindness [11,29].

2.3. Metabolic Syndrome

Prediabetes and T2D are often manifestations of a much broader underlying disorder known as metabolic syndrome [7]. This syndrome is described as a cluster of conditions that include abdominal obesity, hypertension, dyslipidemia, and elevated blood glucose [30,31]. The associations and clustering of these factors have been known for decades. Metabolic syndrome is not only associated with an increased risk of T2D, but also CVD. It affects 22% of all Canadian adults and its prevalence is increasing both in Canada and worldwide, causing it to become a public health concern [31]. Factors associated with the risk of developing metabolic syndrome include age, excess body weight, physical inactivity, poor diet and smoking, which can be correlated with lower education level and household income [32].

Metabolic syndrome is the outcome of a complex relationship between the environment, genetics, physiology, and biochemistry [39]. While the pathogenesis of the disease remains unclear, it is believed that multiple scenarios happen simultaneously which explain the syndrome [43]. The most accepted hypothesis to describe the pathophysiology of the metabolic syndrome is insulin resistance due to an excess of circulating NEFA. In addition, abdominal obesity appears to play a key role [42]. Dyslipidemia, endothelial dysfunction, genetic susceptibility, elevated BP, hypercoagulable state, and chronic stress are additional factors which play a role in the metabolic syndrome progression.

Various diagnostic criteria have been proposed by different organizations over the past decade [33]. When three of the five criteria listed in Table 1 are abnormal, the individual has the metabolic syndrome. They include high BP, high FBG, high TG, low HDL-C, and an elevated WC. Prevention and treatment of the metabolic syndrome may be crucial to decreasing the incidence of CVD and T2D [30]. Lifestyle intervention studies have demonstrated that diet and exercise programs can reverse metabolic syndrome status [34]. The fact that the metabolic syndrome is highly related to the risk of developing T2D and CVD, emphasizes the importance of understanding, preventing, and treating the disorder.

Table 1:
Harmonized definition of the metabolic syndrome: ≥3 measures to make the diagnosis of metabolic syndrome[1]

Measure	Categorical cutpoints	
	Men	Women
Elevated WC		
• Canada, United States	≥102 cm	≥88 cm
• Europid, Middle Eastern, sub-Saharan African, Mediterranean	≥94 cm	≥80 cm
• Asian, Japanese, South and Central American	≥90 cm	≥80 cm
Elevated TG[2]	≥1.7 mmol/L	≥1.7 mmol/L
Reduced HDL-C[2]	<1.0 mmol/L	<1.0 mmol/L
Elevated BP[2]	Systolic ≥130 mm Hg and/or diastolic ≥85 mm Hg	Systolic ≥130 mm Hg and/or diastolic ≥85 mm Hg
Elevated FPG[2]	≥5.6 mmol/L	≥5.6 mmol/L

[1]Adapted from Alberti et al. [33]

[2]Alternate indicators when drug treatment is involved

BP: blood pressure, FPG: fasting plasma glucose, HDL-C: high-density lipoprotein cholesterol, TG: triglycerides. WC: Waist circumference.

2.4. The Economic Burden of T2D

As previously mentioned, T2D is one of the most costly and burdensome chronic diseases of our time, in Canada and throughout the world [35]. Costs for treating T2D related conditions have escalated sharply over the last decade and are expected to continue their rapid climb for the foreseeable future [36]. The economic burden of diabetes in Canada was estimated at $20.7 billion in 2015 and is projected to rise to $26.8 billion by 2040 [4]. Globally, the IDF estimated that more than 425 million people worldwide have T2D and that treating this accounted for at least $727 billion USD yearly [4]. A study has also estimated that both indirect and direct losses from 2011 to 2030 will total US$ 1.7 trillion worldwide [37].

This chronic disease is not an only an economic burden on the national health care system, but it also imposes significant direct and indirect costs on individuals living with T2D. People with this disease incur medical costs that are up to three times higher than those without T2D. High out of pocket costs have also been identified as one predictor of non-adherence. In fact, 57% of Canadians with T2D reported they cannot adhere to prescribed treatment due to the cost of needed medications, devices, and supplies [36,38]. These costs are particularly difficult for low-income Canadians, such as rural adults. Moreover, employers of those living with T2D also incur financial loss. It was found that the largest component of indirect costs was increased absenteeism and reduced productivity while at work [38,39]. Thus, there is consensus that delaying and/or preventing T2D is cost-beneficial for health systems in Canada, for individuals, and society as a whole [39].

2.5. Rural Adults and Communities

There are additional challenges and issues that affect rural communities, they often cover broad geographic areas, have lower population densities, less financial resources, less education, and higher mortality rates [40]. Additionally, most rural communities have a large proportion of elderly people with relatively few people of working age, resulting in a higher dependency ratio. The elderly population is generally less physically robust and more prone to chronic illnesses. A barrier to physical activity in rural communities can be the perception of the lack of a safe place to be active [41]. Safety concerns keep 20% Canadians from walking or biking [42]. In addition, a lack of adequate public transportation in rural areas impacts health care access [43]. In comparison to the urban residents, rural residents have to travel farther to access care and they

face additional barriers such as poor quality roads, poor access to walking paths, trails and sidewalks, and lack of public transportation [44].

Physical activity is also directly affected by several aspects of the built environment. The influence of built environments in rural settings has not been studied in great depth and urban-based approaches are not necessarily transferable to rural settings [41,45]. The built environment is defined as "a part of our physical surroundings and includes the buildings, parks, schools, road systems, and other infrastructure that we encounter in our daily lives" by the Public Health Agency of Canada (PHAC) [46]. Factors in the environment can positively or negatively influence patterns of health [45]. It can encourage or get in the way of healthy behaviours such as physical activity, healthy eating, mental health, and health equity [46]. Nearly 1 in 5 Canadian live in a rural community, according to the 2016 Census data [47]. Rural communities in Southwestern Ontario, such as Tavistock and Stratford, have a population with more obesity, T2D, and elevated BP than nearby urban centers, which includes London, Ontario [48]. That is in part related to the built environment in rural communities as it is vastly different from that of an urban environment.

Rural communities are at a health disadvantage. The reality of living in rural areas is that health care facilities in those communities are small, often provide limited services and have fewer specialized health care services such as dietitians and social workers [49]. Geographic isolation and shortage of providers and services are multidimensional problems [50]. Canadian rural residents have half as many physicians (1 per 1000) as their urban counterparts and have less access to healthcare [44]. The limited availability of specialist physicians and/or specialized equipment creates barriers for rural adults in need of care [51].

The difficulties to access health care facilities may impair health outcomes by increasing individual's physical and emotional stress and reducing the likelihood of seeking follow-up care [52]. Therefore, more research should evaluate the effects of the rural built environment on chronic disease prevention and management as there is a lack of studies that examined Canadian communities and most studies were conducted in the United States.

2.6. Prediabetes and the Importance of Prevention

In recent years, several medical treatments and advances have improved complications for people with T2D. However, a significantly less amount of research has been completed when it comes to the primary prevention of T2D, also known as prediabetes [53]. Without lifestyle changes, 15-30% of adults with prediabetes will develop T2D within 5 years [54]. Prediabetes is defined as a condition in which people have higher than normal blood glucose concentrations but not high enough for a diagnosis of T2D [55]. Those with prediabetes are said to have IGT, IFG, and/or a glycated hemoglobin (A1C) of 6.0% to 6.4%. Similar to T2D, rates of prediabetes diagnosis have also been increasing [26]. Rising obesity rates, sedentary lifestyles, population ageing, and changes in the ethnic mix of new immigrants is contributing to these increases [3,56]. Individuals who have prediabetes are more likely to develop T2D in the absence of any intervention over time [57–59]. For this reason, the growing importance of screening to detect prediabetes is undeniable. Screening for prediabetes is carried out using the recommended screening tests, such as FBG, OGTT, and A1C, as shown in Table 2 [6,26]. While there is no worldwide agreement on the definition of IFG, Diabetes Canada defines IFG as an FPG value of 6.1 to 6.9 mmol/L and IGT is defined as an OGTT value of 7.8 to 11.0 mmol/L [60,61]. An A1c of 6.0 to 6.4% is currently the primary marker of prediabetes and can be used to measure long

term glycemic control as it indicates how much exposure red blood cells have had to glucose in the last 3 months [62].

Furthermore, many cases of prediabetes and T2D can go unnoticed as symptoms can be delayed, therefore, many individuals may have the disease and not know it [21]. It is estimated that as high as 9 out of 10 people with prediabetes do not know they have the condition allowing it to progress to T2D unchecked [63]. There are several risk factors associated with T2D, both non-modifiable and modifiable [6]. Non-modifiable risk factors include genetic predisposition, age, history of gestational diabetes, or having given birth to a baby that weighed more than four kilograms. Other non-modifiable risk factors include being a member of certain high risk ethnicities such as Africans, Hispanics, Native Americans, and South Asians [64,65]. Ethnic groups are at a higher risk of T2D development due to multifactorial reasons that include genetic susceptibility, altered fat distribution, and higher prevalence of the metabolic syndrome [33,34]. Modifiable risk factors associated with the development of T2D include having been diagnosed with prediabetes, being overweight or obese, having abdominal obesity, being physically inactive, and having poor dietary habits [9,64].

In conclusion, prediabetes is a state which places individuals at high risk of developing T2D. Research has shown that screening individuals with risk factors for T2D as early as age 40 has proven to be useful to help prevent T2D and its complications [66,67]. Thankfully, not everyone with prediabetes will develop T2D as it can be reversible through lifestyle changes. The Diabetes Prevention Program (DPP) proved that with lifestyle changes, there is a significant decrease in the rate of development of T2D and its complications such as retinopathy, nephropathy, neuropathy, cardiovascular issues, and premature death [68,69].

Table 2: Blood test concentrations for diagnosis of prediabetes and T2D [26].

	FBG (mmol/L)	**OGTT** (mmol/L)	**A1C** (%)
T2D	≥ 7.0	≥ 11.1	≥ 6.5
Prediabetes	6.1 – 6.9	7.8 – 11.0	6.0 – 6.4
Normal	3.9 - 6.0	≤ 7.7	4.5 - 5.9

FBG: Fasting blood glucose. OGTT: Oral glucose tolerance test. A1C: Glycated Hemoglobin. mmol/L: millimoles per litre

2.7. Lifestyle Interventions

Luckily, T2D is largely preventable. While there is a genetic predisposition for T2D, it is estimated that many cases could be delayed, better yet prevented, with healthier eating patterns and regular physical activity [3]. This is because obesity and lack of physical activity are important risk factors for T2D. Since the DPP concluded that T2D can be prevented or delayed in individuals with prediabetes, translation of knowledge to the at-risk populations, such as rural adults, has been a research priority [68]. A meta-analysis found that lifestyle interventions that target physical activity and diet could reduce the risk of developing T2D by about 58% [58]. In addition, a weight loss of 5% to 10% of initial body weight through a healthy lifestyle which includes a dietary modification that promotes a low-energy, low-fat, low-saturated fat, high-fibre diet and moderate intensity physical activity of at least 150 minutes per week has been shown to significantly reduce the risk of T2D [58,70]. Furthermore, all participants were offered further lifestyle interventions for an average of 5.7 more years and benefits were sustained for up to 10 years [71]. For that reason, the DPP study was a hallmark study, providing strong evidence that

behavioural interventions are more effective in reducing T2D risk than medications or no intervention [68].

Accordingly, Diabetes Canada recommends that all individuals diagnosed with prediabetes participate in a structured program of lifestyle modification program that includes moderate weight loss and regular physical activity [7]. Individuals, health systems, and society as a whole benefits from effective education programs that reduce the risk factors for developing T2D [36,69,71]. Raising public awareness about this disease requires an interdisciplinary approach with the involvement of all medical and health professionals to effectively communicate information and increase patient engagement to help delay and/or prevent T2D through early interventions [6,72]. Conclusively, the development of these practical education programs for prediabetes in community settings will thus help increase awareness about the causes, symptoms, and preventative methods of T2D [58].

2.8. Social Cognitive Theory

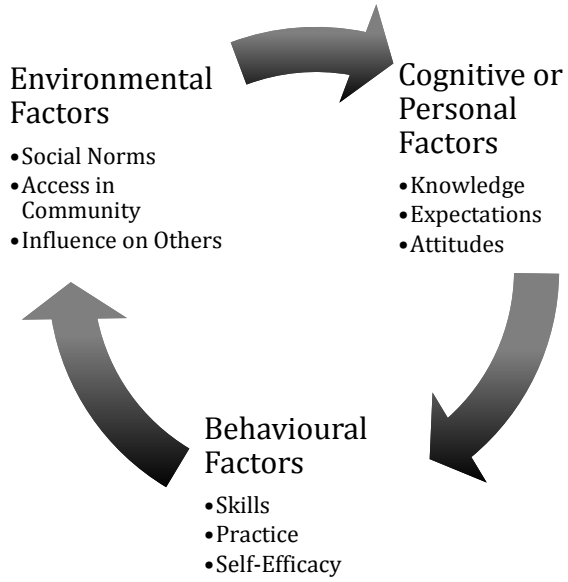
Recent interventions for individuals with T2D and prediabetes are focusing on problem-solving and coping skills development, which have successfully increased adherence [73,74]. Individuals adapt or change their behaviour after mentally processing information they have received from the social world. In addition, various other cognitive processes such as conceptions about the self, beliefs, attitudes and emotions can directly affect or mediate behaviour [75,76]. The properties of human agency are cognitive processes that reflect individuals' ability to envision themselves in the future, make judgments about ability, predict outcomes based on a behavior, make goals, and actualize those goals through planning and strategizing [77]. The social cognitive theory (SCT) of behavior change by Bandura has

influenced these types of interventions, as it suggests that developing problem solving and coping skills enhances self-confidence and feelings of efficacy, which make it easier to modify health-related behaviors and work through some of the perceived barriers in their lives [78]. Individuals with higher levels of self-efficacy have also been shown to engage in more frequent goal setting, planning, and monitoring of their behavior [79]. SCT has been effectively used to change many health behaviors by promoting the initiation and maintenance of positive lifestyle changes such as physical activity and healthy eating habits [73,80]. SCT specifies a core set of psychosocial determinants, such as self-efficacy, outcome expectations, goals, and impediments and facilitators, which influence behavioral outcomes. These factors are related such that individuals with higher levels of self-efficacy have more positive expectations about the effects of the behavioral change, set higher goals for themselves, and are more likely believe that they are capable of overcoming barriers resulting in a greater likelihood of engaging and maintaining specific behaviors [75,77].

Bandura described two central constructs of SCT that are essential to behavior change: self-efficacy and self-regulation. SCT proposes that belief and intention alone are inadequate for behavior change. Purposeful action is necessary to influence change [81]. Self-efficacy is one's confidence or belief in the ability to perform a behavior. It predicts effort and the ability to persevere as belief in one's personal ability can either motivate or prevent the individual's behaviour change. A key component to achieve greater self-efficacy is by breaking down larger goals into smaller, more achievable goals. This strategy is particularly important in T2D prevention, where modest excess weight loss has a significant impact on delaying or preventing this disease [82]. Self-monitoring refers to increasing awareness of environmental, emotional,

and social indications related to a behavior. It directs one's attention to the desired behavior through self-monitoring, goal setting and problem solving. When individuals self-monitor, they recognize patterns of behavior which they can begin to alter [75,77,81].

Figure 1: Social cognitive theory adapted from the work of A. Bandura [89]



2.9. Nutrition Therapy in Prediabetes and T2D Management

Along with urbanization and economic growth, many countries such as Canada have experienced dietary changes favoring increased energy consumption [9]. Lifestyle changes such as healthy eating can be very powerful in preventing and/or delaying T2D making it an integral part of the treatment and the self-management. Individuals with T2D or prediabetes should receive nutrition counselling by a RD with expertise in T2D management, as it has been associated with better adherence [83]. Adapting healthy eating patterns is associated with a significant reduction in the risk of developing T2D as it can improve glycemic control and can further improve clinical and metabolic outcomes [58,83–86]. In addition, targeting barriers to

healthy eating in vulnerable populations, such as rural adults, has been shown to increase behaviour change, improve A1C, nutrition knowledge and diabetes self-management [87,88]. These barriers include cost of healthy food and stress-related overeating [87].

Modern dietary management for the prevention of T2D essentially involves modifications of the quality and quantity of food consumed by the individual [57]. In general, individuals with T2D or prediabetes should follow the healthy diet recommended for the general population in Eating Well with Canada's Food Guide (CFG) [89]. This diet promotes eating a variety of foods from all four food groups to meet nutrient requirements. The four food groups are vegetables and fruit, grain products, milk and alternatives, and meat and alternatives. Guidelines emphasize the consumption of whole grains and complex carbohydrates such as legumes, vegetables and fruit, low-fat dairy products, and lean meats. The diet recommendations based on the CFG favor a diet of high quality with a high ratio of monounsaturated fatty acids to saturated fatty acids, a low intake of trans fatty acids, lower sodium intake, and high ingestion of dietary fiber, antioxidants, and polyphenols rich foods [26,90]. Overall, it is also generally characterized by a lower degree of energy density in order to prevent excessive weight gain and promote a healthy weight in overweight individuals [90]. Furthermore, nutrition counselling should also be individualized based on the individual's age, coexisting medical therapies, physical activity level, culture, lifestyle, economic status, culinary abilities, and readiness to change [90–93].

2.10. Sedentary Lifestyles and Physical Activity

Lifestyle is the way in which an individual performs daily activities. It is an important aspect of the human life as most of the health related problems are a consequence of the lifestyle

ones adapt, such as sedentary behaviour [94,95]. A sedentary lifestyle is defined as one with little to no physical activity, it is one of the major factors that are responsible for the increased prevalence of obesity, which is subsequently related with an increased risk of T2D development [59]. The increase in modernization of working environments has contributed to the rise in individuals with sedentary lifestyles. Nowadays, a large proportion of the time spent at work involves sedentary activities such as sitting [96]. Physical activity helps the body cells take up glucose and thus lower blood glucose concentrations and decrease insulin resistance [82]. It can also reduce mortality, improve quality of life, and reduce the risk for many physical and mental health conditions [97]. Exercise also helps promote the decrease of total cholesterol, improves the ratio of serum LDL-C to HDL-C, and reduces TG concentrations. Physical activity can also help individuals with prediabetes or T2D achieve a variety of goals such as reaching/maintaining a healthy body weight and keeping excess weight off, decreasing elevated serum total cholesterol concentration, improving the ratio of serum LDL-C to HDL-C, normalizing elevated serum levels of TG concentrations, reducing elevated BP, and managing stress levels [80,82,98].

Both aerobic and resistance exercises are recommended for most people with prediabetes or T2D. Diabetes Canada and the Canadian Society of Exercise Physiology recommends 150 minutes of moderate- to vigorous-intensity aerobic exercise with no more than 2 consecutive days without exercise and at least 2 sessions of resistance exercise per week [99,100]. Choosing a physical activity program that is safe is an important component. Walking, an aerobic exercise, is known as one of the easiest and healthiest ways to exercise as it does not require special equipment and has little risk of injury [10]. Resistance exercise performed 2 or 3 times per week may provide benefits that complement those of aerobic training [101–103]. In order to maximize

benefits and minimize the risk of injury, individuals should be instructed and supervised by a qualified exercise specialist [98,99]. Self-efficacy, a cognitive predictor of both aerobic and resistance exercise participation, can also be improved by setting physical activity goals in order to develop strategies to overcome physical activity barriers such as lack of time and weather [104].

2.11. Summary

T2D is a chronic and complex disease that occurs when the pancreas does not produce enough insulin and/or when the body does not effectively use it, which is also known as impaired fasting glucose or impaired glucose tolerance [11]. It can develop at any age and an increasing number of youth are diagnosed each year [6]. In Canada, 11 million individuals have T2D or prediabetes [10]. This is related to an aging population, an increase in obesity rates, and a sedentary lifestyle, which are all factors contributing to this rise in T2D [3]. In addition, prediabetes is a T2D risk factor and it is defined as a condition in which people have higher than normal blood glucose concentrations, however not high enough for a diagnosis of T2D [55]. Less attention has been given to prediabetes management, which has been found to help prevent T2D [53]. Without lifestyle changes, 15-30% of adults with prediabetes will develop T2D within 5 years [54]. In the short term, the symptoms of T2D are associated with a reduced quality of life, while in the longer term; the disease may lead to serious or fatal complications such as blindness, kidney failure, heart disease, stroke and amputations. That being said, the risk of premature death for adults with T2D is 50% higher than for adults without this disease [2,105]. T2D is also influenced by the geographic location and the socioeconomic status of the community. In

consequence, rural adults tend to be diagnosed later, tend to receive substandard healthcare and tend to be less educated about their conditions [106,107].

Fortunately, T2D is largely preventable. While there is a genetic predisposition for this disease, it is estimated that many cases could be delayed, or even prevented, by educating the patient about the importance of a healthy diet and physical exercise [1,26]. Through prevention programs, it is possible to increase the effectiveness of disease management, reduce its the economic burden, and improve the quality of life for individuals who have or are at risk for T2D, such as rural adults living with prediabetes [57,58,70]. For that reason, providing rural adults with the skills and knowledge to manage their prediabetes through a community-based lifestyle intervention program is essential to allow them to better care for their health and delay or better yet prevent the onset of T2D.

CHAPTER 3: Objectives, Hypothesis and Significance

This chapter justifies the purpose and pertinence of the study. The hypothesis and objectives are also introduced.

3.1. Purpose of the Study

The purpose of this study was to determine if a healthy lifestyle and behavior change intervention program could result in increased participant awareness and self-efficacy toward making positive lifestyle changes known to decrease the risk of T2D development, such as physical activity and healthy dietary habits. It has been shown that T2D can be prevented or delayed with lifestyle intervention. This may be especially helpful for those at increased risk for the disease [71]. Since the DPP clinical trial was published in 2002, a variety of research projects on the prevention of T2D have been conducted across practice settings [58]. However, significantly less research has been conducted with rural adults in a community setting. For this reason, the program was tailored for rural adults with prediabetes from the communities of Stratford and Tavistock and was offered through the STAR Family Health Team (FHT).

3.2. Hypothesis

The study hypothesizes that providing healthy lifestyle education, targeting rural adults with prediabetes, will result in increased participant awareness and self-efficacy toward making positive lifestyle changes. The program was offered through the STAR FHT over six monthly visits and included hands-on activities in the areas of nutrition and physical activity.

3.3. Objectives

3.3.1. Primary Objective

To determine if healthy lifestyle education, as part of a 6-month community-based intervention education program for rural adults with prediabetes in Southwestern Ontario, offered through the STAR FHT, will result in increased participant awareness, knowledge, self-

efficacy, and behaviours toward making positive lifestyle changes known to decrease the risk of developing T2D.

3.3.2. Secondary Objectives

1. To assess the baseline characteristics of the population of adults diagnosed with prediabetes through the STAR FHT and to compare the characteristics of the intervention program attendees versus the control group. These characteristics include demographic characteristics, diet, physical activity habits, anthropometric and biochemical parameters.

2. To evaluate the effect of the prediabetes healthy lifestyle intervention program on key biochemical, anthropometric and hemodynamic markers known to increase the risk of developing T2D in adults with prediabetes, such as fasting blood glucose (FBG), oral glucose tolerance test (OGTT), A1C, lipid profile, body mass index (BMI) waist circumference (WC), and blood pressure (BP).

3. To determine the effectiveness of the healthy lifestyle intervention program in rural adults with prediabetes regarding the practicality, feasibility, and acceptability during the program and at follow up (6 months) after participating in the program.

4. To investigate if lifestyle changes, such as healthy eating and physical activity, were positively influenced throughout the program at follow up (6 months) after participating in the program.

3.4. Significance

The importance of preventing T2D is highlighted by the substantial worldwide increase in the prevalence of T2D, especially in recent years [4]. Many individuals with prediabetes or T2D are unaware of the severity of the many related complications. This lack of understanding, in addition to the unawares of the social and economic impacts, are presenting as a large barrier to effective prevention strategies that could reduce the rise in T2D [108]. Due to the immediate and long-term complications, The IDF proposed implementing strategies for those at high risk of developing T2D, such as rural adults, and the entire population [4]. Providing early intervention can prevent the negative effects and health risks of T2D [54,109].

Moreover, there was a need to develop community-based intervention programs that are feasible and effective in reducing the modifiable risk factors for developing T2D in rural adults, whom are a higher risk population. Controllable risk factors include excess body weight, lack of physical activity, and poor nutrition [7]. For this reason, in 2011, the STAR FHT started to provide enhanced screening, early identification, and self-management support to patients with prediabetes to meet the increasing demand. Concurrently, they identified a need to justify the resources required by the health care system to offering such an intervention program by measuring through this research project's practicality, feasibility and acceptability by participants, as well as its impact on their lifestyle and T2D risk factors.

The STAR FHT provides comprehensive primary healthcare and health promotion services to 18 000 patients in the town of Tavistock, the city of Stratford, and the surrounding catchment areas. The rural cities of Stratford and Tavistock have a population of about 31,465 and 7,129

individuals, respectively [110,111]. Based on data from 2003-2014 from Perth County, a district within the STAR FHT rostered patient population, almost 30% of residents had one or more chronic health conditions, which includes T2D, heart disease, and hypertension [112]. In addition, based on self-reported data collected in 2013-2014, 61.7% of the adult population indicated that they are either obese or overweight, 58.3% are not meeting their vegetables and fruit daily requirements, and 41.5% are not physically active during their leisure time [113].

CHAPTER 4: Methodology

This chapter describes the methodology of the program starting from pre-recruitment to the intervention procedures.

4.1. Pre-recruitment of clients with prediabetes

Clients diagnosed with prediabetes were informed of the new prediabetes intervention program by the STAR Family Health Team (FHT) physicians and nurse practitioners (as explained in Figure 1). A Letter of Information was also sent to family physicians in the Stratford and Tavistock area, so that they inform their clients diagnosed with prediabetes about the prediabetes education program options. The Letter of Information for physicians described 3 options available to their patients with prediabetes. Option 1 includes 6 monthly 2-hour education sessions (intervention program). Option 2 includes a one-time 2-hour session (control arm). Option 3 is the current standard of care including a referral to a STAR FHT dietitian for individual counselling (no research component). The letter included the Physical Activity Readiness Questionnaire (PAR-Q & You) for physicians to screen their clients. In addition, a poster and brochure about the program options were posted in physician offices and provided to patients. The poster and brochure were also posted on the STAR FHT website. Interested individuals were asked to contact the STAR FHT to book an initial visit (Visit 1; baseline). Patients who screened positive for prediabetes were contacted directly by FHT staff to discuss their potential involvement. Clients contacting the STAR FHT to schedule their Visit 1 were asked their name, phone number, email and mailing address. The STAR FHT sent them a letter to remind them of the date and location of their Visit 1, informed them about the prediabetes education program options and the research project (Letter of Information), and asked them to complete a 3-Day Food Intake Record and Medication Log. They also received a brief reminder phone call by the STAR FHT that reminded them about their visit and ensuring that they bring their 3-Day Food Intake Record and Medication Log.

4.2. Recruitment of study participants

At Visit 1 (baseline), individuals were presented with the prediabetes education program options. After listening to a short presentation about the intervention program, interested individuals were invited to complete a Screening Questionnaire to confirm their eligibility to participate. For those individuals who do not wish to participate or do not meet the eligibility criteria (non-participants), the current standard of care (individual session with STAR FHT dietitian) were offered. For those individuals interested in the prediabetes intervention program, they were asked to review the study's Letter of Information and provide written informed consent to either participate in the prediabetes intervention program (full participation) or to be part of the control arm (monitoring only, minor participation). Inclusion criteria included being 18 years of age or older, being diagnosed with prediabetes by their doctor or other healthcare provider, being able to attend educational presentations at STAR FHT once per month for six months, being able to perform low impact physical activity, such as walking and stretching, being able to chew and swallow food with little difficultly, and being able to fill out written questionnaires about their health and behaviours. Exclusion criteria included currently taking part in another lifestyle education program or research study, being pregnant or lactating (breastfeeding) having Type 1 or Type 2 Diabetes, having a digestive disease (e.g. Crohn's disease, celiac disease, etc) and having a diagnosed mental illness (e.g. major depression, eating disorder, schizophrenia, etc).

4.3. Pre-intervention procedures

Once written informed consent was obtained, participants were asked for their completed 3-Day Food Intake Record and Medication Log. In addition, all study participants were asked to

complete the following questionnaires: Demographic Questionnaire (e.g. age, income level, etc.), Lifestyle Questionnaire parts A and B (e.g. weight history, etc.), and Short Last 7-Day International Physical Activity Questionnaire (S7D-IPAQ). These questionnaires took about 40 minutes to complete. After this is complete, the individuals who selected to participate in the control arm had their height, weight, waist circumference and BP measured. They then joined a dietitian in another room to receive the 2-hr education session.

Once intervention participants have completed their questionnaires, they underwent the following anthropometric and hemodynamic measurements: height, weight, waist circumference, and BP. This took approximately 20 minutes to complete. Following this, participants were shown by a dietitian how to use a pedometer and provided instructions on how to complete a 7-Day Physical Activity and Step Log at home.

In addition, intervention participants were provided with a requisition form for Laboratory Blood Work at LifeLabs® in Stratford or New Hamburg which were required to be completed before Visit 2. The blood tests included: FBG, 2-hour OGTT, A1C, and a lipid profile (blood total cholesterol, triglycerides, high density lipoprotein cholesterol, and low density lipoprotein cholesterol). Finally, participants were asked to provide written informed consent to share relevant data (e.g. blood tests) collected during the study with their family physician.

4.4. Intervention procedures

Intervention participants returned to the STAR FHT monthly for six 2-hour educational sessions and two post-intervention data collection sessions (post-intervention [Visit 8] and six months follow-up [Visit 9]). The intervention program provided clients with information and promoted the development of skills regarding healthy eating and physical activity strategies known to help prevent or delay the development of T2D. Each session of 120 minutes consisted of roughly 50 minutes of nutrition education, 10 minutes of break, 40 minutes of physical activity and education, 10 minutes of food demonstrations and/or community resource sharing, and 10 minutes of goal setting and session feedback at the end. At each educational session (Visits 2-7), the following information were collected from each participant: physical measurements (weight, WC, BP), Goal Setting Sheet, and Session Feedback Form.

At Visit 5 (4th educational session), Visit 8 (post intervention) and Visit 9 (6 month follow up), participants were also asked to complete all procedures and questionnaires as was done at baseline, with the exception of the Demographic and Lifestyle questionnaire part A. Finally, at Visit 8 participants were asked to complete a program feedback survey about their opinions regarding the intervention program. All participants were also invited to participate in a 1-hour focus group session to gather a more in-depth assessment of the feasibility, practicality, and acceptability of the intervention program. The study only involved minimum disruption of the schedule for adult participants as they can participate in evening or daytime monthly sessions; whatever was more convenient for them.

Control participants were asked to complete the following questionnaires at times corresponding to Visit 8 and Visit 9 in the intervention arm: Lifestyle Questionnaire part B, 3-

Day Food Intake Record and Medication Log, Short Last 7-Day International Physical Activity Questionnaire (S7D-IPAQ), and T2D status. At baseline, a phone number was collected and another preferred method of contact information (i.e. mail or email address) from each control participant and this method of contact was used to send and receive the above data collection. More specifically, they were called by phone to ask about their self-reported T2D status at times corresponding to Visits 8 and 9. No more than three attempts were made to reach the control participants by phone. Sending them the questionnaires by mail (or email if they prefer) was also made. Incentives were provided as described in the Letter of Information.

4.5. Timeline

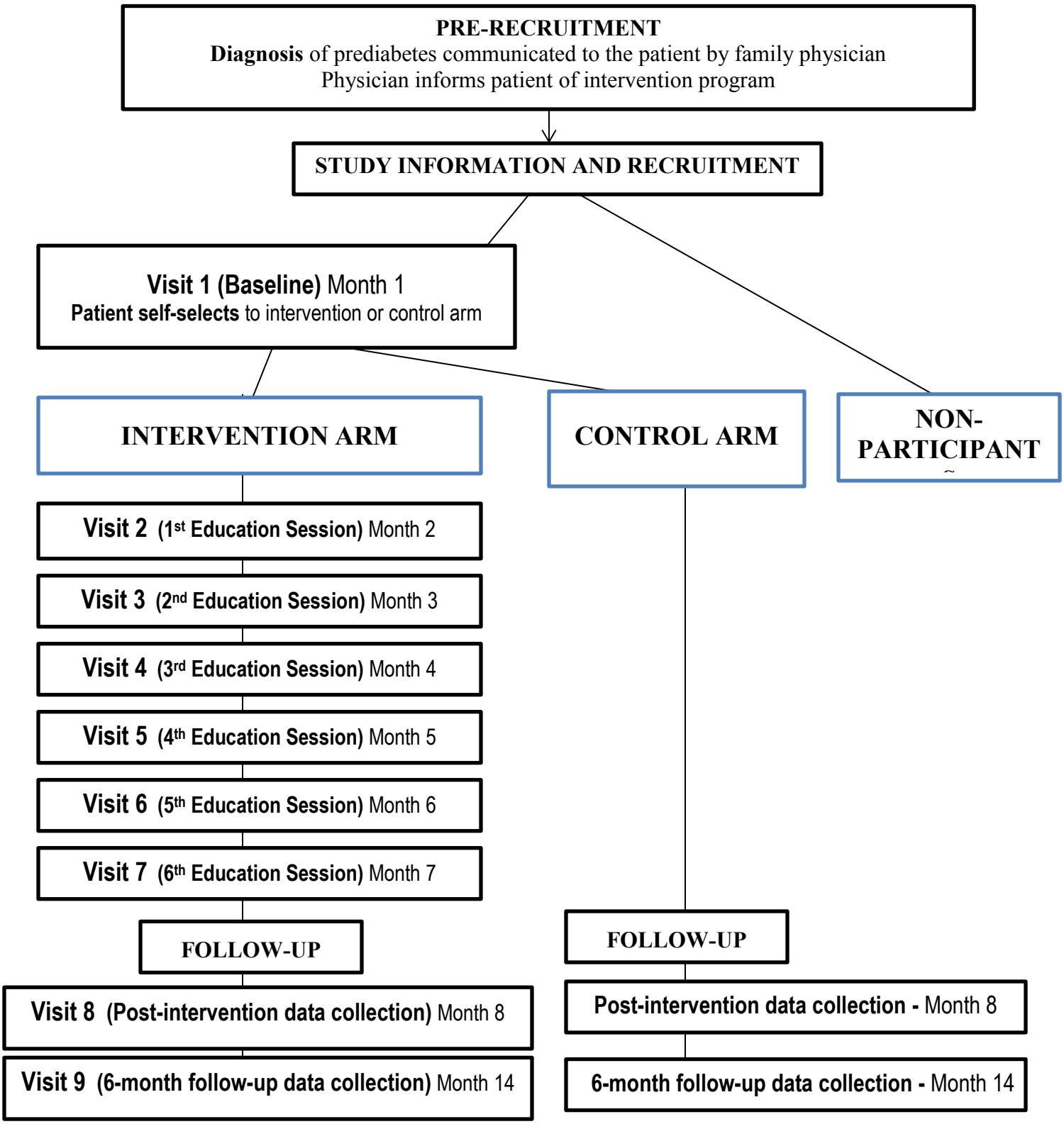


Figure 2: Flow chart of methodology and timeline

CHAPTER 5: Characteristics of rural adults from

Southwestern, Ontario, with a diagnosis of prediabetes

This article is written in the format of the Canadian Journal of Diabetes (CJD). This chapter answers the second secondary objective of the thesis, which is to assess the characteristics of the program. The authors are Mathilde Lavigne-Robichaud RD, MSc, Sarita Azzi RD, Adrienne Vermeer RD, Teresa Barresi RN MSc, Sean Blaine MD, and Isabelle Giroux RD PhD.

Characteristics of rural adults from Southwestern, Ontario, with a diagnosis of prediabetes

5.1. Abstract

Objectives: To assess the characteristics of adults living in Southwestern Ontario rural areas with a diagnosis of prediabetes.

Methods: Patients identified with prediabetes were invited on a voluntary basis to a 2-hour education session or 6 monthly lifestyle intervention education sessions. Data collection for both groups included a 3-day food intake record and the short 7-day international physical activity questionnaire, as well as anthropometrics measures.

Results: Eighty-three participants (45 men, 38 women) aged 61.5 ± 9.1 (mean±sd) were referred by their physician for education on prediabetes. Their body mass index was 32.9 ± 5.5 kg/m2 and 96.3% presented abdominal obesity based on their waist circumference. More than half reported having 1 or more comorbidities (51.8%). A minority reported smoking (3.6%) while 54.2% of them reported having made lifestyle changes, mainly related to nutrition, since their prediabetes diagnosis. The majority (52.0%) were sedentary and exceeded the daily dietary recommendations in terms of average sodium, fat, added sugars and cholesterol intake.

Conclusion: According to these results, it is reasonable to conclude that rural adults with a diagnosis of prediabetes have multiple risk factors putting them at high risk of developing type 2 diabetes. A prediabetes prevention program, with emphasis on healthy lifestyle, could help address rural adults' risk factors in order to support them in their efforts to prevent or delay type 2 diabetes and its comorbidities.

MeSH keywords: Prediabetic State; Population Characteristics; Rural Population; Rural Health Services; Diet, Food and Nutrition; Sedentary Lifestyle; Self Care

5.2. Introduction

Diabetes Mellitus in Canada

In 2015, 3.4 million Canadians were living with a diagnosis of type 2 diabetes (T2D) [1]. By the year of 2025, this prevalence is predicted to rise by as much as 44%. The increasing rates of T2D mirrors the prevalence of obesity, physical inactivity and metabolic syndrome in Westernized populations [2]. Modifiable and non-modifiable risk factors for T2D development are well known. T2D risk increases with age and is higher among men [3]. Lifestyle risk factors include a body mass index (BMI) of 25.0 kg/m2 or above, abdominal obesity, arterial hypertension, excessive energy intake and a sedentary lifestyle [3]. The combination of some of these risk factors can trigger the insulin resistance cycle and subsequently lead to the onset of T2D. Complications associated with elevated and uncontrolled hyperglycaemia are often permanent and irreversible. Identifying individuals at high risk of developing T2D and the associated macro- and microvascular complications should be a priority but can represent a serious challenge when addressing this growing issue [3].

Epidemiology of Prediabetes

Prediabetes refers to the state of impaired glucose homeostasis preceding the development of T2D [4]. Many epidemiological studies have documented the prevalence of prediabetes worldwide [4–8]. In 2012, the Canadian prevalence of prediabetes has been estimated in 2012 to 5.7 million, representing 22.1% of the adult population [1]. While T2D is a chronic condition to be managed; prediabetes is a reversible condition [9]. The transition between both distinct stages of impaired glucose homeostasis might take several years, however,

it is estimated that up to 70% of individuals with prediabetes will eventually develop T2D [9]. Prediabetes screening represents an opportunity to prevent or delay the onset of T2D [4,9,10].

Rural Adults' Special Considerations

Rural adults have additional environmental challenges and social factors, which impact their lifestyle and contribute to increasing obesity, prediabetes, and diabetes risks [11]. Individuals in most rural areas are challenged by specific barriers when accessing healthcare services, such as geographic isolation, lower population density, economic difficulties as well as lower education levels [12,13]. Rural adults may have to travel longer distances to have access to recreational facilities or a safe environment to perform physical activities in the community, such as walking or biking [11,14,15]. Distance to grocery stores as well as the limited availability of healthy and varied foods may also represent barriers to healthy eating in rural communities and contribute to important health disparities [11,16,17]. Prevalence of nicotine and alcohol use, obesity, T2D and associated morbidities are higher in rural areas [18,19]. The magnitude of undiagnosed cases of T2D in rural areas suggests that these adults, at higher risk of developing T2D, may benefit from tailored intervention to help individuals avoid or delay the onset of T2D [20].

The Prediabetes Lifestyle Education

Lifestyle intervention, based on behavioural models, with a focus on healthy eating and regular physical activity practice, have been shown to reduce the risks of developing T2D in several population [10,21,22]. However, there are limited lifestyle interventions for the prevention of T2D specifically tailored to rural adults' needs and their profile of risk factors.

With that perspective, education sessions on healthy lifestyle with a focus on nutritional education and increasing physical activity were collaboratively developed by the interdisciplinary STAR Family Health Team in Stratford and Tavistock (Ontario), in collaboration with registered dietitians from the University of Ottawa.

Objective

The objectives of this manuscript are 1) to assess the characteristics of a sample of the population of rural adults diagnosed with prediabetes through the STAR Family Health Team, including demographic, lifestyle, anthropometric, and dietary information and 2) to compare the characteristics of rural adults with a diagnosis of prediabetes who enrolled in a 6 months lifestyle intervention program versus those who only attended a one-time 2-hour education session on prediabetes.

5.3. Methods

Patients diagnosed by their physician with impaired fasting glucose and/or impaired glucose tolerance were solicited to participate in a lifestyle education program. On a voluntary basis, patients were invited to either take part in a 6-month lifestyle education program (intervention arm) or attend a one-time 2-hour group education session on prediabetes (control arm). Individuals who did not wish to participate in the education program or did not meet the eligibility criteria, were offered standard health-care services.

Study inclusion criteria were being: 1) 18 years of age or older, 2) diagnosed with prediabetes by the health-care physician, 3) available to attend educational sessions at The Star

Family Health Team once a month over a 6-month period, 4) fit to perform low impact physical activity, 5) able to chew and swallow food, 6) understand written and spoken English, and 7) capable of filling out written questionnaires on health behaviours. Participants were excluded from the study if they were currently enrolled in another lifestyle education program or research study, pregnant or lactating, or having a diagnosis of type 1 or T2D, digestive disease or mental illness. Written and informed consent was obtained from all participants prior to the commencement of data collection. The project was submitted and approved by the University of Ottawa Office of Research Ethics and Integrity (REB: H10-12-10) and the Public Health Agency of Canada Research Ethics Board (REB: 2010-0072).

Data collection was identical for the intervention group and control group and included demographics, anthropometric measures as well as lifestyle and health related information. To assess these characteristics, participants representing four cohorts were recruited from April 2012 to February 2013 and asked to fill a demographic and lifestyle questionnaire, a 3-Day food intake record as well as the Short-7-Day-International Physical Activity Questionnaire (S7D-IPAQ) [23]. The trained research nurse also took anthropometric measurements.

Demographic and Lifestyle Information

Eighty-three intervention participants and control participants were asked to complete a 3-Day Food Intake Record. Instructions were given to participants to assist them in completing these forms. The dietary information was reviewed by a registered dietitian and analyzed using ESHA Food Processor SQL 10.15.0 database™ (V.10.14,0 ESHA Research, Salem, Oregon) with the most recent Canadian Nutrient File. In addition, all study participants were asked to

complete the following questionnaires: Demographic questionnaire (e.g. age, income level, etc.), lifestyle questionnaire and the validated S7D-IPAQ calculating metabolic equivalent of task (MET) [24]. MET categories were based on the current guidelines: high is defined as 12,500 steps per day, or the equivalent in moderate and vigorous activities, moderate as half an hour of at least moderate-intensity physical activity on most days and the remaining participants not meeting these criteria are considered as low [24]. These questionnaires allowed assessing modifiable behaviour contributing to T2D risk factors.

Anthropometric

Height was measured to the nearest centimetre (cm) using a measuring tape with the participant standing barefoot on a hard floor surface. Body weight was measured in kilograms (kg) using a digital scale (Tanita TBF-300A, Tanita Corporation of America, Illinois, USA) to the nearest 0.1 kg. Waist circumference (WC) was measured to the nearest 0.5 cm upon exhalation with the measuring tape at midpoint between the last floating rib and the iliac crest [25]. In order to increase validity and reliability, anthropometric measures were collected in duplicates and the averages of those values were used for analyses. Body mass index (BMI: kg/m2) was calculated by dividing participants' measured weight (kg) by the squared height (m2). In accordance with international cut-off points, overweight was defined as BMI≥25.0 kg/m2 and <30.0 kg/m2 and obesity as a BMI≥30.0 kg/m2 [26]. Central obesity was defined as a WC > 94 cm for men and 80 cm for women. Risk interpretation of those anthropometric data was based on the Diabetes Canada Clinical Practice Guidelines of 2013 [3].

Data Analysis

The questionnaires were reviewed by a research dietitian or nurse with the participants during the initial education session and were then compiled by the dietitian in EpiData™ (v 3.1 The EpiData Association, Odense, Danemark) [27]. All files were saved on the research coordinator's computer and were password protected. Participants were identified with an electronic code to maintain participants' confidentiality. The code was used to label all data. Blinded research assistants performed a double entry of the collected data. Discordances in the data entry process were solved by discussion between research staff.

The S7D-IPAQ was cleaned and interpreted according to the current guidelines [28]. Outliers were identified according to the IPAQ data processing rules. The final S7D-IPAQ sample was 50 complete records.

Statistical Methodology

To assess differences between intervention and control participants, Student's t-tests were performed on quantitative (continuous) variables. When criteria for parametrical data were not met because of abnormal distribution or unequal variance, Shapiro-Wilk tests were performed. Pearson's chi-squared tests were used to test group differences between intervention and control participants. Fisher's Exact tests were used when the number of expected cases were inferior to 5. Two-sided significance levels were set at 5% ($\alpha<0.05$). This offered 1) a comprehensive description of demographics, lifestyle, behavioural and anthropometric characteristics of participants, and 2) an assessment of differences between the groups with respect to key

characteristics known to influence the risk of developing T2D. The software SAS™ (v.9.4, SAS Institute Inc., North Carolina, USA) was used to perform statistical analysis [29].

5.4. Results

Characteristics of rural adults with a diagnosis of prediabetes

Rural adults (n=83) with a diagnosis of prediabetes referred to the STAR Family Health Team for education were aged between 44 and 79 years old (61.5±9.1) (mean±SD) and over half (54.2%)were men (Table 1). The prevalence of overweight and obesity in our sample of rural adults with prediabetes was 94.0% and mirrored the prevalence of abdominal obesity of 96.0% as indicated by the WC above the cut-off points described above (43 men, 37 women). The mean BMI was 32.9±5.5kg/m2, and only 6% of participants were of normal weight. Only three participants (3.61%) reported being current smokers and the majority of the participants (47.6%, n=37) interviewed reported no alcohol consumption in the previous week (Table 2). The vast majority of participants were Caucasian (97.6%, n=81) and married or in a common-law union (82.1%, n=69). Education levels varied, with nearly half (48.2%, n=40) of participants having a high school degree diploma or less. More than half were employed (56.6%, n=47) and 37.3% (n=31) were retired.

About 90% of the participants from both intervention and control arms handed in a 3-day food intake record. Post-hoc analysis revealed no statistical differences in the participants' characteristics between those who provided dietary information (n=76) and those who did not (n=7) (results not shown). On average, rural adults did not meet the Canadian recommendations in terms of sodium intake, dietary fibre (Table 3) and vegetables and fruit intake (Table 4).

More than half of those rural adults (52%) referred by their physician with a diagnosis of prediabetes had a low level of physical activity according to the S7D-IPAQ as seen in Table 5. Only a minority of them met the current Canadian Physical activity guidelines. More than half of the adults (54%) referred to our program by their physician reported having made lifestyle changes after receiving the diagnosis of prediabetes (Table 2). The majority of them opted for nutrition-related changes (25 participants, 19 controls).

Comparing intervention and control participants

When comparing the anthropometric and demographic characteristics of the 6-month lifestyle intervention participants versus the control participants, no significant difference between the two groups was found for average BMI, WC, body weight history or weight satisfaction. A larger proportion of intervention participants reported more than one co-morbidity ($p=0.008$) compared to their control counterparts and they had a significantly higher income than control participants ($p<0.001$).

No differences were observed between lifestyle intervention participants and control participants in terms of energy, macro and micro-nutrients (data not shown). Control participants reported consuming more servings of vegetables and fruit from the Eating Well with Canada's Food Guide ($p=0.020$). Than lifestyle intervention participants (Table 4).

No significant differences were noted between the two groups in terms of time reported doing vigorous and moderate physical activity as well as time spent walking (Table 5).

5.5. Discussion

The purpose of this analysis was assessing the characteristics of adults diagnosed with prediabetes in rural areas of Stratford and Tavistock, and to compare the characteristics of those who decided to participate in the intervention program versus those who opted for the 2-hour education session (control arm). We analyzed the data from demographic and lifestyle questionnaires, 3-day food intake record, S7D-IPAQ, and anthropometric parameters for both intervention and control arm participants.

The demographic and health characteristic of adults with prediabetes in Stratford and Tavistock in Ontario is consistent with the current literature on the disease burden specific to Canadian rural areas [30]. In general, clients referred to our program were older adults, presenting class 1 obesity and an abdominal distribution of excess adiposity, as shown by their increased WC, placing them at increased risk of developing T2D and cardio metabolic disease [3,19]. According to a national survey, the Canadian Health Measures Survey in 2007 to 2009, approximately 24% of the Canadian adult population was obese [31]. Our study population is presenting a much higher rate of obesity among rural Canadian adults from Southwestern Ontario. Our observation is coherent with other reports confirming a higher prevalence of obesity among Canadian rural communities [30,32]. In the present study, only a marginal proportion of adults with a diagnosis of prediabetes met the health recommendations in regards to BMI, WC, physical activity and diet in order to help reduce their risk of developing T2D [3].

Based on the latest Canadian Physical Activity Guidelines [33], a large proportion of the rural adults with prediabetes from our study were not meeting the recommendation of 150

minutes of moderate to vigorous physical activity per week, accumulated in bouts lasting at least 10 minutes. Similarly, according to Colley et al (2011), only about 15% of Canadian adults surveyed were meeting those recommendations [34]. Other reports of lower level of physical activity among rural adults support this observation [35–39]. Although the S7D-IPAQ is a validated questionnaire and is widely used to assess physical activity levels of Canadian adults [24,40,41], caution in the interpretation of data must be used [40–42]. Standard errors suggest a large confidence interval and a lack of precision in the data reported by clients. Nonetheless, the self-reported amount of time spent being active in comparison to time spent sitting by our participants reveals that, in majority, they perceived themselves as having a low level physical activity. Barriers to physical activity specific to rural areas can contribute to the larger proportion of obesity in those communities [11,15]. A large prevalence of sedentary behaviors combined with a higher energy intake contributes to an increased risk of obesity, T2D and coronary heart disease in our study population.

Dietary and physical activity information provided by the rural adults in the present study suggested that without education on healthy lifestyle, a large proportion of these adults are not likely to meet the daily physical activity recommendations, nor the recommended food intake recommendations to achieve a balanced diet. Although both men and women met the Average Macronutrient Distribution Range (AMDR) recommendations, which advise on the percentage of the energy intake, which should come from macronutrients, certain unhealthy food selection trends were observed. The majority of participants exceeded the daily dietary recommendations in terms of average sodium, fat, total sugars and cholesterol intake. Both rural men and women significantly exceeded the adequate sodium intake recommended for health. Also, results show

that rural adults had trouble reaching daily dietary fibre recommendations. An adequate dietary fibre intake has been shown to be helpful in weight management strategies as they help maintain satiety [43]. Older men and women both seemed to have difficulties meeting the recommended daily calcium intake of 1200 and 1 000 mg per day respectively based on age and sex.

Rural adults with a diagnosis of prediabetes self-reported in a large proportion that in the past year their weight increased. Addressing sedentary behaviors and unhealthy dietary patterns may be effective areas for lifestyle intervention to assist rural adults with T2D prevention. Nonetheless, participants reported having made healthy lifestyle changes after their prediabetes diagnosis, mainly in terms of healthy eating. This illustrates the perceived importance of nutrition in the prevention of T2D. Increased awareness, knowledge and competence has been shown to be effective ways to promote self-management skills [3]. Lifestyle intervention tailored to rural adults should include an important segment on healthy eating to increase clients knowledge and self-efficacy [3].

These results suggest that our study participants with prediabetes exhibited a high prevalence of modifiable risk factors for T2D, including a higher BMI, a lower level of physical activity, and a lower intake of vegetables and fruit than the current recommendations for health [3].

When comparing the demographic characteristics of rural adult participants from Tavistock and Stratford (Ontario) with a diagnosis of prediabetes, no significant differences were observed in the demographic profile of lifestyle intervention and control participants, other than

the difference of annual household income. No significant difference was observed in the education level of the control participants and lifestyle intervention participants. This is consistent with current epidemiologic studies on rural Canadian areas. Rural adults living in rural communities have been reported to have a lower annual income and a lower level of education than in urban areas, as well as a higher prevalence of high-risk health behaviours such as physical inactivity and a poor diet quality [30]. Furthermore, according to current literature on health disparities, lower income and education level may act as barriers to making positive lifestyle changes and engaging in a lifestyle intervention program [11,15].

There is very limited information about the health and lifestyle behaviours of rural adults with prediabetes and little is known about their specific health education needs. This study is offering a new insight on T2D risk factors and lifestyle of adults with prediabetes in Southwestern Ontario in Stratford and Tavistock.

The current analysis is based upon a cross-sectional data and therefore the causal relationships of the observed characteristics cannot be established. All demographic and lifestyle data presented in this paper were self-reported. Under reporting of food intake has been documented with food intake records [44]. This bias is inherent to all food intake record methodologies. However, food intake records were reviewed with a registered dietitian to increase accuracy. There is also a possibility of under-representation of a portion of the population. There may be differences between people who decided to contribute to this study as lifestyle intervention or control participants and those who opted for the standard care without participating in an education program.

5.6. Conclusion

According to these results, it is reasonable to conclude that those rural adults with a diagnosis of prediabetes had multiple risk factors putting them at high risk of developing T2D. They were older, sedentary and had BMI and WC values above recommendations. A prediabetes prevention program, with an emphasis on healthy lifestyle changes, was needed and justified to address those rural adults' risk factors in order to support them in their efforts to prevent or delay T2D and its comorbidities. Only marginal differences in dietary intake, physical activity and anthropometric indicators were noticed between the control and lifestyle intervention participants. However, those who decided to participate in the lifestyle intervention program reported having more comorbidities than control participants, a higher average household income and limited vegetables and fruit intake. These results offer some justification of the need for education from which rural adults may benefit from in the optic of reducing the health gap in rural communities and to help reduce the T2D prevalence in those communities.

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Author contributions

MLR and IG contributed substantially to conception and design, or acquisition of data, or analysis and interpretation of data, drafted the article or revised it critically for important intellectual content and gave final approval of the version to be published. AV, SA, TB and SB Contributed substantially to conception and design, or acquisition of data, or analysis and interpretation of data and gave final approval of the version to be published.

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Table 3: Characteristics of adults from Stratford and Tavistock diagnosed with prediabetes from the 6 monthly lifestyle intervention program and the 2-hour education control participants

Demographic, Anthropometric, and Other Characteristics	***Lifestyle Intervention Participants***	***Control Participants***	**All Participants**	**Statistical analysis**
N	49	34	83	
Age (years)*	60.6 ± 8.1	62.9 ± 10.4	61.5 ± 9.1	NS[1]
Sex (% male)	55.1 [n=27]	52.9 [n=18]	54.2 [n=45]	NS[2]
BMI (kg/m^2)*	33.1 ± 5.5	32.6 ± 5.7	32.9 ± 5.5	NS[1]
Normal (%)	6.1 [n=3]	5.9 [n=2]	6.0 [n=5]	
Overweight (%)	24.5 [n=12]	29.4 [n=10]	26.5 [n=22]	NS[2]
Obesity (%)	69.4 [n=34]	64.7 [n=22]	67.5 [n=56]	
Waist Circumference (cm)*	108.5 ± 12.9	107.0 ± 11.3	107.8 ± 12.2	NS[1]
Male at high health risk (%WC≥ 94 cm)	96.3 [n=26]	94.4 [n=17]	95.6 [n=43]	NS[2]
Female at high health risk (%WC≥ 80 cm)	95.5 [n=21]	100.0 [n=16]	97.4 [n=37]	NS[2]
Body Weight History				
Increased (%)	34.7 [n=17]	14.7 [n=5]	26.5 [n=22]	
Decreased (%)	14.3 [n=7]	26.5 [n=9]	19.3 [n=16]	
Variable weight (%)	20.4 [n=10]	11.8 [n=4]	16.9 [n=14]	NS[2]
Stayed the same (%)	30.6 [n=15]	44.1 [n=15]	36.1 [n=30]	
Not answered (%)	0 [n=0]	2.9 [n=1]	1.2 [n=1]	
Weight Satisfaction				
Not satisfied at all (%)	57.1 [n=28]	44.1 [n=15]	51.8 [n=43]	
Somewhat satisfied (%)	26.5 [n=13]	38.2 [n=13]	31.3 [n=26]	
Unsure (%)	8.2 [n=4]	2.9 [n=1]	6.0 [n=5]	
Satisfied (%)	6.1 [n=3]	8.8 [n=3]	7.2 [n=6]	NS[2]
Very satisfied (%)	0 [n=0]	0 [n=0]	0 [n=0]	
Not answered (%)	2.0 [n=1]	5.9 [n=2]	3.6 [n=3]	
Ethnicity (% Caucasian)	98.0 [n=48]	97.1 [n=33]	97.6 [n=81]	NS[2]
Marital Status				
(% married/common- law)	79.6 [n=39]	88.2 [n=30]	82.1 [n=69]	NS[2]
Highest Education Level				
≤ High school (%)	46.9 [n=23]	43.6 [n=17]	48.2 [n=40]	
University: Bachelor's degree (%)	16.3 [n=8]	17.6 [n=6]	16.9 [n=14]	
University: Post-graduate degree (%)	6.1 [n=3]	0 [n=0]	3.6 [n=3]	NS[2]
Professional degree: MD, JD etc. (%)[3]	4.1 [n=2]	2.9 [n=1]	3.6 [n=3]	
Employment Status				
Employed (%)	59.2 [n=29]	52.9 [n=18]	56.6 [n=47]	
Retired (%)	32.7 [n=16]	44.1 [n=15]	37.3 [n= 31]	NS[2]
Unemployed (%)	6.1 [n=3]	2.9 [n=1]	4.8 [n=4]	
Annual Household Income				
Under $25,000 (%)	2.0 [n=1]	17.6 [n=6]	8.4 [n=7|	
$25,000 - $49,999 (%)	26.5 [n=13]	26.5 [n=9]	26.5 [n=22]	
$50,000 - $74,999 (%)	22.4 [n=11]	23.5 [n=8]	22.9 [n=19]	
$75,000 - $99,999 (%)	30.6 [n=15]	0 [n=0]	18.1 [n=15]	
$100,000 - $124,999 (%)	2.0 [n=1]	8. 9 [n=3]	3.6 [n=3]	p <0.001[2]
$125,000 – 149,999 (%)	8.2 [n=4]	5.9 [n=2]	7.2 [n=6]	
$150,000 or more (%)	2.0 [n=1]	2.9 [n=1]	2.4 [n=2]	
Prefer not to say (%)	2.0 [n=1]	14.7 [n=5]	7.2 [n=6]	

Not answered (%)	4.1 [n=2]	0 [n=0]	2.4 [n=2]

** Mean ± Standard deviation, n = number of participants, WC = waist circumference, BMI = Body Mass Index.*

[1]T-Test; [2]Pearson's Chi-Square Test; [3]Profesionnal degree considered as Doctor (MD) or Judge (JD) etc.

Table 4: Modifiable lifestyle behaviours and self-reported health beliefs of adults with prediabetes referred to the STAR FHT education sessions on healthy lifestyle.

Modifiable Lifestyle Behaviours	***Lifestyle Intervention Participants***	***Control Participants***	**Statistical analysis**
N	49	34	
Nicotine Use			
Never smoked (%)	55.1 [n=27]	61.8 [n=21]	
Former smoker (%)	36.7 [n=18]	38.2 [n=13]	NS[2]
Current smoker (%)	6.1 [n=3]	0 [n=0]	
Alcohol Consumption in previous week			
None (%)	38.8 [n=19]	47.1 [n=16]	
1-3 drinks (%)	20.4 [n=10]	29.4 [n=10]	
4-6 drinks (%)	26.5 [n=13]	2.9 [n=1]	
7-9 drinks (%)	4.1 [n=2]	5.9 [n=2]	NS[2]
10-12 drinks (%)	6.1 [n=3]	2.9 [n=1]	
13-14 drinks (%)	2.0 [n=1]	5.9 [n=2]	
15 drinks (%)	2.0 [n=1]	5.9 [n=2]	
High-risk alcohol consumption (%)	6.1 [n=3]	11.8 [n=4]	NS
Stress level on a scale of 0 to 10 (%)	4.4 ± 2.8	3.9 ± 2.8	NS[1]
Hours of Sleep per night on average	7.2 ± 1.4	6.8 ± 0.9	NS[1]
Lifestyle Changes made since prediabetes diagnosis			
Yes (%)	55.1 [n=27]	52.9 [n=18]	NS[2]
No (%)	40.8 [n=20]	32.4 [n=11]	
Not answered (%)	4.1 [n=2]	14.7 [n=5]	
For those who made lifestyle changes			
Alcohol (%)	22.2 [n=6]	27.7 [n=5]	NS[2]
Nutrition (%)	92.6 [n=25]	100.0 [n=18]	NS[2]
Physical Activity (%)	74.1 [n=20]	41.2 [n=14]	NS[2]
Smoking (%)	3.7 [n=1]	0 [n=0]	NS[2]
Weight Loss (%)	48.1 [n=13]	32.4 [n=11]	NS[2]
Co-morbidities			
Heart disease (%)	10.2 [n= 5]	2.9 [n=1]	NS[2]
Hypertension (%)	57.1 [n= 28]	64.7 [n=22]	NS[2]
High blood cholesterol/triglycerides (%)	44.9 [n=22]	35.3 [n=12]	NS[2]
Kidney disease (%)	0 [n=0]	0 [n=0]	NS[2]
PCOS (%)	0 [n=0]	0 [n=0]	NS[2]
≥ 1 co-morbidity (%)	67.3 [n=33]	29.4 [n=10]	p = 0.0008

**Mean ± Standard deviation, n = number of participants, [1]Student'sT-Test; [2]Pearson's Chi Square*

Table 5: Average daily intake of rural adults, from 3-Day Food Record data in relation to the current Canadian Dietary Reference Intakes (n=76)

	Dietary Reference Intakes[¥]	**WOMEN [n=35]**	**p**[1]	**MEN [n=41]**	**p**[1]	**p**[2]
Carbohydrates	AMDR [45-65 % of energy intake]	49.2 ± 7.5 %	NS	46.3 ± 8.7%	NS	NS
Proteins	AMDR [10-35% of energy intake]	16.6 ± 3.2%	NS	16.9 ± 3.8%	NS	NS
Fats	AMDR [20-35% of energy intake]	32.9 ± 6.2%	NS	34.9 ± 7.7%	NS	NS
Sodium (mg/d)	UL = 2 300•	2 911.7 ± 1 423.5	p=0.0157	3 143.3 ± 1 013.9	p<0.0001	NS
Phosphorus (mg/d)	*AI= 700*	958.1 ± 389.4	p=0.0004	786.4 ± 251.1	p=0.0333	p=0.03
Potassium (mg/d)	*AI= 4700*	2 284.2 ± 769.7	p<0.0001	2 440.6 ± 846.9	p=0.0001	NS
Dietary Fibres (g/d)						
31-50 y	*Women AI = 25 g/d (n=7)*	21.2 ± 10.3	NS	21.6 ± 8.5	p=0.0310	
	Men AI = 38 g/d (n=4)	21.9 ± 8.4	NS	24.0 ± 8.6	p=0.0006	
51-70 y	*Women AI = 21 g/d (n=20)*	26.2 ± 12.8	NS	21.6 ± 10.0	NS	
> 70 y	*Men AI = 30 g/d (n=30)*					
	Women AI= 21 g/d (n=8)					
	Men AI = 30 g/d (n=7)					
Calcium (mg/d)						
31-50 y	Women RDA = 1000 mg/d *(n=7) Men RDA = 1000 mg/d (n=4)*	1 185.1 ± 616.8	NS	1 367.6 ± 803.7	NS	
			p<0.0001			
51-70 y	Women RDA = 1200 mg/d *(n=20)*	719.1 ± 224.9		686.0 ± 247.3	p<0.0001	
	Men RDA = 1000 mg/d *(n=30)*		p=0.0004		p=0.0004	
> 70 y		714.4 ± 215.6		621.4 ± 217.8		
	Women RDA = 12000					

	mg/d(n= 8) *Men RDA = 1200 mg/d(n=7)*					
Iron (mg/d)						
31-50 y	Women RDA = 18 mg/d *(n=7)* *Men RDA* = 8 mg/d	18.8 ± 22.8	NS	13.3 ± 4.7	NS	
> 51 y	*(n=4)*	13.3 ± 6.7	p=0.0002	14.6 ± 7.0	p<0.0001	
	Women RDA = 8 mg/d (n=28) *Men RDA* = 8 mg/d *(n=37)*					
Zinc (mg/d)	Women RDA = 8 mg/d (n=35) *Men RDA* = 11 mg/d (n=41)	8.3 ± 8.9	NS	7.97 ± 3.45	p<0.0001	

*Mean ± Standard deviation, n=number of participants, 1One-Sample T-test were used to assess the statistical differences between Dietary Recommendation Intake and participants' average intake. 2 Student T-test assessing difference in means between men and women significant at alpha=0.05
•Tolerable Upper Intake Levels (ULs), Recommended Dietary Allowances (RDAs) in bold type, Adequate Intakes (AIs) in italics. ¥ Dietary Reference Intakes (Health Canada, 2005, http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/nutrition/dri_tables-eng.pdf)

Table 6: Analysis of Average 3-Day Dietary Intake of Rural Adults with Prediabetes Using Eating Well with Canada's Food Guide and the Diabetes Canada Carbohydrate Exchange Equivalents (n=76)

	Lifestyle Intervention Participants	***Control Participants***	**All Participants**	**Statistical analysis**[1]
n	48	28	76	
Eating Well with Canada's Food Guide Portions				
Vegetables & Fruit (servings)	3.5 ± *2.1*	4.9 ± *2.5*	4.0 ± *2.4*	p=0.020
Grains Products (servings)	4.7 ± *1.9*	4.2 ± *1.5*	4.5 ± *1.8*	NS
Milk & Alternative (servings)	1.4 ± *1.1*	1.2 ± *0.7*	1.3 ± *0.9*	NS
Meat & Alternative (servings)	2.8 ± *1.3*	3.0 ± *1.2*	2.9 ± *1.3*	NS
Diabetes Canada Food Group Exchange System Carbohydrate-Containing Food Groups [3]				
- Grains & Starches (servings) *	7.7 ± *4.6*	7.1 ± *2.5*	7.5 ± *3.9*	NS
- Fruits (servings) *	1.9 ± *1.7*	2.7 ± *2.1*	2.2 ± *1.9*	NS
- Vegetables (servings) *	1.9 ± *1.4*	3.4 ± *3.7*	2.5 ± *2.6*	NS
- Milk & Alternatives (servings)*	0.6 ± *0.6*	0.5 ± *0.5*	0.5 ± *0.6*	NS
- Other Choices (servings)*	3.3 ± *2.7*	3.4 ± *2.2*	3.3 ± *2.5*	NS
Other Food Groups:				
- Meat & Alternatives (servings)*	12.4 ± *6.3*	10.6 ± *3.9*	11.7 ± *5.6*	NS
- Fats (servings)*	5.9 ± *3.0*	6.6 ± *2.5*	6.2 ± *2.8*	NS
- Alcohol (servings)*	0.6 ± *0.9*	0.5 ± *0.9*	0.6± *0.9*	NS

**Mean ± Standard deviation, n = number of participants, [1]Student's T-Test;*

Table 7: Baseline Short 7-Day International Physical Activity Questionnaire of rural adults with a diagnosis of prediabetes referred to the STAR FHT intervention program (n=50)

S7D-IPAQ		***Lifestyle Intervention Participants* [n=32]**	***Control Participants* [n=18]**	**All Participants [n=50]**	***Statistical analysis***
"During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics or fast bicycling?"***** (days)		0.8 ± 1.5	1.0 ± 1.7	0.9 ± 1.6	NS
*"How much time did you usually spend doing **vigorous** physical activities on one of those days?" (mins)*		*22.3 ± 40.3*	*46.7 ± 69.2*	31.1 ± 53.2	NS
Average METS from vigorous physical activity		*403.8 ± 879.3*	*1 133.3 ± 2 245.1*	661.4 ± 1 537.2	NS
"During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis?" (days)		0.7 ± *1. 4*	1.3 ± *1.5*	0.9 ±1.5	NS
*"How much time did you usually spend doing **moderate** physical activities on one of those days?" (mins)*		*20.0 ± 45.9*	*51.1 ± 66.0*	31.2 ± 55.4	NS
Average METs from moderate physical activity (METs)		*271.3 ± 845.6*	*437.8 ± 630.0*	331.2 ±772.4	NS
Meeting the weekly Canadian Physical Activity Guidelines (%)		[n=6] 18.8%	[n=7] 38. 9%	[n=13] 26.0%	NS
"During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?" (days)		2.7 ± 2.5	1.8 ± 2.3	2.4±2.5	NS
*"How much time did you usually spend doing **walking** on one of those days?" (mins)*		*48.9 ± 61.8*	*28.6 ± 34.9*	41.6 ± 54.2	NS
Average METS from walking (METs)		*701.8 ± 1 041.2*	*316.3 ± 443.7*	563.0 ± 888.2	NS
Average METS in a week (METs)		*1 376.8 ± 1 752.9*	*1 887.4 ± 2 613.1*	1 560.6 ± 2 091.5	NS
Categorical Score	*LOW*	*53.1% [n=17]*	*50.0% [n=9]*	52.0% [n=26]	NS
	MODERATE	*31.3 % [n=10]*	*33.3% [n=6]*	32.0% [n=16]	
	HIGH	*15.6 % [n=5]*	*16.7% [n=3]*	16.0% [n=8]	

"During the last 7 days, how much time did you spend sitting on a week day?" (mins)	438.9 ± 224.8	345.6± 219.7	392.3±222.3	NS

CHAPTER 6: Improving Awareness, Knowledge, Self-Efficacy, and Behaviours Through a 6-Month Community-Based Intervention Program for Rural Adults with Prediabetes

This article is the primary objective of the thesis, determining if awareness, knowledge, self-efficacy, and behaviours were achieved pre- to post-program by the intervention participants. It is written in the format of the CJD. The authors are Sarita Azzi RD, Adrienne Vermeer RD, Mathilde Lavigne-Robichaud RD, MSc, Teresa Barresi RN MSc, Sean Blaine MD, Jayson Azzi BSc, and Isabelle Giroux RD PhD.

Improving Awareness, Knowledge, Self-Efficacy, and Behaviours Through a 6-Month Community-Based Intervention Program for Rural Adults with Prediabetes

6.1. Abstract

Objectives: To determine if a healthy lifestyle intervention program targeting rural adults with prediabetes could help increase awareness, knowledge, self-efficacy, and behaviours toward making positive lifestyle changes known to decrease the risk of developing type 2 diabetes (T2D). The intervention program took place in Southwestern Ontario and had 6 monthly community-based education sessions.

Methods: Rural adults with prediabetes were referred to the program by the STAR Family Health Team. Participants chose to be part of the intervention program or control group. Following the baseline assessment, intervention program participants attended six monthly education sessions that focused on adopting healthy lifestyle behaviours, such as healthy eating and regular physical activity (PA). To assess aforementioned parameters, questionnaires and food records were collected from all participants pre- and post-program. Additionally, intervention participants completed monthly goal setting sheets.

Results: Forty-nine intervention and 34 control participants aged 61.5±9.1 (mean±SD) participated in the prediabetes program. From pre- to post-program, only intervention participants significantly increased their T2D risk perception, knowledge about PA guidelines, and recommended servings of vegetables and fruit. Behaviour changes were also implemented by intervention participants who reduced daily energy, carbohydrates, sugars, fat, and sodium intake. They also increased daily phosphorus intake, energy intake from protein, and reported time spent walking and doing moderate PA.

Conclusion: There were improvements in prediabetes intervention program participants' awareness, knowledge, and lifestyle behaviours pre- to post-program. Further improvements could be accomplished to increase knowledge retention and self-efficacy by simplifying recommendations and providing additional take-home resources for rural adults with prediabetes.

MeSH keywords: Prediabetes; Rural Adults; Awareness; Knowledge; Self-Efficacy; Behaviour Change

6.2. Introduction

Rural Adults:

Rural adults were the focus population for this study. In Canada, nearly 1 in 5 Canadians live in a rural community, according to the 2016 Census data [1]. The influence of built environments in rural settings has not been studied in great depth and urban-based approaches are not necessarily transferable to rural settings [2,3]. The built environment is part of the physical surroundings and can strongly influence health-related behaviours such as physical activity (PA), healthy eating, mental health, and health equity [2,4]. Not surprisingly, the prevalence of type 2 diabetes (T2D) is higher in rural areas than in urban areas. Compared to their urban counterparts, rural adults with T2D tend to be diagnosed later and have poorer socio-economic conditions, less education, higher rates of tobacco and alcohol use, and higher mortality rates at a relatively younger age [5]. They also tend to be less physically active partly due to poor sidewalk walkability and a decrease in physical labor as a result of mechanised agriculture, which may emphasize the vulnerability of rural residents to T2D [3,6].

The intervention program developed for this study through the STAR family heath team (FHT) clinics was carried out in the rural city of Stratford and the community of Tavistock in Southwestern Ontario. [7,8]. Two of the three STAR FHT clinics are in Stratford, which is situated in Perth County. The third clinic, based in Tavistock, is in Oxford County. Self-reported data concerning the STAR FHT rostered patient population involved in the study was collected in 2013-2014. The data revealed that 61.7% of adults indicated that they had either obesity or were overweight, 58.3% were not meeting their daily requirements of vegetables and fruit based on the CFG and 41.5% were inactive during their leisure time [9]. As for Tavistock, 52.2% of the

adult population indicated that they had either obesity or were overweight, 62.2% were not meeting their daily requirements of vegetables and fruit, and 49.5% were inactive during their leisure time [9]. In addition to having obesity or being overweight, not meeting dietary and PA recommendations puts rural adults at risk for chronic diseases such as prediabetes, which may progress to T2D.

Prediabetes:

In recent years, several medical advances have improved the overall management of T2D complications. However, there is a significant gap in research when it comes to community-based management of prediabetes, the primary prevention of T2D [10]. Prediabetes is a condition in which people have higher than normal blood glucose concentrations but not high enough for a diagnosis of T2D [11]. Those with prediabetes have impaired glucose tolerance (IGT), impaired fasting glucose (IFG), or an A1C of 6.0% to 6.4% [11]. Similar to T2D, rates of prediabetes diagnosis have been increasing in Canada, including rural areas [12]. Rising obesity rates, sedentary lifestyles, an aging population, and changes in the ethnic mix of new immigrants is contributing to these increases [13,14].

Lifestyle Intervention Programs:

It is estimated that many cases of T2D could be delayed, or even prevented, with healthier eating patterns and regular PA [13]. This is because obesity and sedentary behaviours are important risk factors for T2D. Since the Diabetes Prevention Program (DPP) in 2002 concluded that T2D can be prevented or delayed in individuals with prediabetes, knowledge translation has been a research priority for the Public Health Agency of Canada (PHAC) [15]. A

meta-analysis found that lifestyle interventions that target PA and diet could reduce the risk for developing T2D by about 58% [16]. In addition, a weight loss of 5% to 10% of initial body weight through a healthy lifestyle and exercising 150 minutes at a moderate level has been shown to significantly reduce the risk of T2D [16,17]. Developing practical education programs for rural individuals with prediabetes in their own community settings could aid by progressively increasing their awareness about the causes and symptoms of T2D, as well as its prevention [16].

Social Cognitive Theory:

Various cognitive processes such as perceptions about the self, beliefs, attitudes, and emotions can directly affect or mediate behaviour [18]. An intervention program for rural adults with prediabetes based on social cognitive theory (SCT) of behavior change by Bandura could be helpful since this theory supports developing problem solving and coping skills which enhance self-confidence and feelings of efficacy, making it easier to complete health-related behaviors and work through some of the individuals' personal daily barriers [18,19]. In fact, SCT has been effectively used to help reshape many health behaviors by promoting the initiation and maintenance of positive lifestyle changes such as increasing PA and healthy eating practices [20,21].

6.3. Methodology

Objective:

The objective of this research was to determine if healthy lifestyle education, as part of a 6-month community-based intervention program for rural adults with prediabetes, would help in

T2D prevention by increasing participant awareness, knowledge, self-efficacy, and behaviours toward making positive lifestyle changes known to decrease the risk of developing T2D.

Recruitment of Study Participants:

Clients diagnosed with prediabetes were informed of the new prediabetes intervention program by the STAR FHT physicians and nurse practitioners. Interested individuals were asked to contact the STAR FHT to book an initial visit (Visit 1; baseline), where eligible clients were then presented with the prediabetes education program options: either fully participate in the intervention program and take part in a 6-month lifestyle education program or be part of the control group and participate in a one-time 2-hour group education session on prediabetes.

Inclusion criteria included being 18 years of age or older, being diagnosed with prediabetes by their doctor or other healthcare provider, being able to attend educational program presentations at STAR FHT, being able to perform low impact PA, such as walking and stretching, being able to chew and swallow food with little difficultly, and being able to fill out written questionnaires about their health and behaviours. Exclusion criteria included currently taking part in another lifestyle education program or research study, being pregnant or breastfeeding, having type 1 diabetes (T1D) or T2D, having a digestive disease (e.g. Crohn's disease, celiac disease, etc.) and having a diagnosed mental illness (e.g. major depression, eating disorder, schizophrenia, etc.).

Overall, 49 intervention program participants and 34 control participants took part in the prediabetes lifestyle education program between April 2012 and February 2013. Informed

written consent was obtained from all participants prior to the commencement of data collection and participation in the program. The project was approved by the University of Ottawa Office of Research Ethics and Integrity (REB: H10-12-10) and the Public Health Agency of Canada Research Ethics Board (REB: 2010-0072).

Description of the Program:

Following the baseline visit (Visit 1), intervention participants returned to the STAR FHT monthly for six 2-hour educational sessions and a post-intervention data collection session (Visit 8). The intervention program provided participants with information and promoted the development of skills regarding healthy eating and PA strategies known to help prevent or delay the development of T2D. Each session of 120 minutes was roughly divided into 50 minutes of nutrition education, 10 minutes of break, 40 minutes of PA and education, 10 minutes of food demonstrations and/or community resource sharing, and 10 minutes of individual goal setting and session feedback at the end. Anthropometric measurements were also taken: height at baseline, as well as body weight and waist circumference (WC) at each visit. The sessions were provided by a registered dietitian (RD). They were tailored to the needs of rural adults with prediabetes, alongside the help of local community partners, who provided the accessible and interactive PA demonstrations and education.

Data Collection:

To assess change in participant awareness, knowledge, self-efficacy, and behaviours toward making positive lifestyle modifications known to decrease the risk of developing T2D, the following was collected at baseline and at the end of the 6-month program from both the

intervention participants and the control groups: demographic questionnaire, lifestyle questionnaire, 3-day food intake record, and Short-7-Day-International Physical Activity Questionnaire (S7D-IPAQ). In addition, Goal Setting Sheets were collected as an indicator of behaviour change from the intervention group. Participants were invited to formulate one or two personal SMART (Specific, Measurable, Attainable, Reward-based, and with a Time frame) goals per education visit related to nutrition and/or PA. Throughout the program, the RD assisted lifestyle intervention participants to progressively build on making one simple positive lifestyle change at a time.

Data Analysis:

Data collected was entered in the data entry and analysis software Epidata (v 3.1 The EpiData Association, Odense, Denmark). Food records were analysed with the ESHA Food Processor SQL (v 10.15.0 ESHA Research, Salem, Oregon, USA) nutrition analysis and fitness software. Food intake records were reviewed with each participant by an RD to increase accuracy. Fifty-two participants (33 intervention, 19 control) handed in their food intake records prior to the start of the program. SAS software (v 9.4 SAS Institute Inc., Cary, NC, USA) was used to analyse the data. BMI and WC were analysed and interpreted based on current guidelines [22,23]. All files were saved in the researcher's computer and were protected by a password. Participant codes were used to label data and preserve participants' confidentiality.

Statistical Methodology:

Baseline and post-intervention data were compared for intervention and control participants who provided information for both time points and was analyzed using paired T-

tests and Wilcoxon signed-rank tests. Data is reported as means ± standard deviations. A p-value of <0.05 was considered significant.

6.4. Results

Participants' Characteristics:

Participants' baseline characteristics are shown in Table 1. Intervention program participants and control group participants did not significantly differ on any variable other than annual household income. Program participants were predominantly male (54%), middle-aged (61.5±9.1 years), Caucasian (98%), employed (57%), and had a high school education (48%). As for their anthropometric measurements, participants were on average obese (33.1±5.5 kg/m2) and had abdominal obesity measured by WC (108.5±12.9 cm).

Awareness:

A lifestyle questionnaire was used to evaluate their T2D risk awareness pre- and post-program (Table 2). Intervention participants significantly ($p<0.05$) increased their T2D risk perception unlike control participants (58.5±22.8 to 65.0±23.4 % vs 44.4±20.6 to 49.4±20.1 %). Perception of seriousness of T2D complications was unchanged for intervention participants and increased for control participants (86.9±20.1 to 91.1±9.6 % vs 82.8±19.0 to 90.8±12.8 %). There was no significant difference regarding their perception of the likelihood of preventing or delaying the T2D development pre-post program.

Knowledge:

There was a significant improvement of intervention participants' knowledge compared to the control group when it came to knowing the recommended daily servings of vegetables and fruit (4.9±2.4 to 6.7±2.0 portions vs 5.9±2.6 and 7.0±2.2 portions) and the number of daily steps recommended for achieving and maintaining good health (27.8 to 66.7 % vs 15.0 to 40.0 %) (Table 2). In addition, there was no difference in knowledge about specific elements of PA and healthy eating, such as knowing which foods are high in fat, from baseline to post-program between intervention and control participants (data not shown).

Self-Efficacy:

There was no significant improvement in the intervention and control participants' reported confidence levels regarding making healthier eating choices and participating in regular PA in the next 6 months (Table 2).

A total of 348 SMART goals (half about nutrition and half about PA) were formulated by the intervention program participants during Visits 2-8 (Table 3). Nutrition and PA goals were set by almost all participants. At Visit 2, participants mostly aimed at increasing vegetables and fruit consumption (23 of 54 goals), eating breakfast (9 of 54 goals), and controlling their food and beverages portion sizes (7 of 54 goals), with an average score of 6.7, 6.3, and 3.8 of 10, respectively, when it came to reaching their goals. At Visit 8, participants mostly aimed at increasing vegetables and fruit consumption (6 of 20 goals), controlling their portion size (6 of 20 goals), and reducing sodium intake (5 of 20 goals), with an average score of 6.5, 5.5, and 7.3 of 10, respectively, in relations to reaching their goals.

Dietary Behaviours:

A significant reduction of daily energy intake was observed for both intervention and control group participants (2015.7 ± 629.8 kcal/d to 1749.9 ± 518.6 kcal/d vs 1909.9 ± 473.1 kcal/d to 1718.5 ± 466.9 kcal/d) based on the 3-day food intake records (Table 4). A significant improvement was observed in the intervention program group but not in the control group related to reducing carbohydrates (241.3±86.9 to 201.6±50.0 g/d vs 231.6±73.8 to 209.0±67.7 g/d), sugars (90.4±42.2 to 73.2±31.1 g/d vs 90.2±43.0 to 80.5±34.3 g/d), fat (81.2±34.7 to 67.3±30.8 g/d vs 67.0±22.8 to 61.2±22.6 g/d), and sodium intake (3311.9±1387.8 to 2297.7±1673.5 mg/d vs 2828.2±742.3 to 2763.4±794.0 mg/d), as well as in increasing phosphorus intake (791.0±280.5 to 941.1±343.3 mg/d vs 982.7±334.8 to 875.9±278.6 mg/d) and energy from protein (16.3±3.7 to 19.2±3.4 % energy/d vs 17.7±3.3 to 17.6±2.7 % energy/d). There were no other changes in nutrients intake based on 3-day food records.

Physical Activity Behaviours:

An analysis comparing pre- and post-program IPAQ data (data not shown) revealed statistically significant differences ($p<0.05$) for the intervention participants only in the reported time spent doing moderate PA (30.3±48.9 to 46.0±52.7 mins vs 50.6±46.5 to 51.3±64.4 mins) and time spent walking (71.4±121.7 to 120.5±141.7 mins vs 51.9±67.6 to 116.1±145.4 mins). Also, 76 % of intervention participants reported doing the same amount or more moderate PA minutes per week and 65 % of the intervention participants reported spending more time walking at post-program compared to baseline. There was no other change based on IPAQ questionnaire results.

Lifestyle Behaviours:

Based on the lifestyle questionnaire, the number of intervention participants who knew the recommended number of portions of vegetables and fruit per day and also felt they met CFG recommendations in the past week significantly increased (7.1 to 78.6 % ($p=0.001$)), unlike control participants (70.0 to 57.1 %) (Table 2).

Furthermore, the intervention participants' correct answers significantly increased ($p<0.05$) when it came to knowing the number of steps recommended daily and knowing the recommended number of steps while feeling that they met that amount (22.2 to 30.5% vs 35.0 to 50.0 %), unlike the control participants (12.5 to 63.6% vs 0.0 to 40.0%).

6.5. Discussion

Proper management of prediabetes and the prevention of T2D require patients to be aware of the nature of the disease, its risk factors, treatment, and complications [24]. Awareness of the T2D risk factors can assist rural adults in early prevention and reduction of incidence. In respect to the perception of their risk of developing T2D, intervention participants significantly increased from baseline to post-program, unlike control participants. However, at post-program it was still low compared to their actual risk for T2D. More analysis is needed to determine how T2D awareness can be further increased and if those with a family history of T2D or history of gestational diabetes had a higher awareness of their risk.

The perception of seriousness of the complications of T2D remained high for intervention participants from baseline to post-program, whereas it increased for control participants, likely

reflecting the 2-hour group education session received and follow up discussions with their family physicians.

In addition, the participants' perception of the likelihood of preventing or delaying T2D remained unchanged throughout the program. Since self-efficacy has an influence on outcome expectations, it is possible that some participants felt that their self-efficacy was still low compared to their perceived barriers to prevent and/or delay the onset of T2D even though many of them believed they could prevent or delay the development of T2D [25].

Knowledge was assessed by comparing self-reported health beliefs of intervention participants and control participants from baseline to post-program. On average, intervention participants significantly increased their knowledge when it came to broad recommendations associated with a healthy lifestyle from baseline to post-program, while those remained unchanged for control participants. These broad recommendations related to knowledge included the number of servings per day of vegetables and fruit recommended by CFG and the number of steps per day recommended for achieving and maintaining good health. Increasing knowledge about behaviors associated with health may motivate individuals with prediabetes to positively modify their personal behaviors [25].

On the other hand, regarding more specific knowledge pieces about nutrition and PA, there was no increase from baseline to post-program for both groups. It is possible that it may have been too much information for the intervention participants to retain from baseline to post-program. Breaking it down to even smaller pieces of hands-on knowledge and only including the

critical information during the intervention program may help the intervention participants retain more of what is important for self-management [26]. Keeping additional information available such as handouts for those who are looking to learn more may also be beneficial. In addition, the level of literacy and numeracy of the information and research questionnaires may need to be reduced to better meet the participants' needs and reduce their barriers to learning and doing self-assessments as almost half of participants reported having a high-school education or less. Even though our participants were told that they could always skip over questions they did not want to answer, questionnaire fatigue may also be influencing results for some individuals.

Furthermore, people tend to forget information they do not use [27]. This highlights the importance of skill building through goal setting which was strengthened at every monthly education session and may have helped intervention participants use and retain some of the information they learned. More interactive and practical follow ups, as part of the education sessions, may also remind participants about the credible information already presented to support healthy behavior changes.

Self-efficacy is one's confidence or belief in the ability to perform a behavior. It predicts effort and the ability to persevere, as belief in one's personal ability can either motivate or prevent the individual's behaviour change [19]. Goal intention and goal setting are other components of the SCT which are taught to facilitate the behavior change process [19,25]. With the help of an RD, the intervention program encouraged participants to reflect on their personal health behaviours and develop the skills to set SMART eating and PA goals. The program also allowed significant others to be present at each session to provide participants ongoing support

and reinforcement towards making one positive behaviour change at a time, so that participants were not feeling overwhelmed or discouraged. Supporting rural adults with the challenges of prediabetes and T2D self-management have been found to positively influence behaviour change [26].

Many intervention participants learned to set personal lifestyle goals and their average confidence level in achieving them was about 7 out of 10. This shows the importance of a monthly intervention program to help participants reflect each month on the goal set the previous month and to discuss barriers and facilitators to that behaviour change. Since it is not easy for individuals to change their behaviour, some participants progressively worked at a goal for more than a month or had to break it down into smaller, more achievable personal goals.

Although the number of personal goals handed in was lower from Visit 2 to Visit 8, participants' goals were more centered towards small achievable goals such as ensuring sufficient vegetables and fruit intake and paying attention to portion control, thus also increasing their ability to achieve them. When asked why they were not able to reach their goal, most participants noted that it was tough with their work and stress, as well as the inability to watch what they eat on holidays or during summer vacations. In addition, as participants became comfortable with SMART goals, some of them felt less of a need to write them down.

Additionally, personal SMART goal setting was found to be helpful by our lifestyle participants, their long-term self-efficacy confidence levels evaluated in the lifestyle questionnaire did not significantly increase. This highlights the benefit of making small

attainable goals as larger and longer term goals can be perceived as overwhelming and unattainable. Other studies also emphasised the importance of making small, simple, and achievable goals, which lead to greater behavior change over the long term [28,29].

Furthermore, pre- and post-program analysis of a 3-day food intake record to further assess the study hypothesis was done in order to examine participants' ability to meet the healthy eating guidelines of Health Canada (CFG) and Diabetes Canada (previously CDA). A significant reduction of the average daily energy intake of intervention program participants was observed from pre- to post-program. Although the same was observed for the control participants, it is only in the intervention participants' food records that an important improvement in dietary intake patterns was also observed. Contrary to control participants, intervention program participants managed to reduce their average daily intake of carbohydrates, total sugars, sodium, and fat intake, as well as increase their phosphorus and energy from protein intake. These dietary improvements can be explained as participants' learned to balance meals during the education session with the program RD. Indeed, dietary prevention of T2D goes beyond the reduction of excess total carbohydrate intake, as expressed in the Diabetes Canada Clinical Practice Guidelines (2013)[30].

In this regard, it is important to underline where there were no statistical differences observed from baseline to post-program for the intervention participants. Generally, when carbohydrate intake is reduced, dietary fibres, folate, as well as potassium consumption often also decrease significantly. This was not observed among the intervention participants as they were able to maintain their average intake of above-mentioned beneficial nutrients while

controlling their carbohydrate and total sugar intake. This is believed to be related to the improvement of the quality of their food choices with the guidance of our program RD and using personal goal setting.

Therefore, on average, intervention participants succeeded at making significant improvements to their dietary habits from baseline to post-program based on their 3-day food intake records and lifestyle questionnaire. By accomplishing ongoing small and incremental changes and setting monthly SMART nutrition goals, rural participants improved their dietary habits.

The IPAQ data analysed helped evaluate behaviour changes. Intervention participants reported an increase in perceived levels of PA from baseline to post-program. An analysis comparing IPAQ data revealed significant differences in the reported time spent doing moderate PA and time spent walking. This increase in participants' PA levels could have been facilitated by the activities led by the local community partners during the program. This may have increased their awareness about resources and tools in their local environment available to them to increase their PA level. It is also important to note that although the IPAQ is a useful tool to assess PA, its reliability has been found insufficient by other studies [31,32]. Considering that rural adults are more likely to be sedentary due to their built environment, the simple act of promoting an active lifestyle can translate in significant positive health outcomes [33]. Increasing or maintaining a certain level of PA can assist in delaying the onset of T2D and its complications in this high-risk population [20].

Self-reported data, such as food records and IPAQ, represent a limitation of this study. In addition, the sample size is small and the participants were not randomly selected. Consequently, the results are specific to the sample population and may not reflect the general population of rural adults with prediabetes.

6.6. Conclusion

As knowledge translation of T2D prevention has been a research priority, the 6-month lifestyle intervention program targeting rural adults from Southwestern Ontario was designed based on the SCT [15]. Participants of the program were educated on healthy lifestyle changes, such as healthy eating and PA, to reduce their risk of developing T2D and help delay/prevent the onset of this disease. Improvement of some elements related to awareness, knowledge, and lifestyle behaviours was achieved by the intervention participants from baseline to post-program, unlike their control counterparts. Still, further improvements in knowledge retention and self-efficacy could be accomplished by simplifying recommendations and providing additional resources to further increase rural adults with prediabetes' ability to apply the learning into their daily life. These strategies are emphasized by the SCT [25].

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Author Disclosures

The authors certify that they have no conflict of interest.

Author Contributions

SA and IG contributed substantially to conception and design, acquisition of data, analysis and interpretation of data, drafted the article and revised it critically for important intellectual content and gave final approval of the version to be published. AV, MLR, TB and SB contributed substantially to conception and design, or acquisition of data, or analysis and interpretation of data and gave final approval of the version to be published. JA contributed to acquisition of data, revised the manuscript and provided final approval of the version to be published.

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Table 8:
Baseline characteristics of control participants and participants in the 6-monthly lifestyle intervention program for rural adults with prediabetes*

Demographic and Anthropometric Characteristics	All Participants (n=83)	Intervention Participants (n=49)	Control Participants (n=34)	P value
Age, years, Mean ± SD	61.5 ± 9.1	60.6 ± 8.1	62.9 ± 10.4	NS[1]
Sex, % male	54.2	55.1	52.9	NS[2]
BMI, kg/m^2, Mean ± SD	32.9 ± 5.5	33.1 ± 5.5	32.6 ± 5.7	NS[1]
Normal (18.5-24.9 kg/m^2), %	6.1	6.3	5.9	
Overweight (25.0-29.9 kg/m^2), %	26.8	25.0	29.4	NS[2]
Obesity (≥30.0 kg/m^2), %	67.1	68.8	64.7	
Waist Circumference, cm, Mean ± SD	107.8 ± 12.2	108.5 ± 12.9	107.0 ± 11.3	NS[1]
Male at high health risk (WC≥ 94 cm), %	95.6	96.3	94.4	NS[2]
Female at high health risk (WC≥ 80 cm), %	97.4	95.5	100.0	NS[2]
Ethnicity, % Caucasian	97.6	98.0	97.1	NS[2]
Marital Status, % married/common- law	82.1	79.6	88.2	NS[2]
Highest Education Level				
≤ High school, %	48.2	46.9	43.6	
University: Bachelor's degree, %	16.9	16.3	17.6	
University: Post-graduate degree, %	3.6	6.1	0	NS[2]
Professional degree: MD, JD etc., %	3.6	4.1	2.9	
Employment Status				
Employed, %	56.6	59.2	52.9	
Retired, %	37.3	32.7	44.1	NS[2]
Unemployed, %	4.8	6.1	2.9	
Annual Household Income				
Under $25,000, %	8.4	2.0	17.6	
$25,000 - $49,999, %	26.5	26.5	26.5	
$50,000 - $74,999, %	22.9	22.4	23.5	
$75,000 - $99,999, %	18.1	30.6	0	
$100,000 - $124,999, %	3.6	2.0	8. 9	
$125,000 – 149,999, %	7.2	8.2	5.9	
$150,000 or more, %	2.4	2.0	2.9	p <0.001[2]
Prefer not to say, %	7.2	2.0	14.7	
Not answered, %	2.4	4.1	0	

*SD: Standard deviation. n = number of participants. NS = no significant statistical difference found (i.e. p≥0.05) between intervention and control participants. WC = waist circumference [22]. BMI = Body Mass Index [23]. MD = Doctor of Medicine. JD = Juris Doctor. [1]Paired t-test. [2]Pearson's Chi-Square Test.

Table 9:
Evolution of perceived type 2 diabetes risk and self-reported health beliefs at baseline and post-program of rural adults with prediabetes participating in the lifestyle intervention program and control participants*

Diabetes risk perception and outcome expectations	Intervention Program Participants		P value	Control Participants		P value
	Baseline	Post-Program		Baseline	Post-Program	
Awareness						
Risk of developing diabetes, %, Mean ± SD (n)	58.5 ± 22.8 (34)	65.0 ± 23.4 (34)	p=0.04[1]	44.4 ± 20.6 (18)	49.4 ± 20.1 (18)	NS[1]
Seriousness of diabetes and complications, %, Mean ± SD (n)	86.9 ± 20.1 (36)	91.1 ± 9.6 (36)	NS[1]	82.8 ± 19.0 (20)	90.8 ± 12.8 (20)	p=0.008[1]
Likeliness of preventing or delaying T2D development, %, Mean ± SD (n)	73.9 ± 20.3 (36)	73.9 ± 19.3 (36)	NS[1]	77.5 ± 16.2 (20)	76.0 ± 25.8 (20)	NS[1]
Knowledge						
Recommended number of serving of vegetables and fruit from CFD, serving, Mean ± SD (n)	4.9 ± 2.4 (36)	6.7 ± 2.0 (36)	p<0.001[1]	5.9 ± 2.6 (20)	7.0 ± 2.2 (20)	NS[1]
Participants who answered correctly, % (n)	27.8 (10)	75.0 (27)	p<0.001[2]	45.0 (9)	65.0 (13)	NS[2]
Steps per day recommended for achieving and maintaining good health?" *(10 000 steps), % of participants who answered correctly (n)*	27.8 (10)	66.7 (24)	p=0.03[2]	15.0 (3)	40.0 (8)	NS[2]
Self-Efficacy						
Confidence in making healthier eating choices in next 6 months, %, Mean ± SD (n)	78.1 ± 20.1 (36)	73.4 ±15.9 (36)	NS[1]	81.1 ± 20.5 (20)	78.0 ± 17.7 (20)	NS[1]
Confidence in participating in regular physical activity in next 6 months, %, Mean ± SD (n)	79.7 ± 19.8 (36)	70.0 ± 21.1 (36)	NS[1]	80.0 ± 21.3 (20)	68.1 ± 43.6 (20)	NS[1]
Lifestyle Behaviours						
Meeting recommended number of servings of vegetables and fruit according to CFG in the last week, answered yes, % (n)	38.9 (14)	38.9 (14)	NS[2]	50.0 (10)	70.0 (14)	NS[2]

Participants who knew the recommended portions of vegetables and fruit per day and felt they met CFG's recommendations in the past week, % (n)	7.1 (1)	78.6 (11)	p=0.001[2]	70.0 (7)	57.1 (8)	NS [2]
Meeting recommended number of steps per day or equivalent for achieving and maintaining good health in the last week, yes, % (n)	22.2 (8)	30.5 (11)	p=0.02[2]	35.0 (7)	50.0 (10)	NS[2]
Participants who knew the recommended steps per day and felt they met the recommendations in the past week, % (n)	12.5 (1)	63.6 (7)	p=0.04[2]	0.0 (0)	40.0 (4)	NS[2]

*Self-reported data from the lifestyle questionnaire. T2D: type 2 diabetes. CFG: Canada's Food Guide. SD: Standard deviation. n = number of participants. NS = no significant statistical difference found (i.e. $p \geq 0.05$). [1] Paired t-test. [2] Wilcoxon test for paired samples.

Table 10:
Analysis of nutrition and physical activity personal SMART goals of prediabetes intervention program participants (n=49)*

Personal SMART goals formulated	Lifestyle Program Participants
Nutrition	178 goals
Set a SMART nutrition goal, % of participants (n)	98.0 (48)
Number of goals per participant, Mean ± SD	3.7 ± 1.7
Confidence level to achieve goal, scale from 0 to 10, Mean ± SD	6.9 ± 1.7
Goals reached, scale from 0 to 10, Mean ± SD	6.3 ± 2.7
Physical activity	170 goals
Set a SMART physical activity goal, % of participants (n)	95.9 (47)
Number of goals per participant, Mean ± SD	3.5 ± 1.8
Confidence level to achieve goal, scale from 0 to 10, Mean ± SD	7.1 ± 1.7
Goals reached, scale from 0 to 10, Mean ± SD	5.5 ± 3.3

*SMART: Specific, Measurable, Attainable, Reward-based, and Time frame. SD: Standard deviation. n = number of participants. SMART goals were collected between visit 2 and visit 8.

Table 11:
Average intake of macronutrients and micronutrients reported in the 3-day food records of prediabetes lifestyle intervention education program participants and control participants at baseline and post-program*

Average Daily Intake	Lifestyle Intervention Program Participants (n=33)		P value[1]	Control Participants (n=19)		P value[1]
	Baseline	Post-Program		Baseline	Post-Program	
Total Energy, kcal/d (KJ/d)	2015.7 ± 629.8 (8433.7 ± 2635.1	1749.9 ± 518.6 (7321.6 ± 2169.8	p=0.02	1909.9 ± 473.1 (7991.0 ± 1979.5	1718.5 ± 466.9 (7190.2 ± 1953.5	p=0.02
Macronutrients						
Carbohydrates, % of energy intake	48.1 ± 8.6	47.4 ± 8.2	NS	48.3 ± 7.7	48.9 ± 9.2	NS
Carbohydrates, g/d	241.3 ± 86.9	201.6 ± 50.0	p=0.01	231.6 ±73.8	209.0 ± 67.7	NS
Dietary Fibers, g/d	24.0 ± 8.5	21.7 ± 7.0	NS	24.1 ± 11.0	21.9 ± 9.2	NS
Sugars, g/d	90.4 ± 42.2	73.2 ± 31.1	p=0.003	90.2 ± 43.0	80.5 ±34.3	NS
Proteins, % of energy intake	16.3 ± 3.7	19.2 ± 3.4	p<0.001	17.7 ± 3.3	17.6 ± 2.7	NS
Proteins, g/d	79.4 ± 22.7	84.0 ± 29.4	NS	83.1 ± 21.6	74.9 ± 23.0	NS
Fats, % of energy intake	35.2 ± 6.7	33.4 ± 7.6	NS	31.5 ±6.7	32.0 ± 6.7	NS
Fats, g/d	81.2 ± 34.7	67.3 ± 30.8	p=0.03	67.0 ± 22.8	61.2 ± 22.6	NS
Saturated Fat, g/d	25.9 ±10.5	21.4 ± 10.9	NS(p=0.07)	22.7 ± 10.3	21.1 ± 9.4	NS
% of energy	11.4 ± 2.9	10.5 ± 3.1	NS	10.6 ± 3.5	10.9 ± 3.2	NS
Polyunsaturated Fat, g/d	8.7 ± 5.7	8.6 ± 4.6	NS	8.2 ± 3.2	7.8 ± 3.8	NS
% of energy	3.8 ± 2.1	4.5 ± 1.9	NS	4.0 ± 1.6	4.1 ± 1.8	NS
Monounsaturated Fat, g/d	14.8 ± 9.2	15.4 ± 8.6	NS	13.6 ± 4.2	13.9 ± 7.4	NS
% of energy	6.6 ± 3.4	7.9 ± 3.1	NS	6.6 ± 1.8	6.9 ± 2.4	NS
Trans Fatty Acids, g/d	0.96 ± 1.0	0.85 ± 82	NS	0.95 ± 0.87	0.66 ± 0.51	NS
Micronutrients						
Sodium, mg/d	3311.9 ± 1387.8	2297.7 ± 1673.5	p=0.002	2828.2 ± 742.3	2763.4 ± 794.0	NS
Calcium, mg/d	813.5 ± 413.2	708.8 ± 314.3	NS	729.8 ± 227.0	756.1 ± 301.9	NS
Iron, mg/d	13.6 ± 7.2	12.6 ± 5.0	NS	15.2 ± 6.8	14.6 ± 6.7	NS
Phosphorus, mg/d	791.0 ± 280.5	941.1± 343.3	p=0.04	982.7 ± 334.8	875.9 ± 278.6	NS
Potassium, mg/d	2233.1 ± 619.4	2464.9 ± 810.1	NS	2838.7 ± 955.3	2453.2 ± 630.3	NS
Zinc, mg/d	7.1 ± 3.3	8.2 ± 4.6	NS	8.5 ± 2.7	7.5 ± 2.7	NS
Folate, mcg/d[a]	345.0 ± 264.7	318.1 ± 160.4	NS	410.7 ±	448.2 ± 243.4	NS

				277.7		
Vitamin B12, mcg/d	3.7 ± 3.5	4.6 ± 6.4	NS	4.8 ± 3.6	4.6 ± 5.6	NS

*NS = no significant statistical difference found (i.e. p≥0.05). g/d = grams per day. mg/d = milligrams per day. mcg/d = microgram per day. kcal = kilocalories. KJ = kilojoules. [1]Paired t-test. [a] As dietary folate equivalents (DFE); [b]As cholecalciferol; [c]As alpha-tocopherol.

CHAPTER 7: Evaluating the Effect of Lifestyle Changes

Intervention in Rural Adults with Prediabetes in Southwestern Ontario

This article is the second and fourth secondary objective of the thesis, evaluating lifestyle changes and its effect on key biochemical, anthropometric, and hemodynamic markers known to increase the risk of developing Type 2 Diabetes. It is written in the format of the Canadian Journal of Dietetic Practice and Research. The authors are Sarita Azzi RD, Adrienne Vermeer RD, Mathilde Lavigne-Robichaud RD, MSc, Renate van Dorp PhD, Teresa Barresi RN MSc, Sean Blaine MD, Jayson Azzi BSc, and Isabelle Giroux RD PhD.

Evaluating the Effect of Lifestyle Changes Intervention in Rural Adults with Prediabetes in Southwestern Ontario

7.1. Abstract

Objectives: To evaluate the effect of lifestyle changes, related to healthy eating and physical activity, on key biochemical, anthropometric, and hemodynamic markers known to increase the risk of developing T2D in rural adults with prediabetes from Southwestern Ontario using a 6-month community-based intervention program.

Methods: Rural adults diagnosed with prediabetes were referred to the STAR Family Health Team (FHT) to participate in the prediabetes intervention program. Food records, step logs, biochemical, anthropometric, and hemodynamic markers were collected from 41 participants at baseline, midpoint, post-program, and at 6-month follow-up.

Results: A significant reduction ($p<0.05$) of the average number of daily servings of grain products, FBG, OGTT, LDL-C, BMI, and WC, as well as a significant increase in their servings of vegetables and fruit was observed from baseline to follow-up. No changes in hemodynamic markers were observed.

Conclusion: Through healthy lifestyle changes, participants improved many markers, which are known controllable risk factors for developing T2DM. Additionally, based on the average FBG, OGTT, and A1C concentrations at follow-up, twelve participants (n=12) were no longer considered in the prediabetes range. Engaging rural adults in a healthy lifestyle intervention program tailored to their specific needs may have contributed to significantly reducing key controllable T2D risk factors.

Keywords: Prediabetes, Rural Adults, Diet, Physical Activity, Biochemical, Anthropometric, Lifestyle Intervention

7.2. Introduction

T2D and its increasing prevalence:

In 2016, diabetes prevalence in Canada was estimated to increase by 41% in the next 10 years [1]. Type 2 Diabetes (T2D) is the most prevalent form of diabetes and it is defined as a chronic condition that affects the way the body metabolizes glucose [2]. In the short term, the symptoms of T2D are associated with a reduced quality of life, while in the longer term, the disease may lead to serious complications such as cardiovascular diseases (CVD), blindness, renal failure and amputation [3,4]. Rising obesity rates, sedentary lifestyles, and an aging population, are likely to continue driving these increases [2,5]. T2D is also influenced by the geographic location and the socioeconomic status of the community. Rural adults tend to be diagnosed later, have poorer socio-economic conditions, have limited healthcare services, have less education, and higher mortality rates [6–8].

Prediabetes and the importance of screening for T2D:

Prediabetes is a T2D risk factor and it is defined as a condition in which people have higher than normal blood glucose concentrations, however not high enough for a diagnosis of T2D [9]. Furthermore, many cases of prediabetes and T2D can go unnoticed as symptoms can be delayed, therefore, many individuals may have the disease and not know it [10]. It is estimated that as high as nine out of 10 people with prediabetes do not know they have this condition, allowing it to progress to T2D unchecked [11]. For this reason, the growing importance of screening to detect prediabetes is undeniable. Similar to T2D, rates of diagnosis have also been increasing [9]. Screening is carried out using the recommended screening tests, such as fasting blood glucose (FPG), oral glucose tolerance test (OGTT) and glycated hemoglobin (A1C) [9].

Those with prediabetes are said to have impaired glucose tolerance (IGT), impaired fasting glucose (IFG), and/or an A1C of 6.0% to 6.4% [9]. Diabetes Canada defines IFG as an FPG value of 6.1 to 6.9 mmol/L and IGT is defined as an OGTT value of 7.8 to 11.0 mmol/L [9,12,13]. An A1C of 6.0 to 6.4% is currently the primary marker of prediabetes [9,14].

Lifestyle interventions:

Without lifestyle changes, 15-30% of adults with prediabetes will develop T2D within 5 years [15]. For that reason, providing rural adults with the skills and knowledge to manage their prediabetes through a community based lifestyle intervention program is crucial to allow them to better care for their needs and prevent/delay the onset of T2D.

Dietary management for the prevention of T2D promotes eating a variety of foods from all four food groups to meet nutrient requirements. Guidelines emphasize whole grains, complex carbohydrates such as legumes, vegetables and fruits, low-fat dairy products, and lean meats. When it comes to PA, a sedentary lifestyle is defined as one with little or no PA, it is one of the major factors that are responsible for the increased prevalence of obesity, which is subsequently related with an increased risk of T2D development [16]. The Canadian Society for Exercise Physiology (CSEP) recommends a minimum of 150 minutes of moderate to vigorous physical activity (PA) weekly. The Perth District Health Unit (PDHU) also recommends aiming for 10 000 steps a day and wearing a pedometer to help increase rural adults' PA levels [17]. Aiming for 10 000 steps a day was made popular by the media based on Japanese walking clubs but has been backed up by emerging research [18,19]. There is a research gap between guidelines and its practical application in the rural community setting, a gap this study's objective will help to fill.

Objective:

The objective of this research was to evaluate the effect of lifestyle changes (healthy eating and PA), as part of a 6-month community-based intervention program, on key biochemical, anthropometric, and hemodynamic markers known to increase the risk of developing T2D in rural adults from Southwestern Ontario.

7.3. Methodology

Recruitment of Study Participants:

Clients diagnosed with prediabetes were informed of the prediabetes intervention program by the STAR FHT physicians and nurse practitioners. Overall, 49 individuals from Stratford and Tavistock took part in the prediabetes lifestyle intervention program between April 2012 and March 2014.

Inclusion criteria included being 18 years of age or older, being diagnosed with prediabetes by their doctor or other healthcare provider, being able to attend educational program presentations at STAR FHT, being able to perform low impact PA, being able to chew and swallow food with little difficultly, and being able to fill out written questionnaires about their health and behaviours.

Written and informed consent was obtained from all participants prior to the commencement of data collection and participation in the program. The project was approved by

the University of Ottawa Office of Research Ethics and Integrity (REB: H10-12-10) and the Public Health Agency of Canada Research Ethics Board (REB: 2010-0072).

Description of the Program:

Following the baseline visit (Visit 1), intervention participants returned to the STAR FHT monthly for six 2-hour educational sessions (Visits 2-7), a post-intervention data collection session (Endpoint - Visit 8), and a 6-month follow-up visit (Visit 9). The intervention program provided participants with information and promoted the development of skills regarding healthy eating and PA strategies known to help prevent or delay the development of T2D. The sessions were provided by a registered dietitian (RD). They were tailored to the needs of rural adults with prediabetes with accessible and interactive education with the help of local community partners, who provided the PA demonstrations and education.

Data collection:

Out of 49 intervention participants, measurements on 41 of them were analyzed at baseline, midpoint (Visit 5), endpoint (Visit 8), and at 6-months follow-up (Visit 9). Data was insufficient for the remaining 8 participants and they were excluded from the analysis. Biochemical measurements were not collected at midpoint.

Dietary outcome measures included vegetables and fruit, grain products, milk and alternatives, and meat and alternatives consumption. Portion sizes were calculated based on the Eating Well with Canada's Food Guide (CFG). An RD administered and analyzed a 3-day food

intake record at all 4 above mentioned visits. Participants were given pedometers at the start of the program and PA level was measured through a self-reported 7-day physical activity step log.

Biochemical, anthropometric, and hemodynamic outcome measures included FBG concentrations, OGTT, A1C concentrations, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), total cholesterol (TC) and triglycerides (TG), body mass index (BMI), waist circumference (WC), and BP. Height was taken at baseline only and was measured in centimeters (cm), body weight was measured in kilograms (kg) using a digital scale, and blood pressure was taken by the research nurse before the start of each visit. Waist circumference was measured in cm. An average of three measures were taken for anthropometric measurements. The BMI (kg/m2) was calculated using the participants' weight and height. BMI and WC were interpreted based on the Diabetes Canada guidelines [20,21].

Data Analysis:

Datum to evaluate key biochemical, anthropometric, and hemodynamic markers from the intervention participants were collected at baseline, midpoint, endpoint, and at 6-month follow-up to verify the study hypothesis. All data collected were entered in Epidata (v 3.1 The EpiData Association, Odense), a data entry and analysis software. Food records were inputted in ESHA Food Processor SQL (v 10.15.0 ESHA Research, Salem, Oregon, USA), a nutrition analysis and fitness software. Food intake records were reviewed with each participant by an RD to increase accuracy and CFG portions were calculated and verified by two other RDs. SAS software (v 9.4 SAS Institute Inc., Cary, NC, USA) was used to analyze the data. All files were saved in the

researcher's computer and were protected by a password. Participant codes were used to label data and preserve the participant confidentiality.

Statistical Methodology:

To test the study hypotheses, a Proc Mixed model, using ML (maximum likelihood) estimation, was conducted in SAS. Several covariance structures, such as autoregressive (AR1), toeplitz (TOEP), and unstructured (UN) were explored. The AR1 model was identified, based on the modeling results, as the most appropriate covariance structure. Fixed effects were included in the model. The covariates explored as potential risk factors in the model were: salary, employment status, sex, and visit number. The data are reported as means ± standard deviations, which were calculated using least squares means (LS-means). A p-value of <0.05 was considered significant.

7.4. Results

Participants' Characteristics:

The baseline characteristics of the intervention program participants are displayed in Table 1. Participants were predominantly male (55.1%), middle-aged (60.6 ± 8.1 years), Caucasian (97.6%), employed (59.2%), and did not complete high school or had a high school education (48.7%). As for their anthropometric measurements, participants were on average obese (33.1±5.5 kg/m2) and had abdominal obesity measured by WC (108.5±12.9 cm), placing them at an increased risk of developing T2D and CVD [2,22]. Post-hoc analysis showed no

statistical differences in the participants' characteristics between those who has sufficient data collected (n=41) and those who did not (n=8).

Diet and PA:

Intervention participants handed in a 3-day food intake record throughout the program and at follow-up. A significant increase in the self-reported average number of servings of daily vegetables and fruit intake ($p<0.001$) and a significant decrease in the servings of grain products intake based on CFG ($p=0.02$) was also observed (Table 2). There were no statistical difference over time in milk and alternatives intake, meat and alternatives intake, average steps per day, and average minutes per week spent exercising.

Biochemical markers:

The intervention participants, on average, succeeded at significantly reducing their FBG ($p=0.003$), OGTT ($p=0.01$), and LDL-C ($p=0.05$) serum concentrations from baseline to follow-up. There was no statistical difference over time when it came to evaluating other biochemical markers such as average A1C, and serum TC, TG, and HDL-C concentrations.

Anthropometric and hemodynamic markers:

From baseline to 6-months follow-up, average BMI ($p=0.04$) and WC ($p=0.004$) were statistically decreased. There was no statistical difference in intervention participants' average BP throughout the program.

7.5. Discussion

Rural adults who were enrolled in the community-based prediabetes intervention program improved their average FBG, OGTT, and LDL-C serum concentrations and decreased their average BMI, and WC. These markers are known controllable risk factors for developing T2D, thus are key in delaying and/or preventing this disease [9]. The effect of these markers was evaluated through time, spanning over a timeline of 1 year (Visits 1 to 9).

The lifestyle changes that were emphasized during the program includes healthy eating for the prevention of T2D, which promotes eating a variety of foods from all four food groups to meet nutrient requirements, as outlined in CFG. Timing of meals and portion sizes were also emphasized in the healthy eating guidelines. From baseline to follow-up, intervention participants significantly reduced their average grain products intake. As carbohydrates are foods that have the biggest effect on blood glucose levels, this dietary change positively reflected in their average FBG and OGTT serum concentrations, as those were also significantly reduced and were no longer in the prediabetes range.

In addition, although intervention participants did not significantly reduce their A1C, their average A1C by the end of the program were no longer in the prediabetes range. Attaining A1C levels within the normal limit minimizes the risk for developing microvascular complications and may also have a protective effect against cardiovascular diseases (CVD) [23]. Although these reductions are small, they are of clinical significance as it reversed certain participants' prediabetes diagnosis and it no longer classified them as having IGT (64%), IFG (52%), or an A1C in the prediabetes range (67%). Additionally, 12 participants (48%) were no

longer classified as having prediabetes based on all three diagnostic criteria (FBG, OGTT, and A1C) at the end of the program.

Intervention participants also significantly increased their average number of servings of vegetables and fruit intake based on CFG. The antioxidants found in this food group, such as vitamins A, D, and E, and selenium, alongside fiber, have been found to improve regulation of blood glucose [24]. These results have also been found in other studies who concluded that targeting barriers to healthy eating in vulnerable populations, such as rural adults, improves blood A1C levels, lipid profile, and help reduce excess body weight [25,26].

It is also important to note that their intake of the two remaining food groups, milk and alternatives and meat and alternatives, were maintained. As saturated fat increases LDL-C in the blood, which was significantly reduced from baseline to follow-up, such as healthy eating and physical activity, participants likely made healthy dietary substitutions in their diet when it came to those two food groups. Foods containing saturated fat include processed foods, fatty meats, full-fat milk products, and butter [27]. This positive dietary change likely had an impact on the average reduction of the participants' LDL-C concentrations.

These above mentioned healthy dietary lifestyle changes are reflected positively in the observed significant decrease in the intervention participants' BMI and WC. Weight loss is also particularly relevant in explaining their biochemical improvements [22]. Even a modest weight loss of 5%, through lifestyle interventions that target PA and diet, can reduce the risk of progression from IFG or IGT to T2D by 58% [28].

Overall, the intervention participants' reported intake was likely under-reported as the average of the CFG portions was below recommendations. Under-reporting of food intake is unfortunately an obstacle in getting accurate data, an issue encountered by other studies as well [29,30].

The promotion of PA was highlighted in the program, which encouraged 150 minutes of moderate to vigorous exercise weekly and 10 000 steps daily, as recommended by CSEP and PDHU [17,31,32]. Unfortunately, no significant improvement in terms of the average number of steps per day or minutes of PA per week was observed based on the 7-day PA step log from baseline to midpoint, endpoint, and follow-up. Although, more analysis on the step log must be conducted before drawing conclusions from these results. High variability in participants' step log responses and the misusage of the pedometer reduced its statistical power and made it difficult to detect significant differences throughout the program [33]. However, these tools assisted participants in self-monitoring.

Rural adults are a population that tends to become more sedentary with time. The inability to meet PA requirements is likely due to the poor built environment in rural cities and lack of access to exercise facilities and sidewalks [34]. The promotion of an active lifestyle can translate in significant positive health outcomes, such as improving the ratio of serum LDL-C to HDL-C and reducing BP, TG, and TC concentrations [35]. This is related to the fact that regular PA helps the body cells take up glucose and thus lower blood glucose concentrations and decrease insulin [35]. From baseline to follow-up, only LDL-C concentrations had significantly improved however it is also important to note that although HDL-C, TG, and TC did not meet

statistical significance, their improving trend can represent a clinical significance in the prevention of T2D and its related co-morbidities.

There was no significant difference when it came to evaluating BP as an hemodynamic marker at baseline and at follow-up. It is possible that those who had elevated BPs might have been on blood pressure medications, which could have been adjusted any time throughout the program.

Self-reported data, such as food records and the 7-day PA step log, represent a limitation of this study. In addition, the sample size is small and the participants were not randomly selected. Consequently, the results are specific to the sample population and may not reflect the general population of rural adults with prediabetes.

7.6. Conclusion

The results provided in this study revealed the positive effects of lifestyle changes of rural adults with prediabetes following a community-based lifestyle program targeting healthy eating and physical activity. The data were collected at baseline, midpoint, post-program, and to 6-months follow-up. The results of the program indicated a significant increase of the participants' mean self-reported number of daily servings of vegetables and fruit and a significant reduction in their mean daily intake of grain products from baseline to follow-up. Enrollment in the prediabetes education program also resulted in beneficial changes in their biochemical and anthropometric measurements, which included a significant reduction in their

average serum FBG, OGTT, and LDL-C concentrations, alongside a reduction in their average BMI and WC from baseline to follow-up. No significant improvement was observed in their BP, a hemodynamic marker, throughout the program. Additionally, based on the average serum FBG, OGTT, and A1C concentrations 6 months after the completion of the program, almost half of the participants were no longer considered in the prediabetes range.

Considering intervention participants were at high risk of developing T2D, this represents a major clinical significance in the reduction of T2D development. Engaging rural adults from Southwestern Ontario in a healthy lifestyle intervention program tailored to their specific needs may have contributed to significantly reducing key controllable risk factors for T2D. Moreover, further research is needed to evaluate approaches to increase PA engagement.

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Author Disclosure

The authors certify that they have no conflict of interest.

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Table 12: Baseline characteristics of program participants in the 6-monthly lifestyle intervention program for rural adults with prediabetes

Demographic and Anthropometric Characteristics	Intervention Participants (n=49)
Age, years, Mean ± SD	60.6 ± 8.1
Sex, % male	55.1
BMI, kg/m^2, Mean ± SD	33.1 ± 5.5
Normal (18.5-24.9 kg/m^2), %	6.3
Overweight (25.0-29.9 kg/m^2), %	25.0
Obesity (≥30.0 kg/m^2), %	68.8
Waist Circumference, cm, Mean ± SD	108.5 ± 12.9
Male at high health risk (WC≥ 94 cm), %	96.3
Female at high health risk (WC≥ 80 cm), %	95.5
Ethnicity, % Caucasian	98.0
Marital Status, % married/common- law	79.6
Highest Education Level	
≤ High school, %	46.9
University: Bachelor's degree, %	16.3
University: Post-graduate degree, %	6.1
Professional degree : MD, JD etc., %	4.1
Employment Status	
Employed, %	59.2
Retired, %	32.7
Unemployed, %	6.1
Annual Household Income	
Under $25,000, %	2.0
$25,000 - $49,999, %	26.5
$50,000 - $74,999, %	22.4
$75,000 - $99,999, %	30.6
$100,000 - $124,999, %	2.0
$125,000 – 149,999, %	8.2
$150,000 or more, %	2.0
Prefer not to say, %	2.0
Not answered, %	4.1

*SD: Standard deviation. N = number of participants. WC = waist circumference (20). BMI = Body Mass Index (21). MD = Doctor of Medicine.

Table 13:
Mean values of primary outcomes at baseline, midpoint, endpoint, and at 6-month follow-up after participating in the prediabetes intervention program for rural adults

Outcome variable	N	Baseline	Mid-point	Endpoint	Follow-up	P value
CFG Portions						
Vegetables and Fruit, servings/day (SD)	41	3.5 (0.3)	5.3 (0.3)	5.0 (0.3)	5.7 (0.3)	**<0.001**
Grain Products, servings/day (SD)	41	4.5 (0.3)	4.1 (0.3)	3.5 (0.3)	3.3 (0.4)	**0.02**
Milk and Alternatives, servings/day (SD)	41	1.5 (0.2)	1.4 (0.2)	1.1 (0.2)	1.1 (0.2)	0.5
Meat and Alternatives, servings/day (SD)	41	0.9 (0.1)	0.9 (0.1)	1.0 (0.1)	0.9 (0.1)	0.5
Physical Activity						
Average Steps per Day, steps/day (SD)	37	13 050 (1 450)	14 290 (1 656)	14 176 (1 521)	9 150 (2 373)	0.2
Minutes per week spent exercising, minutes/week (SD)	37	91 (13)	111 (15)	103 (15)	85 (21)	0.3
Biochemical Markers						
FBG, mmol/L (SD)	41	6.2 (0.1)	N/A	5.9 (0.1)	5.7 (0.1)	**0.003**
A1C, % (SD)	41	6.0 (0.5)	N/A	5.9 (0.6)	5.9 (0.6)	0.2
OGTT, mmol/L	41	8.0 (0.4)	N/A	7.8 (0.5)	6.4 (0.6)	**0.01**
TC, mmol/L (SD)	41	3.8 (0.2)	N/A	3.5 (0.2)	3.6 (0.2)	0.1
LDL-C, mmol/L (SD)	41	2.9 (0.2)	N/A	2.6 (0.2)	2.6 (0.2)	**0.05**
HDL-C, mmol/L (SD)	41	1.4 (0.05)	N/A	1.4 (0.05)	1.5 (0.05)	0.3
TG, mmol/L (SD)	41	1.9 (0.1)	N/A	1.7 (0.1)	1.7 (0.1)	0.1
Anthropometric Markers						
BMI, kg/m^2 (SD)	41	32.1 (0.7)	31.7 (0.7)	31.7 (0.7)	31.9 (0.8)	**0.04**
WC, cm (SD)	41	106.6 (1.4)	105.4 (1.4)	103.9 (1.4)	103.9 (1.6)	**0.004**
Hemodynamic Markers						
Systolic blood pressure, mmHg (SD)	41	133.5 (2.5)	129.6 (2.9)	127.2 (2.7)	134.3 (4.3)	0.2
Diastolic blood pressure, mmHg (SD)	41	78.8 (1.4)	77.5 (1.6)	76.3 (1.5)	79.2 (2.4)	0.5

SD: Standard deviation. N = number of participants. FBG: Fasting blood glucose. OGTT: Oral glucose tolerance test. A1C: Glycated Hemoglobin. LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol. TC = Total cholesterol. TG = Triglycerides. WC = waist circumference. BMI = Body Mass Index. mmol/L: millimoles per litre

CHAPTER 8: Evaluating the practicality, feasibility and acceptability of a prediabetes intervention program designed for rural adults

This article is the third secondary objective of the thesis, evaluating the practicality, feasibility, and acceptability of the program. It is written in the format of the Canadian Journal of Dietetic Practice and Research. The authors are Jayson Azzi BSc, Sarita Azzi RD, Adrienne Vermeer RD, Mathilde Lavigne-Robichaud RD, MSc, Teresa Barresi RN MSc, Sean Blaine MD, and Isabelle Giroux RD PhD.

Evaluating the practicality, feasibility and acceptability of a prediabetes intervention program designed for rural adults

8.1. Abstract

Purpose: The type 2 diabetes epidemic is a global crisis threatening the health and economies of many nations. This study aimed to determine if a prediabetes intervention program designed for South-Western Ontario rural adults was perceived as acceptable, feasible and practical by participants.

Methods: Rural adults with prediabetes were referred to the intervention program by their physician. At the end of the 6 monthly education sessions, participants were given a program feedback questionnaire. In addition, 6 focus groups consisting of 5-9 participants were conducted to assess acceptability, feasibility and practicality of the program.

Results: Thirty-five participants aged 60.8±7.1 (mean±standard deviation) evaluated the program. Participants reported finding the program to be acceptable, feasible and practical due to the interactive nature of the sessions (100%), the group setting (97.1%) and the availability of health professionals (97.1%).

Conclusion: This prediabetes lifestyle intervention program designed for rural adults was perceived as acceptable, feasible and practical by most participants. Feedback received will help improve this program through additional emphasis on peer support and key messages.

8.2. Introduction

Type 2 diabetes in Canada

Type 2 diabetes (T2D) is rapidly on the rise to threaten the health and economy of many nations [1]. The situation in Canada is no exception with the yearly economic burden estimated to surpass $16.9 billion by 2020 [2,3]. Sedentary lifestyles, unhealthy diets, as well as increasing obesity rates have been identified as contributing factors [1]. In 2011, 51.9% of the Canadian population had obesity or was overweight and this number is expected to rise to 55.4% by 2019 [4]. Prediabetes, which affects roughly 7.5 million Canadians, refers to a state of impaired fasting glucose, impaired glucose tolerance or elevated glycated hemoglobin, significantly increasing the risk of developing T2D by five to ten times [5–7].

Lifestyle Interventions

Successful T2D prevention and self-management programs addressing physical inactivity, unhealthy eating patterns and obesity management have been shown to help reduce T2D risks [8,9]. In addition, meta-analyses have demonstrated the clinical pertinence of self-management education [10–16]. Despite the conclusiveness of these results, only a handful of Canadian community-based long-term lifestyle intervention programs have been designed to help rural individuals at high risk for developing T2D [17,18].

The lifestyle intervention program offered through the STAR Family Health Team (FHT) to rural adults with a diagnosis of prediabetes aimed to address health disparities and gaps in services for this high-risk population by building a program that would help delay or prevent the onset of T2D. The program was built on evidence that for an individual to successfully integrate

long-term lifestyle changes, adequate and ongoing interdisciplinary interventions are essential [19–22].

The group-based monthly education sessions at the STAR FHT were led by an interdisciplinary team composed of a Registered Dietitian (RD) and a Registered Nurse (RN). Participants were invited to a baseline session (visit 1) followed by 6 monthly educational sessions (visits 2-7) and one post-intervention and data collection session (visit 8) the following month.

Each 120-minute session consisted of nutritional education, social interactions, PA and active lifestyle education followed by food demonstrations and sharing of a healthy snack. At the end of each session, participants were invited to set personal SMART goals and complete a feedback questionnaire. Anthropometric values were taken at every session. Participants were also invited to complete a 7-day step log and a 3-day food intake record prior to every educational session. A pedometer was provided to participants as a self-monitoring tool. Individualized nutrition counseling was provided by the RD to participants at every session. Each participant could invite a significant other to participate in sessions for support.

Patient-Centered Program Evaluation

Program evaluations are essential for ongoing program monitoring, development or modifications. They document program quality outcome measures and the efficacy of the program to justify the need for resources [23]. Furthermore, systematic evaluation of lifestyle intervention programs is needed to ensure their practicality, feasibility and acceptability from the

perspective of clients they serve in order to ensure quality patient-centered care [24]. As per the precede-proceed program evaluation framework, the success of an intervention program relies on the identification of health problems, behavioral and environmental risk factors, factors affecting behavior and resources in terms of policy and organizations [25].

Objective

The objective was to determine if the STAR FHT prediabetes lifestyle intervention program tailored to the needs of adults living in a rural area is effectively meeting the needs of participants in terms of acceptability, practicality and feasibility.

8.3. Methods

Patient recruitment and ethics approval

Rural adults aged 18 and older with a diagnosis of prediabetes from Tavistock and Stratford in Southwestern Ontario were referred by their physician to the STAR FHT lifestyle intervention program. Individuals with a diagnosis of mental illness such as major depression, eating disorder or schizophrenia, were offered other individualized care. Other exclusion criteria included being pregnant or lactating, having T1D or T2D and having a digestive disease thereby requiring other individualized services from the STAR FHT. A total of 49 rural adults aged 60.6±8.1 completed the intervention program, of which 35 provided feedback at program completion for program evaluation purpose. Written and informed consent was obtained from study participants. This project was approved by the University of Ottawa and the Public Health Agency of Canada Research Ethics Boards.

Program evaluation

Program evaluation was based on the Precede-Proceed model [25]. It included a program feedback form and a focus group discussion for the participants (n=35) who attended the post-intervention session and data collection (visit 8). The program feedback forms were filled out confidentially and included open and close ended questions, multiple choice questions and Likert scale questions. Focus group discussions were led by an independent moderator who was not involved with the intervention program to minimize bias and ensure honest and open dialogue. A set of semi-structured questions were asked by the moderator to commence discussions and help evaluate and receive insight on the participants' perspectives on the feasibility, acceptability and practicality of the program (Table 1). Feasibility was also assessed by evaluating the logistics of the program, which was tailored to meet the learning needs of rural adults with prediabetes. In total, 6 focus groups comprised of 5 to 9 participants were conducted and each lasted approximately 1hour.

Data Analysis

Participant answers to questions in the feedback questionnaire were compiled by trained research assistants in EpiData™ (v 3.1, The EpiData Association, Odense, Danemark, 2003). Data entry procedure involved a double entry process to check data entered and reduce possible information bias and errors. Focus groups discussions were recorded and transcribed verbatim by a Registered Nurse. No names were included to ensure confidentiality. Transcripts were then analyzed and coded with the software NVivo (v 11.2.2, The QSR International's NVivo, London & Los Angeles, Version 11, 2015). Deductive (i.e. predetermined) and inductive (i.e. based on participants' feedback) coding was used. Two trained research assistants read the transcripts

separately, discussed recurring themes and subthemes as well as their how to group them (Table 2) to standardize the coding of transcripts. These major topics and associated subthemes were then reviewed and approved by the senior researcher. The research assistants then independently read and coded the transcripts before comparing codes and discussing discrepancies. The coding agreement was 70%. When no agreement on a discrepancy was reached, the senior researcher was involved to reach a consensus. The list of themes and sub-themes was updated during the process of analyzing the transcripts to clearly identify major emerging themes [26]. Several quotes from the focus groups were then used to support and illustrate major emerging themes. Participants' language was preserved to best reflect what they wanted to say [27].

8.4. Results

The thirty-five participants (21 men, 14 women) who provided program feedback by completing the questionnaire and participating in the focus groups were Caucasian (100%) aged 60.8±7.1 and attended on average 6.2±1.3 of 8 program sessions (Table 3). Nearly half the participants had a high school education or less (46.2%) and were retired or unemployed (42.9%). At baseline, twenty-eight (80%) participants presented with abdominal obesity based on the interpretation of waist circumference [28]. Twenty-five (71.4%) participants were obese and 7 (20.0%) overweight.

Practicality

When asked if they thought information provided in the educational sessions was useful, all participants agreed that it was.

"…Don't see how program could be any more effective."

Both the nutrition and physical activity (PA) components of the program was reported as being practical, useful and helpful. Participants expressed confidence in making lifestyle changes due to the newly acquired active living and nutrition skills.

"…both information on diet and exercise have helped – now got us into a routine we can stick with."

Both the nutrition and PA education session components were perceived as helpful based on focus group discussions with 91.4% and 74.3% reporting benefiting from nutrition and PA education, respectively. When asked, 85.7% of participants agreed that the nutrition component enhanced their food-related skills and applicable knowledge on healthy eating. Often mentioned were healthy fats, sodium content, serving sizes, healthy alternate foods to enjoy, Canada's Food Guide and label reading.

"[The most significant is]… how to read labels – all the good stuff and bad stuff - found that to be helpful – because sometimes you don't know."

Based on the program feedback questionnaire, 82.9% and 71.4 % said they found the food intake and PA records respectively useful for keeping them on track with their healthy lifestyle goals.

"…with having to write down everything, it makes you realize 'did I actually eat all that today?' – which helps to point out what is wrong and what is right that you are doing."

When discussing the PA component, most participants enjoyed learning about the importance of exercise and the different options available in their community.

"…it was pretty thrilling to know there are things out there that I didn't even know about practically at the end of my street. […] made me aware of inexpensive services I could use…"

Feasibility

When participants were asked if they have been able to make positive changes to their diet during the program, 89% responded yes.

"... Magnets on the fridge of the plate size I am allowed. I really like it, very helpful. Was a constant reminder to my portion sizes."

When asked, 85.7% participants agreed that they would continue to set a healthy eating goal to stay on track in the future. Sixty percent reported the same concerning PA goals.

"[For me the most significant change is to ...] Learn to become accountable; learn to pay attention – because I had to write it down."

Also, 91.4% felt confident that they could continue implementing many of the eating strategies they had acquired during the program. While discussing difficulty of PA exercises, few found it to be a little too difficult with 97% of participants agreeing that the interactive PA sessions were easy to follow since they could choose their level of difficulty.

"... Had an opportunity with the activities to take from it what works for you."

As a result, some participants were easily able to tailor PA to their lifestyles.

"...I now do the Nordic pole walking every morning for a ½ hr [...] so I didn't have to change up my routine to make a difference."

Acceptability

More than 90% of the participants surveyed said they would recommend this program to a friend or family member. When asked which part of the program they enjoyed most, both PA and nutrition education were mentioned numerous times.

"…I think the big thing for me is physical activity – I feel so good! My weight hasn't changed –but I feel so much better with myself - I love yoga and I can do things that I couldn't do before."

Participants also reported on the value of the knowledge they have gained due to the program.

"I have already shared what I have learned with friends and family."

However, when asked which part of the program was the most strenuous, participants seemed to least enjoy the amount of paperwork due to questionnaire fatigue. Despite this, 77.1% of participants said yes when asked if they would be interested in receiving long-term follow-up.

Social support

Another common theme identified during the focus group discussions was the benefits of peer support. Of surveyed participants, all agreed when asked if they enjoyed the group nature of the program. Often mentioned was appreciation for the support offered by the group of participants and staff.

"…the peer support has been really key for me"

"… great to have both, support of the program staff and then everyone in this group work as a team to make changes."

Others mentioned the opportunity and convenience of being able to invite their spouse along to participate in the program.

"…good to have the person who does the cooking included in the discussion - it makes a big difference to be both on the same page, this helps to change diet in the home."

Some even expanded on the advantages of being able to motivate each other during the PA sessions.

"Even the exercise – I didn't feel like a failure- we cheered each other on, and supported each other... and you participated with others that were like you, so it was okay."

8.5. Discussion

Our research hypothesis was that the STAR FHT lifestyle intervention program for individuals with prediabetes would be considered acceptable, practical and feasible by participants as it was tailored to the needs of rural adults from Stratford and Tavistock. Indeed, this was the case (Table 4).

Acceptability of the self-management education received by participants was assessed with focus group discussions and a feedback questionnaire and showed evidence of participant appreciation, enjoyment, willingness to recommend the program, desire for longer term follow-up and ability to make positive lifestyle changes.

Feasibility was demonstrated by participants' ability to find and apply lifestyle strategies with the help of SMART goals beyond the duration of the program, managing difficulties and challenges encountered. The program was assessed to be feasible due to its high attendance rate (6.1±1.3 of 8 sessions), which was well planned to meet learning needs. Based on our results, rural adults want to continue to apply what they have learned from this tailored intervention to help reduce their risk of T2D, which resulted in the program being continuously offered to this day.

Practicality was assessed as participants' report on usefulness and convenience of the program. Participants expressed clear interest in participating in a lifestyle change intervention, particularly in nutritional and physical education. From feedback provided, the program helped rural adults address several barriers to healthy living such as lack of resources, education and motivation, while building on enablers and increasing their motivation to self-manage their prediabetes with the support of healthcare professionals, significant others and peers.

While the interactive nature of the PA component was very much appreciated by some participants, some barriers were identified such as lack of self-management skills and confidence. However, many community resources and exercises of varying difficulties were introduced to accommodate everyone. As also seen in other studies, barriers to PA include the lack of time and energy [29]. However, pedometers and goal-setting, have been shown to increase motivation [30–32]. These components were included in the intervention program to increase feasibility.

Parallel to what was described by Genkinger et al, who performed a meta-analysis of 18 randomized trials on the importance of positive and collaborative relations between patient and healthcare professionals, the support of the staff at the STAR FHT was reported as a major contribution to the acceptability of the lifestyle intervention program [12]. Such support can have a significant impact on the participant by acting as a source of motivation and encouragement while improving healthy lifestyle self-management skills. Studies have also observed a positive correlation between recurrent communication and adherence to treatment or success in reducing T2D related risks [33,34]. Similarly, participants reported on the importance of frequent

communication and open dialogue with the healthcare professionals from the STAR FHT lifestyle intervention program.

Participants were also encouraged to attend the lifestyle intervention program with significant others, which contributed to the acceptability of the program. Several studies have illustrated the importance of family and social support in self-management behaviors [33,35]. This particularity of the program was identified as being a key facilitator in making healthy lifestyle changes by participants, especially when the significant other was the one responsible for cooking and groceries. The group nature of the lifestyle intervention program was also very much appreciated by participants as peers tend to provide a source of motivation and encouragement to better complete the task at hand [36]. Additionally, in a rural community setting, a group approach to a lifestyle intervention program may increase perception of social support and further facilitate lifestyle changes [37]. By inviting community partners to support and present resources at group meetings, community support and awareness were also reinforced.

Limitations and strengths of the study

Discussions from the focus groups and data from the program feedback questionnaire indicated a high level of acceptability, feasibility and practicality. The high rate of program attendance and the fact that two-thirds of participants (71%) partook in focus groups discussions also represents a strength. The 35 participants who agreed to attend the focus group discussions most likely represented the most highly motivated participants and doesn't take into account those who didn't regularly attend the program, representing a potential bias [38]. Going forward,

this bias could be circumvented by mailing a program feedback form to those who did not attend the focus group discussions.

Males are often less represented in lifestyle intervention programs and therefore their feedback is lacking [39]. They have been reported to be less in touch with health services to help manage their chronic conditions [10]. Thus, the high recruitment rate and participation level of men represents a strength. Despite this, our results indicated no difference in acceptability, practicality and feasibility between men and women (data not shown).

The intervention was strengthened by the combination of personalized intervention by team staff and group-based monthly interventions. The group-based approach has been reported to improve cost-effectiveness and increase accessibility to care [40,41].

8.6. Conclusions

More intervention programs addressing important healthy lifestyle knowledge and self-management skills gaps are necessary in rural areas. Such group programs should be tailored to rural adults needs, combining interactive nutritional education with a variety of PA and resources accessible to them. Social support, such as group-based intervention, community partnerships and family support was also reported as being a key component of the program.

Relevance to practice

The results of this patient-centered program evaluation showed that the STAR FHT group-based approach with a focus on healthy lifestyle tailored for rural adults with prediabetes was viewed as acceptable, feasible and practical by participants using program evaluation. Through rigorous program evaluation and feedback acquisition, the committed interdisciplinary team of health care professionals and researchers managed to develop and implement a satisfactory lifestyle intervention program adapted to the needs of rural adults with prediabetes. Evaluating this intervention program with a client-centered approach and systematic mixed-methods' approach provided a confirmation of its quality. The program has stood the test of time as it continues to offer quality education to participants in Stratford and Tavistock through the STAR FHT.

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

8.7. References

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Table 14: Open-ended questions from the Program feedback questionnaire and the focus group discussion guide

Program feedback questionnaire questions	What I liked most about my experience with the prediabetes education program was: What I liked least about my experience with the prediabetes education program was: Do you have any other thoughts or comments about the program or your experiences at the program?
Focus group	Before beginning the prediabetes education program, did you have any expectations about the program? Did we meet, exceed or fall short of these expectations? What parts of the program did you enjoy the most and why? What parts of the program did you enjoy the least and why? Did you find the information provided in the educational sessions useful? Why or why not? (Prompt: Did you learn anything new that you could use?) What would you say is the most significant change you have made to your lifestyle due to participating in the prediabetes education program? Would you recommend this program to a friend or family member? Why or why not?

Table 15: Major themes and key words/topics emerging from the focus group discussions

Major themes	Associated key words/topics
Practical	Useful, integrated, put in practice, usable, helpful, effect, at home, convenient, etc.
Feasible	Do, did, doable, real life, everyday life, easy, hard, difficult, strenuous, reference to a structure, infrastructure, community partner or resources indicating feasibility, attended, etc.
Acceptable	Appreciated, pertinent, enjoy, liked, great, good, improved, etc.
Nutrition	Education (learnt about healthy eating, label reading, food choices, Canada's Food Guide, etc.), barriers to healthy eating, facilitators to healthy eating, changes (new foods, new habits, developed skills, etc.), nutritional component of program, etc.
Physical activity	Education (learnt about new physical activities, community resources, etc.), barriers to an active lifestyle/PA, facilitators to an active lifestyle/PA, changes (new or more PA), PA component of program, etc.
Support	Staff, team members, dietitian, spouse, family, group nature, peer support, social support

Table 16: Characteristics of lifestyle intervention program participants (n=35)

	Baseline characteristics
Age, years, Mean (SD)	60.8 (7.1)
Male, n (%)	21 (60)
Caucasian, n (%)	35 (100)
Current highest level of education	
Elementary, n (%)	4 (10.3)
High school, n (%)	14 (35.9)
Vocational/technical school, n (%)	3 (7.7)
College, n (%)	4 (10.3)
University, bachelors, n (%)	8 (20.5)
University, Post-graduate, n (%)	2 (5.1)
Current marital status	
Single, n (%)	2 (5.7)
Married, n (%)	28 (80)
Common law, n (%)	2 (5.7)
Separated, n (%)	1 (2.9)
Divorced, n (%)	2 (5.7)
Current employment status	
Employed full-time, n (%)	15 (42.9)
Employed part-time, n (%)	5 (14.3)
Retired, n (%)	13 (37.1)
Unemployed by choice, n (%)	2 (5.7)
Current household income	
$25,000 - $49,999, n (%)	11 (30.6)
$50,000 - $74,999, n (%)	7 (19.4)
$75,000 - $99,999, n (%)	12 (33.3)
$125,000 - $149,999, n (%)	3 (8.3)
$150,000 or more, n (%)	1 (2.8)
Body Weight, kg, Mean (SD)	
Men (n=21)	99.0 (14.3)
Women (n=14)	89.6 (20.2)
BMI, kg/m^2, Mean (SD)	
Men (n=21)	32.4 (4.5)
Women (n=14)	35.0 (7.9)
Waist circumference, cm, Mean (SD)	
Men (n=21)	112.8 (10.4)
Women (n=14)	105.4 (16.9)

*SD: Standard deviation, n = number of participants, BMI = Body Mass Index,

Additional table: Table 17: Post-intervention program feedback from the prediabetes lifestyle intervention education program participants (n=35)*

Program feedback (% of participants)	Disagree ξ	Neither agree nor disagree	Agree ψ	Not answered
"I would recommend this program to a friend or family member."	5.7 [n=2]	2.9 [n=1]	**91.4 [n=32]**	0.0 [n=0]
"I valued having a health professional available"	0.0 [n=0]	2.9 [n=1]	**97.1 [n=34]**	0.0 [n=0]
"I enjoyed the interactive nature of the sessions"	0.0 [n=0]	0.0 [n=0]	**100 [n=35]**	0.0 [n=0]
"I enjoyed the group nature of the program."	2.9 [n=1]	0.0 [n=0]	**97.1 [n=34]**	0.0 [n=0]
Nutritional Component				
"I benefited from the nutrition sessions"	2.9 [n=1]	0.0 [n=0]	**91.4 [n=32]**	5.7 [n=2]
"I found the nutrition sessions practical"	0.0 [n=0]	5.7 [n=2]	**91.4 [n=32]**	2.9 [n=1]
"I took away some practical ideas from the food demonstrations"	5.7 [n=2]	17.1 [n=6]	**68.6 [n=24]**	8.6 [n=3]
"I feel confident that I can continue to implement many of the eating strategies I have learned as part of the prediabetes program"	0.0 [n=0]	5.7 [n=2]	**91.4 [n=32]**	2.9 [n=1]
Physical Activity Component				
*"I **benefited** from the PA sessions"*	0.0 [n=0]	22.9 [n=8]	**74.3 [n=26]**	2.9 [n=1]
"I found the interactive PA sessions easy to follow"	0.0 [n=0]	2.9 [n=1]	**97.1 [n=34]**	0.0 [n=0]
"I found the interactive PA sessions useful"	2.9 [n=1]	2.9 [n=1]	**94.3 [n=33]**	0.0 [n=0]
Goal setting				
"I will continue to set healthy eating goals to keep me on track in the future."	2.9 [n=1]	8.6 [n=3]	**85.7 [n=30]**	2.9 [n=1]
"I found the food records useful for keeping me on track with my healthy eating goals"	2.9 [n=1]	8.6 [n=3]	**82.9 [n=29]**	5.7 [n=2]
"I found the PA and step log useful for keeping me on track with my PA goals"	5.7 [n=2]	22.9 [n=8]	**71.4 [n=25]**	0.0 [n=0]
	Too much	Just right	Not enough	Not answered
"I found the amount of information provided at each session to be"	5.7 [n=2]	**85.7 [n=30]**	5.7 [n=2]	2.9 [n=1]

*Self-reported data from the feedback questionnaire. PA: Physical activity. ξ Participants who answered "Strongly disagree" and "disagree" were considered in this column ψ Participants who answered "Strongly agree" and "agree" were considered in this column

CHAPTER 9: General Discussion and Conclusion

This chapter concludes the thesis by stating the key findings, the interpretation, the limitations and strength of the program, the implication for policy makers and for health professionals, the direction for future research, and the general conclusion.

9.1. Key Findings

9.1.1. Characteristics of Participants (chapter 5)

Baseline Characteristics:

The 6-month intervention program was tailored for rural adults from Stratford and Tavistock in Southwestern Ontario with a diagnosis of prediabetes at the STAR FHT. Forty-nine intervention participants and 34 control participants took part in the program. They were between 44 and 79 years old (61.5±9.1) (mean±SD) and over half (54%) were men. The mean BMI was 32.9±5.5kg/m^2, and only 6% of participants were in the normal BMI range. Most participants were Caucasian (98%, n=81) and married or in a common-law union (82%, n=69). Education levels varied, with nearly half (48%, n=40) of participants having a high school degree diploma or less. More than half were employed (57%, n=47) and almost a third were retired (37%, n=31).

Characteristics of Intervention vs Control Participants:

When comparing the anthropometric and demographic characteristics of the control group (n=34) vs the 6-month lifestyle intervention participants (n=49), no significant difference between the two groups was found for average BMI, WC, body weight history or weight satisfaction. Sixty-seven percent (n=33) intervention participants and 29% (n=10) reported more than one co-morbidity (p=0.008). Intervention participants also had a significantly higher income than control participants (p<0.001).

No differences were observed in terms of average daily energy, macro, and micro-nutrients intake at baseline. Control participants reported consuming more average daily CFG

servings of vegetables and fruit (p=0.02). No significant differences were noted between the two groups in terms of time reported doing vigorous and moderate physical activity as well as time spent walking daily.

9.1.2. Awareness and Knowledge about T2D (chapter 4)

Awareness:

Unlike control participants, intervention participants significantly increased their perception of their risk of developing T2D from baseline to post-program (p=0.04). The perception of seriousness of the complications of T2D remained high for intervention participants from baseline to post-program, whereas it increased for control participants (p=0.008). Lastly, when it comes to awareness, the participants' perception of the likelihood of preventing or delaying T2D remained unchanged by staying elevated throughout the program by both groups.

Knowledge:

On average, intervention participants significantly increased their knowledge when it came to broad recommendations associated with a healthy lifestyle from baseline to post-program, while those remained unchanged for control participants (p<0.001). On the other hand, regarding more specific knowledge piece about recommendations related to nutrition and PA, there was no increase from baseline to post-program for both groups. Intervention participants learned to set personal lifestyle goals and their average confidence level in achieving them was

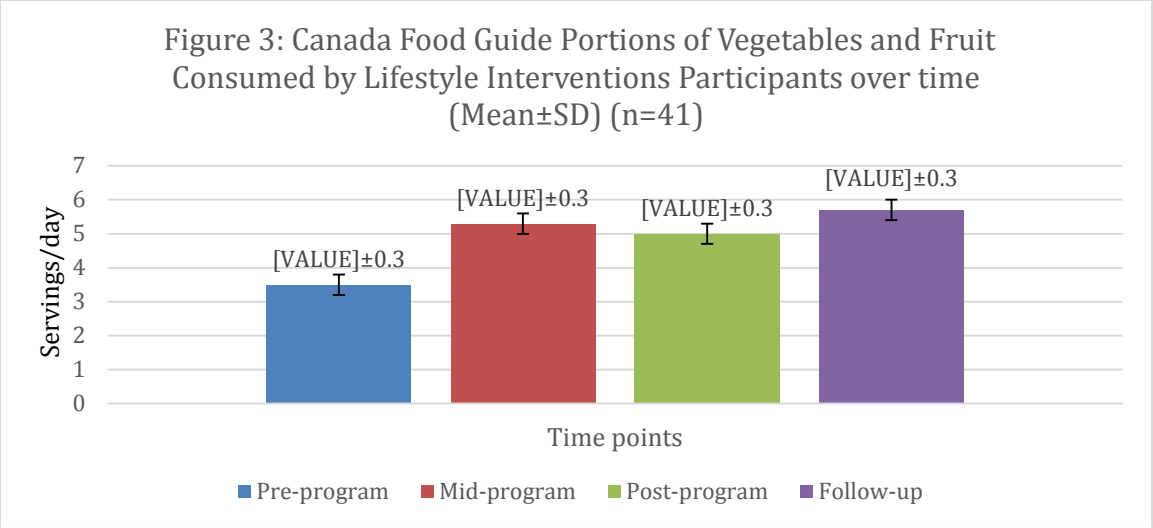
about 7 out of 10. Regarding PA, intervention participants reported an increase in their perceived time spent doing PA from baseline to post-program ($p<0.05$).

9.1.3. Self-efficacy, Behaviours, and Markers of T2D (chapters 4, 5, and 6)

Nutrition:

Significant reduction of the average daily energy intake of intervention program participants was observed from pre- to post-program ($p=0.02$). Although the same was observed for the control participants ($p=0.02$), it is only in the intervention participants' food records that an important improvement in dietary intake patterns was also observed. Indeed, contrary to control participants, intervention program participants managed to reduce their average daily intake of carbohydrates ($p=0.01$), total sugars ($p=0.003$), sodium ($p=0.002$), and fat intake ($p=0.03$), as well as increase their phosphorus ($p=0.04$) and energy from protein intake ($p<0.001$).

When their food intake records were analysed in terms of CFG servings, the intervention participants significantly reduced their average intake of grain products servings from pre- to post-program ($p=0.02$). Program participants also significantly increased their number of servings of daily vegetables and fruit intake based on CFG ($p<0.001$). It is also important to note that their intake of daily servings from the two remaining food groups, milk and alternatives and meat alternatives, were maintained.



Physical Activity:

When it came to PA, intervention participants reported an increase in their average daily time spent walking and in their reported time spent doing moderate PA from baseline to post-program through the IPAQ questionnaire ($p<0.05$). However, no significant improvement in terms of the average number of steps per day or minutes of PA per week was observed based on the 7-day PA step log from baseline to program follow-up.

Anthropometric Markers:

From pre- to post-program, BMI ($p=0.04$) and WC ($p=0.004$) were statistically decreased for the invention participants.

Biochemical Markers:

The intervention participants, on average, succeeded at significantly reducing their FBG ($p=0.003$), OGTT ($p=0.01$), and LDL-C ($p=0.05$) serum concentrations from pre- to post-

program. There was no statistical difference over time when it came to evaluating other biochemical markers such as A1C, TC, TG, and HDL-C.

9.1.4. Program Evaluation (chapter 7)

Acceptability:

More than 90% of the participants surveyed said they would recommend this program to a friend or family member. Both PA and nutrition were mentioned numerous times when asked what parts of the program they enjoyed most. Participants also reported on the value of the knowledge they have gained due to their participation in the program and 77% of participants said they would be interested in receiving long-term follow-up. All participants also indicated that they enjoyed the group nature of the program and the support offered by their spouse, group of participants, and staff involved in the intervention program.

Practicality*:*

Most participants reported that the delivery of the nutrition (91%) and physical activity (74%) components of the program was practical, useful, and helpful. Eighty-five percent of participants agreed that the nutrition component of the prediabetes education had enhanced their food-related skills. Based on the program feedback questionnaire, most participants found that the food intake records (83%) and PA logs (71%) were useful for keeping them on track with their healthy lifestyle goals.

Feasibility:

Ninety-four percent of the participants found the information provided during the nutrition sessions easy to understand and 8 out of 10 participants agreed that they would continue to set a healthy eating goal to stay on track in the future. Sixty percent reported the same concerning PA goals. Also, 91% felt confident that they could continue implementing many of the eating strategies they had acquired during the program and 97% of participants agreed that the interactive PA sessions were easy to follow since they could choose their level of difficulty and tailor it to their lifestyle.

9.2. Interpretation of Findings

Knowledge translation is central and a research priority. Proper management of prediabetes and the prevention of T2D requires individuals to be aware of the nature of the disease, its risk factors, treatment, and complications [24]. The DPP study demonstrated that lifestyle intervention is an effective way to reduce the risk of T2D in adults with prediabetes [58]. However, translating these findings in a community setting and targeting individuals at high risk of developing T2D, such as rural adults, was the subsequent challenge. There is very limited information and research about the health and lifestyle behaviours of rural adults with prediabetes and little is known about their specific health education needs. For that reason, a community-based program at the STAR FHT in Stratford and Tavistock was developed and included T2D screening, recruitment of rural adults with prediabetes, implementation of group-based classes broken down into six educational sessions focusing on nutrition and physical

activity with behavioural change strategies, and a 6-month follow up to evaluate the overall long-term impact of the program in reducing key controllable T2D risk factors.

Those who participated in the program had multiple risk factors putting them at high risk of developing T2D, which were consistent with the current literature on the disease burden specific to Canadian rural areas [114]. They were older, sedentary, and had BMI and WC values above recommendations. When it came to comparing the intervention and control groups, only marginal differences in dietary intake, physical activity, and anthropometric indicators were noticed. However, those who decided to participate in the lifestyle intervention program reported having more comorbidities than control participants, a higher average household income, and a lower average of vegetables and fruit intake at baseline.

The **primary objective** of this project was to determine if community-based healthy lifestyle education would result in increased participant awareness, knowledge, self-efficacy, and behaviours toward making positive lifestyle changes known to decrease the risk of developing T2D. Behavioural strategies, like those emphasized in the SCT, have been identified to promote long-term weight loss and compliance, unlike dietary interventions alone [93,115]. Long-term improvement of certain T2D modifiable risk factors were achieved by the intervention participants from baseline to post-program, unlike their control counterparts. Similar studies also found that the beneficial effect of lifestyle interventions appears to persist for years after the end of the study [71,116–119]. An observational study, the Diabetes Prevention Program Outcomes (DPPOS), reported that the benefit of the lifestyle intervention persisted over 10 years [71,119]. As for the STAR FHT healthy lifestyle intervention program, further improvements in

knowledge retention and self-efficacy to maximize long-term benefits could be accomplished by simplifying recommendations and providing additional resources to further increase rural adults with prediabetes' ability to apply the learning into their daily life and routine.

The **secondary objectives** of the program looked at the data at baseline, midpoint, post-program, and at 6-months follow up, spanning over a timeline of 1 year. Throughout the program, participants were educated on healthy eating based on the CFG, which promotes eating a variety of foods from all four food groups to meet nutrient requirements. This approach allows flexibility and personal preference in dietary choices and may improve long-term adherence [120]. An improvement in dietary intake patterns suggesting that healthier food choices were made was only observed in intervention participants. Intervention participants also significantly reduced their average daily intake of grain products servings and increase their average consumption of vegetables and fruit servings. Similarly, these results have also been found in other studies who concluded that targeting barriers to healthy eating in vulnerable populations, such as rural adults, can help improve blood A1C levels, lipid profile, as well as assist in reducing excessive body weight [121,122].

The promotion of PA was also highlighted throughout the program, which encouraged 150 minutes of moderate to vigorous exercise weekly and 10 000 steps daily, as recommended by CSEP and PDHU [123–125]. The benefit of exercise in preventing T2D has been demonstrated in several studies [58,73,126]. Intervention participants reported an increase in their time spent walking and in their reported time spent doing moderate PA from baseline to post-program through the IPAQ questionnaire. Unfortunately, no significant improvement in

terms of the average number of steps per day or minutes of PA per week was observed based on the 7-day PA step log from baseline to follow-up. However, this finding may not be surprising given the characteristics of the rural adults who participated in the program, which were older, had a higher BMI, and a higher WC than the general population [114]. Further analysis of the step logs is needed in the future as there were variability in participants' responses throughout the program and possible misusage of the pedometer may have reduced its usefulness as an assessment tool. Nevertheless, it helped by motivating participants to do physical activity and increased self-monitoring, a key skill to lean to manage prediabetes, by tracking their steps [127].

Enrollment in the prediabetes intervention program also resulted in beneficial changes in their biochemical and anthropometric measurements, which includes a significant reduction in their FBG, OGTT, and LDL-C concentrations, alongside a reduction in their BMI and WC. Additionally, based on the average FBG, OGTT, and A1C at follow up, almost half of the participants were no longer considered in the prediabetes range, having IGT, or IGF. Similar results have also been found in meta-analyses of trials looking at lifestyle interventions aimed at weight loss and increasing activity levels [127–129].

As for program evaluation, the results showed that the STAR FHT group-based approach with a focus on healthy lifestyle was viewed as practical, feasible, and acceptable by participants (n=35) who completed the program and partook in focus group discussions. Other studies have observed a positive correlation between recurrent communication and adherence to the treatment or success of a program in reducing T2D related risks [130]. The lifestyle intervention program

had six monthly education visits and the continuous support emerged as a strength in the focus groups discussions. Furthermore, the intervention program has been appreciated by its participants and has stood the test of time as it continues to offer quality education to participants in Stratford and Tavistock through the STAR FHT.

Overall, the STAR FHT prediabetes intervention program was aimed to promote positive lifestyle changes, such as healthy eating and PA, by increasing knowledge, awareness, self-efficacy, and behaviours to allow the participants to learn and apply this education. As outlined in the SCT framework, intervention participants perceived less barriers when it came to making these lifestyle changes and were able to set realistic goals, in return facilitating behaviour change. By empowering the participants through information and tools tailored to their needs as rural adults, they were able to manage their health and reduce their T2D risk factors, therefore preventing and/or delaying the development of this chronic disease.

9.3. Study Limitations and Strengths

This study applied a quasi-experimental design, which presents a selection bias as the intervention and control participants were not randomly selected [131]. Those who wished to participate in the intervention self-selected into the intervention program and those who did not wish to participate were either part of our control group (minimal data collection) or were non-participants (no data collection). There is also the possibility that the food records data collected were biased as participants may have chosen healthier foods, deliberately or intentionally, to get better results [132].

Consequently, the results were specific to the population and may not reflect the understanding of the general population of adults with prediabetes. As the intervention program was implemented in a rural area, it may not be applicable in urban settings. In addition, other results from lifestyle intervention programs may be found in different rural areas of the country since the project findings are only in reference to participants living in Startford and Tavistock, Ontario.

Furthermore, the project is limited by the fact that the sample size is small and obtaining information is mostly collected through participants. And although the intervention program was interdisciplinary, the participants could have further benefitted with the addition of a kinesiologist, who could have assessed participants' PA levels and provided individualised coaching, and a psychologist, who could have helped target barriers in behaviour change [87,99,115].

Additional limitations arise from measurement errors. A few trained researcher assistants entered the information into statistical software, which might have limited the integrity and consistency of the data; however, a rigorous data checking was done. The retention of some intervention participants was also challenging since the program spanned over nine visits and 14 months. Moreover, follow up with control participants is known to be challenging as they usually tend to have less interest in the study and less incentives to participate [131].

The strengths of the program included filling gap in knowledge when it comes to rural adults with prediabetes in Southwestern Ontario and their distinctive characteristics and barriers to

positive lifestyle changes. The program was given by a dedicated interdisciplinary team of health professionals helping to strengthen the group based approach and provide social support [133]. Also, the study included a mixed method approach, where both quantitative and qualitative data were collected to evaluate and enrich the findings of the study.

Positively, the program had a high participation rate, 80% of the participants were high attendees and attended at least 5 of the 6 monthly educational visits. One of the reasons that could explain the program's high attendance rate is that motivation was maintained throughout the program as the RD provided the participants a passport summary at each visit, which provided ongoing feedback regarding the participants' diet, PA, and laboratory results. Additionally, over half of the participants (54%) were men, which is a study asset as men are typically underrepresented in intervention programs [134].

9.4. Implications for Professional Practice

The intervention program offered at the STAR FHT demonstrated that tailored education can positively influence behaviours known to increase risk of developing T2D by increasing awareness, knowledge, and self-efficacy. Healthcare professionals, including registered dietitians, nurses, and family physicians, are in key roles to make sure the evidence, knowledge, and insights gained from prediabetes clinical research trials are translated and fully applied in community-based practice. To ensure accurate dissemination and application of this information, healthcare professionals should receive ongoing training focused on effective delivery of lifestyle interventions aimed at high risk individuals. Furthermore, they should receive

opportunities to identify what roles they might play in T2D prevention and should recognize the importance of utilizing the expertise of community members to offer an effective community-based program.

Based on our finding from the program evaluation, participants appreciated the group based approach and value the knowledge they have gained. Unfortunately, prediabetes continues to be underdiagnosed which raises the need to identify more efficient methods to increase awareness of prevention programs to healthcare providers and high risk individuals, such as rural adults [7,66]. Individuals with prediabetes and T2D report that lack of information from their physician and lack of referrals to prevention programs are the main barriers to not attending a prediabetes prevention program [135,136]. This indicates that communicating the positive findings of this T2D prevention program to healthcare professionals is an important first step in addressing this issue.

9.5. Implications for Policy

Policymakers can contribute to T2D prevention efforts by supporting larger longitudinal studies that target high risk individuals to determine if prediabetes intervention programs are achievable in community settings towards the long-term prevention of T2D. Additionally, they can contribute in supporting the development of a prediabetes intervention program model that can be used by other rural communities. The model would then get adapted to their own challenges and community resources.

9.6. Directions for Future Research

Based on the program results and limitations, the study highlights the need that an effort needs to be made to include more high risk individuals in T2D prevention programs and identify effective interventions to help prevent and/or delay the development of this disease. Future studies should also develop a standardized high-quality community-based program that focuses on T2D prevention through lifestyle changes in rural adults. Standardization of study designs and outcome measures would improve the ability to identify successful programs. Without uniform outcome measures, making comparisons across studies is challenging [137,138].

Furthermore, delivering online virtual courses as part of the program can expand the reach of the intervention all while reducing the costs and sustainability of future programs, enhancing leaning outcomes, and maintaining the success of the interventions [139].

The results presented the effect of a 6-month intervention program with a follow up after 6 months on lifestyle habits of participants from Stratford and Tavistock. However, there is an additional need for more longitudinal studies, which will allow for more effective data collection, as the long-term effects of community based lifestyle interventions have not been evaluated extensively. Evidence remains limited as to whether a community based lifestyle intervention will have a lasting effect on outcome measures and how comparable it is to the DPPOS long-term outcomes [119]. Additionally, a larger sample size might be considered to eliminate attrition and increase statistical significance [137].

During the program, diet and PA data were self-reported. Participants may have underreported their food intake, recorded better food choices than were consumed, or overstated their level of PA, which can influence the outcome measures and make the interventions look less effective [132,140,141]. Finding alternative methods to record diet, sedentary behaviour, and PA data such as using mobile phone applications, fitness trackers, or other electronic methods can maximize accuracy, quality, completeness of the data, and reduce questionnaire/record fatigue [142].

Moreover, continuous nutritional and physical education is fundamental. Information must be repeated and made readily available beyond the duration of the intervention program, either through brochures or online resources, to support long term lifestyle changes.

Lastly, considering social and emotional support was reported as being a key component of the program, it is our recommendation that future programs focus on group nature, an interdisciplinary team approach, community partnerships, and family support. By considering the implication of spouses or significant family members in the educational and PA component, we believe we can facilitate changes for high risk participants. By inviting community partners to support and present resources to group meetings, social and community support, knowledge, as well as awareness, may be reinforced.

9.7. General Conclusion

This program has allowed a committed interdisciplinary team of health care professionals and researchers to successfully develop and implement a healthy lifestyle intervention program based on the SCT. The program was adapted to the needs of rural adults from Southwestern Ontario in Stratford and Tavistock. Improvement of some elements related to awareness, knowledge, and lifestyle behaviours known to help prevent and/or delay the development of T2D were achieved by the intervention participants from baseline to post-program, unlike their control counterparts. These positive changes translated in improvements in certain controllable T2D risk factors, which were maintained at the 6-month follow up visit.

Considering participants were at high risk of developing T2D, the program findings represent a major change of clinical significance for the lifestyle education program participants, more specifically to those who no longer had prediabetes after the competition of the program. The study demonstrated that positive lifestyle changes, known to reduce key controllable risk factors for T2D, can be made successfully through a 6-month program and can be sustained over a 6-month follow up period. The study findings also support the need for further research as questions remain in relation to whether participants could sustain long-term lifestyle changes after the 6-month follow up.

CHAPTER 10: Bibliography

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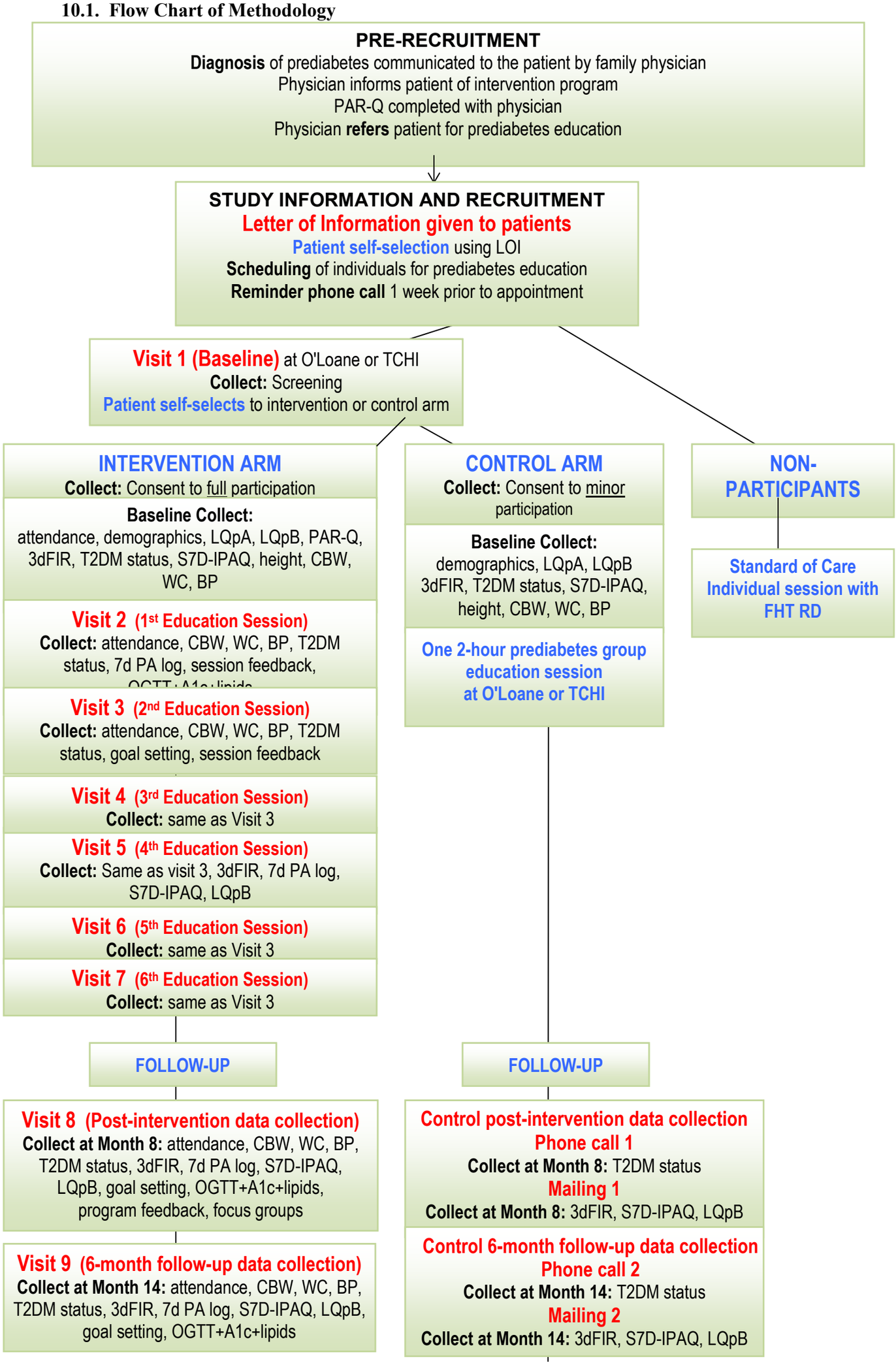
CHAPTER 11: Appendix

This chapter presents materials used for the study.

10.1. Flow Chart of Methodology



Acronym List for the Flow Chart of Methodology

Acronym / Name	Definition / Data Collected	Time to Complete
PAR-Q	Physical Activity Readiness Questionnaire	5 minutes
LOI	Letter of Information & Consent Form	20 minutes
O'Loane	O'Loane Medical Centre	n/a
TCHI	Tavistock Community Health Inc	n/a
screening	Screening Questionnaire	2 minutes
attendance	Attendance Rate Monitoring	10 seconds
demographics	Demographics Questionnaire	3 minutes
LQpA	Lifestyle Questionnaire part A	7 minutes
LQpB	Lifestyle Questionnaire part B	13 minutes
3dFIR	3-Day Food Intake Record and Medication Log	12 minutes/day (done at home)
T2DM status	Type 2 Diabetes Mellitus Status	1 minute
S7D-IPAQ	Short Last 7-Day International Physical Activity Questionnaire	10 minutes
CBW	Current Body Weight	2 minutes
WC	Waist Circumference	4 minutes
BP	Blood Pressure	4 minutes
7d PA log	7-Day Physical Activity and Step Log	2 minutes/day (done at home)
session feedback	Session Feedback Form	4 minutes
OGTT+ A1c+lipids	Oral Glucose Tolerance Test, Blood Glycosylated Hemoglobin, and Lipid Profile Blood Work	2.5 hours*
goal setting	Goal Setting Sheet / Recording of Goal Attainment	5 minutes
program feedback	Program Feedback Form	5 minutes
focus groups	Focus Groups Discussions	1 hour

*All blood work (OGTT, A1c, lipids) is completed in one 2.5 hour session at the laboratory

10.2. Letter of Information and Consent Form

RESEARCH TITLE: "Rural Adults: Reducing their Risk of Diabetes."

MEMBERS OF THE RESEARCH TEAM:
Dr. Isabelle Giroux, PhD, RD, Honours Bachelor in Nutrition Sciences, University of Ottawa, Ottawa, Ontario.
Dr. Sean Blaine, MD, STAR Family Health Team, Stratford, Ontario
Adrienne Vermeer, Registered Dietitian, STAR Family Health Team.
Bridget Whebby, Registered Dietitian, STAR Family Health Team.
Monique Hancock, Executive Director, STAR Family Health Team.
Teresa Barresi, Clinical Health Team Program Coordinator, STAR Family Health Team

BACKGROUND:
Thank you for your participation in the research study that assesses the impact of a prediabetes education program on your food choices, physical activity level and blood glucose (sugar) levels.

Please read the following information carefully, feeling free to ask questions to clarify any points or phrases. Please initial each page to confirm that you have read the information. If after reading the below information you wish to participate in this study, please sign the consent form provided.

WHAT ARE MY OPTIONS? There are two options available to you.

OPTION 1: The first option is to participate in the follow up visit of the research intervention and education program. This is a 2 hour session offered approximately 3 years after the start of the prediabetes education program in which you participated. This session will include a review of nutrition and physical activity education to help you gain knowledge and skills to make positive lifestyle choices. It is a pilot study to test the effectiveness of this type of health-care program in individuals with prediabetes. Your consent is required to participate in option 1. If you choose this option call the Tavistock clinic at 519-655-2322 and speak with our Administrative Assistant for booking.

OPTION 2: The second option is to decide not to participate further in the research. Individuals selecting this option will receive the current standard of care for prediabetes, which includes monitoring of blood sugars at the discretion of your family physician as well as access to individual meeting(s) with the FHT dietitian and other appropriate FHT allied health professional staff. You will not receive any further follow-up care or contact with the research team. This is not part of the research study and you do not need to fill out the consent form. If you choose this option and wish to book an individual meeting with the Family Health Team dietitian call the Tavistock clinic at 519-655-2322 and speak with our Administrative Assistant for booking.

Whatever you decide, the choice is up to you. No matter what you decide, it will not affect your ability to receive the current standard of care. You should feel free to discuss your options with

your doctor, family members, and friends. The research investigators involved with this study will also be available to answer any questions you have about participating in the program.

WHY IS THIS STUDY BEING DONE?

Type 2 diabetes is a serious and complex disease affecting many Canadians. People with prediabetes are especially at risk of developing Type 2 diabetes. While many factors affect the risk of developing Type 2 diabetes, physical activity and dietary habits are important modifiable factors you can influence to help reduce your risk. We know that education programs aimed at changing eating and physical activity habits and building healthy lifestyle skills can be effective to help reduce the risk for developing Type 2 diabetes.

The purpose of this research study is to gain a better understanding of the effect of a 6-month education program in adults with prediabetes from the Stratford and Tavistock area to see if it successfully helps individuals make better lifestyle choices, including food choices and physical activity habits. The goal of this research is to determine if this program helps prevent or delay the onset of Type 2 diabetes by improving your food choices and increasing your physical activity, as well as to gather your feedback about the program. It is hypothesized that the education program will better assist individuals to make healthy food choices, increase their physical activity, and may help to prevent the development of Type 2 diabetes. The number of participants in this study is estimated to be 83 individuals with prediabetes.

WHO IS ELIGIBLE FOR THIS STUDY?

Adults 18 years of age and older from the Stratford, Tavistock or surrounding area, who have participated in the prediabetes research and education program at the STAR Family Health Team are eligible. You must be able to understand English enough to participate in the educational discussions and activities and to fill in required questionnaires. You must not be currently participating in another lifestyle or behaviour change education or research program.

To be eligible to this follow up visit, you must have participated in the prediabetes education program.

WHAT IS BEING ASKED OF YOU AS A PARTICIPANT?

OPTION 1: *VISIT 10*

Your appointment at the STAR Family Health Team will require about 2 hours of your time. You will interact with members of the research team in order to complete the following assessments and questionnaires:

- ***Consent Form:*** You must sign a Consent Form to participate in this research study. The Consent Form will allow us to reach you by phone or email to remind you to come to scheduled education sessions. We will also send you information by mail, such as a reminder to complete a food intake record to bring at your next visit. Signing the Consent Form will serve as a medical information release through which you allow the research team to contact your doctor in order to share such information as your height, weight, body mass index, blood pressure, blood glucose and blood fat tests to better assist in your care.
- ***Lifestyle Questionnaire:*** This will assess your knowledge and beliefs about physical activity and eating. This will take about 20 minutes to complete.

- ***PAR-Q Questionnaire*:** If you have not already completed this short physical activity readiness questionnaire with your doctor, you will be asked to complete it. It will take about 5 minutes to complete. If you answered "yes" to any of the questions on this questionnaire, you will be required to visit your doctor and obtain his/her consent to participate in this study.
- ***Physical Activity Questionnaire***: You will be asked to complete a short questionnaire to determine your current physical activity level, which will take about 10 minutes.
- ***Physical Measurements:*** You will have your weight, waist circumference and blood pressure measured by trained staff. This will take about 12 minutes to complete.
- ***3-Day Food Intake Record and Medication Log:*** Included with the letter of information is a 3-Day Food Intake Record and Medication Log to complete at home prior to your visit. This form asks you to record all beverages, foods, and supplements consumed and all medications taken on 2 week days and 1 weekend day, and it takes about 12 minutes to complete per day. We will ask you to give us that form and we will go over it with you. This will take 1 to 5 minutes.
- ***7-Day Physical Activity and Step Log:*** Included with the letter of information is a physical activity log to be completed for 1 week just prior to the appointment. This log will require you to record all physical activity for the one week and includes you recording all your steps taken with a pedometer. This will take about 1 minute to complete each day and can be filled out at home.
- ***Laboratory Blood Tests:*** You will be asked to visit a Stratford/Tavistock location of LifeLabs® Medical Laboratories Services for your blood tests at least one week prior to your appointment. Thirteen milliliters or a little less than a tablespoon of blood will be taken at the laboratory, which is far less than what would be taken if you donated blood. In order to make sure that each test we do is similar throughout the study, we will need you to: 1) refrain from consuming alcohol and caffeine 48 hours prior to the test, 2) avoid physical activity 24 hours prior to the test and 3) be fasted (no eating, but water is allowed) 12 hours prior to reporting to the laboratory. At the laboratory, the following three tests will be performed at the same visit and the cost will be covered by Ontario Health Insurance Plan (OHIP):
    - ***Blood Sugar Testing:*** This test, called the Oral Glucose Tolerance Test (OGTT), lasts about 2.5 hours in length. Blood samples will be collected from a very small needle placed into a vein in your arm 2 times during the procedure (at the beginning and two hours later). The total amount of blood collected for this test will be 4 milliliters or a little less than a teaspoon of blood. This test allows researchers to see how your blood sugar levels are affected in the 2 hours following the consumption of a sugary drink. If you have already been diagnosed with Type 2 diabetes, then this test will not be required. Only the Fasting Blood Sugar test will be required.
    - ***Blood Lipid Profile:*** This test will require 5 milliliters or about a teaspoon of blood to measure the different levels of healthy and unhealthy fats, including cholesterol, in your blood.
    - ***Hemoglobin test (HbA1c):*** This test will require 4 milliliters or a little less than a teaspoon of blood to measure your average plasma blood sugar level within the past 3 months.
- ***Type 2 Diabetes Status:*** You will be asked if you have been diagnosed with Type 2 diabetes by your doctor (yes or no). This will take less than 1 minute to complete.
- ***Lifestyle Goal Setting Log*:** You will be asked to formulate a goal to help improve your health. It will take about 5 minutes to formulate a new goal and to review your previously set goals.
- ***Program Feedback Form***. This form will ask your feedback on the whole program and your suggestions for the future. This form will take you about 15 minutes to complete.

WHEN DO THE VISITS TAKE PLACE?

Sessions will be held at the Kiwanis Centre in Stratford Tuesday evenings (6-8pm) and Tavistock Community Health Inc Thursday mornings (9:30-11:30am). You have the option to choose which session works best for you. The next available Visit 10 appointment times are:

Stratford (111 Lakeside Dr.)	Tavistock (80 Maria Street)

We will contact you by phone or email, as you prefer, one week before the visit to remind you of your upcoming visit. This will take only 1 minute.

ARE THERE ANY RISKS TO YOU BY PARTICIPATING IN THE RESEARCH?

There may be some risk for your participation in this study.

- ***Laboratory Blood Tests:*** Blood testing will require a very small needle to be placed in an arm vein, which is a very common medical procedure that involves few risks. There is a slight risk of infection at the puncture site. There may be some initial discomfort. There may be some minor bruising at the puncture site. On very rare occasions, there is a slight risk of a small blood clot forming, which normally dissolves within 12 hours. To minimize these risks, only experienced personnel from LifeLabs®, a reputable company with experienced and certified staff, will perform the procedure using clean technique (e.g. wearing gloves, using alcohol swabs).
- ***Dietary Recommendations:*** There is no known risk to consuming healthy foods (such as vegetables and fruit) in individuals with prediabetes who do not have other significant medical issues (e.g. kidney disease). Please speak with the research team if your doctor or any other healthcare provider has discussed any special dietary considerations with you related to a health condition. All dietary recommendations will be reviewed and monitored by Registered Dietitians who are involved with this study.
- ***Physical Activity:*** While our physical activity sessions are of low intensity, there are risks to beginning any physical activity program. To minimize this, we ask that if you answer "yes" to any question on the PAR-Q, that you consult your physician and get his/her approval before partaking in the program. Also, the presentations have been developed by experienced and qualified health care professionals and the sessions will be lead by a health care professional who will guide you in modifications during the physical activity sessions if needed.
- ***Physical Measurements:*** There are no known risks to collecting your height, weight, waist circumference, and blood pressure. The measurements will be taken in a way to respect your privacy with only yourself and the researcher present. Furthermore, measurements will be taken with your clothes on. If at any time you are uncomfortable during the measurements, let the study investigators know.
- ***Questionnaires:*** There are no known risks to filling out the questionnaires for this study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no direct cost to you for being involved with this study. Parking will be provided free of charge when you attend the educational sessions at the STAR Family Health Team. The cost of all requested blood tests is covered through OHIP.

YOUR RIGHTS

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.

You do not waive any legal rights by signing the consent form.

WHAT ABOUT CONFIDENTIALITY?

Maintaining your confidentiality and privacy is our utmost priority. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The following measures have been taken to keep your identity and information, as well as all questionnaires, confidential and secure. To protect the confidentiality of the data we collect from you, your name will be coded with a participant identification number at all points throughout the study. This number will appear on all documents pertaining to you. Records of your study participation will be locked and kept in a confidential file at the STAR Family Health Team. The master list linking participants to unique identification codes will be stored separately from the questionnaires and other research data in a locked filing cabinet in a locked office at the STAR Family Health Team and will be accessible only by the Principal Investigators and the Project Coordinator. The confidentiality of any computer records will also be carefully guarded by security measures (e.g. password protected files and encryption when necessary). Your research records will include your medical history, medications, results from your blood work, physical measurements collected during the study (i.e. weight, blood pressure, etc.), food intake records, physical activity records, and answers you provide to other questionnaires administered during the study.

When you go to LifeLabs® Medical Laboratories Services for your blood tests, their qualified staff will collect a sample of your blood, analyze it and dispose it safely. They will keep the sample for five days in a refrigerator to do the tests and then a certified biomedical waste disposal company will destroy them.

Research data will be retained for 5 years after the study results have been published and will be destroyed at the end of that time. All computer data will be erased and all paper data will be shredded. When the results of the study are published, your name and personal information will not appear within any of the reports.

You have the right to withdraw from the study at any time. If you chose to leave the study, you may choose to have some of the data we have collected from you excluded from the study. In addition, if you complete the study and the results are published in a scientific journal or a graduate dissertation, we cannot allow your data to be withdrawn at a later date. If the research study results are published, none of your personal information will be identified. This is to ensure that no one will be able to tell that you took part in the research study. If you wish, you will be able to take a look at the main research study results posted on the following internet page when the study is completed: www.starfht.ca.

Please be aware that Representatives of The University of Ottawa Health Sciences and Science Research Ethics and Integrity may contact you or require access to your study-related records to monitor the conduct of the research. However, no information by which you may be identified will be released or published.

ARE THERE ANY BENEFITS TO YOU BY PARTICIPATING IN THIS RESEARCH?

There may or may not be direct medical benefit to you for participating in this study. Your participation in this study will allow you to have access to six months of free education sessions offered by a team of specialists in nutrition and physical activity. It is possible that you may find that you are better able to make informed decisions about your lifestyle, including healthy food choices and physical activity. Throughout this study you will receive guidance about how to improve your dietary intake and will be given opportunities to partake in physical activity. You will be provided with resources and opportunities to build skills to help you improve your diet and move toward a healthier lifestyle. The guidance provided to you by study personnel will be personally relevant as the program includes many activities in which you can reflect on your eating patterns and personal life environments. This may lead to positive lifestyle changes that have been shown to reduce the risk of developing Type 2 diabetes.

WHO CAN ANSWER QUESTIONS ABOUT THE STUDY?

You can speak with the Co-Principle Investigators, Dr. Sean Blaine and Dr. Isabelle Giroux, if you have any questions or concerns about the study. They can be reached at:

Dr. Sean Blaine, MD	**Email:** blaines@sympatico.ca	**Tel:** 519-273-1060
Dr. Isabelle Giroux, PhD, RD	**Email:** igiroux@uottawa.ca	**Tel:** 613-562-5800 ext. 2398

If you have any questions about your rights as a research participant or the conduct of the study, you can contact the Office of Research Ethics (University of Ottawa) by email at ethics@uottawa.ca, by phone at 613-562-5387 or by mail at:
Office of Research Ethics and Integrity, University of Ottawa, 550 Cumberland (Tabaret Hall), room 154, Ottawa, Ontario, K1N 6N5.

This letter is yours to keep.

Consent Form

'Rural Adults: Reducing their Risk of Diabetes."

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

Please check ONE of the following options:

☐ I consent to **OPTION 1** of the research study as outlined in the letter of information (includes 6 months of nutrition and physical activity education) and for my data to be shared with the STAR Family Health Team and my family physician.

Initials_____

☐ I consent to **OPTION 2** of the research study as outlined in the letter of information (does not include the 6 months of nutrition and physical activity education) and for my data to be shared with the STAR Family Health Team and my family physician.

Initials_____

Name of participant (please print):_____ _____
Signature: _____ Date: _____

Person obtaining consent (please print):_____

Signature:_____ Date:_____

Participant Contact Information

Name of Participant (please print): _____

Participant's Phone Number: _____ _____
Area Code *Phone Number*

Participant's Email: _____

Participant's Address: _____ _____
Street *Postal Code*

Name of Doctor:
_____

10.3. Screening Questionnaire

PART A: *Please read the following statements to see if you are eligible to participate in this research study.*

Eligibility Criteria	Check One	
1. I am 18 years of age or older.	☐ Yes	☐ No
2. My doctor or other healthcare provider has told me that I have prediabetes.	☐ Yes	☐ No
3. I am able to attend educational presentations at the O'Loane Medical Building on Tuesday evenings (6-8 pm) or at Tavistock Community Health Inc Thursday mornings (9:30-11:30 am) once per month for six months.	☐ Yes	☐ No
4. I am able to perform low impact physical activity, such as walking and stretching.	☐ Yes	☐ No
5. I am able to chew and swallow my food with little difficultly and can eat a balanced diet.	☐ Yes	☐ No
6. I am able to fill out written questionnaires about my health and behaviours.	☐ Yes	☐ No
7. I am currently taking part in another lifestyle education program or research study.	☐ Yes	☐ No
8. I am currently pregnant or lactating (breastfeeding).	☐ Yes	☐ No
9. I have Type 1 or Type 2 Diabetes.	☐ Yes	☐ No
10. I have a digestive disease (e.g. Crohn's disease, celiac disease, etc).	☐ Yes	☐ No
11. I have a diagnosed mental illness (e.g. major depression, eating disorder, schizophrenia, etc).	☐ Yes	☐ No
Administrative Use Only: Any boxes checked that are shaded in grey exclude participant from research study. Deemed ☐ **ELIGIBLE** ☐ **NOT ELIGIBLE** to participate in the intervention arm. Initials:_____		

PART B: I acknowledge the information provided is accurate to the best of my ability.

Participant Signature:_____ Date:_____
day/month/year

PART C: *Complete only if you are not eligible or are not interested in participating in the* **prediabetes** *program. Check all reasons that apply.*

- ☐ Did not meet the study's eligibility criteria (see Part A)
- ☐ Time constraints / too busy
- ☐ Location is not accessible to me
- ☐ Not available on the days/times program is offered
- ☐ Not interested
- ☐ Financial constraints
- ☐ Receiving education & care elsewhere
- ☐ Other (please specify):_____

10.4. Par-Q & You

Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO		
☐	☐	1.	**Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	2.	**Do you feel pain in your chest when you do physical activity?**
☐	☐	3.	**In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	4.	**Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	5.	**Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	6.	**Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	7.	**Do you know of any other reason why you should not do physical activity?**

If you answered YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

Supported by: Health Canada Santé Canada

continued on other side...

Physical Activity Readiness
Questionnaire - PAR-Q
(revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO		
☐	☐	1.	**Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	2.	**Do you feel pain in your chest when you do physical activity?**
☐	☐	3.	**In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	4.	**Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	5.	**Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	6.	**Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	7.	**Do you know of any other reason why you should not do physical activity?**

If you answered YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

Supported by: Health Canada Santé Canada

continued on other side...

10.5. Letter to Family Physicians

Dear [Name of family physician]:

The STAR Family Health Team has received funding through Health Canada to offer a prediabetes education program. We have partnered with the University of Ottawa, nutritional sciences program, to assist in the research component of this program.

This program is a community-based, healthy lifestyle research project targeting adults with prediabetes. This program emphasizes goal-setting and self-management approaches to engage and support patients in making positive lifestyle changes to prevent or delay the development of Type 2 diabetes. All education will be based on the most recent clinical practice guidelines for prediabetes.

Program Highlights	Eligibility Criteria
• 6 months of free interdisciplinary nutrition and physical activity education and hands-on activities (2 hours per session) • Ongoing monitoring of weight, waist circumference, blood pressure, HbA1c, fasting BG (OGTT), and blood lipid profile • Use of a lifestyle log to help formulate realistic goals and increase self-management • Access to drop-in periods with a Registered Dietitian • Free pedometer to record daily steps • Participants may bring a family member or friend for support to each session • Program offered at TCHI and O'Loane sites to all STAR FHT patients	• 18 years of age or older • Diagnosis of prediabetes (FBS 6.1-6.9 and/or 2 hr pc OGTT 7.7-11.0) • Ability to eat a normal diet • Ability to stand and engage in low-impact physical activity (i.e. walking) • Ability to complete written questionnaires in English • Not currently involved in another lifestyle program or research project • Have not seen a dietitian for at least 1 year • Not pregnant or breastfeeding • No diagnosis of Type 1 or Type 2 diabetes • Mental illness (e.g. major depression, binge eating disorder, schizophrenia) • Digestive disorder (e.g. Crohn's disease)

The program flowchart can be found on the back of this letter. Please inform all patients you diagnose with prediabetes about this intervention program and message Amanda with the referral to this program. Eligible patients will be given a letter of information in the mail and directed to contact Jen at the O'Loane office to book their first session if interested. Those patients who are not eligible or do not wish to participate in research are still invited to the current standard of care (an individual appointment with a FHT dietitian). With your support, we are excited to move forward with the prediabetes group education program to assist individuals with prediabetes make healthy lifestyle changes to help prevent or delay Type 2 diabetes. We are including a copy of the PAR-Q & You screening form for your patients. This form is also

included in the handouts section of the EMR for your convenience. Please contact Adrienne Vermeer or Bridget Whebby, Registered Dietitians with the STAR Family Health Team if you have questions.

Sincerely,

Adrienne Vermeer, RD
Registered Dietitian
STAR Family Health Team
Tavistock Community Health Inc: 519-655-2322

Bridget Whebby, RD
Registered Dietitian
STAR Family Health Team
O'Loane Medical Building: 519-273-1060

Dr. Sean Blaine, MD
Family Physician
STAR Family Health Team
O'Loane Medical Building: 519-273-1060

Dr. Isabelle Giroux, PhD, RD, PHEc
Associate Professor and Prediabetes Coordinator
Nutritional Sciences Program
University of Ottawa: 613 562 5800 ext:2398

Enclosed: Prediabetes group education brochure, Poster, and PAR-Q & You

10.6. Phone Script for Clients at Baseline

Patient's Name:_____ Subject Code: _____

Prediabetes Baseline Phone Script

All Potentially Eligible Participants (Reminder about Visit 1)

Hello, my name is _____, and I am calling on behalf of the STAR Family Health Team. May I please speak with (patient's name).

The reason for my call is to remind you of your first prediabetes appointment, which will be held at (site: O'Loane Medical Building OR Tavistock Community Health Inc) on (date of appointment, i.e. Thursday April 26, 2012) from (state timeframe, i.e. 9:30-11:30am) .

You should have received a letter in the mail from us, providing further details about the prediabetes education program options that are available to you. Did you receive this letter yet?

IF PATIENT ANSWERS YES:
That's great! In the letter you may have seen that we are asking you to please complete the 3-day Food Intake Record and Medication Log provided with your letter and to do so prior to your appointment. When completing a 3-day Food Intake Record, it is really important to pick days that are **typical** of your current eating patterns and provide as much detail as possible. For example, the exact portion sizes and brand names. Do you have any questions about filling out that form at the present time?

If yes, answer questions.
If no, proceed to below.

Just as a final note, the information you provide in this food intake record is crucial for your participation in the prediabetes education program if you would like to participate. It will allow us to assess your current eating habits and provide you with specific feedback on the areas of your diet that might need some improvements. In addition, we will be using these records throughout the program as an education tool, so it is really important to fill them out as accurately as possible. Unfortunately, without this information, we cannot provide you with the best experience in the prediabetes education program and therefore cannot invite you to participate in the program. Therefore, please ensure that it is completed before we see you on the (date of appointment, i.e. Thursday, April 26, 2012), from (state time frame, i.e. 9:30-11:30am).

Do you have any questions for me at the present time?
If yes, answer questions.
If no, proceed to closing remarks.

IF PATIENT ANSWERS NO:

Oh okay. Would it be okay if I sent you the letter now?

If yes, see below.

If no, ask if there is a better time to send the information.

How would you like to receive the letter? I can send it by mail or email?
Record method here: mailing address or email address.

In the meantime while you are waiting for your letter, please let me fill you in on some of the important details of the letter.

- Again, your appointment date is:_____ from _____(time) _____

  If you need to reschedule your appointment for any reason, please call in advance. The number to call is 519-273-1060.
- The location is at site: O'Loane Medical Building OR Tavistock Community Health Inc)
- For your appointment, we ask that you wear light comfortable clothing. We will be recording your weight, height, waist circumference, and blood pressure.
- If you wish, you are most welcome to bring a friend, family member, spouse, and/or partner for support.

Finally, the letter provides you with the opportunity to participate in the prediabetes education program research study. We are asking all of those interested to please complete the 3-day Food Intake Record and Medication Log prior to coming to your appointment. When completing a 3-day Food Intake Record, it is really important to pick days that are **typical** of your current eating patterns and provide as much detail as possible. For example, the exact portion sizes and brand names. The information you provide in this food intake record is crucial for your participation in the prediabetes education program if you would like to participate. It will allow us to assess your current eating habits and provide you with specific feedback on the areas of your diet that might need some improvements. In addition, we will be using these records throughout the program as an education tool, so it is really important to fill them out as accurately as possible. Unfortunately, without this information, we cannot provide you with the best experience in the prepare program and therefore cannot invite you to participate in the program. Therefore, please ensure that it is completed before we see you on the (date of appointment, i.e. Thursday, April 26, 2012), from (state time frame, i.e. 9:30-11:30am).

Do you have any questions for me at the present time?

If yes, answer questions.

If no, proceed to closing remarks.

SAME CLOSING REMARKS FOR EVERYONE:
Thank you very much for talking with me today and for your interest in receiving education for your prediabetes. We look forward to seeing you soon at your first appointment. Take care.

IMPORTANT: If the patient is not home, please do not leave any information with other members of the household or on voice meal. Kindly ask the household member when the patient can be reached and thank them for their assistance.

For the Research Team to Complete:

Date of Call	Time of Call	Outcome / Notes
1.		
2.		
3.		

Research Team Member to read the questionnaire verbatim and clarify as indicated.

10.7. Recruitment Brochure

Aim of the program

- The prediabetes education program is designed to assist adults with prediabetes in making positive lifestyle changes to help them to delay or prevent the development of diabetes.

Who can I contact if I have questions?

- There is more program information and education session dates on our website: **www.starfht.ca**

Contact the Research Dietitians:

Adrienne Vermeer, RD 519-655-2322
vadrienne@starfht.ca

Bridget Whebby, RD 519-273-1060
wbridget@starfht.ca

Our Partners

uOttawa
L'Université canadienne
Canada's university

- Funded by Health Canada: Canadian Diabetes Strategy Community-Based Program (Ontario)

Health Canada

- STAR Family Health Team

STAR Family Health Team
Family Health Team

STAR Family Health Team
Family Health Team

RURAL ADULTS

Reducing their risk of Diabetes

Ontario

Am I eligible to participate?

- 18 years or older
- Family doctor is a member of the STAR Family Health Team:
  Dr. Sean Blaine, Dr. Shawn Edwards, Dr. Laurel Moore, Dr. Anne Martin, Dr. Erin Heisz, Dr. Stacey Snider, Dr. Leanne Peters, Dr. Donna Tomlinson, Dr. Ken Hook, Dr. Gregory Stewart, Dr. Paul Bartlett, Dr. Barbara Cowing.
- Diagnosed with prediabetes, impaired glucose tolerance, or impaired fasting glucose
- Not diagnosed with diabetes

Where and when is the program offered?

- O'Loane Medical Building. 700 O'Loane Ave., Stratford, ON.
  Tuesday evenings from 6-8pm.
- Tavistock Community Health Inc. 80 Maria St. Tavistock, ON.
  Thursday mornings from 9:30-11:30am

Program Options

Option 1

- A baseline information session and assessment (Month 1)
- Six monthly education sessions focused on development of self-management skills (Months 2-7)
  Nutrition and physical activity component to each of the education sessions
- A post program assessment (Month 8)
- A 6-month follow up visit after the education sessions (Month 14).

STAR Family Health Team
Family Health Team

Option 2

- One education session led by a Registered Dietitian and baseline assessment (Month 1)
- A follow up phone call and questionnaire at 6 months and 1 year following the education session.

Ontario

10.8. Information Poster for Physician Office

uOttawa
L'Université canadienne
Canada's university

STAR Family Health Team
Family Health Team

Health Canada Santé Canada
Health Canada
www.hc-sc.gc.ca

RURAL ADULTS

Reducing their risk of Diabetes

- The prediabetes education program is designed to assist adults with prediabetes in making positive lifestyle changes to help them to delay or prevent the development of diabetes.
- There is more program information and education session dates on our website: **www.starfht.ca**

Contact the Research Dietitians:

Adrienne Vermeer, RD **519-655-2322** vadrienne@starfht.ca
Bridget Whebby, RD **519-273-1060** wbridget@starfht.ca

Ontario

10.9. Demographics Questionnaire

Please answer the following questions about yourself. This personal information will be held in strict confidence. Only averages from a large group will be reported at the end of data collection period.

1. What is your age?_____ years old

2. Sex: O Male O Female

3. How would you classify yourself?

O Arab	O Asian	O African American/Black
O Caucasian/White	O First Nations	O Hispanic
O Inuit	O Métis	O Multiracial
O Pacific Islander	O Would prefer not to say	
O Other:_____		

4. What is your current marital status?

O Single	O Married	O Common-Law
O Separated	O Divorced	O Widowed
O Would prefer not to say		

5. What is the highest level of education you have completed? Please check only one answer.

O Less than elementary school	O Elementary school
O High school	O Vocational/technical school
O College	O University: Bachelor's degree
O University: Post-graduate degree	O Professional degree (MD, JD, etc.)
O Other, please specify_____	

6. What is your current employment status? *More questions on back of page. Please flip over.*

O Employed Full-Time	O Employed Part-Time	O Retired
O Student	O Unemployed Not By Choice	O Unemployed By Choice
O Would prefer not to say		

7. What is your current household income in Canadian dollars?

O Under $25,000	O $25,000-$49,999	O $50,000-$74,999
O $75,000-$99,999	O $100,000-$124,999	O $125,000-$149,999
O $150,000 or more	O Would prefer not to say	

8. How many adults are supported by this household income (including yourself)?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 or more

9. How many children are supported by this household income?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 or more

End of questionnaire. Thank you for your time!

10.10. 3-Day Food Intake Record & Medication Log

3-Day Food Intake Record & Medication Log

Please keep a record of *everything* you **EAT** and **DRINK** for **3 days**; 2 week days and one weekend day. Include all meals, snacks, and beverages, and the time of day you are eating or drinking. **Please pick days that are <u>TYPICAL</u> for your current eating patterns.**

Please also record your **MEDICATION and SUPPLEMENT schedule** in detail, including: the **name of the drug or supplement**, the **amount** you take, **how often** you take it, **when you started/stopped** the medication or supplement, and **your reason for taking it**.

The purpose of filling out these food and medication records is to help better understand **<u>WHAT</u>** you are eating, **<u>WHEN</u>** you are eating, and **<u>HOW MUCH</u>** you are eating. It also helps the healthcare team understand the role that medications and supplements play in helping you to manage your health conditions. Please be as honest and accurate as you can, as the information you provide will help you better reflect on your eating habits.

<u>FOOD/BEVERAGE RECORDING INSTRUCTIONS:</u>

1. Record all food and beverages consumed during a 24 hour period. Provide the following:

- **Type of Food Eaten:** e.g. chicken noodle soup
- **Brand Name:** e.g. Campbell's, Lipton, Weight Watchers
- **Food or Beverage Characteristics:**
  - **Colour:** e.g. green vs. yellow beans; white vs. whole wheat bread
  - **Fat Content:** % fat (e.g. skim, 1%, 2% or homo milk), leanness of meat (e.g. extra lean ground beef), fat claims (e.g. "light", "low-fat"), was skin removed from poultry?
  - **Freshness:** e.g. fresh, frozen, canned, or dried?
  - **Other Details:** e.g. 25% reduced sodium, "diet" products, etc.
- **Time of Day** you ate or drank

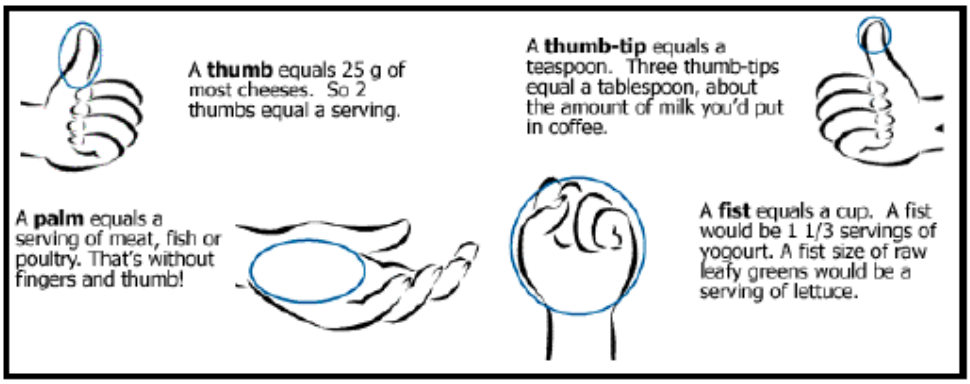
2. Please MEASURE and describe the amount of food eaten as best as possible. Diet records are only reliable with accurate measurements.

- **Always estimate portion sizes of food after cooking.**
- **Use household measures to specify serving sizes.**

  1 cup = 250mL = 8 fluid oz 1 tablespoon (Tbsp) = 15mL
  1 ounce (oz) = 30g 1 teaspoon (tsp) = 5mL
- **Measuring cups (examples):** Put cooked pasta or rice into a measuring cup to record the correct amount before placing it on your plate. Measure your cereal out before pouring into a bowl, and don't forget to measure your milk as well!

- **Teaspoons/tablespoons (examples):** Measure out butter, margarine, mayonnaise, salad dressings, ketchup, mustard, ground flaxseed, sugar, milk/cream, and other condiments, seasonings, and toppings before adding to your food or beverages.
- **Count the number of food items if practical:** e.g.: 20 grapes, 15 baby carrots, 8 medium-sized shrimp, etc.
- **Fluids:** Record amounts in fluid ounces (oz), milliliters (mL), or in cups. Remember 1 cup = 250mL = 8 fl. oz
- **Use food labels to estimate quantities:** Food labels can help you estimate the quantity of food eaten based on weight or volume. For example, write down a 355mL can of pop, ½ of a 60g can of tuna, a 37g granola bar, etc.
- **Use your hand to estimate portion sizes quickly:**

  Whole Thumb = 1 Tablespoon Tip of your Thumb = 1 Teaspoon
  Palm of Your Hand = 3 oz of meat Fist = 1 cup (250mL)



3. Record if anything was ADDED when preparing the food, such as oil (list specific kind), sauce, butter, margarine, or other condiments or seasonings.

4. For COMBINATION DISHES such as lasagna, casseroles, chili, soups, or stews include a description of the main ingredients. E.g. Lasagna: lean ground beef (¼ cup per piece), mozzarella cheese (1 oz per piece), cottage cheese (1 oz per piece), ½ cup tomato sauce, 2 noodles, ¼ cup spinach.

5. Include SNACK FOODS eaten. Don't forget to include candy, chips, cookies, popcorn, ice cream, and beverages such as soft drinks, juice, coffee, or tea.

6. Use the "notes" column to record any additional PRODUCT INFORMATION if available (e.g. 6 crackers – 80 calories, 2.5g fat, 1g fibre, 210mg sodium).

7. Don't forget to write down any ALCOHOLIC BEVERAGES consumed and how much you drank. This includes all wine, beer, and liquor.

When in doubt… include more details!

Current Medication/Supplement Use

Baseline Question: Are you taking any **pills, drugs, or medications?** This includes all over-the-counter and prescribed medications. ☐ Yes ☐ No **If yes,** please list all medications in the table below.

All Follow-Up Visits: Have you had any changes to your medications since your last visit? ☐ Yes ☐ No
If yes, please indicate in the table below which medications you have started or stopped taking, or if the dose or frequency has changed for any current medications.

Name of Medication (Brand Name)	Dose	Frequency	Start Date	Stop Date	Reason for Medication (Medical Problem)
e.g. Lipitor	80 mg	1x / day at dinner	Jan. 2007	--	High cholesterol

Baseline Question: Are you taking any **supplements?** This includes all over-the-counter and prescribed supplements (e.g. multivitamin, iron, fish oil, etc.). ☐ Yes ☐ No
If yes, please list all supplements in the table below.

All Follow-Up Visits: Have you had any changes to your supplements since your last visit? ☐ Yes ☐ No
If yes, please indicate in the table below which supplements you have started or stopped taking, or if the dose or frequency has changed for any current supplements.

Name of Supplement	Dose	Frequency	Start Date	Stop Date	Reason for Taking Supplement
e.g. Vitamin D	1000 IU	1x / day	Oct. 2010	--	Bone health (osteoporosis)

Sample 1-Day Food Record

Below is an *EXAMPLE* of how to keep accurate records. Include a detailed description and amounts for each item. Remember to record **water**, notes on **product details**, and the **times of day** you ate.

TIME	AMOUNT	DESCRIPTION	NOTES
8am	Large	Coffee	Tim Horton's
	1 Tbsp	Cream	
	2 tsp	Sugar	
11 am	2 slices	Bread, whole wheat	
	2 oz.	Turkey, lunchmeat	Oven-roasted from deli
	1 Tbsp	Mayo (Hellman's)	"light", 4.5g fat per Tbsp
	1 leaf	Romaine Lettuce	
	1 tsp	Becel Margarine	Salt-free
11:30pm	2 cups	water, tap	
2 pm	1 medium	Apple (granny smith)	
	6	Whole wheat crackers (Premium Plus)	80 cals, 2.5g fat, 210mg sodium (from label)
	1"x1" cube	Marble cheese, 35%MF	Crackerbarrel
4pm	1 large	Muffin, blueberry	store-bought
	500mL	Water, tap	
7:30pm	1 patty	Hamburger, BBQ'd (regular ground beef)	M&M Meat Shops (~4oz.)
	1	Hamburger Bun, white bread	
	1 leaf	Iceburg Lettuce	
	2 slices	Tomato, raw	
	1 slice	Red Onion, raw	
	2 Tbsp	Kethcup, Heinz	45 calories per tsp
	1 bottle	Beer (12 oz, 5% alcohol)	Moosehead
10pm	2 cups	Chocolate ice cream	Chapman's

Was this a typical day? If not, why? Usually drink more water (forgot water bottle at home)

Did your take all of your usual medications and supplements as prescribed? ☑ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: ____________________ Date: ____________________ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why? ____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: ______________________ Date: ______________________ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

10.11. 7-Day Physical Activity and Step Log

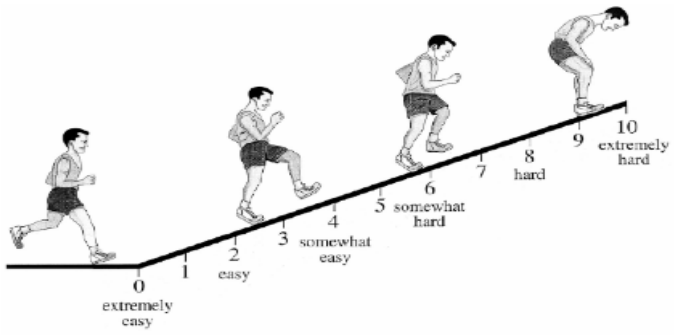
7 Day Physical Activity and Step Log Participant ID#: _____

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Date							
Physical Activity #1	Activity:	Activity:	Activity:	Activity:	Activity:	Activity:	Activity:
	Duration:	Duration:	Duration:	Duration:	Duration:	Duration:	Duration:
	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10
Physical Activity #2	Activity:	Activity:	Activity:	Activity:	Activity:	Activity:	Activity:
	Duration:	Duration:	Duration:	Duration:	Duration:	Duration:	Duration:
	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10	Exertion Level (RPE): /10
Daily Steps Taken							
Activity time (hr. and min.)							
Hours of Pedometer Use							

- Please record your daily physical activity for an entire week (7 days) prior to your next prediabetes session.
- Only record activities performed for **10 or more consecutive minutes**. Please see back of sheet for explanation of exertion levels. Do not wear your pedometer for activities counted separately.
- If you complete more than 2 activities in one day, please attach a sheet with the activity, duration, and exertion level of that activity.
- Lastly, please wear your pedometer for a **minimum of 10 hours** for the 7 days recorded, and record the **number of steps, activity time** as well as the **total hours worn** for each day.

Rating of Perceived Exertion (RPE)

Exertion Level	1	2	3	4	5	6	7	8	9	10
Intensity	Extremely Easy	Easy		Somewhat Easy		Somewhat Hard		Hard		Extremely Hard
Breathing Rate	Normal	Slight increase. Can still carry on a conversation.		Greater increase. Can still speak in short sentences.			More out of breath. Can only speak 1-2 words at a time.		Greatly increased.	Completely out of breath, gasping.
Body Temp	Normal	Start to feel warm		Warm, may be starting to sweat			Quite warm, sweating		Hot, sweating quite a bit	Very hot, sweating lots
Examples	Easy golf, dusting, stretching	Brisk walking, climbing stairs, mowing the lawn, swimming		Brisk walking or dancing, moderate biking			Jogging, fast cycling, hockey, basketball		Running fast	Sprinting all-out



There is no "right" answer for rating your perceived exertion, as the levels are very subjective, that is, they depend on how YOU FEEL.

Here are some tips for helping you to rate your RPE level:

- During the physical activity, try to make a conscious effort to assess your breathing rate (Can you still speak in sentences?), your body temperature (Are you sweating at all?), as well as how intense the activity feels (Is it really hard? Do your legs muscles ache?)
- You may find that your RPE changes during an activity, for example, maybe you were at level 7 while walking up a hill, but at level 4 for the rest of your walk. Try to estimate your average RPE, and if you struggle to do this, please write the range that you experience, or in this case, 4 to 7.

Utter, A. Robertson, R. Med. Sci. Sport Exerc. V36 N10 2004

10.12. Short Last 7-Day International Physical Activity Questionnaire

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRES

IPAQ: SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken in 12 countries (14 sites) across 6 continents during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages. IPAQ is suitable for use in regional, national and international monitoring and surveillance systems and for use in research projects and public health program planning and evaluation. International collaboration on IPAQ is on-going and an international prevalence study is under development.

Using IPAQ

Worldwide use of the IPAQ instruments for monitoring and research purposes is encouraged.

It is strongly recommended, to ensure data quality and comparability and to facilitate the development of an international database on health-related physical activity, that

- no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments,
- if additional questions on physical activity are needed they should follow the IPAQ items,
- translations are undertaken using the prescribed back translation methods (see website)
- new translated versions of IPAQ be made available to others via the web site to avoid duplication of effort and different versions in the same language,
- a copy of IPAQ data from representative samples at national, state or regional level be provided to the IPAQ data storage center for future collaborative use (with permission) by those who contribute.

More Information

Two scientific publications presenting the methods and the pooled results from the IPAQ reliability and validity study are due out in 2002.

More detailed information on the IPAQ process, the research methods used in the development of the IPAQ instruments, the use of IPAQ, the published papers and abstracts and the on-going international collaboration is available on the IPAQ web-site.

www.ipaq.ki.se

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

IPAQ: SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS

NOTE: EXAMPLES OF ACTIVITIES MAY BE REPLACED BY CULTURALLY RELEVANT EXAMPLES WITH THE SAME METS VALUES (SEE AINSWORTH *ET AL*., 2000).

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. This is part of a large study being conducted in many countries around the world. Your answers will help us to understand how active we are compared with people in other countries.

The questions are about the time you spent being physically active in the last 7 days. They include questions about activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Your answers are important.

Please answer each question even if you do not consider yourself to be an active person.

THANK YOU FOR PARTICIPATING.

In answering the following questions,

- **vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder that normal.

- **moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder that normal.

1a. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling,?

Think about *only* those physical activities that you did for at least 10 minutes at a time.

_____ **days per week** ⇨

1b. How much time in total did you usually spend on one of those days doing vigorous physical activities?

_____ **hours** _____ **minutes**

or

☐ **none**

2a. Again, think *only* about those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week** ⇨

2b. How much time in total did you usually spend on one of those days doing moderate physical activities?

_____ **hours** _____ **minutes**

or

☐ **none**

3a. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

_____ **days per week** ⇨

3b. How much time in total did you usually spend walking on one of those days?

_____ **hours** _____ **minutes**

or

☐ **none**

The last question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading traveling on a bus or sitting or lying down to watch television.

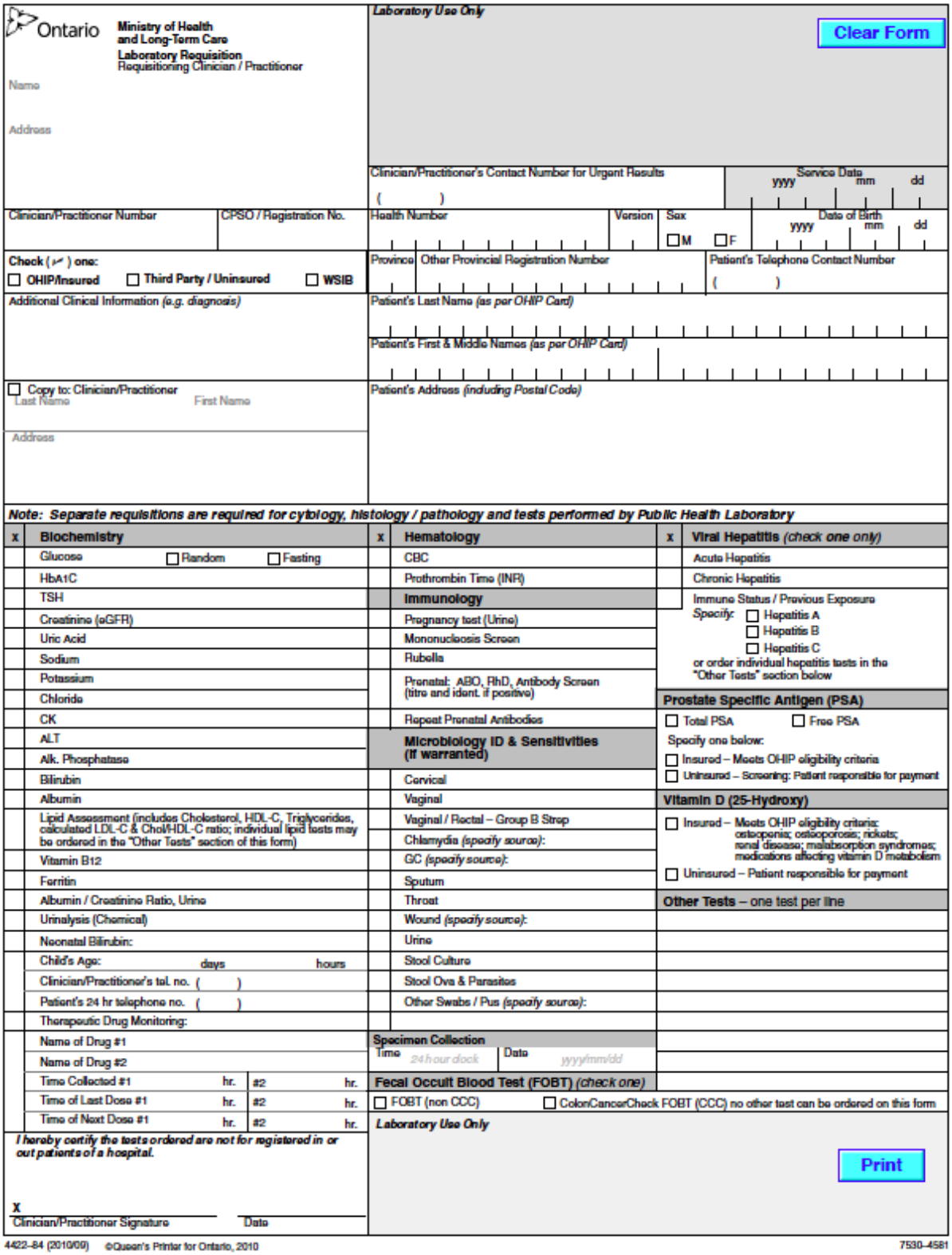
4. During the last 7 days, how much time in total did you usually spend *sitting* on a **week day?**

____ **hours** _____ **minutes**

This is the end of questionnaire, thank you for participating.

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

10.13. Laboratory Blood Work Requisition Form



Ontario
Ministry of Health and Long-Term Care
Laboratory Requisition
Requisitioning Clinician / Practitioner

Name

Address

Laboratory Use Only

Clear Form

Clinician/Practitioner's Contact Number for Urgent Results ( )

Service Date yyyy mm dd

Clinician/Practitioner Number | CPSO / Registration No.

Health Number | Version | Sex ☐M ☐F | Date of Birth yyyy mm dd

Check (✓) one:
☐ OHIP/Insured ☐ Third Party / Uninsured ☐ WSIB

Province | Other Provincial Registration Number | Patient's Telephone Contact Number ( )

Additional Clinical Information (e.g. diagnosis)

Patient's Last Name (as per OHIP Card)

Patient's First & Middle Names (as per OHIP Card)

☐ Copy to: Clinician/Practitioner
Last Name First Name

Address

Patient's Address (including Postal Code)

Note: Separate requisitions are required for cytology, histology / pathology and tests performed by Public Health Laboratory

x	Biochemistry
	Glucose ☐ Random ☐ Fasting
	HbA1C
	TSH
	Creatinine (eGFR)
	Uric Acid
	Sodium
	Potassium
	Chloride
	CK
	ALT
	Alk. Phosphatase
	Bilirubin
	Albumin
	Lipid Assessment (includes Cholesterol, HDL-C, Triglycerides, calculated LDL-C & Chol/HDL-C ratio; individual lipid tests may be ordered in the "Other Tests" section of this form)
	Vitamin B12
	Ferritin
	Albumin / Creatinine Ratio, Urine
	Urinalysis (Chemical)
	Neonatal Bilirubin:
	Child's Age: days hours
	Clinician/Practitioner's tel. no. ( )
	Patient's 24 hr telephone no. ( )
	Therapeutic Drug Monitoring:
	Name of Drug #1
	Name of Drug #2
	Time Collected #1 hr. #2 hr.
	Time of Last Dose #1 hr. #2 hr.
	Time of Next Dose #1 hr. #2 hr.

x	Hematology
	CBC
	Prothrombin Time (INR)
	Immunology
	Pregnancy test (Urine)
	Mononucleosis Screen
	Rubella
	Prenatal: ABO, Rhd, Antibody Screen (titre and ident. if positive)
	Repeat Prenatal Antibodies
	Microbiology ID & Sensitivities (if warranted)
	Cervical
	Vaginal
	Vaginal / Rectal – Group B Strep
	Chlamydia (specify source):
	GC (specify source):
	Sputum
	Throat
	Wound (specify source):
	Urine
	Stool Culture
	Stool Ova & Parasites
	Other Swabs / Pus (specify source):

Specimen Collection
Time 24 hour clock | Date yyyy/mm/dd

Fecal Occult Blood Test (FOBT) (check one)
☐ FOBT (non CCC) ☐ ColonCancerCheck FOBT (CCC) no other test can be ordered on this form

x	Viral Hepatitis (check one only)
	Acute Hepatitis
	Chronic Hepatitis
	Immune Status / Previous Exposure

Specify: ☐ Hepatitis A ☐ Hepatitis B ☐ Hepatitis C
or order individual hepatitis tests in the "Other Tests" section below

Prostate Specific Antigen (PSA)
☐ Total PSA ☐ Free PSA
Specify one below:
☐ Insured – Meets OHIP eligibility criteria
☐ Uninsured – Screening: Patient responsible for payment

Vitamin D (25-Hydroxy)
☐ Insured – Meets OHIP eligibility criteria: osteopenia; osteoporosis; rickets; renal disease; malabsorption syndromes; medications affecting vitamin D metabolism
☐ Uninsured – Patient responsible for payment

Other Tests – one test per line

I hereby certify the tests ordered are not for registered in or out patients of a hospital.

X
Clinician/Practitioner Signature Date

Laboratory Use Only

Print

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10.14. Procedure for Physical Measurements

RESPECT OF PRIVACY AND CONFIDENTIALITY

When measuring anthropometrics, it is important to ensure that the **privacy and confidentiality of participants** are always respected. To do this, you must ensure that measurements are taken on a one-on-one basis (just you and the participant present). Also, it is very important that you explain to the participant exactly what you are going to be doing and to allow them the opportunity to ask any questions that they may have.

STATURE (STANDING HEIGHT)

Stature, or standing height, can be measured for subjects who are cooperative and able to stand without assistance. A stadiometer (height rod) will be used in this study to determine an accurate height for each subject.

This measurement will take about 2 minutes.

How to Set-Up a Stadiometer

- Stadiometers must be stable, calibrated and dedicated to the purpose. This requires:
    - ✓ A vertical board with an attached metric ruler (when assembling the stadiometer, ensure that the tiny icons at the top and bottom of each piece fit together with the piece that has the same corresponding icon. For example, put the top of the piece with the * symbol into the bottom of the piece that has the same * symbol)
    - ✓ An easily moveable horizontal headpiece that can be brought into contact with the most superior part of the head. Ensure that the flat side of the headpiece faces the floor.
    - ✓ A wide and stable platform or firm uncarpeted floor as the base

How to Measure Stature Using a Stadiometer

Step 1. Ask the subject to remove the following items:

- Shoes
- Hair ornamentation (clips, headbands, barrettes, etc.)
- Bulky outer layers (minimal clothing is best)

Step 2. Position the subject as follows:

- Stand with heels together
- Arms to the side
- Legs straight
- Shoulders relaxed
- Head in the Frankfort horizontal plane ("look straight ahead", make sure the chin is parallel to the floor)
- The following four body points should be gently touching the stadiometer vertical board: head, shoulder blades, buttocks, and heels

Note: Some people may not be able to touch all four points against the stadiometer because of obesity, protruding buttocks, or curvature of the spine. Rather than creating an embarrassing situation by trying to force a subject into a physically impossible position, have the subject touch two or three of the four points to the vertical surface of the stadiometer. Also make sure that the points are just touching, and that the person is not leaning on the stadiometer.

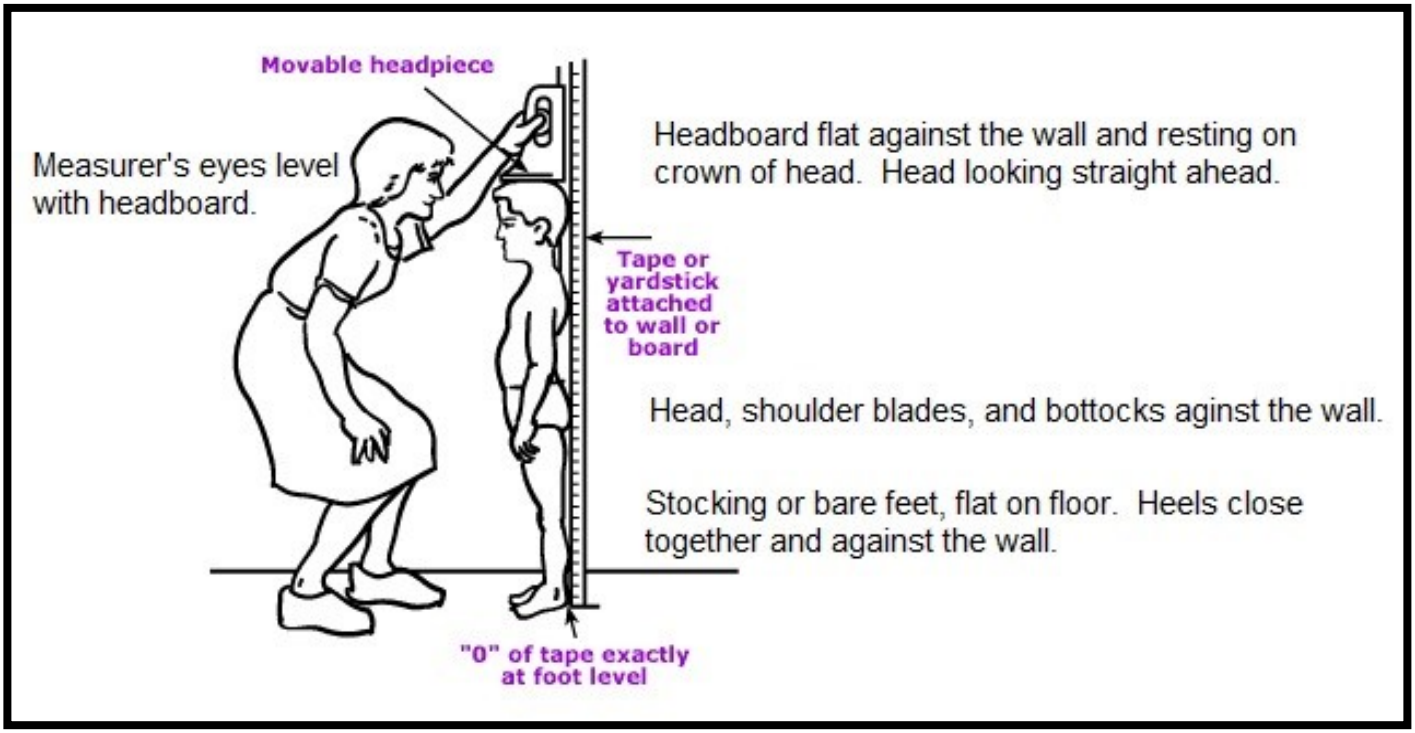
Step 3. Just before the measurement is taken, the subject should:

- Relax and maintain an erect posture ("stand up tall" and ensure that the chin is parallel to the floor and arms are at the participants' sides).

Step 4. Collect the stature measurement as follows:

- Lower the headboard to the highest point of the head with enough pressure to compress the hair
- Eye level of the observer should be level with the headboard to avoid errors caused by parallax.

  Parallax: Is a difference in the apparent reading of a measurement scale when viewed from various points not in a straight line with the eye.
- Read the measurement to the nearest 0.1 cm (1/8")
- Repeat the measurement one more time to ensure accuracy and average the two readings.
- If the initial two measurements are more than 0.5 cm apart, perform another measurement and take an average measurement between the two closest measurements.



WEIGHT (CURRENT BODY WEIGHT)

Weight will be collected using an electronic scale.

This measurement will take about 2 minutes.

How to set up an Electronic Scale

- Ensure that the scale is set up on a hard flooring surface and is as level as possible.

How to Measure Weight Using an Electronic Scale

Step 1. Ask the subject to remove the following items:

- Shoes
- Bulky outer layers (minimal clothing is best)
- Heavy items in pockets / on the person (cell phone, wallet, coins, keys, heavy belts)

Step 2. Collect the weight measurement as follows:

- Turn the electronic scale on
- Ask the subject to stand still in the middle of the scale's platform without touching anything
- Body weight should be equally distributed on both feet
- Read the weight to the nearest 100 g (0.1 kg)
- Repeat the measurement one more time to ensure accuracy and average the two readings.
- If the two measurements are more than 100 g (0.1 kg) apart, perform another measurement and take an average measurement between the two closest measurements.

Considerations:

- The scale should be placed on a flat, hard surface that will allow it to sit securely without rocking or tipping.
- The scale will be calibrated monthly.
- Ideally, individuals should be weighed after voiding (going to the bathroom) and dressed in lightweight clothing.
- The scale will be placed in a spot where adequate privacy will be provided.
- While participants have the right to ask for their current measurement value, do not tell the participant how optimal their weight is.

WAIST CIRCUMFERENCE

The United States National Institute of Health (NIH) recommends using waist circumference to assess abdominal fat content. It is a valuable guide in assessing health risk in persons categorized as normal or overweight (in terms of BMI) and provides an independent prediction of risk over and above that of BMI.

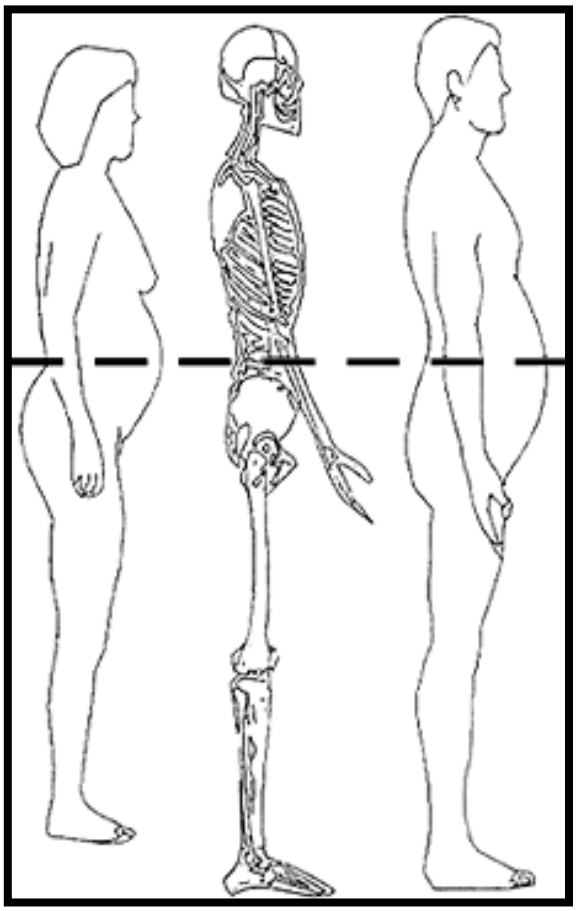
This measurement will take about 6 to 8 minutes.

How to Measure Waist Circumference Using a Measuring Tape

Step 1. Ask the subject to remove the following items:

- Outer clothing that restricts or may interfere with the measurement (e.g. the placement of the measuring tape against bare skin, compressing the abdomen, etc.)

Step 2. Collect the waist circumference measurement as follows:



- Locate the right iliac crest by using the fingertips to gently feel for the highest point of the hip bone on the subject's right side.
- Locate the lowest right rib.
- Find the midway point between the iliac crest and lowest right rib, and use this as the reference point for which to measure the subject's waist circumference.
- Place an inelastic, flexible measuring tape in a horizontal plane (parallel to the floor) around the abdomen at the midway point between the iliac crest and lowest right rib.
- The tape should be snug but should not compress the skin.
- Ensure that the participant is standing with their feet hip width apart and that their arms are at their sides.
- Have the participant take a breath and exhale. You can also ask the participants to talk (e.g. ask them their favorite movie), as this helps with relaxation.
- Take the reading.
- Record the measurement to the nearest 0.1 cm.
- Repeat the measurement one more time to ensure that an accurate measurement and average the two readings.
- If the two measurements are more than 0.5 cm apart, perform another measurement and take an average between the two closest measurements.

BLOOD PRESSURE

This measurement will take about 7 to 10 minutes (including 5 minutes to sit and relax)

How to Blood Pressure Using a Blood Pressure Cuff

Step 1. Ask the subject to remove the following items:

- Any outer clothing restricting easy access to an arm and interfering with the placement of blood pressure cuff against the bare skin of the upper arm.

Step 2. Ask the subject to sit and relax:

- The individual will be asked to sit comfortably in a chair that supports his/her back and beside a table that supports his/her arm.
- A pillow or towel will be used to ensure that the centre of the cuff is at heart level.
- The legs of the individuals will not be crossed.
- The correct size cuff (i.e. S, M, L, XL) will be placed around a bare arm. The cuff will be placed on the anterior part of the arm. The bottom of the cuff will rest approximately two fingers above the elbow. The tube that connects the cuff to the machine will sit on the table.
- The individual will rest and relax for 5 minutes.

Step 3. Measure the blood pressure:

- Blood pressure will be measured using a BP tru machine on the 3-cycle setting
- Individual readings will be recorded by a member of the research team or support staff.

Reference: The Canadian Hypertension Education Program (CHEP) http://hypertension.ca/

Considerations:

- The participant should not talk during the measurement
- The participant's arm and fingers should remain still (i.e. No wiggling their fingers)
- The breath of the participant should be normal (i.e. No holding of the breath or breathing deeply)
- Try to minimize distractions around the participant during the measurement (i.e. No loud noises or exciting events that would elevate the heart rate of the participant)

10.15. SMART Goal Setting Sheet

Specific: Goals should be straightforward and emphasize what you want to happen. Write out clear details to help you focus and visualize your success.

Measurable: Establish concrete, objective ways to measure the outcome. If you can't measure it, you can't manage it!

Attainable: Set a goal for yourself that is challenging yet realistic. One of the strongest predictors of long-term success lies in setting the right goal at the start. You'll be more likely to stick with it by setting and achieving realistic, short-term goals.

Reward-based: Many people find it helpful to have a "prize" for their hard work, especially when the going gets tough. This reward needs to be personal and something you really want. It should be something special that you ordinarily do not give yourself. Reward ideas include a book or magazine, a massage, a new pair of shoes or T-shirt, a manicure, a new music disk, or a fun activity.

Time frame: Establish a deadline for reaching your goal. Write down a beginning and ending date.

Sample Goal Setting for a SMART Short-Term Goal

S – Specific	Walk at a brisk pace for 15 minutes Monday through Friday from 12:30- 12:45 p.m. around the perimeter of the office building starting on May 1st and ending on May 31st.
M – Measurable	Each walking session will be recorded in my food and exercise journal.
A – Attainable	This is a realistic and attainable goal for me.
R – Reward-based	Upon completion of this goal, I will reward myself with a new plant.
T – Time frame	The goal begins on May 1st and ends on May 31st.

My SMART Nutrition Goal

S – Specific	
M – Measurable	
A – Attainable	
R – Reward-based	
T – Time frame	
Some **challenges** I may face include	
Available **support** and resources	
Confidence level that I can achieve my goal	not confident at all 0 1 2 3 4 5 6 7 8 9 10 extremely confident
Did I **reach my goal?**	not at all 0 1 2 3 4 5 6 7 8 9 10 fully achieved my goal
Why or why not?	

My SMART Physical Activity Goal

S – Specific	
M – Measurable	
A – Attainable	
R – Reward-based	
T – Time frame	
Some **challenges** I may face include	
Available **support** and resources	
Confidence level that I can achieve my goal	not confident at all 0 1 2 3 4 5 6 7 8 9 10 extremely confident
Did I **reach my goal?**	not at all 0 1 2 3 4 5 6 7 8 9 10 fully achieved my goal
Why or why not?	

10.16. Focus Groups Script with Participant Interview Questions

Hello everybody and welcome. My name is _____, and I will serve as the moderator for today's focus group discussion. Assisting me is _____. The purpose of today's discussion is to find out your thoughts and ideas about the prediabetes program that you recently attended at STAR Family Health Team.

Please be aware that there are no right or wrong answers to the questions being asked of you. We will be recording this discussion to ensure that we do not miss any of your comments and that we can report your comments accurately. The information that you provide will be grouped together as themes and not identifiable to any one participant, so please feel free to be as open and honest as you wish with your answers.

Please keep in mind the following limits on confidentiality in the context of focus groups. All participants' comments made during the focus group session(s) should be kept confidential. Although the researchers can promise to maintain confidentiality, they cannot guarantee that focus group members will do so. Therefore all focus group participants should be aware of the importance of maintaining confidentiality, and that it is possible that other participants may speak about their comments outside of the focus group.

Are there any questions? If no, okay, let's begin.

- Before beginning the prediabetes education program, did you have any expectations about the program?
    - Did we meet, exceed or fall short of these expectations?

- Did you find the location, length and frequency of the sessions appropriate?

- What did you think about the prediabetes education program personnel?
    - Did you feel that they were appropriately prepared?
    - Were the program team members welcoming, helpful and professional?

- What parts of the program did you enjoy the most and why?

- What parts of the program did you enjoy the least and why?

- Did you find the information provided in the educational sessions useful? Why or why not? (Prompt: Did you learn anything new that you could use?)

- Did you find the skill building components useful? For example, the goal setting sheet, label reading, physical activity sessions, etc. Why or why not?

- What would you say is the most significant change you have made to your lifestyle due to participating in the prediabetes education program?

- Do you have any suggestions for the program?
- Would you recommend this program to a friend or family member? Why or why not?
- Do you have any final comments you wish to share?
- Thank you so much for participating in this discussion. Your comments have been most informative and are greatly appreciated.

Have a nice evening!

10.17. Phone Script for Control Group at Months 8 and 14

Phone Script to be used by Research Team Members

Control Arm (Month 8 and 14 after Baseline)

Hello, may I please speak with (client's name). Hello (client's name). My name is _____, and I am calling on behalf of Dr. Isabelle Giroux and the Prediabetes Study Team. At this time, we would like to ask you one question over the phone to help us with our research study.

Has your doctor told you that you have been diagnosed with Type 2 diabetes (<u>not prediabetes</u>) since your baseline visit with us (six months or one year) ago? You can answer:

☐ **YES**
☐ **NO** or
☐ **I DON'T KNOW**

Thank you very much for providing this information for our study.

At this time, we would also like to remind you to complete the package that came in the mail containing three additional questionnaires for our study, and to mail those back as soon as you can. Thanks very much for your involvement with this important research. Take care.

<u>IMPORTANT: If the participant is not home, please do not leave any information with other members of the household or on voice mail. Kindly ask the household member when the participant can be reached and thank them for their assistance.</u>

For the Research Assistant to Complete:

Date of Call	Time of Call	Outcome / Notes
1.		
2.		
3.		

10.18. Letter to Clients of Control Group at Months 8 and 14

Dear [client's name],

Thank you for your ongoing participation in the prediabetes research study. It has been approximately (indicate timeframe: *six months* or *one year*) since you attended the Prediabetes Group Education Session at (indicate site: O'Loane Medical Building or Tavistock Community Health Inc).

Within this package are three data collection forms the research team would like you to fill out and mail back. They include:

1. **3-Day Food Intake Record and Medication Log:** Please complete the package and record all beverages and foods consumed, as well as all medications/supplements taken on 2 week days and 1 weekend day. Please pick days that are typical for your current eating patterns. This log will take approximately 12 minutes to complete per day.
2. **Physical Activity Questionnaire:** Please complete this short questionnaire to help the researchers determine your current level of physical activity. This form will take about 10 minutes to fill out.
3. **Lifestyle Questionnaire part B:** Finally, please fill out the last questionnaire about your intentions and beliefs towards physical activity, eating, and making changes to your habits. This questionnaire will take approximately 15 minutes to complete.

Once completed, please place all three items in the enclosed envelope *(pre-addressed and postage pre-paid for your convenience)* and place in any Canada Post mailbox for return.

As an appreciation for your time and effort, we will send you a $10 grocery store gift card by mail when we receive your completed forms.

Thank you very much,

Dr. Sean Blaine and Dr. Isabelle Giroux, on behalf of the Prediabetes Research Team

10.19. Certificate of Ethics Review

Health Canada and Public Health Agency of Canada
Research Ethics Board

Santé Canada et l'Agence de la santé publique du Canada
Comité d'éthique de la recherche

CERTIFICATE OF ETHICS REVIEW

Principal Investigator:
Name: Isabelle Giroux

Project Title: Rural Adults: Reducing their Risk of Diabetes

Project File Number: REB 2010-0072

Contact Department/Agency: PHAC

Document Name:

Date:

List of all documents submitted to the REB on: January 19, 2011

1. Application
2. Draft Proposed Letter of Information
3. Letter of Support from John Mitchell
4. Approval from University of Western Ontario REB
5. Demographics Questionnaire
6. Lifestyle Questionnaire
7. 3-Day Food Intake Record and Medication Log
8. 7-Day Physical Activity and Step Log
9. Smart Goal Setting Sheet
10. Session Feedback Form
11. Focus Group Script with Participant Interview Questions
12. Program Feedback Form
13. IPAQ: Short Last 7 Days Self-Administered Format
14. Perceived Exertion Scale
15. Excerpts from Application for PHAC Funding: Project description, workplan, evaluation plan
16. Detailed Budget

Answers to the REB questions/observations and additional material provided on July 15, 2011:
Appendix A: Summary of peer reviewers' feedback, comments to address the feedback (July 13,2011)
Appendix B: Feedback Peer Reviewer 1 (April 5, 2011)
Appendix C: Feedback Peer Reviewer 2 (May 9, 2011)
Appendix D: Revised Ethics Application with changes (underlined & highlighted) (July 13, 2011)
Appendix E: Consent Form for the STAR FHT Focus Group Draft (June 20, 2011 IG)
Appendix F: Revised Focus Group Script + Q (Revised June 20, 2011 IG)
Appendix G: Revised Letter of Information (STAR FHT LOI & Consent Draft June 15, 2011)
Appendix H: Revised Demographics Questionnaire IG (June 28, 2011)
Appendix I: Revised International Physical Activity Self-administered Questionnaire (June 28, 2011)
Appendix J: Revised Detailed Budget (STAR FHT Budget July 13, 2011)

Canada

ETHICS REVIEW:
Your application to the Health Canada and Public Health Agency of Canada's Research Ethics Board (REB) regarding the above-referenced research project has been reviewed on February 17, 2011 and on July 27, 2011. The most recent versions of the documents listed above were found to meet ethical requirements for research involving humans.

SEP 0 8 2011

Janet Storch, RN, BScN, MHSA, PhD, DSc (Hon) — Date
Chair, Research Ethics Board

Certificate Expiry Date:
July 27, 2012

Principal Investigator's responsibilities:

I confirm that I will:

1. Carry-out the research in accordance with the above-referenced protocol by the REB;
2. Obtain an annual ethical review until the research is complete (The certificate is given for one year);
3. Seek ethics review of the REB for any amendment or modification of the research protocol or consent form;
4. Report immediately to the REB Secretariat, any adverse or unexpected events resulting from the research involving humans; and
5. Notify the REB Secretariat, upon termination or completion of the project.

Principal Investigator — Date

Once signed, please return a copy of this certificate to the REB Secretariat.

File Number: H10-12-10 Date (mm/dd/yyyy): 02/10/2015

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Ethics Approval Notice

Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

First Name	Last Name	Affiliation	Role
Isabelle	Giroux	Health Sciences / Others	Principal Investigator
Sean	Blaine	Others / Others	Co-Principal Investigator
Sarita	Azzi	Health Sciences / Others	Student Researcher
Emilie	Comtois-Rousseau	Health Sciences / Others	Research Assistant
Clodie	Gravel	Health Sciences / Others	Research Assistant
Mathilde	Lavigne-Robichaud	Health Sciences / Others	Research Assistant

File Number: H10-12-10

Type of Project: Professor

Title: Rural Adults: Reducing Their Risk of Diabetes

Renewal Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
12/05/2014	12/04/2015	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:
N/A

File Number: H10-12-10 **Date (mm/dd/yyyy):** 02/10/2015

Université d'Ottawa University of Ottawa
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement (2010) and other applicable laws and regulations in Ontario, has examined and approved the ethics application for the above named research project. Ethics approval is valid for the period indicated above and subject to the conditions listed in the section entitled "Special Conditions / Comments".

During the course of the project, the protocol may not be modified without prior written approval from the REB except when necessary to remove participants from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the project (e.g., change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, including consent and recruitment documentation, should be submitted to the Ethics Office for approval using the "Modification to research project" form available at: http://research.uottawa.ca/ethics/submissions-and-reviews.

Please submit an annual report to the Ethics Office four weeks before the above-referenced expiry date to request a renewal of this ethics approval. To close the file, a final report must be submitted. These documents can be found at: http://research.uottawa.ca/ethics/submissions-and-reviews.

Signature:

Mélanie Rioux
Ethics Coordinator
For Catherine Paquet, Director of the Office of Research Ethics and Integrity