Health Coaching Patients with Type 2 Diabetes with and without Smartphone Support in a Lower Socioeconomic Strata Community

Noah M.A. Wayne

A DISSERTATION SUBMITTED TO THE FACULTY OF GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

GRADUATE PROGRAM IN KINESIOLOGY AND HEALTH SCIENCE
YORK UNIVERSITY
TORONTO, ONTARIO

NOVEMBER 2015

ABSTRACT

Background: Although the adoption of self-management behaviors is crucial for maintaining good health after a type 2 diabetes diagnosis, many individuals with T2DM fail to meet target blood glucose levels. Adherence to gluco-regulating behaviors like regular exercise and balanced diet can be challenging, especially for individuals of lower socioeconomic status (SES). Providing cost effective interventions that improve adherence to self-management behaviours is important for improving quality of life for patients and the sustainability of health care systems.

Objective: To design and test a health coaching protocol administered by trained health coaches in a lower SES community aimed at improving the health profile of patients with poorly controlled T2DM, with and without smartphone connectivity.

Methods: Dissertation methodology is described in two studies. The first study describes the pilot trial run at the Black Creek Community Health Centre (BCCHC) between February 2010 and March 2011which recruited a total of n=21 participants intervened with by n=1 health coach. The second study describes the randomized controlled trial conducted primarily at BCCHC from March 2012 to March 2014 and intervened with n=131 participants with n=6 health coaches. The primary outcome is change in glycated hemoglobin (HbA1c) from baseline to 6-month follow-up for each study. Secondary outcomes include changes in weight, waist circumference, and BMI, as well as within group changes of HbA1c. Psychometric measures collected pre/post for the RCT include the Satisfaction with Life Scale, Positive and Negative Affect Schedule, Hospital Anxiety and Depression Scale, and the 12-item Short Form Health Survey (SF-12v2).

Hypothesis: Patients who receive health coaching with electronic support will exhibit greater reductions in HbA1c than the health coach only group. There will also be greater improvements

in anthropometric and psychometric outcomes favouring the group who receives electronic support.

Results: In the pilot study, a total of 21 individuals consented to participate, of whom 19 (90.4%) completed the 6 month trial; 12 had baseline glycated hemoglobin (HbA1c) levels >7.0% and these participants demonstrated a mean reduction of 0.43 (0.63) ($p<.05$) with minimal changes in medication. In the RCT, a total of 131 patients were randomized, with n=67 and n=64 in the intervention and control groups, respectively. Primary outcome data were available for n=97 participants (74%). While both groups reduced their HbA1c, there were no significant between-group differences in change of HbA1c at 6 months using intention to treat (LOCF) ($p=.481$) or per protocol ($p=.825$) principles. However, the intervention group demonstrated an accelerated reduction in HbA1c, leading to a significant between groups difference at 3 months ($p=.032$). This difference was reduced at the 6 month follow up as the control group continued to improve, achieving an HbA1c reduction of 0.81% (8.9 mmol/mol) ($p=.001$) compared with a reduction of 0.84% (9.2 mmol/mol)($p=.001$) in the intervention group. Intervention group participants also had significant decreases in weight ($p=.006$) and waist circumference ($p=.011$) while controls did not. Both groups reported improvements in mood, satisfaction with life and quality of life.

Discussion: Health coaching with and without access to mobile technology appeared to improve gluco-regulation and mental health in a lower SES, T2DM population. The accelerated improvement in the smartphone group suggests the connectivity provided may more quickly improve adoption and adherence to health behaviors within a clinical diabetes management program. Overall, health coaching in primary care appears to deliver significant benefits for patients from lower SES with poorly controlled type 2 diabetes.

DEDICATION

To my wife, Manesha, who continues to inspire me with her endless capacity for compassion and love.

ACKNOWLEDGEMENTS

First, I would like to express my gratitude to my graduate supervisor, Dr. Paul Ritvo, for his mentorship, creativity, and patience. His guidance helped me stay balanced through the challenges and during the times of writing. I cannot imagine having a better mentor as a graduate supervisor.

This work could not have been possible without the trust and support of the patients and staff at the Black Creek Community Health Centre. They opened their space and their hearts to our team, and made my time conducting the research incredibly rewarding.

I cannot thank enough the amazing team of health coaches and the hundreds of volunteer kinesiology students who believed in our vision and worked tirelessly to make it a reality.

And finally, thank you to my family and friends who provided so much spiritual and emotional support.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

ANOVA – analysis of variance
APPS – mobile applications
BCCHC – Black Creek Community Health Centre
BMI – body mass index
CSEP – Canadian Society for Exercise Physiology
CWP/CHWP – Connected Wellness Platform/Connected Health and Wellness Platform
DCCT – Diabetes Control and Complications Trial Units
ECG - electrocardiogram
EEG – electroencephalography
EEP – Exercise Education Program
GAD – generalized anxiety disorder
GPS – global positions system
HADS – Hospital Anxiety and Depression Scale
HC – health coach
HbA1C – glycated hemoglobin/hemoglobin A1c
HRQOL – health-related quality of life
IFCC – International Federation of Clinical Chemistry Units
LOCF – last observation carried forward
NA – negative affect
PA – positive affect
PANAS – Positive and Negative Affect Schedule
PTSD – Post Traumatic Stress Disorder
RCT – randomized controlled trial
ROI – return on investment
SES – socioeconomic status
SF-12 - Short Form Health Study-12 (Version 2)
SMS – Short Message Service
SWLS – Satisfaction with Life Scale
T2DM – type 2 diabetes mellitus

CHAPTER 1: INTRODUCTION

1.1 OVERVIEW OF DISSERTATION

The sustainability of Canada's health system depends on the management and prevention of chronic diseases including Coronary Artery Disease (CAD) and Type 2 Diabetes Mellitus (T2DM). Diabetes is particularly important because current and future estimated prevalence rates coupled with the predictive relationships between T2DM with CAD [1], cancer [2] and other severe illnesses suggest significant strain on healthcare system resources [3], while continued improper management of the condition will lead to accelerating costs that could overwhelm the system [4].

This dissertation describes my recent efforts to develop and study a novel, evidence-based health coaching intervention coupled with a mobile health software application for improving the overall health of individuals with T2DM. In the first section, I describe the prevalence, pathophysiology, comorbidities, and complications of T2DM to illustrate the severity of the problem and the need and opportunity for behavioural interventions such as ours. The next chapter encapsulates the pilot trial run at the Black Creek Community Health Centre (BCCHC) between February 2010 and March 2011 (Chapter 2). Pilot study results with 21 participants and 1 health coach lead to grant funding from the Public Health Agency of Canada (PHAC) ($175,000) and the Federal Development Agency of Southern Ontario (FedDev) ($100,000), which provided funding for the randomized controlled trial (RCT). The RCT (Chapter 3) was conducted primarily out of BCCHC from March 2012 to March 2014 and intervened with 131 participants with 6 health coaches. The dissertation concludes with a summary of findings and recommendations for further research.

1.2 TYPE 2 DIABETES MELLITUS

1.2.1 Prevalence

The concern surrounding T2DM is due mainly to escalating rates and the risk of dangerous and costly complications, as well as worsening quality of life when the condition is poorly managed. While best practices for management of this disease are well known, medical interventions are only effective when supported by permanent lifestyle changes in diet, physical activity, and medication adherence. In Ontario, latest estimates (2012) indicate approximately 1,100,696 Ontarians (10.2%) of the population have diabetes, compared with 8.4% Ontarians in 2008, representing a 28.3% increase in prevalence, or an additional 242,886 diagnosed individuals [5] while Canada as a whole has 2.8 million diabetics [6]. In the United States, it was estimated 26 million individuals had T2DM in 2010, while 79 million had pre-diabetes, leading researchers to estimate that without intervention, rates will reach 1 in 3 persons by 2050 [7]. Although diabetes has been a condition typically afflicting developed nations, evidence now suggests the majority of individuals with diabetes (80%) live in low- and middle-income countries [8]. To put this into perspective, estimates in 2013 suggested that diagnosed diabetics in the US numbered between 24.4-29.1 million [8,9], dwarfed by China with 98.4 million and India with 65.1 million [8] indicating the international impact of diabetes as well as its impact in North America.

1.2.2 Economic Impact

In 2014, the Ontario budget for the Ministry of Health and Long Term Care (MHLTC) was $48.7 billion, equal to approximately 40% of the province's gross budget [10]. Accounting for both direct medical costs (emergency room visits, doctor's appointments) and indirect costs (loss of income from missed work), diabetes cost the public system $4.9 billion in 2009, a cost

predicted to increase to $7.0 billion by 2020 [3]. Coupled with demographic shifts towards an older population, the increasing costs of diabetes treatment relative to overall health expenditures is significant in an already resource-stretched health care system. As expenses increase, without simultaneous increases in funding, there must be a redirection of funds from the management, treatment, and service provisions for other conditions. From a cost perspective, conditions like T2DM where changes in individual behaviour directly lead to improved patient outcomes can provide the greatest return on investment (ROI) from behavioural intervention. Unlike medication-based interventions, individuals who successfully modify behaviour can conceivably maintain long-term adherence, deriving multiple years or lifelong benefits from a relatively brief intervention. The potential cost savings achievable was demonstrated by Nundy et al. [11] who assessed a smartphone-based, automated text messaging and counselling intervention with Type 2 Diabetes patients. In a quasi-experimental, two-group, pre-post design, intervention participants appeared to be 8.8% less costly during the 6-month intervention than during the 6 months preceding intervention engagement as measured by hospitalizations and visits to physician offices. These subjects also reduced their HbA1c by an average 0.7%, leading to other potential longitudinal savings not included in the analysis. Because all subjects were participants in the University of Chicago employee health plan, relevant health care cost data were accessible although all individuals were insured (in the US) and employed, and from mid-level socio-economic strata (SES) or above. This intervention was based on a standardized curriculum delivered to participants mostly through an online portal controlled by registered nurses who only spoke in person to participants when an exceptional situation was indicated by the participant. The quasi-experimental design also left this trial vulnerable to selection bias as all their intervention participants chose to receive the intervention and their control group either

refused or was unable to be contacted. As well, a factor leading to the health care costs reductions of the intervention group could have been because they had phone and text access to a registered nurse who was able to advise them on concerns which would have lead them to visit their family physician or the emergency room without that medical reassurance.

1.2.3 Social Determination

The healthy self-management of T2DM require behavioural changes, yet research on the promotion of such changes remains modest when compared with other chronic diseases, with few studies addressing individuals from lower socio-economic-strata (SES). Research involving individuals with T2DM at lower SES are particularly important because findings related to the social determinants of health suggest SES and educational status (a standard SES proxy) predict costly T2DM complications [12]. In Canada, data from the Canadian Health Community Survey (2005) suggest individuals from the lowest income group are 4.14 times more likely than the highest group to have T2DM [13], while less walkable neighbourhoods [14], where lower income individuals frequently reside [15], also increase risk for T2DM development and hamper management following diagnosis [16].

As Canada's population grows and new Canadians comprise an increasing proportion of the population, their health and health care utilization become increasingly important for long-term system sustainability. In the Study of Health Assessment and Risks in Ethnic Groups, it was found that significantly higher rates of type 2 diabetes were found amongst Indo-Asians compared with other Canadians [17]. Despite this predictable impact and the surges of interest in obesity and disease incidence, relatively little attention has been paid to urban, low SES, immigrant/minority groups. As an example from the United States, the US Federal agency charged with supporting research to improve health care quality and broaden access to essential

services (the Agency for Health Research Quality), conducted a MEDLINE review of research on diabetes in minorities in the US published from 1976-1994. In 290 articles, it was found that all US minorities, except Alaskan natives, had a prevalence of T2DM 2 to 6 times greater than that of the Caucasian population. Improving the lipid profile of African Americans with diabetes could help lower the prevalence of diabetes-related cardiovascular disease, and implementing interventions sensitive to cultural and population-specific characteristics could help reduce the prevalence/severity of diabetes and its resulting complications [18].

The lived experience of individuals from lower SES populations reflects the struggle and frustration experienced when managing T2DM with limited resources. Researchers from York University using semi-structured interviews and qualitative analysis spoke with 60 individuals living with diabetes in low SES communities in the City of Toronto [19]. Several themes that recurred across interviews cemented the importance of patient-centred care, especially as poverty is considered a risk factor for developing T2DM as patients have difficulties accessing resources to manage their condition.

Another important consideration in the development of T2DM is the exposure to psychological trauma and the presence of Post Traumatic Stress Disorder (PTSD). Some literature has demonstrated a connection between early childhood trauma as a predictor of elevated blood lipid profile in men from lower-SES community [20] and a dose response relationship with moderate to severe physical and sexual abuse in childhood or adolescence and the onset of T2DM in adult women [21]. Miller et al. [22] reported that in a lower SES, multiethnic community in New York that 24% of T2DM patients presented clinical or subclinical PTSD. The majority of participants (79%) reported at least one traumatic event and 24% reported early childhood abuse. As well, patients with PTSD had significantly greater

HbA1c levels compared to those without (7.3% vs. 6.9%, p=0.03). As these connections between victimization in early age [23] and as an adult [24] and T2DM has been well replicated, interventions aimed at seeking to enhance self-management of T2DM should incorporate trauma-informed service delivery into such protocols [25].

1.2.4 Pathophysiology of DM

Glucose is necessary for healthy physical and mental functioning. The ingestion of glucose signals release of the hormone insulin from pancreatic beta-cells and insulin binds to glut-4 receptors on muscle cells, opening the protein transporter bringing glucose into the cell. Glucose is metabolized by the mitochondria to produce Adenosine Triphosphate (ATP), which ultimately powers cellular function. Diabetes is characterized by poor regulation of this system and a reduced ability to metabolize sugars, typically referred to as glucose intolerance. Glucose intolerance often progresses as a function of two distinct physiological phenomenon: 1) insulin-producing pancreatic beta-cells decrease in number leading to less release of insulin into the body and available in the extracellular space; and 2) with fewer glut-4 receptors on muscle cells the efficiency of transporting glucose into the cells is also reduced, leading to a reduction in overall system efficiency [26]. While the exact aetiology of Type 1 Diabetes is unknown, it is believed to be predominantly an autoimmune disorder involving a swift and total destruction of pancreatic beta cells that necessitates supplementation (injection) of exogenous insulin as the main component of glucose regulation [27]. Type 2 Diabetes, in contrast, is a slow, progressive reduction of pancreatic beta cells exacerbated by decreasing insulin sensitivity (reductions in glut-4 receptor capacities). This gradual increase in glucose intolerance has a genetic component whereby individuals from certain ethno-cultural groups appear more prone to develop the condition [28]. Despite genetic influences, the most significant factor in the development of

glucose intolerance is behavioural – stemming from actions that produce chronically high serum glucose levels [27] suggests monitoring as an important step in glucose control.

When blood glucose levels are elevated, the pancreas responds by secreting insulin, prompting glucose uptake by various cells (skeletal muscle, liver, and adipose tissues) and a consequent drop in serum glucose. When serum glucose levels are chronically elevated, the pancreas begins down-regulating the number of beta cells, contributing to obesity [26]. When diet remains constantly high in sugar, without sufficient insulin (delivery *or* uptake) to facilitate the glucose transport into cells, serum glucose remains chronically elevated, leading to toxic effects, tissue damage, and eventual development of dangerous complications associated with diabetes.

1.2.5 Complications

Complications associated with poorly managed T2DM can be profoundly debilitating and include vision loss, neuropathy, cardiovascular disease, limb amputation and death [27]. They result from the non-enzymatic attachment of glucose to body tissues (glycation) caused by chronic hyperglycemia [29]. Diabetes complications can for the most part be avoided by maintaining serum glucose levels approximating normal levels (i.e., less than 7.0mmol/L) [30], and HbA1c <6.0% [31]. Glucoregulation is evaluated using three types of tests: fasting plasma glucose, the oral glucose tolerance test, and glycated hemoglobin (HbA1c). HbA1c is especially useful as a direct measure of the glycation of hemoglobin and provides an excellent clinical indicator of gluco-regulation over a three-month period since red blood cells are renewed every three months. Although an HbA1c of less than 6.0% can be difficult to achieve with diagnosed T2DM, it is possible through medication adherence, regular exercise and a carbohydrate restricted diet [32].

Individuals with T2DM in comparison with healthy individuals are at a 1.5-2.5 greater risk at developing dementia [33]. The micro- and macro-vascular damage caused by chronic hyperglycemia increases the risk of developing complications by 4-15% for every 1% increase of HbA1c, while reducing HbA1c by 1% leads to a 21% reduction in risk of death from diabetes [31].

1.2.6 Comorbidities

Behavioural and psychological factors are heavily implicated in T2DM management. In a meta-analysis, Anderson et al. (2001) found approximately 20% of people living with diabetes experience depression, about double the depression rate in the general population [34]. It is possible that depression plays a causal role in T2DM to some degree, particularly as depression commonly predates T2DM onset [35,36]. Prospective studies have shown that depression (in those with no prior diabetes history) increased the likelihood of developing T2DM two-fold [37], while a recent meta-analysis determined depressed individuals are at a 41% increased risk of developing T1DM, and a 32% increased risk of developing T2DM, although the underlying causal mechanism remains unclear [38].

Depression, anxiety, phobias and other psychological problems may also intensify the disease [39]. By definition, T2DM implies insulin resistance (i.e., cells unable to use endogenous insulin), resulting from chronic energy imbalances (i.e., too much energy intake and/or too little expenditure of energy) at least partly remediable and preventable by behaviour changes related to exercise and diet. However, these key changes are not often undertaken with sufficient consistency and intensity. This may be partly explained by the tendency of individuals to avoid hypoglycemic states that lead to symptoms like confusion/disorientation, shaking/trembling,

anxiety and even loss of consciousness [40], as well as the well-established difficulty of changing habits and making permanent lifestyle changes when will power is challenged [41].

Even mild hypoglycemic episodes are often unpleasant and occur about 1-2 times per week on average per diagnosed diabetic [40]. Although not associated with enduring negative effects, they can be alarming, and contribute to significant and immediate cognitive impairments [42]. Excess fears of hypoglycemia motivate a protective maintenance of higher blood glucose concentrations [43] which is a barrier to optimal glycemic control [40]. Individuals who maintain excessively high glucose concentrations are likely to develop significant microvascular and macrovascular complications [44]. At the other extreme are individuals who fear serious medical complications and consequently try to maintain lower mean blood glucose levels to minimize long-term risks. If blood glucose levels are managed too aggressively, some individuals risk severe hypoglycemic episodes [45].

Because of endocrine dysfunction, individuals with prolonged chronic hyperglycemia and poorly managed T2DM are often required to self-administer exogenous insulin through intra-muscular injections. Consequently, clinical and sub-clinical blood-injection phobias can motivate avoidance and inconsistent pharmacological self-management [39]. The prevalence of specific phobias is estimated at 20% across diabetes subtypes, although the prevalence of specific blood-related phobias is unclear. Yet, results of cross-sectional studies have shown that fears of blood and injury (assessed by self-report instruments) are inversely associated with the frequency of blood glucose monitoring and glycemic control [46,47] and are associated with an increased likelihood of such individuals developing macrovascular complications [46].

Finally, the excessive worry characteristic of Generalized Anxiety Disorder (GAD) also co-occurs in individuals with diabetes with notable frequency. The prevalence of GAD in T1DM

and T2DM patients was estimated at 14% [48], about 2.5 to 3 times greater than the 4-5% prevalence in the general population of the United States [49]. Although there appears a significantly higher GAD (co-morbid) prevalence in individuals with diabetes, its effect on diabetes self-management behaviours is not entirely clear. Further research investigating this subpopulation is warranted.

1.3 HEALTH MANAGEMENT BEHAVIOURS

1.3.1 Exercise

Regular exercise has been shown to be effective for both prevention [50,51] and successful T2DM management [52,53]. According to the Canadian Diabetes Association's (CDA) Clinical Practice Guidelines [30], individuals with T2DM should accumulate at least 150 minutes of moderate intensity aerobic exercise over a 1 week period, and engage in resistance training for at least 20 minutes, 3 days per week [30]. Chronic sedentariness is strongly associated with increasing insulin resistance and glucose disregulation [54]. From a behaviour-change perspective, an individual who has been mostly sedentary over years or a lifetime prior to diagnosis will likely have great difficulty making the changes necessary to meet the CDA guidelines post-diagnosis [55] due to reasons such as low motivation, low self-efficacy, discomfort, and lack of an understanding of exercise initiation.

The effects of physical activity on glucose regulation have been demonstrated in studies illustrating acute, post-exercise decreases in serum glucose levels as well as chronic increases in insulin sensitivity and action [56]. A comprehensive RCT by Sigal et al. [52] involved an intervention with 251 T2DM patients, employing a structured 22-week group exercise protocol, with assessments of the individual and combined effects of aerobic and resistance training in glucose regulation while maintaining stable pharmaceutical and diet regimens. Researchers found a 0.51% decrease in HbA1c in the aerobic only group (3 exercise-days per week), and a

0.31% decrease in the resistance only group when compared with the control group. Combined aerobic and resistance training demonstrated an additional decrease in HbA1c of 0.46%, 95% CI [0.09,0.83%] when compared to the aerobic only group and an additional decrease of 0.59%, 95% CI [0.23, 0.95%] when compared with the resistance only group [52]. The findings of beneficial effects of combined resistance and aerobic training for patients with T2DM have since been replicated [53] and continue to be explored.

Regular physical activity is essential for sustained health, with the potential to significantly reduce morbidity, mortality, and improve quality of life. Despite the well-studied benefits of regular physical activity in T2DM patients, there are few resources within Ontario's health care system dedicated to assisting T2DM patients meet the recommended exercise accumulation indicated by the CDA [57]. As well, despite overwhelming evidence demonstrating the protective effects of exercise, it is estimated that only 15% of Canadians meet national recommended guidelines of 150 minutes of aerobic exercise and 2-3 sessions of resistance training per week [58]. Typically exercise needs are addressed by nurses and dieticians on diabetes education teams, who are unable to provide exercise prescriptions, leading to a consensus amongst many health care providers, that qualified exercise specialists are needed on diabetes teams [57,59].

1.3.2 Diet

Due to the body's decreased ability to metabolize sugar, carbohydrate restricted diets are recommended to improve glucoregulation in patients with T2DM [60]. Carbohydrate restriction must be carefully regulated when patients are taking medications that effectively decrease serum glucose, as the combination elevates risks of hypoglycemic episodes. Current literature and many practicing dieticians suggest the Mediterranean diet as a model diet for diabetic patients [61]. A

recent meta-analysis concluded that low carbohydrate, low glycemic-index, Mediterranean diets were effective at reducing HbA1c in T2DM patients [62].

Dietary considerations are not limited to carbohydrate intake, especially if the client suffers from or is at risk for developing comorbid conditions such as cardiovascular disease and obesity. The consumption of lower levels of sodium and saturated fats, along with increasing fibre and micronutrients, is favourable for increasing overall health. This also means avoiding most processed foods, including fast food and sugary beverages, which have a strong relationship with T2DM development [63,64].

These dietary goals can be difficult to achieve; many patients with T2DM have spent many years routinely consuming high sugar-containing foods with low nutritional value, or are from ethnic backgrounds where traditional foods (particularly rice or other starchy staples) need to be limited to protect the client's health – an exceedingly difficult lifestyle change to make. It has been demonstrated that sugary beverages, high glycemic index foods, fat quality and eating patterns all increase the risk of developing T2DM [60].

1.3.3 Medication Adherence

Various medications target different aspects of T2DM pathophysiology in order to normalize serum glucose levels. Metformin is the first-line medication prescribed for T2DM in conjunction with lifestyle change, and is sometimes prescribed to patients with pre-diabetes [65] as a pre-emptive measure. Metformin is a bigaunide class drug, which prevents the liver from metabolizing glucagon and releasing it into the blood stream, as well as increasing insulin sensor sensitivity in cellular membranes [66]. Estimates on the effectiveness of metformin are mixed, with some studies claiming reduced risk of complications [67] while others indicate ineffectiveness [65].

Another frequently used medication class are sulfonylureas (e.g. glyburide), which stimulate pancreatic beta cells to produce more insulin [68]. While effective, this class of drug has an increased probability of causing hypoglycaemia if not properly balanced with diet and exercise [69]. It should also be noted that the hyper-stimulation of pancreatic beta cells achieved with sulfonylureas may further increase the rate of degradation of insulin producing beta cells, quickening the onset of exogenous insulin dependency. Other classes of common diabetic drugs include alpha-glucosidase inhibitors (e.g. Miglitol) which act in the small intestine to delay the absorption of post-prandial glucose and dipeptidyl peptidase-inhibitors (DPP-4) (e.g. Januvia) which slows inactivation of incretins that stimulate the pancreas to release insulin. The last of the common drugs used to help control serum glucose levels in T2DM patients is the insulin hormone itself. Injectable (exogenous) insulin is less a drug and more a supplement of the naturally occurring hormone responsible for the uptake of serum glucose by body tissue. As T2DM progresses and the pancreas loses its ability to produce insulin, even with the support of pharmacological agents, it becomes necessary to supplement with external sources of insulin.

Each of the various forms of insulin has precise guidelines that suggest optimal dosage times in relation to food intake. Typically, most diabetes drugs (including insulin) must be taken with a meal to properly interact with the glucose ingested. Deviations from the optimal dosing times decrease drug effectiveness and increase hypoglycaemia risks. Missed medication doses are common [70] and more common when patients suffer from depression [71]. The problem of missed doses typically assumes the patient has medications to use and either forgets or decides not to take it, but recent literature suggests that an astonishing 28.8% of all new diabetes prescriptions are never even filled [72].

The United Kingdom Prospective Diabetes Studies investigated an intensive glucose control therapy for newly diagnosed T2DM patients using sulphonylurea class drugs or insulin or metformin versus dietary restriction only found significant reductions in HbA1c for the intensive intervention group [73] which were persisted after a 10-year follow-up [74], reinforcing the importance of pharmacological therapy for the successful management of T2DM.

1.3.4 Stress Management

A significant indicator of quality of life in patients with T2DM is their ability to manage stress [48], as perceived stress is an important long-term predictor of T2DM progression [75,76] and the development of adipose tissue [77]. Cortisol, secreted by the adrenal gland under stress conditions has been demonstrated to interfere with insulin action [78], and work-related stress, in particular, has a demonstrated link with T2DM onset [76]. Living with diabetes, and trying to incorporate many of the lifestyle modifications that have evidential support, while balancing the responsibilities of everyday life like going to work and raising children can be overwhelming for many people [19]. Services provided by clinical psychologists can be expensive and are likely inaccessible for many people with T2DM; finding lower cost, more accessible strategies for stress management is preferable.

Mindfulness meditation is an ancient technique that has gained academic and clinical recognition for its scientifically supported health benefits which include decreased cortisol levels [79,80], increased grey matter density in the brain [81], reduction of negative automatic thoughts [82] and general stress reduction [83]. Mindfulness meditation is the practice of paying attention, on purpose while practicing non-avoidant cognitive-emotional processing and equanimity [84] and has been demonstrated to lower cortisol levels in T2DM patients and helps reduce HbA1c levels [83,85].

1.3.5 Symptom Monitoring

Optimal management of T2DM revolves around glucose control, with an ideal serum glucose range typically 4-7mmol/L, with fluctuations after meals [30]. Amidst the natural fluctuations in T2DM, the range typically depends on disease severity, diet, activity levels, stress and medication dosing. Patients can manually check their blood sugar by analyzing a fingertip blood sample with a portable glucometer, and this is preferably done several times per day. Although necessary, it can be painful, inconvenient, and expensive. Although glucometers are usually provided free of charge, a single-use test strip for each assessment is typically priced between $0.85-$1.00 CAD, which becomes problematic for poorer patients for whom an extra few dollars a day is significantly challenging or impossible.

While extreme blood sugar readings, such as < 4mmol/L and > 18mmol/L can have noticeable cognitive and physical consequences, many patients may not notice major sugar fluctuations until more severe symptoms set in. Nonetheless, it is important for good diabetes management that a patient check their blood glucose multiple times daily, preferably upon waking, pre-prandial, two hours postprandial, pre and post exercise, and before going to sleep [86]. Frequent checking has been shown to improve glycemic control [87], although the best improvements in management are found when monitoring is paired with education and clinical support [88].

In addition to checking serum glucose levels throughout the day, it is important for patients to have regularly scheduled lab blood tests to assess their overall glucose management. As previously mentioned, glycation is the process of glucose molecules attaching to body tissues, which cause micro and macro-vascular damage over time with T2DM [31]. The glycation of red blood cells (measured by HbA1c) is a measure of the damage to red blood cells over a period of

2-3 months and has been shown to be strongly correlated with serum glucose management and the onset of diabetes complications [31,89]. Alarmingly, a recent investigation found >50% of Canadians with T2DM do not have their HbA1c tested at least once a year [90].

1.4 HEALTH COACHING

1.4.1 Previous Literature

The evidence in support of the importance of healthy lifestyles for chronic disease prevention and management illustrates the need for behaviourally-focused interventions, as health education alone is apparently insufficient [91]. Health coaching (HC) has gained momentum in the literature as a potentially effective means of supporting clients to adopt and adhere to health related goals relevant to improving outcomes from a variety of chronic disease states [92]. Health coaches specialize in behaviour change methods that assist clients to adopt healthy behaviours, overcome resistance and resolve ambivalence to achieve optimum health. A recent meta-analysis found the number of peer reviewed articles investigating health coaching has increased from only 22 articles published before 2003, to 152 articles published between 2010 and 2012 [93].

While a recent feasibility study suggests that providers and patients at Family Health Teams and Community Health Centres in Ontario would welcome health coaching as an added service for their patients [94], health coach program delivery focusing on T2DM management varies significantly across the literature, with intensity of health coach interaction, professional credentials of health coaches, and behaviour change-specific training health coaches receive all approached differently across studies. In this context, intensity refers to the frequency and duration of each session/interaction. In theory, the intensity of health coach interactions should have a linear relationship with outcomes, as continued support will help manage relapse and

adherence. However, titration of intensity to find the optimal levels is necessary since intensity is directly related to intervention cost, yet without adequate intensity, health-coaching interventions run the risk of being ineffective.

Health provider administered health coaching has been tested with a range of strategies and clinical diabetes outcomes. A recent cluster-RCT evaluated telephonic health coaching provided by general practitioner nurses in 59 general practices in Victoria, Australia focused on poorly managed T2DM patients [95]. Based on two days of training from a general practice nurse, health coaches delivered a median of four coaching sessions/participant over 18 months, averaging 30 min/session and focused primarily on increasing medication adherence, lifestyle modification and symptom monitoring [96]. Results showed no significant differences between intervention and usual care control group in the assessed outcome variables (HbA1c, lipid profile, weight, Diabetes Self-Efficacy Scale, Assessment of Quality of Life Instrument, and the Patient Health Questionnaire-9) [95].

Another trial conducted by general practice nurses investigated the effect of five sessions of telephone coaching over a 6-month period to a control group in poorly controlled, low SES, T2DM patents (n=201). The control group received a 20-page educational brochure at study initiation. No significant differences were found in outcome variables (HbA1c, lipid profile) between intervention and control groups, and the investigators concluded a more intensive intervention was required [97]. In another trial with a telephone based coaching protocol, participants received up to 10 calls (4- to 6-week intervals) over a 1-year intervention with nurses as the health coaches and were compared with a print-only group who received regular mailings of diabetes health promotion materials. While both groups received the printed materials, only the health coach group was prompted to use them. While an effect was observed

suggesting that the receipt of more calls led to greater gluco-regulation improvements, intervention group participants had a mean HBA1c reduction of 0.23±0.11% while the active control group slightly increased by 0.13±0.13%(p=.04) [98]. Nashita et al. [99] intervened with a group of T2DM patients (HbA1c ≥ 6.5%; employed at least 10 hours per week) by pairing them with a 'life coach' and pharmacist who supported adherence to self-determined goals. Coach and participants met an average of 10 sessions for 60 minutes/session over the intervention period (12 months), and pharmacists met with participants a mean of 4 times over the intervention period for about 45 minutes per session. Coaches received training in the International Coach Federation core competencies, and on diabetes self-management strategies from a registered nurse. In total, coaches received 65 hours of training based on the International Coaching Federation core competencies including rapport building, active listening and goal setting [100], prior to seeing participants. Coaches received continuing training by meeting with a certified life coach periodically throughout the intervention. The comparison group was a care as usual control group. No between-group differences were detected for HbA1c (p=.24) (and no change within groups), although between-group differences were detected for diabetes self-efficacy (p=.002), BMI (p=.004) and quality of life (p=.01) [99].

Ruggiero et al. [101] conducted a large RCT (n=270) targeting patients from visible minority/lower SES communities with T2DM (HbA1c ≥ 6.5%). In this trial, medical assistant coaches provided face-to-face (30min) and phone calls interactions (15min) over 6-months compared with a care as usual control group. In-person coaching sessions occurred twice, once at study commencement, and the second at three months, following their physician appointment. Telephone sessions were done during months 1 - 5 between in-person session visits, and when patients missed their appointments. Investigators found no significant differences between

groups over 12 months. Medical assistant coaches received training from the study PI and/or project manager on topics ranging from diabetes self-management, epidemiology, risk factors, complications and medications, behavioral counselling strategies based on the trans-theoretical model of behaviour change, motivational interviewing and a structured coaching protocol. Results indicated no differences in HbA1c between or within groups from baseline to 6 or 12-month follow-up [101].

Varney et al. [102] conducted another 12-month health coaching RCT (n=94) with registered dieticians as health coaches and patients from an outpatient Diabetes Clinic at St. Vincent's Hospital, Melbourne. Intervention participants received 6 telephone coaching sessions (45 minutes for the initial session, 20 minutes each follow-up session) that focused mainly on diet, and also discussed appropriate physical activity, medication adherence, foot screening, etc., while the control group received care as usual. The type and duration of counselling specific training was not included in study methods. Results indicated a difference in reduction of HbA1c, fasting glucose and diastolic blood pressure between groups at 6-months, but these changes disappeared by 12-months. Within-group changes were not presented. Overall, the study authors suggest that telephone coaching can be effective at maintaining adherence to health behaviours for patients attending outpatients diabetes care, but new strategies must be developed to ensure long-term adherence [102].

The largest coaching and lifestyle modification intervention investigating lifestyle modification for the prevention of T2DM was the Diabetes Prevention Program [103]. In this trial, 3234 non-diabetic patients with elevated fasting and post load (IGTT) glucose levels were randomized to either metformin (850 mg twice daily) and an intensive lifestyle modification program supervised by a case manager, or usual lifestyle recommendations with placebo tablets

ingested twice daily. Participants in the intensive lifestyle intervention arm met with a case manager on a one-on-one basis and received a 16-lesson curriculum during the first 24 weeks of the trial covering diet, exercise and behaviour change focused on achieving participant goals. The curriculum was delivered in a personalized and culturally sensitive manner. After the initial 16 session after enrolment, participants met with case managers via monthly in-group sessions which acted as reinforcement for the behaviour change curriculum [104]. Participants aimed to achieve a 7% reduction in baseline body weight by accumulating the recommended 150 minutes of physical activity per week, and by maintaining a healthy, low calorie, low fat diet. Results indicated that 50% of the lifestyle modification group was able to achieve the 7% body weight reduction. Incidence of T2DM was reduced by 58%, 95% CI [48, 66%] and 31%, 95% CI [17, 43%] in the life-style intervention and metformin groups respectively, compared with control. Comparing the two intervention groups, the life-style intervention group resulted in a 39% lower incidence of T2DM than the metformin group, 95% CI [24, 51%] [103].

Trials that report more successful outcomes for diabetic patients usually employ a more intensive health coach protocol. In a cluster RCT, Quinn et al. [105] compared four intensity levels of health coach based support using an internet-based communication tool and found significant reductions in HbA1c when comparing usual care with the most intense intervention level ($p<0.001$). This system relied primarily on automatically generated messages, prompted by patient entries (e.g., self-assessed blood glucose) and excluded any individuals from lower SES [105]. Usual care was compared with three intensities of intervention including: (1) coaching only, (2) coaching with electronic support, and (3) coaching with electronic support and an automatic decision support system. Although telephone communication with their health coach was, on average, the same one contact per month, participants also received multiple automated

messages per day, which were customized by the health coach. This trial reported significant HbA1c reduction differences between the most intensive study arm versus the control group of 1.9%, with the coach-only arm still demonstrating quite impressive reductions in HbA1c of 1.6% [105]. This trial also demonstrated older patients were just as likely to benefit from and use the electronic system, reducing their HbA1c by 1.8%, 95% CI [1.1, 2.4] in the intervention group and 0.3%, 95% CI [-0.3, 0.9] in the control group [106] which contradicts a common perception that older adults will not adopt mHealth interventions [107]. Another secondary analysis from this trial suggests that the modification and intensification of antihyperglycemic medications was not significantly different for the mHealth group versus care as usual control group [108].

Another trial trained dental professionals as health coaches and intervened with T2DM patients in Istabul, Turkey [109]. Investigators reported 5-6 in-person coaching sessions, with 4 telephone sessions over a 10-month period, supplemented by meetings with dieticians and nurses at an undisclosed frequency. Results demonstrated a 0.6% reduction in HbA1c and no change for the care as usual health education control group at the 16-month follow-up, after a 6-month period following intervention termination [109].

Another group of researchers from the Faculty of Medicine in the University of Oslo, Norway recently tested the use of a mobile phone–based self-management system with and without telephone health coaching support in improving HbA1c level, self-management, and health related quality of life compared with usual care. Study participation was open to individuals with T2DM who had an HbA1c ≥7.1% and aged ≥18 years. Both intervention groups had access to a mobile phone–based self-management system called “Few Touch Application” which enabled users to track blood glucose, diet, physical activity, and personal goals. One intervention group received health coaching delivered by a diabetes specialist nurse for the first 4

months of the 12 month intervention [110]. Data at follow-up was available for 120 participants (79%) and indicated that there was no significant difference between HbA1c for control and either of the intervention groups (p=.57/.97). HbA1c reductions within groups were also non-significant with modest effect sizes ranging from -0.31%, 95% CI [–0.67, 0.05] for the app only group, -0.16%, 95% CI [-.58, 0.29] for app with health coaching, and -0.15%, 95% CI [-0.5, 0.18] for control participants [110].

Peer health coaching is another model of health coach intervention delivery that promises even lower costs due to the potentially reduced need for less professional intervention. A group from the University of California, San Francisco, Grorob et al. [111] tested the efficacy of training and employing peer health coaching with a lower SES T2DM population. After peer coaches received 36 hours of training over an eight-week period, their skills were examined, and they were provided $150 for attending and $25/month/patient coached over a six-month period. In this trial, coaches and patients interacted at least twice a month either in person or over the phone (at the discretion of the coach and patients) and were required to meet at least twice in person during the 6-month intervention. Results indicated a 1.0% drop in HbA1c in the coaching arm and a 0.3% drop in the care as usual control arm demonstrating a significant effect [112].

1.4.2 Defining Health Coaching

Academic and clinical communities have not yet reached final consensus on a formal definition of a health coach. Therefore, existing studies that claim to evaluate health coaching interventions use a variety of working definitions, although all follow a similar emphasis on behaviour change. For example, some researchers use the following definition:

> "Health coaching is the practice of health education and health promotion within a coaching context, to enhance the wellbeing of individuals and to facilitate the achievement of their health-related goals" [92,113].

Others define it this way:

> "…a behavioural health intervention that facilitates participants in establishing and attaining health-promoting goals in order to change lifestyle-related behaviours, with the intent of reducing health risks, improving self-management of chronic conditions and increasing health-related quality of life" [114,115]

Recently, the National Consortium for Credentialing Health and Wellness Coaches, a conglomeration of several researchers pursuing health coaching evaluation define health coaches as:

> "…professionals from diverse backgrounds and education who work with individuals and groups in a client-centered process to facilitate and empower the client to achieve self-determined goals related to health and wellness." [116].

As the research matures, and health coaching becomes more commonplace among medical and academic communities, the need of a universal, operational definition may decrease in relevance as the purpose and efficacy of different subtypes of health coaches become more understood. From our point of view, a health coach is defined as:

> "A behaviour-change counselling specialist with expertise in chronic disease management and evidence-based theory adapted for disease state, SES, and ethno-cultural backgrounds".

1.4.3 Health Coach Training and Credentialing

Another issue concerns the credentialing and educational background of the individual providing the health coaching services. This concern has two distinct components that must be considered: 1) the depth and duration of training in behaviour change theory and the supervised practice coaches receive; 2) their professional designation and/or liability insurance coverage. When engaging with a client in behaviour change counselling with a chronic health condition

like T2DM or CVD, there is a risk, however small, of the occurrence of an adverse event such as a heart attack, injury or even death. Professional designation and membership to a regulated college provides the health coach with the necessary protection and accountability to provide care while protecting the client.

In regards to the training, a recent literature review found that only 22% published health coach intervention studies discuss the training health coaches receive [93]. Training for health coaches is typically focused on Motivational Interviewing (42% of studies) and the trans-theoretical model of behaviour change (60.8% of studies), while the length of training varied widely among trials, ranging from just two hours to as much as two hundred hours [93].

Among trials that required professional designations for coaches, studies have employed individuals with a masters in psychology [117], certified medical assistants [118], registered nurses [95,96,119], physiotherapists [119], and peer health coaches [120]. Despite the spectrum of professional designation of the health coach, most literature discusses the core competencies of a health coach, suggesting the skills can be taught to any health care provider.

1.4.4 Health Coaching Skills

The health coach is a specialist in behaviour change, and the process of behaviour change can be approached using a variety of evidence-based techniques. Relying solely on a single technique runs the risk that the health coach becomes philosophically fixed in a behaviour change paradigm that does not serve the needs of a particular client, leading to tension in the therapeutic relationship. A broad set of methods can help coaches understand the complexities of health behaviour, and contextualize the client's behaviour in a more nuanced way. This can in turn help prevent coaches from viewing a failure to make desired changes as an indicator of a 'bad patient' and reduce provider frustration. For example, a 2005 study by Wens et al. asked

physicians about how they dealt with the typically poor adherence to prescribed treatments demonstrated by their patients with T2DM. The physicians described intense frustration with the lack of lifestyle changes made by their patients, which led to a paternalistic attitude towards patient communication, attempts to shock or pressure the patients into making changes, or to refer them to hospital care. The authors believed a lack of communication skills and training was a major factor hindering care in this situation [121]. Using an integrative health coaching model to provide holistic care, addressing multiple lifestyle, social, psychological and medical factors is one way to assist healthcare providers in bridging this communication gap with their patients.

The approach to health coaching that maximizes the probability of successful interaction must be open to any of the evidence-based techniques that demonstrate effective behaviour change outcomes. Within the health coach literature, groups typically commit to only one technique, with the most common evidence-based behaviour change technique being Motivational Interviewing (MI) [115,122]. MI involves strategies for engaging in conversation with clients to encourage ‘change talk’, overcoming resistance to behaviour change and developing strategies for sustainable positive behaviours [122]. For example, an important part of MI is ‘rolling with resistance’. This is the process of conversing about states of relapse and an individual’s resistance to changing important behaviours while not directly confronting the client, in an effort to reduce psychological reactance [123]. Occasionally, rolling with resistance can be problematic when it fails to generate change over a long period of time.

When a more direct approach is needed when working with a given client, Cognitive Behavioural Therapy (CBT) is a useful tool. Traditionally used to assist with problematic psychological states such as depression and anxiety, CBT has recently demonstrated efficacy in health behaviour change programs working with patients with poorly controlled T2DM [124]

and metabolic syndrome [125]. CBT is based on a theoretical model that connects a person's thoughts, emotions, and behaviours in an interconnected matrix. Using a CBT framework, coaches engage in a systematic approach to assist their client(s) become aware of these connections and adapt specific activities and strategies to change them [126]. Other tools within the health coach arsenal may include Acceptance Commitment Therapy (ACT), Interpersonal Therapy (IT) and Emotion Focused Therapy (EFT) [125]. All of these approaches can be effective at supporting the behaviour change process when the health coach is open to their use. Across all techniques, the most important commonality is that a strong therapeutic alliance with the client must be developed and sustained, nurturing a deep level of trust. Only once the therapeutic alliance has been established will the adaptation of whatever technique is most suited for that client be effective [127].

1.5 ELECTRONIC CONNECTIVITY

1.5.1 Mobile Technology

Mobile technology has permeated Western culture to a point of intense saturation with 27,863,660 Canadian cellular subscribers in 2014, accounting for ~80% of the population [128], indicating the vast majority of Canadians have access to instant communication in both mobile voice and text mediums. Smartphones with internet connectivity provide access to email, news, social media, cloud storage, search, and an expanding library of downloadable applications and multiple methods of real-time communication. Current estimates put smartphone market saturation at ~56% of Canadians [129].

In the context of health, a high number of mobile applications (apps) are available for download in the online market that enable users to track health and fitness indicators such as weight, exercise, sleep, diet, calories, steps, heart rate, and distance travelled. Compared with

paper and pen tracking methods, mobile health apps excel in immediacy and accuracy for real time self-reporting and tracking of health information [130].

1.5.2 Health Apps

Many health apps provide users sophisticated feedback and detailed information on exercise bouts. For example, Adidas MiCoach (http://micoach.adidas.com/ca/) uses the Global Positioning System (GPS) to track users while they walk/run/bike and to generate reports of average speed, distance, and pace. Apps with similar characteristics can also connect users to social networks and share health-related accomplishments with friends and family, using social support to help reinforce these healthy behaviours. The app Strava (http://www.strava.com/), for example, not only uses GPS to track users while they run or bike, but also compares one user's performance with others who have navigated the same stretch of road, adding a competitive ranking system that some users may find motivational, although no research in this area has been completed to date.

There are also apps that more intensively focus on diet, such as MyFitnessPal (www.myfitnesspal.com). MyFitnessPal is one of a cluster of apps that maintain a food information database that provides users who wish to keep track of the specific food they eat to know exactly how many micro-and-macronutrients they consume. This can be extremely valuable for users attempting to reach specific goals, such as losing weight or reducing sodium intake to better control hypertension. A recent RCT found that MyFitnessPal use demonstrated only modest reductions in weight, with no differences between controls (who were not encouraged to download the app) and intervention groups (who were specifically asked to download and use the app). While it was noted that some control participants did downloaded the MyFitnessPal app (13%), there were a significant loss of subjects at followup (32% of the intervention group was assessed while 19% of the control group) and although reported

satisfaction with the app was apparently high, use of the app decreased sharply after the first month of the trial [131]. In line with research into other app-based health interventions, without a real person (e.g. health coach) to support software use, outcomes reflect modest or no significant between-group or within-group differences [110].

1.5.3 Wearable Technology

A new area in mobile health that has been growing aggressively is the market for wearable technology. Connecting via Bluetooth, a wireless communication technology standard on nearly all mobile devices (www.bluetooth.com), external peripherals link seamlessly to phones with a fast, wireless connection. This has resulted in a wide variety of personal health monitoring devices developed with the specific intention of connecting with health tracking apps. Examples of popular Bluetooth health devices include pedometers and accelerometers (e.g. Fitbit, Jawbone Up), heart rate monitors (Polar, Garmin), and weight scales (Fitbit, Aria). The research validating these commercially available products is, however, in its infancy. Fitbit devices alone have been subject to investigative reports providing evidence of accuracy in counting steps [132], but an underestimation of energy expenditures and tenuous measurement of sleep quality [133]. The next generation of Bluetooth health technology that is still not widely distributed includes smart watches (Pebble, Apple iWatch, Samsung Gear), glucometers (OneTouch Verio), sleep trackers (Body Media, Fitbit), blood pressure cuffs (iHealth, Withings), pulse oximeters (iHealth), EEG recorders (Muse), ECG recorders (Alive Technologies, Texas Instruments) and smart shirts capable of a number of measurements (Om Signal Biometric Smartwear, Underarmour E39). These technologies have the potential to radically change how medicine is practiced by integrating continuous, non-burdensome medical evaluation outside the clinic and within the daily life-schedules of patients. The potential for a heart failure patient to have a 24-hour ECG lead transmitting heart rhythm in real time with a monitoring system that

can identify abnormalities before they become symptomatic, and warn the patient and contact emergency medical services is a real possibility. This type of device could simultaneously be able to communicate directly with medical practitioners and/or family members.

1.5.4 Clinical/Medical Integration

Despite the popularity and potential of health apps, the medical community has yet to embrace mobile technology in practice. These types of technologies are still mainly in the research phase of implementation, with new insights being published every month. The switch from research to clinical practice is imminent, as the latest findings suggest that when patients track health measures electronically and share the information with providers, the quality of their health care increases [134]. There have been concerns that some populations (namely older adults) may have difficulty using newer technology [135]. Although recent clinical trials indicate that the learning curve for initiating app use may be greater when compared to younger populations, there are no effects on outcomes that appear to be grossly mitigated by age [106].

Technology provides the health coach an immediate and cost effective way to maintain consistent interaction with clients, even when not in direct contact within the clinical environment [136]. In the literature, apps have been used to support behaviour change for individuals with chronic disease, and it has been discussed that although they can be a powerful facilitator of health behaviour, apps and wearable devices are not necessarily motivators behind sustained behaviour change [137]. The best combination may be some combination of personalized interaction by a health coach with the strategic use of smart phone applications.

1.6 CONCLUSION

The literature suggesting the importance of the regular engagement in positive health behaviours for individuals with T2DM illustrates a decisive need for behavior-focused interventions. This dissertation seeks to test the combination of health coaching with the use of a

web-portal that provides two-way communication and behaviour tracking/monitoring for poorly managing T2DM patients from a lower SES community. We first determined the feasibility of this research in a pilot trial where we assisted with the mobile-phone app development and created health-coaching protocol and applied both to patients at the Black Creek Community Health Centre (BCCHC). Then, in a larger RCT, we sought to compare health coaching with and without app connectivity in improving gluco-regulation and psychological well being among T2DM patients.

CHAPTER 2: MEASURES INCLUDED IN DISSERTATION

2.1 GLYCATED HEMAGLOBIN

The primary outcome variable for this dissertation is the change in glycated hemoglobin (HbA1c) from baseline to 6-months. Glycation is the process of the non-enzymatic attachment of glucose to body tissues as a result of chronic hyperglycemia [29]. HbA1c is a clinical tool that accurately represents overall glucose management in diabetic patients and is a strong predictor of diabetic complications [31]. While glucoregulation can be evaluated using three types of tests (fasting plasma glucose, the oral glucose tolerance test, and HbA1c), HbA1c especially useful as it provides an excellent clinical indicator of gluco-regulation over a three-month period since red blood cells are renewed every three months. HbA1c is often thought of as an 'average' blood glucose reading to patients and, although this is not technically correct, it does provide a summary measure. HbA1c is also used as a diagnostic tool for T2DM, where a value of 6.5% indicates sufficiently high glycation to warrant the diagnosis [30] (healthy range is 4.5%-5.7%). The clinical target for HbA1c with diagnosed patients is 7.0%, although lower values are preferred, and unfortunately many patients have HbA1c levels that range as high as 13%. Pharmacological and other clinical interventions typically aim for reductions of 0.5% HbA1c to be considered clinically relevant [138]. Although an HbA1c of less than 6.0% can be difficult to achieve with diagnosed T2DM, it is possible through medication adherence, regular exercise and a carbohydrate restricted diet [32].

2.2 ANTHROPOMETRIC ASSESSMENTS

Three measures of anthropometric or body composition associated with health-related fitness were collected and used as secondary outcomes. These measures include: body mass index (BMI), waist circumference (WC), and weight (kg). BMI was calculated using the

participant's weight and height (BMI=weight (kg)/height (m^2)). WC was measured using a tape measure according to guidelines identified by the Canadian Diabetes Association [30] (align bottom edge of tape with the top of the hip bone and wrap the tape all the way around the waist ensuring it remains parallel with the floor. Measurements were taken to the nearest 0.5 cm. T2DM is highly correlated with excess body weight and BMI in such that some literature suggests obesity playing a causal role in insulin resistance [139].

2.3 PSYCHOMETRIC ASSESSMENTS

2.3.1 Satisfaction with Life Scale

The **Satisfaction with Life Scale (SWLS)** (Appendix B1) is a five item self-report measure developed to assess an individual's global satisfaction with life as a cognitive judgement and has shown high internal consistency and temporal reliability [140]. Participants respond to questions such as: "In most ways my life is close to my ideal" and "So far I have gotten the important things I want in life". Each item is measured on the following seven-point Likert scale: (1) strongly disagree, (2) disagree, (3) slightly disagree, (4) neither agree or disagree, (5) slightly agree, (6) agree, (7) strongly agree. The seven items are summed to achieve a total score of 5-35 which are categorized into: scores from 5-9 indicating extreme dissatisfaction with life; 10-14 indicate dissatisfaction with life; scores from 15-19 show below average in life satisfaction; 20-24 indicates average satisfaction with life; 25-29 indicates high satisfaction with life; and scores from 30-35 represent extreme satisfaction with life.

2.3.2 Hospital Anxiety and Depression Scale

The **Hospital Anxiety and Depression Scale** (HADS) (Appendix B2) is a 14-item questionnaire designed to be easily administered (taking between 2-5 minutes to complete) and able to distinguish emotional or mood disorders that would have the most clinical relevance for treatment considerations, specifically anxiety and depression [141]. In an effort to capture the

most useful underlying experience of the depressive experience, authors used the state of anhedonia, which is the inability to experience a pleasurable response to a given situation. Participants were asked to respond to statements such as “I no longer get pleasure from the things I normally enjoy” and “I have lost interest in my appearance” as well as items framed positively, for example: “I feel cheerful” and “I can laugh and see the funny side of things”. Participants respond by underlining the response that most accurately reflects their feelings over the past week out of four options. Examples of possible responses are: (1) Definitely as much, (2) Not quite so much, (3) Only a little, (4) Hardly at all. Responses are scored between 0-21 for anxiety and 0-21 for depression. A score of 0-7 is considered with ‘normal’ range, a score higher than 11 indicating probable presence of the mood disorder, and a score of 8 to 10 being suggestive of the mood disorder.

2.3.3 Positive and Negative Affect Schedule

The **Positive and Negative Affect Schedule (PANAS)** (Appendix B3) is a 20-item scale with 10 positive and 10 negative descriptors developed to provide separate indicators of positive affect (PA) and negative affect (NA) [142]. PA is defined to the degree one experiences the activation of positive valenced affects or pleasurable interactions with the environment, while NA is an indication of the extent one experiences negative valenced effects or subjective distress and unpleasurable engagement [143]. Participants are asked to indicate how they were feeling at the current moment by providing a response next to words that corresponded to either PA (e.g. strong, confident, excited) or NA (e.g. incompetent, fearful, ashamed). Possible responses were: (1) very slightly or not at all, (2) a little, (3) moderately, (4) quite a bit, (5) extremely. Respondents are measured independently per subscale resulting in a separate score for PA and NA, with scores of each subscale ranging from 10-50. The internal consistency is high for both subscales, with Cronbach’s alpha ranging from .86 to .90 for PA, and from .84 to .87 for NA

[142,143]. NA and PA scales have shown to have a poor correlation (r = -0.12) [142], indicating that these subscales measure distinctive constructs and should not necessarily be considered to be inversely proportional to one another.

2.3.4 Short Form Health Survey-12 (Version 2)

The Short Form Health Survey-12 Version 2 (**SF-12v2)** (Appendix B4) is a widely used health related quality of life measure that is used to predict functioning level, health care utilization and health outcomes [144]. Mental and Physical Health composite scores of the SF-12v2 are calculated from twelve items, which were derived from the larger SF-12 and improved upon from the original SF-12 in 2002 [145]. Participants are asked if, and to what extent, aspects of their life have been interrupted by health issues. For example, participants are asked "In general, would you say your health is:" and "During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical/mental health?". Participants respond with either a three or five point Likert scale tailored to the question. The twelve items of the SF-12 are derived from a larger questionnaire, the SF-36, and has demonstrated excellent comparative validity [146,147]. The SF-12 has demonstrated excellent test-retest reliability in determining health status been used on a wide number of populations including HIV patients [148], older adults [149], trauma populations [146], and stroke victims [150] among others. As well, the SF-12 scoring algorithm utilizes norm based scoring, which compares the responses of any participant with that of a normative sample of the US population collected in 2009 (mean=50, SD=10) [145].

CHAPTER 3: STUDY #1 - SINGLE-ARM PILOT TRIAL

Title: Smartphone-Enabled Health Coach Intervention for People With Diabetes From a Modest Socioeconomic Strata Community: Single-Arm Longitudinal Feasibility Study

Wayne N & Ritvo P. (2014). Smartphone-enabled health coach intervention for people with diabetes from a modest socioeconomic strata community: single-arm longitudinal feasibility study. Journal of Medical Internet Research;16(6):e149. PMID: 24907918

3.1 RATIONALE FOR STUDY #1

3.1.1 Objectives

The intent of the study was to develop and test a smartphone-assisted intervention that improves behavioral management of type 2 diabetes in an ethnically diverse, lower SES population within an urban community health setting.

3.1.2 Hypotheses

Participants will be receptive to the health coaching with remote connectivity intervention, and will achieve significant clinical improvement in glucose management, as indicated by reductions in HbA1c of greater than 0.5% (6 mmol/mol).

3.2 ABSTRACT

Background: Lower socioeconomic strata (SES) populations have higher chronic disease risks. Smartphone-based interventions can support adoption of health behaviors that can, in turn, reduce the risks of type 2 diabetes-related complications, overcoming the obstacles that some patients may have with regular clinical contacts (eg, shiftwork, travel difficulties, miscommunication).

Objective: The intent of the study was to develop and test a smartphone-assisted intervention that improves behavioral management of type 2 diabetes in an ethnically diverse, lower SES population within an urban community health setting.

Methods: This single-arm pilot study assessed a smartphone application developed with investigator assistance and delivered by health coaches. Participants were recruited from the Black Creek Community Health Centre in Toronto, and had minimal prior experience with smartphones.

Results: A total of 21 subjects consented and 19 participants completed the 6 month trial; 12 had baseline glycosylated hemoglobin (HbA1c) levels >7.0% and these subjects demonstrated a

mean reduction of 0.43 (0.63) ($p<.05$) with minimal changes in medication.

Conclusions: This project supported the feasibility of smartphone-based health coaching for individuals from lower SES with minimal prior smartphone experience.

3.3 INTRODUCTION

3.3.1 Background

A consensus of medical professionals and academic researchers indicates that type 2 diabetes mellitus (T2DM) is a chronic condition that progresses to more debilitating complications if certain unhealthy behaviors persist [30]. Regular exercise conversely prevents deteriorating health and disease onset [151] and has measurable benefits for T2DM-diagnosed populations [53,152]. Because high carbohydrate diets increase risks for diabetes-related complications due to chronic hyperglycemia, dietary modification can also result in risk reductions [153]. The adoption of optimal health behaviors in those diagnosed with T2DM requires behavior change and support for diabetic individuals from lower socioeconomic strata (SES) is especially important as this population confronts additional challenges in maintaining good health [19]. Data from the Canadian Healthy Community Survey (2005) suggest individuals from the lowest income group are over 4 times more likely to have T2DM [13]. Furthermore, education and personal wealth variables, typically viewed as SES proxies, are the strongest predictors of premature death associated with T2DM [12]. Despite recent surges of interest in disease incidence related to SES, little attention has been paid to urban, low SES immigrant/minority groups. As our experience indicates, these individuals are often less willing to volunteer for research and are less reliable subjects after enrollment. This is mainly related to the competing demands they confront and the lack of flexibility in their working conditions.

Health coaches promote adoption and maintenance of health behaviors, using validated theoretical frameworks (eg, Motivational Interviewing [122] and Cognitive Behavioral Therapy [126]). Health coaches primarily focus on helping patients define and attain personal goals and discover intrinsic health-oriented motivations [154]. Recent trials involving health coaching in chronic disease demonstrate positive gains for patients such as increased exercise and medication adherence [117,154], improved psychological functioning [154], and more positive illness-coping strategies [154].

Mobile technologies complement health coaching by enabling patients and coaches to maintain multiple channels of contact via remote monitoring, voice, and text message communications. The use of mobile phones potentially provides unprecedented precision in supporting health-related behavior since it facilitates responses to immediate needs and serves to maintain communication consistency. Once an individual agrees on the intensity, frequency, and duration of contacts with the health coach, it is possible to detect non-adherence lapses quickly to the point where supportive-corrective responses can be provided while the non-adherent pattern is still unfolding. Reminder and reinforcement messages of different types can be sent to patients at any hour of day or evening, enabling interactions that purposefully blend with the patient's daily lifestyle.

Remote monitoring has been associated in numerous controlled studies with significant benefits in improving blood pressure and blood glucose regulation [155–158], exercise adherence [159], and dietary control [160,161]. Mobile technologies enable immediate and inexpensive communication with patients exemplified in the use of text messages (SMS) to boost medication adherence and decrease viral load in HIV-positive Kenyan populations [162], and to

deliver supportive SMS to patients at risk for developing type 2 diabetes [163], and have demonstrated results with a variety of other chronic medical conditions [164].

3.3.2 NexJ Connected Health and Wellness Platform (CHWP)

The Connected Health and Wellness Platform (CHWP) Health Coach app is designed to support multi-channel communications between clients and health coaches, and supportive family members. The app was collaboratively designed by software developers (NexJ Systems Inc.) and study investigators to support participants in electronically tracking health behaviors (eg, exercise, diet, stress reduction practices) and self-monitoring health data (eg, blood glucose, blood pressure, mood, pain, energy). Provider-client communications require two-way, certificate-based authentication and passwords stored in encrypted columns, with entered data recalled by client and health coach through a secure online portal.

3.4 METHODS

3.4.1 Study Design

This experimental pre/post, single-arm trial assessed a 24-week intervention where interactions in person, by phone, and by smartphone (eg, secure messaging, email) with a personal health coach supported adoption of and adherence to self-generated health-behavior change goals. The primary study outcome was glycosylated hemoglobin (HbA1c) assessed at baseline and 24 weeks (see Table 2). HbA1c is a clinical indicator of glucose regulation correlated with debilitating and costly diabetic complications. The clinical goal for self-management of diabetes is an HbA1c of 7.0% or less, although further reductions are preferred. Interventions that reduce HbA1c in elevated risk populations are of significant value in diabetes care.

3.4.2 Health Coaching Intervention

The health coach intervention was carried out by a graduate student trained in behavior change techniques. After obtaining informed consent and collecting demographic information and baseline lab reports, the participants and the health coach communicated about eating, physical activity patterns, and overall health goals. Wellness plans were collaboratively created in multiple interactions focused on exercise instruction and reviews of electronic monitoring entries, with diet and medication guidelines set by primary care physicians and dieticians.

3.4.3 Recruitment

Participants were recruited and consented at the Black Creek Community Health Centre in Toronto, Ontario, Canada. Recruitment was through health care provider referral and poster advertising. Eligible participants were patients over 18 years old, diagnosed with type 2 diabetes, and able to read and speak English. Participants were excluded if their baseline HbA1c was greater than 9.5%. All study procedures were approved by the York University Human Participants Research Committee and participants provided informed consent.

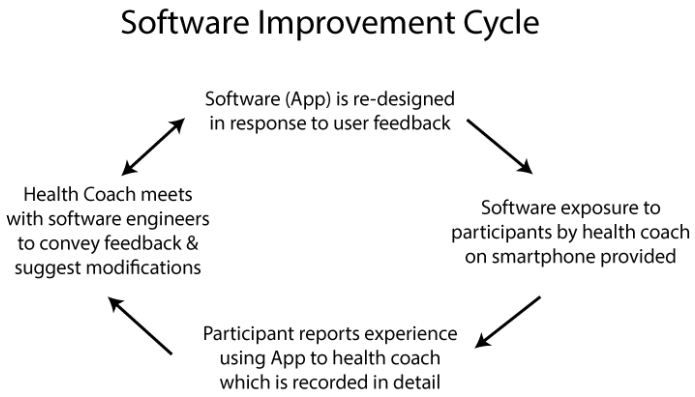
3.4.4 NexJ Health Coach App Access

All clients were given access to the custom smartphone app on a loaned Blackberry Curve 8900 with full data access for the duration of the trial (n=19), unless they possessed their own Blackberry (n=2), in which case the software was installed on their personal device.

3.4.5 App Feedback and Development

Research staff collected participant experience with version 1.0 of the Health Coach app, reporting errors and overall feedback. Feedback was organized and relayed back to the software design team as described in Figure 1.

Figure 1 - Software Improvement Cycle.
Feedback loop conveys user experience and smartphone software redesign



As the Health Coach app was version 1.0, periodic malfunctions hindered client communications during the trial. Due to the close relationship between the health coach and software production team, the feedback and user experience was communicated as received, resulting in upgrades installed on the server at frequent intervals. This feedback loop led to significant improvements in the software throughout the trial. Some of the most important modifications included user-interface enhancements, general usability, and solution of software instability issues. Screenshots of the mobile phone app with an explanation of the various trackers and functions are found in Figures 2-11.

Figure 2 - Exercise Tracker is designed to easily track multiple exercise modalities. Users can capture duration of exercise, rate perceived intensity (light, moderate, vigorous), and enter additional text comments.

Figure 3 - Food Tracker automatically triggers the smartphone's camera, enabling photo capture of meals. Users can subjectively rate food portion, source, and healthiness.

Figure 4 - Satisfaction survey: at a customizable timeframe (usually 20 minutes), the program prompts for reports on satiety level (not enough, just right, too full).

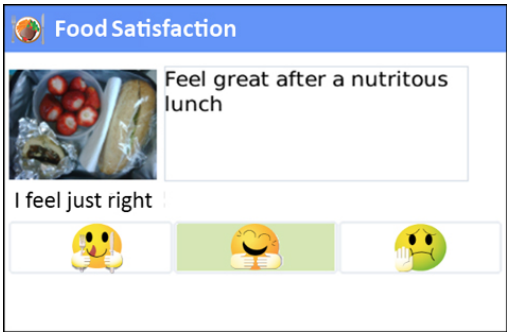


Figure 5 - Blood Glucose Tracker: Clients enter blood glucose level and comments on readings.

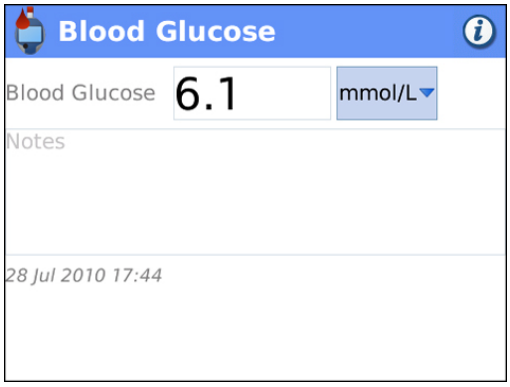


Figure 6 - Mood Tracker: Clients enter "How They Feel" using a simple 5-pt scale: I feel (great, very good, good, bad, very bad) and comment on entry.

Figure 7 - Weight Tracker: Clients enter weight and enter comments on the reading.

Figure 8 - Pain Tracker: Clients can enter subjective pain ratings using a 5-pt scale: pain level is (none, mild, moderate, severe, very severe).

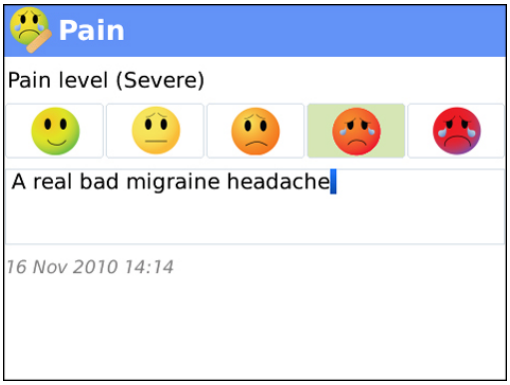


Figure 9 - Blood Pressure Tracker: Clients enter blood pressure including systolic, diastolic, and heart rate and are able to comment on the reading.

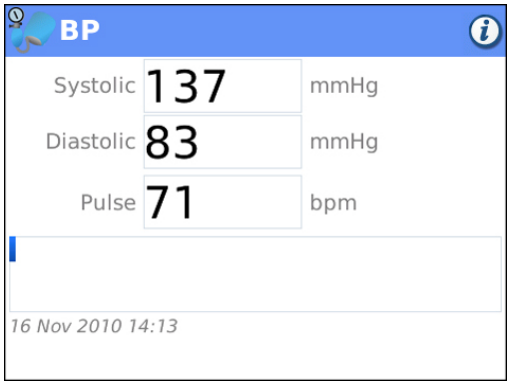


Figure 10 - Messaging allows for two-way secure messaging between participant and health coach who can selectively promote healthy choices at pivotal times of client decision-making, providing support immediately after healthy behaviors have been logged, and/or addressing questions and/or sending relevant materials.

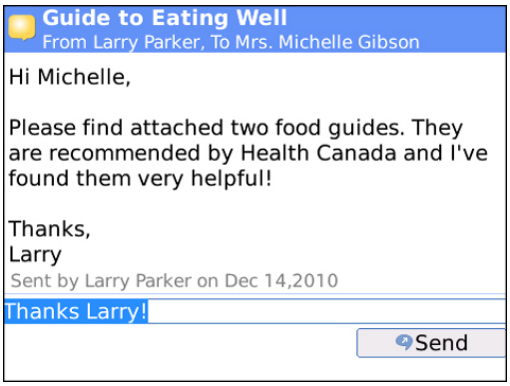


Figure 11 - Reminders: The trackers use employ alarm-type entry reminders, which provide convenient ways to prompt clients to engage in health behaviors like exercise, dietary modifications, stress reduction, and self-reported mood. Reminders can be turned on and off easily by health coach and/or participant.

3.4.6 Statistical Analysis

Data was analyzed using SPSS (version 21.0, 2012, IBM, Chicago, IL). Descriptive statistics are reported (means and standard deviations). Differences in outcome variables (baseline to 24 weeks) were analyzed using a paired samples *t* test. Participants were split into groupings according to baseline assessments (HbA1c≥7.0% and HbA1c<7.0%). Significance was set to $p<.05$.

3.5 RESULTS

Of the 21 participants, final outcome variables were collected for 19. The primary reason for missing data was primary care physician failure to forward lab results (n=2).

Demographics are summarized in Table 1. There was a mean reduction of 0.28% (0.57) (p=.05) in HbA1c found over the entire sample. Since participant glucose control varied across optimal levels at baseline, data was re-analyzed for those who began the trial with sub-optimally managed glucose and those with optimally managed glucose. A total of 12 participants started the trial with sub-optimally managed glycemic control (HbA1c≥7.0% [DCCT] or 53 mmol/mol [IFCC]) and experienced a greater mean reduction of 0.43% (0.63) (p=.04), while the n=7 participants who had baseline HbA1c levels within acceptable clinical control range (HbA1c<7.0%) had no significant changes in HbA1c at 6 month follow up (0.01, p=.91).

Table 1 - Demographic characteristics at baseline (n=21).

Characteristic		n (%)
Age (years), mean (SD)		55.6 (12.3)
Gender		
	Male	9 (43%)
	Female	12 (57%)
Marital Status		
	Single	5 (24%)
	Married or common law	14 (67%)
	Widowed	2 (10%)
Children		
	Yes	18 (86%)
	No	3 (14%)
Educational Background		
	Less than high school	3 (14%)
	Completed high school	4 (19%)
	Some college/university	7 (33%)
	College diploma	6 (29%)
	University degree	1 (5%)
Employment		
	Full-time	12 (57%)
	Part-time	2 (10%)
	Not presently employed	7 (33%)
Ethnicity		
	Hispanic	3 (14%)
	African	3 (14%)

	Caribbean	3 (14%)
	South Asian	3 (14%)
	Caucasian	9 (43%)

Table 2 - Change in outcomes of patients participating in the health coach intervention.

		n	Baseline, mean (SD)	Post, mean (SD)	Mean change, Mean (SD)	*P* value
Entire sample						
	HbA1c (%)	19	7.58 (1.13)	7.31 (0.95)	−0.28 (0.57)	.05
	Weight (kg)	14	94.6 (16.8)	93.2 (15.8)	−1.3 (1.9)	.02
	BMI	13	34.4 (5.5)	33.9 (5.3)	−0.4 (0.7)	.05
	Waist Cir. (cm)	11	109.4 (16.1)	112.1 (16.1)	2.7 (4.3)	.06
Baseline A1c ≥7.0%						
	HbA1c (%)	12	8.26 (0.80)	7.83 (0.78)	−0.43 (0.63)	.04
	Weight (kg)	9	100.1 (18.0)	98.1 (17.1)	−1.9 (1.7)	.01
	BMI	8	36.2 (5.8)	35.6 (5.7)	−0.7 (0.7)	.04
	Waist Cir. (cm)	7	114.4 (17.1)	116.5 (16.4)	2.1 (5.3)	.33
Baseline A1c <7.0%						
	HbA1c (%)	7	6.43 (0.39)	6.41 (0.38)	−0.01 (0.32)	.91
	Weight (kg)	5	84.6 (8.7)	84.4 (8.8)	−0.2 (1.8)	.81
	BMI	5	31.4 (3.7)	31.3 (3.8)	−0.1 (0.7)	.80
	Waist Cir. (cm)	4	100.6 (11.0)	104.4 (10.0)	3.8 (1.6)	.02

3.6 DISCUSSION

3.6.1 Principal Results

In this trial, patients with a range of glucose regulation efficacy were recruited to pilot a smartphone-based mobile software application app and personal health coach program and demonstrated an overall improvement in HbA1c. Given the objective of demonstrating intervention effectiveness for poorly managed diabetic clients, analysis was rerun distinguishing poorly controlled from well controlled subjects at baseline (HbA1c>7.0% (53 mmol/mol). Participants, who began the trial at a poorly managed level had significant improvements in HbA1c and a greater effect than the whole sample, while those who started within an acceptable HbA1c range had no improvements, demonstrating the potential clinical relevance of the intervention for poorly control diabetic patients

3.6.2 Socioeconomic Strata and Intervention Applicability

Lower SES populations often have difficulty navigating and accessing the health care system [165] to a degree where SES appears to be the best predictor of health status in Canada and the United States [166,167], with SES-related factors manifesting as substantial barriers to the health of many Canadians. This intervention attempted to address some of these issues by engaging participants in a health coaching relationship to overcome accessibility barriers. During the course of the intervention, it was observed that participants were sometimes prevented from attending appointments with their health care team due to familial obligations and work obligations (mainly shift work). With low workplace flexibility, when work had to be interrupted to attend a health care session, losing out on the day's pay was a significant obstacle. The intervention reduced this barrier by providing 24-hour electronic access to the health coach, enabling participants to initiate communication when possible and convenient.

Of our study sample, 34% completed either a college or university degree, compared to the 59% of Ontario's population (and 53% of Canada's population) who have a university or college level designation [168]. Education is a commonly used proxy of socioeconomic strata, but educated immigrants to Canada are frequently unable to work in their former disciplines at their achieved educational levels due to domestic policies [169]. The intervention demonstrated the effectiveness of a personalized, electronically assisted health coaching intervention in an underserved population that is not typically the focus of technology-assisted health research. Most participants (n=19) did not own a smartphone and were loaned a device for the trial duration. Nonetheless, as the costs of mobile technology decrease, mobile technology interventions will be increasingly feasible and useful at all SES levels.

3.6.3 From Single-Arm Pilot to Randomized Controlled Trial

The pilot study was intended to generate results guiding the eventual design of a randomized controlled trial (RCT). Several points of guidance were readily apparent. First, the lower SES participants, according to our pilot experience, would not likely sustain participation if they perceived that randomization to the control group resulted in an inferior intervention. This was due to generic participation obstacles, especially taking time out of inflexible work schedules to attend assessment sessions. This observation combined with our interest in seeing what additional benefits were attributable to health coaching with the smartphone software vs health coaching alone. Accordingly, the health coaching intervention was designed to be fundamentally equivalent across comparison arms except for use of the smartphone plus software in the experimental group. Second, our experience with primary care providers involved their inconsistent provision of HbA1c tests. Accordingly, we ensured a point-of-care HbA1c Analyzer was available (via finger-prick A1c blood samples) throughout the current RCT.

3.6.4 Limitations

This pilot study enrolled a small convenience sample with no control group, limiting the generalizability of intervention results. Throughout the pilot trial, temporary software malfunctions and upgrades inevitably resulted in service disruptions. Although participants could directly log healthy behaviors via smartphone, their self-report could be falsified or exaggerated. Future studies can employ Bluetooth connected technology (ie, glucometers, accelerometers) to omit some self-report biases. To more rigorously assess intervention efficacy, the RCT now in the field is being undertaken with stabilized, consistently functional software. The goal is to assess whether health coaching without vs with the use of the smartphone software is equivalent (or non-inferior). In order to address this question, subjects were randomly allocated to experimental and control groups, and the same coaches delivered health coaching in both arms.

This approach aims to better understand which intervention features are most important to effective intervention. We understand that there are limitations to this assessment approach but it represents an important step in investigating these interventions.

3.6.5 Comparison with Prior Work

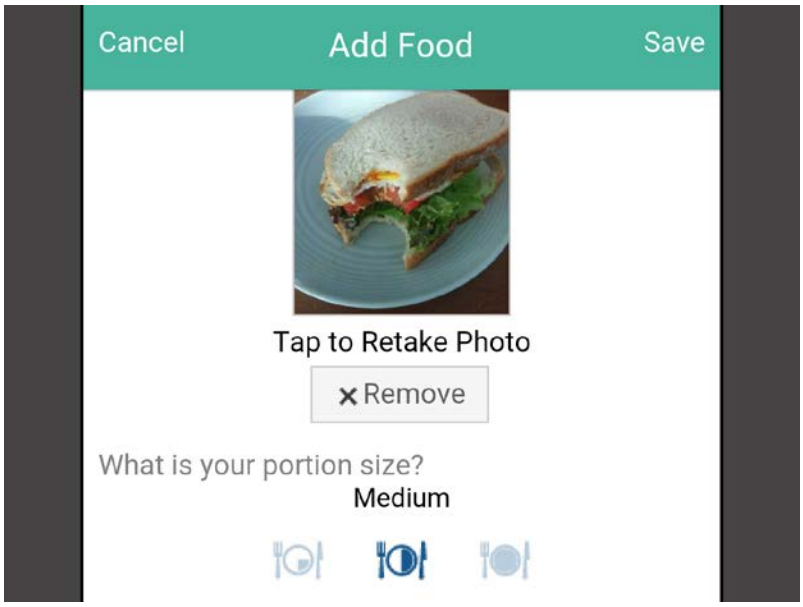
The most comparable intervention is the WellDoc diabetes trial [105,170,171] in which 26 primary health practices were randomized to provide one of four possible health coach intervention options to their patients. Across participating practices, 163 patients were intervened with intensities ranging from usual care to use of smartphone-assisted health coaching. Investigators found significant decreases in HbA1c in the highest intensity group. In that trial, participants on Medicaid and Medicare and those without health insurance were excluded. Our trial specifically targets individuals from a lower-resource sector of a large Canadian city, most of whom would have been excluded from the WellDoc trial. Since the association between type 2 diabetes and poverty has been well demonstrated [12,13,19], our interests focus on interventions that serve people of all SES and have demonstrated efficacy with subjects from lower SES.

3.6.6 Conclusions

As mobile technology becomes more accessible, electronically assisted health coaching may emerge as a viable and effective means of managing chronic conditions through improved health behaviors across all SES. To help understand what parts of the intervention were responsible for changes in behavior (health coaching, remote monitoring), the RCT currently being conducted will assess the effectiveness of health coaching in type 2 diabetic patients both with and without the use of smartphone technology at multiple sites with diverse populations.

CHAPTER 4: STUDY #2 - RANDOMIZED CONTROLLED TRIAL

Title: Health Coaching Reduces HbA1c in Type 2 Diabetic Patients from a Lower SES Community: A Randomized Controlled Trial



Wayne N, Perez DF, Kaplan DM, Ritvo P. (2015). Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. Journal of Medical Internet Research; 17(10):e224. DOI: 10.2196/jmir:4871

4.1 RATIONALE FOR STUDY #2

4.1.1 Objectives

To compare the effectiveness of improving the health profile of patients with poorly controlled T2DM with a health coaching protocol administered by health coaches with and without the use of a mobile (smartphone) app in a lower SES community.

4.1.2 Hypotheses

While both groups will experience improvements in HbA1c, anthropometric and psychometric outcomes, participants who receive health coaching with mobile (smartphone) connectivity will achieve significantly greater improvements in HbA1c of near 0.6% (7 mmol/mol) compared with those who receive health coaching alone. Intervention participants will also achieve significantly greater reductions in weight as well as improved mood as measured by the Satisfaction with Life Scale, PANAS, HADS, and SF-12 (V2).

4.2 ABSTRACT

Background: Adoptions of health behaviors are crucial for maintaining good health after type 2 diabetes mellitus (T2DM) diagnoses. However, adherence to glucoregulating behaviors like regular exercise and balanced diet can be challenging, especially for people living in lower-socioeconomic status (SES) communities. Providing cost-effective interventions that improve self-management is important for improving quality of life and the sustainability of health care systems.

Objective: To evaluate a health coach intervention with and without the use of mobile phones to support health behavior change in patients with type 2 diabetes.

Methods: In this pragmatic randomized controlled trial (RCT), patients from two primary care health centers in Toronto, Canada, with type 2 diabetes and a glycated hemoglobin/hemoglobin A1c (HbA1c) level of ≥7.3% (56.3 mmol/mol) were randomized to receive 6 months of health coaching with or without mobile phone monitoring support. We hypothesized that both

approaches would result in significant HbA1c reductions, although health coaching with mobile phone monitoring would result in significantly larger effects. Participants were evaluated at baseline, 3 months, and 6 months. The primary outcome was the change in HbA1c from baseline to 6 months (difference between and within groups). Other outcomes included weight, waist circumference, body mass index (BMI), satisfaction with life, depression and anxiety (Hospital Anxiety and Depression Scale [HADS]), positive and negative affect (Positive and Negative Affect Schedule [PANAS]), and quality of life (Short Form
Health Survey-12 [SF-12]).

Results: A total of 138 patients were randomized and 7 were excluded for a substudy; of the remaining 131, 67 were allocated to the intervention group and 64 to the control group. Primary outcome data were available for 97 participants (74.0%). While both groups reduced their HbA1c levels, there were no significant between-group differences in change of HbA1c at 6 months using intention-to-treat (last observation carried forward [LOCF]) (p=.48) or per-protocol (p=.83) principles. However, the intervention group did achieve an accelerated HbA1c reduction, leading to a significant between-group difference at 3 months (p=.03). This difference was reduced at the 6-month follow-up as the control group continued to improve, achieving a reduction of 0.81% (8.9 mmol/mol) (p=.001) compared with a reduction of 0.84% (9.2 mmol/mol)(p=.001) in the intervention group. Intervention group participants also had significant decreases in weight (p=.006) and waist circumference (p=.01) while controls did not. Both groups reported improvements in mood, satisfaction with life, and quality of life.

Conclusions: Health coaching with and without access to mobile technology appeared to improve glucoregulation and mental health in a lower-SES, T2DM population. The accelerated improvement in the mobile phone group suggests the connectivity provided may more quickly

improve adoption and adherence to health behaviors within a clinical diabetes management program. Overall, health coaching in primary care appears to lead to significant benefits for patients from lower-SES communities with poorly controlled type 2 diabetes.

Trial Registration: ClinicalTrials.gov NCT02036892; http://clinicaltrials.gov/ct2/show/NCT02036892 (Archived by WebCite at http://www.webcitation.org/6b3cJYJOD)

4.3 INTRODUCTION

4.3.1 Overview

The type 2 diabetes mellitus (T2DM) epidemic is an increasing economic and personal health burden that could be cost-effectively addressed with health coach (HC) interventions, assisted by mobile phone technologies [172]. HC interventions target health behavior changes aligned with self-determined goals leading to improved physical and mental health outcomes [113]. Chronic medical conditions are targeted when health behaviors adopted by patients can significantly reduce risks of worsened disease and disease complications [173].

Amid promising reports of computer and mobile phone-assisted health interventions [174], a dearth of studies focus on which types of personal interactions combine most effectively with current technologies. Prior to this randomized controlled trial (RCT), we codeveloped, with NexJ Systems Inc, mobile phone software for logging health data (eg, blood glucose, blood pressure, mood, energy, and pain) and related activities (eg, exercise, diet, and stress) using secure, cloud-based storage. The software permits innovative comonitoring of client behaviors (eg, photographing meals) and transmission of reminder messages encouraging activation and adherence. As the HC reviews participant activities in real-time experience, these immediately responsive communications can prevent relapse and/or assist relapse recovery, as demonstrated

in a pilot study [173].

Internet-based interventions have demonstrated significant improvements in glucoregulation in T2DM patients, as exemplified in a cluster RCT undertaken by Quinn et al. [105] where 4 different intensity levels of Internet-based support were compared; significant between-group differences in reduced glycated hemoglobin/hemoglobin A1c (HbA1c) were found when the most intense intervention ($p<.001$) was compared to usual care. This intervention consisted mainly of automated messages prompted by patient entries (eg, self-assessed blood glucose) and the patients studied were all health insured, after exclusion of the noninsured population that is often associated with lower socioeconomic status (SES), higher T2DM prevalence, and poorer glucose control [12,13]. In contrast, our intervention included a high proportion of lower-SES patients as all Ontario residents are able to access essential health services free of charge via the Ontario Health Insurance Program (OHIP). Our trial focused on supporting participants in surmounting the additional challenges confronted by lower-SES community residents, such as poor neighbourhood walkability [16] and elevated consumption of energy-dense/nutrient-poor foods [175]. Failure to surmount these challenges often leads to an increased longitudinal use of health care resources due to more reactive use combined with poorer health status [176]. A further contrast was that our study was based on assessing HC interactions, with and without mobile phone-based support.

Another more recent trial compared a mobile phone-based, self-management system with and without telephone-based health coaching in improving HbA1c levels, with a usual care control group. Both intervention groups accessed a mobile phone-based self-management system that enabled users to track blood glucose, diet, physical activity, and personal goals. The most intensive intervention group received health coaching delivered by a diabetes specialist nurse for

the first 4 months of the 12-month trial, with a total of five 20-minute phone contacts. Results indicated no significant between-group or within-group HbA1c differences [110]. The intensity of this HC intervention—five 20-minute phone contacts—was considerably lower than the levels applied in this study.

The importance of lowering HbA1c and improving glucoregulation in T2DM patients cannot be overemphasized as HbA1c is a robust indicator of complication risks and a widely accepted tool for T2DM diagnosis [30]. Without proper management, patients with T2DM are at increased risk for debilitating complications, particularly stroke [89], neuropathy leading to amputation and blindness [31], and death [177]. HbA1c reductions have been associated with carbohydrate control [178], vigorous exercise [179], and medication adherence [180].

While the economic pressures of funding interventions motivate technological developments that can, in part or whole, replace personal counseling interventions, studies that compare different HC intensities combined with different technologies are necessary to determine optimal proportions. The usefulness of such studies is exemplified by Nundy et al. [11] who assessed a mobile phone-based, automated text messaging and counselling intervention with type 2 diabetes patients. In a quasi-experimental, two-group, pre-/post-design, intervention participants appeared to be 8.8% less costly *during* the 6-month intervention, than during the 6 months preceding intervention engagement. These participants also reduced their HbA1c by 0.7% leading to other potential longitudinal cost savings not yet evaluated [11]. Because all were participants in the University of Chicago employee health plan, relevant health care costs were accessed and compared. Once again, our study differs in that our sample included unemployed individuals who would have been ineligible for the health plan which this previous study relied on.

4.3.2 Objective

Based on data from a previous pilot trial, this pragmatic RCT tested the effectiveness of a mobile phone-based health coaching protocol, versus one without mobile phone support, in reducing the HbA1c of patients with T2DM from a lower-SES community.

4.4 METHODS

4.4.1 Overview

This pragmatic RCT proceeded with a 1:1 allocation ratio. Participants were recruited from 2 primary health clinics in Toronto, Canada, between March 2012 and October 2013. The populations served were from a lower-income neighborhood (90% of participants) and a midlevel-SES community (10% of participants). Patients were eligible for participation if diagnosed with T2DM, if they had an HbA1c ≥ 7.3% (56.3 mmol/mol) measured within 1 month of consent, and if they were under 70 years of age. Following pragmatic trial guidelines, there were no additional exclusion criteria (eg, no exclusion of individuals with psychiatric diagnoses). All study protocols were approved by the Research Ethics Boards at York University, North York Family Health Team, and North York General Hospital. This RCT was registered with ClinicalTrials.gov (NCT02036892) and reported following CONSORT-EHEALTH statement guidelines [181].

Recruitment was undertaken through phone contacts with eligible individuals identified via clinic electronic medical records. Additional recruitment assistance was obtained from associated diabetes education programs, primary care physicians, and locally practicing endocrinologists.

When participants agreed to an initial meeting to discuss the study, their HbA1c findings were verified, the study protocol was explained, and informed consent was obtained. Eligible patients then completed demographic and psychometric questionnaires and were randomized. Table 1 presents the baseline characteristics of the participants.

Table 3. Baseline characteristics (as per study protocol).

Baseline characteristics		Whole sample (n=97), mean (SD) or n (%)[a]	Intervention group (n=48), mean (SD) or n (%)[a]	Control croup (n=49), mean (SD) or n (%)[a]
Age in years, mean (SD)		53.2 (11.3)	53.1 (10.9)	53.3 (11.9)
Location, n (%)				
	Site #1: BCCHC[b]	90 (93)	46 (96)	44 (90)
	Site #2: NYFHT[c]	7 (7)	2 (4)	5 (10)
Gender, n (%)				
	Male	27 (28)	17 (35)	10 (20)
	Female	70 (72)	31 (65)	39 (80)
Ethnicity, n (%)				
	First Nations	1 (1)	0 (0)	1 (2)
	Black: African	5 (5)	3 (6)	2 (4)
	Black: Caribbean	39 (40)	19 (40)	20 (41)
	Caucasian	26 (27)	12 (25)	14 (29)
	Hispanic	9 (9)	4 (8)	5 (10)
	South Asian	4 (4)	3 (6)	1 (2)
	South East Asian	4 (4)	2 (4)	2 (4)
	West Indian	6 (6)	3 (6)	3 (6)
	Other	3 (3)	2 (4)	1 (2)
Highest education level achieved, n (%)				
	Less than high school	22 (23)	10 (21)	12 (24)
	High school diploma	35 (36)	17 (35)	18 (37)
	College or vocational training	25 (26)	11 (23)	14 (29)
	University degree	12 (12)	8 (17)	4 (8)
	Not disclosed	3 (3)	2 (4)	1 (2)
Employment, n (%)				
	Unemployed	35 (36)	16 (33)	19 (39)
	Student	4 (4)	3 (6)	1 (2)
	Part time	6 (6)	1 (2)	5 (10)
	Full time	25 (26)	13 (27)	12 (25)
	Retired	11 (11)	6 (13)	5 (10)
	Self-employed	9 (9)	6 (13)	3 (6)
	Work in home (eg, take care of children)	4 (4)	2 (4)	2 (4)
	Not disclosed	3 (3)	1 (2)	2 (4)
Income in Can $, n (%)				
	$0-$9999	21 (22)	9 (19)	12 (25)
	$10,000-$25,000	23 (24)	10 (21)	13 (27)

	$25,000-$50,000	20 (21)	12 (25)	8 (16)
	$50,000-$75,000	9 (9)	3 (6)	6 (12)
	$75,000 and higher	5 (5)	4 (8)	1 (2)
	Not disclosed	19 (20)	10 (21)	2 (4)
Car access, n (%)				
	Owns a car	35 (36)	19 (40)	16 (33)
	Has access to car	12 (12)	9 (19)	3 (6)
	No access to car	48 (50)	19 (40)	29 (59)
	Not disclosed	2 (2)	1 (2)	1 (2)

[a]Percentages may not add up to 100% due to rounding.

[b]Black Creek Community Health Centre (BCCHC).

[c]North York Family Health Team (NYFHT).

4.4.2 Intervention

The HC intervention extended for 6 months from the date of consent (Figure 12) following a behavior-change curriculum designed by 2 study authors (PR and NW) at York University that incorporated feedback from the prior pilot study [173]. In the intervention, a health coach was defined as a behavior-change counselling specialist with expertise in chronic disease management and evidence-based theory adapted for disease state, SES, and ethnocultural backgrounds. With HC assistance, clients determined health-related goals and monitored daily progress. The HC comonitored the client's mobile phone input and directed immediate attention (on a 24-hour/day and 7-day/week basis) to episodes of desirable progress, relapse, and resistance. The HC protocol has been manualized, emphasizing those situations observed to frequently arise when behavior change is addressed in T2DM-affected individuals.

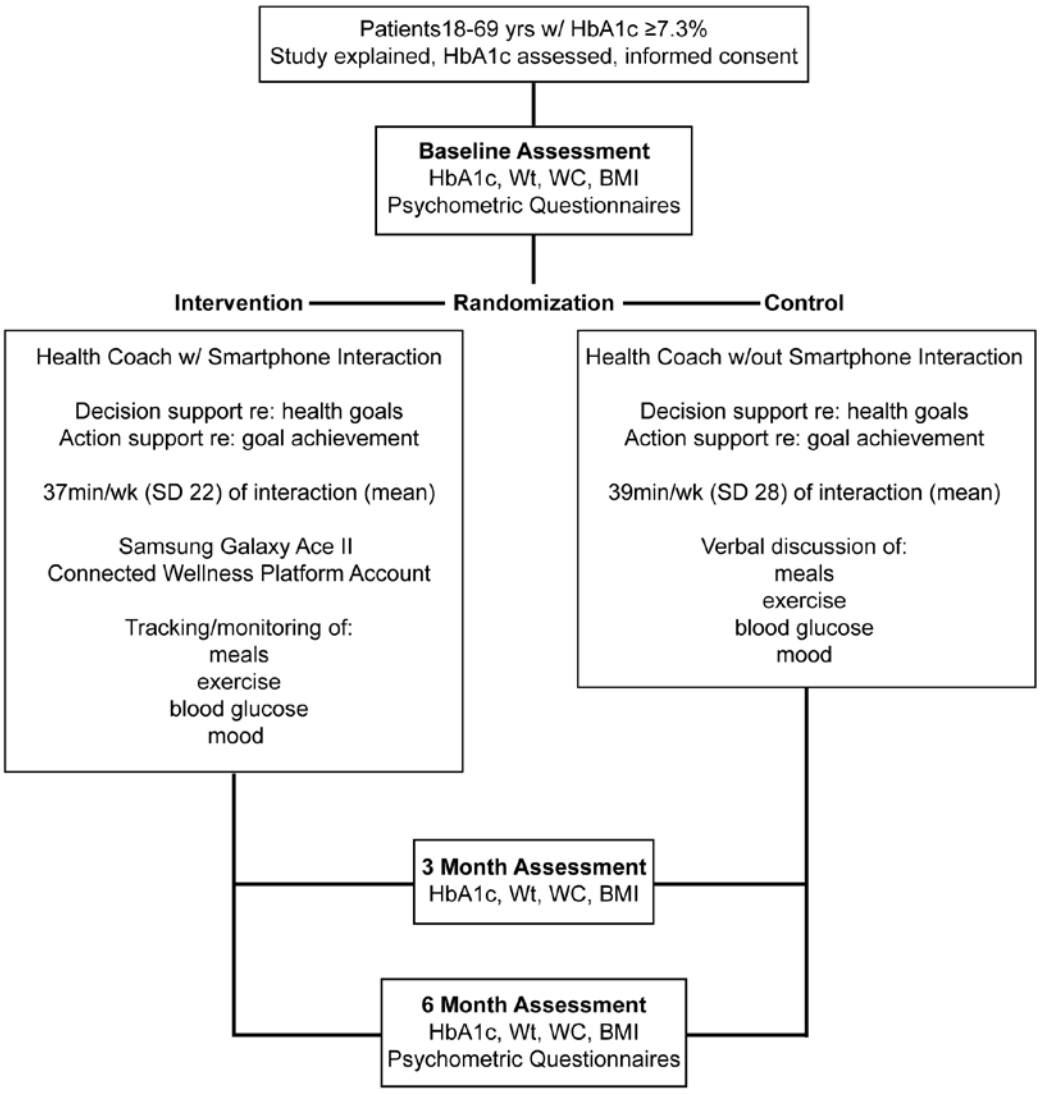
Eligible participants were randomized to the respective study groups (with and without mobile phone support), with HCs in both groups guiding participants in planning and reaching health targets aimed at reducing HbA1c. Efforts focused primarily on increasing exercise (frequency, duration, intensity) and modifying diet to reduce carbohydrate intake. Additional

goals emphasized stress management, medication adherence, and effective communication with primary care physicians and, generally, within the health system.

Six HCs intervened with experimental and control group participants. These individuals held bachelor's degrees in kinesiology and health science and/or were graduate students in the School of Kinesiology and Health Science at York University. Five HCs were certified exercise physiologists—certified by the Canadian Society for Exercise Physiology (CSEP)—and one was a certified personal trainer—certified by the CSEP. All attended weekly seminars prior to and throughout the trial where they received training in the HC curriculum by the lead investigator (PR). HCs also participated in weekly team meetings led by the study coordinator (NW) where they discussed applications of behavior theory in specific strategies for each participant.

The Black Creek Community Health Centre (BCCHC) concurrently provided the Exercise Education Program (EEP) to all community members (free of charge) that featured exercise prescription, monitoring, and adherence support. Participants were monitored on both an individual and group basis by trainers during exercise sessions and patients with T2DM were provided with special blood glucose testing before and after each exercise session. The program included group exercise classes, resistance training with weights and bands, and cardiovascular exercise using a treadmill and stationary bicycles. Both intervention and control group participants had EEP access for the trial duration.

Figure 12 - Experimental design & timing of data collection.



4.4.3 Intervention Group

The intervention group was provided with a Samsung Galaxy Ace II mobile phone running Google Android Ice Cream Sandwich (Android 4.0.2) for the study intervention period, with a data-only carrier plan. They were also provided a user account with the Connected Wellness Platform (CWP) provided by NexJ Systems, Inc., which supported participants in health-related goal setting and progress monitoring. Participants could track key metrics, notably

blood glucose levels (Figure 13), exercise frequency/duration/intensity (Figure 14), food intake (via photo journaling) (Figure 15), and mood (Figure 16). They could communicate with their health coach at any time in the 24-hour cycle via secure messaging, scheduled phone contact, and/or during in-person meetings. The mean total contact (for all these activities) was 38 minutes/week (SD 25). All health data entered by participants into the CWP were immediately visible to health coaches through a secure, Web-accessible portal. Although participants were encouraged to use the system daily, individual usage patterns varied. Participant data and software-enabled communication required two-way, certificate-based authentication and passwords that were stored in encrypted columns. The CWP exceeds Canadian privacy standards for software carrying health information. Based on patient goals, HCs used the 24-hour/day logging function to guide healthy lifestyle choices, while providing support when clients diverged from intended health goals and routines.

Figure 13 - Screenshot of blood glucose tracker.

Figure 14 - Screenshot of exercise tracker.

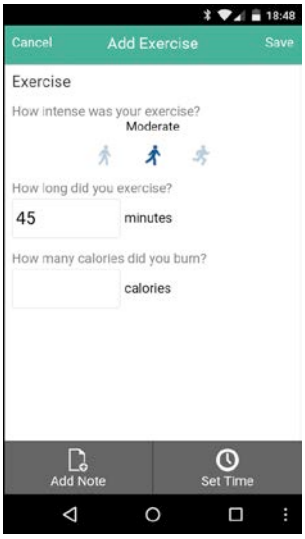


Figure 15 - Screenshot of food tracker.

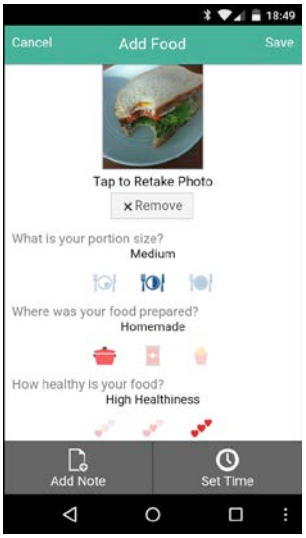
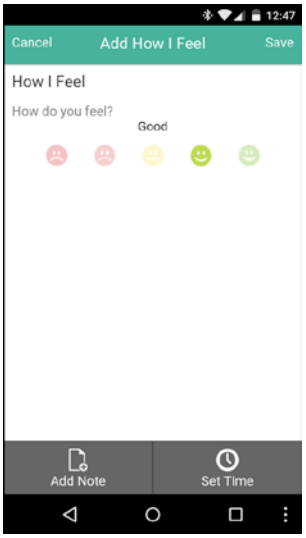


Figure 16 - Screenshot of mood tracker.



4.4.4 Control Group

Control group participants received HC support in selecting and progressing toward goals without access to a (study-provided) mobile phone or the CWP software. Control group participants accessed the EEP, as did the intervention group participants for the study duration, in addition to in-person meetings and health coach phone contacts.

4.4.5 Primary Outcomes

The primary outcome was the difference between intervention and control group means of HbA1c levels from baseline to 6 months. Intention-to-treat and per-protocol analyses were both undertaken and are presented below. HbA1c levels were assessed by physician requisition or, when unobtainable, by a point-of-care HbA1c analyzer (Siemens DCA Vantage 3000) which has met performance criteria in efficacy trials [182] and has been employed in comparable research [110,183]. To ensure consistency, the type of HbA1c collection at baseline was the same at follow-up sessions. While the 3-month assessment allowed an evaluation of trends, the 6-month assessment was used to calculate the primary outcome. Measures of blood work were accepted

within 4 weeks of the 3- and 6-month measurement intervals providing flexibility for participant schedules and physician requisitions.

4.4.6 Secondary Outcomes

Differences between HbA1c mean levels within groups were also analyzed. Additional outcomes included anthropometric measurements for weight (kg), body mass index (BMI) (kg/m^2), and waist circumference (cm) collected at baseline and six-month time points. Changes in psychometric assessments at baseline and 6-months were analyzed using the Satisfaction with Life Scale [140], the Hospital Anxiety and Depression Scale [141], the Positive and Negative Affect Schedule [143], and the Short Form Health Survey-12 (SF-12) [144]. All measures were obtained on site by research staff.

4.4.7 Sample Size

An a priori power calculation indicated 48 participants were needed per group to detect an estimated difference of HbA1c of 0.65%, assuming a significance level of 5% (two-tailed), standard deviation of 1.4 and a statistical power of 80%. We over-enrolled to allow for attrition, setting our final recruitment target at 65 participants per group.

4.4.8 Randomization

A random number sequence was generated using a random number-generating program without constraints (www.randomizer.org). After the sequence was generated by the research coordinator, a research assistant with no connection to the trial sealed the sequence in individual, opaque envelopes and numbered each based on sequence generation. Once a candidate participant consented and their HbA1c was verified as meeting the inclusion criteria, the next envelope was opened (in sequence) to ascertain group allocation, and the health coaching intervention commenced. Patient and coach blinding was impossible as participants readily

identified receipt of a mobile phone with experimental group participation and the absence of receipt with control group participation.

4.4.9 Statistical Analysis

Data were double entered by 2 independent research assistants to ensure accuracy. Baseline characteristics between intervention and control groups were compared for differences using independent samples *t* tests for continuous variables and chi-square for dichotomous variables. Primary outcome comparison was conducted with an independent samples *t* test using per-protocol (only those who completed the trial) and intention-to-treat analyses (last observation carried forward [LOCF]). Secondary outcome comparisons were conducted solely using per-protocol comparisons with a factorial repeated-measures analysis of variance (ANOVA) (randomization group as factor). Data were analyzed using SPSS 21.0 (IBM Corp, Armonk, NY, USA).

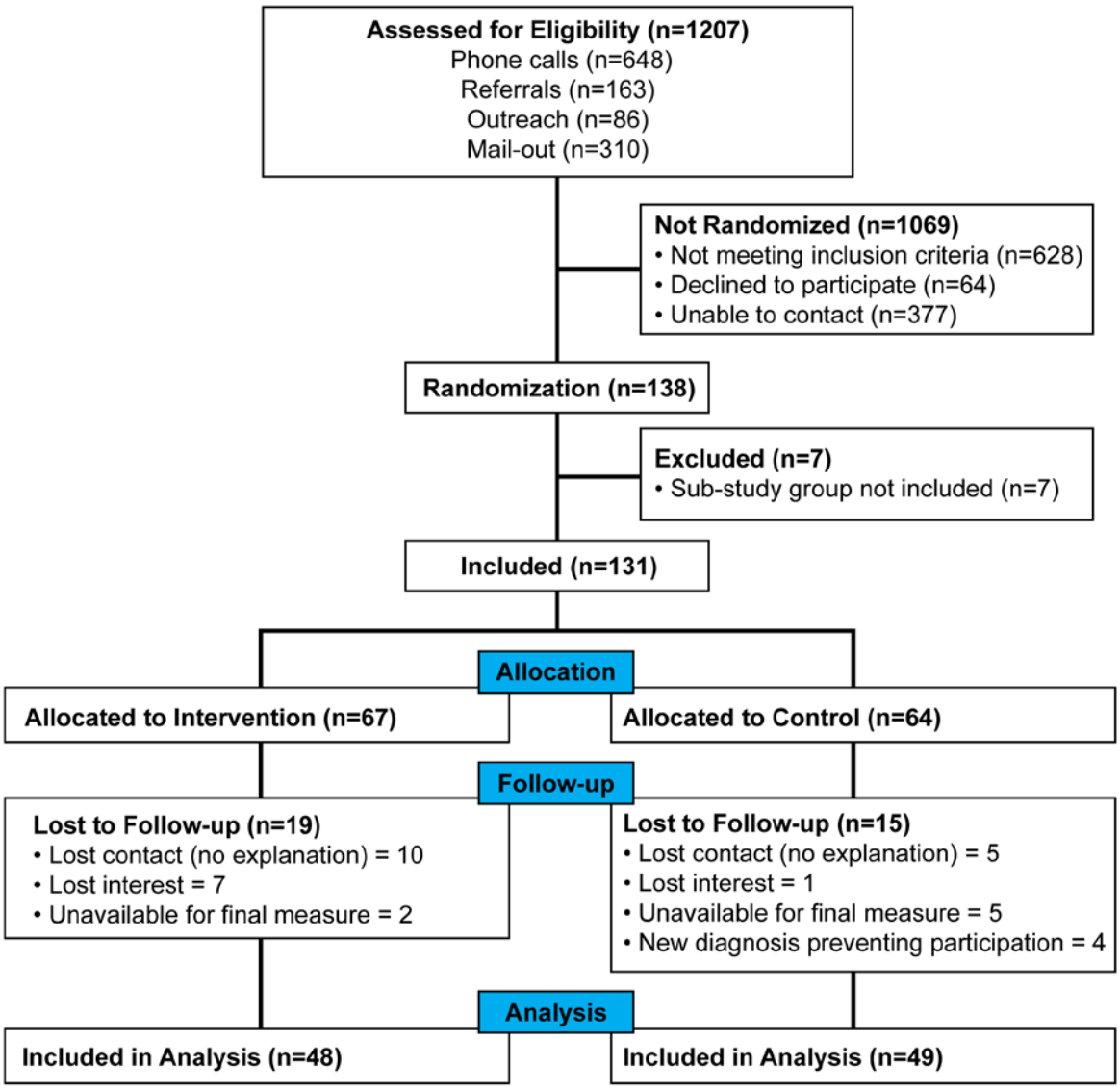
4.5 RESULTS

4.5.1 Overview

Between March 2012 and October 2013, 138 participants were recruited; 67 were randomized to the experimental arm and 64 to the control arm (7 were excluded for substudy analysis) as seen in the CONSORT diagram (Figure 6). A majority of participants (57/97, 59%) had not completed postsecondary education and 35 out of 97 (36%) were unemployed, while a total of 64 out of 97 (66%) reported household incomes of Can $50,000 or less. A majority of participants were recruited from Site Number 1 (90/97, 93%) and were female (70/97, 72%). Of the 131 participants included in the study, there were 34 dropouts (26%), with 19 out of 67 (28%) from the intervention group and 15 out of 64 (23%) from the control group. Independent samples *t* tests indicated no statistically significant differences between dropouts and trial completers for HbA1c or for demographic variables. Final per-protocol analysis included 97

participants out of 131 (74%), with 48 in the intervention group and 49 in the control group. Of the measures collected, differences at baseline between groups were only detected for the SF-12 Mental Health Composite Scores. Of the 48 participants allocated to the mobile phone group, mobile phone use data indicated that 39 out of 48 participants (81%) used the CWP with consistency (at least once per week through the trial) to communicate with their health coach and track various health measures (eg, blood glucose, food, and/or exercise).

Figure 17 - Flow Chart of enrolment and patient status (n=131)



4.5.2 Hemoglobin A1c

Independent samples *t* tests indicated no significant between-group differences in HbA1c from baseline to 6 months when analyzed with intention-to-treat (p=.48) and per-protocol (p=.83) principles (Table 4).

Table 4 – Independent samples *t* test measuring differences in HbA1c levels from baseline to 6 months

	N	Intervention mean (SD)	Control mean (SD)	Difference	*P* (two-tailed)
HbA1c: Per Protocol	97	-0.815 (1.050)	-0.759 (1.390)	0.055	.83
HbA1c: Intention to Treat	131	-0.642 (1.040)	-0.974 (1.400)	0.152	.48

Results from a repeated-measures ANOVA indicated trends for between-group HbA1c differences in a per-protocol analysis—$F_{1,89}$=3.022, p=.09 (Table 5).

Table 5 Between-group analysis of variance measuring differences in HbA1c levels.

	N	Type II Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared
HbA1c – Per Protocol	97	3.004	1	3.004	3.002	.086	.034
HbA1c – Intention to Treat	131	1.463	1	1.463	1.142	.287	.009

These differences reflected significant HbA1c within-group reductions from baseline to 6 months in the intervention group—0.84% (9.2 mmol/mol), 95% CI [0.46-1.17]; p=.001—and in the control group—0.81% (8.9 mmol/mol), 95% CI [0.41-1.11]; p=.001—(Table 4), and a significantly greater reduction for the intervention group versus the control group at the 3-month follow-up (p=.03; Table 6).

Table 6. Change in HbA1c levels by group.

Measurement time point		Intervention group			Control group		
		n	Mean % (SD or 95% CI)	Total value (mmol/mol)	n	Mean % (SD or 95% CI)	Total value (mmol/mol)
HbA1c included in *t* test (n=97)							
	Baseline, mean (SD)	48	8.69 (1.32)	71.5	49	8.89 (1.30)	73.7
	6 months, mean (SD)	48	7.88 (1.17)	62.6	49	8.13 (1.27)	65.4
	Change from baseline to 6 months, mean (95% CI)	48	0.82 (0.46-1.17)[a]	8.9	49	0.76 (0.41-1.11)[a]	8.3
HbA1c included in ANOVA[b] (n=89)							
	Baseline, mean (SD)	45	8.60 (1.19)	70.5	44	8.88 (1.32)	73.6
	3 months, mean (SD)	45	7.74 (1.06)	61.1	44	8.26 (1.16)	66.8
	6 months, mean (SD)	45	7.76 (1.00)	61.3	44	8.07 (1.29)	64.7

	Change from baseline to 3 months, mean (95% CI)	45	0.86 (0.47-1.26)[a]	9.4	44	0.62 (0.23-1.03)[a]	6.8
	Change from baseline to 6 months, mean (95% CI)	45	0.84 (0.38-1.26)[a]	9.2	44	0.81 (0.34-1.28)[a]	8.9

[a]Significant at the p=.001 level

[b]Analysis of variance (ANOVA).

A data discrepancy was detected during the repeated-measures ANOVA as 3 participants in the intervention group and 5 in the control group were not assessed at 3 months but were evaluated at 6 months. They had either refused the 3-month testing or their family physicians failed to provide their test results. Subsequent *t* tests indicated a lesser reduction in HbA1c (baseline to 6 months) for the controls lacking the 3-month data versus completers (p=.03). There were no differences in HbA1c (baseline to 6 months) for intervention participants lacking 3-month data versus those with complete data. Furthermore, no significant differences were found in baseline HbA1c levels for either intervention or controls participants with or without a 3-month HbA1c measure.

Table 7. HbA1c values for participants with and without 3-month measurements.

Measurement	Intervention group			Control group		
	3-month measure absent (n=3)	3-month measure present (n=45)	*P*	3-month measure absent (n=5)	3-month measure present (n=44)	*P*
Baseline HbA1c, mean % (SD)	9.97 (2.64)	8.60 (1.19)	.47	8.92 (1.19)	8.88 (1.33)	.95
Total HbA1c value (mmol/mol)	85.5	70.5		74	73.6	
Change in HbA1c (6 month-baseline), mean % (SD)	-0.40 (0.46)	-0.84 (1.08)	.47	-0.28 (0.19)	-0.81 (1.45)	.03

Table 8 presents that the HbA1c trend differences indicated with the repeated-measures ANOVA—$F_{1,89}$=3.022, p=.09—were due to the greater reduction of HbA1c at 3 months in the intervention versus control group. This between-group difference disappeared at 6 months with gains in the control group, and no further gains in the intervention group.

Table 8. Time-point comparison of HbA1c levels for intervention versus control groups.

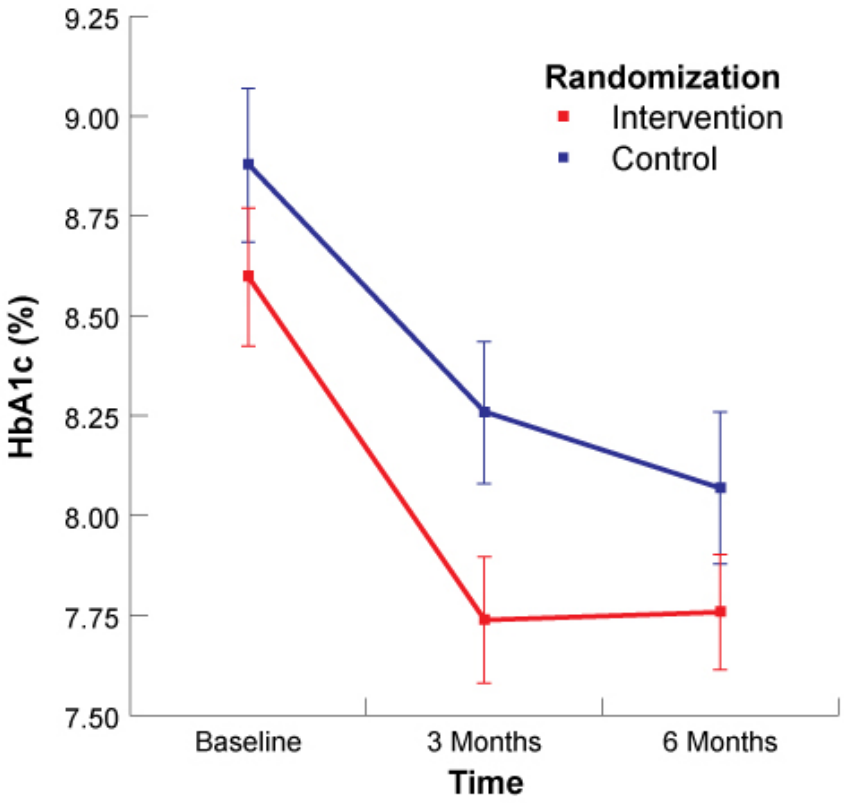
Time point	Between-group difference of % HbA1c (95% CI)	*P*
Baseline	0.280 (-0.250 to 0.810)	.30
3 months	0.515 (0.500 to 0.990)	.03
6 months	0.308 (-0.180 to 0.800)	.21

When the factorial repeated measures ANOVA was rerun controlling for participation in the EEP as a possible confounding variable, the model suggested change in HbA1c was independent of use of the onsite exercise program $F_{1,82}$=2.264, p=.136.

Table 9: Between-Group Effects on HbA1c controlling for the Exercise Education Program (Per Protocol)

	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
EER Participation	3.663	1	3.663	1.201	.276	.014
Group	6.907	1	6.907	2.264	.136	.027

Figure 18 – Mean HbA1c Levels Over Time



4.5.3 Secondary Outcomes: Body Composition (Per protocol)

We detected significant reductions in body weight (1.22 kg, 95% CI [0.35, 2.08]; p=.006) and waist circumference (2.23 cm, 95% CI [0.53, 3.93]; p=.01) in the intervention group, while the control group had no change. There were no significant changes in BMI in either group (10).

4.5.4 Secondary Outcomes: Psychometric Questionnaires (Per protocol)

A significant number of trial completers chose not to complete psychometric questionnaires at follow-up, resulting in their baseline outcomes being omitted from additional analyses (Table 10). Comparison of the baseline psychometric outcomes of completers and noncompleters indicated no significant differences.

Within-group, pre/post improvements in life satisfaction were detected in the intervention (+3.72, 95% CI [1.50, 5.94]; p=.001) and control groups (+3.77, 95% CI [1.30, 6.24]; p=.003) (Satisfaction with Life Scale). Similar improvements for both intervention and control groups were detected in the Hospital Anxiety and Depression Scale (HADS) depression subscale (-1.81, 95% CI [-2.81, -0.81]; p=.001; -1.70, 95% CI [-2.73, -0.67]; p=.002), and the Physical Composite Score of the SF-12 (+2.69, 95% CI [0.21, 5.17]; p=.03; +2.92, 95% CI [0.24, 5.60]; p=.03) (Table 10), although the control group demonstrated a significantly reduced HADS anxiety subscale score (-1.50, 95% CI [-2.73, -0.27]; p=.02), while the intervention group did not (-1.12, 95% CI [-2.29, 0.05]; p=.06) (Table 10). Significant between-group differences were found at the 6-month follow-up for negative affect (negative affect subscale of the Positive and Negative Affect Schedule [PANAS]) (+5.27, 95% CI [1.51, 9.04]; p=.007) favoring the intervention group (Table 10).

Table 10. Baseline, follow-up, and change values for all secondary outcomes.

Variable by group		n	Baseline, mean (SD or 95% CI)	6-month follow-up, mean (SD or 95% CI)	Change, mean (95% CI)	*P*
Weight (kg)						
	Intervention	41	93.66 (20.23)	92.44 (20.24)	-1.22 (0.35-2.08)[a]	.006
	Control	39	98.76 (24.02)	99.21 (24.77)	+0.45 (-1.33 to 0.44)	.32
	Difference between groups		5.10 (-4.78 to 14.98)	6.76 (-3.29 to 16.81)		
	P		.31	.18		
Waist circumference (cm)						
	Intervention	40	112.11 (14.50)	109.88 (14.82)	-2.23 (0.53-3.93)[a]	.01
	Control	37	113.88 (17.04)	114.00 (18.12)	+0.122 (-1.89 to 1.64)	.89
	Difference between groups		1.78 (-5.39 to 8.94)	4.13 (-3.36 to 11.62)		
	P		.62	.28		
Body mass index (kg/m^2)						
	Intervention	39	33.74 (6.70)	33.53 (6.80)	-0.21 (-0.24 to 0.66)	.35
	Control	36	37.00 (7.92)	37.21 (8.22)	-0.21 (-0.68 to 0.25)	.37
	Difference between groups		3.26 (-0.11 to 6.63)	3.69 (0.22-7.15)[a]		
	P		.06	.04		
Satisfaction with Life						
	Intervention	32	20.50 (7.71)	24.22 (6.33)	+3.72 (1.50-5.94)[b]	.001
	Control	26	18.04 (7.01)	21.81 (7.15)	+3.77 (1.30-6.24)[b]	.003
	Difference between groups		-2.46 (-1.46 to 6.38)	-2.41 (-1.14 to 5.96)		
	P		.21	.18		
HADS[c]: anxiety subscale						
	Intervention	33	7.39 (4.53)	6.27 (4.18)	-1.12 (-2.29 to 0.05)	.06
	Control	30	9.50 (4.49)	8.00 (5.06)	-1.50 (-2.73 to -0.27)[a]	.02
	Difference between groups		2.11 (-0.17 to 4.39)	1.73 (-0.60 to 4.06)		
	P		.07	.14		
HADS: depression subscale						
	Intervention	32	6.25 (3.99)	4.44 (3.32)	-1.81 (-2.81 to -0.82)[b]	.001
	Control	30	7.77 (4.06)	6.07 (4.38)	-1.70 (-2.73 to -0.67)[b]	.002
	Difference between groups		1.52 (-0.53 to 3.56)	1.63 (-0.34 to 3.60)		
	P		.14	.10		
PANAS[d]: positive affect subscale						
	Intervention	30	34.43 (8.46)	36.03 (7.65)	+1.60 (-1.00 to 4.20)	.22
	Control	27	31.22 (10.29)	31.67 (9.71)	+0.44 (-2.30 to 3.18)	.75
	Difference between groups		-3.21 (-1.77 to 8.19)	-4.37 (-0.25 to 8.98)		
	P		.20	.06		
PANAS: negative affect subscale						
	Intervention	31	16.58 (7.85)	14.55 (5.03)	-2.03 (-4.87 to 0.80)	.16
	Control	28	20.39 (9.57)	19.82 (9.04)	-0.57 (-3.55 to 2.41)	.70
	Difference between groups		3.81 (-0.73 to 8.36)	5.27 (1.51-9.04)[a]		
	P		.10	.007		

SF-12[e]: Physical Composite Score						
	Intervention	34	42.89 (8.69)	45.57 (7.54)	+2.69 (0.21-5.17)[a]	.03
	Control	29	41.63 (10.08)	44.55 (10.89)	+2.92 (0.24-5.60)[a]	.03
	Difference between groups		1.25 (-3.48 to 5.98)	1.02 (-3.65 to 5.68)		
	P		.60	.66		
SF-12: Mental Composite Score						
	Intervention	34	47.74 (11.11)	50.22 (10.29)	+2.48 (-1.10 to 6.05)	.17
	Control	29	41.68 (11.82)	44.50 (10.15)	+2.82 (-1.05 to 6.69)	.15
	Difference between groups		6.06 (0.28-11.85)[a]	5.72 (0.56-10.89)[a]		
	P		.04	.03		

[a]The change is significant, $p<.05$.
[b]The change is significant, $p<.005$.
[c]Hospital Anxiety and Depression Scale (HADS).
[d]Positive and Negative Affect Schedule (PANAS).
[e]12-Item Short Form Health Survey (SF-12).

4.5.5 Secondary Outcomes: Body Composition (Intention to Treat)

We detected significant reductions in body weight (0.798 kg, 95% CI [0.35, 2.08]; $p=.006$) and waist circumference (1.69 cm, 95% CI [0.55, 2.83]; $p=.004$) in the intervention group, while the control group had no change. There were no significant changes in BMI in either group (10).

4.5.6 Secondary Outcomes: Psychometric Questionnaires (Intention to Treat)

Within-group, pre/post improvements in life satisfaction were detected in the intervention (+2.16, 95% CI [0.84, 3.49]; $p=.002$) and control groups (+1.44, 95% CI [0.16, 2.72]; $p=.028$) (Satisfaction with Life Scale). Similar improvements for both intervention and control groups were detected in the Hospital Anxiety and Depression Scale (HADS) depression subscale (-1.04, 95% CI [0.42, 1.65]; $p=.001$; -0.79, 95% CI [0.18, 1.40]; $p=.012$), and the Physical Composite Score of the SF-12 (+1.63, 95% CI [0.17, 3.09]; $p=.029$; +1.46, 95% CI [0.3, 2.90]; $p=.046$) (Table 11), although the control group demonstrated a significantly reduced HADS anxiety subscale score (-0.71, 95% CI [0.02, 1.39]; $p=.044$), while the intervention group did not (0.69, 95% CI [-0.03, 1.40]; $p=.059$) (Table 11).

Table 11. Baseline, follow-up, and change values for all secondary outcomes (ITT)

Variable by group		n	Baseline, mean (SD or 95% CI)	6-month follow-up, mean (SD or 95% CI)	Change, mean (95% CI)	*P*
Weight (kg)						
	Intervention	63	91.64 (19.14)	90.84 (19.05)	-0.798 (.235 to 1.361)[a]	.006
	Control	63	95.80 (23.63)	96.11 (24.04)	+.312 (-.875 to 0.251)	.275
	Difference between groups		4.16 (-11.741 to 3.43)	5.27 (-12.92 to 2.38)		
	P		.28	.18		
Waist circumference (cm)						
	Intervention	61	110.96 (15.02)	109.27 (15.45)	-1.69 (.55 to 2.83)[b]	.004
	Control	62	112.17 (16.61)	112.40 (17.06)	+.23 (-1.36 to 0.91)	.694
	Difference between groups		1.21 (-6.86 to 4.45)	3.12 (-8.94 to 2.69)		
	P		.674	.290		
Body mass index (kg/m^2)						
	Intervention	58	33.56 (6.55)	33.41 (6.61)	-0.14 (-.15 to 0.44)	.336
	Control	61	35.91 (8.02)	36.07 (8.18)	+0.16 (-.44 to 1.26)	.271
	Difference between groups		2.36 (5.02 to 0.31)	2.66 (5.37 to 0.05)		
	P		.083	.054		
Satisfaction with Life						
	Intervention	55	19.58 (7.96)	21.74 (7.72)	+2.16 (0.84 to 3.49)[b]	.002
	Control	59	19.17 (7.00)	20.61 (7.19)	+1.44 (0.16 to 2.72)[a]	.028
	Difference between groups		.412 (-2.36 to 3.19)	1.14 (-1.63 to 3.90)		
	P		.769	.418		
HADS[c]: anxiety subscale						
	Intervention	54	7.50 (4.56)	6.81 (4.40)	+0.69 (-0.03 to 1.40)	.059
	Control	58	8.95 (4.52)	8.24 (4.73)	-0.71 (0.02 to 1.39)	.044
	Difference between groups		1.45 (-3.13 to 0.23)	1.43 (-3.14 to 0.29)		
	P		.091	.102		
HADS: depression subscale						
	Intervention		6.11 (3.98)	5.07 (3.68)	-1.04 (0.42 to 1.65)[b]	.001
	Control		7.18 (4.12)	6.39 (3.68)	-0.79 (0.18 to 1.40)[a]	.012
	Difference between groups		1.07 (-2.58 to 0.44)	1.32 (-2.80 to .17)		
	P		.164	.082		
PANAS[d]: positive affect subscale						
	Intervention	55	33.76 (8.39)	34.64 (8.07)	+0.87 (-2.30 to .55)	.227
	Control	55	32.40 (9.19)	32.69 (8.84)	+0.29 (-1.71 to 1.13)	.686
	Difference between groups		1.36 (-7.96 to 4.69)	1.95 (-1.25 to 5.15)		
	P		.418	.231		
PANAS: negative affect subscale						
	Intervention	55	17.13 (7.23)	15.98 (5.86)	-1.15 (-.44 to 2.73)	.154
	Control	56	20.20 (9.89)	20.18 (9.60)	-0.2 (-1.55 to 1.55)	.982

	Difference between groups		3.07 (-6.33 to .194)	4.20 (-7.20 to -1.2)		
	P		.065	.007[a]		
SF-12[e]: Physical Composite Score						
	Intervention	56	41.37 (9.54)	43.00 (9.31)	+1.63 (0.17 to 3.09)[a]	.029
	Control	58	40.90 (10.13)	42.36 (10.74)	+1.46 (0.3 to 2.90)[a]	.046
	Difference between groups		0.47 (-3.19 to 4.12)	0.64 (-3.10 to 4.37)		
	P		.801	.73		
SF-12: Mental Composite Score						
	Intervention	56	47.91 (10.02)	49.42 (9.52)	+1.50 (-3.57 to 0.56)	.152
	Control	58	44.10 (11.23)	45.51 (10.15)	+1.41 (-3.44 to 0.62)	.171
	Difference between groups		3.81 (-0.14 to 7.77)	3.91 (0.25 to 7.56)		
	P		.059	.036		

[a]The change is significant, $p<.05$.
[b]The change is significant, $p<.005$.
[c]Hospital Anxiety and Depression Scale (HADS).
[d]Positive and Negative Affect Schedule (PANAS).
[e]12-Item Short Form Health Survey (SF-12).

4.6 DISCUSSION

4.6.1 Principal Findings

Personalized health coaching with and without the provisions of mobile phone and related software support was assessed in a predominantly lower-SES population with poorly controlled T2DM. A total of 45% of participants reported household incomes of Can $25,000 or less, qualifying them as living at or beneath the Canada poverty line [184] while an additional 20.9% of participants reported household incomes between Can $25,000 and Can $50,000. Our findings suggest clinically significant within-group reductions in HbA1c in both groups but no significant between-group differences in HbA1c from baseline to 6 months according to per-protocol ($p=.83$) and intention-to-treat (LOCF) ($p=.48$) analyses.

There was a significant between-group difference in HbA1c at the 3-month time point (0.52%, $p=.03$) favouring the mobile phone-assisted group. However, this difference lost significance at 6 months as the control group's mean HbA1c reduction continued to improve while the intervention group's HbA1c level remained stable between 3 and 6 months (Figure 18).

This result indicates that clinically significant HbA1c reductions occurred at a faster rate with HC and mobile phone support than with solely HC support. The repeated-measures ANOVA analysis of three time points was affected by missing data; however, all missing control participants had no HbA1c reductions, resulting in an increased mean difference in remaining controls necessitating a larger effect size in the experimental condition to reflect a significant difference.

The purpose of increasing the frequency and intensity of any health behavior in T2DM patients is improved glucoregulation, which directly and/or indirectly influences health-related quality of life (HRQOL). It is important to assess HRQOL outcomes independently through secondary RCT analyses, as improvements in physical health not associated with positive changes in quality of life are not likely sustainable.

Observed weight and waist circumference differences also suggested comparative benefits for the mobile phone-assisted group versus controls. These included significant reductions in weight and waist circumference in the mobile phone group, which may be related to the food photo-journaling function of the CWP. By reviewing photographs of their meals, participants could reflect on portion size and nutritional value in discussion *with* the health coach. These photo-stimulated "teachable moments" appeared to improve dietary choices more than was evident in the health coach-only group. Those in the mobile phone group also subjectively reported value in photographing meals and recording glucose levels in response to in-depth semistructured interviews [185]. Reductions in negative affect are likely linked to intervention participants feeling fundamentally connected in their health-focused program as their mobile phone became a constant symbol of being able to access a genuinely concerned person (24 hours a day/7 days a week) whose sole purpose was to help address health concerns.

This feeling of health coach connectedness was a principal theme in the qualitative analyses of participant interviews [185].

Lower-SES populations confront higher mortality risks than equivalent higher-SES populations [12]. Due to a variety of challenges to health maintenance, individuals from lower-SES communities have poorer health status *and* use health care services more reactively [176]. They are also more likely to suffer from mental health conditions [186], *but* less likely to access mental health resources [187]. Our results indicate that psychological well-being within the overall sample improved from baseline to 6-month follow-up, specifically demonstrated in outcomes on the Satisfaction with Life and the Hospital Anxiety and Depression Scales. It is our conjecture that frequent (minimum once per week) communication with their HC was related to the improvements in self-reported mood. Although differences in our primary outcome (HbA1c level) were only trending toward significant between-group differences, significant differences appeared in other markers of basic health (ie, weight and waist circumference), and in the negative affect subscale of the PANAS. Once again, those who used the mobile phone subjectively reported value in photographing meals and recording blood glucose levels when responding to in-depth semistructured interviews [185].

The Connected Wellness Platform enabled self-monitoring and health coach interactions with intervention participants, providing a cloud-based platform for mobile phone-based health management. This system provided secure, two-way communication between client and health coach, with mobile phone data entry on relevant behaviors entered manually. While the restriction to manual entry was not ideal, Bluetooth functionality for glucometers and pedometers was not yet integrated into the system during the trial. Other chronic disease management systems with similar features have been tested for usability and functionality.

Notably, Martinez-Millana et al. [188] comprehensively tested a diabetes management system with 30 patients and assessed the speed accuracy of tracking with several Bluetooth-enabled devices (ie, glucometers and pedometers) and their performance with a variety of mobile phones and network connections. Although we did not focus on the same performance analysis criteria during this trial, the CWP went through multiple upgrades during the pilot trial [173], ensuring smoother functionality and a more refined user interface (Figures 13-16) for the RCT. Detailed user experience with the CWP was collected using semistructured interviews and is reported in a full-length article [185]. CWP-user data logs were also extracted and analyzed with data mining methods to evaluate more finely tuned associations between app use and clinical outcomes (in a submitted manuscript).

Careful titrations of health coach interventions, typically measured by the frequency and duration of patient-coach interactions, are important elements in determining the optimal HC contact for eliciting improved health at minimal cost. With too little interaction, HC interventions risk insignificant or unsustainable health improvements, while too much interaction results in overly expensive implementation. As such, studies using multiple intervention intensities are necessary to ultimately determine appropriate contact level. Although we did not specify a minimum-maximum intervention intensity during the trial (providing weekly contact was maintained), the mean interaction intensity was 38 min/week (SD 25). In both intervention and control conditions, significant improvements in HbA1c levels and psychological functioning were found. The mobile technology appeared useful in engaging participants more quickly such that significantly greater HbA1c reductions were evident at 3 months (compared to controls), which may have cost-effectiveness implications as these gains were stabilized and evident at 6 months, although additional improvements in controls ultimately erased the 3-month differences.

While the gains made at 3 months were sustained at 6 months (in the intervention group), there is no evidence that gains made in either group were sustained beyond the 6-month follow-up.

In contrast to our relatively high intensity human interaction intervention, Nundy et al. [11] used a mostly automated messaging system that followed a standardized curriculum delivered to participants electronically, while a registered nurse monitored their progress and only made outbound calls to patients in exceptional circumstances, specifically when the patient activated an 'alert'. While investigators were successful improving gluco-regulation in their intervention group by 0.7% (HbA1c) compared to control, this was a quasi-experimental, non-randomized design, where participants chose which group they participated in, leading to selection bias. This trial did succeed in estimating potential cost savings of $437USD for intervention participants [11]. Blackberry et al. [95] tested a less intensive telephonic health coach intervention provided by general practitioner nurses delivering a median of four coaching sessions/participant over 18 months, averaging 30 min/session and focused primarily on increasing medication adherence, lifestyle modification and symptom monitoring. Results indicated no differences between or within intervention and usual care control groups in HbA1c. Similarly, Holmen et al. [189] also found no differences in HbA1c between groups and only modest reductions within groups ranging from 0.31%, 95% CI [–0.67, 0.05] for the app only group, 0.16%, 95% CI [-.58, 0.29] for app with health coaching, and 0.15%, 95% CI [-0.5, 0.18] for control participants, also suggesting more intensive health coaching interventions are needed when accompanying remote monitoring technology.

A unique feature of our study was the enhanced usual care that at least partly explains gains achieved by both control and intervention participants. The BCCHC site maintained a clinical exercise program that was several yards from the primary care physician and diabetes

education team offices, symbolizing the importance of exercise in health maintenance, while serving patients in need. Moreover, the program provided T2DM patients with education, exercise prescription, and monitoring, which included the assessment of blood glucose levels before and after every supervised exercise session. This supported patients in recognizing the benefits of exercise in blood glucose regulation, and helped encourage adoption of home-based exercise programs. Since the HCs in this trial were all certified exercise specialists (through the Canadian Society for Exercise Physiology), exercise prescription was undertaken safely, with no adverse events, according to the highest evidence-based standards. A total of 23 intervention patients and 22 control patients participated in the Exercise Education Program. Although we might have included a control condition that did not access the EEP, the EEP was adopted as usual care at BCCHC and denial of access would have been unethical.

4.6.2 Limitations

As with any behavioral intervention, motivations to participate introduce potential biases as those who met inclusion criteria but declined to participate represent an unstudied population. This limits the generalizability of the intervention [122]. As well, the comparison group received health coach support (without mobile monitoring) as opposed to usual care. Not only did this enable a more clear understanding of the effect of electronic monitoring of health behavior on clinical outcomes, pilot trial findings suggested a usual care control condition (ie, no health coaching) would result in an unacceptably high attrition rate in the controls. The lack of between-group differences at 6 months may be due to other, more complex factors. For example, since health coaches were randomly assigned to participants in both arms, it is possible that more effort was expended in coaching the mobile phone-assisted arm. However, since the effect size of HbA1c reduction was similar across groups, this was unlikely. Furthermore, there could have been bias in the opposite direction, with health coaches expending more effort in assisting the

behavior change of control participants since these controls did not have the support of the mobile phone interactions. Also, although it would have been ideal to compare multiple glucose measures (eg, random blood sugar, fasting blood sugar), it was not possible at the participating sites. We were limited to reliable access only to HbA1c blood tests. We recognize, with other researchers, that glucose regulation is more complex than what is solely indicated in HbA1c assessment.

4.6.3 Conclusions

Although this trial did not indicate a significant between-group difference in improved glucoregulation, there were overall clinical and statistically significant improvements in HbA1c for participants in both health-coached groups. Given the pragmatic trial design, our findings suggest health coaching in primary care can improve the glucose management of poorly controlled T2DM in lower-SES community residents. It is evident that using mobile phones to further connect patients to health coaches and monitor health behaviors can lead to faster reductions in HbA1c, which may have specific benefits for cost savings and quality of life. Further research comparing health-coaching interventions of different contact intensities, using wearable biomonitoring devices, and using a true waitlist/control group will help evaluate health coach intervention effectiveness, as well as long-term adherence levels and cost/benefit results.

4.6.5 Acknowledgements

Funding was obtained through the Public Health Agency of Canada (Project #0690490). Additional funding was obtained from York University (Connected Health and Wellness Project) through the Federal Development Agency of Southern Ontario. We would also like to thank our community partners for their support and trust which made this trial possible, most specifically Ms Michelle Westin, Ms Cheryl Prescod, Dr Ali Torshizi, and Dr Howard To.

CHAPTER 5: GENERAL DISCUSSION

5.1 SUMMARY OF FINDINGS

This dissertation was aimed at determining whether health coaching with (and without) the use of smartphone technology could improve glucose management, clinical diabetes outcomes and well-being in a lower SES community in Toronto. Lessons learned from the pilot trial were instrumental in helping design the RCT protocol. Due to factors that affected our target population such as inflexible work schedules and distrust of academic research, we determined a usual care control group would have reduced recruitment, resulted in an unacceptable attrition rate and contributed to misinterpretations of academic goals and collaboration. This led to the decision to provide health coaching to the control group and compare it to health coaching with smartphone support. Experience from the pilot also demonstrated needs for adequate control of the measurement of our main outcome variable (HbA1c) and, specifically, to overcome inconsistent communication and testing from attending physicians, be they primary care physicians or endocrinologists. The pilot trial also provided opportunities to increase our academic collaboration within the Jane-Finch community of Toronto, which assisted in recruitment of the larger trial. It provided time to further develop the health coach curriculum and protocol, and recruit undergraduate kinesiology volunteers who were ultimately trained and employed as health coaches for the RCT. This pilot period served also to increase collaboration with the Black Creek Community Health Centre (BCCHC) and fully integrate the Exercise Education Program, a clinically-oriented community exercise program that became usual care at BCCHC and a model for other community health and primary care centres (Innovator of the Year Award - Association of Ontario Health Centres, 2014).

The pilot trial, which was executed by a single health coach, resulted in significant reductions in HbA1c for participants whose baseline HbA1c values were greater than 7.0% (-

.43%, p=.04). This finding suggested the RCT eligibility criteria should be set at a sufficiently high level that a significant effect-size was achievable and that a transition was theoretically reflected from poor glycemic control (≥7.3%) to a level of control where future complications would be minimized (7.0 or below).

The full scale RCT compared health coaching with smartphone support to health coaching alone and recruited n=131 participants who were intervened with by 6 health coaches. We found no significant differences in HbA1c changes when health coaching was delivered with or without smartphone-based connectivity using both per protocol (p=.481) and intention to treat (p=.825) principles. However, there were observed strong pre-post within-group effect sizes in HbA1c for both experimental and control groups (p=.001). Reductions in HbA1c values have the direct benefits of reducing the risks of diabetes-related complications, which are associated with significant detriments to quality of life [31], as well as increasing use of health care resources [190]. There were also significant reductions in body weight (1.22kg, 95% CI [0.351, 2.08]; p=.006) and waist circumference (2.23cm, 95% CI [0.53, 3.93]; p=.011) in the intervention group, while the control group had no change. We detected pre-post improvements with the Satisfaction with Life Scale for both the intervention (+3.72, 95% CI [1.50, 5.94]; p=.001) and control groups (+3.77, 95% CI [1.30, 6.24]; p=.003). Improvements in both groups were detected in the HADS-depression subscale (-1.81, 95% CI [-2.81, -.81]; p=.001; -1.70, 95% CI [-2.73, -.67]; p=.002) and the Physical Composite Score of the SF-12 (+2.69 95% CI [.21, 5.17]; p=.034; +2.92 95% CI [.24, 5.60]; p=.033). The control group did demonstrate a significantly reduced HADS-anxiety subscale score (-1.50, 95% CI [-2.73, -.27]; p=.017) while the intervention group did not (-1.12, 95% CI [-2.29, .05]; p=.060). There were also significant

between-group differences detected at 6 months in the Negative Affect subscale of the PANAS (5.27, 95% CI [1.51, 9.04]; p=.007) favoring the intervention group.

5.2 OVERALL LIMITATIONS

Both studies included in this dissertation contain methodological weaknesses that can be addressed in future studies. As with any behaviorally focused intervention, motivation to agree to participate introduces potential bias as those who met inclusion criteria but declined participation represent an unstudied population with potentially significant implications for intervention generalizability. While the pilot study enrolled only a small convenience sample with no control group (limiting generalizability of results), the comparison group in the RCT did receive health coach support (without smartphone monitoring) as opposed to usual care. This approach aimed to better understand which intervention features are most important in achieving better outcomes. But the absence of a third, usual care group (no health coaching), makes it impossible to validate the intervention effects. Despite this limitation, the decision to not include a usual care control in this trial was done purposefully to improve retention. Nonetheless, patients with type 2 diabetes typically do not improve at the levels observed without significant changes in behaviour [30]. In comparison with other HC interventions, our trial had specific differences that merited further exploration (especially the positive pre/post differences), in a lower SES population. It was also novel to integrate exercise education as a usual care service in both participating health care centre sites.

The mobile technology also did not always perform as planned. In the pilot trial, some participants experienced sporadic software glitches and server downtime that resulted in service disruptions. Although participants could directly log healthy behaviour self-observations via smartphone, their self-reports (like all self-reports) could have been falsified or exaggerated. Future studies could employ Bluetooth connected technology (i.e., glucometers, accelerometers)

to omit some self-report biases. While software glitches were minimized in the RCT, Bluetooth connected devices were out of the scope of the project and therefore there was still reliance on self-reported manual entry.

In the RCT, health coaches were randomly assigned to provide support to participants in both study arms, and it is possible that they purposely invested more effort in coaching the smartphone-assisted arm. However, it is likely that this was not the case and based on similar results between groups there could have been bias in the opposite direction, with health coaches putting more effort into assisting control participants since they did not have the support of the smartphone and related interactions.

Statistical methods employed in both studies separated subsamples from the larger sample to conduct the analysis. As we were interested in testing the feasibility of the intervention in the pilot trial with all patients, we set no minimum inclusion criteria, which resulted in n=7 well-managed diabetic patients to be enrolled (HbA1c<7.0%). This subsample had less room for improvement in their gluco-regulation, and therefore were more difficult to make any changes in HbA1c. To demonstrate an effect with the sample of interest (poorly managed diabetics) we split the sample and reanalyzed. This splitting of the sample has implications for validity of results, as it was a matter of convenience that the sample be split, and there may be other, underlying reasons why participants with <7.0% HbA1c did not change.

In the full scale RCT, we were most interested in the differences in HbA1c values from baseline to 6 months. Nonetheless, the presence of a 3-month time point permitted a trend analysis. An independent samples t-test was used as a primary outcome for the baseline to 6 month difference between groups, and we used a factorial repeated measures ANOVA (group as factor) to evaluate trends in the outcomes for both within-group and between-group differences.

Unfortunately, due to a small number of participants who did not provide a 3 month measure, the ANOVA ignored their measures all together (n=6). Separate analysis on this subsample revealed no baseline difference with the rest of participants. Similar literature uses linear mixed effects models for analysis of repeated measures, which is able to handle missing data using random effects [101,105,106]. In our situation, the decision was made to not use linear mixed effects since we had at most only three time points, and were most interested in the difference between baseline and 6 months. Using factorial repeated measures ANOVA, there was some data loss, but we have a robust outcome illustrating the effects between intervention groups, and within intervention groups.

Finally, both trials relied on HbA1c, although it would have been ideal to compare multiple glucose measures (e.g. random blood sugars, fasting blood sugar). This was simply not possible at participating sites. We had reliable access to HbA1c blood tests only. We recognize, with other researchers, that glucose regulation is more complex than what is evident in HbA1c assessment.

5.3 FUTURE DIRECTIONS

Health coaching for the management and prevention of chronic disease is gaining momentum in the literature and suggests excellent promise at helping health care systems better manage the inflating rates of chronic disease. Ensuring health coaches receive sufficient evidence-based training, and maintain an intensity of interaction with participants during the intervention period that will elicit the intended behaviour change are important considerations when planning health coach interventions. While a mean of 38 minutes (SD 25) per week of health coach interaction in our trial produced significant improvements in our sample population (in both groups), further research should titrate other intensities of interaction to determine the most cost effective intensity levels. While determining optimal levels of health coaching can be

difficult due to individual differences in clients and coaches, a range of potential intensities with estimated outcome probabilities would help future health coaching interventions anticipate personnel costs and anticipate realistic outcomes.

Although our RCT indicated no significant differences in the primary outcome between the mobile vs. health coach only groups, personal testimony regarding the mobile system suggests the delivery of health coach interventions will improve when they rely on a combination of competent health coaching and the seamless integration of mobile technology in assisting with communication with and monitoring of participants [185]. The integration of automatically entered behavioural and outcome data into a smartphone monitoring system such as Bluetooth enabled accelerometers and glucometers will reduce self-report bias and error, and improve health coach/participant interaction efficiency by reducing unnecessary interaction events, and increasing timely interactions when a relapse event occurs. As technology improves, patients and coaches will have access to better measurement instruments that can monitor in real time, are not cumbersome to wear, and indicate deviations from predefined parameters of acceptable biomarkers. Examples of upcoming technologies that may be highly beneficial to health coach/ patient interaction by providing 24-hour monitoring include heart rate variability [191], ECG [192], continuous glucose monitoring [193], and tidal volume variability and respiration rate [194]. These technologies will make health coaching patients with other chronic diseases like Chronic Obstructed Pulmonary Disorder (COPD), Cardiovascular Diseases, T2DM and Heart Failure more precise by integrating disease relevant behaviour change with more sophisticated monitoring technologies.

Health coach interventions will have an even greater impact for Canada's most vulnerable and marginalized populations, who have greater disease prevalence yet use more health care

services [176], have more trouble accessing service in Canada's public health system [165], and struggle to manage their conditions [19]. Although more research is needed, as clients change their behaviour toward healthier outcomes, they should have fewer complications, less visits to the emergency room, and use less health care resources. When titration of health coaching intensity is properly balanced, the system should experience a net positive return for health care dollars, especially if peer health coaching is utilized [112].

5.4 CONCLUSION

Concerns over the growing prevalence of chronic disease and public healthcare sustainability in Canada necessitate creative, evidence-based interventions to reduce systemic and personal loss associated with preventable illness. Traditionally, the Canadian Medicare system originated as a model that focused on treating acute medical conditions such as trauma and infection, where treatments were relatively brief and patients were 'cured'. Our public health system was not intended to manage primarily chronic, lifelong conditions. Tommy Douglas, the father of Canada's medical system stated that, "Only through the practice of preventive medicine will we keep the costs from becoming so excessive that the public will decide that Medicaid is not in the best interest of the people of the country" – Tommy Douglas [195]. Yet the majority of healthcare costs now come from chronic conditions with significant behavioural risk factors [196]. Although effort is needed to prevent chronic disease, once a patient develops a condition, obtaining optimal control of identifiable disease processes (like blood glucose regulation) is pivotal to maintaining quality of life and limiting healthcare expenditures. Health behaviour change, with health coach and smartphone support, may prove to be an effective and cost effective way to improve the health of patients living with chronic disease. This set of studies, amongst other demonstrations, indicated that individuals with minimal pre-exposures to smartphone technology could use the devices effectively, and achieve clinical benefits.

REFERENCES

1. Hu FB, Stampfer MJ, Haffner SM, Solomon CG, Willett WC, Manson JE. Elevated risk of cardiovascular disease prior to clinical diagnosis of type 2 diabetes. Diabetes Care 2002/06/28 ed 2002;25(7):1129–1134. PMID: 12087009

2. Leitzmann MF, Park Y, Blair A, Ballard-Barbash R, Mouw T, Hollenbeck AR, et al. Physical activity recommendations and decreased risk of mortality. Arch Intern Med 2007 Dec 10;167(22):2453–60. PMID: 18071167

3. Assocation CD. The Cost of Diabetes in Ontario. 2009.

4. Association CD. An Economic Tsunami: The Cost of Diabetes in Canada. Toronto; 2009.

5. Branch HA. Key Performance Measures for the Ontario Diabetes Strategy Final Report. Toronto: Health Analytics Branch Ontario Ministry of Health and Long-Term Care; 2013.

6. McBrien K a, Manns BJ, Chui B, Klarenbach SW, Rabi D, Ravani P, et al. Health care costs in people with diabetes and their association with glycemic control and kidney function. Diabetes Care 2013 May;36(5):1172–80. PMID: 23238665

7. Seaquist ER. Addressing the burden of diabetes. JAMA 2014 Jun 11;311(22):2267–8. PMID: 24915253

8. Federation ID. IDF Diabetes Atlas (6th ed.). Brussels, Belguim: International Diabetes Federation; 2013.

9. American Diabetes Association. National Diabetes Statistics Report , 2014 Estimates of Diabetes and Its Burden in the Epidemiologic estimation methods. Natl Diabetes Stat Rep 2014;2009–2012.

10. Ministry of Finance. TABLE 1 - Operating : Summary for the Fiscal Year of Total Including Consolidation and Other Adjustments. 2014.

11. Nundy S, Dick JJ, Chou CH, Nocon RS, Chin MH, Peek ME. Mobile phone diabetes project led to improved glycemic control and net savings for chicago plan participants. Health Aff 2014 Feb 3;33(2):265–272. PMID: 24493770

12. Saydah SH, Imperatore G, Beckles GL. Socioeconomic status and mortality: contribution of health care access and psychological distress among U.S. adults with diagnosed diabetes. Diabetes Care 2013 Jan;36(1):49–55. PMID: 22933434

13. Dinca-Panaitescu S, Dinca-Panaitescu M, Bryant T, Daiski I, Pilkington B, Raphael D. Diabetes prevalence and income: Results of the Canadian Community Health Survey. Health Policy 2011;99(2):116–123. PMID: 20724018

14. Saelens BE, Sallis JF, Frank LD. Environmental correlates of walking and cycling: findings from the transportation, urban design, and planning literatures. Ann Behav Med 2003;25(2):80–91. PMID: 12704009

15. Perez DF, Ritvo PG, Brown PE, Holowaty E, Ardern C. Perceived walkability, social support, age, native language, and vehicle access as correlates of physical activity: a cross-sectional study of low-socioeconomic status, ethnic, minority women. J Phys Act Health 2011;8(8):1098–1107. PMID: 22039128

16. Booth GL, Creatore MI, Moineddin R, Gozdyra P, Weyman JT, Matheson FI, et al. Unwalkable neighborhoods, poverty, and the risk of diabetes among recent immigrants to Canada compared with long-term residents. Diabetes Care 2013 Feb;36(2):302–8. PMID: 22988302

17. Davachi S, Flynn MA, Edwards AL. A Health Region / Community Partnership for Type 2 Diabetes Risk Factor Screening in Indo-Asian Communities. Can J diabetes 2005;29(2):87–94.

18. Stryer D. Diabetes Disparities Among Racial and Ethnic Minorities. Rockville, MD; 2001.

19. Pilkington B, Daiski I, Bryant T, Dinca-panaitescu M, Dinca-panaitescu S, Raphael D. The Experience of Living with Diabetes for Low-income Canadians. Can J Diabetes 2010 Jan;34(2):119–126.

20. Spann SJ, Gillespie CF, Davis JS, Brown A, Schwartz A, Wingo A, et al. The association between childhood trauma and lipid levels in an adult low-income, minority population. Gen Hosp Psychiatry Elsevier Inc.; 2014;36(2):150–155. PMID: 24315076

21. Rich-Edwards JW, Spiegelman D, Lividoti Hibert EN, Jun H-J, Todd TJ, Kawachi I, et al. Abuse in childhood and adolescence as a predictor of type 2 diabetes in adult women. Am

J Prev Med 2010;39(6):529–36. PMID: 21084073

22. Miller SA, Mancuso CA, Boutin-Foster C, Michelen W, McLean-Long C, Foote B, et al. Associations between posttraumatic stress disorder and hemoglobin A1C in low-income minority patients with diabetes. Gen Hosp Psychiatry Elsevier Inc.; 2011;33(2):116–122. PMID: 21596204

23. Kendall-Tackett K a, Marshall R. Victimization and diabetes: an exploratory study. Child Abuse Negl 1999;23(6):593–6. PMID: 10391516

24. Mason SM, Wright RJ, Hibert EN, Spiegelman D, Jun H-J, Hu FB, et al. Intimate partner violence and incidence of type 2 diabetes in women. Diabetes Care 2013;36(5):1159–65. PMID: 23248189

25. Elliott DE, Bjelajac P, Fallot RD, Markoff LS, Reed BG. Trauma-informed or trauma-denied: Principles and implementation of trauma-informed services for women. J Community Psychol 2005;33(4):461–477.

26. Kahn SE. The relative contributions of insulin resistance and beta-cell dysfunction to the pathophysiology of Type 2 diabetes. Diabetologia 2003 Jan;46(1):3–19. PMID: 12637977

27. Association AD. Diagnosis and classification of diabetes mellitus. Diabetes Care 2010 Jan;33 Suppl 1:S62–9. PMID: 20042775

28. Creatore MI, Moineddin R, Booth G, Manuel DH, DesMeules M, McDermott S, et al. Age- and sex-related prevalence of diabetes mellitus among immigrants to Ontario, Canada. CMAJ 2010 May 18;182(8):781–9. PMID: 20403889

29. Sacks DB, John WG. Interpretation of hemoglobin a1c values. JAMA 2014 Jun 11;311(22):2271–2. PMID: 24915255

30. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes 2013;37(suppl 1):S1–S212.

31. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 2000 Aug 12;321(7258):405–12. PMID: 10938048

32. Lim EL, Hollingsworth KG, Aribisala BS, Chen MJ, Mathers JC, Taylor R. Reversal of type 2 diabetes: normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol. Diabetologia 2011/06/10 ed 2011 Oct;54(10):2506–14. PMID: 21656330

33. Strachan MWJ, Reynolds RM, Marioni RE, Price JF. Cognitive function, dementia and type 2 diabetes mellitus in the elderly. Nat Rev Endocrinol Nature Publishing Group; 2011 Feb;7(2):108–14. PMID: 21263438

34. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. Diabetes Care 2001 Jun;24(6):1069–78. PMID: 11375373

35. Everson-Rose S a, Lewis TT. Psychosocial factors and cardiovascular diseases. Annu Rev Public Health 2005 Jan;26:469–500. PMID: 15760298

36. Knol MJ, Twisk JWR, Beekman a TF, Heine RJ, Snoek FJ, Pouwer F. Depression as a risk factor for the onset of type 2 diabetes mellitus. A meta-analysis. Diabetologia 2006 May;49(5):837–45. PMID: 16520921

37. Eaton WW, Armenian H, Gallo J, Pratt L, Ford DE. Depression and risk for onset of type II diabetes. A prospective population-based study. Diabetes Care 1996 Oct;19(10):1097–102. PMID: 8886555

38. Yu M, Zhang X, Lu F, Fang L. Depression and Risk for Diabetes: A Meta-Analysis. Can J Diabetes Elsevier Ltd; 2015;39(4):266–272.

39. Zambanini A, Newson RB, Maisey M, Feher MD. Injection related anxiety in insulin-treated diabetes. Diabetes Res Clin Pract 1999 Dec;46(3):239–246.

40. Frier BM. How hypoglycaemia can affect the life of a person with diabetes. 2008;(December 2007):87–92.

41. Neal DT, Wood W, Drolet A. How do people adhere to goals when willpower is low? The profits (and pitfalls) of strong habits. J Pers Soc Psychol 2013 Jun;104(6):959–75. PMID: 23730907

42. Biessels GJ, Deary IJ, Ryan CM. Cognition and diabetes: a lifespan perspective. Lancet

Neurol 2008 Feb;7(2):184–90. PMID: 18207116

43. Cryer PE. Hypoglycemia: still the limiting factor in the glycemic management of diabetes. Endocr Pract 2008 Sep;14(6):750–6. PMID: 18996798

44. Yang B, Cross DF, Ollerenshaw M, Millward B a, Demaine AG. Polymorphisms of the vascular endothelial growth factor and susceptibility to diabetic microvascular complications in patients with type 1 diabetes mellitus. J Diabetes Complications 2003 Jan;17(1):1–6.

45. Perlmuter LC, Flanagan BP, Shah PH, Singh SP. Glycemic control and hypoglycemia: is the loser the winner? Diabetes Care 2008 Oct;31(10):2072–6. PMID: 18820231

46. Bienvenu OJ, Eaton WW. The epidemiology of blood-injection-injury phobia. Psychol Med 1998 Sep;28(5):1129–36. PMID: 9794020

47. Metsch J, Tillil H, Köbberling J, Sartory G. On the relation among psychological distress, diabetes-related health behavior, and level of glycosylated hemoglobin in type I diabetes. Int J Behav Med 1995 Jan;2(2):104–17. PMID: 16250780

48. Anderson RJ, Grigsby AB, Freedland KE, de Groot M, McGill JB, Clouse RE, et al. Anxiety and poor glycemic control: a meta-analytic review of the literature. Int J Psychiatry Med 2002 Jan;32(3):235–47. PMID: 12489699

49. Kessler RC, Petukhova M, Sampson NA, Zaslavsky AM, Wittchen H-U. Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. Int J Methods Psychiatr Res 2012 Sep;21(3):169–84. PMID: 22865617

50. Riddell M, Burr J. Evidence-based risk assessment and recommendations for physical activity clearance: diabetes mellitus and related comorbidities. Appl Physiol Nutr Metab 2011 Jul;36 Suppl 1:S154–89. PMID: 21800941

51. Riddell M, Fowles J. How to treat prediabetes with exercise – effectively. Diabetes Clin Pract Guid 2010;

52. Sigal RJ, Kenny GP, Boulé NG, Wells GA, Prud'homme D, Fortier M, et al. Effects of aerobic training, resistance training, or both on glycemic control in type 2 diabetes: a randomized trial. Ann Intern Med 2007 Sep 18;147(6):357–69. PMID: 17876019

53. Church TS, Blair SN, Cocreham S, Johannsen N, Johnson W, Kramer K, et al. Effects of aerobic and resistance training on hemoglobin A1c levels in patients with type 2 diabetes: a randomized controlled trial. JAMA 2010 Nov 24;304(20):2253–62. PMID: 21098771

54. Lynch J, Helmrich SP, Lakka TA, Kaplan GA, Cohen RD, Salonen R, et al. Moderately intense physical activities and high levels of cardiorespiratory fitness reduce the risk of non-insulin-dependent diabetes mellitus in middle-aged men. Arch Intern Med 1996 Jun 24;156(12):1307–14. PMID: 8651839

55. Fortier MS, Sweet SN, Tulloch H, Blanchard CM, Sigal RJ, Kenny GP, et al. Self-determination and exercise stages of change: results from the Diabetes Aerobic and Resistance Exercise trial. J Health Psychol 2012 Jan;17(1):87–99. PMID: 21610009

56. Goodyear LJ, Kahn BB. Exercise, glucose transport, and insulin sensitivity. Annu Rev Med 1998 Jan;49:235–61. PMID: 9509261

57. Gornall A, Lévesque L, Sigal RJ. A Pilot Study of Physical Activity Education Delivery in Diabetes Education Centres in Ontario. Can J Diabetes 2008 Jan;32(2):123–130.

58. Colley RC, Garriguet D, Janssen I, Craig CL, Clarke J, Tremblay MS. Physical activity of Canadian adults: accelerometer results from the 2007 to 2009 Canadian Health Measures Survey. Heal reports 2011 Mar;22(1):7–14. PMID: 21510585

59. Dillman CJ, Shields CA, Fowles JR, Perry A, Murphy RJL, Dunbar P. Including Physical Activity Exercise in Diabetes Management: Diabetes Educators' Perceptions of Their Own Abilities the Abilities of Their Patients. Can J Diabetes 2010 Jan;34(3):218–226.

60. Salas-Salvadó J, Martinez-González MÁ, Bulló M, Ros E. The role of diet in the prevention of type 2 diabetes. Nutr Metab Cardiovasc Dis 2011 Sep;21 Suppl 2:B32–48. PMID: 21745730

61. Salas-Salvadó J, Bulló M, Babio N, Martínez-González MÁ, Ibarrola-Jurado N, Basora J, et al. Reduction in the incidence of type 2 diabetes with the Mediterranean diet: results of the PREDIMED-Reus nutrition intervention randomized trial. Diabetes Care 2011 Jan;34(1):14–9. PMID: 20929998

62. Ajala O, English P, Pinkney J. Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes. Am J Clin Nutr 2013 Mar;97(3):505–16. PMID: 23364002

63. Malik VS, Popkin BM, Bray G a, Després J-P, Willett WC, Hu FB. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. Diabetes Care 2010 Nov;33(11):2477–83. PMID: 20693348

64. de Koning L, Malik VS, Rimm EB, Willett WC, Hu FB. Sugar-sweetened and artificially sweetened beverage consumption and risk of type 2 diabetes in men. Am J Clin Nutr 2011 Jun;93(6):1321–7. PMID: 21430119

65. Lily M, Godwin M. Treating prediabetes with metform: Systematic review and meta-analysis. Can Fam Physician 2009;55(4):363–369.

66. Viollet B, Guigas B, Sanz Garcia N, Leclerc J, Foretz M, Andreelli F. Cellular and molecular mechanisms of metformin: an overview. Clin Sci (Lond) 2012 Mar;122(6):253–70. PMID: 22117616

67. Ekström N, Schiöler L, Svensson A-M, Eeg-Olofsson K, Miao Jonasson J, Zethelius B, et al. Effectiveness and safety of metformin in 51 675 patients with type 2 diabetes and different levels of renal function: a cohort study from the Swedish National Diabetes Register. BMJ Open 2012 Jan;2(4). PMID: 22798258

68. Harper W, Clement M, Goldenberg R, Hanna A, Main A, Retnakaran R, et al. Pharmacologic management of type 2 diabetes. Can J diabetes Canadian Diabetes Association; 2013 Apr;37 Suppl 1:S61–8. PMID: 24070965

69. Clemens KK, McArthur E, Dixon SN, Fleet JL, Hramiak I, Garg AX. The Hypoglycemic Risk of Glyburide (Glibenclamide) Compared with Modified-Release Gliclazide. Can J Diabetes Elsevier Inc; 2015;39(4):308–316.

70. Marcum Z a, Zheng Y, Perera S, Strotmeyer E, Newman AB, Simonsick EM, et al. Prevalence and correlates of self-reported medication non-adherence among older adults with coronary heart disease, diabetes mellitus, and/or hypertension. Res Social Adm Pharm Elsevier Inc; 2013;9(6):817–27. PMID: 23291338

71. Gonzalez JS, Schneider HE, Wexler DJ, Psaros C, Delahanty LM, Cagliero E, et al. Validity of medication adherence self-reports in adults with type 2 diabetes. Diabetes Care 2013 Apr;36(4):831–7. PMID: 23204245

72. Tamblyn R, Eguale T, Huang A, Winslade N, Doran P. The incidence and determinants of primary nonadherence with prescribed medication in primary care: a cohort study. Ann Intern Med 2014 Apr 1;160(7):441–50. PMID: 24687067

73. Turner R, Holman R, Cull C. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. Lancet 1998;352(9131):837.

74. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAW. 10-Year Follow-Up of Intensive Glucose Control in Type 2 Diabetes. N Engl J Med 2008 Oct 9;359(15):1577–89. PMID: 18784090

75. Novak M, Björck L, Giang KW, Heden-Ståhl C, Wilhelmsen L, Rosengren a. Perceived stress and incidence of Type 2 diabetes: a 35-year follow-up study of middle-aged Swedish men. Diabet Med 2013 Jan;30(1):e8–16. PMID: 23075206

76. Brunner EJ, Kivimäki M. Epidemiology: work-related stress and the risk of type 2 diabetes mellitus. Nat Rev Endocrinol Nature Publishing Group; 2013 Aug;9(8):449–50. PMID: 23797820

77. Daubenmier J, Kristeller J, Hecht FM, Maninger N, Kuwata M, Jhaveri K, et al. Mindfulness Intervention for Stress Eating to Reduce Cortisol and Abdominal Fat among Overweight and Obese Women: An Exploratory Randomized Controlled Study. J Obes 2011 Jan;2011:651936. PMID: 21977314

78. Rooney DP, Neely RD, Cullen C, Ennis CN, Sheridan B, Atkinson AB, et al. The effect of cortisol on glucose/glucose-6-phosphate cycle activity and insulin action. J Clin Endocrinol Metab 1993 Nov;77(5):1180–3. PMID: 8077310

79. Jacobs TL, Shaver PR, Epel ES, Zanesco AP, Aichele SR, Bridwell DA, et al. Self-reported mindfulness and cortisol during a Shamatha meditation retreat. Health Psychol 2013 Oct;32(10):1104–9. PMID: 23527522

80. Matousek RH, Dobkin PL, Pruessner J. Cortisol as a marker for improvement in mindfulness-based stress reduction. Complement Ther Clin Pract Elsevier Ltd; 2010 Feb;16(1):13–9. PMID: 20129404

81. Pagnoni G, Cekic M. Age effects on gray matter volume and attentional performance in Zen meditation. Neurobiol Aging 2007 Oct;28(10):1623–7. PMID: 17655980

82. Ritvo P, Vora K, Irvine J. Reductions in Negative Automatic Thoughts in Students Attending Mindfulness Tutorials Predicts Increased Life Satisfaction. Int …

2013;2(3):274–298.

83. Surwit RS, van Tilburg MAL, Zucker N, McCaskill CC, Parekh P, Feinglos MN, et al. Stress management improves long-term glycemic control in type 2 diabetes. Diabetes Care 2002 Jan;25(1):30–4. PMID: 11772897

84. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. Gen Hosp Psychiatry 1982 Apr;4(1):33–47. PMID: 7042457

85. Rosenzweig S, Reibel DK, Greeson JM, Edman JS, Jasser SA, McMearty KD, et al. Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: a pilot study. Altern Ther Health Med 2007;13(5):36–8. PMID: 17900040

86. Zhang D a., Katznelson L, Li M. Postprandial Glucose Monitoring Further Improved Glycemia, Lipids, and Weight in Persons with Type 2 Diabetes Mellitus Who Had Already Reached Hemoglobin A1c Goal. J Diabetes Sci Technol 2012 Mar 1;6(2):289–293.

87. Polonsky WH, Fisher L, Schikman CH, Hinnen D a, Parkin CG, Jelsovsky Z, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. Diabetes Care 2011 Feb;34(2):262–7. PMID: 21270183

88. Evans JMM, Mackison D, Swanson V, Donnan PT, Emslie-Smith A, Lawton J. Self-monitoring among non-insulin treated patients with type 2 diabetes mellitus: Patients' behavioural responses to readings and associations with glycaemic control. Diabetes Res Clin Pract Elsevier Ireland Ltd; 2013 May;100(2):235–42. PMID: 23523283

89. Rocco A, Heuschmann PU, Schellinger PD, Köhrmann M, Diedler J, Sykora M, et al. Glycosylated hemoglobin A1 predicts risk for symptomatic hemorrhage after thrombolysis for acute stroke. Stroke 2013 Aug;44(8):2134–8. PMID: 23715962

90. Baillot A, Pelletier C, Dunbar P, Geiss L, Johnson J a, Leiter L a, et al. Profile of adults with type 2 diabetes and uptake of clinical care best practices: results from the 2011 Survey on Living with Chronic Diseases in Canada - Diabetes component. Diabetes Res Clin Pract 2014 Jan;103(1):11–9. PMID: 24369983

91. Funnell MM. Peer-based behavioural strategies to improve chronic disease self-

management and clinical outcomes: evidence, logistics, evaluation considerations and needs for future research. Fam Pract 2010;27 Suppl 1(June 2009):17–22. PMID: 19509083

92. Palmer S, Tubbs I, Whybrow A. Health coaching to facilitate the promotion of healthy behaviour and achievement of health-related goals. Int J Heal Promot Educ 2003;41(3):91–93.

93. Wolever RQ, Simmons LA, Sforzo GA, Dill D, Kaye M, Bechard EM, et al. A Systematic Review of the Literature on Health and Wellness Coaching: Defining a Key Behavioral intervention in Healthcare. Glob Adv Health Med 2013 Jul;2(4):38–57. PMID: 24416684

94. Liddy C, Johnston S, Nash K, Ward N, Irving H. Health coaching in primary care: a feasibility model for diabetes care. BMC Fam Pract BMC Family Practice; 2014 Jan;15(1):60. PMID: 24708783

95. Blackberry ID, Furler JS, Best JD, Chondros P, Vale M, Walker C, et al. Effectiveness of general practice based, practice nurse led telephone coaching on glycaemic control of type 2 diabetes: the Patient Engagement and Coaching for Health (PEACH) pragmatic cluster randomised controlled trial. BMJ 2013 Jan;347(September):f5272. PMID: 24048296

96. Young D, Furler J, Vale M, Walker C, Segal L, Dunning P, et al. Patient Engagement and Coaching for Health: The PEACH study--a cluster randomised controlled trial using the telephone to coach people with type 2 diabetes to engage with their GPs to improve diabetes care: a study protocol. BMC Fam Pract 2007 Jan;8:20. PMID: 17428318

97. Frosch DL, Uy V, Ochoa S, Mangione CM. Evaluation of a Behavior Support Intervention for Patients With Poorly Controlled Diabetes. Arch Intern Med 2011;171(22):2011–2017. PMID: 21986347

98. Walker EAE, Shmukler C, Ullman R, Blanco E, Scollan-Koliopoulus M, Cohen HW. Results of a Successful Telephonic Intervention to Improve Diabetes Control in Urban Adults A randomized trial. Diabetes … 2011 Jan;34(1):2–7. PMID: 21193619

99. Nishita C, Cardazone G, Uehara DL, Tom T. Empowered Diabetes Management: Life Coaching and Pharmacist Counseling for Employed Adults With Diabetes. Heal Educ Behav 2013 Oct 1;40(5):581–591.

100. Griffiths KE, Campbell M a. Regulating the regulators: Paving the way for international, evidence-based coaching standards. Int J Evid Based Coach Mentor 2008;6(1):19–31.

101. Ruggiero L, Riley BB, Hernandez R, Quinn LT, Gerber BS, Castillo a., et al. Medical Assistant Coaching to Support Diabetes Self-Care Among Low-Income Racial/Ethnic Minority Populations: Randomized Controlled Trial. West J Nurs Res 2014;36(9):1052–1073.

102. Varney J, Weiland T, Inder W, Jelinek G. The effect of hospital-based telephone coaching on glycaemic control and adherence to management guidelines in type 2 diabetes, a randomised controlled trial. Intern Med J 2014;44(9). PMID: 24963611

103. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker E a, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002 Feb 7;346(6):393–403. PMID: 11832527

104. Venditti EM, Wylie-Rosett J, Delahanty LM, Mele L, Hoskin M a, Edelstein SL. Short and long-term lifestyle coaching approaches used to address diverse participant barriers to weight loss and physical activity adherence. Int J Behav Nutr Phys Act International Journal of Behavioral Nutrition and Physical Activity; 2014 Jan;11(1):16. PMID: 24521153

105. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011 Sep;34(9):1934–42. PMID: 21788632

106. Quinn CC, Shardell MD, Terrin ML, Barr E a, Park D, Shaikh F, et al. Mobile Diabetes Intervention for Glycemic Control in 45- to 64-Year-Old Persons With Type 2 Diabetes. J Appl Gerontol 2014 Aug 6; PMID: 25098253

107. Grindrod KA, Li M, Gates A. Evaluating User Perceptions of Mobile Medication Management Applications With Older Adults: A Usability Study. JMIR mhealth uhealth 2014 Mar 14;2(1):e11.

108. Quinn CC, Sareh PL, Shardell ML, Terrin ML, Barr E a, Gruber-Baldini AL. Mobile Diabetes Intervention for Glycemic Control: Impact on Physician Prescribing. J Diabetes Sci Technol 2014 Feb 5;8(2):362–370. PMID: 24876589

109. Basak Cinar A, Schou L. Health promotion for patients with diabetes: health coaching or formal health education? Int Dent J 2014 Feb;64(1):20–8. PMID: 24117102

110. Holmen H, Torbjornsen A, Wahl AK, Jenum AK, Smastuen MC, Arsand E, et al. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type 2 Diabetes, Part 2: One-Year Results From the Norwegian Randomized Controlled Trial RENEWING HEALTH. JMIR Mhealth Uhealth 2014;2(4):e57. PMID: 25499872

111. Ghorob A, Vivas MM, De Vore D, Ngo V, Bodenheimer T, Chen E, et al. The effectiveness of peer health coaching in improving glycemic control among low-income patients with diabetes: protocol for a randomized controlled trial. BMC Public Health LONDON; 236 GRAYS INN RD, FLOOR 6, LONDON WC1X 8HL, ENGLAND: BIOMED CENTRAL LTD; 2011 Jan;11(Journal Article):208. PMID: 21457567

112. Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: A randomized controlled trial. Ann Fam Med 2013;11(2):137–144. PMID: 23508600

113. Huffman M. Health coaching: a new and exciting technique to enhance patient self-management and improve outcomes. Home Healthc Nurse 2007 Apr;25(4):271–4; quiz 275–6. PMID: 17426499

114. Butterworth SW, Linden A, McClay W. Health Coaching as an Intervention in Health Management Programs. Dis Manag Heal Outcomes 2007;15(5):299–307.

115. Linden A, Butterworth SW, Prochaska JO. Motivational interviewing-based health coaching as a chronic care intervention. J Eval Clin Pract MALDEN; COMMERCE PLACE, 350 MAIN ST, MALDEN 02148, MA USA: WILEY-BLACKWELL PUBLISHING, INC; 2010;16(1):166–174.

116. Snyder S. Health coaching education: a conversation with pioneers in the field. Glob Adv Health Med 2013 May;2(3):12–24. PMID: 24416669

117. Wolever RQ, Dreusicke M, Fikkan J, Hawkins T V, Yeung S, Wakefield J, et al. Integrative health coaching for patients with type 2 diabetes: a randomized clinical trial. Diabetes Educ 2010;36(4):629–39. PMID: 20534872

118. Thom DH, Hessler D, Willard-Grace R, Bodenheimer T, Najmabadi A, Araujo C, et al. Does health coaching change patients' trust in their primary care provider? Patient Educ Couns Elsevier Ireland Ltd; 2014 Jul;96(1):135–8. PMID: 24776175

119. Sahlen K-G, Johansson H, Nyström L, Lindholm L. Health coaching to promote healthier lifestyle among older people at moderate risk for cardiovascular diseases, diabetes and

depression: a study protocol for a randomized controlled trial in Sweden. BMC Public Health 2013 Jan;13:199. PMID: 23497163

120. Goldman ML, Ghorob A, Eyre SL, Bodenheimer T. How do peer coaches improve diabetes care for low-income patients?: a qualitative analysis. Diabetes Educ 2013;39(6):800–10. PMID: 24168838

121. Wens J, Vermeire E, Royen P Van, Sabbe B, Denekens J. GPs' perspectives of type 2 diabetes patients' adherence to treatment: A qualitative analysis of barriers and solutions. BMC Fam Pract 2005;6(1):20. PMID: 15890071

122. Miller W, Rollnick S. Motivational interviewing: Helping people change. Third. New York, New York, USA: Guilford Press; 2013.

123. Brehm S, Brehm JW. Psychological Reactance: A Theory of Freedom and Control. New York, New York, USA: Academic Press Inc.; 2013.

124. Clarke DM, Baird DE, Perera DN, Hagger VL, Teede HJ. The INSPIRED study: a randomised controlled trial of the Whole Person Model of disease self-management for people with type 2 diabetes. BMC Public Health BMC Public Health; 2014 Jan;14(1):134. PMID: 24507417

125. Lappalainen R, Sairanen E, Järvelä E, Rantala S, Korpela R, Puttonen S, et al. The effectiveness and applicability of different lifestyle interventions for enhancing wellbeing: the study design for a randomized controlled trial for persons with metabolic syndrome risk factors and psychological distress. BMC Public Health 2014 Apr 4;14(1):310. PMID: 24708617

126. Beck J. Cognitive Behavior Therapy: Basics and Beyond. Second Edi. New York, New York, USA: Guilford Press; 2011.

127. Ackerman SJ, Hilsenroth MJ. A review of therapist characteristics and techniques positively impacting the therapeutic alliance. Clin Psychol Rev 2003;23(1):1–33. PMID: 12559992

128. Canadian Wireless Telecommunications Association. Wireless Phone Subscribers in Canada - Facts and Figures. 2014.

129. Google. Our Mobile Planet: Canada. 2013.

130. Farmer A, Gibson O, Hayton P, Bryden K, Dudley C, Neil A, et al. A real-time, mobile phone-based telemedicine system to support young adults with type 1 diabetes. Inform Prim Care 2005 Jan;13(3):171–7. PMID: 16259856

131. Laing BY, Mangione CM, Tseng C-H, Leng M, Vaisberg E, Mahida M, et al. Effectiveness of a Smartphone Application for Weight Loss Compared With Usual Care in Overweight Primary Care Patients. Ann Intern Med 2014;161:S5.

132. Takacs J, Pollock CL, Guenther JR, Bahar M, Napier C, Hunt M a. Validation of the Fitbit One activity monitor device during treadmill walking. J Sci Med Sport Sports Medicine Australia; 2013;17(5):496–500. PMID: 24268570

133. Rowland JL, Sasaki JE, Hickey A, Mavilia M, Tedesco J, John D, et al. Validation of the Fitbit Wireless Activity Tracker(R) for Prediction of Energy Expenditure. J Med Internet Res 2014; PMID: 24770438

134. Agarwal S, Lau C. Remote Health Monitoring Using Mobile Phones and Web Services. Telemed e-Health 2010;16(5).

135. Lee J-A, Nguyen AL, Berg J, Amin A, Bachman M, Guo Y, et al. Attitudes and Preferences on the Use of Mobile Health Technology and Health Games for Self-Management: Interviews With Older Adults on Anticoagulation Therapy. JMIR mHealth uHealth 2014 Jul 23;2(3):e32.

136. Azevedo ARP, de Sousa HML, Monteiro JAF, Lima ARNP. Future perspectives of Smartphone applications for rheumatic diseases self-management. Rheumatol Int 2014 Aug 29; PMID: 25168866

137. Patel MS, Asch DA, Volpp KG. Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change. JAMA 2015 Jan 8;19104:12–13.

138. Karyekar CS, Frederich R, Ravichandran S. Clinically relevant reductions in HbA1c without hypoglycaemia: Results across four studies of saxagliptin. Int J Clin Pract 2013;67(8):759–767. PMID: 23795975

139. Das P, Bhattacharjee D, Bandyopadhyay SK, Bhattacharya G, Singh R. Association of obesity and leptin with insulin resistance in type 2 diabetes mellitus in Indian population. Indian J Physiol Pharmacol 2013;57(1):45–50. PMID: 24020098

140. Diener E, Emmons RA, Larsen RJ, Griffin S. The Satisfaction With Life Scale. J Pers Assess 1985 Feb;49(1):71–5. PMID: 16367493

141. Snaith RP. The Hospital Anxiety And Depression Scale. Health Qual Life Outcomes 2003 Jan;1:29. PMID: 12914662

142. Watson D, Clark L a, Tellegen a. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988 Jun;54(6):1063–70. PMID: 3397865

143. Crawford JR, Henry JD. The positive and negative affect schedule (PANAS): construct validity, measurement properties and normative data in a large non-clinical sample. Br J Clin Psychol 2004 Sep;43(Pt 3):245–65. PMID: 15333231

144. Cheak-Zamora NC, Wyrwich KW, McBride TD. Reliability and validity of the SF-12v2 in the medical expenditure panel survey. Qual Life Res 2009;18(6):727–735. PMID: 19424821

145. Ware JE, Kosinski M, Turner-bowker DM, Gandek B. User's Manual for the SF-12v2 Health Survey With a Supplement Documeting SF-12 Health Survey. Heal (San Fr. Lincoln, RI; 2002.

146. Kiely JM, Brasel KJ, Guse CE, Weigelt J a. Correlation of SF-12 and SF-36 in a trauma population. J Surg Res 2006 May 15;132(2):214–8. PMID: 16566939

147. Ware J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34(3):220–233. PMID: 8628042

148. Delate T, Coons SJ. The discriminative ability of the 12-item short form health survey (SF-12) in a sample of persons infected with HIV. Clin Ther 2000;22(9):1112–1120. PMID: 11048908

149. Resnick B, Nahm ES. Reliability and validity testing of the revised 12-item Short-Form Health Survey in older adults. J Nurs Meas 2001;9(2):151–161. PMID: 11696939

150. Ellis C, Grubaugh AL, Egede LE. Factors associated with SF-12 physical and mental health quality of life scores in adults with stroke. J Stroke Cerebrovasc Dis

2013;22(4):309–317. PMID: 22005038

151. Burr JF, Rowan CP, Jamnik VK, Riddell MC. The role of physical activity in type 2 diabetes prevention: physiological and practical perspectives. Phys Sportsmed 2010 Apr;38(1):72–82. PMID: 20424404

152. Reid RD, Tulloch HE, Sigal RJ, Kenny GP, Fortier M, McDonnell L, et al. Effects of aerobic exercise, resistance exercise or both, on patient-reported health status and well-being in type 2 diabetes mellitus: A randomised trial. Diabetologia 2010;53(4Reid, R. D., Tulloch, H. E., Sigal, R. J., Kenny, G. P., Fortier, M., McDonnell, L., … Coyle, D. (2010). Effects of aerobic exercise, resistance exercise or both, on patient-reported health status and well-being in type 2 diabetes mellitus: A randomised):632–640. PMID: 20012857

153. Abete I, Astrup A, Martínez JA, Thorsdottir I, Zulet MA. Obesity and the metabolic syndrome: Role of different dietary macronutrient distribution patterns and specific nutritional components on weight loss and maintenance. Nutr Rev. 2010. p. 214–231. PMID: 20416018

154. Kreitzer MJ, Sierpina VS, Lawson K. Health coaching: innovative education and clinical programs emerging. Explore (NY) 2008;4(2):154–5. PMID: 18316060

155. Melko CN, Terry PE, Camp K, Healey ML. Diabetes Health Coaching Improves Medication Adherence: A Pilot Study. Am J Lifestyle Med 2009 Oct;4(2):187–194.

156. Logan AG, McIsaac WJ, Tisler A, Irvine MJ, Saunders A, Dunai A, et al. Mobile phone-based remote patient monitoring system for management of hypertension in diabetic patients. Am J Hypertens 2007 Sep;20(9):942–8. PMID: 17765133

157. Cuspidi C, Meani S, Fusi V, Salerno M, Valerio C, Severgnini B, et al. Home blood pressure measurement and its relationship with blood pressure control in a large selected hypertensive population. J Hum Hypertens 2004;18(10):725–731. PMID: 15103315

158. Halifax NVD, Cafazzo J a, Irvine MJ, Hamill M, Rizo C a, McIssac WJ, et al. Telemanagement of hypertension: a qualitative assessment of patient and physician preferences. Can J Cardiol 2007;23(7):591–594. PMID: 17534469

159. Nguyen HQ, Wolpin S, Chiang K-C, Cuenco D, Carrieri-Kohlman V. Exercise and symptom monitoring with a mobile device. AMIA Annu Symp Proc 2006;1047. PMID: 17238666

160. Wang D-H, Kogashiwa M, Ohta S, Kira S. Validity and reliability of a dietary assessment method: the application of a digital camera with a mobile phone card attachment. J Nutr Sci Vitaminol (Tokyo) 2002;48(6):498–504. PMID: 12775117

161. Arsand E, Tufano JT, Ralston JD, Hjortdahl P. Designing mobile dietary management support technologies for people with diabetes. J Telemed Telecare 2008 Jan;14(7):329–32. PMID: 18852310

162. Lester RT, Mills EJ, Kariri A, Ritvo P, Chung M, Jack W, et al. The HAART cell phone adherence trial (WelTel Kenya1): a randomized controlled trial protocol. Trials 2009 Jan;10:87. PMID: 19772596

163. Abebe NA, Capozza KL, Des Jardins TR, Kulick DA, Rein AL, Schachter AA, et al. Considerations for community-based mHealth initiatives: Insights from three Beacon Communities. J Med Internet Res 2013;15(10). PMID: 24128406

164. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013/01/26 ed 2013;10(1):e1001362. PMID: 23349621

165. Olah ME, Gaisano G, Hwang SW. The effect of socioeconomic status on access to primary care: an audit study. Can Med Assoc J 2013;185(6):E263–E269.

166. Chen E, Miller GE. Socioeconomic Status and Health: Mediating and Moderating Factors. Annu Rev Clin Psychol 2013;9(1):723–749. PMID: 23245339

167. Prus SG. Comparing social determinants of self-rated health across the United States and Canada. Soc Sci Med Elsevier Ltd; 2011 Jul;73(1):50–9. PMID: 21664020

168. Canada S. Education Indicators in Canada: Report of the Pan-Canadian Education Indicators Program. 2013.

169. Creese G, Wiebe B. “Survival Employment”: Gender and Deskilling among African Immigrants in Canada. Int Migr Blackwell Publishing Ltd; 2009;50(5):56–76.

170. Quinn CC, Clough SS, Minor JM, Lender D, Okafor MC, Gruber-Baldini A. WellDoc mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. Diabetes Technol Ther 2008

Jun;10(3):160–8. PMID: 18473689

171. Quinn CC, Gruber-Baldini AL, Shardell M, Weed K, Clough SS, Peeples M, et al. Mobile diabetes intervention study: testing a personalized treatment/behavioral communication intervention for blood glucose control. Contemp Clin Trials Elsevier Inc.; 2009 Jul;30(4):334–46. PMID: 19250979

172. Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemed J E Health 2009 Apr;15(3):231–40. PMID: 19382860

173. Wayne N, Ritvo P. Smartphone-enabled health coach intervention for people with diabetes from a modest socioeconomic strata community: single-arm longitudinal feasibility study. J Med Internet Res 2014 Jun 6;16(6):e149. PMID: 24907918

174. Moore JO, Marshall MA, Judge DC, Moss FH, Gilroy SJ, Crocker JB, et al. Technology-Supported Apprenticeship in the Management of Hypertension: A Randomized Controlled Trial. J Clin Outcomes Manag 2014;21(3).

175. Konttinen H, Sarlio-Lähteenkorva S, Silventoinen K, Männistö S, Haukkala A. Socio-economic disparities in the consumption of vegetables, fruit and energy-dense foods: the role of motive priorities. Public Health Nutr 2013 May;16(5):873–82. PMID: 22857602

176. Alter D a, Stukel T, Chong A, Henry D. Lesson from Canada's universal care: Socially disadvantaged patients use more health services, still have poorer health. Health Aff 2011 Feb;30(2):274–283. PMID: 21289349

177. Riddle MC, Ambrosius WT, Brillon DJ, Buse JB, Byington RP, Cohen RM, et al. Epidemiologic relationships between A1C and all-cause mortality during a median 3.4-year follow-up of glycemic treatment in the ACCORD trial. Diabetes Care 2010;33(5):983–990. PMID: 20427682

178. Krebs JD, Bell D, Hall R, Parry-Strong A, Docherty PD, Clarke K, et al. Improvements in glucose metabolism and insulin sensitivity with a low-carbohydrate diet in obese patients with type 2 diabetes. J Am Coll Nutr 2013 Jan;32(1):11–7. PMID: 24015695

179. Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C, White RD. Physical activity/exercise and type 2 diabetes: a consensus statement from the American Diabetes Association. Diabetes Care 2006 Jun;29(6):1433–8. PMID: 16732040

180. Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2012 Jun;35(6):1364–79. PMID: 22517736

181. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011;13(4). PMID: 22209829

182. Lenters-Westra E, Slingerland RJ. Six of eight hemoglobin A1c point-of-care instruments do not meet the general accepted analytical performance criteria. Clin Chem 2010 Jan;56(1):44–52. PMID: 19926777

183. Willard-Grace R, DeVore D, Chen EH, Hessler D, Bodenheimer T, Thom DH. The effectiveness of medical assistant health coaching for low-income patients with uncontrolled diabetes, hypertension, and hyperlipidemia: protocol for a randomized controlled trial and baseline characteristics of the study population. BMC Fam Pract BMC Family Practice; 2013 Jan;14(1):27. PMID: 23433349

184. Canada S. Table 202-0808 - Low income measures by income source and household size, 2011 constant dollars. CANSIM (database).

185. Pludwinski S, Ahmad F, Wayne N, Ritvo P. Participant experiences in a smartphone-based health coaching intervention for type 2 diabetes: A qualitative inquiry. J Telemed Telecare 2015 Jul 21;0(0):1–7. PMID: 26199275

186. Alegría M, Bijl RV, Lin E, Walters EE KR. Income differences in persons seeking outpatient treatment for mental disorders: a comparison of the United States with Ontario and The Netherlands. Arch Gen Psychiatry 2000;57(4):383–91. PMID: 10768701

187. Steele LS, Glazier RH, Lin E. Inequity in mental health care under Canadian universal health coverage. Psychiatr Serv 2006;57(3):317–324. PMID: 16524988

188. Martinez-Millana A, Fico G, Fernandez-Llatas C, Traver V. Performance assessment of a closed-loop system for diabetes management. Med Biol Eng Comput 2015 Feb 11; PMID: 25667016

189. Torbjørnsen A, Jenum AK, Småstuen MC, Årsand E, Holmen H, Wahl AK, et al. A Low-Intensity Mobile Health Intervention With and Without Health Counseling for Persons With Type 2 Diabetes, Part 1: Baseline and Short-Term Results From a Randomized

Controlled Trial in the Norwegian Part of RENEWING HEALTH. JMIR mHealth uHealth 2014;2(4):e52.

190. O'Brien JA, Patrick AR, Caro JJ. Cost of managing complications resulting from type 2 diabetes mellitus in Canada. BMC Health Serv Res 2003 Mar 21;3(1):7. PMID: 12659641

191. Xhyheri B, Manfrini O, Mazzolini M, Pizzi C, Bugiardini R. Heart Rate Variability Today. Prog Cardiovasc Dis Elsevier Inc.; 2012;55(3):321–331. PMID: 23217437

192. Borromeo S, Rodriguez-Sanchez C, Machado F, Hernandez-Tamames J a, de la Prieta R. A reconfigurable, wearable, wireless ECG system. Conf Proc IEEE Eng Med Biol Soc 2007 Jan;2007:1659–62. PMID: 18002292

193. Cai YY, Cao D, He XH, Wang QX. Continuous glucose monitoring system based on smart phone. Procedia Eng 2012;29:3894–3898.

194. Bates A, Ling MJ, Mann J, Arvind DK. Respiratory Rate and Flow Waveform Estimation from Tri-axial Accelerometer Data. 2010 Int Conf Body Sens Networks IEEE; 2010. p. 144–150.

195. Rachlis M. M. Medicare: Facts, Myths, Problems, Promise. Heal Policy Anal 2007;1–28.

196. Rosella LC, Fitzpatrick T, Wodchis WP, Calzavara A, Manson H, Goel V. High-cost health care users in Ontario, Canada: demographic, socio-economic, and health status characteristics. BMC Health Serv Res 2014 Dec;14(1):532.

APPENDICES

Demographics (Appendix A)

- Gender
  - What is your Gender?
    - ☐ Male ☐ Female

- Age
  - What is the year of your birth? _____

- Ethnicity
  - Which of the following racial or ethno-cultural groups best describe you?
    - ☐ Aboriginal (Inuit, Métis, North American Indian)
    - ☐ West Asian (e.g., Armenian, Egyptian, Iranian, Iraqi, Lebanese, Moroccan)
    - ☐ Black - African (e.g., African, Somali, etc)
    - ☐ Black – Caribbean (e.g. Haitian, Jamaican, etc)
    - ☐ White (Caucasian – European/American)
    - ☐ Hispanic
    - ☐ Latin American
    - ☐ Chinese
    - ☐ Filipino
    - ☐ Japanese
    - ☐ Korean
    - ☐ South Asian
    - ☐ South East Asian
    - ☐ Other (Fill in):
    - ☐ _____

- Language
  - What language(s) do you speak?
    - ☐ English
    - ☐ French
    - ☐ Do you also speak another language (s): _____

- Time-in-country
  - How many years have you lived in Canada?
    - ☐ # of years or “Since birth”: _____

- Educational Status
  - What is the highest level of education you have completed?
    - ☐ Elementary School
    - ☐ Middle School
    - ☐ High School
    - ☐ Some College or University or Trade/Vocational Training
    - ☐ Trade, Vocational Training or Certificate
    - ☐ College Diploma
    - ☐ University Degree
    - ☐ Post-Graduate Degree
- Employment Status
  - What is your employment status?
    - ☐ Unemployed
    - ☐ Student
    - ☐ Part-Time

- ☐ Full-Time
- ☐ Retired
- ☐ Self-Employed
- ☐ Work in the home (take care of children, etc)

- Income Status
  - What is your annual income status?
    - ☐ $0 – $9999
    - ☐ $10,000 – $25,000
    - ☐ $25,000 – $50,000
    - ☐ $50,000 – $75,000
    - ☐ $75,000 – $100,000
    - ☐ $100,000 – Up

- Car ownership
  - Do you own or have access to a car?
    - ☐ Own
    - ☐ Have access
    - ☐ No car access

(Appendix B)
Use of a Blackberry Enabled Health Coach in the Self-Management of Type 2 Diabetes

QUESTIONNAIRE PACKAGE

Study ID: _____

Date: _____

PRE/POST

The Satisfaction with Life Scale (Appendix B-2)

By Ed Diener, Ph.D.

DIRECTIONS: Below are five statements with which you may agree or disagree. Using the 1-7 scale below, indicate your agreement with each item by placing the appropriate number in the line preceding that item. Please be open and honest in your responding.

1 = Strongly Disagree
2 = Disagree
3 = Slightly Disagree
4 = Neither Agree or Disagree
5 = Slightly Agree
6 = Agree
7 = Strongly Agree

_____ 1. In most ways my life is close to my ideal.

_____ 2. The conditions of my life are excellent.

_____ 3. I am satisfied with life.

_____ 4. So far I have gotten the important things I want in life.

_____ 5. If I could live my life over, I would change almost nothing.

The Hospital Anxiety and Depression Scale (HADS)
(Appendix B-3)

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings s/he will be able to help you more.
This questionnaire is designed to help your doctor to know how you feel. Read each item and underline the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long, thought-out response.

1. **I feel tense or "wound up":**
   - **3 Most of the time**
   - **2 A lot of the time**
   - **1 From time to time, occasionally**
   - **0 Not at all**

2. **I still enjoy the things I used to enjoy:**
   - **0 Definitely as much**
   - **1 Not quite so much**
   - **2 Only a little**
   - **3 Hardly at all**

3. **I get a sort of frightened feeling as if something awful is about to happen:**
   - **3 Very definitely and quite badly**
   - **2 Yes, but not too badly**
   - **1 A little, but it doesn't worry me**
   - **0 Not at all**

4. **I can laugh and see the funny side of things:**
   - **0 As much as I always could**
   - **1 Not quite so much now**
   - **2 Definitely not so much now**
   - **3 Not at all**

5. **Worrying thoughts go through my mind:**
   - **3 A great deal of the time**
   - **2 A lot of the time**
   - **1 From time to time but not too often**
   - **0 Only occasionally**

6. **I feel cheerful:**
   - **3 Not at all**
   - **2 Not often**
   - **1 Sometimes**
   - **0 Most of the time**

7. I can sit at ease and feel relaxed:
- **0 Definitely**
- **1 Usually**
- **2 Not often**
- **3 Not at all**

8. I feel as if I am slowed down:
- **3 Nearly all the time**
- **2 Very often**
- **1 Sometimes**
- **0 Not at all**

9. I get a sort of frightened feeling like "butterflies" in the stomach:
- **0 Not at all**
- **1 Occasionally**
- **2 Quite often**
- **3 Very often**

10. I have lost interest in my appearance:
- **3 Definitely**
- **2 I don't take so much care as I should**
- **1 I may not take quite as much care**
- **0 I take just as much care as ever**

11. I feel restless as if I have to be on the move:
- **3 Very much indeed**
- **2 Quite a lot**
- **1 Not very much**
- **0 Not at all**

12. I look forward with enjoyment to things:
- **0 As much as I ever did**
- **1 Rather less than I used to**
- **2 Definitely less than I used to**
- **3 Hardly at all**

13. I get sudden feelings of panic:

- **3 Very often indeed**
- **2 Quite often**
- **1 Not very often**
- **0 Not at all**

14. I can enjoy a good book or radio or television programme:

- **0 Often**
- **1 Sometimes**
- **2 Not often**
- **3 Very seldom**

Now check you have answered all questions

Positive and Negative Affect Scale (PANAS)
(Appendix B-4)

This scale consists of a number of words that describe different feelings and emotions. Read each item and then mark the appropriate answer in the space next to that word. Indicate to what extent you feel this way **right now**, that is, at the present moment. Use the following scale to record your answers:

1	**2**	**3**	**4**	**5**
very slightly or not at all	a little	moderately	quite a bit	extremely

___ interested
___ distressed
___ excited
___ upset
___ strong
___ guilty
___ scared
___ hostile
___ enthusiastic
___ proud

___ irritable
___ alert
___ ashamed
___ inspired
___ nervous
___ determined
___ attentive
___ jittery
___ active
___ afraid

Your Health and Well-Being (SF-12 v.2)

This survey asks for your views about your 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 ☒ in the one box that best describes your answer.

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

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. The following questions are about activities you might do during a typical day. Does your health now limit you 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, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
b Climbing several flights of stairs	☐1	☐2	☐3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
b Were limited in the kind of work or other activities	☐1	☐2	☐3	☐4	☐5

4. During the <u>past 4 weeks</u>, how much of the time 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)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐1	☐2	☐3	☐4	☐5
b Did work or other activities <u>less carefully than usual</u>	☐1	☐2	☐3	☐4	☐5

5. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

6. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. 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 <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
c Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5

7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> 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
☐1	☐2	☐3	☐4	☐5

CONSENT FORM
(Appendix C)
TITLE: Investigating Improved Self Management in Type II Diabetes
PRINCIPAL INVESTIGATOR: Dr. Paul Ritvo

You are being asked to take part in a research study. Before agreeing to take part in this study, it is important that you read and understand the following explanation of the proposed study procedures.
The following information describes the

- Purpose
- Procedures
- Benefits
- Discomforts
- Risks and
- Precautions associated with this study

It also describes your right to refuse to participate or to withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about it to make an informed decision.
This is known as the informed consent process. Please ask the researcher to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

PURPOSE:
You have been asked to participate in a study designed to help you better manage your Type II Diabetes through reading especially developed manuals, engaging in face-to-face meetings and telephone contacts with carefully trained and supervised health coaches and using a Blackberry Smartphone that will enable you to record what healthy behaviours you do on a day-by-day basis.

PROCEDURES:
Your participation in this study will entail a time commitment of **6 months**. If you agree to participate in this study, you will be asked to complete a set of questionnaires that help us understand your experience with diabetes and help us understand you better. You will then be randomly assigned to one of two comparison groups 1) the full intervention group will receive all the multiple-modalities cited (web-based promotion, Blackberry smartphone and HealthCoach software, cell phone text messaging, direct exercise promotion and health coaching); 2) the electronic-engagement and usual care group who will receive all the multiple modalities (web-based promotion, cell phone text messaging, direct exercise promotion) except for use of the Blackberry smartphone, HealthCoach software and related health coaching. All participants, regardless of group assignment, choose from the set of communication modalities available which they want to use at a personally selected intensity level.

If you participate in the full intervention, you will also be loaned a Samsung Galaxy Ace 2 smart phone that is preloaded with Health Coach Software. This software helps you record what you do and can, when agreeable to you, remind you to take medications, exercise, eat foods considered healthy, track how you feel. Although the Blackberry device will not be able to make or receive phone calls, the data service will allow use of the Health Coach software, as well as other data related activities you would like to use the device for (ie: email, surfing). You will not be held liable for damage or loss of the device. You will have access to a health coach who will further assist you in telephone-based and face-to-face discussions. You will, at times, meet with your Health Coach at agreed on times for designated time periods.

To help assess the effectiveness of the program, researchers will ask for you to share regularly scheduled blood work results (specifically Hemoglobin A1C) with the research team at 3 month intervals. You may also be asked to engage in more than usual blood glucose and HbA1c testing. All finger pricking for the purpose of drawing a drop of blood to assess blood glucose or HbA1c will be done by you. You will also be asked to complete fitness measures including:

- weight
- waist circumference
- body mass index (BMI)
- Psychological Measures (30-40min to complete): SF – 12; Profile of Mood States – Vigor Scale; Center for Epidemiological Studies Depression Scale; Scale of Psychological Well-Being; Positive and Negative Affect Schedule

RISKS AND BENEFITS

There are no known personal risks or benefits associated with taking part in this research study. It is our hope that your Diabetes will become more manageable to you with the help of this study, and that you will feel more energized and healthier on a daily basis.

CONFIDENTIALITY:

All information obtained during the study will be held in strict confidence. You will be identified by a study number and initials only. Names or identifying information will not be used in any publication or presentation.

Your data will be safely stored in a locked facility and only research staff will have access to this information. Data will be retained for five years after publication of the study results. Data entered into the Healthcoach program is stored in a secure server and not stored on the device. Researchers will be able to monitor any data you store in the Healthcoach program.

This is done to assist you with your health activities (ie: diet and exercise) as well to assist researchers in better understanding the best use of the software. Any personal data stored in the blackberry (pictures, email) will be cleared upon study completion.

PARTICIPATION:

Your participation in the study is voluntary. You may withdraw from the study at any time, and you can also choose not to answer any questions that you do not feel

comfortable answering. This will not affect your care. Your refusal to participate or your withdrawal from the study will not affect your relationship with the researchers, York University or impact the services you receive from Black Creek Community Health Centre. If you decide to withdraw from the study and you wish us to destroy the information and data you provided, we will do so upon your request. When you choose no longer to be a part of the study, or the study period ends, the blackberry device is to be returned to us.

QUESTIONS:

If you have questions about the research in general or about your role in the study, please feel free to contact Dr. Paul Ritvo (York University) by telephone at (xxx) xxx-xxxx ext. xxxxx or by e-mail or Michelle Westin (Black Creek Community Health Centre) by telephone at (xxx) xxx-xxxx ext. xxxx or by email. This research study has been reviewed and approved by the Human Participants Review Committee (Certificate #: **2012 - 033**), 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, **Office of Research Ethics, 5th Floor, York Research Tower,** York University (telephone (xxx) xxx-xxxx or e-mail, or Ms. Cheryl Prescod, Executive Director, Black Creek Community Health Centre (telephone (xxx) xxx-xxxx ext. xxxxx or email).

Legal Rights and Signatures:

I_____, consent to participate in the Investigating Improved Self Management in Type II Diabetes research study. 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.

Name of Participant	Signature of Participant	Date
Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Data Collection Checklist
(Appendix D)
Blackberry Enabled Health Coach in the Self-Management of Type 2 Diabetes

Participant: _____

☐ **Consent (Date: _____)**

Baseline Assessment

- ☐ **Demographics (Date: _____)**
- ☐ **Questionnaires (Date: _____)**
- ☐ **PARQ (Date: _____)**
- ☐ **Body Comp (Date: _____)**
- ☐ **A1Cs (Date: _____)**
- ☐ **Randomization (Group: Intervention/Control)**
    - o **Assign Smartphone (#) – Give instruction manual**

3 Month

- ☐ **Body Comp (Date: _____)**
- ☐ **A1Cs (Date: _____)**

6 Month

- ☐ **Questionnaires (Date: _____)**
- ☐ **Body Comp (Date: _____)**
- ☐ **HbA1Cs (Date: _____)**
- ☐ **Retrieve Smartphone (Date: _____)**

Body Composition Chart

	Baseline	3 Month	6 Month
HbA1c			
Weight (kg)			
BMI			
Waist Cir. (cm)			

(Appendix E)
Black Creek Community Health Centre
Investigating Improved Self-Management in Type 2 Diabetes
1 Yorkgate Blvd, Suite 202, Toronto, ON M3N 3A1
Phone: (xxx) xxx-xxxx Fax: (xxx) xxx-xxxx

REQUEST FOR LAB RESULTS AND PERMISSION OF COMMUNICATION

RE: _____ DATE OF BIRTH: _____/_____/_____
DAY MONTH YEAR

_____ (Patient Name) has consented to participate in the research project at Black Creek Community Health Centre titled: Investigating Improved Self-Management in Type 2 Diabetes.

This study is designed to help patients better manage their Type 2 Diabetes through contact with specially trained Black Creek CHC health coaches / exercise specialists. Patients will engage in face-to-face and telephone contact with health coaches who will support them in managing their condition. Health coaches are all certified exercise specialists, and will incorporate safe and effective exercise modalities into patients' care routines, as well as support other health related behaviours as indicated by their care team (diet, medication, etc.).

Please fax the most recent results of any pertinent lab results including: HbA1C, fasting glucose, cholesterol profile, liver function test, albumin/creatinine ratio, creatinine, eGFR, and Microalbumin to **416-650-0971.**

Declaration
I, _____, give permission for my health care team (which may include my physician, nurse practitioner, dietitian and diabetes nurse educator) to share information with my health coach on any matters that may help me better manage my diabetes, and health coach to share information with my health care team. This may include discussing my participation in this study, the sharing of blood test results, dietary practices, exercise routines and other information that is directly associated with my diabetes management, until such time as I rescind this permission or my participation in the study ends.

Signatures
Client Name: _____ Signature: _____
Date: _____

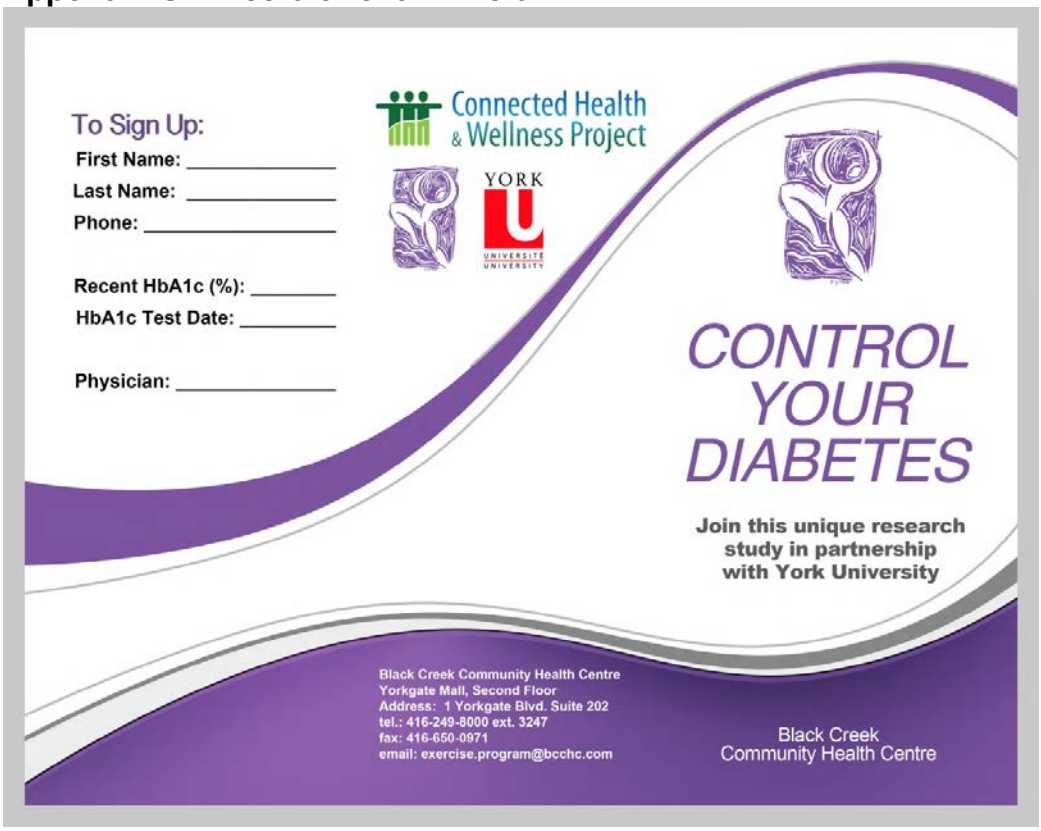
Witness Name: _____ Signature: _____
Date: _____

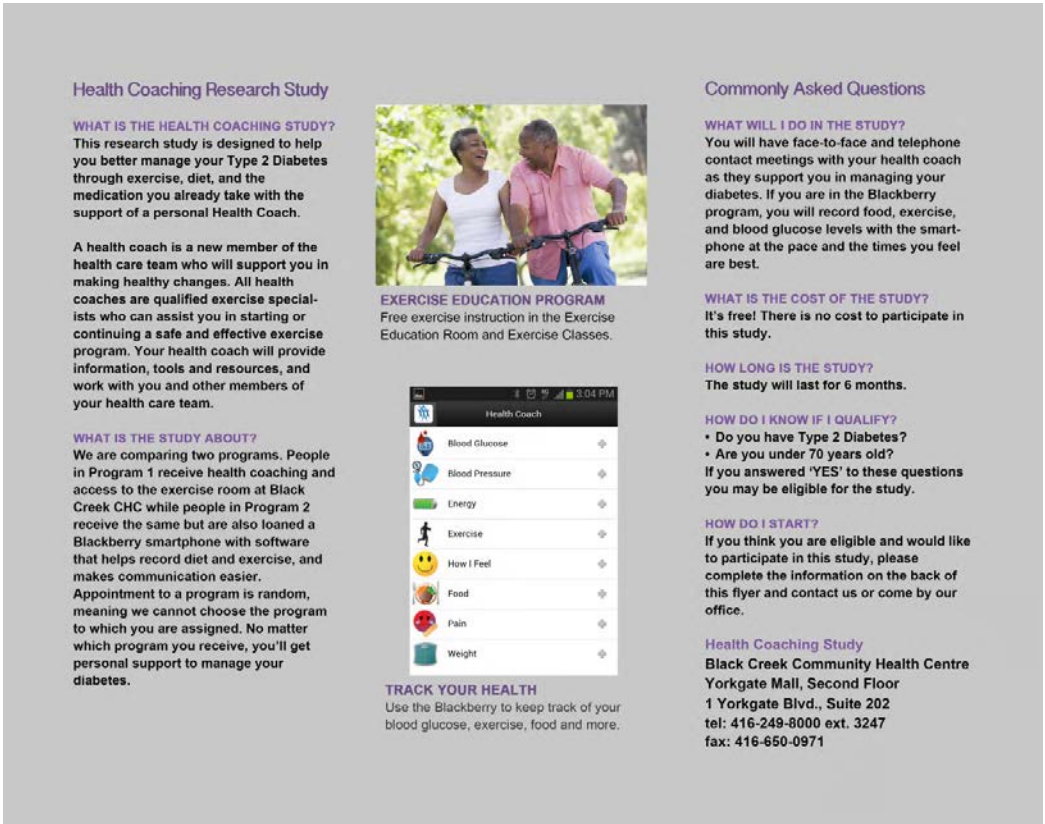
Please contact us if you require any other information

Health Coach: _____ Signature: _____
Phone Number: (xxx) xxx-xxxx Date: _____

Appendix F – Recruitment Poster

Appendix G – Recruitment Tri-Fold





Appendix H – Information Sheet (Participant)

Control Your Diabetes

...and live a healthier life with the Health Coaching Research Study

What is the Health Coaching Research Study?

This research is designed to help you better manage your Type 2 Diabetes through exercise, diet, and medication with the support of a personal Health Coach. This project is funded by the Public Health Agency of Canada and is a partnership between Black Creek CHC and York University.

What does 'Research Study' mean?

We are comparing two programs. People in Program 1 receive health coaching and access to the exercise room at Black Creek CHC while people in Program 2 receive the same but are also loaned a Blackberry smartphone with software that helps record diet and exercise, and makes communication easier. Appointment to a program is random, meaning we cannot choose the program to which you are assigned. No matter which program you receive, you'll get personal support to manage your diabetes.

What is a Health Coach?

A Health Coach is a new member of the health care team who will support you in making healthy changes. All health coaches are qualified exercise specialists who can assist you in starting or continuing a safe and effective exercise program. Your Health Coach will provide information, tools and resources, and work with you and other members of your health care team.

What do I have to do if I am part of this study?

You will have face-to-face and telephone contact meetings with your Health Coach as they support you in managing your diabetes. If you are in the Blackberry program, you will record food, exercise, and blood glucose levels with the smartphone at the pace and at the times you feel are best.

How much does it cost?

This is a **FREE** program!

How long is the study?

The study will last for 6 months.

How do I know if I am eligible for the study?

- Do you have Type 2 Diabetes?
- Are you under 70-years-old?

If you answered yes to these questions, you may be eligible for the study.

For more information or to book an appointment
please contact Black Creek Community Health Centre at: 416-249-8000 EXT. 3247

Public Health Agency of Canada | Agence de santé publique du Canada

Appendix I – Information Sheet (Provider)

YORK UNIVERSITÉ UNIVERSITY

Study Title:
Investigating Improved Self Management in Type II Diabetes

Funding Agency: Public Health Agency of Canada
Lead Agency: Black Creek Community Health Centre
Principal Investigator: Dr. Paul Ritvo, Associate Professor – School of Kinesiology and Health Science, and Department of Psychology, York University

Rational of Project
The future viability of the Canadian health system depends on better management of chronic diseases like Type 2 Diabetes (T2DM). Not only does the current prevalence directly tax the healthcare system, predictive relationships between T2DM and other severe illnesses suggest poor management will additionally tax the future system. Current predictions are that diabetes-linked health care costs will increase to > $8 billion annually by 2016.

Behavioural and psychological factors are heavily implicated in T2DM management, as about 20% of people living with diabetes experience **depression**, doubling the population rate. Behaviourally, chronic sedentariness is highly associated with T2DM onset while, conversely, ***exercise*** reduces insulin resistance, an important factor in improved T2DM management. Meanwhile ***dietary modification*** reduces the energy richness of food intake and ***blood glucose self monitoring*** aligns symptomatic experience with the effects of good vs. poor management, via direct associations between blood glucose, mood and physical experience. The healthy self-management of T2DM (through exercise, diet, and glucose monitoring) requires major changes of behavior, yet research on promoting such changes is modest when compared with other chronic diseases. **Notably, very few studies involve individuals with T2DM who face the additional challenge of being from a lower socio-economic-strata (SES). This latter gap in existing studies is being addressed in the PHAC project.**

Summary of the Project:
This study is designed to help patients better manage their Type 2 Diabetes through contact with trained Black Creek-CHC health coaches and exercise specialists. Patients engage in face-to-face and telephone contacts with health coaches who support improved management of their condition through healthy behaviours. Using a Blackberry Smartphone (provided by the project), patients record healthy behaviours on a day-by-day basis (photographing food, logging exercise and reporting blood glucose levels). Health coaches log-in to a secure online portal to monitor patient activities, and provide real-time feedback and support. Health coaches are certified exercise specialists, and incorporate safe-effective exercise routines into the patients self-care plan.

Recruitment
The target sample size for the program is 120 participants, randomly allocated to an intervention (smartphone) group (60) and augmented usual care control group (60) (everything is provided but the smartphone). The control group will still receive exercise and limited health coaching support. The program is available to patients with Type 2 Diabetes who have a baseline HbA1c >= 7.3%.

Program Deliverables:
1) Statistical analyses describing differences in Hemoglobin A1c, depression, and anxiety when intervention and control group are compared.
2) A detailed, publishable Operations Manual of the onsite Exercise Education Program available to other health centres.
3) Additional online web-video tools to assist with dissemination of exercise

Vision:
Health coaching, utilizing technological methods of monitoring and communication has real applicability in Ontario's Healthcare System. Electronically assisted health coaching has the potential for increasing patient support and engagement, and decreasing disease burden on our system.

YORK
UNIVERSITÉ
UNIVERSITY

Appendix J – Study Summary Sheet (Provider)
Public Health Agency of Canada
Investigating Improved Self Management in Type II Diabetes

Summary of the Project:
This study is designed to help patients better manage their Type II Diabetes through contact with specially trained Black Creek CHC health coaches / exercise specialists. Patients will engage in face to face and telephone contact with health coaches who will support them as they manage their condition. Using a Blackberry Smartphone, patients will be able to record what healthy behaviours they do on a day-by-day basis. Health coaches are all certified exercise specialists, and will also incorporate safe and effective exercise modality into patients care routine.

Recruitment
The target sample size for the program is 120 participants, evenly randomized into an intervention (smartphone) group and augmented control (everything but smartphone) group. The control group will still receive exercise and health coaching support.

Inclusion Criteria
The program is available to patients of Black Creek CHC with Type 2 Diabetes who are younger than 70 years old and have a baseline HbA1c => 7.3%.

Timeline
The study intervention length is six months long and it is scheduled to complete March 2014. Recruitment will continue until September 2013, at which point active recruitment will end.

Recruitment Process
Recruitment Method #1 – Black Creek staff are calling a list of patients with type 2 diabetes and inviting them to participate.
Recruitment Method #2 – Through promotion at diabetes classes, participants are invited to participate.
Recruitment Method #3 – Referrals directly from health care providers

Ethical and Study Staff
Once patients agree to participate, they read, understand and sign an informed consent document which outlines the details of the project.

Health coaches are employees (and one placement student) who have been hired by the Black Creek CHC Diabetes Education Program to carry out this study.

Communication: Once a client is recruited into the study, Health Coaches contact the BCCHC providers. Providers and Health Coaches have consent from clients to share information that is deemed relevant to the study, and the client's self-management of diabetes.

Appendix K – Study Referral Form

YORK
UNIVERSITÉ
UNIVERSITY

Study Referral Form

Investigating Improved Self-Management in Type 2 Diabetes Patients

Client First Name: _____ Client Last Name: _____

Gender: ☐ Male ☐ Female ☐ other DOB: _____/_____/_____
DD MM YYYY

Telephone (H): _____ Telephone (C): _____

Date of last HbA1c result: _____/_____/_____ Last HbA1c result (%): _____
DD MM YYYY

Referring Provider / Stamp:

Provider Phone Number: _____

Referring Organization: _____

***Upon receiving the referral, the patient will be contacted by a Health Coach to book a follow-up meeting.**

Questions or Concerns? Please call 416-249-8000 ext. 3247

PLEASE COMPLETE AND FAX TO 416-650-0971

"Attention Exercise Education Program – PHAC Study"

****Study Inclusion Criteria****
- **Type 2 Diabetes**
- **Age < 70**
- **A1C >=7.3%**

For Internal Use Only:

Referral Accepted by Health Coach (Name): _____ Date: _____

This project is funded by the Public Health Agency of Canada 01/13

Appendix L – Physical Activity Readiness Questionnaire + (PARQ+)

CSEP approved Sept 12 2011 version: for use by CSEP Certified Exercise Physiologists®

PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

Regular physical activity is fun and healthy, and more people should become more physically active every day of the week. Being more physically active 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.

SECTION 1 - GENERAL HEALTH

	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)?	☐	☐
5.	Are you currently taking prescribed medications for a chronic medical condition?	☐	☐
6.	Do you have a bone or joint problem that could be made worse by becoming more physically active? Please answer NO if you had a joint problem in the past, but it does not limit your current ability to be physically active. For example, knee, ankle, shoulder or other.	☐	☐
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 Section 3 to sign the form. You do not need to complete Section 2.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow the Canadian Physical Activity Guidelines for your age (www.csep.ca/guidelines).
- You may take part in a health and fitness appraisal.
- If you have any further questions, contact a qualified exercise professional such as a CSEP Certified Exercise Physiologist® (CSEP-CEP).
- If you are over the age of 45 yrs. and NOT accustomed to regular vigorous physical activity, please consult a qualified exercise professional (CSEP-CEP) before engaging in maximal effort exercise.

If you answered YES to one or more of the questions above, please GO TO SECTION 2.

Delay becoming more active if:

- You are not feeling well because of a temporary illness such as a cold or fever – wait until you feel better
- You are pregnant – talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the PARmed-X for Pregnancy before becoming more physically active OR
- Your health changes – please answer the questions on Section 2 of this document and/or talk to your doctor or qualified exercise professional (CSEP-CEP) before continuing with any physical activity programme.

CSEP | SCPE THE GOLD STANDARD IN EXERCISE SCIENCE AND PERSONAL TRAINING

 1 / 4

SECTION 2 - CHRONIC MEDICAL CONDITIONS

Please read the questions below carefully and answer each one honestly: check YES or NO.			YES	NO
1.	Do you have Arthritis, Osteoporosis, or Back Problems?		☐ If yes, 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)	☐	☐
	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)?	☐	☐
	1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	☐	☐
2.	Do you have Cancer of any kind?		☐ If yes, 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?	☐	☐
	2b.	Are you currently receiving cancer therapy (such as chemotherapy or radiotherapy)?	☐	☐
3.	Do you have Heart Disease or Cardiovascular Disease? This includes Coronary Artery Disease, High Blood Pressure, Heart Failure, Diagnosed Abnormality of Heart Rhythm		☐ If yes, answer questions 3a-3e	☐ 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)	☐	☐
	3b.	Do you have an irregular heart beat that requires medical management? (e.g. atrial brillation, premature ventricular contraction)	☐	☐
	3c.	Do you have chronic heart failure?	☐	☐
	3d.	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)	☐	☐
	3e.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	☐	☐
4.	Do you have any Metabolic Conditions? This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes		☐ If yes, answer questions 4a-4c	☐ If no, go to question 5
	4a.	Is your blood sugar often above 13.0 mmol/L? (Answer YES if you are not sure)	☐	☐
	4b.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, and the sensation in your toes and feet?	☐	☐
	4c.	Do you have other metabolic conditions (such as thyroid disorders, pregnancy-related diabetes, chronic kidney disease, liver problems)?	☐	☐
5.	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 yes, answer questions 5a-5b	☐ If no, go to question 6
	5a.	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)	☐	☐
	5b.	Do you also have back problems affecting nerves or muscles?	☐	☐

Please read the questions below carefully and answer each one honestly: check YES or NO.			YES	NO
6.	Do you have a Respiratory Disease? This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure		☐ If yes, answer questions 6a-6d	☐ 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)	☐	☐
	6b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	☐	☐
	6c.	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?	☐	☐
	6d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	☐	☐
7.	Do you have a Spinal Cord Injury? This includes Tetraplegia and Paraplegia		☐ If yes, answer questions 7a-7c	☐ 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)	☐	☐
	7b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	☐	☐
	7c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	☐	☐
8.	Have you had a Stroke? This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event		☐ If yes, answer questions 8a-c	☐ 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)	☐	☐
	8b.	Do you have any impairment in walking or mobility?	☐	☐
	8c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	☐	☐
9.	Do you have any other medical condition not listed above or do you live with two chronic conditions?		☐ If yes, answer questions 9a-c	☐ If no, read the advice on page 4
	9a.	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?	☐	☐
	9b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	☐	☐
	9c.	Do you currently live with two chronic conditions?	☐	☐

Please proceed to Page 4 for recommendations for your current medical condition and sign this document.

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:

- It is advised that you consult a qualified exercise professional (e.g., a CSEP-CEP) 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 – 20-60 min. 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 yrs. and NOT accustomed to regular vigorous physical activity, please consult a qualified exercise professional (CSEP-CEP) before engaging in maximal effort exercise.

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

- You should seek further information from a licensed health care professional before becoming more physically active or engaging in a fitness appraisal.

Delay becoming more active if:

- You are not feeling well because of a temporary illness such as a cold or fever – wait until you feel better
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise profesional, and/or complete the PARmed-X for Pregnancy before becoming more physically active OR
- Your health changes - please talk to your doctor or qualified exercise professional (CSEP-CEP) before continuing with any physical activity programme.

SECTION 3 - DECLARATION

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The Canadian Society for Exercise Physiology, the PAR-Q+ Collaboration, and their agents assume no liability for persons who undertake physical activity. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.
- 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.
- Please read and sign the declaration below:

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 they maintain the privacy of the information and do not misuse or wrongfully disclose such information.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact:
Canadian Society for Exercise Physiology
www.csep.ca

KEY REFERENCES
1. Jamnik VJ, Warburton DER, Makarski J, McKenzie DC, Shephard RJ, Stone J, and Gledhill N. Enhancing the eectiveness 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 BC Ministry of Health Services.

CSEP | SCPE
THE GOLD STANDARD IN EXERCISE SCIENCE AND PERSONAL TRAINING

CSEP approved Sept 12 2011 version

YORK
UNIVERSITÉ
UNIVERSITY

Memo

Certificate #: 2010 - 037

Approval Period: 02/05/10-02/05/11

Office of
Research Ethics
(ORE)

5th Floor,
York Research Tower,
4700 Keele St.
Toronto ON
Canada M3J 1P3
Tel 416 736 5914
Fax 416 650 8197
www.research.yorku.ca

To: Professor Paul Ritvo, Faculty of Health, pritvo@yorku.ca

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

Date: Friday 5th February, 2010

Re: Ethics Approval

Diabetes Self Management in Individuals from Modest Socieconomic Status (SES) Backgrounds

---

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

Should you have any questions, please feel free to contact me at: (xxx) xxx-xxxx or via email.

Yours sincerely,

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

YORK UNIVERSITÉ UNIVERSITY

Office of Research Ethics (ORE)

5th Floor,
York Research Tower,
4700 Keele St.
Toronto ON
Canada M3J 1P3
Tel 416 736 5914
Fax 416 650 8197
www.research.yorku.ca

Memo

Certificate #: 2012 - 033

Approval Period: 02/14/12-02/14/13

To: Professor Paul Ritvo, Faculty of Health, pritvo@yorku.ca, noway@yorku.ca

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

Date: Tuesday 14th February, 2012
Re: Ethics Approval
Investigating Improved Self Management in Type II Diabetes

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

Should you have any questions, please feel free to contact me at: (xxx) xxx-xxxx or via email.

Yours sincerely,

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