The Prediabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Project

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ABSTRACT

Prediabetes is a prevalent condition which is a precursor to type 2 diabetes (T2D) and physical activity is known to counter T2D. Given the potential for alleviating health care expenditures through the prevention or delay of T2D, targeting individuals with prediabetes using physical activity intervention is a critical research question. The aim of this project was to; i) identify persons with prediabetes and thus at high risk for developing T2D, ii) engage individuals with prediabetes in community-based, culturally-preferred physical activity classes led by culturally-matched instructors with the goal of improving glycemic control and iii) investigate how two modes of laboratory-based aerobic exercise intervention (high intensity intervals versus continuous moderate intensity) impact glycemic control in persons with prediabetes.

Participants were recruited in various ethnic communities known to have high prevalence rates of T2D. Critical blood biomarkers and measures of physical and physiological fitness were assessed at different time points to ascertain the effectiveness of both community-based physical activity classes and two modes of laboratory-based exercise. The results of this project show that the PRE-PAID risk questionnaire coupled with point-of-care testing of glycated hemoglobin (A1C) are an effective tool for identifying persons with prediabetes who are at high risk for T2D. Individuals, who participated in community-based culturally matched physical activity classes, experienced improved glycemic control evidenced by reductions in A1C after 3 and 6 months plus improvements in resting blood pressure, combined hand grip strength and aerobic fitness after 6 months. There were no differences between the laboratory-based aerobic exercise interventions of high intensity intervals vs. continuous moderate intensity for any of the measured outcomes. However, the participants who underwent both laboratory exercise modes experienced significant improvements in glycemic control, beta cell function, waist circumference and aerobic fitness following 3 months of supervised exercise. This research provides evidence for early detection of persons with prediabetes and strategies for improving glycemic control

and physical plus physiological fitness in this population. The observed improvements could potentially help prevent or delay the onset of T2D.

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CONTRIBUTIONS OF AUTHORS

Each of the 4 manuscripts include a list of co-authors. In each case, individuals were included as a co-author if they provided significant input towards study design, participant recruitment and data collection, data reduction and analyses and/or preparation and revision of the manuscript. In each of the 4 manuscripts, C. Rowan was the primary author and contributor to each of the above mentioned aspects of the thesis.

FORWARD TO THE THESIS

This thesis is organized as four separate manuscripts preceded by an introductory set of chapters including; a review of literature, list of objectives and hypotheses from each study, and descriptions of common methodologies across each of the studies. The manuscripts are followed by a general discussion and overview of the four manuscripts as well as a summary of conclusions, implications of the work and comments regarding future research in the field. The thesis concludes with a detailed list of references, a list of abbreviations and several appendices relevant to the project.

At the centre of the thesis are the following 4 manuscripts, each principally authored by C. Rowan.

1. The Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Program
   CP Rowan, MC Riddell and VK Jamnik. *Canadian Journal of Diabetes.* 2013. (37) 415-419

2. Identifying persons at risk for developing type 2 diabetes in a concentrated population of high risk ethnicities in Canada using a risk assessment questionnaire and point-of-care capillary blood A1C measurement
   CP Rowan, LA Miadovnik, MC Riddell, MA Rotondi, N Gledhill, and VK Jamnik. *BMC Public Health*. 2014;14(929):1-9

3. Community-based physical activity intervention targeting populations at high risk for prediabetes through culturally-preferred physical activity by detecting changes in glycemic control using glycated hemoglobin (A1C)
   Rowan CP, Riddell MC, Gledhill N, and Jamnik VK. *Canadian Journal of Diabetes* (Submitted, Feb 2016)

4. Comparing high intensity interval versus continuous moderate intensity aerobic training modalities in persons with prediabetes for the improvement of glycemic control measured through changes in glycated hemoglobin (A1C)

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction and Summary of the Project

The prediabetes detection and physical activity intervention delivery (PRE-PAID) project was a multi-phase research study inspired by the current global and Canadian trends in diabetes, associated health care implications and potential for significant health improvement through physical activity (PA)-based prevention strategies targeting those at highest risk for the disease.

Phase I of the project was a community-based prediabetes screening program targeting persons at high risk for developing type 2 diabetes (T2D) from ethnicities that are known to be at elevated risk for developing diabetes based on global trends. The remaining phases of the PRE-PAID project involved a PA program that was supervised by a qualified exercise professional (QEP) who was assisted by a culturally-matched instructor and was offered in a readily accessible, community-based location during Phase II or within a laboratory-based setting during Phase III. The overall goal of the project was to help identify people with prediabetes who are at risk for developing T2D and to prevent or delay the progression towards T2D through various forms of PA participation. In addition, the project aimed to determine if some forms of PA were more effective in their ability to prevent or delay T2D.

Participants were first screened for the presence of diabetes and prediabetes risk factors using a customized and culturally appropriate questionnaire. Interested participants were then offered a fingerstick blood test measuring glycated hemoglobin (A1C) which provides information about blood sugar control over the previous three months. Interested participants were then invited to participate in the community-based PA intervention classes held in close proximity to the location of the screening/recruitment session.

The PRE-PAID PA program was culturally-specific (during Phase II) and was supervised by QEPs who were assisted by culturally-matched instructors to ensure participant safety and appropriate intensity. Phase III was also supervised by QEPs and participants took part in their PA sessions in a laboratory setting and compared two randomly assigned modes of exercise (high intensity intervals and moderate

intensity continuous aerobic exercise). Participants in Phase II were asked to be active for a period of 6 months while those in Phase III were involved for a total of 3 months. Some participants in Phase II were asked to provide extra measurements at the beginning and end of the study while all participants in Phase III provided these additional outcomes which included measurements of physical and physiological fitness as well as additional blood tests.

Throughout the project, an emphasis was placed on reaching high risk populations and the incorporation of QEPs wherever possible. Beyond the results of this research, the role of the QEP and lessons learned from implementing this community-based strategy will help inform future projects with similar goals to potentially enhance their success.

1.2 Review of Literature

1.2.1 Diabetes and prediabetes in Canada and world-wide

Diabetes is a global epidemic that is prevalent among 9% of adults worldwide[1]. Its treatment and management continue to be a primary objective for health care systems in many countries, including Canada. Diabetes typically takes one of two different forms, type 1 diabetes mellitus and T2D where approximately 90% of global diabetes cases are T2D[1]. In Canada prevalence of diagnosed diabetes was 2.4 million in 2009 and there is a projected increase to 3.7 million by 2019[2,3]. Throughout this thesis, when the term diabetes is used, it encompasses both type 1 and T2D unless specified otherwise. Prediabetes, the known antecedent to T2D, has been on the rise globally and in Canada with prevalence and incidence trends that mirror those of diabetes. The Public Health Agency of Canada (PHAC) estimates that approximately 4 million Canadians (12.5%) between the ages of 40 and 74 have impaired fasting glucose and approximately 1.8 million (5%) have impaired glucose tolerance[2,4]. Both conditions are recognized antecedents to T2D and are commonly included in the definition of prediabetes which refers to a state of suboptimal glycemic control. Investigation among American youth shows that prediabetes and T2D are manifesting in persons at an earlier age, potentially during childhood with a 30.5% overall increase in T2D among youth between 2001 and 2009[5]. These data collectively support the notion that prediabetes and T2D are, indeed, critical health care fields.

Prediabetes and diabetes are associated with significant utilization of health care resources and, in Canada, estimated direct and indirect costs of diabetes plus its complications are projecting to approximately $17 billion by the year 2020[6]. Without alteration to the current health care paradigm in Canada, the government will not be able to manage the overwhelming costs of diabetes and prediabetes on the health care system. Persons with diabetes are 3 times more likely to be admitted to hospital and experience longer durations of admission compared to non-diabetics[2,3]. Alleviation of the burden currently faced by primary care physicians and a commitment to diabetes prevention through targeted

approaches focusing on those at highest risk for developing T2D should translate into amelioration of the impact of this disease on the Canadian health care system.

1.2.2 Brief physiological description of diabetes

As previously stated, there are two primary forms of diabetes. Type 1 diabetes develops as a result of an autoimmune attack of pancreatic beta cells rendering them incapable of producing insulin, a vital hormone for regulation of blood glucose. All persons with type 1 diabetes must take exogenous insulin to manage their glycemia to prevent potentially devastating or lethal consequenses[3]. Type 1 diabetes typically manifests during adolescence or early adulthood. T2D is a disease that commonly affects adults over the age of 40 and is typically associated with unhealthy lifestyle behaviours such as poor diet and physical inactivity[3]. In T2D, chronic hyperglycemia occurs as a result of dysfunctional insulin secretion, defective insulin action, or both[3]. In some cases, T2D may progress to a point where beta cell damage occurs resulting in the inability to produce insulin and complete exogenous insulin dependance[3]. Prediabetes is a state in which the body can still regulate blood glucose effectively but early stages of insulin resistance and impaired insulin sensitivity are present. This is problematic given that persons with prediabetes are free of complications or symptoms typically associated with hyperglycemia. As a result, it is logical to infer that a substantial catchment of individuals with prediabetes remain undiagnosed. These undiagnosed individuals plus the high prevalence of diagnosed prediabetes make this population hugely important for targeted strategies with the goal of T2D prevention.

Table 1: Diagnostic criteria for prediabetes. Adapted from the 2013 CDA Clinical Practice Guidelines[3,7]

Classification	FPG	2hPG in a 75g OGTT	A1C
Normal	≤6.0 mmol/L	≤7.7 mmol/L	<5.7% (ADA), <6.0% (CDA)
Prediabetes	6.1-6.9mmol/L	7.8-11.0mmol/L	5.7-6.4% (ADA), 6.0-6.4% (CDA)
Diabetes (T1 or T2)	≥7.0 mmol/L	≥11.1 mmol/L	≥6.5%
FPG: Fasting Plasma Glucose, IFG: Impaired Fasting Glucose, IGT: Impaired Glucose Tolerance, 2hPG: 2 hour plasma glucose, OGTT: Oral Glucose Tolerance Test			

Diabetes often leads to devastating physical and physiological complications which develop as a result of chronic hyperglycemia. These complications are typically broken down into micro- and macro-vascular complications and they include central and peripheral neuropathy, retinopathy leading to blindness, nephropathy leading to kidney failure, myocardial infarction and stroke as well as erectile dysfunction, lower extremity amputation and death[3]. In 2012, diabetes was attributable to 1.5 million deaths globally and expected to be the 7th leading cause of death world-wide by 2030[1]. Persons with diagnosed diabetes are 3 times more likely to be hospitalized with cardiovascular disease (CVD), 12 times more likely to be hospitalized with end-stage renal disease, and 20 times more likely to require non-traumatic lower limb amputation[2,3].

1.2.3 Ethnospecific Approach

In Canada and in particular in the Greater Toronto Area (GTA), there is an ethnically diverse population composed of specific groups that have demonstrated higher rates of metabolic syndrome, impaired glucose tolerance, abdominal obesity and insulin resistance. More specifically, these groups are those who are of South Asian, Chinese, African, Latin or Aboriginal ancestry [8–14]. It is well documented that individuals of South Asian, Chinese, African-Caribbean, or Aboriginal descent are at 3-5 times increased risk of developing T2D, which can happen at an earlier age and at a body composition typically associated with lower risk in Caucasian populations[8,10,12–14]. In addition, those who are from African-Caribbean descent typically experience diabetes-related complications with increased severity[15]. The causes for ethnic disparity in diabetes prevalence are linked to both genetic and environmental factors[9]. Health system barriers such as socioeconomic status, inaccessibility to health care and lack of health insurance coverage are also likely contributors to prevalence and incidence rates of prediabetes and T2D among these populations[9]. These same barriers likely impact health behaviours such as diet and PA participation thus exacerbating the negative health outcomes experienced[16].Beyond these cultural and health system barriers, the individual themselves must assume some level of responsibility and learn

effective self-management techniques to facilitate changes to their lifestyle and, thus, the possibility for enduring health benefits.

There is limited evidence regarding the use of PA interventions as a management strategy among prediabetes populations from these high-risk groups. South Asian individuals in a large scale study from the United Kingdom have been shown to self-report less PA participation and to be less likely to engage in vigorous PA compared to white Europeans[17]. A recent systematic review of PA and dietary interventions for South Asian populations concluded that evidence for the effectiveness of such interventions regarding T2D prevention is limited and that further evaluations using objective measures are warrented[18]. Among Chinese individuals, the Da Qing study showed that lifestyle intervention involving PA and dietary modification is an effective method for reducing the incidence of T2D over 6 years among prediabetic individuals[19]. In this study, the exercise intervention involved counselling and education regarding increasing PA participation habits as opposed to supervised exercise sessions and these counselling sessions occurred weekly for the first 3 months, monthly for the next 3 months and then every 3 months for the remainder of the study[19]. Studies of African-American populations have shown that African-Americans are less likely to utilize diabetes prevention services and have poorer self-management behaviours[20]. Lifestyle interventions involving PA among African-Americans with T2D have been shown to reduce A1C but this has not been demonstrated in African-American prediabetic populations[21]. In aboriginal populations, PA intervention has been shown to improve various health outcomes such as waist circumference, blood lipid profiles and systolic blood pressure (SBP)[22]. The specific effects of PA on glycemic control among Aboriginal populations with prediabetes have not been described in the literature.

There is a tremendous need for primary prevention strategies in Canada that address these high-risk ethnicities and identify ethno-specific recommendations for the assessment of diabetes risk and for effective community-based programs that are supervised and incorporate PA.

1.2.4 Community-based interventions and the role of health workers

It is clear that a fundamental shift is required from the traditional, physician-centric, health care provision paradigm. This shift should allocate a greater portion of responsibility to auxiliary health care providers in the community to reduce the increasing financial burden and monopolization of health care resources attributable to diabetes treatment and management. For this shift to occur, QEPs, non-allied health care community workers and allied health providers who typically have post-secondary education in health-related fields, must be provided the opportunity to become more engaged in; screening for prediabetes and diabetes, the identification of potential barriers to PA participation, and the implementation of lifestyle-based interventions targeting those at high risk within their community. Successful interventions that take place at the community-level are critically important to investigate and implement. The community-based nature of such interventions are beneficial because, in ideal scenarios, they can reach large catchments of participants, they can alleviate the burden on participants leading to increased participation by being conveniently accessible, they can foster social unity, and they can provide a cost-effective method for providing interventions incorporating group-based activities and education sessions[23–25]. These community-based interventions which adopt an ethno-specific approach could also generate volunteer or employment opportunities beyond directly supervising the intervention itself such as translational services, child minding or public health advocacy and education.

The National Diabetes Prevention Program (NDPP) in the United States which aims to deliver prevention programs modelled after the original Diabetes Prevention Program (DPP)[26] at the community level[27] has recently developed a PA strategy thorough various partnerships, including major support from the YMCA. This program is now providing educational workshops about nutrition and PA and is reaching large numbers of individuals at risk for diabetes but it is still in its infancy and currently lacks the federal funding structure to reach a significant portion of those with prediabetes in the United States[27]. The NDPP represents a solid foundation for a national strategy targeting T2D prevention. It does, however come with some limitations. First, it appears to lack a cultural-specificty component which may

potentially limit the attendance from some populations that may be at high risk for T2D development. Second, the lifestyle portion is implemented by "lifestyle coaches" who only require a 2 day training course on group facilitation, monitoring and the delivery of lifestyle program according to the NDPP curriculum. Success of interventions, such as this would be enhanced if QEPs who possess more specialized and formalized theoretical and practical training (i.e. university undergraduates and post graduates with experience/training in exercise evaluation and intervention strategies) were deployed as opposed to relatively untrained "lifestyle coaches".

Working in the community is not without its challenges. Barriers of trust, child supervision, access to space and perceived competition with other programs are all examples of potential factors which may limit project success. To date, Canada has no national strategy for diabetes prevention through lifestyle intervention or PA, although a few of local strategies that are primarily education-based in Alberta have been successfully implemented and evaluated[28,29].

1.2.5 Assessment of risk factors for T2D and prediabetes

T2D and prediabetes are known to be associated with several modifiable and non-modifiable risk factors, several of which are easily identified through self-report. In order to capture the risk profile of a person at high risk for developing T2D, a fast, simple and low-cost option that is validated against standardized diagnostic blood test scores is an essential tool for programs that aim to identify and engage those at high risk for T2D in preventative programs.

There have been several attempts to develop this type of front-line risk assessment tool. The Finnish Diabetes Risk Score (FINDRISC) questionnaire[30,31] was generated as a product of the Finnish diabetes prevention study[32] and has been modified for use in several different countries. An example of this is the Canadian Diabetes Risk Questionnaire (CANRISK) questionnaire by the Public Health Agency of Canada[33]. The FINDRISC questionnaire was selected as a template for similar questionnaires based on its ability to effectively detect impaired glucose metabolism among Scandinavian populations[30–32].

CANRISK was modified for the Canadian population with the goal of accounting for the greater ethnic diversity compared to that of Finland[33]. CANRISK also includes questions about level of education and, for women, if they had given birth to a large baby (over 9 lb) both of which are known to be associated with T2D risk[33]. Neither the FINDRISC, nor the CANRISK questionnaires used A1C as the primary assessment tool for glycemic control, although CANRISK did include A1C measures in a sub-population during their validation process[30,33,34]. The CANRISK is a statistically valid tool, more accurate than FINDRISC for assessing diabetes risk[34] but it appears to lack in its ability to fully capture PA participation as a predictor for T2D.

1.2.6 Diabetes-Specific blood biomarkers

There are several different approaches typically adopted to determine a person's diabetes status. The Canadian Diabetes Association (CDA) provides diagnostic criteria for diabetes via fasting plasma glucose (FPG), random plasma glucose (RPG), oral glucose tolerance testing (OGTT) and A1C[3] (see Table 1, pg 5). In addition to these criteria, homeostatic model assessments for beta cell function (HOMA-β) and insulin resistance (HOMA-IR) can be used to track improvement or deterioration in glycemic control among study cohorts [35,36].

The CDA recommends that[3];

1. All individuals should be evaluated annually for T2D risk on the basis of demographic and clinical criteria.
2. Screening using FPG and/or A1C should be performed every 3 years in individuals ≥40 years of age. More frequent testing with FPG and/or A1C or 2 hour PG in a 75g OGTT should be considered in those at very high risk determined using a "risk calculator" or in people with additional risk factors such as first degree relative with T2D, ethnicity, history of prediabetes, history of gestational diabetes or presence of vascular risk factors such as atypical blood-lipid profile.

3. Testing using a 2 hour PG 75g OGTT is recommended to identify persons with prediabetes or diabetes if FPG and/or A1C are in the prediabetes range.

There are several advantages and disadvantages to each of the diagnostic blood tests that may be performed. Typically, RPG is not utilized by itself given the large degree of variability and dependence on factors such as stress levels, diet and activity performed prior to the test[3]. If a person has an elevated RPG test, they will require a follow-up FPG, A1C or OGTT to confirm any diagnosis.

FPG is a well-established standard that is fast, easy, relatively inexpensive and predictive of microvascular complications, however, samples are prone to high day-to-day variability, patients must be in a fasted state and the results only reflect a single time point[3]. A 2 hour 75g OGTT is also a well-established standard that is predictive of microvascular complications but is also susceptible to a high degree of day-to-day variability, is expensive, requires a 2 hour time commitment and requires the consumption of an unpalatable glucose beverage[3]. A1C is a relatively new diagnostic tool compared to FPG and OGTT and is typically used because it can be tested at any time of day, it does not require patients to be fasted, it predicts microvascular complications, it is a better predictor of macrovascular complications compared to measures of plasma glucose, it is not susceptible to a high degree of day-to-day variability and it provides a long term indication of glycemic control (3 months) rather than a single time point[3]. That said, A1C is more expensive, potentially misleading in the presence of hemoglobinopathies, may be predisposed to variants in some ethnicities and requires the use of NGSP standardized, validated lab equipment for a diagnosis to be made[3].

HOMA-β and HOMA-IR are composite indicators of beta cell function and insulin resistance, respectively. They have been included in hundreds of publications and validated against several physiological outcomes, including hyperinsulinemic euglycemic clamp protocols[35]. The term HOMA refers to “homeostasis model assessment” and the formulae to calculate these values are derived from

basal glucose and insulin levels using the following equations (units of glucose are mmol/L and insulin (mIU/L)[36];

$$HOMA-\beta\ (\%) = \frac{20\ X\ Insulin}{Glucose-3.5} \qquad HOMA-IR = \frac{Glucose\ X\ Insulin}{22.5}$$

The HOMA model is derived based on a mathematical assessment of beta cell function and insulin resistance using calibrations of 100% for HOMA-β and 1.0 for HOMA-IR as "normal" values. From this assessment, estimates of beta cell function and insulin resistance for any pair of basal plasma glucose and insulin concentrations can be made using this model[35,36]. HOMA models are not intended to act as a stand-alone assessment of glycemic control at a single time point, but rather, a cost-effective approach to detect longitudinal changes among study cohorts and assess diabetes progression or the efficacy of interventions[35].

1.2.7 Current PA recommendations for T2D and prediabetes

Based on a number of large-scale randomized controlled trials, persons with prediabetes should be encouraged to accumulate approximately 150 minutes per week of moderate effort PA plus resistance exercise to build/maintain strength with the goal of reducing diabetes development and complications [3,26,37,38]. These recommendations are in line with current global PA Guidelines endorsed and adopted by the CDA as well as other Canadian and international governing bodies[3,38,39]. Doses of exercise in excess of the recommended 150 minutes per week have not been explored in depth among populations of persons with T2D or prediabetes. That said, higher doses of PA, exceeding the 150 minute recommendation, have been shown to be associated with higher energy expenditure, improved body weight management, improved aerobic fitness and reduced rates of other comorbidities such as CVD or hypertension in addition to all cause mortality[40–43]. However, these volumes of PA participation may not be attainable or practical, especially for community-based PA interventions, especially since only 15% of Canadian adults are meeting the current recommendations of 150 minutes of structured PA and only 35% of Canadian adults are considered adequately active in their accumulation of non-structured PA[44]. In

general, naïve exercisers or sedentary persons should start with low-to-moderate intensity PA with gradual progression to more moderate-to-vigorous intensity PA of longer durations to further improve health.

Two important considerations when implementing any PA intervention for the general population, particularly for those who may be sedentary and at risk for diabetes, are exercise safety and PA literacy or comfort level. Two recent reviews relating to adverse events associated with PA have found very little evidence for any PA related death and a low incidence of non-life threatening adverse events with low to moderate intensity exercise [37,45]. In fact, evidence supports the idea that accumulating greater volumes of exercise over time translates into less mortality and morbidity among persons with diabetes [37,46,47]. In order to minimize potential exercise-related adverse events, all individuals with prediabetes should be assessed for additional risk factors for CVD through the use of evidence-based screening tools such as the PAR-Q+ and ePARmed-X+ (www.eparmedx.com) before commencing a PA regimen[48]. Persons with no additional risk factors or symptoms of CVD do not require further screening before the commencement of PA programs involving low to moderate intensity PA[48]. Persons with symptomatic CVD or those who possess several additional risk factors of CVD may require additional medical screening after the completion of the ePARmed-X+ (www.eparmedx.com)[49]. Higher intensity PA such as sprinting, cross country skiing, snow shoveling, or squash should initially be avoided by previously inactive middle aged or older adults [37].

Prevention of exercise-related adverse events should be prioritized when beginning a PA intervention, especially for someone who has confirmed prediabetes or diabetes. In addition to educating and empowering the individuals themselves, it is imperative to make certain that the QEPs, non-allied health community workers and health care providers are knowledgeable about the absolute and relative contraindications to exercise[50] and the use of proper pre-screening procedures.

1.2.8 Types of PA and their role in T2D management/prevention

Previous investigators have targeted persons with prediabetes utilizing lifestyle modification which includes both dietary intervention and incorporation of continuous aerobic and resistance exercise to

prevent or delay the onset of T2D with highly encouraging results [19,32,51]. It is important to note, however, that these studies are primarily education-based intervention geared towards both diet and PA participation with limited supervision of the PA component. Little is known regarding the effect of PA-based interventions, independent from dietary modification, on specific markers of glycemic control such as A1C in persons with prediabetes. There are, however, several well established mechanisms through which both aerobic and resistance-based exercise can benefit persons with prediabetes via improved insulin sensitivity[52]. These mechanisms include increases in skeletal muscle mass and increased GLUT4 content[53] among others. The majority of these mechanisms have been explored among persons with diagnosed diabetes as opposed to populations of prediabetics or those simply at high risk for T2D. Developing strategies involving both aerobic and resistance exercise to take advantage of these mechanisms and improve one's ability to prevent or delay T2D is a high priority.

High-intensity interval training (HIIT) has become a popular alternative to the more traditional moderate-intensity continuous training approach to aerobic exercise. It is extremely important to use caution when interpreting the findings from HIIT interventions given the high degree of variability in approaches which can all be considered HIIT. All HIIT approaches typically incorporate exercise that is ≥80% maximum HR and can range from very short sprint intervals lasting 30-60 seconds with shorter rest between intervals [54,55] or longer lasting 2-4 minutes with longer rest periods [56]. Evidence from studies using comparable HIIT approaches to that utilized in the present study indicate that HIIT is a more effective method for improving cardiorespiratory fitness, reducing blood pressure, improving blood lipid profiles, and improving insulin sensitivity among persons with lifestyle-induced cardiometabolic chronic diseases[57–59]. That said, among persons with T2D, a recent study showed no difference between moderate and high intensity exercise approaches in their ability to improve A1C[60]. Another study showed improvements in insulin sensitivity after a single bout of continuous moderate intensity aerobic exercise but not after a single bout of sprint-based HIIT[61]. To date, no studies have explored how HIIT and

continuous moderate intensity aerobic exercise differ in their ability to induce improvements in A1C when coupled with resistance training among persons with prediabetes

1.3 Rationale

This project was developed based on the overwhelming need for PA-related interventions that are specific to prediabetes and that target persons from ethnicities known to be at highest risk for developing T2D. Given the high prevalence of prediabetes and ethnocultural diversity in Canada, specifically the GTA, York University was a logical and ideal fit to explore the development of such interventions.

After reviewing the literature and existing programs in the GTA, it was abundantly clear that there were very few, if any, programs that were community-based, culturally-specific PA focused and targeting persons with prediabetes as opposed to those already diagnosed with T2D. In addition to providing a valuable community program, this project can help to fill a void in the body of literature on the subject of risk assessment and PA programming for persons at high risk for T2D.

The known link between prediabetes, T2D and modifiable risk factors such as exercise and PA provides ample reason to fully explore how different forms of these modifiable lifestyle habits can be best utilized to prevent or delay T2D development as long as possible.

Finally, the inclusion of QEPs throughout the project is based on the notion that these professionally trained individuals can provide valuable and effective supervision in various settings, including those that are community-based. Better utilization of QEPs may help to reach a broader catchment of persons at risk for diabetes development and alleviate a portion of the burden on physicians that is currently attributable to prediabetes and T2D.

If successful, prediabetes detection and PA intervention strategies would translate into significant cost savings for the health care system which would allow a re-allocation of resources to bolster other areas of need.

1.4 Objectives and Hypotheses of the Study

1.4.1 General Objectives and Hypotheses

The PRE-PAID project had three primary objectives. The first being a community-based screening initiative that identifies individuals at high risk for T2D by assessing their risk using a risk questionnaire and point-of-care fingerstick blood testing. The second objective of the project was to prevent progression toward T2D by engaging those identified during the screening process in a supervised PA program that is culturally-specific, community-based and supervised by a QEP assisted by a culturally-matched instructor. Finally, the project aims to determine if differences exist between different forms of exercise in their ability to elicit changes in glycemic control among prediabetic participants through a randomized, laboratory-based study design.

It was hypothesized that the screening approach adopted during Phase I would show strong correlation between the risk questionnaire classification and fingerstick A1C values providing evidence that the PRE-PAID screening model accurately predicts the risk of individuals screened. It was also hypothesized that the community-based PA program would elicit positive changes to participants' risk profiles and blood test scores after 6 months of participation. Finally, it was hypothesized that participation in aerobic exercise consisting of high-intensity intervals would induce greater improvements in glycemic control demonstrated by reductions in A1C.

1.4.2 Phase I Objectives and Hypotheses

The objective of Phase I of the PRE-PAID project was to determine if a pen-and-paper questionnaire could accurately capture persons with prediabetes and stratify a person's overall risk for developing T2D in a manner that is comparable to risk classification based on capillary blood A1C measurement.

The hypothesis for Phase I was that the questionnaire would be effective in identifying individuals at risk for the development of T2D and that there would be strong correlation between the questionnaire risk classification and risk classification based on A1C measurement.

1.4.3 Phase II Objectives and Hypotheses

The primary goal of Phase II was to achieve improvements in A1C over a six month period of time among participants identified during Phase I of the PRE-PAID project. Additional measures of physical and physiological fitness and health were also examined in a subset of participants to evaluate potential concurrent health benefits relevant to prediabetes and T2D as well as several other chronic diseases.

The hypotheses for Phase II were that the community-based PA program would be effective in reducing the risk for progression to T2D demonstrated by reductions in A1C after 6 months of participation among a predominantly prediabetic population. It was also expected that, among those who elect to provide secondary outcomes, health-related improvements in fitness and the additional blood biomarkers would be observed.

1.4.4 Phase III Objectives and Hypotheses

The primary aim Phase III of the PRE-PAID project was to investigate the effectiveness of HIIT compared to traditional moderate-intensity continuous training in a prediabetic population with both interventions supplemented by resistance training and the goal of improving glycemic control as measured by A1C. The secondary aim of Phase III was to examine how these two interventions impact body composition, musculoskeletal and aerobic fitness.

The hypotheses for Phase III anticipated that the use of HIIT coupled with resistance training would elicit the greatest reduction in A1C compared to traditional moderate-intensity aerobic training with an identical resistance training component. It was also hypothesized that any reductions in A1C would not be as pronounced as reductions observed in previous studies among persons who were already

diagnosed with T2D. Finally, it was hypothesized that all secondary outcomes, with the exception of strength measures, would show greater improvements among those in the HIIT group compared to those who performed moderate intensity exercise.

CHAPTER 2: OVERALL RESEARCH DESIGN AND METHODOLOGY

The following chapter outlines common methodologies across all phases of the project. The intervention portion of each phase was different and, thus, detailed descriptions of all methodologies specific to each phase are included in the manuscript from each study.

2.1 Participant Recruitment and Screening

All protocols were reviewed and approved by the York University Human Participants Research Subcommittee prior to participant recruitment for each phase of the project. Relevant procedures were also reviewed and approved by York University's Biosafety Officer. Certificates of approval are included in Appendix B.

Participants for Phases I and II were recruited from various community-based locations such as community health centres, religious centres and shopping malls through partnerships with various community agencies. Recruitment strategies for each phase are described in detail within their corresponding manuscript. Communities were selected based cultural demographics and prevalence rates of T2D. Community partners assisted recruitment by providing volunteer support, access to patients/clients and by helping to promote the project during various community outreach events. A list of community partners is included in Appendix C.

Participants for Phase III of the project were recruited from the York University staff population. This was accomplished via email through the York University Staff Association as well as the *Yfile* online daily newsletter.

Prior to any data collection, participants in all phases provided written, informed consent. The consent documents are included in Appendix B and were translated into Chinese, Punjabi and Hindi to enhance clarity during Phases I and II.

Detailed inclusion and exclusion criteria are described in the phase-specific manuscripts but in all phases, persons, aged 18 or older, who were at high risk for prediabetes were targeted during the recruitment process. In all phases, participants possessing any limitation that prevented their involvement in moderate intensity PA were not included. Prior to engagement in any form of PA, participants completed the Physical Activity Readiness Questionnaire (PAR-Q+) which is included in Appendix A. This questionnaire is used to identify any potential contraindications or risks to PA participation. In all

cases, definitions of "normal", "prediabetes" and "diabetes" were based on the American Diabetes Association (ADA) diagnostic criteria.

Once informed consent was received, the screening of participants, during all phases, incorporated a written questionnaire which gathered information about diabetes-specific risk factors combined with a point-of-care fingerstick blood test for A1C. The risk questionnaire was adapted from the, previously validated, FINDRISC and CANRISK questionnaires[30,62]. Slight alterations from the CANRISK questionnaire were made to minimize participant burden by removing questions about fruit and vegetable consumption, level of education and giving birth to a large baby. The questionnaire was also modified in order to include more detailed information (frequency and intensity) regarding the PA habits of those completing the questionnaire. The PRE-PAID questionnaire is included as APPENDIX D. Upon completion of the seven questions, an overall risk score was tabulated, based on a scoring paradigm similar to that of CANRISK, placing individuals into one of five different risk categories; "Small" (score 0–6), "Moderate" (score 7–11), "High" (score 12–14), "Very High" (score 15–20) and "Extreme" (score over 20). Trained members of the research team assisted study participants with questionnaire completion, and all questionnaire responses were based on self-reported information. BMI charts were provided to simplify the estimation of BMI from body mass and height (kg/m^2). Participants were only required to complete the questions that contributed to the calculated risk score. The additional information collected on the questionnaire was used to better describe the study population. The A1C test is described in detail in the "Blood Measures" section (2.2.1).

2.2 Measurements

2.2.1 Blood Measures

Glycated Hemoglobin

The primary blood outcome measure was A1C and it was measured using the Bio-Rad in2it point-of-care device which performs the analysis using boronate affinity chromatography (Bio-Rad

Laboratories, CA, USA). Capillary blood samples (approx. 10µl) were collected via fingerstick using sterile techniques. From a subset of participants, a second sample from the same fingerstick was collected using the Bio-Rad capillary tube (Bio-Rad Laboratories, CA, USA) for analysis by high performance liquid chromatography (HPLC) which is a National Glycohemoglobin Standardization Program (NGSP) approved form of A1C analysis[63]. These analyses were performed by Clearstone Central Laboratories (Mississauga, ON) using the Bio-Rad Variant II Hemoglobin testing system.

A1C was selected as the primary biomarker for inclusion for several reasons; it provides indicator of glycemic control spanning a three month period, it is less variable than fasted blood glucose sampling, and A1C does not require participants to be fasted allowing for more convenient scheduling of participants interested in the study. Results of the A1C tests were interpreted based on both the 2013 CDA Clinical Practice Guidelines diagnostic criteria which define prediabetes using an A1C range of 6.0-6.4% and T2D using an A1C range of ≥6.5%[3] and the American Diabetes Association (ADA) Standards of Medical Care which use an A1C range of 5.7-6.4% for prediabetes and ≥6.5% for diabetes[64]. The specific cut-points used in each of the phases of the project are described in each manuscript. All participants were informed that the results from the blood tests taken for the PRE-PAID project were not designed to provide medical diagnosis of prediabetes or T2D. Individuals who had A1C scores ≥6.5% were provided with a letter describing their results and encouraged to see their primary care physician for further confirmatory testing.

Oral Glucose Tolerance Test

A 75g oral glucose tolerance test (OGTT) was also performed on a sub-set of participants who elected to provide the secondary outcome measures during Phase II and for all participants in Phase III. During Phase II, participants arrived at the laboratory in a fasted state (no food or drink for a minimum of 8 hours) and provided a baseline intravenous blood sample (10mL). Upon sample collection, participants were provided with a 75g dose of glucose (Trutol™, Thermo Scientific, USA) to be consumed within a 5

minute period. Blood samples (5mL) were then drawn every 30 minutes from an indwelling venous catheter so that a single venipuncture was required for the entire test to alleviate the potential burden or discomfort to the participants. Participants were asked to remain seated and refrain from activity during the remainder of the protocol. All blood collection was performed by a trained phlebotomist who in most cases was a registered nurse. Blood samples were delivered to Lifelabs (Lifelabs, ON, Canada) for analysis of the following biomarkers; fasting glucose, fasting insulin, HDL-Cholesterol, LDL-Cholesterol, Total Cholesterol, Triglycerides, HDL:LDL as well as glucose and insulin values for each of the time points (30, 60, 90, and 120 minutes).

During Phase III, slight alterations were made in order to minimize participant burden and discomfort. In this phase, after arriving in a fasted state (no food or caloric drinks for a minimum of 8 hours prior), fingerstick capillary blood was collected and whole blood glucose was analyzed using the OneTouch UltraMini blood glucose monitoring system (LifeScan Canada Ltd. BC, Canada). A second sample of approximately 200µl was collected from the same fingerstick via microvette. The second sample was centrifuged and plasma was separated and stored (-18°C) for the analysis of insulin. The insulin samples were analyzed using a Human Insulin ELISA kit (Abcam®, MA, USA). After the fasting samples were collected, participants consumed a 75g glucose beverage (Trutol^{TM}, Thermo Scientific, USA) within a 5 minute period and were then asked to remain seated and refrain from activity during the remainder of the protocol. After two hours, participants provided a second fingerstick blood sample from a different finger and both the blood glucose and insulin samples were collected. The second sample was only collected for the fasted sample, not after 2 hours.

From the results of the OGTT, the calculation of HOMA-β and HOMA-IR were performed using standard equations[35,36]. These measures provide indirect information about the participants' beta cell function and insulin resistance status. Each of these measures represents an important consideration for prediabetic populations to help describe the participant's overall diabetes risk and potentially predict further disease progression.

2.2.2 Physical and Physiological Fitness Measures

During Phase II and III, physical and physiological fitness were assessed in the sub-set of participants who agreed to come to the laboratory for additional testing in Phase II and among all participants in Phase III. The assessment included measures of anthropometry, body composition, resting heart rate (HR) and blood pressure as well as upper body strength, lower body power and aerobic fitness. Height was measured using a stadiometer and body mass plus percent body fat were measured using a digital scale (Tanita Corporation of America, IL, USA). Waist circumference was measured by a trained exercise professional following the National Institutes of Health (NIH) guidelines[65]. Resting blood pressure and resting HR using the BpTRU™ device (BpTRU™ Medical Devices Ltd. BC Canada). Upper body strength was assessed using a hand grip dynamometer (Takei T.K.K. 5401, Niigata, Japan) and lower body power was measured via vertical jump (Vertec, JumpUSA, CA, USA and Probotics Just Jump Mat, Probotics Inc., AL, USA). A customized, incremental aerobic fitness treadmill walking protocol was used and oxygen consumption (VO_2) was measured by direct analysis of expired gas using open-circuit spirometry (S-3A/II oxygen, CD-3A carbon dioxide; AEI Technologies, Pittsburgh, PA). Aerobic fitness test termination was determined by volitional fatigue. During the aerobic fitness test, HR and VO_2peak were recorded, along with time on treadmill and maximum speed and grade achieved. These fitness protocols are thoroughly described within each manuscript.

2.2.3 Lifestyle Measures

Several additional outcomes were assessed during the various phases of the PRE-PAID project. These additional outcomes are phase-specific and therefore described, in detail, within the manuscript for each component of the study. These outcomes include questionnaires assessing health, acculturation, stress, lifestyle behaviours and quality of life.

CHAPTER 3: MANUSCRIPTS

MANUSCRIPT 1:

The Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Program

CP Rowan, MC Riddell and VK Jamnik. The Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Program. *Canadian Journal of Diabetes.* 2013. (37) 415-419

Contribution of Authors

For this manuscript, CPR was the primary author and was the primary facilitator of data collection and entry, data analysis and interpretation as well as the primary contributor to overall project design and manuscript preparation. CPR was also the point person for developing community partnerships during recruitment. MCR and VKJ provided guidance regarding project design and were involved in the interpretation of the data analysis as well as revision of the manuscript. MCR and VKJ also helped to facilitate community partnerships during project recruitment. VKJ and MCR provided support with data collection

3.1.1 Introduction

The diabetes epidemic is a global health care concern that continues to dominate the attention of health care practitioners, researchers, qualified exercise professionals (QEPs), non-health community workers and policy makers. Over the past two decades, the incidence of prediabetes, which is the precursor to type 2 diabetes (T2D) for most individuals, has been increasing in Canada and projections indicate that based on current lifestyle and population trends, the prevalence of T2D will become financially overwhelming for the current Canadian health care system[6]. Emerging evidence suggests that focussing on lifestyle intervention for prediabetes is more effective and comparatively cost-saving for diabetes prevention compared with pharmacological approaches [19,26,66]. Early insulin therapy in prediabetes is not effective for diabetes prevention or reduction in CVD risk [67]. Moreover, based on results from the US Look AHEAD trial, intensive lifestyle intervention after diabetes diagnosis typically fails to cause disease remission [68], although it can reduce body adiposity obesity and improve glycemic control in patients who already have T2D [69].

The Public Health Agency of Canada estimates that approximately 4 million Canadians (12.5%) between the ages of 40 and 74 have impaired fasting glucose and approximately 1.8 million (5%) have impaired glucose tolerance [4]. Both conditions are recognized antecedents to T2D and are commonly included in the definition of prediabetes which refers to a state of suboptimal glycemic control. The study of lifestyle intervention on prediabetes, specifically, is a relatively new research area and the majority of theories and knowledge have been adapted from what has been shown in people with T2D. Physical activity (PA) can elicit several positive outcomes in persons with T2D including; improved glycemic control, improved insulin sensitivity, and reductions in diabetes-related comorbidities such as CVD [52]. Despite prediabetes emerging as a specific research area, research typically uses progression to T2D as the primary outcome and, consequently, the role of PA has yet to be fully explored with respect to quantifying the potential improvements in glycemic control, as measured by A1C in persons with prediabetes[19,26,66]. Furthermore, the majority of studies involving PA in pre-diabetic populations involve lifestyle modification which

includes BOTH PA intervention and dietary modification[19,26,66]. While dietary modification is an important and recommended addition to any PA regimen, the authors seek to determine the effect of PA on glycemic control, independent of any modification to diet in order to inform the allocation of future resources put towards T2D prevention. In Ontario, while there exists several diabetes awareness programs that may be culturally appropriate, they are primarily education-based and there lacks a PA specific approach that offers structured opportunities to become active at the community level in an environment where the PA is provided by people who are qualified to recommend and supervise these programs. Culturally appropriate PA options, such as group fitness classes offered in different languages that utilize music and movements specific to different cultures, may be more enjoyable, may provide a more comfortable environment, and may enhance adherence to PA compared to conventional exercise sessions.

This paper presents important perspectives regarding front-line screening to detect individuals with prediabetes and provides strategies for implementing culturally appropriate PA interventions to reduce the incidence of T2D.

3.1.2 A Culturally Appropriate Approach

Canada has an ethnically diverse population composed of specific groups that have demonstrated higher rates of metabolic syndrome, impaired glucose tolerance, abdominal obesity and insulin resistance. More specifically, these groups are those who are of South Asian, Chinese, African, Latin or Aboriginal ancestry [8–14]. It is believed that the causes for ethnic disparity in diabetes prevalence are linked to both genetic and environmental factors [9]. There are also health system barriers such as socioeconomic status, inaccessibility to health care and lack of health insurance coverage [9]. These same barriers likely impact health behaviours [16].

There is limited evidence regarding the use of PA, specifically, among prediabetes populations among these high-risk groups. South Asian individuals in a large scale study from the United Kingdom have

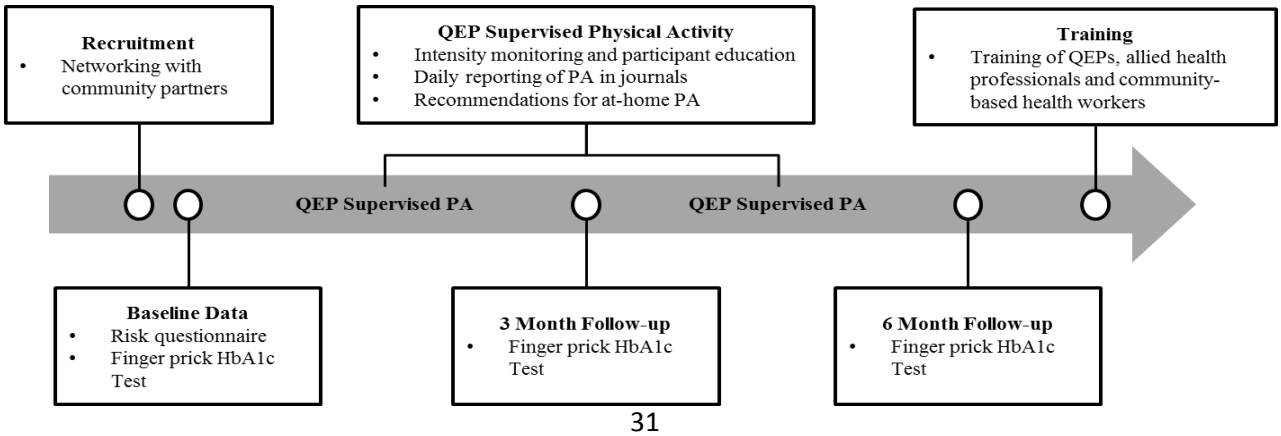
been shown to self-report less PA participation and to be less likely to engage in vigorous PA compared to white Europeans[17]. A recent systematic review of PA and dietary interventions for South Asian populations concluded that evidence for the effectiveness of such interventions regarding T2D prevention is limited and that further evaluations using objective measures are warrented[18]. Among Chinese individuals, the Da Qing study showed that lifestyle intervention involving PA and dietary modification is an effective method for reducing the incidence of T2D over 6 years among pre-diabetic individuals[19]. Studies of African-American populations have shown that African-Americans are less likely to utilize diabetes prevention services and have poorer self-management behaviours[20]. Lifestyle interventions involving PA among African-Americans with T2D have been shown to reduce A1C but this has not been demonstrated in pre-diabetic populations[21]. In aboriginal populations, PA intervention has been shown to improve various health outcomes such as waist circumference, blood lipid profiles and SBP[22]. The specific effects of PA on glycemic control among Aboriginal populations with prediabetes have not been described in the literature.

3.1.3 The Role of Community Health Employees:

It would appear that fundamental shift is required from the traditional, physician-centric, health care provision paradigm such that a greater portion of responsibility falls on other health care providers in the community to reduce the increasing financial burden and monopolization of health care resources attributable to diabetes treatment and management. For this shift to occur, QEPs, non-allied health care community workers, health care and allied health providers who typically have post-secondary education in health-related fields, must be provided the opportunity to become more engaged in screening for prediabetes and diabetes as well as the identification of potential barriers to PA participation within their community. The evidence-based CDA Clinical Practice Guidelines (CPG)[3] include information pertinent to all health care providers for the implementation of PA prescriptions involving aerobic and resistance exercise. It should be noted that the majority of information provided by the CPG is directed toward individuals with diagnosed diabetes, rather than prediabetes, although the minimum prescription of PA

for the prevention of diabetes is likely identical to that prescribed for patients with a diabetes diagnosis (i.e. 150 minutes of accumulated aerobic exercise plus resistance exercise 2-3 times per week). The National Diabetes Prevention Program (NDPP) in the United States which aims to deliver prevention programs modelled after the original Diabetes Prevention Program (DPP)[26] at the community level[27] has recently developed a PA strategy thorough various partnerships, including major support from the YMCA. This program is now providing educational workshops about nutrition and PA and is reaching large numbers of individuals at risk for diabetes but it is still in its infancy and currently lacks the federal funding structure to reach a significant portion of those with prediabetes in the United States [27]. The NDPP represents a solid foundation for a national strategy targeting T2D prevention. It does, however come with some limitations. First, it appears to lack a cultural component which may potentially limit the attendance from some populations that may be at high risk for diabetes development. Second, the lifestyle portion is implemented by "lifestyle coaches" who only require a 2 day training course on group facilitation, monitoring and the delivery of lifestyle program according to the NDPP curriculum. It is the opinion of the authors that PA recommendations to individuals who could potentially be at elevated risk for an adverse event associated with PA participation should be made by QEPs who possess more specialized and formalized theoretical and practical training (i.e. university undergraduates and post graduates with experience/training in exercise evaluation and intervention strategies). To date, Canada has no national strategy for diabetes prevention through lifestyle intervention or PA, although a few of local strategies have been successfully implemented and evaluated[28,29].

Figure 1: PRE-PAID project illustrated pathway of participation. The boxes on the top of the arrow represent the overview of project participation while the boxes below the arrow represent the three different data collection time points.



3.1.4 The Pre-diabetes Detection and Physical Activity Intervention Delivery Project (PRE-PAID):

The PRE-PAID project is a multi-phase initiative, funded by the Ontario Ministry of Health Promotion and the Ontario Trillium Foundation, commencing in the GTA. PRE-PAID focusses on identifying persons who have prediabetes. Culturally appropriate and preferred PA interventions are provided at the community level to help improve biomarkers for glycemic control and, theoretically, prevent or delay the progression to T2D. The PRE-PAID project also features a training component for QEPs and other community workers that deploy the targeted screening process and prediabetes specific education pertaining to PA recommendations for high risk populations. This training takes place via a series of educational workshops focusing on the assessment of prediabetes risk, the utilization of point-of-care blood testing equipment and specific recommendations for safe and effective PA prescription and pre-screening. Figure 1 depicts the PRE-PAID approach to prediabetes screening and PA intervention and this paper provides details regarding participant recruitment, screening and the initial phases of PA intervention delivery. Follow-up data collection is on-going and will not be addressed in this publication.

Recruitment took place in various locations within the target communities through the establishment of partnerships with existing community service providers. Details regarding the recruitment process are described, in detail, in a latter section of this paper. Communities were selected using the most recent data (2001/2002) from the Institute of Clinical Evaluative Studies (ICES) [70] that provided mapped information regarding diabetes prevalence in the GTA. The communities with highest diabetes prevalence were selected because they also possessed the greatest percentage of the target, high risk ethnicities (South Asians, Chinese and African-Caribbean). While the ICES data is based on persons with diagnosed diabetes, the rates of prediabetes are thought to be highly correlated. Additionally, a community in the Sault Ste. Marie region was selected to participate in the project to capture information from an on-reserve Aboriginal population.

3.1.5 Risk Factors and Screening for Prediabetes and Diabetes:

The first step in PRE-PAID risk assessment process is the administration of a prediabetes risk questionnaire that has been modified from the CANRISK questionnaire[62] developed by the Public Health Agency of Canada, to reduce participant burden and to include a slightly more descriptive question about PA participation. The questionnaire, through seven questions, identifies various risk factors for prediabetes including a detailed assessment of PA patterns and provides a risk classification score ranging from 0 – 25. Immediately following the administration of the risk questionnaire, the PRE-PAID approach then utilizes point-of care A1C (Bio-rad Laboratories, Hercules CA, USA: in2it analyzer) as the primary blood screening measure of glycemic control. This measurement device is recommended due to the ease with which blood samples can be collected, the short analysis time (10 minutes), and because individuals being screened do not need to be in a fasted state for the test. Combining self-reported risk factor assessment (modified CANRISK questionnaire) with a reasonably reliable physiological biomarker (A1C) provides a detailed front-line assessment of the individual's metabolic risk (normal, pre diabetic, diabetic).

Demographic data from the PRE-PAID questionnaire are highly informative and in line with expectations related risk factor prevalence. Table 2 provides a summary of the questionnaire results from 691 PRE-PAID participants. It should be noted that the sample was predominantly female (73%) which may be a result of tendencies for females to demonstrate increased health-seeking behaviours for chronic conditions [71]. Of particular importance are that; 56% of participants self-reported that they were physically active only 2x/week or less, 66% of respondents had a family history of diabetes and the average risk score from the questionnaire was 9.6 which coincides with the occurrence of 3-5 known diabetes risk factors. Mean (± standard deviation) point-of-care A1C was 6.0% ± 0.90 which falls within the ADA range for prediabetes [64]. Comparing various communities showed that the least healthy communities based on mean questionnaire risk classification score and mean A1C were one of the Toronto communities (Jane-Finch) and the Sault Ste Marie (Garden River) Aboriginal community. Both had mean risk questionnaire scores over 12 (High Risk) and A1C values ≥6.1%. These communities also had the highest self-reported levels

of physical inactivity, previous diagnoses of hypertension and hyperglycemia as well as the highest percentage of participants with family history of diabetes. Socioeconomic status was not included on the risk questionnaire but the selected communities, based on the ICES data [70], had among the highest rates of unemployment, lowest household incomes, and lowest percentage of the population completing high school in the entire GTA.

Table 2: PRE-PAID participant demographics (males and females combined) and summary of risk factor identification results acquired from the risk questionnaire during recruitment/baseline screening. Results are shown as totals as well as percentages.

	Total (n)	% of Subjects
Sex		
Male	187	27
Female	504	73
Ethnicity		
African Caribbean	306	45
South Asian	110	16
Chinese	145	21
Caucasian	57	8
Aboriginal	30	4
Other	35	5
PA Participation /week		
Rarely/Never	160	24
1 or 2	219	32
3+	299	44
Previous Diagnosis of High Blood Pressure		
Yes	210	31
No	473	69
Previous Diagnosis of High Blood Sugar		
Yes	101	15
No	576	85
Family History of Diabetes		
None	229	34
Distant Relative	138	20
Immediate Relative	307	46
Risk Classification*		
Small	211	31
Moderate	240	35
High	104	15
Very High	106	15
Extreme	29	4

*Small refers to a questionnaire score of <7, Moderate 7-11, High 12-14, Very High 15-19, Extreme 20-25. Increasing score coincides with increased self-reporting of known T2D risk factors.

3.1.6 Risks with Physical Activity and Exercise Participation:

One important consideration when implementing any PA intervention for the general population, particularly for those who may be at risk for diabetes, is exercise safety. Two recent reviews relating to adverse events associated with PA have found very little evidence for any PA related death and a low incidence of non-life threatening adverse events with low to moderate intensity exercise [37,45]. In fact, evidence supports the idea that accumulating greater volumes of exercise over time translates into less mortality and morbidity among persons with diabetes [37,46,47].

Prevention of exercise-related adverse events should be prioritized when beginning a PA intervention, especially for someone who has confirmed prediabetes or diabetes. It is imperative to make certain that the QEPs, non-allied health community workers and health care providers are knowledgeable about the absolute and relative contraindications to exercise[50] and the use of proper pre-screening procedures.

3.1.7 Physical Activity Recommendations for Persons with Pre-diabetes:

In order to minimize potential exercise-related adverse events, all individuals with prediabetes should be assessed for additional risk factors for CVD through the use of the PAR-Q+ and ePARmed-X+ before commencing a PA regimen[48]. Persons with no additional risk factors or symptoms of CVD do not require further screening before the commencement of PA programs involving low to moderate intensity PA[48]. Persons with symptomatic CVD or those who possess several additional risk factors of CVD may require additional medical screening after the completion of the ePARmed-X+[49]. Higher intensity PA such as sprinting, cross country skiing, snow shoveling, or squash should initially be avoided by previously inactive middle aged or older adults [37]. Based on a limited number of large-scale randomized controlled trials, persons with prediabetes should be encouraged to accumulate approximately 150 minutes per week of light-to-moderate effort PA to induce reductions in diabetes development [3,26,37,38]. These recommendations are in line with current global PA Guidelines endorsed by the CDA as well as other Canadian and international governing bodies[3,38,39]. The effectiveness of more moderate-to-vigorous

aerobic exercise or of resistance training is unknown but in general, naïve exercisers or sedentary persons should start with low-to-moderate intensity PA with gradual progression to more moderate-to-vigorous intensity PA to further improve health.

3.1.8 Lessons Learned from the PRE-PAID Project: Implementation and Monitoring of a Community-based Program:

Various methods of participant recruitment were utilized by the PRE-PAID team. Initial recruitment efforts consisted of a relatively low-visibility presence in shopping centres and signage/flyers in various high traffic community locations such as physician offices and recreation centres. It was clear that individuals in the community were skeptical or disinterested in becoming involved with the program. After limited success, a different approach was adopted that emphasized partnership with various organizations within the target communities, more specifically, community health centres, churches and other organizations mandated towards the provision of health programming to their community. Through these partnerships, access to participants in previous programs, dissemination of project information as well as facilitation of screening events was possible. The highest yielding screening events were those held in conjunction with other programming offered by partner organizations. Moreover, the community partners provided space and volunteer resources to assist with screening and PA program implementation through existing networks within the community. Partnership with community service providers provided credibility and trust that were essential to the success of the screening initiative. Participants were much more willing to be involved in both the screening and PA intervention components knowing that there was alignment with a known community organization.

The PA portion of the intervention differed across the several targeted catchment areas and varied based on the ethno-cultural background of each group. Upon completion of pre-exercise screening using the PAR-Q+, informal evaluations of participant PA programming identified specific activities that were deemed “culturally preferred”. These activities ranged from, tai chi and line-dancing in the Chinese

groups, to group fitness classes that incorporated culturally appropriate music and dance styles such as *Socasize or Bollyfit* and aimed to meet the PA guidelines set forth by the CDA and CSEP. In most cases, additional body-weight resistance training exercises were added to supplement the largely aerobic based classes. Highest adherence rates were among the Chinese participants and one of the African-Caribbean groups (Malvern Community, Toronto) which has continued the program beyond the PRE-PAID team's involvement. In general, the culturally appropriate approach was met with extremely positive feedback from the participants. Additionally, the inclusion of child-minding services provided by our community partners proved to greatly enhance the interest and attendance of the PA classes.

Facilitation of these PA classes was always supervised by a QEP with assistance from specialized, culturally matched, group fitness instructors as well as other community volunteers for duties such as child minding. The QEPs were matched to each intervention group based on ethno-cultural background and were tasked with providing continuous feedback and education regarding PA intensity monitoring during classes. They also gave recommendations for PA options to be performed outside the group classes. Intensity monitoring was performed predominantly using rating of perceived exertion with the goal of achieving 12-13 on the 15 point Borg Scale (6-20). In a subgroup of participants, HR and oxygen consumption data were collected which confirmed that moderate intensities were being elicited in these classes (METs $\geq$5). PA journals were also provided to participants to record their activity throughout the duration of their involvement in the program and to assist the PRE-PAID team with program evaluation. Many of these monitoring responsibilities could be taken on by other non-QEP community health workers while the QEP remains an "arm's length" consultant for all exercise screening and prescription.

3.1.9 Summary

As the prevalence of prediabetes continues to grow in Canada, so too must the number of targeted prevention strategies aimed at helping people improve their lifestyle through the inclusion of regular PA. Access to health care and allied health professionals is typically limited to brief appointments with

primary care physicians or nurse practitioners who often have inadequate education pertaining to specific PA recommendations for persons at high risk for developing a chronic disease. Detection of prediabetes is the first step toward diabetes prevention and by advancing the role of QEPs and other non-health related community workers, the capacity to provide screening opportunities and PA interventions at the community level would be enhanced. Findings from the PRE-PAID project emphasize the need for effective community partnership and help to inform further community-based PA intervention program targeting people with prediabetes, especially those from high risk ethnicities, living in communities known to possess higher rates of diabetes.

3.1.10 Acknowledgements

The authors would like to thank PRE-PAID participants, volunteers and community partners. Funding for this initiative was provided by the Ontario Ministry of Health Promotion and Sport, as well as the Ontario Trillium Foundation.

MANUSCRIPT 2:

Identifying persons at risk for developing type 2 diabetes in a concentrated population of high risk ethnicities in Canada using a risk assessment questionnaire and point-of-care capillary blood HbA_{1c} measurement

CP Rowan, LA Miadovnik, MC Riddell, MA Rotondi, N Gledhill, VK Jamnik. Identifying persons at risk for developing type 2 diabetes in a concentrated population of high risk ethnicities in Canada using a risk assessment questionnaire and point-of-care capillary blood HbA 1c measurement. *BMC Public Health*. 2014;14(929):1-9. doi:10.1186/1471-2458-14-929

Contribution of Authors

CPR, NG, MCR and VKJ initiated and designed the study while MAR was involved in consultation regarding data analyses. CPR, LM and VKJ were all involved in data collection. CPR, LM and MAR analysed and interpreted the data. CPR with input from LM composed the first draft of the manuscript while CPR, LM, MAR, MCR, NG and VKJ all contributed revisions. All authors approved the final version of the manuscript prior to submission

3.2.1 Background

Type 2 diabetes (T2D) mellitus in Canada is rapidly progressing into a dire situation with enormous public health and economic implications. As of 2009, approximately 2.4 million Canadians were living with a diagnosis of T2D, a number that is expected to grow to approximately 3.7 million by 2019[2]. Perhaps of greater concern is that approximately 20% of T2D cases remain undiagnosed in addition to more than 5 million Canadian adults with prediabetes [2]. The economic burden of diabetes and its antecedent condition, prediabetes, is unsustainable moving into the future. The Canadian Diabetes Association (CDA) reports that the 2009 cost of T2D and its complications was $12.2 billion and forecasts an additional $4.7 billion in costs by 2020 [6]. This projected cost underscores the urgent need to identify those who are undiagnosed or who have prediabetes so that progression toward a T2D diagnosis can be avoided or, at the very least, delayed.

T2D is acknowledged to be a preventable condition, a premise that is substantiated by seminal randomized clinical trials [19,32,51]. The Diabetes Prevention Program is widely recognized as a landmark research study which showed a 58% reduction in diabetes incidence over a 4 year time frame among individuals with prediabetes who participated in a lifestyle intervention involving PA and nutritional counselling[51]. From a public health perspective, the first step in the prevention process, should be the identification of frequently occurring risk factors for T2D, including: age ≥40 years, family history of T2D, history of gestational diabetes, poor blood lipid profile, hypertension, abdominal obesity, physical inactivity and being a member of a high-risk population such as persons of Aboriginal, South Asian, Chinese, or African descent [3]. Of particular interest are those risk factors that are directly modifiable through lifestyle interventions such as abdominal obesity, hypertension, blood lipid profile and PA level. Identification of these risk factors not only provides an assessment of diabetes risk, but also acts as an important first step providing awareness and education with the goal of eliciting healthy lifestyle changes. As it pertains to disease management [72,73], the type and volume of PA has been widely studied among those with T2D but little is known about the result of PA interventions for those with prediabetes. Also,

programs that are designed to be culturally specific and community-based may provide a unique opportunity to offer screening and intervention opportunities to individuals at highest risk[74], although the effectiveness of such programs as interventions has yet to be studied. An effective exercise prescription showing an appreciation for the various physiological adaptations to regular aerobic and resistance training as they pertain to T2D prevention is essential[52]. For persons with prediabetes and T2D, the CDA[3] and ADA[75] recommends participation in a minimum of 150 minutes of moderate intensity (50-70% age-predicted maximum HR) aerobic PA per week such as brisk walking, cycling or water aerobics in addition to resistance training exercises 2–3 times per week using weight machines, free weights or body-weight exercises.

There have been several attempts to create a front-line risk assessment tool that can readily identify those at highest risk for developing T2D. The Finnish Diabetes Risk Score (FINDRISC) questionnaire was generated in Finland as a product of the Finnish diabetes prevention study and it has been modified for use in several different countries, such as the Canadian Diabetes Risk Questionnaire (CANRISK) questionnaire by the Public Health Agency of Canada. The FINDRISC questionnaire was selected as a template based on its ability to effectively detect impaired glucose metabolism among Scandinavian populations[30,31]. CANRISK was modified for the Canadian population with the goal of accounting for the greater ethnic diversity compared to that of Finland[33]. CANRISK also includes questions about level of education and, for women, if they had given birth to a large baby (over 9 lb) both of which are known to be associated with T2D risk[33]. Neither the FINDRISC, nor the CANRISK questionnaires used A1C as the primary assessment tool for glycemic control, although CANRISK did include A1C measures in a sub-population[31,33,34].

Regardless of the questionnaire being used, a fast, simple and low-cost option for detecting T2D risk that is validated against standardized diagnostic blood test scores is an essential tool for programs that aim to reduce the incidence of T2D. The purpose of this investigation was to test the hypothesis that a pen and paper risk questionnaire could accurately capture T2D risk factor profiles and stratify a person's overall

risk for developing T2D that is comparable to results of a capillary blood test for A1C collected via fingerstick.

3.2.2 Methods

3.2.2.1 Study design

The Prediabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) project focuses on the detection of individuals at high risk for developing T2D using a community-based public health approach. The mandate of the PRE-PAID program was to focus efforts on ethnicities known to be at elevated risk for developing T2D, which include persons of South Asian, African-Caribbean, Chinese and Aboriginal descent.

Selected communities had an elevated prevalence of T2D and a concentrated population of high risk ethnicities. Demographic information was taken from the Institute for Clinical Evaluative Sciences diabetes atlas for the city of Toronto which provided information about diabetes incidence and prevalence by neighbourhood as well as a breakdown of the population by ethnicity[70]. Study participants were recruited through an established network of community partnerships with various organizations that provide public health-related programs to their constituents. Participants were recruited through printed materials, e-mail distribution lists and public diabetes screening events held in high-traffic areas such as shopping malls and community health centres. All participants provided written, informed consent prior to collection of data and all protocols utilized by the PRE-PAID project were approved by the York University Human Participants Review Committee.

3.2.2.2 Questionnaire design

The FINDRISC and CANRISK questionnaires provided a detailed and well-established framework upon which the PRE-PAID risk questionnaire was modeled. Slight alterations from the CANRISK

questionnaire were made to minimize participant burden by removing questions about fruit and vegetable consumption, level of education and giving birth to a large baby. The PRE-PAID investigators opted to streamline the time taken to complete the questionnaire due to the fact that the capillary blood testing immediately followed its completion and some participants may have been lost due to the additional 15 minute commitment for the blood testing component. The questionnaire was also modified in order to include more detailed information (frequency and intensity) regarding the PA habits of those completing the questionnaire. These changes were also adopted as a result of the published validation of the CANRISK questionnaire which showed that the question regarding fruit and vegetable consumption, PA and macrosomia (birth to a large baby) were not significant contributors to their logistic regression model[34]. The PRE-PAID questionnaire is included as Appendix D. Upon completion of the seven questions, an overall risk score was tabulated, based on a scoring paradigm similar to that of CANRISK, placing individuals into one of five different risk categories; "Small" (score 0–6), "Moderate" (score 7–11), "High" (score 12–14), "Very High" (score 15–20) and "Extreme" (score over 20). Trained members of the research team assisted study participants with questionnaire completion, and all questionnaire responses were based on self-reported information. BMI charts were provided to simplify the estimation of BMI from body mass and height (Kg/m^2). Participants were only required to complete the questions that contributed to the calculated risk score. The PRE-PAID questionnaire included space to self-report specific values for height, body mass, age and waist circumference. The inclusion of these values was encouraged to allow future analysis of participant demographics, but not required to attain a complete risk score.

3.2.2.3 Study participants

Persons were considered eligible for inclusion if they were over 18 years of age and if they did not possess any condition that would preclude them from having a capillary blood test to assess their glycemic control. English language proficiency was encouraged but not essential as the questionnaire was

translated into Chinese (simplified and traditional), Punjabi, and Hindi. A total of 691 individuals were recruited in this study.

3.2.2.4 Blood testing

Point-of-care fingerstick capillary blood testing was performed to validate the risk questionnaire outcomes. A1C was selected as the primary blood biomarker because it is a simple, minimally invasive measure that does not require the person to be in a fasted state, thus allowing for flexible testing capabilities. A1C is an indicator of three-month glycemic control and is less variable than fasted blood glucose sampling on a day-to-day basis. A1C has also been adopted as part of the prediabetes and type 2 diagnostic criteria by CDA as well as the ADA[3,64]. For these reasons, A1C is a highly appropriate biomarker for the evaluating the validity of the risk questionnaire.

A1C was analyzed using the Bio-Rad in2it (Bio-Rad Laboratories, Hercules, CA) point-of-care device and boronate affinity chromatography. All capillary blood samples were collected by a trained phlebotomist and sterile techniques were utilized in accordance with York University biosafety and ethics requirements. In a sub-set of individuals, a second A1C sample (from the same fingerstick) was collected using Bio-Rad capillary tubes for analysis using high-performance liquid chromatography (HPLC), a standardized A1C analysis criterion method that is in accordance with National Glycohemoglobin Standardization Program regulations. The HPLC analyses described above were performed by Clearstone Central Laboratories (Mississauga, ON) using the Bio-Rad Variant II Hemoglobin testing system.

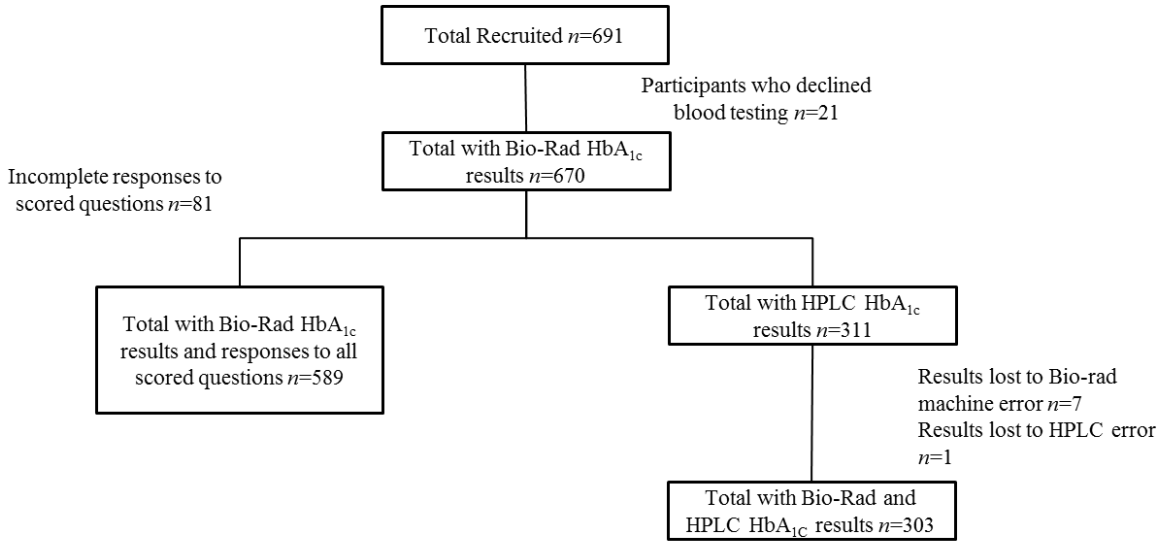
Results of the A1C tests were interpreted based on the 2013 CDA clinical practice guidelines diagnostic criteria[3] which define prediabetes using an A1C range of 6.0-6.4% and T2D using an A1C range of ≥6.5%[3]. It should be noted that the ADA use an A1C range of 5.7-6.4% for prediabetes and ≥6.5% for diabetes[64]. Participants were informed that the results from the blood tests taken for the PRE-PAID project were not designed to provide medical diagnosis of prediabetes or T2D. Individuals who had A1C

scores ≥6.5% were provided with a letter describing their results and encouraged to see their primary care physician for further confirmatory testing.

3.2.2.5 Statistical analyses

Descriptive statistics as well as frequencies of questionnaire responses were analyzed for all participants who completed the risk questionnaire. Various exclusions within the dataset took place for further analyses based on missing data that was attributable to participant error, data entry error, or the participant's unwillingness to provide a blood sample. Figure 2 shows the participant flow diagram for the PRE-PAID risk questionnaire administration. A comparison of the two methods for determining A1C

Figure 2:PRE-PAID Project participant recruitment and inclusion in the data analyses



was performed using the Bland-Altman method[76] to detect any potential biases between the two methods of analysis. All analyses described in this investigation were performed using a two-sided 5% level for significance.

ANOVA with post-hoc pairwise comparisons was performed using Tamhane's T_2 approach, which allows for unequal variances to compare risk classification based on the questionnaire score to mean A1C measured using the Bio-Rad device. Prior to analysis, the "Very High" and "Extreme" groups were

merged because of a very small number of participants falling within the "Extreme" classification. From a clinical perspective, individuals within both of the highest risk groups would be strongly encouraged to visit a physician for further assessment regardless. In addition to the ANOVA, additional analyses including the area under the receiver-operator curve and examination of sensitivity and specificity were performed to examine reliability. These analyses used a cut-point of 6.5 which corresponds to the "moderate" risk category to better describe the ability of the risk questionnaire to predict dysglycemia defined by A1C $\geq$ 6.0%.

Finally, step-wise, backward elimination linear regression was performed to quantify the amount of variance in A1C values that was attributable to each of the variables included on the risk questionnaire. The Bland Altman plots were performed using GraphPad Prism 6 and all other analyses were performed using SPSS version 20.

3.2.3 Results

3.2.3.1 Study participants

A total of 691 participants completed the risk questionnaire. The participants were primarily female (71%) and 83% of participants reported having two parents from an ethnicity known to be at high-risk for developing T2D.

3.2.3.2 Questionnaire results

The mean overall risk score for all participants was 9.7 ± 5.3 (mean ± SD) which corresponds to the "Moderate" risk classification. Notable findings include 44.1% of the respondents reported to be physically active 3 or more times per week compared to 33.1% who reported once or twice per week and 22.8% reported being physically active rarely or never. In terms of body composition, self-reported BMI results show that 43.6% fall into the normal range (BMI <25) while 33.3% were overweight (BMI 25–29)

and 23.1% were obese (BMI ≥30) based on World Health Organization BMI cut points for adults[77]. The adjusted cut points for Asian populations[78] were not used because of the heterogeneity of the participant population. Also of note, 28.9% of participants reported having been told that they have high blood pressure by a physician and 14.8% of participants responded "yes" to having been told by a physician that they have high blood sugar. Finally, 65.5% of participants noted that they had a family history of diabetes and among these participants, 68.4% noted that this was an immediate relative (mother, father, brother, sister or own child). Based on the overall risk score, 30.2% of participants fell into the "Small" risk category, 33.1% into the "Moderate" risk category, 16.5% into the "High" risk category, 15.4% into the "Very High" risk category, and 4.8% into the "Extreme" risk category. The frequency data from the questionnaire responses are summarized in Table 3 along with descriptive data for questionnaire and blood test outcomes.

Table 3: Summary of questionnaire and capillary blood testing outcomes (both males and females combined)

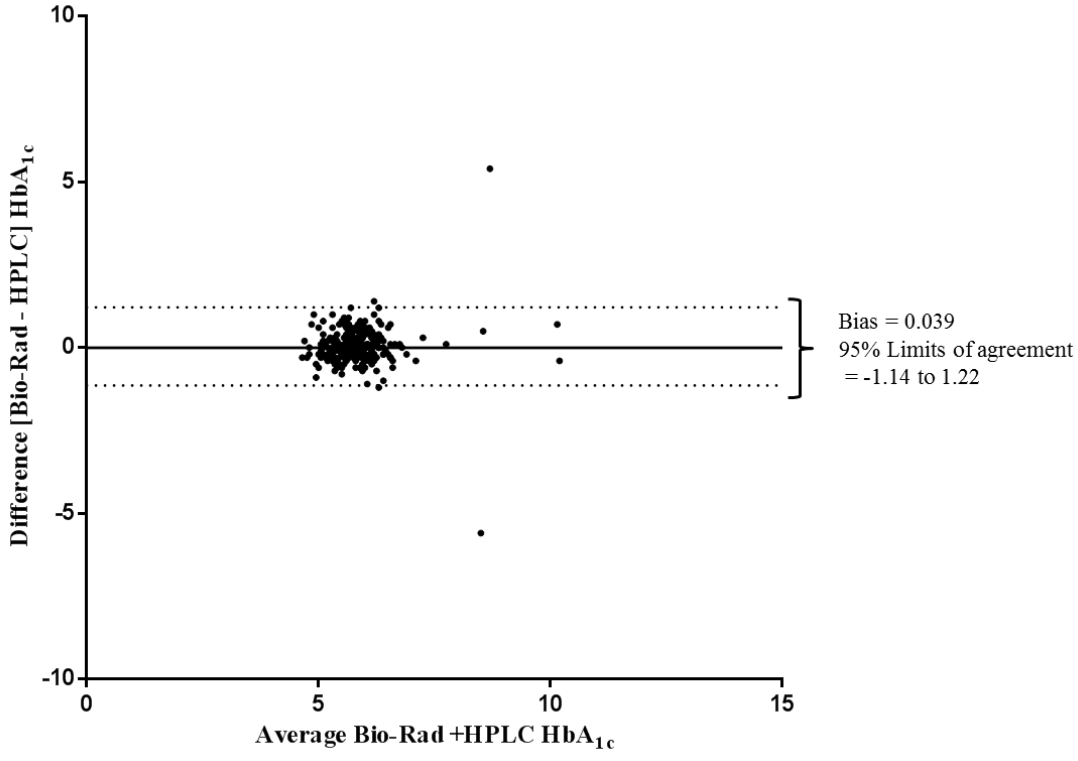
Questionnaire Item	Response	Frequency (*n*)	Percent (%)
Sex	Female	418	71
	Male	171	29
Number of high risk parents	None	86	14.6
	One	14	2.4
	Two	489	83
Age categories	<40	190	32.3
	40-44	68	11.5
	45-54	142	24.1
	55-64	131	22.2
	65+	58	9.8
BMI (Kg/m^2)	<25	257	43.6
	25-29.9	196	33.3
	30+	136	23.1
Waist circumference*	Healthy	245	41.6
	Overweight	150	25.5
	Obese	194	32.9
PA participation	3+ Times per week	260	44.1
	1 or 2 Times per week	195	33.1
	Rarely or Never	134	22.8
High blood pressure	No	419	71.1
	Yes	170	28.9
High blood sugar	No	502	85.2
	Yes	87	14.8
Family history of diabetes	None	203	34.5
	2^{nd} degree relative	122	20.7
	1^{st} degree relative	264	44.8
Risk classification	Small	178	30.2
	Moderate	195	33.1
	High	97	16.5
	Very High	91	15.4
	Extreme	28	4.8
Descriptive Variables	***n***	**Mean**	**Std. Deviation**
Bio-Rad A1C %	670	5.99	0.84
HPLC A1C %	311	5.81	0.97
Questionnaire Score	589	9.7	5.4
*Waist circumference range	Males	Females	
Healthy	<94 cm	<80cm	
Overweight	94-102cm	80-88cm	
Obese	>102cm	>88cm	

3.2.3.3 Blood results

A total of 670 people went on to provide a capillary blood sample using the Bio-Rad point-of-care device after completing the risk questionnaire. From this group, a subset of 311 provided a sample for analysis using HPLC. The mean Bio-Rad A1C (n = 670) was 5.99 ± 0.84% while the mean HPLC value was 5.81 ± 0.97%.

Analysis comparing the A1C scores collected using the two different methods (Bio-Rad and HPLC) took place for 303 persons and Figure 3 provides a Bland-Altman plot that describes the relationship between the two test measures. A non-significant bias of 0.039 (95% limits of agreement = −1.14 to 1.22) was observed when comparing absolute A1C scores using both devices (n = 303).

Figure 3:Bland-Altman plot comparing Bio-Rad and HPLC A1C analyses

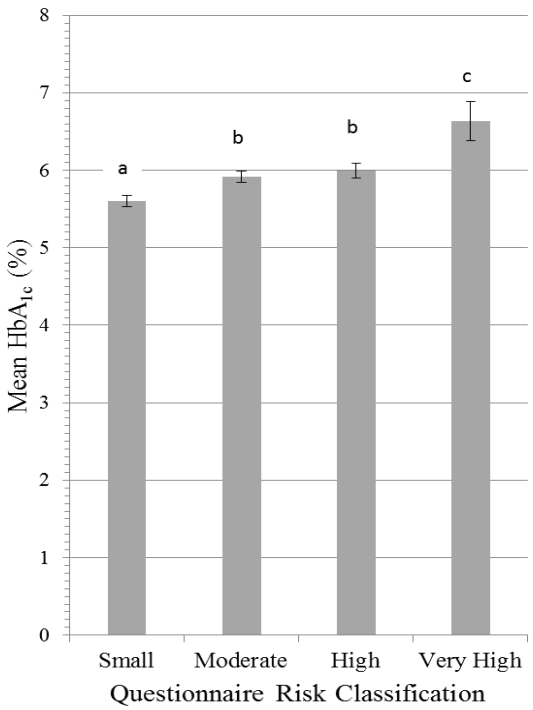


3.2.3.4 Comparison of risk questionnaire and blood outcomes

For this portion of the analysis, participants were excluded if they were missing data for any component of the risk score on the questionnaire or if they did not have a Bio-Rad A1C value. A total of 589 participants were included in the analysis. A one-way ANOVA was performed to describe the relationship between A1C values and overall risk score classification. The results of the ANOVA revealed that the assumption of homogeneity of variance was violated (Levene's statistic 20.6, $p < 0.001$). Welch tests were performed which showed that there were significant differences between groups (Welch Statistic 30.449, $p < 0.001$). Post-hoc comparisons, using Tamhane's T_2 approach, which allows for unequal variances, revealed only the "Moderate" and "High" risk groups were not significantly different ($p = 0.72$) from each other in terms of mean A1C. The results of the ANOVA are presented in Figure 4.

The results of the step-wise, backward elimination linear regression analysis (n = 589) revealed that the number of high risk parents (standardized $\beta = 0.15$, $p < 0.001$), age category (standardized $\beta = 0.12$, $p <$

Figure 4: Risk classification based on questionnaire score compared to mean A1C [(%) ± 95% Confidence Interval] measured using the Bio-Rad in2it device.



a, b and c denote significant differences ($p < 0.05$)

0.001), BMI (standardized $\beta = 0.11$, $p < 0.001$), PA participation (standardized $\beta = 0.12$, $p < 0.001$) and previous diagnosis of high blood sugar (standardized $\beta = 0.28$, $p < 0.001$) were all significant contributors to the variance in Bio-Rad A1C. The R^2 for this model was 0.235. Results from the linear regression are shown in Table 4. The area under the receiver-operator curve (AUC) was 0.716 using the definition of dysglycemia as A1C ≥6.0%. The sensitivity and specificity using a score of 6.5 as a cut-point were 0.853 and 0.435, respectively. This shows that, if a person scored 7 or higher (there are no half points allocated) which corresponds to "moderate" risk or higher, then the likelihood of detecting true dysglycemia is promising. These results resemble the values for moderate risk and mirror the incremental reduction in sensitivity with increased cut-point score selected for the sensitivity/specificity analysis observed using the CANRISK questionnaire[34].

Table 4: Results from the full step-wise, backward elimination linear regression model

Questionnaire Item	Standardized Beta	t	Sig.
Increasing number of high risk parents	0.15	3.78	<0.001
Increasing age category	0.12	2.87	<0.001
Increasing BMI	0.11	2.42	0.02
Increasing waist circumference	0.06	1.25	0.21
Decreasing PA participation	0.12	3.30	<0.001
High blood pressure	0.02	0.53	0.60
High blood sugar	0.28	7.38	<0.001
Family history of diabetes	0.05	1.23	0.22

$R^2 = 0.235$, Adjusted $R^2 = .224$

Although participants were made aware that this project was not intended to diagnose prediabetes or diabetes, it was still possible to ascertain valuable information regarding the detection of participants previously unaware (undiagnosed) of their high blood sugar through comparison of their A1C value to their response to the question, "have you ever been told by a doctor or nurse that you have high blood sugar?". This process showed that 79.7% of participants with an A1C ≥ 5.7% (ADA prediabetes cut point), 75% with an A1C ≥ 6.0% (CDA prediabetes cut point) and 61.7% with an A1C ≥ 6.5% had never been told that they had high blood sugar.

3.2.4 Discussion

When comparing the classifications of diabetes risk based on questionnaire overall risk score to A1C values, significant and expected increases in A1C were observed as participants progressed from a risk classification of "Small" toward "Very High" or "Extreme". After collapsing the "Very High" and "Extreme" groups, the only groups that did not significantly differ were the "Moderate" and "High" risk groups. Of particular interest, those in the "Small" risk category based on the questionnaire responses had average A1C values corresponding to the healthy glycemic control while those in the "Moderate" risk group had average A1C values that were approaching a state of prediabetes based on the CDA diagnostic criteria[3]. Furthermore, these "Moderate" risk individuals would be in the prediabetes range based on ADA standards which define prediabetes using an A1C of 5.7-6.4%[64]. Those in the "High" risk group, based on their questionnaire responses, had corresponding blood test scores with an average A1C value at the cusp of the prediabetes classification according to the CDA range (mean A1C of "High" risk group = 5.99%, CDA Range = 6.0-6.4%) and in the middle of the ADA prediabetes range (A1C of 5.7-6.4%) . Finally, those in the "Very High" risk group had average A1C values (Mean A1C = 6.6%) in the diabetes range (≥6.5%) based on both the CDA and ADA guidelines. Another related finding, with substantial clinical significance, was the extent to which the screening process identified individuals who were previously unaware of their poor glycemic control. With 75% of persons in the prediabetes range and ~62% of persons in the diabetes range based on their A1C report having never been told by a physician or nurse that they had high blood sugar, serious implications regarding the need for diabetes and prediabetes screening are magnified.

Further investigation into the relationship between questionnaire outcomes and blood values using multivariate linear regression revealed that, in descending order of standardized beta values, previous diagnosis of high blood sugar (standardized $\beta = 0.28$), number of high risk parents (standardized $\beta =$ 0.0.15), PA participation (standardized $\beta = 0.12$), age category (standardized $\beta = 0.12$), and BMI (standardized $\beta = 0.11$) were all independent significant contributors to the variability in A1C. While the

R^2 statistic suggests that the model only explains 23.5% of the variance in A1C, a receiver operator characteristic (ROC) analysis was performed and the area under the curve (AUC) was 0.716 using dysglycemia (A1C ≥6.0%) as the primary outcome with the intention of drawing comparisons to existing diabetes risk questionnaires. The observed AUC for the ROC analysis is consistent with findings from the CANRISK (AUROC = 0.75) and FINDRISC (AUROC = 0.648 for men, 0.659 for women) questionnaires for the prediction of dysglycemia (prediabetes + T2D)[31,34]. The relatively low R^2 of this model identifies a legitimate area of further investigation to decipher what may be contributing to the remainder of the variance in A1C within high risk populations. Interestingly, an analysis of the CANRISK questionnaire outcomes found that the response to their PA participation question was not a significant contributor to their model[34]. This disparity between the CANRISK questionnaire and the PRE-PAID questionnaire, with respect to the significance of PA in the model is likely due to the fact that the PRE-PAID questionnaire had an altered version of the question which was more descriptive in its assessment of PA and ascertained information about PA frequency. These findings and the corresponding standardized beta values will be used in the future to establish weighted responses on the questionnaire with the goal of enhancing its predictive value.

The utilization of A1C as the primary blood biomarker for confirmation of risk provided the investigators with a great deal of freedom in scheduling recruitment and screening events. Through the use of minimally-invasive point-of-care capillary blood testing, a broad pool of potential participants was reached. The ability to test blood in a non-fasted state and provide rapid results made this test more accessible and appealing to potential participants, thus enhancing the efficacy of recruitment efforts. The comparison between the Bio-Rad device and HPLC revealed no significant bias between the two measures which led to the decision to use the Bio-Rad samples (n = 589 with Bio-Rad values versus 304 with HPLC) for the data analysis comparing blood results to questionnaire outcomes via ANOVA and linear regression. Further, the accordance between the two A1C supports the use of minimally-invasive point-of-care capillary blood testing for future T2D and prediabetes detection initiatives that are focused

on screening, awareness and education. These tests may be accessible to a larger population because they can be performed at lower costs and less intrusive to persons at risk while providing relatively accurate information, especially when used in conjunction with a risk questionnaire.

One of the primary limitations of this investigation is the demographics of the sample. In an ideal setting, a more diverse sample would provide an opportunity to enhance the validation of the PRE-PAID questionnaire for use on a broader population. In spite of this, the mandate of the PRE-PAID investigators and the funding agencies was to reach those at highest risk for developing T2D, thus leading to more targeted recruitment efforts. The concentrated efforts aimed at reaching high risk ethnicities supports the notion that the PRE-PAID questionnaire provides a unique and appropriate tool for use in public health screening initiatives that target these populations. Another limitation of this investigation is the fact that all responses to the risk questionnaire were self-reported and several studies have shown that individuals tend to under-report their weight and waist circumference[79,80] while over-reporting their PA habits[81,82]. Although this may be a limitation, it is important to realize that during many public health initiatives, questionnaires are distributed in a similar manner and self-reported data is easier and less expensive to obtain when compared to actual measurement of the various risk factors assessed on the PRE-PAID questionnaire which may require equipment and trained personnel. Another limitation of the investigation pertains to the wording of questions assessing previous diagnoses of high blood pressure, blood sugar and family history of diabetes. Those who "didn't know" were given a score of zero. Moving forward, a more conservative approach should be taken so that those who do not know how to respond, are assumed to possess that risk factor and therefore receive a score for that question, thus contributing to their overall risk score. Finally, there have been some studies that have documented the presence of hemoglobinopathies or other conditions such as iron deficiency which would make the use of A1C inappropriate for the assessment of diabetes status[3,83]. The prevalence of hemoglobinopathies varies greatly depending on country and race but has been reported as high as 10% in some African populations[83].During the HPLC assessment of A1C, no participants were identified as having

hemoglobinopathies that would warrant their removal from the comparative analysis. It is possible, however, that some of the study participants who only provided Bio-Rad A1C samples possessed some form of hemoglobinopathy. Additionally, there may be other factors such as prescription medication which may contribute to altered A1C values[84] and it should be noted that this data was not captured by the risk questionnaire during this study. Adding questions regarding medication use would increase the complexity and duration of completing the questionnaire which would increase subject burden.

While the strength of the CANRISK questionnaire lies in its validation using a large, and representative Canadian sample population, the PRE-PAID risk questionnaire has shown to be an effective alternative tool for use among high risk ethnicities in Canada. As a result of the PRE-PAID investigation, the CANRISK questionnaire may enhance its own predictive value if more detailed questions were included with respect to PA participation such as; active transport, sedentary time, physical nature of their occupation, structured exercise, leisure time PA plus intensity and frequency of daily activities of living. The analysis of the number of high risk parents is also unique to the PRE-PAID questionnaire which provides important information to enhance the identification of risk based on ethnicity. The ultimate goal of this investigation was to develop an inexpensive front-line questionnaire that could accurately assess a person's risk for developing diabetes.

3.2.5 Conclusions

Using a simple screening approach involving risk factor identification and A1C point-of-care testing, large and diverse population groups become more accessible and the identification of prediabetes can occur earlier. This early detection provides increased awareness and opportunity to individuals allowing them to make important lifestyle changes as quickly as possible with the goal of preventing, or delaying, the progression towards T2D and the known associated complications. The potential reduction in T2D incidence and prevalence would likely translate into substantial positive implications regarding health care resource utilization and the current socio-economic burden attributed to diabetes.

Competing interests

The authors declare that they have no competing interests.

3.2.6 Acknowledgements

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MANUSCRIPT 3:

Community-based physical activity intervention targeting populations at high risk for prediabetes through culturally-preferred physical activity by detecting changes in glycemic control using glycated hemoglobin (A1C)

Rowan CP, Riddell MC, Gledhill N, Jamnik VK

Journal: Canadian Journal of Diabetes (formatting needs to take place)

Contribution of Authors

For this manuscript, CPR was the primary author and was the primary facilitator of data collection and entry, data analysis and interpretation as well as the primary contributor to overall project design and manuscript preparation. CPR was also the point person for developing community partnerships during recruitment. MCR, VKJ and NG all provided guidance regarding project design and were involved in the interpretation of the data analysis as well as revision of the manuscript. MCR, VKJ and NG also helped to facilitate community partnerships during project recruitment. VKJ, MCR and NG provided support with data collection.

3.3.1 Introduction:

As type 2 diabetes (T2D) continues to dramatically impact funding of health care systems around the world, the development of effective and targeted prevention strategies appears to remain a distant secondary objective when considering the volume of resources and research put toward treatment and management of those already diagnosed with the disease. A shift in focus toward prevention is imperative considering that diabetes and prediabetes have been referred to by the CDA as an "Economic Tsunami" with estimated costs of diabetes and its complications projecting to approximately $17 billion by the year 2020[85]. Without alteration to the current health care paradigm in Canada, the government will not be able to manage the overwhelming financial burden of diabetes and prediabetes on the health care system. A shift of responsibility allowing physicians to share the treatment and prevention burden with other qualified professionals would broaden the reach of community-based diabetes prevention initiatives. Individuals fitting the high-risk profile must also become accountable for facilitating changes in their own lives. Furthermore, targeted approaches focusing on those at highest risk for developing diabetes should translate into reducing the impact of this disease on the health care system. There has been a great deal of research into the effects of PA on T2D[72,73] and it is believed that these relationships may be mirrored in individuals with prediabetes[52], however, this has not been fully established through scientific research, especially when considering community-based interventions.

When considering the growing knowledge of modifiable risk factors, their potential impact on progression from prediabetes to T2D and the well documented role that physical activity (PA) has on various chronic diseases that are also lifestyle related, it seems logical to focus research and programming efforts on better understanding the role of PA in the prevention of diabetes. Previous studies have shown the effectiveness of lifestyle modification on the progression of diabetes[5,6], however, very little is known about the effectiveness of PA alone, independent of dietary modification. Even less is known about the effectiveness of community-based PA programs that are tailored toward persons with prediabetes with the

aim of improving glycemic control using A1C as the primary biomarker. A large divide exists between the efficacy of laboratory-based clinical trials involving PA and those conducted at the community level.

In Canada, specifically in Toronto and the rest of Ontario, there exists a highly diverse population consisting of several ethnicities that are known to be at elevated risk for T2D. It is well documented that individuals of South Asian, Chinese, African-Caribbean, or Aboriginal descent are at 3-5 times risk for developing T2D, which can happen at an earlier age and at a seemingly healthier body composition[7–10]. It is important that prevention strategies in Canada address these high risk ethnicities and identify ethno-specific recommendations for the assessment of diabetes risk and for effective PA-focused intervention. When targeting high-risk ethnicities in the community, volunteer support plus "buy in" and engagement by community members can be key contributors to successful intervention[11,86].

This study was designed to identify persons with prediabetes from specific high-risk ethnicities and enrol them in a PA program that was community-based and culturally specific. The primary goal of the study was to achieve improvements in A1C over a six month period of time. Additional measures of health-related physical and physiological fitness were also examined in a subset of participants to evaluate potential concurrent health benefits relevant to prediabetes and T2D as well as several other chronic diseases.

3.3.2 Methods:

3.3.2.1 Study Design: This was a non-randomized longitudinal effectiveness study designed to investigate persons at high risk for prediabetes, as determined by the Prediabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) risk questionnaire[11,12] and point of care blood screening (A1C), for a period of 6 months during which these persons participated in various forms of community-based PA. This investigation received ethics approval from the York University Human Participants Review Sub-committee and prior to screening and baseline data collection, all participants provided written, informed consent. Recruitment efforts and screening opportunities were concentrated in specific communities

chosen based on their cultural demographics as well as their known prevalence of diabetes. The selection process relied upon the City of Toronto neighbourhood profiles that were developed in conjunction with Statistics Canada[11] as well as the Institute for Clinical Evaluative Studies (ICES) Atlas of Diabetes[12], a resource that provides visual depictions of neighbourhoods in the GTA and their corresponding prevalence and incidence of diabetes[12]. In each community, recruitment took place in various public locations such as community health centres, religious centres, and shopping malls and relied heavily upon partnerships with community organizations to provide access to space, volunteer support, and a recognizable/trusted relationship with community members. A schematic of participant flow through the components of the study is shown in Figure 5 and select participant demographics are illustrated in Figure 6.

Figure 5: Participant flow diagram including participation in the PA intervention, provision of follow-up A1C samples plus participants who provided secondary outcomes at baseline and upon follow-up.
SA = South Asian, AC = African-Caribbean, SSM = Sault Ste Marie

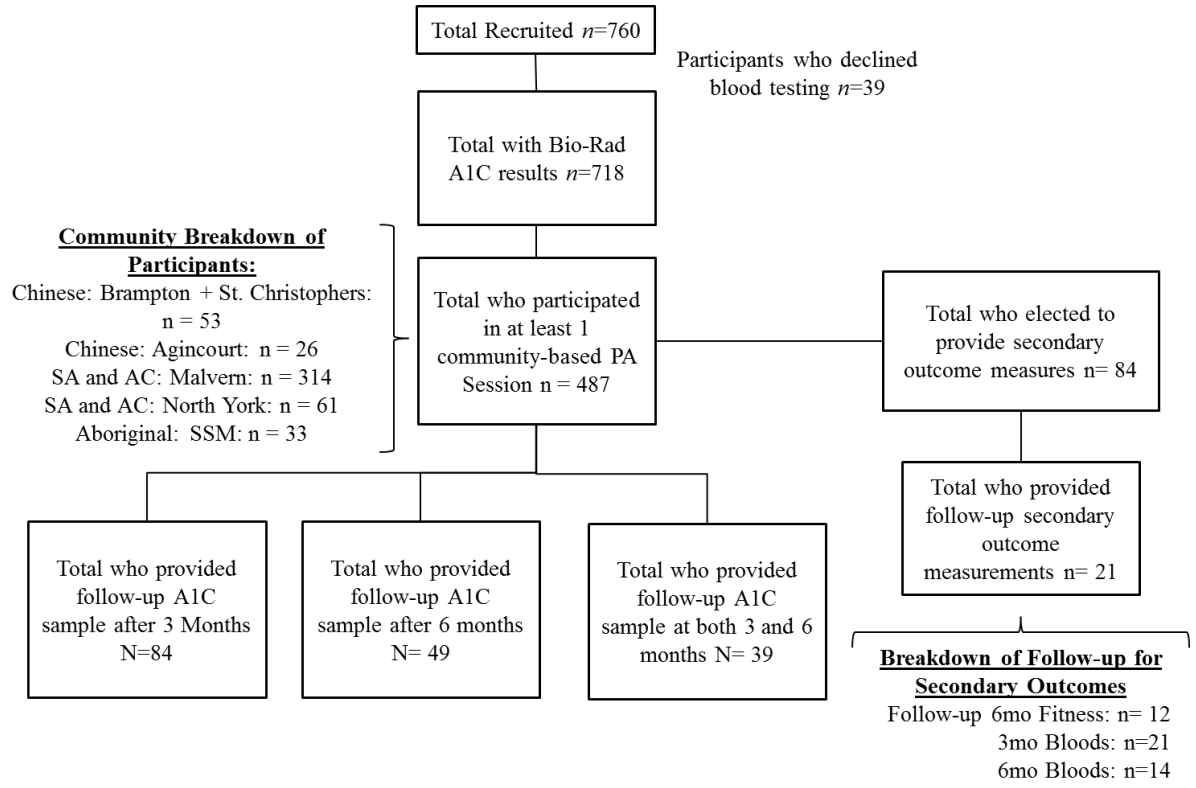
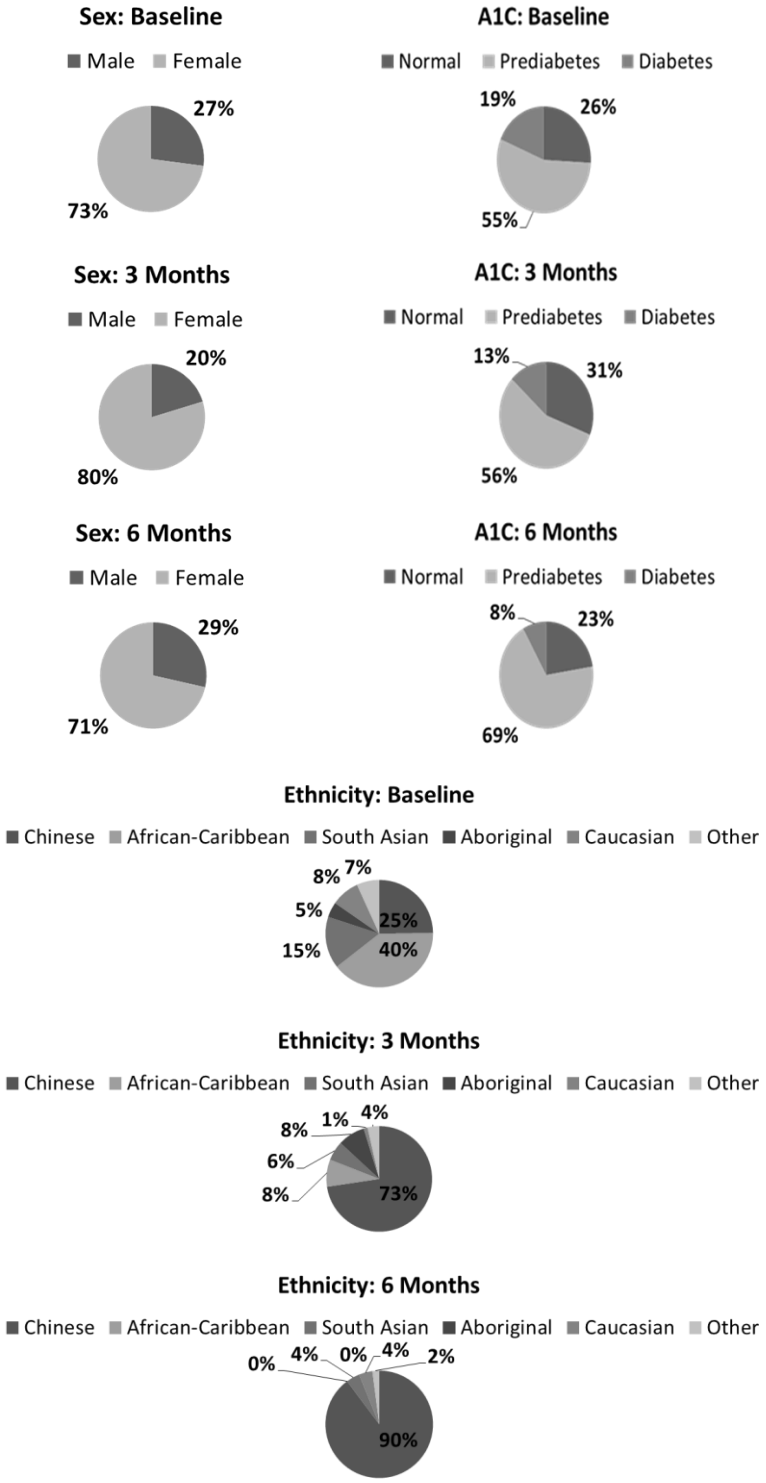


Figure 6: Summary of demographics (% of total N) of participants at baseline (N=718), at 3 months (N=84) and at 6 months (N=49).



3.3.2.2 Participant Inclusion/Exclusion Criteria:

Men and women were recruited from high-risk ethnicities (Chinese, African-Caribbean, Aboriginal, and South Asian). Participants were initially screened using the PRE-PAID risk questionnaire and point-of-care fingerstick A1C. All participants who underwent screening were invited to attend the community-based PA intervention regardless of diabetes status in an effort to promote participation and social support. It should be noted that the definitions discussed in this paper are based on the ADA diagnostic cut-points for prediabetes (5.7-6.4%)[15]. Participants were excluded if they were under the age of 18, or if they possessed a condition/functional limitation that would preclude their engagement in moderate intensity PA. All participants completed the PAR-Q+ to identify any potential risks for PA participation[90]. English proficiency was encouraged but not required, as crucial project materials were translated into Chinese, Punjabi and Hindi to enhance clarity for participants. Wherever possible, volunteer translators were also present to facilitate participant recruitment, adherence and the delivery of the PA program.

3.3.2.3 Blood Biomarkers:

The primary blood outcome measure was A1C and it was measured using the Bio-Rad in2it point-of-care device which performs the analysis using boronate affinity chromatography (Bio-Rad Laboratories, CA, USA). Capillary blood samples were collected via fingerstick using sterile techniques. A second sample from the same fingerstick was collected using the Bio-Rad capillary tube (Bio-Rad Laboratories, CA, USA) for analysis by HPLC which is a National Glycohemoglobin Standardization Program (NGSP) approved form of A1C analysis [63]. These analyses were performed by Clearstone Central Laboratories (Mississauga, ON) using the Bio-Rad Variant II Hemoglobin testing system. A1C was selected as the primary biomarker for inclusion for several reasons; it provides indicator of glycemic control spanning a three month period, it is less variable than fasted blood glucose sampling, and A1C does not require participants to be fasted allowing for more convenient scheduling of participants interested in the study.

A 75g OGTT was also performed on a sub-set of participants who elected to provide the secondary outcome measures. For this test, participants arrived at the laboratory in a fasted state (no food or drink for a minimum of 8 hours) and provided a baseline intravenous blood sample (10mL). Upon sample collection, participants were provided with a 75g dose of glucose (Trutol^{TM}, Thermo Scientific, USA) to be consumed within a 5 minute period. Blood samples (5mL) were then drawn every 30 minutes from an indwelling venous catheter so that a single venipuncture was required for the entire test to alleviate the potential burden or discomfort to the participants. All blood collection was performed by a trained phlebotomist who in most cases was a registered nurse. Blood samples were delivered to Lifelabs (Lifelabs, ON, Canada) for analysis of the following biomarkers; fasting glucose, fasting insulin, HDL-Cholesterol, LDL- Cholesterol, Total Cholesterol, Triglycerides, HDL:LDL as well as glucose and insulin values for each of the time points (30, 60, 90, and 120 minutes).

From the results of the OGTT, the calculation of HOMA-β, HOMA-IR was performed using standard equations[16,17]. These measures provide indirect information about the participants' beta cell function and insulin resistance status. Each of these measures represents an important consideration for prediabetic populations to help describe the participant's overall diabetes risk and potentially predict further disease progression.

3.3.2.4 Physical and Physiological Fitness:

Physical and physiological fitness was assessed in the sub-set of participants who agreed to come to the laboratory for additional testing. The assessment included measures of body composition, resting blood pressure and resting HR using the BpTRU^{TM} device(BpTRU^{TM} Medical Devices Ltd. BC Canada), aerobic fitness and various strength measures. All participants completed exercise pre-screening by completing the PAR-Q+[90] to reveal any pre-existing conditions that may preclude participation in exercise of moderate intensity. Height was measured using a stadiometer and body mass plus percent body fat were measured using a digital scale (Tanita Corporation of America, IL, USA). Waist

circumference was measured by a trained exercise professional following the National Institutes of Health (NIH) guidelines[19]. Upper body strength was assessed using a hand grip dynamometer (Takei T.K.K. 5401, Niigata, Japan) and lower body power was measured via vertical jump (Vertec, JumpUSA, CA, USA and Probotics Just Jump Mat, Probotics Inc., AL, USA). Leg power was calculated using a previously validated formula[92]. A customized, incremental aerobic fitness treadmill walking protocol was used and VO_2 was measured by direct analysis of expired gas using open-circuit spirometry (S-3A/II oxygen, CD-3A carbon dioxide; AEI Technologies, Pittsburgh, PA). The protocol was adapted from that of Ebbeling et al[93] where the participant walks for 4 minutes at 0% grade to determine a walking speed that is safe and comfortable while inducing a HR that is 50-70% age-predicted HRmax. Participants then walk for an additional 4 minutes at 5% grade at the same walking speed. After the second 4 minute workload, participants completed subsequent 2 minute intervals at the same walking speed while adding 2% grade each interval until the test was terminated. Aerobic fitness test termination was determined by volitional fatigue. During the aerobic fitness test, HR and VO_2peak were recorded, along with time on treadmill and maximum speed and grade achieved. The fitness test was only repeated at the 6 months, not at 3 months in order to minimize participant burden.

3.3.2.5 Health and Lifestyle-Related Questionnaires:

During the time spent between OGTT samples, participants completed a questionnaire package. The questionnaires were selected to thoroughly describe the lifestyle habits and psychosocial characteristics of the study participants at baseline. The package included a study participation questionnaire in which participants identified their place of birth, time entering Canada, languages spoken, religion and level of religious devotion, level of education, marital status and number of children, menopausal status and whether or not they had a family doctor. A medical questionnaire queried current and past health issues that may be relevant such as medication use and the presence of various medical or musculoskeletal problems. In addition to these two forms, the International Physical Activity Questionnaire (IPAQ) [94] was administered ascertain participants' levels of job related PA participation, transportation PA, house work

or maintenance PA, recreational, sport and leisure-time PA and time spent sitting. An acculturation scale[95,96] assessed the adjustment level to Canadian living if participants were not born in Canada. The EQ-5D[97] was included to assess perceived levels of mobility, self-care, activity, pain, anxiety and overall health status. A risk factor knowledge and lifestyle habits questionnaire gauged participants' perceptions and awareness of recommended healthy lifestyle habits including both diet and PA participation. A perceived stress scale[98] was completed and, finally, the SF-12 was administered to assess participants' health-related quality of life [99].

3.3.2.6 Community-Based Physical Activity Intervention:

At conveniently situated locations in each of the target communities, culturally-preferred PA classes were provided 2-3 times per week for 60-90 minutes per session. The primary goal of the PA classes was for participants to attain 150 minutes per week of supervised moderate intensity PA. This goal is in accord with recommendations set forth by Canadian and international governing bodies, including the CDA and the WHO[20,21]. In addition, participants were encouraged to increase their PA during other days of the week and document this in a PA journal that was provided. The selection of culturally-preferred PA was identified through informal focus group interviews with participants prior to their engagement in the program. Based on these interviews and after a survey of available community-based instructors, the following PA programs were selected; Socasize and African-Dance for the African-Caribbean population, Bollyfit for the South Asian population, line dancing and tai chi for the Chinese population. These group-based classes all involve whole body, rhythmic and aerobic movements and were supplemented with body weight-based resistance exercises to enhance the stimulus for health benefits. The classes were set to culturally-themed music and provided by culturally matched instructors. The Aboriginal group indicated preference for a more traditional PA regimen involving walking and traditional calisthenics. PA participation and adherence were recorded on attendance lists at all PA sessions.

3.3.2.7 Assessment of Physical Activity Intensity and Role of Qualified Exercise Professional:

Throughout the PA intervention, the sessions were monitored by qualified exercise professionals (QEPs) to ensure safety and appropriate PA intensity. Both the QEP and the culturally-matched PA instructor received specific training to ascertain intensity levels during the group-based PA classes. Indicators such as breathing rate, perspiration and rating of perceived exertion (RPE)[100] were all used to gauge the PA intensity. QEPs also coached the participants to use these tools when they were exercising on their own so that they could ensure that appropriate intensities were met. The instructors of the PA classes were also instructed to provide both less and more intense alternatives to the exercises performed during the classes to accommodate the needs of a broader spectrum of participants.

For verification purposes, during some of the PA classes, volunteer participants were outfitted with HR monitors and portable VO_2 equipment (COSMED FITMATE PRO, Image Monitoring Inc., ON, Canada) to confirm the PA stimulus provided during the exercise classes.

3.3.2.8 Statistical Analyses:

Participant demographics and various baseline outcome measures were analyzed using descriptive statistics. Baseline questionnaire data were summarized using descriptive statistics and frequencies. Temporal changes in A1C, fitness and additional blood tests were analyzed using repeated measures analysis of variance (ANOVA) with sex built into the model as a covariate. Pairwise comparisons using estimated marginal means are reported for all temporal changes. The analysis adopted an intent-to-treat model, therefore all subjects who provided follow-up measures, regardless of their adherence to the intervention were included. Analyses described in this investigation were performed using a two-sided 5% level of significance. All analyses were performed using IBM SPSS version 22 (IL, USA).

3.3.3 Results:

A total of 760 participants were directly reached by the PRE-PAID study personnel and 718 elected to provide a baseline A1C measurement. The results of the prediabetes screening portion of the study have been previously published[14]. A total of 487 participants were exposed to the PA intervention and took part in a minimum of one PA class over the entire study duration and 84 individuals elected to provide all of or some of the secondary outcome measures at baseline. Baseline characteristics for all study participants, including those who provided secondary outcomes, are presented in Table 5. Figure 5 illustrates that a total of 84 participants provided follow up A1C measurements at 3 months, 49 provided A1C at 6 months, and 39 provided A1C at all 3 time points. Figure 5 also illustrates that 21 participants provided a portion of, or all, of the follow-up secondary measures.

Table 5: Baseline A1C and physical characteristics of (A) all participants enrolled in the study plus descriptive baseline information specific to those who provided (B) 3 month and/or (C) 6 month A1C follow-up measurements.

Primary Outcome	N	Mean	±Std. Deviation
A: Baseline data for all recruited participants			
Bio-Rad A1C (%)	718	6.09	0.87
Age (yrs)	400	50.08	13.48
BMI (Self-reported using BMI chart)	522	27.30	5.35
Waist Circumference (Self-reported cm)	346	90.63	14.38
B: Baseline data for participants who provided 3 month follow-up A1C			
Bio-Rad A1C (%)	84	6.13	0.79
Age (yrs)	55	54.2	11.8
BMI (Self-reported using BMI chart)	65	25.0	4.9
Waist Circumference (Self-reported cm)	55	87.0	13.3
C: Baseline data for all participants who provided 6 month follow-up A1C			
Bio-Rad A1C (%)	49	6.05	0.41
Age (yrs)	30	58.1	7.3
BMI (Self-reported using BMI chart)	35	23.6	4.3
Waist Circumference (Self-reported cm)	30	82.3	9.4

3.3.3.1 Participant Adherence:

Given the nature of this community-based intervention, a great deal of participant attrition was expected as reported in previous research[26]. Of the 718 participants who provided baseline A1C measurements, 66% attended one or more PA intervention sessions but only 20% of those who attended PA sessions provided a follow-up A1C measurement at either 3 or 6 months. When examining the participation rates, there was a great deal of variability based on which ethno-cultural community the participants came from and rates of participation ranged from 1.2% - 100% with a mean participation rate for all participants of 19.2%. This is equivalent an average of 10.3 sessions over a period of 6 months. The Chinese cohort displayed by far the greatest adherence to the program with an average adherence rate of 57.5%. Participants from this cohort were also the only group to provide 3 and 6 month follow-up data for any of the secondary outcomes assessed at baseline. This point should be considered when interpreting the results shown in Tables 8 and 9. No adverse events were reported during the sessions or laboratory testing days. There was inadequate completion of the PA journals documenting participation in activity outside of the supervised classes for inclusion in the analysis.

3.3.3.2 Blood Biomarkers:

The mean A1C for the entire subject pool (n= 718) at baseline was 6.1% (SD±0.867) which equates to a prediabetes classification based on both the CDA and ADA diagnostic criteria[15,20] and is unsurprising given the targeted approach to recruitment. Results from all baseline blood testing are summarized in Table 6. These data include both the A1C results from the entire pool of participants as well as the findings from those who provided secondary outcomes assessed during the OGTT.

Table 6: Baseline characteristics of participants who provided secondary blood and fitness outcomes.

Outcome		N	Mean	Std. Deviation	p value (M vs F)	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	*Normal Healthy Range*
A1C (%)	Combined	80	6.2	0.4				
	Female	64	6.1	0.4	0.247	-0.4	0.1	*<5.7*[1]
	Male	15	6.3	0.4				*<5.7*
Age (yrs)	Combined	83	52.8	7.2				
	Female	66	52.6	7.0	0.634	-4.8	3.0	
	Male	17	53.5	8.0				
Height (cm)	Combined	80	161.0	8.1				
	Female	63	158.2	6.1	<0.001	-16.7	-10.2	
	Male	17	171.6	5.8				
Weight (Kg)	Combined	80	68.2	15.1				
	Female	63	65.9	14.5	0.007	-18.9	-3.2	
	Male	17	76.9	14.3				
BMI (Kg/m^2)	Combined	80	26.2	4.9				
	Female	63	26.2	5.2	0.833	-2.4	2.9	*<25*[2]
	Male	17	26.0	3.4				*<25*
Waist	Combined	79	91.7	11.2				
Circumference	Female	62	91.5	11.5	0.697	-7.3	4.9	*<88*
(cm)	Male	17	92.7	10.0				*<102*
Body Fat (%)	Combined	79	32.3	9.1				
	Female	63	34.3	8.7	<0.001	5.6	14.8	*23-35*
	Male	16	24.1	5.7				*11-22*
Resting HR	Combined	74	69.5	9.0				
(bpm)	Female	57	69.7	7.3	0.821	-6.4	7.9	*60-100* [3]
	Male	17	68.9	13.5				*60-100*
Systolic BP	Combined	77	124.7	14.8				
(mmHg)	Female	61	122.8	14.0	0.021	-17.5	-1.5	*≤ 120*[4,5]
	Male	16	132.3	15.6				*≤ 120*
Diastolic BP	Combined	77	83.6	13.7				
(mmHg)	Female	61	83.1	14.7	0.574	-9.9	5.5	*≤ 80*
	Male	16	85.3	9.0				*≤ 80*
Combined Grip	Combined	79	47.4	17.9				
(Kg)	Female	62	40.7	10.6	<0.001	-40.8	-22.1	
	Male	17	72.1	17.5				
Vertek VJ (cm)	Combined	53	23.5	7.6				
	Female	42	21.9	6.8	0.002	-12.4	-3.0	
	Male	11	29.6	7.7				
Jump Mat Height	Combined	76	10.9	3.3				
(in)	Female	60	10.2	3.0	<0.001	-5.3	-1.9	
	Male	16	13.8	3.0				
Peak VO_2	Combined	71	26.8	5.7				
$mLl \cdot Kg^{-1} \cdot min^{-1}$	Female	57	25.6	5.1	<0.001	-8.9	-2.7	*29-30*[6]
	Male	14	31.5	5.9				*38-42*
Peak Treadmill	Combined	70	3.4	3.0				
Speed (mph)	Female	56	2.9	0.4	0.171	-6.3	1.3	
	Male	14	5.4	6.6				
Peak Treadmill	Combined	70	13.2	2.8				
Grade (%)	Female	56	12.8	2.9	0.033	-3.4	-0.2	
	Male	14	14.6	1.9				
Peak HR	Combined	70	160.9	16.8				
	Female	56	161.3	16.9	0.647	-7.7	12.4	
	Male	14	159.0	16.7				
Total Cholesterol	Combined	77	5.1	1.0				
(mmol/L)	Female	60	5.0	1.0	0.461	-0.8	0.4	*<5.2*[7]
	Male	16	5.2	1.1				*<5.2*
LDL (mmol/L)	Combined	75	3.1	0.8				
	Female	59	3.1	0.8	0.303	-0.7	0.2	*<2.6*
	Male	15	3.3	1.0				*<2.6*

Table 6: Continued		**N**	**Mean**	**Std. Deviation**	**p value (M vs F)**	**Lower Bound**	**Upper Bound**	***Normal Healthy Range***
HDL (mmol/L)	Combined	77	1.4	0.4				
	Female	60	1.4	0.3	0.059	0.0	0.4	*>1.0*
	Male	16	1.2	0.4				*>1.0*
TC:HDL	Combined	77	3.9	1.0				
(mmol/L)	Female	60	3.7	1.0	0.009	-1.3	-0.2	*<3.5*
	Male	16	4.5	1.1				*<3.5*
Triglycerides	Combined	77	1.3	1.3				
(mmol/L)	Female	60	1.2	1.3	0.218	-1.2	0.3	*<1.7*
	Male	16	1.7	1.2				*<1.7*
Fasting Glucose	Combined	78	5.5	0.7				
(mmol/L)	Female	61	5.5	0.7	0.095	-0.7	0.1	*<6.1*[8]
	Male	16	5.8	0.7				*<6.1*
Fasting Insulin	Combined	80	50.3	33.2				
(pmol/L)	Female	63	47.2	30.6	0.060	-35.6	0.8	
	Male	16	64.6	39.9				
2 hour Glucose	Combined	67	7.5	2.5				
(mmol/L)	Female	53	7.5	2.6	0.498	-1.0	2.1	*<7.8*
	Male	13	7.0	1.9				*<7.8*
2 hour Insulin	Combined	73	516.1	366.8				
(pmol/L)	Female	58	550.4	384.5	0.135	-52.6	381.6	
	Male	14	385.9	267.2				
HOMA-β	Combined	80	86.0	72.8				
	Female	63	83.3	74.6	0.415	-57.6	24.0	
	Male	16	100.1	66.9				
HOMA-IR	Combined	76	12.6	8.5				
	Female	60	11.6	7.7	0.021	-10.3	-0.9	
	Male	15	17.2	9.9				

1= American Diabetes Association, 2 = World Health Organization, 3 = National Institute of Health, 4 = American Heart Association, 5 = Heart and Stroke Foundation, 6 = Heyward, 7 = NCEP, 8 = Canadian Diabetes Association

Results from the analysis of temporal changes in A1C are shown in Table 7. There were a total of 84 valid cases for analysis at 3 months and 49 valid cases at 6 months. Only 39 participants provided both 3 and 6 month follow-up. Pairwise comparisons of the estimated marginal means revealed that there was a significant reduction in A1C of 0.16% from baseline to 3 months follow up (p=0.003). No significant differences were observed between baseline and 6 months or between 3 and 6 months follow-up likely due to the progressive reduction in participant n.

Table 7: Results of repeated measures ANOVA showing temporal changes in A1C at 3 months (n=84) and at 6 months (n=49) measured using the Bio-Rad in2it device. *Sig p<0.05 based on pairwise comparisons of estimated marginal means. Sex included in the model as a covariate.

Variable	Timepoint	N	Mean	Mean Difference from baseline	P Value	95% Confidence Interval	
						Lower Bound	Upper Bound
A1C (%)	Baseline	84	6.1				
	3 Months	84	6.0	-0.16	0.003*	-0.27	-0.06
	Baseline	49	6.1				
	6 Months	49	6.0	-0.1	0.07	-0.71	0.19

Results from the pairwise comparisons of the estimated marginal means showed that there was a significant reduction in fasting glucose of 0.33mmol/L (p=.02) between baseline and 3 months follow-up. HOMA-β also improved by 23.6% between baseline and 3 months (p=0.03), and 45.2% between baseline and 6 months (p=.02) while HOMA-IR had a significant reduction of -7.7 (p<0.001) between baseline and 3 months and -8.5 (p=0.003) between baseline and 6 months. No significant differences were observed in the blood lipid profile. These results are reported in Table 8.

Table 8: Results of repeated measures ANOVA showing temporal changes in secondary blood measures at 3 months (n=21) and at 6 months (n=12) measured during the OGTT. *Sig p<0.05 based on pairwise comparisons of estimated marginal means. Sex included in the model as a covariate.

Variable	Timepoint	N	Mean	Mean Difference from baseline	P Value	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Total Cholesterol (mmol/L)	Baseline	19	5.1				
	3 Months	19	5.1	0.04	0.78	-0.245	0.323
	Baseline	12	5.3				
	6 Months	12	5.3	0.03	0.89	-0.49	0.56
LDL Cholesterol (mmol/L)	Baseline	19	3.0				
	3 Months	19	3.1	0.08	0.41	-0.11	0.27
	Baseline	12	3.1				
	6 Months	12	3.1	-0.01	0.97	-0.37	0.36
HDL Cholesterol (mmol/L)	Baseline	19	1.6				
	3 Months	19	1.5	-0.04	0.26	-0.10	0.03
	Baseline	12	1.6				
	6 Months	12	1.6	0.01	0.76	-0.06	0.07
TC:HDL	Baseline	19	3.4				
	3 Months	19	3.5	0.09	0.41	-0.13	0.31
	Baseline	12	3.5				
	6 Months	12	3.5	0.06	0.68	-0.25	0.36
Triglycerides (mmol/L)	Baseline	19	1.2				
	3 Months	19	1.2	0.001	1.00	-0.29	0.29
	Baseline	12	1.3				
	6 Months	12	1.4	0.07	0.63	-0.25	0.39
Fasting Glucose (mmol/L)	Baseline	19	5.4				
	3 Months	19	5.1	-0.33	0.02*	-0.60	-0.07
	Baseline	12	5.4				
	6 Months	12	5.2	-0.28	0.23	-0.75	0.20
Fasting Insulin (pmol/L)	Baseline	20	35.3	33.2			
	3 Months	20	35.0	-0.30	0.91	-5.92	5.32
	Baseline	12	38.8				
	6 Months	12	48.7	9.92	0.12	-3.05	22.89
HOMA-β	Baseline	20	51.8				
	3 Months	20	75.4	23.60	0.03*	2.37	44.82
	Baseline	12	49.2				
	6 Months	12	94.4	45.21	0.02*	8.41	82.00
HOMA-IR	Baseline	18	9.1				
	3 Months	18	1.4	-7.72	<0.001*	-10.59	-4.84
	Baseline	10	10.6				
	6 Months	10	2.1	-8.49	0.003*	-13.22	-3.77
2 hour Glucose (mmol/L)	Baseline	20	7.1				
	3 Months	20	7.5	0.37	0.25	-0.27	1.00
	Baseline	13	6.7				
	6 Months	13	6.6	-0.07	0.51	-0.29	0.15
2 hour Insulin (pmol/L)	Baseline	21	441.8				
	3 Months	21	584.1	142.29	0.01*	37.99	246.58
	Baseline	12	492.2				
	6 Months	12	808.5	316.33	0.06	-13.09	645.75

3.3.3.3 Physical and Physiological Fitness:

The results of the baseline fitness assessment are derived from the subset of individuals who provided secondary outcomes as summarized in Table 6 (n=83). The body composition profile of this group was characterized by a mean waist circumference of 91.7cm, a mean BMI of 26.2Kg/m^2 and a mean body fat of 32.3%. These measures depict a group of individuals who are moderately overweight and who possess a high-risk distribution of fat around the abdomen. In addition to this, the mean VO_2peak (n= 71) was 26.8mL·Kg^{-1}·min^{-1} which indicates of a low level of aerobic fitness and potentially an impaired functional capacity.

Results of the pairwise comparisons of estimated marginal means (n=12) represent an entirely Chinese population who were by far the most adherent to the PA intervention. The results indicate that after 6 months there was a significant reduction in resting SBP of 11.25mmHg (p=.005) and a reduction in diastolic blood pressure (DBP) of 14.5mmHg (p=.04). In addition to the improvement in blood pressure, participants showed that combined grip strength increased 9.32Kg (p<.001), relative VO_2peak increased 5.15mL·Kg^{-1}·min^{-1} (p=.003) and peak treadmill speed increased by 0.29mph (p<.001) during their fitness assessment. The temporal results from the fitness assessment are summarized in Table 9.

Table 9: Results of repeated measures ANOVA showing temporal changes in secondary fitness measured during the follow-up fitness assessment at 6 months (n=12). *Sig p<0.05 based on pairwise comparisons of estimated marginal means. Sex included in the model as a covariate. All subjects providing follow-up fitness data were Chinese.

Variable		N	Mean	Mean Difference from baseline	P Value	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Weight (Kg)	Baseline	12	55.8				
	6 months	12	56.2	0.40	0.25	-0.34	1.14
Waist Circumference (cm)	Baseline	12	85.1				
	6 months	12	84.8	-0.26	0.67	-1.6	1.08
% Body Fat	Baseline	12	27.2				
	6 months	12	27.5	0.31	0.55	-0.81	1.43
Resting HR (bpm)	Baseline	12	70.1				
	6 months	11	71.8	1.74	0.50	-3.91	7.38
Resting SBP (mmHg)	Baseline	12	125.3				
	6 months	12	114.0	-11.25	0.005*	-18.06	-4.44
Resting DBP (mmHg)	Baseline	12	91.9				
	6 months	12	77.4	-14.50	0.04*	-28.17	-0.83
Combined Grip (Kg)	Baseline	11	37.0				
	6 months	12	46.3	9.32	<0.001*	6.84	11.8
Vertical Jump Height (cm)	Baseline	10	20.2				
	6 months	12	21.2	0.97	0.29	-1.0	2.95
Jump Mat Height (in)	Baseline	11	11.2				
	6 months	12	11.5	0.31	0.49	-0.67	1.29
Leg Power (Watts)	Baseline	10	1716.6				
	6 months	12	1802.8	86.2	0.29	-87.91	260.30
VO_2peak ($mL \cdot Kg^{-1} \cdot min^{-1}$)	Baseline	11	27.2				
	6 months	12	32.4	5.15	0.003*	2.26	8.04
Peak Treadmill Speed (mph)	Baseline	11	2.8				
	6 months	12	3.1	0.29	<0.001*	0.17	0.42
Peak Treadmill Grade (%)	Baseline	11	14.1				
	6 months	12	14.4	0.28	0.65	-1.1	1.67
Peak HR (bpm)	Baseline	11	161.5				
	6 months	12	169.0	7.55	0.07	-0.81	15.9

3.3.3.4 Health and Lifestyle-Related Questionnaires:

Among those (n=83) who elected to provide secondary outcomes, 48 completed the questionnaire package. These data indicate that among the pool of participants who completed the questionnaires, 100% were born outside of Canada yet the average time spent living in Canada was 20.4 years. Also, 46.9% reported that English was their second language. According to the IPAQ, respondents were generally inactive as evidenced by a mean time spent sitting of 5.8 hours per week day and 6.1 hours per weekend day as well as less than 2 days per week of participation in leisure-time PA. The EQ-5D results indicated

that participants self-reported no physical limitations in performing self-care and typical activities and 31% of participants reported moderate anxiety or depression. The EQ-5D visual analog scale results also showed a mean score of 73.8/100 for self-reported overall health state. The results of the acculturation scale revealed that the respondents showed moderate agreement with almost all of the items on the questionnaire which reflects a belief that both the practices of their heritage culture and those of "typical" Canadian culture are important and followed. The risk factor knowledge and lifestyle habits questionnaire revealed that 80% of respondents perceived their knowledge of PA to be average or above and 73.3% reported that PA was "Very Important" to them, while only 27.7% reported that they had heard of Canada's PA guidelines. With respect to diet, 88.9% rated their diet as average or better but only 17.4% reported having heard of Canada's Food Guide. Results of the SF-12 questionnaire show that participants had a mean physical health composite score of 47.1/100 and a mean mental health composite score of 50.2/100.

3.3.3.5 Assessment of Physical Activity Intensity:

A total of 12 individuals volunteered to undergo the direct assessment of PA intensity during their exercise session. These 12 individuals were all from the Chinese cohort and their results reflect their participation in the Tai Chi and Line Dancing programs which were both supplemented with body weight strength training exercises. Their results indicated that the mean peak HR during the exercise session was 143.8bpm while the mean VO_2peak attained during the class was 25.0mL·Kg^{-1}·min^{-1} which corresponds to 7.1METs or the lower end of "vigorous intensity" PA[22].

3.3.4 Discussion:

Given that the primary goal of the study was to elicit reductions in A1C through participation in a community-based exercise intervention, the temporal changes described in the results provide good evidence that improvements in glycemic control were achieved. The modest but significant reduction in A1C from baseline to 3 months, brought the mean value from 6.1% at baseline to 6.0% at 3 months and

6.0% at 6 months among participants providing follow-up data (n=84), essentially shifting participants from a prediabetes classification closer to a normal classification based on the CDA clinical practice guidelines[20]. Evidence for this improvement in glycemic control is bolstered by the more robust significant improvements in HOMA-β which improved by 23.6% (p=0.03) at 3 months and by 45.2% (p=0.02) after 6 months indicating a significant improvement in beta cell function. Improvements in glycemic control among persons with prediabetes reduce their likelihood of developing T2D[5] and are associated with reductions in the risk for CVD-related events[27].

In addition to the significant improvements in blood biomarkers, positive changes in several of the secondary outcomes were observed, notably a reduction in both systolic and DBP of -11mmHg and -14mmHg respectively. These reductions correspond to a change in classification from pre-hypertensive to normal based on the American Heart Association guidelines[28,29] and consequently expected reductions in cardiovascular mortality[29,30]. Improvements in grip strength and VO_2peak are indicative of significant improvements in functional capacity and aerobic fitness which are also known to be closely linked to reductions in cardiovascular mortality[30] and improvements in quality of life[31]. All of these significant findings are strengthened further when considering that they were observed using an intent-to-treat model which allowed all participants, regardless of adherence, to be included in the analysis. Had a per-protocol approach been taken, it is likely that even greater improvements to glycemic control and physical fitness would have been observed.

While the intensity of exercise for the entire group of participants was not fully measured, the sub-group of participants who were assessed during the PA classes showed that intensity fell within the moderate-to-vigorous range which is in line with the current CDA recommendations [20]. However, it can only be inferred that intensities during the other PA sessions were meeting this requirement. The presence of QEPs and properly trained, culturally-matched, instructors in place for all classes to maximize likelihood of participants performing their activity at a safe and effective intensity level that minimized risk of adverse events and promoted healthy physiological responses. With respect to the baseline results from

the various questionnaires, the Score on the EQ-5D of 73.8/100 was lower than that of the U.S. general population (79.2/100) as well as a representative sample of U.S. adults aged 40-60 (78.5/100)[33]. The observed EQ-5D score was, however, higher than a representative cohort of U.S. individuals who had diagnosed diabetes (68.5/100)[33]. The results of the PSS-10 indicated that the mean score was indicative of stress levels that are above average compared to normative data [25]. Finally, the results from the SF-12 showed that both of the mean values for physical and mental health composite scores fall slightly below average compared to normative data from individuals aged 45-64 years[26]. These results describe this study population as below average in terms of overall health, perceived stress and PA participation. Noting this provides another key area where the QEP may be able to induce meaningful and enduring changes via lifestyle modification. No adverse events were reported during any of the activity sessions and the observed changes in glycemic control and fitness provide some evidence that intensity was appropriately monitored.

It has been previously established that the approach taken during this study to identify persons with prediabetes is effective[14] yet the ability to then enrol individuals in PA intervention to which they adhere is another meaningful finding from this project. Given that the mean adherence rate for all participants was only 19.2%, there is a great deal of room for improvement when it comes to retention of participants and adherence to PA sessions. Despite efforts to utilize community partners with an established presence in the community, locations in close proximity to the participants' homes and provision of culturally-matched study personnel and PA instructors, adherence rates remained low. The authors strongly believe that, without these measures, adherence would have even been significantly lower. Interestingly, the sub-population of Chinese participants had a 57.5% adherence rate. Closer examination of this sub-group may elicit reasons why adherence was markedly better. While some of the barriers experienced by participants do not always pertain to cultural backgrounds, it is likely that many of these barriers could apply to all populations.

The primary limitation of this study is the lack of adherence to the program and the lack of follow-up data provided by the participants. This was a major challenge faced by the research team because the majority of sessions were held away from the laboratory and there were no guarantees that participants who were eligible for their follow-up testing sessions would be in attendance during the data collection days which were held during the regularly scheduled PA sessions. The lack of follow-up for the laboratory-based secondary outcomes is likely a reflection of the substantial time commitment and comprehensive/invasive nature of the study protocol. Another limitation to this study is the scarcity of male participants, which limits the ability to make conclusions regarding a more representative sample. Finally, there was no control group which would have allowed comparisons between participants who received no intervention and those enrolled in the community-based PA classes. Without a control group, implications of the observed results are limited but not without merit.

Continuing work in this field should pursue a similar study design with a randomized, controlled approach. This will require a great deal of resources and time to adequately evaluate this type of program. There should also be long term follow-up at the community level using T2D diagnosis as an outcome to detect the effectiveness of similar programs and to generate potential cost-savings models associated with reductions in diabetes progression. During these investigations, the role of the QEP and other culturally-matched personnel should also be evaluated. Given their unique skill set and education regarding exercise prescription and lifestyle counselling, it is reasonable to argue that QEPs should be given a larger platform to facilitate programs at the community level with the overall goal of chronic disease prevention and management. In this study, despite the efforts of the investigators and volunteers, barriers to PA persisted as evidenced by the large drop in participant number at each juncture of the study design. An examination of long-term adherence to the program and identification of barriers that are culturally-specific should also take place which may help to improve participant adherence in future programs.

3.3.5 Conclusion:

Participation in a community-based and culturally preferred PA intervention targeting persons with prediabetes was associated with improvements in glycemic control observed using A1C, HOMA-β and HOMA-IR among a small group of individuals who adhered to the program. Other protective health benefits included improvements in strength and cardiovascular fitness, both of which are relevant to persons at risk for T2D as well as several other chronic diseases. Although participant adherence was a limitation to this study, these results are in-line with the project goals, are powerful and should inform the design of future interventions aiming to prevent T2D at the community level. Ongoing identification of barriers to PA, including those that are culturally-specific, needs to take place in order to maximize participation and broaden the catchment of people who may benefit from these observed benefits which may lead to improved quality of life and alleviation of the substantial financial burden faced by the health care system in Canada and world-wide. Further, it is imperative that we make efforts to engage, educate and empower individuals who are at risk to become accountable for their own actions and lifestyle choices.

Manuscript 4:

Comparing high intensity interval versus continuous moderate intensity aerobic training modalities in persons with prediabetes for the improvement of glycemic control measured through changes in glycated hemoglobin (A1C)

CP Rowan, MC Riddell, N Gledhill, VK Jamnik

Journal: TBD

Contribution of Authors

For this manuscript, CPR was the primary author and was the primary facilitator of data collection and entry, data analysis and interpretation as well as the primary contributor to overall project design and manuscript preparation. CPR was also the point person for developing community partnerships during recruitment. MCR, VKJ and NG all provided guidance regarding project design and were involved in the interpretation of the data analysis as well as revision of the manuscript. MCR, VKJ and NG also helped to facilitate community partnerships during project recruitment. VKJ, MCR and NG provided support with data collection.

3.4.1 Introduction:

There is overwhelming evidence to support the importance of habitual non-exercise and exercise physical activity (PA) accumulation for their critical role in preventing and managing a range of chronic conditions including type 2 diabetes (T2D)[32,51,111,112]. Prediabetes cannot be ignored when developing health interventions related to PA but despite being the known antecedent of T2D, it is often included in reports that are heavily focused on T2D management instead of considering prediabetes as a unique entity. In Canada, the expected number of diagnosed T2D cases will be 3.7 million by the year 2019 while it is estimated that approximately 20% of T2D cases remain undiagnosed [2]. The resultant economic impact is substantial with an estimated $12.2 billion spent in 2010 and an estimated increase to $16.9 billion by 2020 [6]. If the expected prediabetes prevalence of 6.3 million by 2016 [2,113] is coupled with the evidence that persons with prediabetes are 5-10 times more likely to develop diagnosed T2D [114], there is an overwhelming need to develop effective intervention strategies that are prediabetes-specific.

The importance of prediabetes is bolstered by the fact that it is closely linked to several modifiable risk factors, most notably all facets of PA participation (both exercise, and non-exercise related), body composition, and diet [115]. Addressing these factors with the goal of preventing and/or delaying the onset of T2D has been shown to result in significant health benefits, including lower rates of CVD [115]. In that regard, the CDA advocates an approach that would identify individuals at risk for prediabetes and T2D, quantify that risk, and then provide intervention for the prevention or delayed onset of T2D [3]. The Prediabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) project is one approach that follows this proposed initiative [74]. Through the development and use of a risk questionnaire plus a targeted population recruitment approach, successful identification of individuals at risk for T2D and prediabetes was achieved and verified via measurement of glycosylated hemoglobin (A1C) [87]. The development of an effective intervention strategy for these at- risk individuals remains an important priority that warrants investigation.

Previous investigators have targeted persons with prediabetes utilizing lifestyle modification to prevent or delay the onset of T2D with highly encouraging results [19,32,51]. It is important to note, however, that these studies are primarily education-based intervention geared towards both diet and PA participation with limited supervision of the PA component. Little is known regarding the effect of exercise-based interventions on specific markers of glycemic control such as A1C in persons with prediabetes. There are several well established mechanisms through which both aerobic and resistance-based exercise can benefit persons with prediabetes via improved insulin sensitivity[52]. Developing strategies to take advantage of these mechanisms and improve one's ability to prevent or delay T2D is very attractive and a high priority.

High-intensity interval training (HIIT) is not a novel concept with roots tracing back to the 1970s.[116] Recently, however, it has become a popular alternative to the more traditional moderate-intensity continuous training approach to aerobic exercise. It is extremely important to use caution when interpreting the findings from HIIT interventions given the high degree of variability in approaches which can all be considered HIIT. All HIIT approaches typically incorporate exercise that is ≥80% maximum HR and can range from very short sprint intervals lasting 30-60 seconds with shorter rest between intervals [54,55] or longer lasting 2-4 minutes with longer rest periods [56]. Evidence from studies using comparable HIIT approaches to that utilized in the present study indicate that HIIT is a more effective method for improving cardiorespiratory fitness, reducing blood pressure, improving blood lipid profiles, and improving insulin sensitivity among persons with lifestyle-induced cardiometabolic chronic diseases [57–59].

The primary aim of the present study was to investigate the effectiveness of HIIT compared to traditional moderate-intensity continuous training in a prediabetic population with both interventions supplemented by resistance training and the goal of improving glycemic control as measured by A1C. The secondary aim of this study was to examine how these two interventions impact body composition, musculoskeletal and aerobic fitness.

3.4.2 Methods:

For this randomized, 12 week PA intervention study, participants were recruited from the York University staff population via email distribution of project materials to staff contact lists and through advertisement in the campus daily e-newsletter. Men and women age 30-65 were eligible to participate if their A1C value fell within the prediabetes range defined by the ADA[64]. Participants were ineligible if they had already been diagnosed with diabetes, if they were currently involved in a structured exercise regimen or if they had a musculoskeletal constraint preventing them from participating in the exercise intervention. All participants completed the PAR-Q+ Physical Activity Readiness Questionnaire prior to engaging in any activity[90]. All protocols were reviewed and approved by the York University Human Participants Research Subcommittee and Biosafety Officer and all participants provided written informed consent.

A total of 73 participants expressed interest during the advertisement phase of recruitment and 35 attended the initial laboratory visit to have their A1C assessed. From this group, 21 were eligible for participation in the exercise intervention based on having an A1C in the prediabetes range. The 21 participants were stratified based on sex and then randomly assigned to one of the two exerciser intervention groups. Randomization was performed using a random number generator in Microsoft Excel.

3.4.2.1 Blood Testing Protocols:

Fingerstick capillary blood was collected using sterile techniques and A1C was analyzed using the Bio-Rad in2it (Bio-Rad Laboratories, Hercules, CA) point-of-care device which performs boronate affinity chromatography. A1C was selected as the primary biomarker because it provides a rolling three-month indicator of glycemic control, it is less variable than fasted blood glucose sampling, and A1C does not require participants to be fasted, allowing for more convenient scheduling of participants. Previously reported work from this lab has shown that there were no significant biases between values from the in2it

device used and those analyzed using the gold standard high-performance liquid chromatography (HPLC)[87].

During the second visit to the laboratory, a two-hour OGTT was performed to support the findings regarding glycemic control among participants. After arriving in a fasted state (no food or caloric drinks for a minimum of 8 hours prior), fingerstick capillary blood was collected and whole blood glucose was analyzed using the OneTouch UltraMini blood glucose monitoring system (LifeScan Canada Ltd. BC, Canada) and a second sample of approximately 200µl was collected from the same fingerstick via microvette. The second sample was centrifuged and plasma was separated and stored (-18°C) for the analysis of insulin. The insulin samples were analyzed using a Human Insulin ELISA kit (Abcam®, MA, USA). After the fasting samples were collected, participants consumed a 75g glucose beverage (Trutol™, Thermo Scientific, USA) within a 5 minute period and were then asked to remain seated and refrain from activity during the remainder of the protocol. After two hours, participants provided a second fingerstick blood sample from a different finger and both the blood glucose and insulin samples were collected. HOMA-β and HOMA-IR were calculated using standard equations as an assessment of beta cell function and insulin resistance[23,24]. Upon completion of the 36 exercise session intervention, all follow-up blood tests were repeated within 4 days of completing their final exercise session.

3.4.2.2 Fitness Assessment and Body Composition:

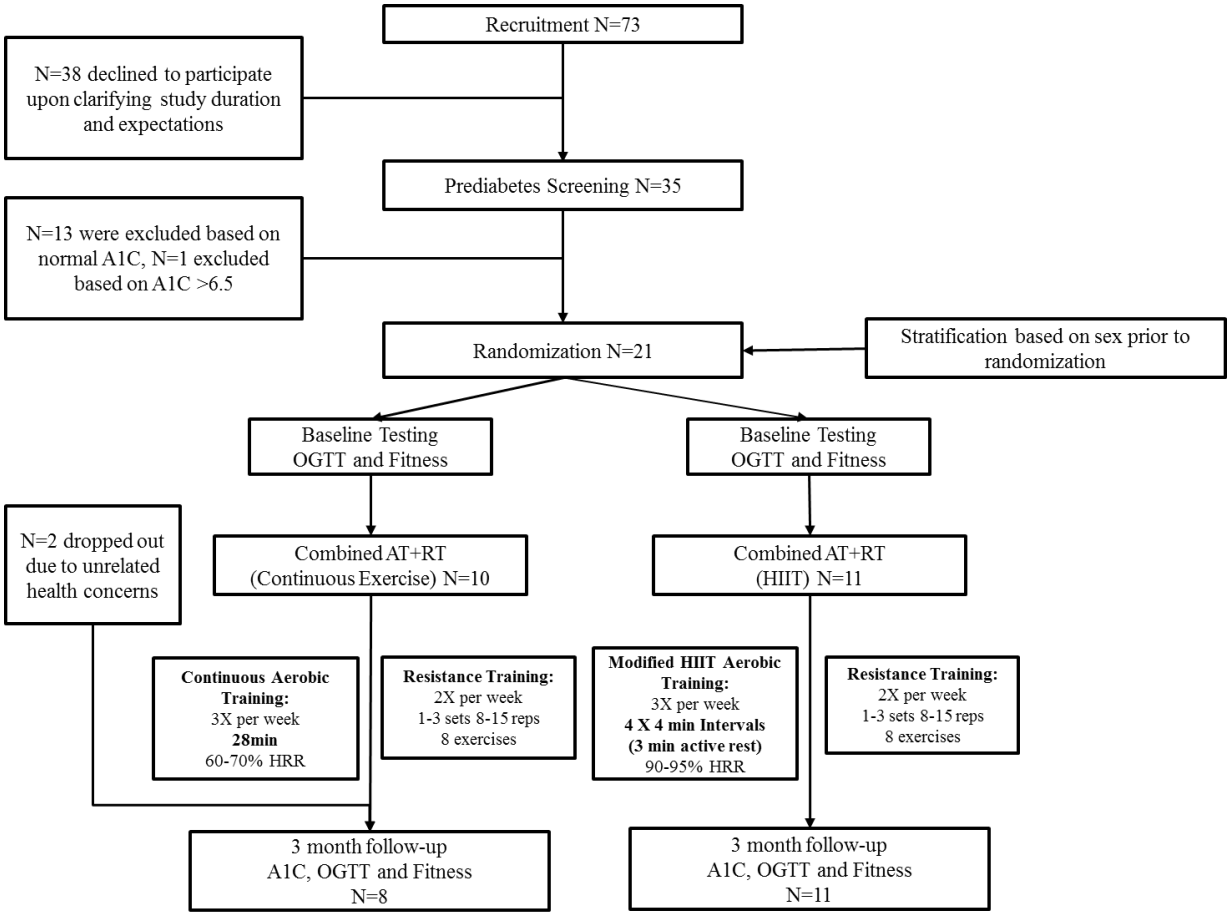
During a third laboratory visit, resting blood pressure and HR were measured with participants in a seated position using the BpTRU™ electronic monitor (BpTRU™ Medical Devices Ltd. BC Canada) which performed 6 cycles of measurement, each separated by 1 minute allowing for the calculation of an average value. Participants were then assessed for height using a stadiometer. Body mass and percent body fat were measured using a bioelectrical impedance analysis (BIA) scale (Tanita Corporation of America, IL, USA). Waist circumference was measured by the same tester for all participants via anthropometric tape using the NIH protocol[25]. The assessment of grip strength took place using a hand

grip dynamometer (Takei T.K.K. 5401, Niigata, Japan) and vertical jump was measured using the Vertec device (JumpUSA, CA, USA). Leg power was calculated using a previously validated equation[92]. Aerobic fitness (VO_2 peak) was assessed via an incremental treadmill walking/jogging protocol and VO_2 was measured by direct analysis of expired gas using open-circuit spirometry (S-3A/II oxygen, CD-3A carbon dioxide; AEI Technologies, Pittsburgh, PA). HR was monitored throughout the aerobic fitness test via the Polar monitoring system (Polar Electro Canada, QC, Canada). The protocol was adapted from that of Ebbeling et al[93] where the participant walks for 4 minutes at 0% grade to determine a walking speed that is safe and comfortable while inducing a HR that is 50-70% age-predicted HRmax. Participants then walk for an additional 4 minutes at 5% grade at the same walking speed. After the second 4 minute workload, participants completed subsequent 2 minute intervals at the same walking speed while adding 2% grade each interval until the test was terminated. Aerobic fitness test termination was determined by volitional fatigue. Participants were offered an opportunity to complete an additional workload after a brief rest period at the end of their test in an attempt to reach a higher VO_2peak. Participants followed the identical treadmill protocol during their final assessment with additional workloads completed following the same loading sequence if the participant was able to exceed his/her baseline termination point. Upon completion of all 36 exercise intervention sessions, all components of the baseline fitness assessment were repeated within 4 days of completing their final exercise session.

3.4.2.3 Physical Activity Intervention:

Participants were randomly assigned to one of two different exercise intervention protocols which both included resistance training along with the aerobic training. The resistance training portion was designed to act as a secondary component aimed to maintain lean body mass rather than improving overall strength. The effects of resistance training and the maintenance of lean body mass also have substantial positive implications among diabetic and prediabetic populations with respect to glycemic control and insulin sensitivity [14,26,27]. The 36 supervised exercise sessions were completed in an average of 16.6 weeks.

Figure 7: Participant flow from recruitment to follow-up assessment including randomization and descriptions of the two intervention arms



Aerobic Training Component:

Group 1 performed high intensity interval training (HIIT) on a motor driven treadmill. Participants were asked to complete supervised sessions in the laboratory three times per week until 36 sessions were completed. After a five minute warm-up on the treadmill, a series of four high intensity intervals were performed at 90% heart rate reserve (HRR) each lasting four minutes and separated by three minutes of active recovery at 50-60% HRR. HRR was selected for prescription of exercise due to the variability in resting HR among the participants. In all cases, the use of %HRR allowed participants to exercise at a slightly higher intensity when compared to percent maximum HR. The total "active component" of this protocol lasted 28 minutes. Upon completion of the four intervals, a five minute cool down took place followed by the resistance training component (see below).

Group 2 performed continuous moderate intensity exercise (60-70% HRR) on a motor driven treadmill. Supervised sessions were completed in the laboratory three times per week until 36 sessions were completed. After a five minute warmup on the treadmill, participants exercised at moderate intensity for a period of 28 minutes. This was followed by an active cool down on the treadmill lasting five minutes.

All sessions for both groups were supervised by a qualified exercise professional (QEP) with HR monitoring taking place every minute. If participants were not meeting their prescribed HR targets, adjustments to the treadmill took place in order to ensure the prescribed exercise intensity.

Resistance Training Component:

All participants, regardless of their randomly assigned aerobic exercise training group, performed resistance training on two of the three training sessions per week immediately following their aerobic fitness session. Exercises were selected to include large muscle groups and multiple joints. The exercises were arranged in a circuit and the participants were asked to perform as many repetitions as possible within a given time while maintaining proper breathing technique. One to two sets of the circuit were performed during each resistance training session. The QEPs supervising these sessions progressed the

training stimulus on the participants on an individualized basis by adding resistance to the movements or by increasing their time thereby requiring more repetitions to complete each component of the circuit. The circuit consisted of the following exercises; marching on the spot with high knees, squats with an overhead kettlebell press, push ups (or modified wall push ups), forearm plank, step-ups with a medicine ball shoulder press, quadra-ped (aka Bird-Dog), wall sit with isometric medicine ball front hold, and stair climb. The resistance training circuit is summarized in Appendix F.

3.4.2.4 Statistical Analyses:

An *a priori* sample size calculation was performed (GPower software v.3.1) using previously reported effect size[73] in A1C resulted in a total sample of 26 required to detect changes in A1C with 80% statistical power. Descriptive statistics for participant characteristics were analyzed using an independent samples t-test to assess potential differences between exercise intervention groups at baseline. Blood and fitness data were analyzed using repeated measures ANOVA to assess within (baseline versus follow-up) and between (Continuous versus HIIT training) group differences. Bonferroni adjustment was used for comparisons of estimated marginal means. The ANOVA included age and sex as covariates in the model. Assumptions of normality and heterogeneity of variance were tested for all variables. All analyses described in this investigation were performed using a two-sided 5% level of significance. All analyses were performed using IBM SPSS version 22 (IL, USA).

3.4.3 Results:

The results of the randomization allocated 11 (3 male, 8 female) participants into the HIIT exercise group while 10 (3 male, 7 female) were randomized into the continuous moderate intensity exercise group. Figure 7 shows the flow of participants from recruitment to study completion.

Baseline participant characteristics are summarized in Table 10. No significant differences between the two groups were observed for any measured variables at baseline.

Table 10: Baseline participant physical characteristics, fitness and blood test results reported by randomly assigned intervention group. P values represent baseline between-group comparisons.

Variable	Group	N	Mean	Std. Dev	P Value (HIIT vs Continuous)	95% Confidence Interval	
						Lower Bound	Upper Bound
Age (years)	Continuous	10	47.7	6.93	0.1	-12.83	1.13
	HIIT	11	53.6	8.21			
	Combined	21	50.8	8.02			
Height (cm)	Continuous	10	166.8	5.47	0.73	-4.46	6.24
	HIIT	11	165.9	6.17			
	Combined	21	166.3	5.72			
Weight (Kg)	Continuous	10	85.9	24.28	0.79	-20.49	15.73
	HIIT	11	88.3	14.66			
	Combined	21	87.2	19.34			
Body Mass Index (Kg/m^2)	Continuous	10	30.8	8.49	0.69	-7.35	4.95
	HIIT	11	32.0	4.61			
	Combined	21	31.4	6.59			
Body Fat (Tanita) (%)	Continuous	10	34.8	12.68	0.37	-13.52	5.3
	HIIT	11	38.9	7.5			
	Combined	21	36.9	10.25			
NIH Waist Circumference (cm)	Continuous	10	105.4	20.06	0.88	-16.43	14.23
	HIIT	11	106.5	10.72			
	Combined	21	106.0	15.46			
A1C (%)	Continuous	10	6.1	0.27	0.3	-0.49	0.16
	HIIT	11	6.3	0.42			
	Combined	21	6.2	0.36			
Fasting Glucose (mmol/L)	Continuous	10	5.8	0.61	0.16	-1.14	0.21
	HIIT	11	6.2	0.85			
	Combined	21	6.0	0.77			
Fasting Insulin (µIU/mL)	Continuous	10	15.7	28.73	0.35	-9.88	26.58
	HIIT	11	7.4	3.48			
	Combined	21	11.4	19.89			
2 Hour Glucose (mmol/L)	Continuous	10	7.9	1.27	0.67	-2.41	1.59
	HIIT	11	8.3	2.8			
	Combined	21	8.1	2.17			
2 Hour Insulin (µIU/mL)	Continuous	10	52.2	62.79	0.46	-28.35	60.72
	HIIT	11	36.0	30.95			
	Combined	21	43.7	48.18			
HOMA-β	Continuous	10	168.1	343.1	0.3	105.57	328.23
	HIIT	11	56.8	30.53			
	Combined	21	109.8	238.09			

Table 10: Continued

Variable	Group	N	Mean	Std. Dev	P Value (HIIT vs Continuous)	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
HOMA-IR	Continuous	10	3.8	6.59	0.4	-2.47	5.93
	HIIT	11	2.1	1.02			
	Combined	21	2.9	4.57			
Resting HR (bpm)	Continuous	10	80.4	14.7	0.63	-8.6	13.94
	HIIT	11	77.7	9.71			
	Combined	21	79.0	12.09			
Resting SBP (mmHg)	Continuous	10	119.8	15.8	0.2	-25.14	5.65
	HIIT	11	129.6	17.72			
	Combined	21	124.9	17.15			
Resting DBP (mmHg)	Continuous	10	76.6	6.75	0.2	-12.78	2.89
	HIIT	11	81.6	9.92			
	Combined	21	79.2	8.73			
Combined Hand Grip (Kg)	Continuous	10	63.7	18.55	0.84	-17.16	14.02
	HIIT	11	65.2	15.56			
	Combined	21	64.5	16.63			
Vertical Jump Max (cm)	Continuous	10	23.5	12.77	0.82	-8.05	10.01
	HIIT	11	22.5	6.2			
	Combined	21	23.0	9.64			
Leg Power (Watts)	Continuous	10	2399.1	1038.0	0.831	-898.9	730.3
	HIIT	11	2483.4	733.3			
	Combined	21	2443.3	869.2			
Peak HR (bpm)	Continuous	10	169.9	24.48	0.9	-17.06	19.23
	HIIT	11	168.8	9.92			
	Combined	21	169.3	17.87			
Absolute VO_2peak ($L \cdot min^{-1}$)	Continuous	10	2.0	0.71	0.72	-0.64	0.45
	HIIT	11	2.1	0.46			
	Combined	21	2.1	0.58			
Relative VO_2peak ($mL \cdot Kg \cdot^{-1} min^{-1}$)	Continuous	10	25.1	10.71	0.86	-7.26	8.6
	HIIT	11	24.4	4.29			
	Combined	21	24.8	7.81			
Time on Treadmill (min)	Continuous	10	15.4	2.99	0.41	-1.66	3.92
	HIIT	11	14.3	3.1			
	Combined	21	14.8	3.03			

3.4.3.1 Blood Testing Results:

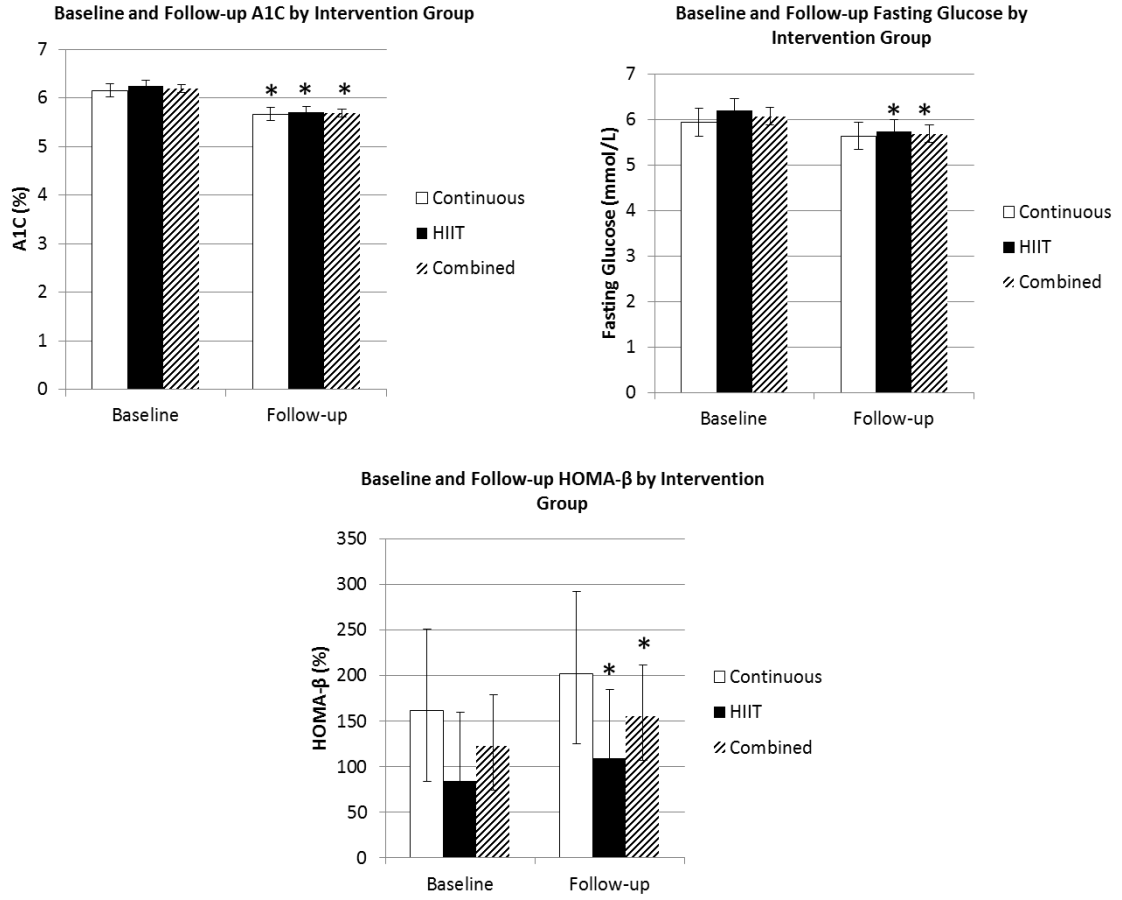
At baseline, as summarized in Table 10, a mean total group A1C value of 6.2% was observed while the results of the OGTT revealed mean fasting glucose and mean 2 hour glucose values of 6.0mmol/L and 8.1mmol/L respectively.

Post intervention blood testing indicated no between-group differences when comparing participants in the HIIT group to those in the continuous moderate intensity exercise group for any of the blood variables measured. However, significant within-group improvements in A1C, and fasting glucose were observed. A summary of blood test outcomes is summariized in Table 11 and visually displayed in Figure 8. HOMA-IR had no significant change over time, nor between intervention groups. It should be noted, however that the mean HOMA-IR at baseline and post-intervention was indicative of insulin resitance. HOMA-β showed significant improvement upon follow-up measurement which is indicative of improved β-cell function. No differences between intervention groups were observed for HOMA-β.

3.4.3.2 Health-Related Physical plus Physiological Fitness Results:

Baseline assessments of fitness and body composition, summarized in Table 10, indicated that the participants possessed characteristics typically associated with a high risk profile for CVD and diabetes. A mean BMI of 31.4Kg/m^2 coupled with a mean waist circumference of 106cm indicates that this group of participants were classified as obese with high central adiposity. Baseline aerobic fitness results showed a mean VO_2peak of 24.8mL·Kg·$^{-1}$min^{-1} which is equivalent to approximately 7METs.

Figure 8: Summary of significant blood test results (mean ±SE) showing temporal changes in both intervention groups and when the groups were combined (* Improvements from baseline, Sig p<0.05)



Post intervention fitness assessment revealed no differences from training between participants in the HIIT group and the continuous moderate intensity exercise intervention group. When examining the within-group changes over time, significant improvements were observed for waist circumference (-4.5cm), vertical jump (+2.6cm), both absolute and relative VO_2peak (+0.4L·min^{-1} and +5.0mL·Kg^{-1}·min^{-1}), and time on treadmill during the aerobic fitness test (+4.8min). A summary of fitness assessment outcomes is provided in Table 11 and visually depicted in Figure 9. Figure 10 shows individual participant data for VO_2peak, A1C, HOMA-β and HOMA-IR. The participants are ranked based on their change in VO_2peak after completion of the intervention.

Figure 9: Summary of significant body composition and aerobic fitness results (mean ±SE) showing temporal changes in both intervention groups and when the groups were combined (*Improvements from baseline, Sig p<0.05)

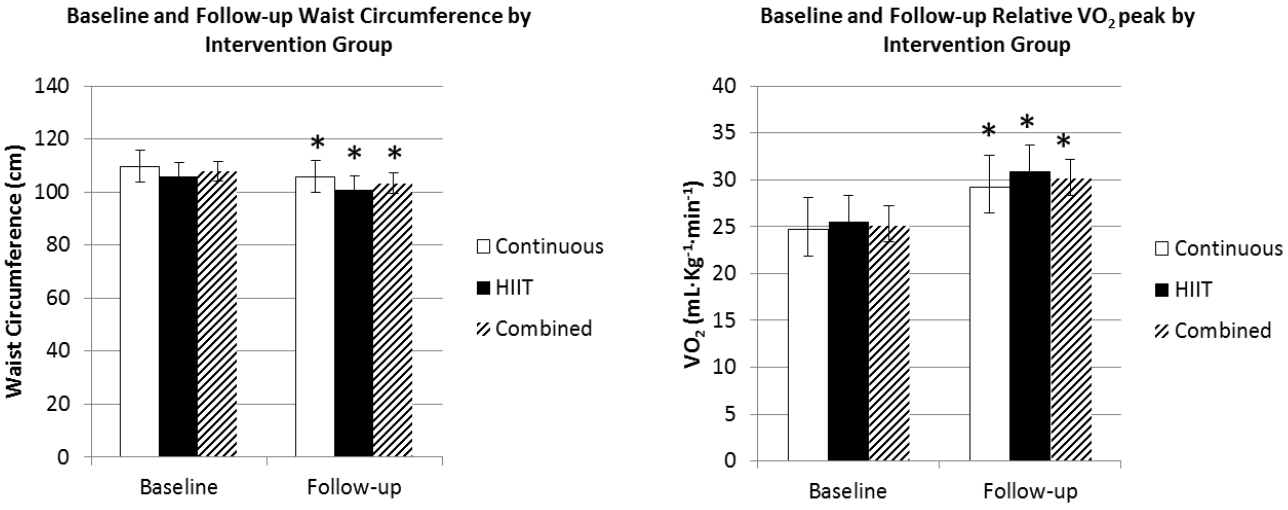


Figure 10: Individual participant data for A1C, HOMA-β and HOMA-IR ranked based on change in VO_2peak after 3 months of intervention. Solid lines represent participants in the continuous aerobic training group while patterned bars represent participants in the HIIT group.

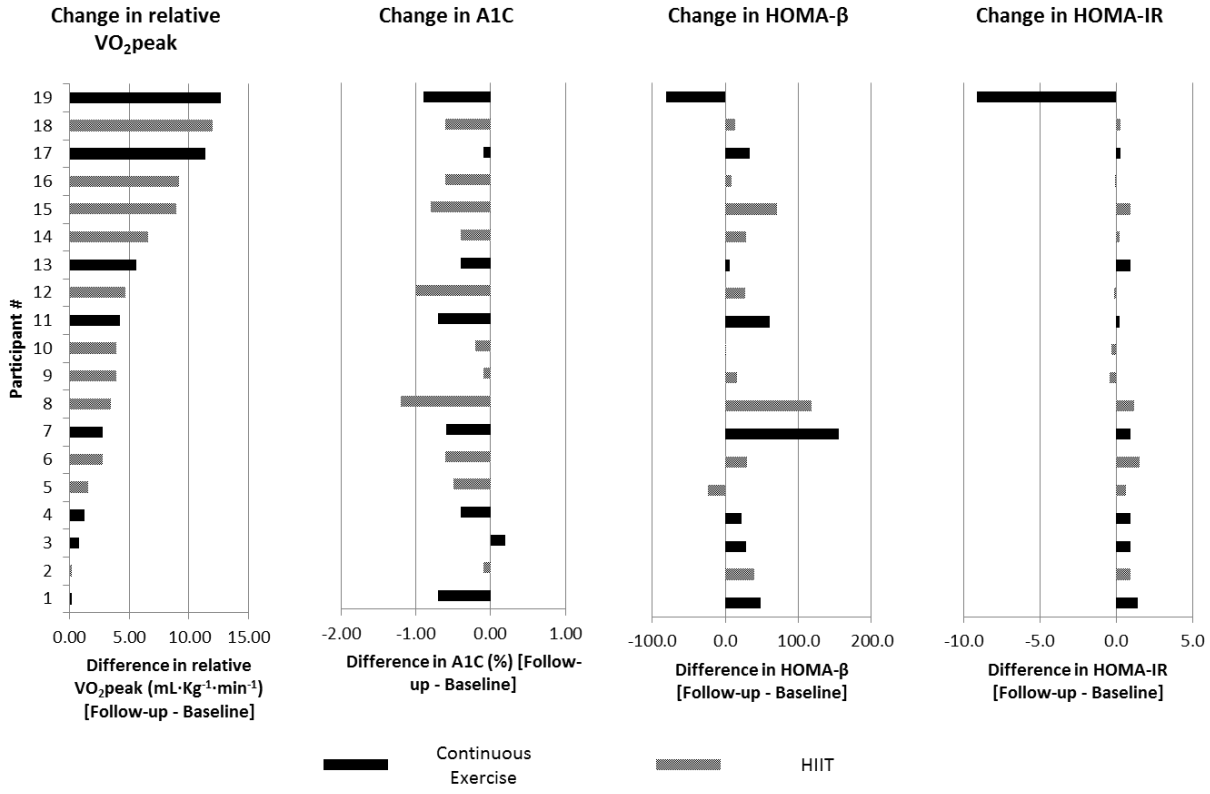


Table 11: Results of the repeated measures ANOVA showing between and within-group differences from baseline to follow-up for the two intervention groups. (*Sig. p<0.05)

Variable	Intervention Group	N	Baseline Value	SE	N	Follow-Up Value	SE	Mean Difference (Follow-up - Baseline) Within-Group Changes	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	P Value	Mean Difference (Continuous - HIIT) Between-Group Changes	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	P Value
A1C (%)	Continuous	10	6.1	0.1	8	5.7	0.1	-0.5*	-0.8	-0.2	0.01	-0.07	-0.4	0.3	0.68
	HIIT	11	6.2	0.1	11	5.7	0.1	-0.6*	-0.8	-0.3	0.00				
	Combined	21	6.2	0.1	19	5.7	0.1	-0.5*	-0.7	-0.3	<0.001				
Fasting Glucose (mmol/L)	Continuous	10	6.0	0.3	8	5.6	0.3	-0.3	-0.7	0.2	0.19	-0.2	-1.0	0.7	0.66
	HIIT	11	6.2	0.3	11	5.7	0.3	-0.5*	-1.0	-0.1	0.03				
	Combined	21	6.1	0.2	19	5.7	0.2	-0.4*	-0.7	-0.1	0.01				
Fasting Insulin (pmol/L)	Continuous	10	15.6	7.5	8	15.8	4.5	-1.2	-12.1	9.8	0.81	5.5	-11.8	22.9	0.51
	HIIT	11	9.6	6.3	11	10.8	3.8	2.2*	0.4	4.0	0.02				
	Combined	21	12.6	4.7	19	13.3	2.8	0.7	-3.6	5.0	0.74				
2h Glucose (mmol/L)	Continuous	10	8.1	0.9	8	7.8	0.9	-0.6	-1.9	0.7	0.34	-0.3	-2.7	2.1	0.78
	HIIT	11	8.3	0.8	11	8.2	0.7	0.2	-1.3	1.6	0.83				
	Combined	21	8.2	0.6	19	8	0.6	-0.2	-1.1	0.8	0.70				
2h Insulin (pmol/L)	Continuous	10	61.2	19.7	8	43.6	10.7	-19.4	-45.4	6.6	0.12	19.8	-23.5	63.0	0.35
	HIIT	11	35.8	16.5	11	29.4	9.0	-5.1	-22.0	11.8	0.52				
	Combined	21	48.5	12.3	19	36.5	6.7	-12.0	-26.4	2.4	0.10				
HOMA-β	Continuous	10	161.2	89.5	8	202.3	77.6	34.4	-20.3	89.0	0.18	85.3	-156.6	327.2	0.46
	HIIT	11	84.1	75.2	11	108.8	65.3	29.6*	4.3	54.9	0.03				
	Combined	21	122.7	55.8	19	155.5	48.4	32.9*	8.3	57.4	0.01				
HOMA-IR	Continuous	10	3.8	1.7	8	3.7	1.0	-0.45	-3.4	2.5	0.73	1.1	-2.7	5.0	0.54
	HIIT	11	2.6	1.5	11	2.7	0.8	0.42	0.0	0.9	0.06				
	Combined	21	3.2	1.1	19	3.2	0.6	0.03	-1.1	1.2	0.95				
Weight	Continuous	10	90.1	7.8	8	89.8	7.9	-0.7	-2.6	1.2	0.42	1.9	-20.9	24.7	0.86
	HIIT	11	88.6	6.5	11	87.5	6.7	-0.8	-2.0	0.4	0.18				
	Combined	21	89.3	4.8	19	88.6	4.9	-0.7	-1.6	0.2	0.13				
BMI (Kg/m^2)	Continuous	10	32.2	2.7	8	32	2.7	-0.3	-0.9	0.4	0.37	0.4	-7.5	8.2	0.92
	HIIT	11	31.9	2.3	11	31.6	2.3	-0.3	-0.7	0.2	0.19				
	Combined	21	32.1	1.7	19	31.8	1.7	-0.3	-0.6	0.1	0.11				
Body Fat (TANITA) (%)	Continuous	10	36.8	2.8	8	36.3	2.9	-0.4	-2.4	1.6	0.67	-1.2	-9.4	7.0	0.76
	HIIT	11	37.8	2.3	11	37.7	2.4	-0.2	-1.0	0.7	0.72				
	Combined	21	37.3	1.7	19	37	1.8	-0.3	-1.1	0.6	0.52				

Table 11: Continued

Variable	Intervention Group	N	Baseline Value	SE	N	Follow-Up Value	SE	Mean Difference (Follow-up - Baseline) Within-Group Changes	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	P Value	Mean Difference (Continuous - HIIT) Between-Group Changes	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	P Value
NIH Waist Circumference (cm)	Continuous	10	109.6	6.1	8	105.6	5.9	-4.3*	-7.7	-1.0	0.02	4.1	-13.2	21.4	0.62
	HIIT	11	106.0	5.2	11	100.9	4.9	-4.8*	-8.0	-1.5	0.01				
	Combined	21	107.8	3.8	19	103.3	3.7	-4.5*	-6.8	-2.2	0.00				
Resting HR (bpm)	Continuous	10	77.7	4.9	8	74	4.4	-4.3	-15.8	7.3	0.41	0.6	-11.4	12.5	0.92
	HIIT	11	78.3	4.1	11	72.3	3.7	-5.6	-12.9	1.6	0.11				
	Combined	21	78.0	3.1	19	73.1	2.8	-4.9	-10.8	1.1	0.10				
Resting SBP (mmHg)	Continuous	10	114.4	5.9	8	116.8	7.3	1.6	-2.2	5.5	0.35	-13.4	-32.3	5.6	0.15
	HIIT	11	129.3	5.0	11	128.7	6.1	-0.1	-5.3	5.1	0.97				
	Combined	21	121.9	3.7	19	122.8	4.5	0.9	-2.3	4.1	0.57				
Resting DBP (mmHg)	Continuous	10	75.1	3.5	8	76.7	4.2	0.9	-3.1	4.9	0.62	-4.2	-14.8	6.4	0.41
	HIIT	11	81.7	2.9	11	78.5	3.5	-2.6	-8.1	2.8	0.30				
	Combined	21	78.4	2.2	19	77.6	2.6	-0.8	-4.3	2.7	0.64				
Combined Hand Grip (Kg)	Continuous	10	62.4	2.9	8	67.4	3.4	4.5	-3.2	12.3	0.21	-4.1	-12.2	4.0	0.30
	HIIT	11	68.2	2.4	11	69.8	2.8	1.9	-2.2	6.0	0.32				
	Combined	21	65.3	1.8	19	68.6	2.1	3.3	-0.6	7.2	0.09				
Vertical Jump (cm)	Continuous	10	21.4	2.1	8	25.3	2.2	1.8	-0.1	3.7	0.06	-1.8	-7.4	3.9	0.51
	HIIT	11	24.5	1.8	11	25.8	1.8	0.3	-1.1	1.7	0.62				
	Combined	21	23.0	1.3	19	25.6	1.4	2.6*	0.1	5.2	0.05				
Leg Power (Watts)	Continuous	10	2399.1	328.4	8	2697.9	337.1	79.4	-63.2	222.3	0.23	43.0	-917.7	1003.8	0.93
	HIIT	11	2483.4	221.1	11	2466.91	234.7	-16.5	-102.4	69.4	0.68				
	Combined	21	2443.3	189.7	19	2564.2	192.5	31.3	-32.3	94.8	0.31				
Absolute VO_2 ($L \cdot min^{-1}$)	Continuous	10	2.1	0.2	8	2.4	0.2	0.3*	0.1	0.6	0.01	-0.2	-0.7	0.2	0.32
	HIIT	11	2.2	0.1	11	2.7	0.1	0.4*	0.2	0.6	<0.001				
	Combined	21	2.2	0.1	19	2.5	0.1	0.4*	0.2	0.5	<0.001				
Relative VO_2 ($mL \cdot Kg^{-1} \cdot min^{-1}$)	Continuous	10	24.7	2.8	8	29.3	3.4	4.9*	0.9	8.9	0.02	-1.3	-9.9	7.5	0.77
	HIIT	11	25.5	2.4	11	30.9	2.8	5.2*	2.8	7.6	0.00				
	Combined	21	25.1	1.7	19	30.1	2.1	5.0*	2.8	7.1	<0.001				
Time on Treadmill (sec)	Continuous	10	14.8	1.2	8	19.7	1.7	5.1*	3.5	6.8	<0.001	0.5	-3.8	4.7	0.82
	HIIT	11	14.4	1.0	11	19.3	1.5	4.6*	3.2	5.9	<0.001				
	Combined	21	14.6	0.8	19	19.4	1.1	4.8*	3.9	5.7	<0.001				

Covariates appearing in the model are age and sex. P values are based on estimated marginal means. Adjustment for multiple comparisons: Bonferroni. * Sig. P<0.05

3.4.3.3 Participant Adherence:

All participants completed 36 supervised exercise sessions over an average of 16.6 weeks. It should be noted that this time frame included a 2 week period over the Christmas holidays during which participants did not come to the laboratory for their training sessions. They were encouraged to be active but not to deviate from their typical lifestyle habits (diet and PA participation) throughout this period. To enhance clarity, if the Christmas hiatus was included in the calculation, participants would have averaged 2.5 supervised sessions per week over a n 18.6 weeks during their participation in the study. There were no significant adverse events reported during the testing or exercise interventions of this study other than muscle soreness that is to be expected with this type of intervention.

Participants were asked to maintain their typical lifestyle habits for the entire duration of the study. A self-report questionnaire was completed by participants after the completion of the intervention to ascertain if the participants did or did not make changes to their lifestyle beyond their participation in the study. This questionnaire revelaed that 9/15 reported that their non- exercise related activities (activities of daily living, active commuting etc…) remained the same or decreased during their time in the study. The questionnaire also indicated that 13/15 participants noted that their participation in structured exercise sessions outside of their participation in the study either stayed the same or decreased. When asked about dietary habits, 7/15 participants noted that their diet was only slightly healthier during their participation in the study while the remaining 8 noted that their diet remained constant or was less healthy. Finally, 9/15 participants perceived their overall lifestyle to be healthier during their participation in the study while the remaining 6 reported that their overall lifestyle did not change. None of the participants revealed a perception of having a less healthy lifestyle.

3.4.4 Discussion:

The primary finding from this study is that, in both intervention groups, A1C significantly improved and there were no significant differences between the two forms of aerobic training. The observed exercise-

induced improvements in glycemic control were corroborated by a significant reduction in fasting glucose and an improvement in beta cell function as evidenced by changes in HOMA-β. The mean reduction in fasting glucose of 0.4mmol/L should be considered clinicially modest but the mean reduction in A1C of 0.5% is highly clinically indicative of improved glycemic control given the nature of A1C as a 3 month indicator of glycemic control and its lack of short term measurement volatility. Previous investigators have reported that reductions in A1C of 1% are associated with reductions in myocardial infarction risk of up to 27% and a 37% reduction of microvascular complications among persons with diabetes[28]. The 0.5% reduction in A1C observed in this study for persons with prediabetes may be associated with improved long term CVD risk and potentially the prevention of progression towards T2D. The mean A1C at baseline fell within both the ADA and CDA diagnostic range[3,64] for prediabetes while the mean A1C at follow up for all participants was 5.7%, which is significantly below the CDA prediabetes cut point of 6.0% and right in line with the lower boundary of the ADA criteria (5.7-6.4%). The observed reduction in A1C is in line with that observed in other exercise intervention studies [29,30] involving T2D, however it is the first that we are aware of to observe such findings among persons with prediabetes. The mean increase in HOMA-β of 32.9% between baseline and follow-up among all subjects provides support for improvements in glycemic control. Given that a value of 100% for HOMA-β is indicative of "normal" beta cell function, it was not surprising that the mean for all participants was above this threshold at baseline[35,36]. It would be unlikely to see damage to the beta cells at this stage of diabetes progression and damage to the beta cells typically occurs as a result of long term hyperglycemia and glucose toxicity[119]. That said, as per the recommended usage of the HOMA model, tracking longitudinal changes in beta cell function is among the primary utilities for this measure and the improvements observed in this study should not be ignored[35]. Upon examination of Figure 10, it appears that there is no predictive relationship between improvements in A1C and improvement in aerobic fitness or which group participants were randomly assigned to. It appears that changes in HOMA-β and the inferred improvements in beta cell function are most closely linked to changes in A1C and this relationship warrants further investigation.

In addition to the observed improvements in glycemic control, participants in both exercise intervention groups had significant improvements in waist circumference, vertical jump, and aerobic fitness with no significant differences between the two groups. The mean reduction in waist circumference of 4.5cm coupled with the finding of no changes to body weight or BMI implies an improvement in body composition and a reduction in central adiposity despite the fact that percent body fat did not change significantly. The relationship between central adiposity, diabetes and cardiovascular risk has been thoroughly explored in individuals who possess greater long term cardiometabolic risk if they have a high waist circumference regardless of BMI classification [25,31]. While classified as "obese" at baseline, based on both BMI and WC values, the reduction in WC post intervention drops the participants' mean WC into a lower risk classification for their given BMI [31]. The lack of weight loss/BMI reduction is in line with similar studies involving aerobic and resistance training [30] and may be explained by a maintenance of muscle mass resulting from the strength training component as well as the fact that participants were told not to modify their diet and typical lifestyle behaviours. This is corroborated by the participants' self-reported information regarding diet and PA participation outside of the intervention sessions. That is, the majority of participants noted that they were equally or less active during the study than they were prior to their involvement and that their dietary habits were also equally or less healthy. None of the participants indicated significant healthy changes to their PA participation or their diet during the study when compared to their pre-study habits. These points support the contention that exercise-induced improvements to glycemic control can be quite significant, even in the absence of dietary modification and weight loss.

The post intervention improvements in aerobic fitness evidenced by both increased VO_2peak and increased time on the treadmill test indicate that the participants significantly improved their functional capacity. The mean gains in VO_2peak extend beyond the typical accepted level of error for this measure which is approximately 2-4%. Previous research has shown that cardiorespiratory fitness has a substantial protective effect for CVD mortality as well as diabetes prevalence regardless of BMI classification [32–35].

In addition to the cardiometabolic impact of improved cardiovascular fitness, PA and the resultant improvements in functional capacity have also been associated with improved quality of life[36].

3.4.4.1 Study Limitations:

Although this study yielded interesting and significant findings pertaining to prediabetes and exercise intervention, there are several limitations that must be addressed. First, the limited sample size and lack of control group limits the generalizability regarding the study outcomes. In addition, even though the resistance training component was only a small relative PA dose, a group which performed no resistance training would further broaden the impact of conclusions drawn from this study. Despite the small number of participants, the post-hoc power analyses revealed that the sample was sufficiently powered for the given within-group comparisons ($\beta>0.80$). Also, it should be noted that the sample was insufficiently powered to detect differences between groups. The within-group findings are significant enough to inform future randomized controlled trials involving larger, more representative samples to fully quantify the potential effects of these training regimens and further examine any potential differences between them.

The study duration may also be considered a limitation. Studies using A1C as a primary outcome typically take place over longer time frames, such as 6 months. However, despite the relatively short duration, this exercise intervention still achieved a significant reduction in A1C. It would be of scientific merit to conduct a similar study taking place over 6 months, or longer, with repeated measurement at more frequent intervals to better describe any potential changes in glycemic control over time as well as any potential enduring effects after the cessation of the structured exercise.

The use of the Bio-Rad in2it point of care device for A1C assessment is also a potential limitation, but in a previous research study, this device was used and compared to HPLC revealing no significant bias between the two techniques[87].

The post-hoc self-reporting of lifestyle and dietary habits during participation in the study is another possible limitation that must be addressed. An ideal study design would have included measured PA participation using accelerometry and quantification of dietary habits using food records throughout the study.

3.4.5 Conclusion:

The completion of 36 supervised exercise sessions over a 16 week period involving either high intensity interval training or continuous moderate intensity aerobic training, both supplemented by resistance training , resulted in significantly improved glycemic control, body composition, musculoskeletal and aerobic fitness in a population of individuals with prediabetes. These findings provide support that the goals of the study were met although further investigation with larger samples may help to identify any differences between aerobic exercise modes. The results of this study should inform future interventions for persons with prediabetes with the goal of preventing T2D and alleviating its resultant global health burden.

CHAPTER 4: OVERVIEW OF THE STUDIES

4.1 Summary of the Research and General Discussion

Inspired by the overwhelming need for PA intervention strategies targeting persons with prediabetes, and the current state of prediabetes and T2D prevalence, the PRE-PAID project set out to build upon the existing body of literature regarding the identification of persons at high risk for developing T2D and utilize both community-based and laboratory-based PA strategies that, in some cases were culturally-specific with the goal of preventing or delaying the onset of T2D.

At the onset of the project, a strategy was developed and enhanced through effective working relationships with various community partners to implement the Phase I screening and recruitment initiative. During this time, the PRE-PAID risk questionnaire and point-of-care blood testing were effectively deployed as a risk assessment tool reaching a broad catchment of participants largely from the targeted, high-risk ethnicities. These participants then were engaged in community-based PA sessions designed to help them accumulate the recommended 150 minutes per week of moderate intensity PA. The sessions were delivered by QEPs assisted by culturally-matched PA leaders and held at venues which were conveniently situated within the target communities involved. The classes were free of charge and provided services such as child minding in an attempt to alleviate as many barriers to PA as possible with hopes of maximizing attendance and adherence to the program.

During the final phase of the project, a more controlled, laboratory-based approach was adopted to examine the effects of two different randomly assigned modes of aerobic training coupled with resistance training on their ability to induce improvements in glycemic control in a population of persons with prediabetes. This type of approach provided an opportunity for enhanced PA supervision and participant adherence/retention. Enhancing the understanding of how different forms of exercise impact glycemic control in prediabetics is vital to the design and implementation of future prevention strategies as well as the development of public health policies and PA recommendations made by various governing bodies.

Considering the entire body of work described in this thesis it is abundantly clear that the findings from the PRE-PAID project will contribute positively to the field and inform further research initiatives involving persons at high risk for T2D involving PA and/or exercise interventions both at the community level and in a standard exercise environment. If the goals of the project are revisited, it is clear that the community-based screening protocol was able to successfully identify individuals at high risk for developing T2D. The risk questionnaire, coupled with point-of-care blood testing for A1C should be considered as a tool for qualified health professionals and diabetes educators to be used during initial contact with prospective patients/clientele. This approach to screening is relatively cost efficient and portable allowing large catchments of individuals to be assessed with enhanced convenience for those being screened. Prior to engagement in any form of intervention, the first step to prevention of T2D is recognition of risk.

The second objective of the project was to prevent persons with prediabetes from progressing toward T2D by engaging those identified during the screening process in a supervised PA program that is culturally-specific, community-based and supervised by a QEP. During Phase II, this goal was met largely as a result of collaboration with various community partners. That said, there was a great deal of participant attrition at various stages of Phase II. First, there was a significant drop (32%) in participant number between the initial screening visit and participation in at least one PA class. This occurrence can possibly be explained by the additional time commitment and travel required to attend the classes. In general, the screening sessions provided a convenient opportunity for persons to get screened and only took approximately 15 minutes. The PA classes were on a fixed schedule and required a 60 minute time commitment or more. It is also possible that several participants simply do not see the value of PA participation or fully understand the potential health consequences of T2D. There were also a large number of participants who, even though they participated in one PA session, decided not to attend regularly or provide follow-up measures. Once again, these participants may have been steered away from the intervention given the regular time commitment. Despite the attrition observed, significant

improvements were observed in A1C, HOMA-β, and strength and aerobic fitness among participants who did provide follow-up measures.

In the final phase of the project, the goal was to determine if differences exist between different forms of exercise in their ability to elicit changes in glycemic control among prediabetic participants. This was accomplished through a randomized, laboratory-based study design. After participation in 3 months of either HIIT or continuous moderated intensity aerobic exercise, no significant differences were observed between the two intervention groups. All participants completed the same resistance training protocol in addition to their randomly assigned aerobic component and mean improvements were observed after 3 months in terms of glycemic control, body composition and physical fitness when analyzed as one group. It is possible that participation exceeding 3 months may elicit differences between the two protocols.

It is also important to note that there were no reported adverse events during any of the community-based PA sessions or the laboratory-based sessions beyond mild muscular discomfort which would be expected during any type of PA intervention involving persons who were previously sedentary. This reaffirms the notion that participation in habitual exercise that is of moderate intensity, or greater, can be performed safely in prediabetic populations. The observed lack of adverse events is attributable, in part, to the presence and training of the QEPs involved in the project. Their strong academic and practical background provided the necessary tools to administer and progress the participants in a safe and effective manner.

The observed improvements in glycemic control, body composition and physical fitness in Phases II and III substantiate the existing evidence for PA participation. Improvements in these traits have been previously shown to reduce risk for comorbid conditions such as hypertension and CVD. The mechanism through which glycemic control was improved was not a primary goal of this investigation, however, several possible explanations could account for the observed improvements in Phase II and Phase III. Insulin sensitivity has been shown to improve with participation in habitual PA through various

mechanisms both at the hormonal level and at the level of the muscle. Also, the observed improvements in HOMA-β in both phases indicates an improvement in beta cell function and, coupled with the observed reductions in A1C, add to the ability to conclude that an improvement in glycemic control has taken place.

Despite there being three distinct phases of the PRE-PAID project, each of the phases are closely linked to the importance of prediabetes as an area of focus for both community-based and laboratory-based interventions. The emphasis on prediabetes, specifically, is a deviation from typical health care practices which are predominantly treatment/management based for persons already diagnosed with T2D. If persons with prediabetes are identified and given the opportunity to participate in interventions that will prevent or delay T2D, the devastating complications and associated health care costs of diabetes could be mitigated.

4.2 Summary of Conclusions

1. Using a simple screening approach involving risk factor identification and A1C point-of-care blood testing, large and diverse population groups become more accessible and the identification of prediabetes can occur earlier.

2. This early detection of prediabetes provides increased awareness and opportunity to individuals allowing them to make important lifestyle changes as quickly as possible with the goal of preventing, or delaying, the progression towards T2D and the known associated complications.

3. The potential reduction in T2D incidence and prevalence would likely translate into substantial positive implications regarding health care resource utilization and the current socio-economic burden attributed to diabetes.

4. Participation in a community-based and culturally specific PA intervention targeting persons with prediabetes is associated with improvements in glycemic control observed using A1C, HOMA-β and HOMA-IR.

5. Other protective health benefits included improvements in strength and cardiovascular fitness, both of which are relevant to persons at risk for T2D as well as several other chronic diseases.

6. Although participant adherence was a limitation to this study, these results are in line with the project goals, are powerful and should inform the design of future interventions aiming to prevent T2D at the community level.

7. Ongoing identification of barriers to PA, including those that are culturally-specific, needs to take place in order to maximize participation and broaden the catchment of people who may benefit from these observed benefits which may lead to improved quality of life and alleviation of the substantial financial burden faced by the health care system in Canada and world-wide.

8. The completion of 36 supervised exercise sessions over a 16 week period involving either high intensity interval training or continuous moderate intensity aerobic training, both supplemented by resistance training , resulted in significantly improved glycemic control, body composition, musculoskeletal and aerobic fitness in a population of individuals with prediabetes.

9. These findings provide support that the goals of the study were met although further investigation with larger samples may help to identify any differences between aerobic exercise modes.

10. The results of this study should inform future interventions for persons with prediabetes with the goal of preventing T2D and alleviating its resultant global health burden.

4.3 Limitations and Areas of Future Research

4.3.1 Limitations

Though the PRE-PAID project was successful in achieving several of its goals, there are several limitations to the research methodology, potentially limiting the scope of conclusions that must be addressed. During the first phase of the project, despite the large number of participants screened, the sample is not perfectly representative of the population in the GTA, or that of Canada. This is reflected in unbalanced numbers of men and women, unbalanced representation from all age cohorts, uneven distribution from each ethnicity and uneven distribution of participants in the "normal", "prediabetes" and "diabetes" classification based on their blood test scored. These divergences from a representative sample occurred as a result of the targeted approach and selection of communities during participant recruitment. Although the sample may not be perfectly representative, it is still important to develop tools for use among high risk populations since these populations may warrant the greatest amount of urgency for intervention and that conclusions made in this project are applicable to these high risk groups.

During the intervention portions of the project (Phases II and III), the lack of control group is likely the most notable limitation to the study. Lacking a control group certainly prevents firm conclusions that imply causality, however, the research is not without merit. Given the scope of the project and the community-based nature, it seemed ethically appropriate to enroll all participants who were interested in the intervention portion. This decision was also made in an attempt to maximize participant social support and adherence. If, for example, a group of participants who have an existing social relationship were screened together and expressed interest in the intervention, having one of them randomly assigned to a control group would likely lead to a lack of motivation from the others to continue with the study.

During Phase II a great deal of participant attrition was observed. In an ideal situation, all subjects who initially provided baseline data would also have measurements taken at each of the follow-up time points. The community-based nature of Phase II is likely largely to blame for this observed trend. Even

though the screening and PA sessions were offered in the community at central locations that were accessible via transit and other means, other barriers to participation prevailed and limited both attendance at the PA sessions and follow-up measurements after 3 and 6 months. These barriers may include; time commitment, transit, familial obligations, and general lack of interest or lack of understanding the potential benefits of the PA classes. As much as possible, barriers to participation were addressed by the researchers through the provision of child minding services at the classes, reimbursement for transit costs in some cases, translation of study materials and use of culturally matched PA instructors. Despite the efforts to eliminate these barriers, reduced participation rates were greatest among all groups except those in the Chinese group. This was an interesting finding and further investigation into ethnospecific reasons for increased participation is certainly warranted.

Despite the lack of control group and high rates of participant attrition in Phase II, statistically significant improvements in blood and fitness measures were observed among those who provided follow-up data. If future research adopts a similar approach and is able to retain a higher percentage of participants, similar results, if found, would be highly informative and impactful from a public health and exercise prescription perspective.

Finally, in Phase III, in addition to the lack of control group, the other primary limitations were the low number of participants and duration of the intervention. Despite the low numbers, post hoc power analyses showed that for the within group analysis, there was sufficient power to determine significance. With respect to study duration, the 3 month timeline is likely the shortest amount of time required to detect any changes in A1C and interventions using A1C as an outcome measure typically run for 6 months or longer. This additional time would potentially increase the likelihood of detecting between-group changes which were not observed in Phase III.

4.3.2 Future Research

This project was novel in its aim to target persons at high risk for developing T2D through an ethnospecific approach. The incorporation of point-of-care A1C assessment in the screening process was a novel approach which greatly enhances the predictive value of pen and paper risk questionnaires and overall assessment of risk. The examination of HIIT versus continuous moderate intensity aerobic exercise among persons with prediabetes was also novel due to the inclusion of resistance training for both groups and the use of A1C as the primary outcome independently of other lifestyle modification.

The collective results of the PRE-PAID project should inform a great deal of future research. With respect to the screening approach developed during Phase I, next steps should aim to recruit a more representative sample with greater total numbers of participants to better understand the predictive value of the questionnaire and enhance its scope. Alterations to the weighting of the included questions could also be made based on the results of Phase I. Re-weighting the questions that contributed most to the variance in A1C could enhance the efficacy of the questionnaire as a screening tool when used in the absence of blood testing.

With respect to the PA intervention studies, future research should incorporate a randomized controlled design. The inclusion of a control group in a longitudinal study would have stronger implications and allow for the inference of causality. Further, longer term follow-up of participants in both community and laboratory-based interventions would enhance the understanding of how PA is impacting glycemic control or other secondary outcomes such as fitness and body composition. During this long term follow-up, participants could be monitored for the development of T2D and other lifestyle-related comorbidities as potential outcomes.

Further investigation into exercise mode should also take place to inform QEPs and any other health professional who prescribes exercise. Randomized, controlled trials including HIIT, continuous moderate intensity aerobic exercise and resistance training alone and in combination with each other

would help to develop an optimal strategy for using exercise as a preventative tool for persons at risk for developing T2D. Ideally, a dose-response relationship could be developed which would inform not only persons at risk but also policy makers and governing bodies who could more accurately create and disseminate PA recommendations.

Interventions incorporating PA plus additional lifestyle and behavioural modification should also be considered. Studies comparing PA with self-management strategies or a combination of both would help to empower and educate individuals at risk and further enhance the ability to make recommendations to persons at risk for T2D and potentially maximize the efficacy of prevention strategies. Also, the assessment of PA that is performed outside the realm of the intervention itself should be performed. In the current study, an attempt was made to capture this through the completion of a PA journal but these were improperly or incompletely filled out by most participants. More accurate methods such as accelerometry would provide a great deal of additional data pertaining to the lifestyle habits of participants.

These future investigations should also take note of the role of the QEP in prevention strategies, especially at the community level. Positive results should advocate for the inclusion of QEPs in family health teams and community health centers which, in the current health care paradigm, typically use nurses and registered dieticians to provide the majority of lifestyle counselling, including exercise recommendations. Further, the impact of QEPs and results of PA interventions targeting prediabetes should undergo rigorous epidemiological analyses focusing on the economic impact of both screening protocols identifying those at high risk and interventions involving PA with the goal of preventing or delaying T2D.

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LIST OF ABBREVIATIONS

A1C	Glycated Hemoglobin
ADA	American Diabetes Association
ANOVA	Analysis of Variance
BMI	Body Mass Index
CDA	Canadian Diabetes Association
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
FPG	Fasting Plasma Glucose
GTA	Greater Toronto Area
HIIT	High Intensity Interval Training
HOMA-IR	Homeostatic Model Assessment – Insulin Resistance
HOMA-β	Homeostatic Model Assessment – Beta Cell Function
HPLC	High Performance Liquid Chromatography
HR	Heart Rate
OGTT	Oral Glucose Tolerance Test
PA	Physical Activity
PAR-Q+	Physical Activity Readiness Questionnaire
PRE-PAID	Prediabetes Detection and Physical Activity Intervention Delivery
RPG	Random Plasma Glucose
SBP	Systolic Blood Pressure
T2D	Type 2 Diabetes
VO_2	Oxygen Consumption

Appendix A PAR-Q+

2015 PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physical activity is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	**YES**	**NO**
1) Has your doctor ever said that you have a heart condition ☐ OR high blood pressure ☐?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____	☐	☐
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer **NO** if you had a problem in the past, but it *does not limit your current ability* to be physically active. **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

✔ **If you answered NO to all of the questions above, you are cleared for physical activity.**
Go to Page 4 to sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at **www.eparmedx.com** before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

2015 PAR-Q+

FOLLOW-UP QUESTIONS ABOUT YOUR MEDICAL CONDITION(S)

1. Do you have Arthritis, Osteoporosis, or Back Problems?

If the above condition(s) is/are present, answer questions 1a-1c If **NO** ☐ go to question 2

1a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
1b.	Do you have joint problems causing pain, a recent fracture or fracture caused by osteoporosis or cancer, displaced vertebra (e.g., spondylolisthesis), and/or spondylolysis/pars defect (a crack in the bony ring on the back of the spinal column)?	YES ☐ NO ☐
1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	YES ☐ NO ☐

2. Do you have Cancer of any kind?

If the above condition(s) is/are present, answer questions 2a-2b If **NO** ☐ go to question 3

2a.	Does your cancer diagnosis include any of the following types: lung/bronchogenic, multiple myeloma (cancer of plasma cells), head, and neck?	YES ☐ NO ☐
2b.	Are you currently receiving cancer therapy (such as chemotheraphy or radiotherapy)?	YES ☐ NO ☐

3. Do you have a Heart or Cardiovascular Condition? *This includes Coronary Artery Disease, Heart Failure, Diagnosed Abnormality of Heart Rhythm*

If the above condition(s) is/are present, answer questions 3a-3d If **NO** ☐ go to question 4

3a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
3b.	Do you have an irregular heart beat that requires medical management? (e.g., atrial fibrillation, premature ventricular contraction)	YES ☐ NO ☐
3c.	Do you have chronic heart failure?	YES ☐ NO ☐
3d.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	YES ☐ NO ☐

4. Do you have High Blood Pressure?

If the above condition(s) is/are present, answer questions 4a-4b If **NO** ☐ go to question 5

4a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
4b.	Do you have a resting blood pressure equal to or greater than 160/90 mmHg with or without medication? (Answer **YES** if you do not know your resting blood pressure)	YES ☐ NO ☐

5. Do you have any Metabolic Conditions? *This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes*

If the above condition(s) is/are present, answer questions 5a-5e If **NO** ☐ go to question 6

5a.	Do you often have difficulty controlling your blood sugar levels with foods, medications, or other physician-prescribed therapies?	YES ☐ NO ☐
5b.	Do you often suffer from signs and symptoms of low blood sugar (hypoglycemia) following exercise and/or during activities of daily living? Signs of hypoglycemia may include shakiness, nervousness, unusual irritability, abnormal sweating, dizziness or light-headedness, mental confusion, difficulty speaking, weakness, or sleepiness.	YES ☐ NO ☐
5c.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, **OR** the sensation in your toes and feet?	YES ☐ NO ☐
5d.	Do you have other metabolic conditions (such as current pregnancy-related diabetes, chronic kidney disease, or liver problems)?	YES ☐ NO ☐
5e.	Are you planning to engage in what for you is unusually high (or vigorous) intensity exercise in the near future?	YES ☐ NO ☐

2015 PAR-Q+

6. **Do you have any Mental Health Problems or Learning Difficulties?** *This includes Alzheimer's, Dementia, Depression, Anxiety Disorder, Eating Disorder, Psychotic Disorder, Intellectual Disability, Down Syndrome*

If the above condition(s) is/are present, answer questions 6a-6b If **NO** ☐ go to question 7

6a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
6b.	Do you **ALSO** have back problems affecting nerves or muscles?	YES ☐ NO ☐

7. **Do you have a Respiratory Disease?** *This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure*

If the above condition(s) is/are present, answer questions 7a-7d If **NO** ☐ go to question 8

7a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
7b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	YES ☐ NO ☐
7c.	If asthmatic, do you currently have symptoms of chest tightness, wheezing, laboured breathing, consistent cough (more than 2 days/week), or have you used your rescue medication more than twice in the last week?	YES ☐ NO ☐
7d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	YES ☐ NO ☐

8. **Do you have a Spinal Cord Injury?** *This includes Tetraplegia and Paraplegia*

If the above condition(s) is/are present, answer questions 8a-8c If **NO** ☐ go to question 9

8a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
8b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	YES ☐ NO ☐
8c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	YES ☐ NO ☐

9. **Have you had a Stroke?** *This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event*

If the above condition(s) is/are present, answer questions 9a-9c If **NO** ☐ go to question 10

9a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
9b.	Do you have any impairment in walking or mobility?	YES ☐ NO ☐
9c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	YES ☐ NO ☐

10. **Do you have any other medical condition not listed above or do you have two or more medical conditions?**

If you have other medical conditions, answer questions 10a-10c If **NO** ☐ read the Page 4 recommendations

10a.	Have you experienced a blackout, fainted, or lost consciousness as a result of a head injury within the last 12 months **OR** have you had a diagnosed concussion within the last 12 months?	YES ☐ NO ☐
10b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	YES ☐ NO ☐
10c.	Do you currently live with two or more medical conditions?	YES ☐ NO ☐

PLEASE LIST YOUR MEDICAL CONDITION(S) AND ANY RELATED MEDICATIONS HERE: _____

_____

GO to Page 4 for recommendations about your current medical condition(s) and sign the PARTICIPANT DECLARATION.

2015 PAR-Q+

If you answered NO to all of the follow-up questions about your medical condition, you are ready to become more physically active - sign the PARTICIPANT DECLARATION below:

- It is advised that you consult a qualified exercise professional to help you develop a safe and effective physical activity plan to meet your health needs.
- You are encouraged to start slowly and build up gradually - 20 to 60 minutes of low to moderate intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
- As you progress, you should aim to accumulate 150 minutes or more of moderate intensity physical activity per week.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.

If you answered **YES** to **one or more of the follow-up questions** about your medical condition:

You should seek further information before becoming more physically active or engaging in a fitness appraisal. You should complete the specially designed online screening and exercise recommendations program - the **ePARmed-X+ at www.eparmedx.com** and/or visit a qualified exercise professional to work through the ePARmed-X+ and for further information.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ **at www.eparmedx.com** before becoming more physically active.
- Your health changes - talk to your doctor or qualified exercise professional before continuing with any physical activity program.

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The authors, the PAR-Q+ Collaboration, partner organizations, and their agents assume no liability for persons who undertake physical activity and/or make use of the PAR-Q+ or ePARmed-X+. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.

PARTICIPANT DECLARATION

- All persons who have completed the PAR-Q+ please read and sign the declaration below.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that a Trustee (such as my employer, community/fitness centre, health care provider, or other designate) may retain a copy of this form for their records. In these instances, the Trustee will be required to adhere to local, national, and international guidelines regarding the storage of personal health information ensuring that the Trustee maintains the privacy of the information and does not misuse or wrongfully disclose such information.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact

www.eparmedx.com
Email: eparmedx@gmail.com

Citation for PAR-Q+
Warburton DER, Jamnik VK, Bredin SSD, and Gledhill N on behalf of the PAR-Q+ Collaboration. The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and Electronic Physical Activity Readiness Medical Examination (ePARmed-X+). Health & Fitness Journal of Canada 4(2):3-23, 2011.

Key References
1. Jamnik VK, Warburton DER, Makarski J, McKenzie DC, Shephard RJ, Stone J, and Gledhill N. Enhancing the effectiveness of clearance for physical activity participation: background and overall process. APNM 36(S1):S3-S13, 2011.
2. Warburton DER, Gledhill N, Jamnik VK, Bredin SSD, McKenzie DC, Stone J, Charlesworth S, and Shephard RJ. Evidence-based risk assessment and recommendations for physical activity clearance; Consensus Document. APNM 36(S1):S266-s298, 2011.

The PAR-Q+ was created using the evidence-based AGREE process (1) by the PAR-Q+ Collaboration chaired by Dr. Darren E. R. Warburton with Dr. Norman Gledhill, Dr. Veronica Jamnik, and Dr. Donald C. McKenzie (2). Production of this document has been made possible through financial contributions from the Public Health Agency of Canada and the BC Ministry of Health Services. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada or the BC Ministry of Health Services.

01-01-2015

Physical Activity and Chronic Disease Unit
York University

Phase I and II Informed Consent Form

Date: _____

Study Name: Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Program

Principle Investigators: Dr. Norm Gledhill, Dr. Veronica Jamnik, Dr. Michael Riddell

Sponsors: York University, Ontario Ministry of Health Promotion

Purpose of the Research: The purpose of this project is to identify persons who have pre-diabetes and use supervised physical activity to reduce their risk of developing type 2 diabetes and improve their health.

What You Will Be Asked to Do in the Research:

You will complete a short questionnaire that will determine your risk for pre-diabetes. If you are at high risk for pre-diabetes you will be asked to attend a group information session that will provide you with more details about the project. During this information meeting you will complete some health related questionnaires and you will undergo a blood test for diabetes by providing a finger prick blood sample. The blood will be collected by a trained professional using sterile (clean) equipment. The results of this test will be available in approximately 10 minutes. If you have normal blood sugar values, you will be told that you do NOT have pre-diabetes or diabetes. If you have a blood sugar score in the type 2 diabetes range, you will be told that you have type 2 diabetes and directed to your family doctor and a diabetes education program for follow-up. If your blood sugar values indicate that you have pre-diabetes, you will be told that you have pre-diabetes and are potentially eligible for participation in the study.

If you have pre-diabetes, you will be asked to take a final confirmatory blood sugar test - an OGTT which will be administered by the medical clinic staff. You must arrive in a fasted state (no food or drink for 8 hours, water is ok) and the test takes approximately 2 hours and involves drawing blood (a needle will be inserted into a vein in your arm and a small amount of blood will be collected in small tubes) at 0, 30, 60, 90, and 120 minutes. An additional small amount (approx 100 microliters) of blood will also be collected and stored for further diabetes-related analyses. After the blood screening visit, you will be scheduled for your fitness assessment.

During the fitness assessment, you will have your height, weight, waist circumference, percent body fat (using skin calipers), grip strength, and vertical jump measured by an exercise professional (of the same gender). Aerobic fitness will be measured by a treadmill test where you will walk/jog, while breathing into a mouthpiece, until a peak value is reached. You will then participate in supervised activity sessions

3 times per week (each session approximately 1 hour) and encouraged to be active on three additional days of the week.

All participants will be asked to complete a mid-point assessment after 3 months of participation that will involve the same blood work and health-related questionnaires that were completed during the initial meeting. There will be no mid-point fitness test.

After 6 months of participation, all participants will be asked to complete all of the tests that were done at the onset including the fitness assessment.

Risks and Discomforts: Participation in any physical activity has some level of associated risk of physical injury. To minimize this risk, physical activity participation in this study will be supervised by Certified Exercise Physiologists who are qualified to provide physical activity counseling to individuals with chronic diseases. They will make sure that the physical activity is performed at an appropriate intensity.

There is also a possible risk of discomfort and/or bruising at the needle site from taking blood sample, and an extremely small risk of infection with the blood draw. All blood samples will be taken by experienced and qualified phlebotomists using sterile equipment and techniques.

Benefits of the Research and Benefits to You: People who become more physically active should expect to see improvements in health and fitness. Common benefits associated with regular physical activity participation are; weight loss, reduced waist circumference, improved strength and aerobic capacity, quality of life, improved blood lipid profile, and reduced risk of various chronic diseases such as cardiovascular disease, type 2 diabetes, and cancer.

Voluntary Participation: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the nature of your relationship with York University either now, or in the future.

Withdrawal from the Study: You can stop participating in the study at any time, for any reason, if you so decide. Your decision to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, York University, or any other group associated with this project. In the event you withdraw from the study, all associated data collected will be immediately destroyed.

Confidentiality: All information you supply during the research will be held in confidence and your name will not appear in any report or publication of the research. Data will be collected using pen and paper methods and then entered into a computer spreadsheet. Your data will be safely stored in a locked facility and only the research team will have access to this information. All electronic data will be password protected and only research personnel will have access. Hard copies of the data will be destroyed after publication of the study results. Confidentiality will be provided to the fullest extent possible by law.

Questions About the Research? If you have questions about the research in general or about your role in the study, please feel free to contact Dr. Norman Gledhill either by telephone at _____ or by e-mail. This research has been reviewed and approved by the Human Participants Review Sub-Committee; York University's Ethics Review Board and conforms to the standards of the Canadian Tri-

Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact Ms. Alison Collins-Mrakas, Manager, Research Ethics.

Legal Rights and Signatures:

I _____ (Printed Name of Participant), consent to participate in the Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Project conducted by Dr. Norman Gledhill. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form. My signature below indicates my consent.

Signature _____ **Date** _____

Participant

YORK UNIVERSITÉ UNIVERSITY
redefine THE POSSIBLE.

Signature _____ **Date** _____

Principal Investigator

Date: _____

Study Name: Pre-Diabetes Detection and Physical Activity Intervention Delivery Project

Researchers: Dr. Norm Gledhill, Dr. Veronica Jamnik, Dr. Michael Riddell

Sponsors: York University, Ontario Ministry of Health Promotion, Trillium Foundation

Purpose of the Research: The purpose of this project is to identify persons who have pre-diabetes and enrol them in a supervised physical activity program to lower their risk of getting type 2 diabetes and improve their health.

What You Will Be Asked to Do in the Research: You will complete a short questionnaire that will determine your risk for pre-diabetes. If you are at high risk for pre-diabetes you will provided with more details about the project. You will then have a blood test for diabetes by providing a finger prick blood sample. This test needs only 1 small drops of blood from your finger. The blood will be collected by a trained professional using sterile (clean) equipment. The results of this test will be available in 10 minutes. If you have normal blood sugar, you will be told that you likely do NOT have pre-diabetes or diabetes. If you have a blood sugar score in the type 2 diabetes range, you will be told that you MAY have type 2 diabetes and directed to your family doctor and a diabetes education program for follow-up. If your blood sugar indicates that you MAY have pre-diabetes, you will be told that you likely have pre-diabetes and may be eligible for being in the study.

After this initial meeting, if you are determined to likely have pre-diabetes, you will be scheduled for your confirmatory blood sugar test and fitness test. This blood test is called an “Oral Glucose Tolerance Test” and it will be performed by a trained professional. You must arrive in a fasted state (no food or drink for 8 hours, water is ok) and the test takes approximately 2 hours. The test involves drawing blood (a needle will be inserted into a vein in your arm and a small amount of blood will be collected in small tubes) at the start and 30, 60, 90, and 120 minutes after taking a sweet tasting drink. Another 2-3 drops (about 100 microliters) of blood will also be collected and stored for further diabetes-related testing. In total, about 10 ml of blood (about 2 teaspoons) will be taken from your arm. This amount is less than what is taken from you when you have a blood test done for your doctor.

The fitness test will take place on the same day as the blood sugar test and will take 1 hour. You will be given a snack after the blood test before the start of the fitness test. During the fitness test, you will have your height, weight, waist circumference, body fat measurements (using a scale), grip strength, and vertical jump measured by an exercise professional of the same gender if requested. Aerobic fitness will be measured using a treadmill test where you will walk/jog, while breathing into a mouthpiece, until a peak value is reached.

We are looking for about 90 participants and the duration of the project is 3 months. You will be randomly placed into 1 of 3 groups. Two of the groups will participate in supervised activity sessions 3

times per week (each session approximately 1 hour) that include aerobic and resistance (strength) training activities. You will also be encouraged to record other activities that are done during the week in a journal. The third group will be asked to make no changes to their current lifestyle for 3 months. After the 3 months, participants in this group will be offered the same activity program as the first 2 groups.

After 3 months, all participants will be asked to complete all of the tests that were done at the beginning, including the fitness assessment. The participants in the 3rd study group (the control group) will have the option to provide a third round of measurements after their physical intervention (6 months after their first test).

Risks and Discomforts: Taking part in any physical activity has some minor risks of injury. To lower this risk, physical activity in this study will be supervised by Qualified Exercise Professionals who are qualified to provide physical activity to people with chronic diseases. They will make sure that the physical activity is done at a safe intensity.

There is a very small risk of infection with the blood test. All blood samples will be taken by experienced and qualified blood samplers using sterile equipment and techniques. There may also be discomfort and/or bruising at the needle site.

Benefits of the Research to You: People who become more physically active should expect to see improvements in health and fitness. Common benefits associated with regular physical activity are; weight loss, lower waist circumference, better strength and aerobic capacity, quality of life, better blood lipid profile. Also a lower risk for chronic diseases such as cardiovascular disease, type 2 diabetes, and cancer.

Compensation for Participation: Participants will be provided with free access to fitness facilities for the duration of the project. Participants will also have free, supervised exercise training with a qualified professional for a period of 3 months. This level of service would typically be valued at $500-$1000.

Voluntary Participation: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence your relationship with York University either now, or in the future.

Withdrawal from the Study: You can stop participating in the study at any time, for any reason, if you decide. Your decision to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, York University, or any other group associated with this project. If you withdraw from the study, you may ask to have all of your data destroyed using a confidential shredding agency.

Confidentiality: All information you supply during the research will be held in confidence and your name will not appear in any report or publication of the research. Data will be collected using pen and paper methods and then entered into a computer spreadsheet. Your data will be safely stored in a locked facility and only the research team will have access to this information. All electronic data will be password protected and only research personnel will have access. Hard copies of the data will be

destroyed using a confidential shredding agency five years after publication of the study results. Confidentiality will be provided to the fullest extent possible by law.

Questions About the Research: If you have questions about the research in general or about your role in the study, please feel free to contact Mr. Chip Rowan either by telephone. This research has been reviewed and approved by the Human Participants Review Sub-Committee; York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact Ms. Alison Collins-Mrakas, Manager, Research Ethics.

Legal Rights and Signatures: I _____ (Printed Name of Participant), consent to participate in the Pre-Diabetes Detection and Physical Activity Intervention Delivery Project conducted by Dr. Norman Gledhill. I have understood the nature of this project and wish to participate. I also consent to being contacted in the future about a follow-up or related study. I am not waiving any of my legal rights by signing this form. My signature below indicates my consent.

Signature _____ **Date** _____

Participant

YORK UNIVERSITÉ UNIVERSITY
redefine THE POSSIBLE.

Signature _____ **Date** _____

Principal Investigator

YORK
UNIVERSITÉ
UNIVERSITY

OFFICE OF
RESEARCH
ETHICS (ORE)

Certificate #:	**2009 - 270**
Approval Period:	**10/22/09-10/22/10**

Memo

To: Dr. Norman Gledhill, Faculty of Health,
Dr. Veronica Jamnik, Faculty of Health
Dr. Michael Riddell, Faculty of Health,

From: Alison M. Collins-Mrakas, Sr. Manager and Policy Advisor, Research Ethics
(on behalf of Daphne Winland, Chair, Human Participants Review Committee)

Date: **Thursday 22nd October, 2009**

Re: Ethics Approval

Pre-Diabetes Detection and Physical Activity Intervention Delivery (Pre-paid) Program

---

I am writing to inform you that the Human Participants Review Sub-Committee has reviewed and granted approval for the above project.

Should you have any questions, please feel free to contact me at:
via email at:

Yours sincerely,

Alison M. Collins-Mrakas M.Sc., LLM
Sr. Manager and Policy Advisor,
Office of Research Ethics

YORK
UNIVERSITÉ
UNIVERSITY

ACOBS Certificate #:	**68**
Approved:	**10/01/09**
Approval period:	**10/01/09-10/01/10**

OFFICE OF RESEARCH ETHICS (ORE)
Fifth Floor, YRT

Memo

To: Professor Veronica Jamnik, Kinesiology and Health Sciences

From: Alison M. Collins-Mrakas, Sr. Manager & Policy Advisor, Research Ethics

Date: **Thursday October 1st, 2009**
Re: Ethics Approval

Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Program

---

I am writing to inform you that the Advisory Committee on Biological Safety has reviewed and approved the above project.

Should you have any questions, please feel free to contact me at:
via email at:

Yours sincerely,

Alison M. Collins-Mrakas M.Sc., LLM
Sr. Manager & Policy Advisor, Research Ethics

Appendix C Community Partners

TAIBU Community Health Centre

Black Creek Community Health Centre

Brampton Chinese Baptist Church

Socasize

Bollyfit

St. Timothy's Anglican Church

St. Christopher's Anglican Church

Canadian Diabetes Association

Mississauga YMCA

Sault College

Garden River First Nations Reserve

Faith Sanctuary

Pre-diabetes/ Type 2 diabetes screening tool for PRE-PAID

This questionnaire is intended for adults aged 18- 64 years who are members of certain ethnic minorities (**Chinese, South Asian, Hispanic, Aboriginal, African or African-Caribbean**) to help find out if you are at risk of developing type 2 diabetes. Please answer as carefully as you can. We will help you complete this form.

What ethnicity are (or were) your biological (blood) parents?

Mother	Father	
☐	☐	White (Caucasian)
☐	☐	Aboriginal
☐	☐	African, African/Caribbean
☐	☐	South Asian (India, Pakistan, Sri Lanka, Nepal, Bangladesh)
☐	☐	Chinese
☐	☐	Other (please specify_____)

AS YOU GET OLDER, YOUR RISK FOR DIABETES INCREASES

1) What year were you born? _____

Select your age group

☐ 18-39 years (0 points)
☐ 40-44 years (0 points)
☐ 45-54 years (2 points)
☐ 55- 64 years (3 points)

BODY SHAPE AND SIZE CAN AFFECT YOUR RISK OF DIABETES

2a) How much do you weigh (either in pounds or in kilograms)?
I weigh _____ pounds *OR* I weigh _____ kilograms

2b) How tall are you without shoes on?
I am _____ feet and _____ inches tall *OR* I am _____centimeters tall

Use the attached height and weight table to find body mass index (BMI)

☐ unshaded area- BMI less than 25 (0 points)
☐ light shaded area- BMI 25-30 (1 points)
☐ darker shaded area- BMI over 30 (3 points)

3) Waist Circumference

I am going to use a tape measure and place it around your waist at the level of the navel (belly button). I will take a measure after you breathing out (do not hold your breath).

_____ inches *OR* _____cm

☐ male

☐ Less than 94cm or 37 inches (0 pts)
☐ Between 94-102cm or 37-40inches (3 pts)
☐ Over 102cm or 40 inches (4 pts)

☐ female

☐ Less than 80cm or 31.5 inches (0 pts)
☐ Between 80-88cm or 31.5-35inches (3 pts)
☐ Over 88cm or 35 inches (4 pts)

Research Staff NAME: _____

YOUR LEVEL OF PHYSICAL ACTIVITY AND WHAT YOU EAT CAN AFFECT YOUR RISK OF HAVING DIABETES OR "PRE-DIABETES".

4) Daily Activity

Over a typical seven-day period (one week), how many times do you engage in physical activity that is prolonged and intense enough to feel warm or cause sweating and an increase in you heart rate?

☐ At least three times per week (0 points)
☐ Normally once or twice per week (1 point)
☐ Rarely or never (3 points)

HIGH BLOOD PRESSURE AND HIGH BLOOD SUGAR ARE ASSOCIATED WITH DIABETES

5) High Blood Pressure

Have you ever been told by a doctor or nurse that you have high blood pressure *OR* are you taking any medication (pills) for high blood pressure?

☐ No or don't know (0 points)
☐ Yes (2 points)

6) High Blood Sugar

Have you ever been told by a doctor or nurse that you have high blood sugar (i.e. during a health exam) or that you have diabetes or "pre diabetes"?

☐ No or don't know (0 points)
☐ Yes (5 points)

SOME TYPES OF DIABETES RUN IN FAMILIES

7) Family

Have any members of your family been diagnosed with diabetes? (You can circle the one below that have)

☐ No or don't know (0 points)
☐ Yes: grandparent, aunt, uncle, or first cousin (3 points) (ignore this one if the one below applies)
☐ Yes: parent (mother or father), brother or sister or own child (5 points)

Note: your score cannot be greater than 5 points

Likelihood of developing diabetes in the next 10 years:	
< 7	small risk
7-11	moderate risk
12-14	high risk
15-20	very high risk
20-25	extreme risk (may already have diabetes)

***SCORE:**

Thank you for filling this questionnaire about diabetes risk. What is the best way for us to contact you if you are eligible and interested in participating in our research study on physical activity and diabetes prevention?

Name _____
Phone number_____
Email address_____

Physical Activity And Chronic Disease Unit
York University

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

Pre-diabetes/ Type 2 diabetes screening tool for PRE-PAID
PRE-PAID 糖尿病前期/2 型糖尿病筛选问卷调查表

This questionnaire is intended for adults aged 40- 64 years who are members of certain ethnic minorities (**Chinese, South Asian, African or African-Caribbean**) to help find out if you are at risk of developing type 2 diabetes. Please answer as carefully as you can. We will help you complete this form.

该问卷旨在调查一些族裔（中国裔，南亚裔，非裔，加勒比非裔）年龄在40到64之间的人患2型糖尿病的风险。 请仔细回答下面的问题， 我们会帮助您完成该问卷调查表。

What ethnicity are (or were) your biological (blood) parents?

您的父母是（曾是）什么族裔的？

Mother 母亲	Father 父亲	
□	□	White (Caucasian) 白人 (高加索人)
□	□	African, African/Caribbean 非裔，加勒比-非裔
□	□	South Asian (India, Pakistan, Sri Lanka, Nepal, Bangladesh) 南亚裔(印度，巴基斯坦，斯里兰卡，尼泊尔，孟加拉国)
□	□	Chinese 中国裔
□	□	Other 其他 (请注明_____)

AS YOU GET OLDER, YOUR RISK FOR DIABETES INCREASES

随着年龄的增长，您患糖尿病的风险也会随之增长

1) What year were you born? 您是出生年份是? _____

Select your age grou 请选择您的年龄组

□ 40-44 years (0 points)

□ 45-54 years (2 points)

STAFF NAME: _____

□ 55- 64 years (3 points)

BODY SHAPE AND SIZE CAN AFFECT YOUR RISK OF DIABETES

身型和体重会影响您患糖尿病的风险

2a) How much do you weigh (either in pounds or in kilograms) 您的体重是多少 (磅或千克)?

我的体重是 _____ pounds 磅 *或*_____ kilograms 千克

2b) How tall are you without shoes on 你的身高是多少（不含鞋子）?

我的身高是 _____ feet 英尺和 _____ inches 英寸 *或*_____ centimeters 厘米

Use the attached height and weight table to find body mass index (BMI)

请用身高体重表找出您的身体质量指数(BMI)

□ unshaded area 无阴影部分 BMI <25 (0 points)

□ light shaded area 浅阴影部分 BMI 25-30 (1 points)

□ darker shaded area 深阴影部分 BMI >30 (3 points)

3) Waist Circumference腰围

I am going to use a tape measure and place it around your waist at the level of the navel (belly button). I will take a measure after you breathing out (do not hold your breath).

我现在会用卷尺测量腰围（肚脐处）， 我会在你呼气后测量（无须屏气）.

_____ inches英寸 *或* _____cm厘米

□ male男性

□ female女性

□ < 94cm or 37 inches (0 pts)	□ < 80cm or 31.5 inches (0 pts)
□ 94-102cm or 37-40inches (3 pts)	□ 80-88cm or 31.5-35inches (3 pts)
□ > 102cm or 40 inches (4 pts)	□ > 88cm or 35 inches (4 pts)

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

STAFF NAME: _____

YOUR LEVEL OF PHYSICAL ACTIVITY AND WHAT YOU EAT CAN AFFECT YOUR RISK OF HAVING DIABETES OR "PRE-DIABETES".
您的运动锻炼和饮食会影响患糖尿病的风险.

4) Daily Activity 日常活动

Over a typical seven-day period (one week), how many times do you engage in physical activity that is prolonged and intense enough to cause sweating and an increase in you heart rate?
通常情况下， 您一周（7天）运动几次？ 该运动的强度和时间足以使您流汗和心跳加速。

- ☐ At least three times per week一周至少三次 (0 points)
- ☐ Normally once or twice per week一般一周一到两次 (1 points)
- ☐ Rarely or never很少或从不 (3 points)

HIGH BLOOD PRESSURE AND HIGH BLOOD SUGAR ARE ASSOCIATED WITH DIABETES
高血压和高血糖与糖尿病有关

5) High Blood Pressure 高血压

Have you ever been told by a doctor or nurse that you have high blood pressure *OR* are you taking any medication (pills) for high blood pressure?
您曾经被医生或护士告之您有高血压吗？ 或您正在吃治疗高血压的药吗？

- ☐ No or don't know没有或不清楚 (0 points)
- ☐ Yes是的 (2 points)

6) High Blood Sugar高血糖

Have you ever been told by a doctor or nurse that you have high blood sugar (i.e. during a health exam) or that you have diabetes or "pre diabetes"?
您曾经被医生或护士告之您有高血糖吗（例如在体检时）？或您有糖尿病或糖尿病前期？

- ☐ No or don't know没有或不清楚 (0 points)
- ☐ Yes是的 (5 points)

SOME TYPES OF DIABETES RUN IN FAMILIES
有些类型的糖尿病是遗传的

7) Family家庭

Have any members of your family been diagnosed with diabetes? (You can circle the one below that have)
您有任何家庭人员被诊断为糖尿病吗? (请选择最适合的一项)

- ☐ No or don't know没有或不清楚 (0 points)
- ☐ Yes: grandparent, aunt, uncle, or first cousin (ignore this one if the one below applies)
  是的: 祖父母, 姨妈, 叔父, 或第一代堂兄妹 (如下面一项更适合，请忽略该项)
  (3 points)
- ☐ Yes: parent (mother or father), brother or sister or own child
  是的: 父母（母亲或父亲），兄弟，姐妹或您的小孩
  (5 points)

Note: your score cannot be greater than 5 points
备注: 你的分数不能够超出5分

Likelihood of developing diabetes in the next 10 years:
10年内患糖尿病的可能性：

< 7 small risk 可能性小
7-11 moderate risk有一定可能性
12-14 high risk可能
15-20 very high risk很可能
20-25 extreme risk (may already have diabetes)
非常有可能 (可能已经是糖尿病)

***SCORE:**

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

Pre-diabetes/ Type 2 diabetes screening tool for PRE-PAID

ਸ਼ੂਗਰ ਤੋਂ ਪਹਿਲਾਂ ਟਾਈਪ ਦਾ ਟੈਸਟ ਦਾ ਟੂਲ

This questionnaire is intended for adults aged 40- 64 years who are members of certain ethnic minorities (**Chinese, South Asian, African or African-Caribbean**)to help find out if you are at risk of developing type 2 diabetes. Please answer as carefully as you can. We will help you complete this form.

ਇਹ ਸਵਾਲਨਾਮਾ ਚਾਲੀ ਤੋਂ ਸਠ ਸਾਲ ਦੀ ਉਮਰ ਤਕਿਆਂ ਦਾਸਤੇ ਹੈ ਜੋ ਜਰਨਾਂ ਕਮਿੰਨੇ ਨੇ ਕਿ ਉਨਾਨੂੰ ਸ਼ੂਗਰ ਦਾ ਖਤਰਾ ਤਾਂ ਨਹੀਂ। ਕਿਰਪਾ ਕਰਕੇ ਕਿਸਦ ਨਾਲ ਜਵਾਬ ਭੇਜਾ ਜੀ। ਅਸੀਂ ਏ ਫਾਰਮ ਤਕ ਕਿਚ ਤੁਹਾਡੀ ਮਦਦ ਕਰੇਗੇ।

What ethnicity are (or were) your biological (blood)parents?

ਤੁਹਾਡੇ ਮਾਂ ਪਿਓ ਕਿਹੜੇ ਨੀ

Mother ਮਾਤਾ	Father ਪਿਤਾ	
☐	☐	White (Caucasian) ਗੋਰਾ
☐	☐	African, African/Caribbean ਅਫਰੀਕਨ
☐	☐	South Asian (India, Pakistan, Sri Lanka, Nepal, Bangladesh) ਇੰਡੀਅਨ/ਪਾਕਿਸਤਾਨੀ/ਸ੍ਰੀਲੰਕਾਈ
☐	☐	Chinese ਚੀਨਾ
☐	☐	Other (please specify___ ਜਾਂ ਕੋਈ ਹੋਰ ਲਿਖੋ_____)

AS YOU GET OLDER, YOUR RISK FOR DIABETES INCREASES

ਉਮਰ ਦੇ ਵਧਣ ਨਾਲ ਸ਼ੂਗਰ ਦਾ ਖਤਰਾ ਵੀ ਵਧਦਾ ਹੈ

1) What year were you born? _____ ਉਮਰ _____

Select your age group ਆਪਣੀ ਉਮਰ ਦਾ ਵਰਗ ਚੁਣੋ

☐ 40-44 years (0 points) ਚਾਲੀ ਤੋਂ ਚਰਲੀ ਸਾਲ

☐ 45-54 years (2 points) ਪੰਤਾਲੀ ਤੋਂ ਚੁਰੰਜਾ ਸਾਲ

☐ 55- 64 years (3 points) ਪਚਪਨ ਤੋਂ ਚੌਂਠ ਸਾਲ

BODY SHAPE AND SIZE CAN AFFECT YOUR RISK OF DIABETES

ਸਰੀਰ ਦਾ ਰੂਪਰੇਖਾ ਅਤੇ ਮੇਚਾ ਸ਼ੂਗਰ ਦਾ ਖਤਰਾ ਵਧ ਸਕਦੇ ਹਨ

2a) How much do you weigh (either in pounds or in kilograms)?

ਤੁਹਾਡਾ ਵਜਨ ਕਿਨਾਂ ਹੈ (ਪਾਊਂਡ ਜਾਂ ਕਿਲੋ ਨਿਚ)

I weigh _____ **pounds** *OR* **I weigh** _____ **kilograms**

ਮੇਰਾ ਵਜਨ _____ ਪਾਊਂਡ ਜਾਂ _____ ਕਿਲੋ ਹੈ

2b) How tall are you without shoes on?

ਤੁਹਾਡਾ ਕਦ ਕਿਨਾਂ ਬੂਟਾਂ ਤੋਂ ਕਿਨਾਂ ਹੈ

I am _____ **feet and** _____ **inches tall** *OR* **I am** _____ **centimeters tall**

ਮੈਂ _____ ਫੁਟ ਅਤੇ _____ ਇੰਚ ਕਦ ਦਾ ਜਾਂ ਮੈਂ _____ ਸੈਂਟੀਮੀਟਰ ਕਦ ਦਾ ਹਾਂ

Use the attached height and weight table to find body mass index (BMI)

ਕਦ ਅਤੇ ਵਜਨ ਦਾ ਚਕਟ ਵੇਖੋ ਅਤੇ ਨਿਸ਼ਾ ਲਭੋ

☐ unshaded area- BMI less than 25 (0 points)
ਸਦ ਖਾਲਾ – ਨਿਸ਼ਾ ਘੱਟੀ ਹੋਣੀ ਤੋਂ ਘੱਟ (ਜੀਰੋ ਪੋਇਟ)

STAFF NAME ਕਰਮਚਾਰੀ ਦਾ ਨਾਂ: _____

☐ light shaded area- BMI 25-30 (1 points)
ਹਲਕੇ ਰੰਗ ਦਾ ਖਾਲਾ – ਨਿਸ਼ਾ ਘੱਟੀ ਹੋਣੀ ਤੋਂ ਤੀਕ (ਇਕ ਪੋਇਟ)

☐ darker shaded area- BMI over 30 (3 points)
ਗੂੜੇ ਰੰਗ ਦਾ ਖਾਲਾ – ਨਿਸ਼ਾ ਘੱਟੀ ਹੋਣੀ ਤੋਂ ਉਪਰ (ਤਿਨ ਪੋਇਟ)

3) Waist Circumference (ਕਮਰ ਦਾ ਮੇਚਾ)

I am going to use a tape measure and place it around your waist at the level of the navel (belly button). I will take a measure after you breathing out (do not hold your breath).

ਮੈਂ ਇੰਚਮੀਟਰ ਨਾਲ ਤੁਹਾਡੀ ਕਮਰ ਦਾ ਮੇਚਾ ਲਵਾਂਗਾ (ਧੁਨੀ ਦੇ ਕੇਂਦਰ) ਜਦੋਂ ਤੁਸੀਂ ਅਮਨਾ ਸਾਹ ਬਾਹਰ ਕਡੋਗੇ

_____ inches *OR* _____ cm

_____ ਇੰਚ ਜਾਂ _____ ਸੈਂਮੀ.

☐ male ਨਰ ☐ female ਜਨਾਨਾ

☐ Less than 94cm or 37 inches (0 pts)
੯੪ ਸੈਂਮੀ. ਜਾਂ ੩੭ ਇੰਚ ਤੋਂ ਘਟ (੦ ਪੋਇਟ)

☐ Between 94-102cm or 37-40inches (3 pts)
੯੪ ਤੋਂ ੧੦੨ ਸੈਂਮੀ. ਤਕ ਜਾਂ ੩੭ ਤੋਂ ੪੦ ਇੰਚ ਤਕ (੩ ਪੋਇਟ)

☐ Over 102cm or 40 inches (4 pts)
੧੦੨ ਸੈਂਮੀ. ਤੋਂ ਉਪਰ ਜਾਂ ੪੦ ਇੰਚ ਤੋਂ ਉਪਰ (੪ ਪੋਇਟ)

☐ Less than 80cm or 31.5 inches (0 pts)
੮੦ ਸੈਂਮੀ. ਜਾਂ ੩੧.੫ ਇੰਚ ਤੋਂ ਘਟ (੦ ਪੋਇਟ)

☐ Between 80-88cm or 31.5-35inches (3 pts)
੮੦ ਤੋਂ ੮੮ ਸੈਂਮੀ. ਤਕ ਜਾਂ ੩੧.੫ ਤੋਂ ੩੫ ਇੰਚ ਤਕ (੩ ਪੋਇਟ)

☐ Over 88cm or 35 inches (4 pts)
੮੮ ਸੈਂਮੀ. ਤੋਂ ਉਪਰ ਜਾਂ ੩੫ ਇੰਚ ਤੋਂ ਉਪਰ (੪ ਪੋਇਟ)

YOUR LEVEL OF PHYSICAL ACTIVITY AND WHAT YOU EAT CAN AFFECT YOUR RISK OF HAVING DIABETES OR "PRE-DIABETES".

ਤੁਸੀਂ ਕਿਨਾਂ ਖੰਚੇ ਹੋ ਅਤੇ ਕਿਨੀਂ ਫਿਰਾ ਕਰਦੇ ਹੋ ਤੁਹਾਡੇ ਸ਼ੂਗਰ ਅਤੇ ਸ਼ੂਗਰ ਪੂਰਬ ਦੇ ਖਤਰੇ ਤੇ ਅਸਰ ਕਰਦੇ ਹਨ

4) Daily Activity ਰੋਜ ਫਿਰਾ

Over a typical seven-day period (one week), how many times do you engage in physical activity that is prolonged and intense enough to cause sweating and an increase in you heart rate?

ਇਕ ਚਲਦੇ ਦਿਨ ਤੁਸੀਂ ਕਿਨੀਂ ਦਾਰ ਆਪਣੀ ਫਿਰਾ ਦਿਨੀਂ ਦਰਾਉਦੇ ਹੋ ਕਿ ਜਿਦੇ ਨਾਲ ਤੁਹਾਨੂੰ ਪਸੀਨਾ ਆਂਦਾ ਚੋਣੇ ਅਤੇ ਦਿਲ ਦੀ ਧੜਕਨ ਚਲਦੀ ਚੋਣੇ

☐ At least three times per week (0 points)
ਤਿਨ ਦਾਰੀ ਜਾਂ ਜਿਆਦਾ (੦ ਪੋਇਟ)

☐ Normally once or twice per week (1 point)
ਇਕ ਜਾਂ ਦੋ ਦਾਰ (੧ ਪੋਇਟ)

☐ Rarely or never (3 points)
ਬੜੇ ਘਟ ਜਾਂ ਬਿਲਕੁਲ ਨਹੀਂ (੩ ਪੋਇਟ)

HIGH BLOOD PRESSURE AND HIGH BLOOD SUGAR ARE ASSOCIATED WITH DIABETES

ਛਾਡ ਪਰੇਸ਼ਰ ਪੂਰਾ ਜਾਂ ਛਾਡ ਸ਼ੂਗਰ ਪੂਰੀ ਹੋਣ ਦਾ ਸੰਬੰਧ ਸ਼ੂਗਰ ਦੇ ਨਾਲ ਹੁੰਦਾ ਹੈ

5) High Blood Pressure ਪੂਰਾ ਛਾਡ ਪਰੇਸ਼ਰ

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

* ਜਾਣਕਾਰੀ ਦਾ ਜਰਿਆ: ਫਿਨਿਡਰਿਸਕ ਅਤੇ ਕੈਨਰਿਸਕ ਸਵਾਲਨਾਮਿਆਂ ਤੋਂ ਅਪਨਾਇਆ ਗਇਆ

Have you ever been told by a doctor or nurse that you have high blood pressure *OR* are you taking any medication (pills) for high blood pressure?
ਕੀ ਤੁਹਾਨੂੰ ਕਦੇ ਕਿਸੇ ਡਾਕਟਰ ਜਾਂ ਨਰਸ ਨੇ ਕਦੀ ਕਿਹਾ ਹੈ ਕਿ ਤੁਹਾਡਾ ਬਲਡ ਪਰੈਸ਼ਰ ਉੱਚਾ ਹੈ ਜਾ ਤੁਸੀਂ ਬਲਡ ਪਰੈਸ਼ਰ ਲਈ ਕੋਈ ਦਵਾਈ ਲੈ ਰਹੇ ਹੋ

- ☐ No or don't know (0 points)
  ਨਹੀਂ ਜਾਂ ਪਤਾ ਨਹੀਂ (0 ਪੁਆਇੰਟ)
- ☐ Yes (2 points)
  ਹਾਂ ਜੀ (2 ਪੁਆਇੰਟ)

6) High Blood Sugar
ਸ਼ੂਗਰ ਦਾ ਬਹੁਤ ਜ਼ਿਆਦਾ ਹੋਣਾ

Have you ever been told by a doctor or nurse that you have high blood sugar (i.e. during a health exam) or that you have diabetes or "pre diabetes"?
ਕੀ ਤੁਹਾਨੂੰ ਕਿਸੇ ਡਾਕਟਰ ਨੇ ਕਦੇ ਕਿਹਾ ਹੈ ਕਿ ਤੁਹਾਡੀ ਸ਼ੂਗਰ ਬਹੁਤ ਜ਼ਿਆਦਾ ਹੈ (ਜਿਵੇਂ ਕਿ ਕਿਸੇ ਸਰੀਰਿਕ ਜਾਂਚਪੜਤਾਲ ਦੌਰੇ) ਜਾਂ ਕਿ ਤੁਹਾਡੀ ਸ਼ੂਗਰ ਸ਼ੂਗਰ ਦੀ ਬਿਮਾਰੀ ਦੇ ਲੇਵੇ ਪੱਹੁਚ ਚੁੱਕੀ ਹੈ

- ☐ No or don't know (0 points)
  ਨਹੀਂ ਜਾਂ ਪਤਾ ਨਹੀਂ (0 ਪੁਆਇੰਟ)
- ☐ Yes (5 points)
  ਹਾਂ ਜੀ (5 ਪੁਆਇੰਟ)

SOME TYPES OF DIABETES RUN IN FAMILIES
ਕੁਝ ਕਿਸਮਾਂ ਦੀ ਸ਼ੂਗਰ ਆਪਣੇ ਪਰਿਵਾਰ ਦੇ ਕਿਸੇ ਕੋਲ ਕੋਈ ਨੂੰ ਸ਼ੂਗਰ ਹੋਣ ਕਰਕੇ ਹੁੰਦੀ ਹੈ

7) Family
ਪਰਿਵਾਰ

Have any members of your family been diagnosed with diabetes? (You can circle the one below that have)
ਕੀ ਤੁਹਾਡੇ ਪਰਿਵਾਰ ਦੇ ਕਿਸੇ ਕੋਲ ਕੋਈ ਨੂੰ ਸ਼ੂਗਰ ਹੈ ? ਚਲੇ ਪੜ ਦੇ ਸਾਮ ਜੀ

- ☐ No or don't know (0 points)
  ਨਹੀਂ ਜਾਂ ਪਤਾ ਨਹੀਂ (0 ਪੁਆਇੰਟ)
- ☐ Yes: grandparent, aunt, uncle, or first cousin (3 points) (ignore this one if the one below applies)
  ਹਾਂ ਜੀ : ਦਾਦੇ, ਨਾਨੇ, ਚਾਚਾ, ਮਾਮਾ, ਭੂਆ ਜਾਂ ਮਾਸੀ ਤਰਾ ਤੋਂ (3 ਪੁਆਇੰਟ) (ਅਗਰ ਅਗਲੇ ਸਟਾਲ ਦਾ ਜਵਾਬ ਹਾਂ ਹੈ)
- ☐ Yes: parent (mother or father), brother or sister or own child (5 points)

Note: your score cannot be greater than 5 points
ਹਾਂ ਜੀ : ਮਾਪੇ ਜਾਂ ਸਕੇ ਤਰਾ ਤੋਂ (5 ਪੁਆਇੰਟ) (ਤੁਹਾਡੇ ਕੋਲ ਤੋਂ ਉੱਪਰ ਪੁਆਇੰਟ ਨਹੀਂ ਹੋਣੇ ਚਾਹਿਦੇ)

Likelihood of developing diabetes in the next 10 years:
ਅਗਲੇ ਦਸ ਸਾਲਾਂ ਅੰਦਰ ਸ਼ੂਗਰ ਹੋਣ ਦਾ ਖਤਰਾ

< 7	small risk
੭ ਤੋਂ ਘਟ	ਥੋੜਾ ਖਤਰਾ
7-11	moderate risk
੭ ਤੋਂ ੧੧ ਤਕ	ਮਧਮ ਖਤਰਾ
12-14	high risk
੧੨ ਤੋਂ ੧੪ ਤਕ	ਜ਼ਿਆਦਾ ਖਤਰਾ
15-20	very high risk
੧੫ ਤੋਂ ੨੦ ਤਕ	ਬਹੁਤ ਜ਼ਿਆਦਾ ਖਤਰਾ
20-25	extreme risk (may already have diabetes)
੨੦ ਤੋਂ ੨੫ ਤਕ	ਬਹੁਤ ਹੀ ਜ਼ਿਆਦਾ ਖਤਰਾ (ਹੋ ਸਕਦਾ ਹੈ ਕਿ ਤੁਹਾਨੂੰ ਸ਼ੂਗਰ ਹੋ ਚੁਕੀ ਹੈ)

*SCORE:
*ਕੁਲ ਅੰਕ:

STAFF NAME ਕਰਮਚਾਰੀ ਦਾ ਨਾਂ: _____

Thank you for filling this questionnaire about diabetes risk. What is the best way for us to contact you if you are eligible and interested in participating in our research study on physical activity and diabetes prevention?
ਇਹ ਸਟਾਲ ਖਤਰ ਤਕਨ ਦਾ ਤੁਹਾਡਾ ਬਹੁਤ ਬਹੁਤ ਧੰਨਵਾਦ। ਅਗਰ ਤੁਸੀਂ ਸ਼ੂਗਰ ਦੇ ਲਵੇ ਸਰੀਰਿਕ ਕਸਰਤ ਅਵੇ ਸ਼ੂਗਰ ਦੇ ਰਾਬੂ ਪਾਲ ਦੀ ਕਸਰਤਾਂ ਦੇ ਰਖਿਛ ਤੋਂ ਅਤੇ ਚਾਹੋਂਦੇ ਹੋ ਕਿ ਤੁਹਾਡੀ ਕੋਲ ਪੁਣਤਾਲ ਲਵਿਦੇ ਤਾਂ ਅਸੀਂ ਤੁਹਾਡੇ ਨਾਲ ਕਿਸ ਤਰਹ ਸੰਪਰਕ ਕਰ ਸਕਦੇ ਹਾਂ

Name _____ Phone number _____
ਨਾਮ _____ ਟੈਲੀਫੋਨ ਨੰਬਰ _____

Email address ਈਮੇਲ ਦਾ ਪਤਾ _____

Mailing address ਘਰ ਦਾ ਪਤਾ _____

_____

DO YOU CURRENTLY HAVE ACCESS TO OHIP MEDICAL COVERAGE
ਕੀ ਤੁਹਾਡੇ ਕੋਲ ਅੱਜਕਲ ਹੈ

- ☐ Yes ਹਾਂ ਜੀ
- ☐ No ਨਾਂ ਜੀ

*Source: Adapted from the FINDRISK and CANRISK Questionnaires
* ਜਾਣਕਾਰੀ ਦਾ ਜਰਿਆ: ਫਿਨਿਡਰਿਸਕ ਅਤੇ ਕੈਨਰਿਸਕ ਸਰਵਖੋਜਾਂ ਤੋਂ ਅਪਨਾਇਆ ਗਇਆ

Pre-diabetes/ Type 2 diabetes screening tool for PRE-PAID
मधुमेह पूर्व छानबीन के प्रश्न

This questionnaire is intended for adults aged 40- 64 years who are members of certain ethnic minorities (**Chinese, South Asian, African or African-Caribbean**) to help find out if you are at risk of developing type 2 diabetes. Please answer as carefully as you can. We will help you complete this form.

यह प्रश्नपत्र चालीस से साठ साल की आयु के इन व्यक्तियों के लिये है जो जानना चाहते हैं कि इन्हें मधुमेह रोग के होने का खतरा तो नहीं। कृपा करके ध्यान से उत्तर दें। हम इस प्रश्नपत्र को भरने में आपकी सहायता करेंगे।

What ethnicity are (or were) your biological (blood) parents?

आपके माता पिता किस जाति के हैं ।

Mother माता	Father पिता	
☐	☐	White (Caucasian) गोरा
☐	☐	African, African/Caribbean अफ्रीकी
☐	☐	South Asian (India, Pakistan, Sri Lanka, Nepal, Bangladesh) हिन्दुस्तानी
☐	☐	Chinese चीनी
☐	☐	Other (please specify___किसी और जाति वाले_)

AS YOU GET OLDER, YOUR RISK FOR DIABETES INCREASES

आयु के बढ़ने से मधुमेह बीमारी का खतरा भी बढ़ता है

1) What year were you born? _आपका जन्म किस साल में हुआ___

Select your age group अपनी आयु का वर्ग चुनिये

☐ 40-44 years (0 points) चालीस से चवालीस – ० अंक

☐ 45-54 years (2 points) पैंतालिस से चव्वन साल – २ अंक

☐ 55- 64 years (3 points) पचपन से चौंसठ साल – ३ अंक

BODY SHAPE AND SIZE CAN AFFECT YOUR RISK OF DIABETES

शरीर की दशा और आकार मधुमेह रोग के खतरे पर असर करते हैं

2a) How much do you weigh (either in pounds or in kilograms)?

आपका वज़न कितना है (पौंड या किलोग्राम में)

I weigh _____ pounds *OR* **I weigh _____ kilograms**

मेरा वज़न _____ पौंड या _____किलो है

2b) How tall are you without shoes on?

आपका कद बिना बूटों के कितना है

I am _____ feet and _____ inches tall *OR* **I am _____centimeters tall**

मैं _____फुट और _____इंच कद या मैं _____सेंटीमीटर कद का हूँ

Use the attached height and weight table to find body mass index (BMI)

कद और वज़न का चार्ट देखकर शरीरिक वज़न सूची अंक ढूँढिये

☐ unshaded area- BMI less than 25 (0 points)
साफ क्षेत्रफल – वज़न सूची अंक पच्चीस से कम (शून्य अंक)

☐ light shaded area- BMI 25-30 (1 points)

STAFF NAME कर्मचारी का नाम _____

हल्के रँग का क्षेत्रफल – वज़न सूची अंक पच्चीस से तीस तक (एक अंक)

☐ darker shaded area- BMI over 30 (3 points)
गहरे रँग का क्षेत्रफल – वज़न सूची अंक तीस से ऊपर (तीन अंक)

3) Waist Circumference (कमर का माप)

I am going to use a tape measure and place it around your waist at the level of the navel (belly button). I will take a measure after you breathing out (do not hold your breath).

अब मैं इँचटेप के साथ आपकी कमर का माप लूँगा (बेल्ली बटन के पास) पहले आपको साँस बाहर निकालना होगा

_____ inches *OR* _____cm

_____इँच या _____सैं.मी.

☐ male नर

☐ female नारी

☐ Less than 94cm or 37 inches (0 pts)
९४ सैं.मी. से या ३७ इँच से कम (शून्य अंक)

☐ Between 94-102cm or 37-40inches (3 pts)
९४ से १०२ सैं.मी. या ३७ से ४० इँच तक (तीन अंक)

☐ Over 102cm or 40 inches (4 pts)
१०२ सैं.मी. या ४० इँच से ज्यादा (चार अंक)

☐ Less than 80cm or 31.5 inches (0 pts)
८० सैं.मी. से या ३१.५ इँच से कम (शून्य अंक)

☐ Between 80-88cm or 31.5-35inches (3 pts)
८० से ८८ सैं.मी. या ३१.५ से ३५ इँच तक (तीन अंक)

☐ Over 88cm or 35 inches (4 pts)
८८ सैं.मी. या ३५ इँच से ज्यादा (चार अंक)

YOUR LEVEL OF PHYSICAL ACTIVITY AND WHAT YOU EAT CAN AFFECT YOUR RISK OF HAVING DIABETES OR "PRE-DIABETES".

आपकी शारीरिक गतिविधि और खान पीना मधुमेह रोग के खतरे पर असर करता है

4) Daily Activity दिन की गतिविधि

Over a typical seven-day period (one week), how many times do you engage in physical activity that is prolonged and intense enough to cause sweating and an increase in you heart rate?

एक सप्ताह में आप कितनी बार अपनी गतिविधि करते हैं जिससे आपको पसीना आता है और दिल की धड़कन बढ़ती है

☐ At least three times per week (0 points)
तीन बार या इससे ज्यादा (शून्य अंक)

☐ Normally once or twice per week (1 point)
एक या दो बार (एकअंक)

☐ Rarely or never (3 points)
बहुत कम या बिल्कुल नहीं (तीन अंक)

HIGH BLOOD PRESSURE AND HIGH BLOOD SUGAR ARE ASSOCIATED WITH DIABETES

ऊँचा ब्लड प्रेशर और ऊँची ब्लड शुगर का सँबंध मधुमेह रोग के खतरे पर होता है

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

* साधन: फ़ाईंडरिस्क और कैनरिस्क से अपनाया गया

5) High Blood Pressure ऊँचा ब्लड प्रेशर

Have you ever been told by a doctor or nurse that you have high blood pressure *OR* are you taking any medication (pills) for high blood pressure?

क्या आपको कभी किसी डाक्टर या नर्स ने कभी चेतावनी दी है कि आपका ब्लड प्रेशर ऊँचा है या क्या आप ब्लड प्रेशर के लिये कोई दवा ले रहे हैं

☐ No or don't know (0 points)
नहीं या मालूम नहीं (शून्य अंक)

☐ Yes (2 points)
हाँ (दो अंक)

6) High Blood Sugar

ऊँची ब्लड शुगर

Have you ever been told by a doctor or nurse that you have high blood sugar (i.e. during a health exam) or that you have diabetes or "pre diabetes"?

क्या आपको कभी किसी डाक्टर या नर्स ने कभी चेतावनी दी है कि आपकी ब्लड शुगर बहुत ज्यादा है (जैसे किसी स्वास्थ्य परीक्षा के समय) या आपकी शुगर मधुमेह रोग के खतरे के बहुत पास पहुँच चुकी है

☐ No or don't know (0 points)
नहीं या मालूम नहीं (शून्य अंक)

☐ Yes (5 points)
हाँ (पाँच अंक)

SOME TYPES OF DIABETES RUN IN FAMILIES

कुछ लोगों को मधुमेह रोग अपने किसी परिवार के और सदस्य को होने के कारण होता है

7) Family

परिवार

Have any members of your family been diagnosed with diabetes? (You can circle the one below that have)

क्या आपके परिवार के किसी सदस्य को मधुमेह रोग है ? नीचे पढकर बताये

☐ No or don't know (0 points)
नहीं या मालूम नहीं (शून्य अंक)

☐ Yes: grandparent, aunt, uncle, or first cousin (3 points) (ignore this one if the one below applies)
हाँ: दादा दादी, नाना नानी, चाचा चाची, चचेरे या ममेरे भाई बहन (तीन अंक, अगर अगले प्रश्न का उत्तर न है)

☐ Yes: parent (mother or father), brother or sister or own child (5 points)

Note: your score cannot be greater than 5 points

हाँ: माता पिता य भाई बहन (तीन अंक, आपके अंक पाँच से ज्यादा न हों)

Likelihood of developing diabetes in the next 10 years:

अगले दस साल तक बहुमेह रोग होने का खतरा

< 7	small risk
कुल अंक सात से कम	कम खतरा
7-11	moderate risk
कुल अंक ७ से ११ तक	मध्यम खतरा
12-14	high risk
कुल अंक १२ से १४ तक	ज्यादा खतरा
15-20	very high risk
कुल अंक १५ से २० तक	बहुत ज्यादा खतरा
20-25	extreme risk (may already have diabetes)
कुल अंक २० थोष २५ थक	बहुथ ही ज्यादा खतरा (हो सकता है कि आपको बहुमेह रोग है)

*SCORE:

*कुल अंक:

STAFF NAME कर्मचारी का नाम _____

Thank you for filling this questionnaire about diabetes risk. What is the best way for us to contact you if you are eligible and interested in participating in our research study on physical activity and diabetes prevention?

इस प्रश्नपत्र के भरने का आपका धन्यवाद। अगर आप मधुमेह रोग से संबंधित शारिरिक गतिविधि की जाँचकारी और मधुमेह रोग से बचने की विधियों की पढाई में हिस्सा लेना चाहते हैं तो हम आपसे कैसे सँपर्क स्थापित कर सकते हैं

Name _____ Phone number_____ _____

नाम _____ फोन नं._____

Email address ईमेल का पता _____

Mailing address घर का पता _____

_____

DO YOU CURRENTLY HAVE ACCESS TO OHIP MEDICAL COVERAGE

क्या आपके पास ओहिप है

☐ Yes हाँ

☐ No नहीं

*Source: Adapted from the FINDRISK and CANRISK Questionnaires

* साभार: फाईंडरिस्क और कैनरिस्क से अपनाया गया

Physical Activity and Chronic Disease Unit York University

STUDY PARTICIPATION AND MEDICAL QUESTIONNAIRE

PERSONAL DATA (please print)

Name: _____

Phone number: _____ Sex: □ Male □ Female

Mailing address: _____

_____

Email: _____

Place of Birth (Region and Country): _____

If born outside of Canada, when did you come to Canada? _____ (Day / Month / Year)

What languages do you speak? _____

What religion do you practice?_____ (e.g., Catholic, Hindu, Islam, etc.)

How strictly do you follow your religion? _____

Highest Level of Education:

□ Primary School (Grade 1-8) □ High School (Grade 9-13)

□ College/University □ No Formal Education

Marital Status: □ Single □ Married □ Common Law □ Divorced □ Widowed

Number of Children: _____

For Women – □ Premenopausal □ Postmenopausal □ Perimenopausal Other: _____

Do you have a family Doctor? □ Yes □ No

If yes, please provide their contact information.

Name: _____

Phone No. : _____

Person to Contact in Case of Emergency

Name: _____

Relationship:_____ Phone Number: _____

MEDICAL HISTORY

A. How do you get most of your health information? (Choose only ONE)

i. From books or magazines ii. From the internet

iii. From a medical doctor or other health professional iv. From friends or family

v. From formal classes or school (please state): _____

B. Are you on hormone replacement therapy or birth control pills? □ Yes □ No

C. Are you taking any other medications? □ Yes □ No

If yes, list all medications and doses

_____

D. Are you taking any vitamins or herbal supplements? □ Yes □ No

If yes, please list brands and doses

_____

_____

E. Do you have, or have you ever had, problems with any of the following?

i. Heart or blood vessels □ Yes □ No

ii. Nerves or brain □ Yes □ No

iii. Breathing or lungs □ Yes □ No

iv. Hormones, thyroid, or diabetes □ Yes □ No

v. Back, Muscles, joints, or bones □ Yes □ No

vi. Other (please list) _____

F. Please list any serious injuries suffered, or surgeries you have had.

_____

_____

G. Are you aware of any other medical conditions or treatments that we should be aware of (ie. illnesses, physiotherapy, chiropractor etc.)?

_____

_____

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. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the 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.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

   Yes

   No ▶ ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ days per week

No vigorous job-related physical activity ▶ ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ hours per day
_____ minutes per day

4. Again, think about only 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 **as part of your work**? Please do not include walking.

_____ days per week

No moderate job-related physical activity

▶ ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ hours per day_____ minutes per day

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ days per week

No job-related walking

▶ ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ hours per day_____ minutes per day

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ days per week No traveling in a motor vehicle

▶ ***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ hours per day_____ minutes per day

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week** No bicycling from place to place

▶ ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ days per week

No walking from place to place

▶ ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only 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 **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ days per week

No vigorous activity in garden or yard

▶ ***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**_____ **minutes per day**

16. Again, think about only 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** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ days per week

No moderate activity in garden or yard

▶ ***Skip to question 18***

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ hours per day_____ minutes per day

18. Once again, think about only 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** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ days per week

No moderate activity inside home

▶ ***Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ hours per day_____ minutes per day

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ days per week

No walking in leisure time

▶ ***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ hours per day_____ minutes per day

22. Think about only 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 **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ days per week

No vigorous activity in leisure time ▶ ***Skip to question 24***

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ hours per day_____ minutes per day

24. Again, think about only 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 bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ days per week

No moderate activity in leisure time ▶ ***Skip to PART 5: TIME SPENTSITTING***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time? **_____ hours per day _____ minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ hours per day_____ minutes per day

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ hours per day_____ minutes per day

ACCULTURATION SCALE

Please answer each question as carefully as possible by circling **one** of the numbers to the right of each question to indicate your agree of agreement or disagreement.

Many of the questions will refer to your heritage culture. This means the culture that has influenced you the most (other than North American culture). It may be the culture of your birth, the culture in which you were raised, or another culture that forms part of your background. If there are several such cultures, please try to identify a culture that may have had an impact on previous generations of your family.

Please write your heritage culture in the space provided here: _____

		Strongly Disagree			Neutral/ Depends			Strongly Agree
1.	I speak my heritage language	1	2	3	4	5	6	7 9
2.	I speak English	1	2	3	4	5	6	7 9
3.	My thinking is done in my heritage language	1	2	3	4	5	6	7 9
4.	My thinking is done in English	1	2	3	4	5	6	7 9
5.	I often participate in my heritage cultural traditions	1	2	3	4	5	6	7 9
6.	I often participate in mainstream Canadian cultural traditions	1	2	3	4	5	6	7 9
7.	My family cooks food from my heritage culture	1	2	3	4	5	6	7 9
8.	My family cooks typical Canadian food	1	2	3	4	5	6	7 9
9.	I enjoy social activities with people from the same heritage culture as myself	1	2	3	4	5	6	7 9
10.	I enjoy social activities with typical Canadian people	1	2	3	4	5	6	7 9
11	I enjoy entertainment (e.g., movies, music, literature) from my heritage culture	1	2	3	4	5	6	7 9
12	I enjoy Canadian entertainment (e.g., movies, music, literature)	1	2	3	4	5	6	7 9
13	I often behave in ways that are typical of my heritage culture	1	2	3	4	5	6	7 9
14	I often behave in ways that are “typically Canadian”	1	2	3	4	5	6	7 9
15	It is important for me to maintain or develop the practices of my heritage culture	1	2	3	4	5	6	7 9
16	It is important for me to maintain or develop Canadian cultural practices	1	2	3	4	5	6	7 9
17	I believe in the values of my heritage culture	1	2	3	4	5	6	7 9
18	I believe in mainstream Canadian values	1	2	3	4	5	6	7 9
19	I am interested in having friends from my heritage culture	1	2	3	4	5	6	7 9
20	I am interested in having Canadian friends	1	2	3	4	5	6	7 9

Derived from: Vancouver Index of Acculturation: Ryder, A. G., Alden, L. E., & Paulhus, D. L. (2000). Is acculturation unideminsional or bidimensional? A head-to-head comparison in the prediction of personality, self-identity, and adjustment. *Journal of Personality and Social Psychology, 79(1),* 49-65.ARSMA-II: Cuellar, I., Arnold, B., & Maldonado, R. (1995). Acculturation Rating Scale for Mexican Americans-II: A revision of the original ARSMA Scale. *Hispanic Journal of Behavioral Sciences, 17 (3),* 275-304.

DIET RECORD: DAY 1

Name:_____ Date:_____

Circle day: Monday Tuesday Wednesday Thursday Friday

Please fill out at least 3 records: 2 weekdays and 1 weekend day
Is this representative of a normal day, i.e. does it reflect your usual eating pattern? ☐YES ☐ NO

If no, how does it differ? ☐ **More than usual** ☐ **Less than usual**

BREAKFAST	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

LUNCH	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

DINNER	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

SNACKS		
FOOD/DRINK (in detail)	QUANTITY	TIME:

DIET RECORD: DAY 2

Name:_____ Date:_____

Circle day: Monday Tuesday Wednesday Thursday Friday

Please fill out at least 3 records: 2 weekdays and 1 weekend day
Is this representative of a normal day, i.e. does it reflect your usual eating pattern? ☐YES ☐ NO

If no, how does it differ? ☐ **More than usual** ☐ **Less than usual**

BREAKFAST _____	TIME:
FOOD/DRINK (in detail)	QUANTITY

LUNCH	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

DINNER _____	TIME:
FOOD/DRINK (in detail)	QUANTITY

SNACKS		
FOOD/DRINK (in detail)	QUANTITY	TIME:

DIET RECORD: DAY 3

Name:_____ Date:_____

Circle day: Saturday Sunday

Please fill out at least 3 records: 2 weekdays and 1 weekend day
Is this representative of a normal day, i.e. does it reflect your usual eating pattern? ☐YES ☐ NO

If no, how does it differ? ☐ **More than usual** ☐ **Less than usual**

BREAKFAST	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

LUNCH	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

DINNER	TIME: _____
FOOD/DRINK (in detail)	QUANTITY

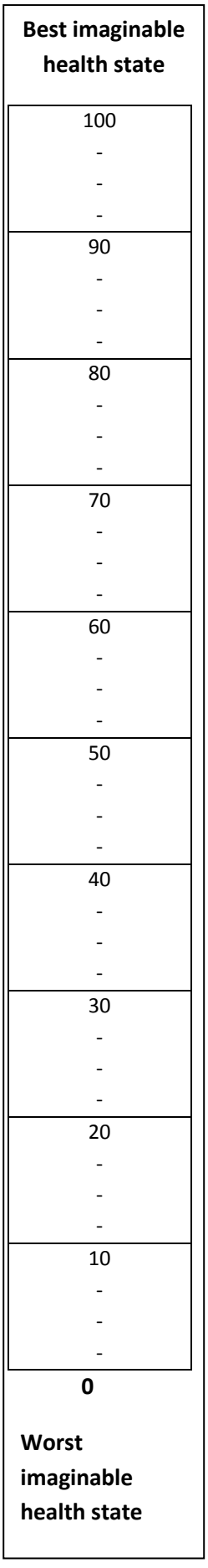
SNACKS		
FOOD/DRINK (in detail)	QUANTITY	TIME:

EQ-5D **By placing a tick in one box in each group below, please indicate which statements best describe your own health state today**.	
Mobility	
I have no problems in walking about	[ ]
I have some problems in walking about	[ ]
I am confined to bed	[ ]
Self-Care	
I have no problems with self-care	[ ]
I have some problems washing or dressing myself	[ ]
I am unable to wash or dress myself	[ ]
Usual Activities (*e.g. work, study, housework, family or leisure activities)*	
I have no problems with performing my usual activities	[ ]
I have some problems with performing my usual activities	[ ]
I am unable to perform my usual activities	[ ]
Pain/Discomfort	
I have no pain or discomfort	[ ]
I have moderate pain or discomfort	[ ]
I have extreme pain or discomfort	[ ]
Anxiety/Depression	
I am not anxious or depressed	[ ]
I am moderately anxious or depressed	[ ]
I am extremely anxious or depressed	[ ]

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



RISK FACTOR KNOWLEDGE AND LIFESTYLE HABITS

Name:_____

1) How much sleep on average to you get each night?
   a) 10 or more hours per night
   b) 8-10 hours per night
   c) 7-8 hours per night
   d) 6-7 hours per night
   e) Less than 5
   f) Not sure – I do not sleep well throughout night.

2) How good is your nutrition knowledge?
   □ Very Poor □ Below Average □ Average □ Above Average □ Excellent

3) How would your physical activity/exercise knowledge?
   □ Very Poor □ Below Average □ Average □ Above Average □ Excellent

4) What is the highest level of education that you have completed?
   □ Some high school or less □ High school diploma
   □ Some college or university □ University or college degree

5) How many alcoholic beverages do you consume on a weekly basis?

   Wine (5 oz) _____ Spirits / Liquor (1.5 oz) _____

   Beer (12 oz) _____ Coolers (12 oz) _____

6) At the present time, do you smoke cigarettes?
   □ Daily □ Occasionally □ Not at all

7) Over your entire lifetime, about how many years in total did you smoke?
   _____ years

8) Rate your current diet: □ Very Poor □ Poor □ Average □ Good □ Very Good

9) How often do you eat vegetables or fruits?
   □ Every day □ Not every day

10) Have you ever heard of Canada's Food Guide? □ Yes □ No

   If yes, have you ever used Canada's Food Guide? □ Yes □ No

   In your own words, what are the recommendations in the Canada's Food Guide?
   _____

   _____

11) How many servings of the following food groups <u>should</u> you get each day?

Servings of Dairy ____ # Servings of Fruits and Vegetables ____

Servings of Grains ____ # Servings of Meat and Meat Alternatives ____

12) Body weight changes over your adult life. Please pick the option best describes you. Do not include times you were pregnant or sick.

a) My body weight has stayed the same
b) Steady weight gain
c) Lost weight as an adult and kept it off
d Weight has gone up and down again by more than 10 pounds

13) How many times have you lost and gained more than:

5 pounds: _____ 10 pounds: _____ 25: _____ 50 pounds: _____

14) Are you currently dieting? □ Yes □ No

If yes, what kind of diet? _____

_____

15) Are you currently trying to lose weight? □ Yes □ No

If yes, how much weight have you lost? _____ pounds

16) How are you trying to lose weight (check all that apply)?

□ Diet □ Pills □ Herbal Remedies □ Exercise

□ Other (please describe):_____

17) What has been your highest body weight (not including pregnancy)? _____ pounds

18) What has been your lowest adult body weight (not including sickness)?____ pounds

19) What would be your ideal body weight? _____ pounds

20) What would be a healthy body weight for yourself? _____ pounds

21) What would you consider yourself?
□ Underweight □ Normal weight □ Overweight □ Obese

22) Have you heard of the Canadian guidelines for Healthy Body Weight? □ Yes □ No

23) What should your Body Mass Index (BMI) be? _____ □ Not sure

24) Would you consider your ***current*** physical activity level to be:

□ Very Active □ Moderately Active □ Average □ Below Average □ Very Poor

25) What is the largest obstacle to being physically activity?

_____

26) Have you ever heard of Canada's Physical Activity Guide? □ Yes □ No

If yes, have you ever used Canada's Physical Activity Guide? □ Yes □ No

27) In your own words, what are the recommendations in the Canada's Physical Activity Guide?

_____

_____

28) How much physical activity should you do to be healthy?

Intensity □ Light □ Moderate □ Vigorous □ Intensity does not matter

Frequency: _____ ***days per week*** □ Frequency does not matter

Time: _____ □ Time does not matter

29) How important is being regularly physically active to you?

□ Not at all important □ Somewhat unimportant

□ Somewhat important □ Very important

PERCEIVED STRESS SCALE

	Never	Almost never	Sometimes	Fairly often	Very often
1.In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties wer piling up so high that you could not overcome them?	0	1	2	3	4

SF – 12 (Version 1) Standard Form (4-Week Recall)

Enrollment No._____ Date: _____

This survey asks for your views about health. This information will help keep track of how you feel and how well you are able to do your usual activities
For each of the following questions, please mark an **[X]** in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
[ ]	[ ]	[ ]	[ ]	[ ]

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?	Yes, limited a lot	Yes, limited a little	No. not limited at all
a) Moderate activities, such as moving a table, pounding maize, collecting fire wood, riding a bike, or tending livestock	[ ]	[ ]	[ ]
b) Walking <u>several</u> minutes	[ ]	[ ]	[ ]

3. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities, <u>as a result of your physical health</u>?	Yes	No
a) <u>Accomplished less</u> than you would like?	[ ]	[ ]
b) Were limited in the <u>kind</u> of work or other activities?	[ ]	[ ]

4. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities, <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?	Yes	No
a) <u>Accomplished less</u> than you would like?	[ ]	[ ]
b) Did work or other activities <u>less carefully than usual</u>	[ ]	[ ]

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all [ ]	A little bit [ ]	Moderately [ ]	Quite a bit [ ]	Extremely [ ]

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....						
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
b) Did you have a lot of energy?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
c) Have you felt downhearted and blue?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?				
All of the time	Most of the time	Some of the time	A little of the time	None of the time
[ ]	[ ]	[ ]	[ ]	[ ]

Appendix F List of Resistance Exercises for Phase III

1. Marching with high knees
    a. Participants were instructed to march on the spot while raising their knees as high as possible and while making a conscious effort to recruit their arms.
    b. This was performed for a specified time which was progressed based on individual capabilities.

2. Squat with overhead kettlebell press.
    a. Participants were instructed to perform a typical squat followed by an overhead press using a kettlebell or medicine ball. In most cases, participants had a bench behind them during the squat to ensure both safety and to encourage range of motion.
    b. Repetitions were performed for a specified time while proper technique was reinforced throughout. Both weight and time were progressed based on individual capabilities.

3. Pushups
    a. Participants were instructed to complete full pushups if able. Modification took place by allowing participants to perform a wall pushup style of movement with their hands on the handle of the treadmill allowing full range of motion.
    b. Repetitions were performed for a specified time while proper technique was reinforced throughout. Time and foot placement (further away from the treadmill handle) were progressed based on individual capabilities.

4. Forearm plank
    a. Participants were instructed to complete a typical forearm plank for a specified time.
    b. Time was progressed based on individual capabilities.

5. Step ups with medicine ball press
    a. Participants were instructed to step up 2 stairs and then complete an overhead shoulder press using a medicine ball.
    b. Repetitions were performed for a specified time while proper technique was reinforced throughout. Both weight and time were progressed based on individual capabilities.

Step-up to overhead press: sagittal plane

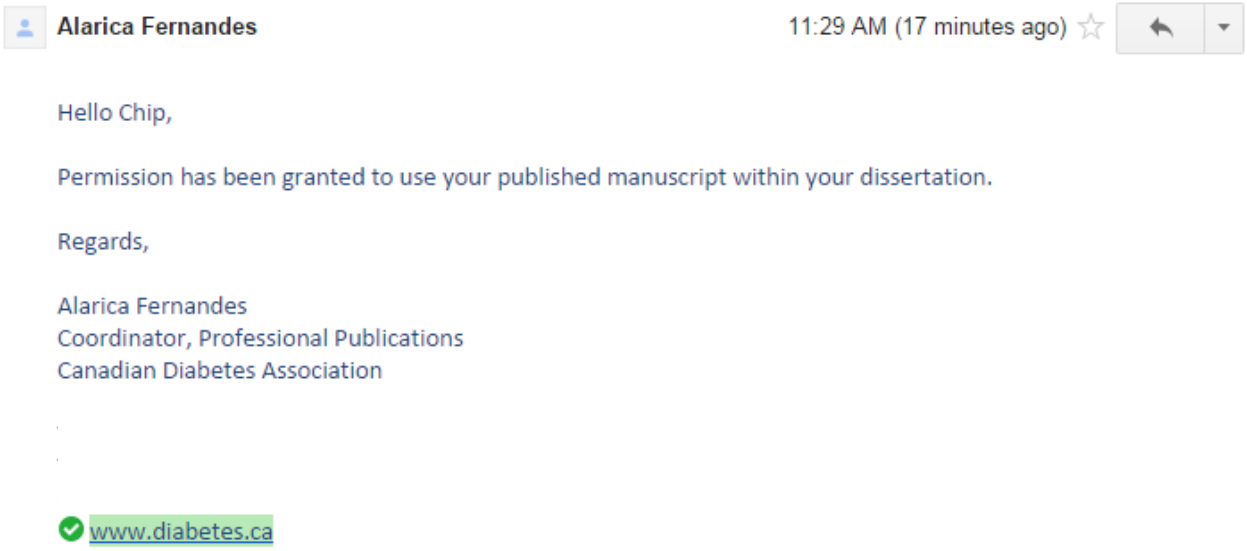
6. Quadra-ped
    a. Participants were instructed to start on their hands and knees and then asked to extend opposite arm and leg while maintaining a controlled core. Participants alternated arms and legs.
    b. Repetitions were performed for a specified time which was progressed based on individual capabilities.

7. Wall sit with isometric medicine ball front hold
    a. Participants were instructed to maintain a wall sit with their knees bent at a 90 degree angle while holding a medicine ball with straight arms directly in front of their chest.
    b. Time was progressed based on individual capabilities.

8. Stairs
    a. Participants were instructed to climb the stairs adjacent to the laboratory
    b. Number of floors climbed was progressed based on individual capabilities.

Appendix G Copyright Permissions

Manuscript 1: Canadian Journal of Diabetes



Alarica Fernandes 11:29 AM (17 minutes ago)

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York University
Chris Ardern

Signature: 

Name: Dr. Norm Gledhill

Title: Professor Emeritus, PRE-PAID Chair.

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Any waiver of any breach or default under this Agreement must be in writing and shall not be deemed a waiver of any other or subsequent breach or waiver. Failure to delay by either party to enforce compliance with any term or condition of this Agreement shall not constitute a waiver of such term or condition.

If any provision is this Agreement is determined to be invalid or unenforceable, the remaining provisions of this Agreement shall not be affected thereby and shall be binding upon the parties hereto, and shall be enforceable, as though the invalid or unenforceable provision were not contained herein.

In the event a Licensed Survey or associated QM intellectual property is exported outside of the United States by Licensee, both parties agree that Licensee is obligated and solely responsible for ensuring compliance with all applicable import and export laws and regulations of the United States of America and any applicable foreign jurisdictions. Licensee shall indemnify, defend and hold harmless QM (including payment of all reasonable costs, fees, settlements and damages) with respect to any suits or proceedings brought against QM arising from Licensee's export of a Licensed Survey.

This Agreement and performance hereunder shall be governed in accordance with the laws of the State of Rhode Island, but excluding Rhode Island choice of law principles. With respect to any dispute arising in connection with this Agreement, Licensee consents to the exclusive jurisdiction and venue in the state and federal courts located in Providence County, Rhode Island.

This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which shall be deemed the same agreement

* * *

APPENDIX B

QUALITYMETRIC LICENSE (OGSR) - LICENSED SURVEYS AND MANUALS

Attached to and Incorporated into QM - SLA - OGSR - 09-2008.doc

Licensed Surveys and Approved Languages

SF-12v2® Health Survey – Standard Recall

China (Chinese)
United States (English)
India (Hindi)
India (Punjabi)
India (Tamil)
India (Urdu)

NO formatting or editing changes to the survey: (Very Important - Please Read)

In order to obtain licensing from Licensor no changes can be made to the survey forms. Any format and/or language changes have the potential to affect the survey data received. Therefore, to maintain the validation and integrity of the SF Health Surveys, **no language or formatting changes** are allowed. The format of the survey was scientifically engineered to facilitate accurate and unbiased data, as well as keeping the SF Health Survey in a visual format that is comprehensible to the patient/participant, including those who may be impaired and/or elderly. **You should administer the survey in the exact format you will receive it in. The only item Licensee may add is a header with patient identification and / or administration information. If you do wish to add a header please ask for a sample copy of the survey to edit and then submit this to your Account Representative for review prior to signing this License Agreement.** Other than this, Licensor can not guarantee the validity and/or reliability of data obtained from using modified surveys and we will not be able to license any modified survey form. Once the licensing process is completed, you will receive a clean set of Survey Forms in a word and pdf. file. These are the forms you will administer. Please do not use any forms you may already have access to as the ones we send you are the most current versions.

Required Manuals (price not included in Administrative Fee)

KIT001 SF-12v2 Reference Kit
MAN003 - How to Score Version 2 of the SF-12® Health Survey
MAN004 - Phys & Mental Hlth Summ Scales

Pre-Diabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) Project:

Training Manual: Essential Implementation Considerations for

Qualified Exercise Professionals

Rowan, C.P, Riddell, M.C., and Jamnik, V.K.

Background

The diabetes epidemic is a global health care concern that continues to dominate the attention of health care practitioners, researchers and policy makers. Over the past two decades the incidence of prediabetes, the precursor to type 2 diabetes (T2D) for most individuals, has been increasing in Canada and projections indicate that based on current lifestyle and population trends, the prevalence will become overwhelming for the current Canadian health care system. However, emerging evidence suggests that focussing on prediabetes intervention may provide a very effective strategy for reducing the incidence of T2D[31,119].

It is projected that, by 2012, more than 2.8 million Canadians (~8.8%) will be living with diabetes, of which, ~90% will have type 2 [4]. It is also projected that there are a large number of persons with undiagnosed diabetes who are not included in this estimate. Although prediabetes is an emerging research area, compared to the diagnosed diabetes, it receives substantially less support for research and intervention. The Public Health Agency of Canada estimates that ~4 million Canadians (12.5%) between the ages of 40 and 74 have impaired fasting glucose and ~1.8 million (5%) have impaired glucose tolerance [4]. Both of these conditions are recognized antecedents to T2D. With the increased prevalence of diabetes and prediabetes, there has been a concomitant rise in health care costs. By 2020, diabetes and its complications are projected to cost the Canadian health care system an estimated $16.9 billion per year[84].Less is known about the projected cost implications of prediabetes, specifically.

Within the current Canadian health care paradigm, primary care physicians are, almost exclusively, responsible for the assessment of diabetes risk and the associated blood screening. Unfortunately, a large proportion of individuals at high risk for T2D are frequently identified and treated only once they have progressed to T2D and are symptomatic. In a landmark randomized clinical trial, the Diabetes Prevention Program (DPP) in the United States showed that lifestyle modification involving dietary counselling and regular PA accomplished a 58% reduction in four year post intervention T2D incidence compared to

controls while Metformin (a commonly used drug to lower blood sugar) showed only a 31% incidence reduction[119]. Surprisingly, despite the strong body of supporting evidence[18,31,119], there are few initiatives in Canada (at the community level) that provide screening and culturally preferred PA intervention for those who are pre-diabetic.

This paper addresses important information regarding front-line screening to detect individuals with prediabetes and provides strategies for implementing culturally-specific /preferred PA interventions.

A Culturally-Specific Approach

Canada has a very ethnically diverse population comprised of approximately 6 million foreign born persons (approximately 19.8% of the population) {{38 Statistics Canada 2007}}. Diabetes prevalence among specific ethnic populations has been well documented showing that there are higher rates of metabolic syndrome, impaired glucose tolerance, abdominal obesity and insulin resistance in those who are of South Asian, Chinese, African, Latin or Aboriginal ancestry[10–12,14,120]. It is believed that the causes for ethnic disparity in diabetes prevalence are linked to both genetic and environmental factors[14].

The environmental influences for the high rate of T2D in various new Canadians from certain ethnic populations are likely numerous and perhaps synergistic. For example, there are many salient culturally-specific barriers to diabetes prevention and management including; poor diabetes specific knowledge, negative attitudes or beliefs about diabetes, a lack of self-management skill and differences in patient-physician expectations. In addition there are language barriers, low English literacy rates, insufficient community engagement and culturally-specific beliefs and attitudes towards PA and lifestyle. There are also health system barriers such as socioeconomic status, inaccessibility to care and lack of health insurance coverage[14].

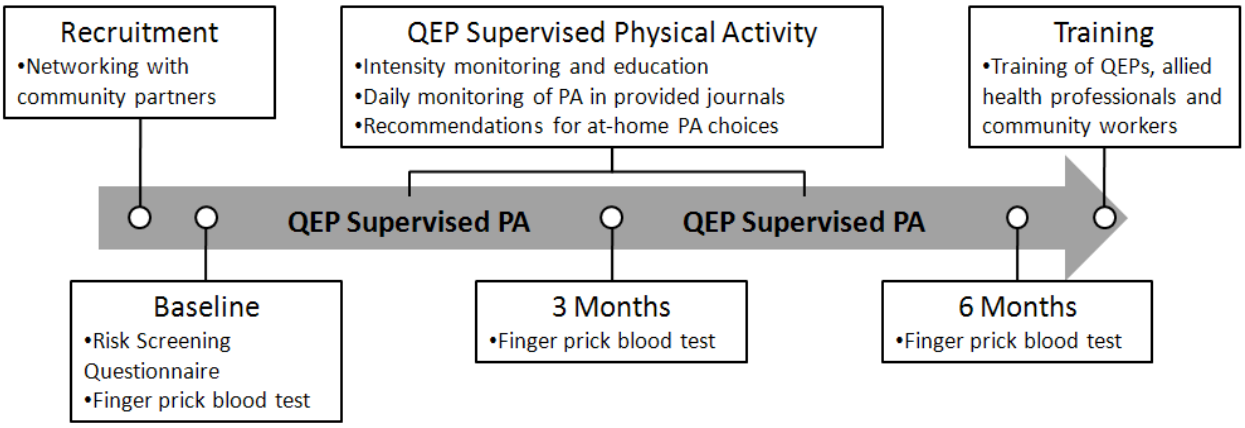
Under-utilization of Community Resources:

Various personnel are housed within community care access centres including qualified exercise professionals (QEPs), diabetes educators, health coaches and other community workers such as program coordinators or outreach workers (provide more examples), in addition to the regular battery of allied health care providers. These individuals, many of whom have post-secondary education in health-related fields, are currently underutilized with respect to promoting and facilitating healthy behaviours in their communities for people at high risk for diabetes development. In a culturally diverse community setting, many of these individuals are employed at community care access centres are from the same ethnicity as the community members (at large), which may be a very valuable resource for more widespread PA/healthy lifestyle programming that is culturally specific and appropriate. For QEPs, non-health care community workers and health care providers, it is crucial that identification of potential barriers to PA participation takes place prior to commencement of any public/community health initiative so that they can be addressed in advance, maximizing the likelihood for a successful intervention. The CDA Clinical Practice Guidelines are a comprehensive and evidence-based resource that could be utilized as reference tool for these workers providing information on PA, diabetes diagnosis and screening, complications and several other relevant topics[3].

The Pre-diabetes Detection and Physical Activity Intervention Delivery Project (PRE-PAID):

The PRE-PAID project is a multi-phase initiative, initiated originally in the GTA and funded by the Ontario Ministry of Health Promotion and Sport and the Ontario Trillium Foundation. The project is aimed at identifying persons who have prediabetes, then using culturally-specific PA interventions at the community level to help prevent or delay the progression to T2D. The PRE-PAID project also features a training component for QEPs and other community health workers that deploy the targeted screening process and prediabetes specific education pertaining to PA recommendations for high risk populations. Figure 1 depicts the PRE-PAID approach to prediabetes screening and PA intervention. The PRE-PAID project team elected to initially target South Asian, Chinese, African or African-Caribbean, Hispanic and Aboriginal populations during the screening and intervention portion of the project.

Figure 1: PRE-PAID project timeline and approach to screening /intervention



The PRE-PAID approach aims to identify persons with prediabetes so that appropriate preventative measures can be taken resulting in a delayed onset of or prevention of T2D. This approach utilizes point-of care A1C measures (Biorad in2it) as the primary blood screening measure of glycemic control due to the ease with which blood samples can be collected, the short analysis time (10 minutes), and because individuals being screened do not need to be in a fasted state for the test. This blood test, is preceded by a prediabetes risk questionnaire that has been modified from the CANRISK questionnaire generated by the Public Health Agency of Canada and originally by Finnish researchers[29,32]. This protocol provides a reasonably accurate front-line assessment of the individual's likelihood for the development of T2D, or if they may have it already[121].

Risk factors and screening for prediabetes and diabetes:

The development of altered glycemic control is acknowledged to have both genetic and environmental contributors. A number of important risk factors for diabetes development have been identified and include those listed in Table 1[3]. Of particular importance to the PRE-PAID project are the ethnicity groups and the modifiable lifestyle factors, most notably PA participation. The CDA recommends that

screening for T2D should take place in all individuals >40 years of age every three years and more regularly in those who are deemed high risk according to Table 1[3]. These recommendations are sometimes poorly adhered to by primary care physicians and, as a result, many individuals are not identified until they have already progressed to a clinical diagnosis of T2D. The limited accessibility to blood screening can, in part, be attributed to the protocols surrounding the medically controlled act of blood collection, analysis, and biohazardous waste disposal. However, with the enhancement of point-of-care devices, such as the Bio-Rad in2it and Bayer A1cnow, for blood analysis, steps could be taken to broaden the scope of practice for various allied health workers such as QEPs who could easily be

Table 1: Risk factors for the development of T2D

Risk Factors for type 2 diabetes	
Modifiable Risk Factors	Non-Modifiable Risk Factors
• Hypertension • Dyslipidemia • Presence of complications associated with diabetes • History of IGT or IFG • Vascular disease (coronary, cerebrovascular or peripheral) • High waist circumference • Physical inactivity • Obesity	• Age > 40 years • First-degree relative with type 2 diabetes • Member of high-risk population (Aboriginal, Hispanic, South Asian, Asian, or African descent • History of gestational diabetes (if mother had it) • Polycystic ovary syndrome • History of delivery of a macrosomic infant (larger than normal due to gestational diabetes) • Acanthosis nigricans (brown-black skin pigmentations) • Schizophrenia

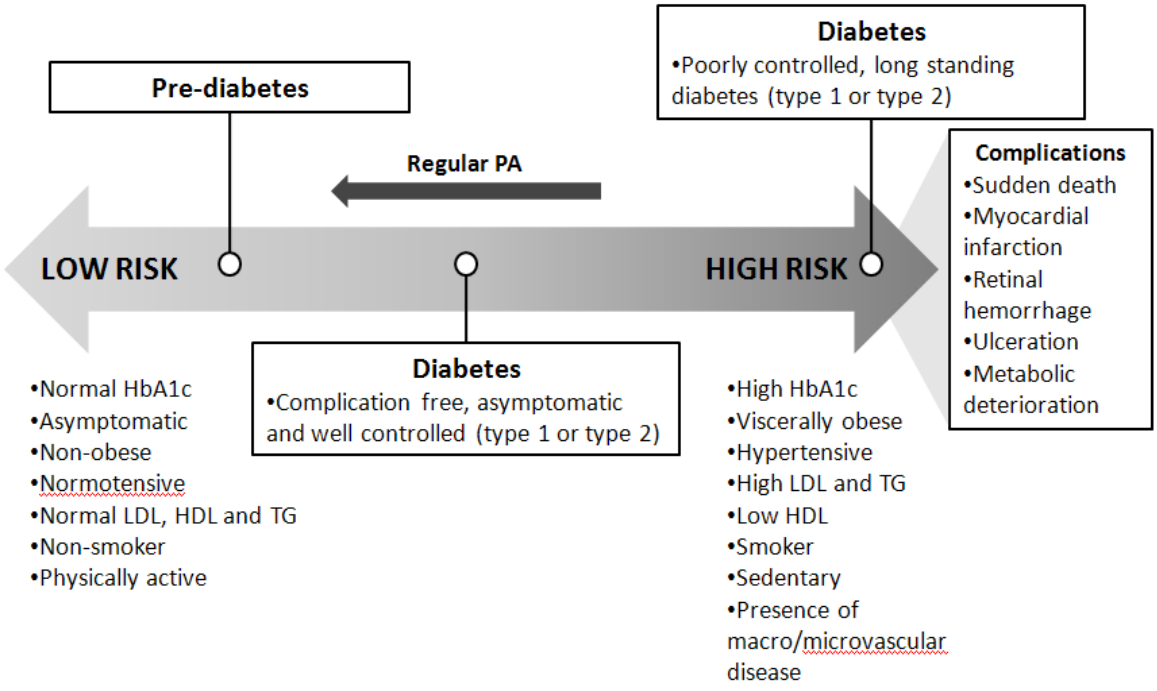
administering these tests with proper training and delegation.

Physical Activity Considerations

Risks with PA/ exercise participation:

One important consideration when implementing any PA intervention for the general population, particularly for those who may be at risk for diabetes, is exercise safety. The research evidence pertaining to the likelihood of a person with diabetes experiencing an adverse cardiac event associated with an acute bout of exercise or with increased PA is equivocal. Two recent reviews on the topic have found very little

Figure 2: Continuum of risk for the development of complications associated with diabetes



evidence for any PA related death and a low incidence of non life threatening adverse events with low to moderate intensity exercise[44,122]. In fact, evidence supports the idea that more exercise means less mortality and morbidity with diabetes[45,122] However, it is critical to note that nearly all of the randomized controls trails (RCTs) published that have had pre-diabetic or diabetic subjects exercising had rigorous pre-screening protocols in place that precluded exercise participation if serious co-morbidities were present (i.e. those with complications from diabetes or other co-morbidities such as CVD were not included in the RCTs on lifestyle intervention). Figure 2 depicts the continuum of risk for the development of metabolic complications and shows how PA participation can mediate the risk[122]. Some

cross sectional evidence supports the notion that vigorous intensity PA including physical labour increases the risk for myocardial infarction dramatically in persons with diabetes (increases relative risk up to 19 fold). However, low to moderate intensity PA should be considered safe for persons who are at elevated risk for CVD (including people with diabetes / prediabetes) [44,122].

Prevention of adverse events should be the first priority when beginning a PA intervention, especially for someone who has confirmed prediabetes or diabetes. It is imperative to make certain that the QEPs,

Table 1: Absolute and relative contraindications to PA for persons with prediabetes and/or T2D

Absolute contraindications	Relative Contraindications
• Recent and significant change in resting ECG that has not been adequately investigated and managed	• Fasting blood glucose > 300 mg/dl or > 250 mg/dl with urinary ketone bodies
• Unstable angina pectoris	• Uncontrolled hypertension with resting systolic blood pressure > 200 mmHg or diastolic > 110 mmHg
• Uncontrolled cardiac arrhythmias causing symptoms or hemodynamic compromise	• Severe autonomic neuropathy with exertional hypertension
• Uncontrolled symptomatic heart failure	• Moderate stenotic valvular heart disease
• Severe symptomatic aortic stenosis	
• Suspected or known dissecting aneurism	• Hypertrophic cardiomyopathy and other forms of outflow tract obstruction
• Acute myocarditis or pericarditis	• Tachyarrhythmias and bradyarrythmias
• Acute thrombophlebitis or intracardiac thrombi	• High-degree AV block
• Acute pulmonary embolus or pulmonary infarction	• Ventricular aneurism
• Untreated high-risk proliferative retinopathy	• Electrolyte abnotmalities (hypokalemia, hypomagnesemia)
• Recent significant retinal hemorrhage	• Uncontrolled metabolic disease (etoxicosis, myxedemia)
• Acute or inadequately controlled renal failure	• Chronic infectious disease (hepatitis, HIV)
• Acute infections	• Neuromuscular, musculoskeletal or rheumatoid disorders that are all exacerbated by exercise
	• Complicated pregnancy

community non-health traditional care workers and allied health professionals are versed in the absolute and relative contraindications to exercise (Table 2) as well as proper pre-screening procedures. The recently released PAR-Q+ and ePARmed-X+ [89] will greatly improve the capabilities of QEPs to minimize potential adverse events in pre-diabetic and diabetic populations.

PA recommendations for persons with pre-diabetes:

All individuals with pre-diabetes should be assessed for other risk factors for CVD through the use of the PAR-Q+ and ePARmed-X+ before commencing a PA regimen. Persons with no additional risk factors or symptoms of CVD require *"no further screening prior to the initiation of a PA program that consists of low to moderate intensity PA. In general, persons considered to be low risk for an adverse cardiac event can exercise at moderate intensities with minimal supervision while persons at intermediate risk should seek PA guidance from a QEP. Persons at high risk for a cardiac adverse event, such as an individual with poorly controlled diabetes and other risk factors, should undergo medically supervised screening and a graded exercise test prior to involvement in a PA program and should be supervised by a QEP throughout their PA regimen"* [123]. *Hig*her intensity PA should initially be avoided by previously inactive

Table 2: Relative intensities for aerobic exercise prescription for activities lasting 30 to 60min (Adapted from Warburton et al. 2006[99])

	Intensity	%HRR	%HRmax	RPE	METs	MET min/week	Breathing Rate	Body Temperature	Example Activity
	Sedentary	<20	<50	<10	<3	< 450*	Normal	Normal	Sitting watching TV, working on the computer
Range Required for Health	Light Effort	20-39	50-63	10-11	3 - 4	450 - 600	Slight Increase	Start to Feel Warm	Dusting, Light Gardening
	Moderate Effort	40-59	64-76	12-13	5 - 6	750 - 900 **	Greater Increase	Warmer	Brisk Walking
	Vigorous Effort	60-84	77-93	14-16	7 - 10	1050 - 1500 ***	More out of Breath	Quite Warm	Jogging
	Very Hard Effort	>84	>93	17-19	> 10	> 1500	Greater Increase	Hot	Running Fast
	Maximal Effort	100	100	20			Completely out of Breath	Very Hot/ Perspiring Heavily	Sprinting All-Out

*3 METs x 30 min x 5 days = 450 MET min/week
** 6 METs x 30 min x 5 days = 900 MET min/week
*** 10 METs x 30 min x 5 days = 1500 MET min/week

%HHR = % heart rate reserve; %HRmax = % maximum heart rate; RPE= rating of perceived exertion; MET = metabolic unit relative to resting metabolism

middle aged or older adults[122]. Based on a limited number of large-scale RCTs, persons with pre-diabetes should be encouraged to accumulate approx. 150 minutes weekly of low to moderate intensity PA (See Table 3) to lower their risk of developing diabetes [3,63,99,122]. The effectiveness of more vigorous aerobic

exercise or of resistance training is unknown but in general, naïve exercisers should start with low to moderate intensity PA with gradual progression to more vigorous intensity PA to improve health.

Summary

As pre-diabetes prevalence continues to grow in Canada, so too must the number of targeted prevention strategies aimed at helping people improve their lifestyle through the inclusion of regular PA. Access to allied health professionals is typically limited to brief appointments with primary care physicians or nurse practitioners who often have inadequate education pertaining to specific PA recommendations for persons at high risk for developing a chronic disease. Detection of pre-diabetes is the first step towards prevention and by advancing the role of QEPs and other non-health related community workers, capacity to provide screening opportunities and PA interventions at the community level would be enhanced. As research into pre-diabetes and PA continues to develop, fundamental understanding of this metabolic condition and how PA can attenuate further progression towards T2D will improve. Through this enhanced body of literature, PA programming that is tailored to specific target populations, cultural or otherwise, will increase the likelihood of successful community based interventions utilizing QEPs as front-line workers.