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The Smart technology to Manage type 2 diabetes and Achieve health goals through Record keeping and Tailored feedback (SMART) Study

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

THE SMART TECHNOLOGY TO MANAGE TYPE 2 DIABETES AND ACHIEVE HEALTH GOALS THROUGH RECORD KEEPING AND TAILORED FEEDBACK (SMART) STUDY

Integrated Article

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ABSTRACT

Lifestyle interventions reduce the risk of diabetic complications; however, many of these interventions are difficult to implement in everyday practice. This study investigated whether a smartphone application and data mining system, GlucoGuide™, could be a feasible and usable tool to supplement a lifestyle intervention in order to enhance patient care for people with prediabetes or type 2 diabetes (T2D). Using a quasi-experimental design, seventeen participants diagnosed with prediabetes or T2D were given the STEP™ test and a lifestyle prescription, and either a paper journal or the GlucoGuide™ system to record important health markers. The primary analysis compared clinical fasting blood glucose, blood pressure and step count at baseline, 1, 2 and 3 months. A significant decrease in diastolic blood pressure was seen over the 12 week study ($F=3.009$, $p<0.05$, $\eta^2_p = 0.158$). GlucoGuide™ is a functional system, and just as effective as the paper journal at promoting healthy behaviour change.

Keywords

Smartphone, mHealth, prediabetes, type 2 diabetes, Health Action Processes Approach, lifestyle intervention, Mediterranean-style diet, exercise prescription, behaviour change

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1 INTRODUCTION

Diabetes is a chronic disease that currently affects almost 2 million Canadians (1). The incidence of diabetes is rising each year, and is predicted to be diagnosed in 2.4 million Canadians by 2016 (2). It is not surprising then, that an ever increasing number of people with diabetes is costing the Canadian health care system (3). Adults with diabetes experience more medical visits to family doctors and specialists, have longer hospital stays, and shorter life expectancies than adults without diabetes (4). It follows that health promotion strategies aimed at primary and secondary prevention of diabetes, reducing the risk of developing diabetes and diabetic complications, need to be implemented to slow down this epidemic.

Type 2 Diabetes (T2D) is the most prevalent form of diabetes in Canada, and is considered a lifestyle disease because the risk of developing further complications can be reduced by changing everyday behaviours. With T2D the body does not respond adequately to the insulin produced by the liver, a phenomenon known as insulin resistance. Due to the body's decreased response to insulin, glucose in the blood remains high (hyperglycaemia), rather than being stored in muscle and fat tissue. This phenomenon is seen on a smaller scale in people diagnosed with prediabetes; 7 million Canadians are diagnosed with prediabetes, and 50% of these cases develop into T2D (5). Both prediabetes and T2D are diagnosed by clinical measures of fasting plasma glucose (FBG) and glycated hemoglobin (HbA_1c). FBG is a measure of the amount of glucose in the blood stream after an 8 hour fast, while the concentration of glycated haemoglobin (HbA_1c), in the blood is also proportionally related to the amount of glucose in the blood stream but is less affected by day-to-day changes. Therefore, HbA_1c provides an indication of blood glucose levels over a longer time frame. A clinical diagnosis of diabetes is made when FBG > 7.0 mmol/L or HbA_1c > 6.5%, while FBG between 6.0 mmol/L and 6.9 mmol/L or an HbA_1c between 6.0% and 6.4% is considered prediabetes (6).

Hyperglycaemia causes damage to insulin-producing beta cells in the pancreas, and leads to complications such as neuropathy, retinopathy, and microvascular and macrovascular damage (7). Possible outcomes include stroke, heart disease, limb amputations, periodontal disease, kidney disease, sexual dysfunction, glaucoma, cataracts, blindness, decreased sensation, and increased sensitivity in the skin (7). After a diagnosis of prediabetes or T2D, it is imperative that patients and their health care providers monitor patients' health closely to prevent the development of these devastating complications.

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Chapter 2

2 LITERATURE REVIEW

To gain an understanding of the SMART Study, first a description of the research behind current evidence-based best practices for prediabetes and T2D care is needed. With a focus on physical activity and healthy eating, the following literature review will also address some of the challenges faced by patients and physicians for providing primary and secondary prevention for T2D. There have been several different approaches to overcome these barriers, and these approaches are shaping the current and future directions of prediabetes and T2D health care. This review will center the SMART Study within current understanding and research of diabetes care. Finally, it will describe how the SMART Study project seeks to add to current knowledge about prediabetes and T2D health care.

2.1 Best Practices

Canada's best practice guidelines for diabetes treatment recommend an integrated approach that combines education, personalized feedback, physical activity, a healthy diet, psychosocial care, communication, and patient monitoring (5). Worldwide, diabetes care guidelines concur with these recommendations, emphasizing the importance of using a health care team approach and glucose monitoring to achieve comprehensive medical care for people with prediabetes or diabetes (7–9). The following paragraphs will outline some of the crucial works that have shaped these guidelines. Interventions that have be found to prevent diabetes or the health complications associated with diabetes include physical activity, healthy eating, and monitoring blood pressure and blood glucose.

2.1.1 Physical activity.

Physical activity, in particular, has been identified as one of the leading strategies to reduce risks associated with T2D and even prevent diabetes incidence in people with prediabetes. The mechanisms by which exercise does this are broad, but positive effects have been observed after exercise training on blood glucose control, glucose tolerance, blood pressure, and the body's sensitivity to insulin (10–17). In the larger picture, regular exercise has yielded reduced cardiovascular events and improved quality of life (10–17). Regular exercise among people with T2D also has a statistically significant effect on cardiorespiratory fitness, measured by the maximal volume of oxygen a person uses (VO_2max) (18). In one study, non-diabetic men with low cardiovascular fitness were found to have an 1.9-fold increased risk of developing prediabetes and a 3.7-fold increased risk of developing T2D (19). Similarly, a meta-analysis from seven studies involving 266 people with low-risk T2D found a strikingly low average VO_2max of 22.4 ml/kg/min, compared to an average population VO_2max value of 34 ml/kg/min (18). This is particularly important because someone who has a low VO_2max will find higher intensity daily activities harder to maintain. Therefore improving cardiorespiratory fitness may make activities such as sweeping the garage and doing home repair feel easier and could lead to an overall more active, and thus healthier, life.

2.1.2 **Healthy eating.**

A healthy diet is also crucial to diabetes management (20,21). Diet has a great influence on blood glucose, hence, a great influence on blood glucose control. While a number of different diets and eating strategies have been prescribed and experimented with over the years to help people with prediabetes and T2D improve diabetes management, diets that emphasize fibre and foods that do not spike blood sugar (low glycemic index foods) have outperformed other diets for blood glucose control (20). Among prescribed eating plans for prediabetes and diabetes, the Mediterranean diet (22) has been given a lot of attention because the foods that are commonly eaten in traditional Mediterranean communities are rich in fibre and largely have lower glycemic indices (23), and therefore should result in lower blood glucose levels and more blood glucose control than the typical Canadian diet. In addition, the Mediterranean diet, which includes a large focus on vegetables and fruits, whole grains and monounsaturated fats, has been found to have a number of cardiovascular benefits (24–26), which may compound the benefits of this diet for people with prediabetes or T2D. Research by Esposito and colleagues found that overweight, sedentary people with newly-diagnosed T2D who followed a Mediterranean-style diet required prescription treatment less often, had greater improvements in glycaemic control, and had greater improvements in their coronary risk factor profile measures than a similar cohort who followed a low fat diet (27). The benefits of a Mediterranean diet for improve glucose control for prediabetes and T2D has been supported in a number of other studies (28,29). While some of the benefits associated with a Mediterranean diet may be due to adherence to diet plan and resulting weight loss, after adjusting for weight loss, Esposito and colleagues found that the gains to health from the Mediterranean diet went beyond weight reduction (28). In addition to health benefits, the Mediterranean diet has been associated with improvements in mental health for people with T2D (30). The evidence for the Mediterranean diet has led researchers to conclude that the Mediterranean diet is a worthwhile eating strategy for people with prediabetes and T2D to follow (31–33).

2.1.3 **Self-monitoring.**

Self-management makes up to 95% of diabetes care (34), therefore it is critical that patients learn to monitor their health (such as blood pressure, blood glucose, diet and physical activity) in order to maintain their health and reduce their risk of diabetic complications. In particular, blood glucose monitoring has been emphasized as an important measure to monitor for people with T2D, in order to reduce the incidence of hyper- and hypoglycaemia. Strict blood glucose control has been demonstrated to be very influential in the prevention of complications associated with T2D, particularly for those newly diagnosed (6,35,36). Improved glucose control also contributes to a reduction in the economic burden associated with diabetes (32,36).

Self-monitoring of blood pressure among participants with diabetes has demonstrated promising results. One study of 33 Canadian participants with diabetes and uncontrolled hypertension had them measure their morning and evening blood pressure at least twice a week for 4 months, and found that blood pressure fell significantly and blood pressure control improved significantly (38). While only a handful of studies have looked at self-monitoring blood glucose for people with prediabetes (39), it follows that results would be similar for this population, albeit to a smaller extent. If patients and their health care providers are able to monitor blood pressure and blood glucose closely, they will have a better idea of the triggers and behaviours that are affecting the patient's blood pressure and blood glucose, and can modify their lifestyle choices and medications accordingly (40).

2.1.4 The family health team setting.

The Family Health Team (FHT) is an ideal setting for people with prediabetes or T2D to access physical activity, nutrition and self-monitoring information as it is a point of entry for patients into health care. It is a setting where people are accustomed to receiving health information, a location that allows for continuity of care, and a place seen as a trusted as a source of health information (41,42). For example, in a systematic review of physical activity counselling in family practice, Petrella and Lattanzio found that family doctors can influence physical activity levels in their practices, and concluded that giving patients written physical activity prescriptions would further encourage increased activity (43). Expanding upon this finding, Petrella and colleagues conducted a study of Canadian family practices to see the effect of exercise prescription on physical activity levels (44). Findings from the study suggested exercise prescription can improve fitness and exercise confidence in patients and exercise prescription from the family doctor can increase patient adherence to exercise and physical activity. More evidence for the importance of physical activity counselling in primary practice was reported recently, with findings that physical activity consults were linked with increases in physical activity by people with T2D (45). Other studies of lifestyle counselling in primary care for people at risk of T2D have found positive responses, including good adherence to office visits, weight loss, decreased FBG and moderate changes in physical activity and dietary intake (46–48).

2.2 Barriers

2.2.1 FHT barriers.

While FHTs strive to provide comprehensive diabetes care, the typical limits of general practice do not allow for day-to-day monitoring and healthy lifestyle education (49–51). Studies have found that family doctors do not regularly provide physical activity and diet counselling, nor do they monitor lifestyle habits (43,52–54). Although regular exercise along with diet and insulin was recognized as good therapy as early as 1927 (55), it is not widely prescribed clinically. Research has found that there are gaps in knowledge, attitude and practice hindering successful management of diabetes (56). Family doctors' reasons for this lack of attention to lifestyle counselling in family practice include time pressures, absence of proper infrastructure and skills, low compliance by patients, lack of reimbursement, feelings of hypocrisy, and inadequate knowledge about physical activity and nutrition prescription (43,51,53,55,57,58).

2.2.2 Patient barriers.

For patients, the overwhelming complexity of self-management is often an insurmountable obstacle to positive change (6,56,59). People with prediabetes and T2D perceive exercise to bring benefits for improving diabetes control (60,61), yet many people with T2D find following a rigorous endurance exercise routine difficult. Despite numerous studies showing the benefits of physical activity for managing diabetes, this research is not translating into action among people with prediabetes and T2D. This is not too surprising, as only 53.8% of Canadians report being physically active in leisure time (1), which is only slightly higher than their American neighbours who report 46.4% of the population is physically active in leisure time (62). These low activity rates are consistent among studies with people who have prediabetes or T2D as well (60,63,64).

Adding to the barriers Canadians face to achieving control of their diabetes is the often confusing riddle of attaining a well-balanced diet. In 2004, the average Canadian scored 58.8 out of 100, considered an average quality diet, on the Canadian Healthy Eating Index, a measure of how well Canadians are eating (65). While the amount of grain products, meats and alternatives and unsaturated fats Canadians ate scored relatively high, Canadians scored relatively low on the amounts of dark green and orange vegetables, whole fruits, whole grains, and it was apparent there were too many calories in the diet that came from foods that do not fit into the Canada's Food Guide food group categories (e.g. "other foods," such as soft drinks and potato chips) (65). These findings extend to people with diabetes (63). Interestingly enough, while many people have an idea of what an 'ideal diet' would look like, it is often at the implementation of healthy guidelines where people feel at a loss, particularly those with T2D (66). Studies have found that people with T2D believe that medication is more important and effective in helping to control blood glucose rather than physical activity and diet (67,68). This belief has been clearly disproven by the studies comparing medication to structured exercise programs (69–73), but still the low rates of physical activity and health eating behaviours persist across prediabetes and T2D populations.

Asking patients to self-monitor their blood pressure and blood glucose yields its own unique challenges. Self-monitoring and management usually requires considerable patient-clinician contact to be implemented (74–77), and many doubts have been raised about the efficacy of blood glucose testing (78–80). Farmer and colleagues found that participants self-monitoring their blood glucose did not know how to interpret their own blood glucose data, and the numbers on the machine have little effect on their diabetic health (79). Due to the high costs of the test strips compared to the minimal change in health status, many researchers have concluded that blood glucose testing in non-insulin using T2D is pointless, and should no longer be included in best practice guidelines (75,76). However, for patients with newly diagnosed diabetes, home blood glucose monitoring has shown to have benefit (76,77). Therefore, people with newly diagnosed diabetes should be taught how to monitor their blood glucose, so that they can start to see the effect that their lifestyle choices have on their blood glucose levels, and consequently their health.

Perceptions of a lack of time, not enough money, low self-motivation, little support from family and friends, low self-efficacy towards healthy living, and poor self-management skills are some of the common reasons people do not incorporate physical activity, healthy eating and self-monitoring into their daily lives (82–86). In a study investigating physical activity behaviour, participants listed feelings of incompetence at setting personal goals, monitoring progress or rewarding progress towards goals, all important strategies for making behaviour change, as part of the reason why they did not participate in physical activity (84). This is important to note because people newly diagnosed with prediabetes and T2D often need to change many different routines in their daily lives in order to manage their disease. The magnitude of these lifestyle changes and the perceived inability to make the changes can lead to feelings of depression and anxiety, which are further barriers to self-care behaviours (87,88).

Other reasons for not doing exercise among people with T2D were worries about physical discomfort, fears of hypoglycaemia, and feeling too overweight (68). Consequently, any intervention that promotes physical activity behaviours should include support for how hypoglycaemia can be managed and treated as well as effective methods for enhancing self-efficacy. Self-efficacy is the belief a person has in their ability to do a behaviour, and it is an important predictor of whether or not a person with prediabetes or T2D will participate in physical activity, eat a healthy diet and improve overall self-management of diabetes (89–91). Examples of methods for increasing self-efficacy are goal setting, social support, and weighing the benefits and consequences of increasing physical activity (45). If newly diagnosed patients feel comfortable setting personal goals, monitoring and rewarding their progress, their ability to manage and implement lifestyle changes is much higher. This is a key finding to remember when designing any intervention for prediabetes and T2D.

2.3 Strategies For Overcoming Barriers

2.3.1 Education.

Traditionally, the approach of the FHT was to educate patients about healthy living and how to accomplish self-monitoring, and then send them forth to act on their newly acquired knowledge. And sometimes this works: education interventions have demonstrated some success at improving glycaemic control (92,93). However, it should be emphasized that problem solving and concrete strategizing about how to make behaviour changes are vital to education, rather than giving people general tips about effective management (87,93). The benefit of diabetes education has been a hot topic of debate in academic circles; some scholars strongly support it (34,94–99), while others have found very little proven benefit (79,100–102). It is likely that the conflicting results of education interventions are due to the differences in self-management practices among individuals and the support the individuals received (103,104). In fact, in a systematic review of the effectiveness of self-management training in T2D, the only program feature that was uniquely predictive of success was the duration of contact between the health care provider and the participant (105). The role of the health care provider in promoting healthy living for people with prediabetes and T2D should be to support self-management through education and collaborative problem solving to create an action plan (56,103,104,106,107), a strategy that requires time and frequent communication to carry out.

It is also likely that the successful education programs were impacted by degree of tailored information delivered to the patients by the health care providers. For example, one successful education intervention integrated patients' medical care data into their education program components, and found patients had better glucose control, lower HbA_1c and total cholesterol at the end of the intervention (108). Similarly, Jacob and Serrano-Gil's best practice guidelines for a successful health promotion program include making the program personally meaningful in order to engage the audience (56). If the audience is engaged, there is improved quality of life, reduced complication rates, and increased self-efficacy, which in turn increases engagement to the program, a positive feedback cycle (56,109). Perhaps the answer to the education debate for improving diabetes health care is that education cannot stand alone, and while necessary, diabetes care requires a more comprehensive behaviour theory-based approach to ensure all parties are engaged in the program and self-efficacy building strategies are incorporated (45,110).

2.3.2 **Behaviour change theories.**

Leading researchers (45,111) recommend using the transtheoretical model (TTM) (112) to encourage behaviour change in T2D. The TTM is based on Social Cognitive Theory, and can be used to assess each person's readiness for changing activity and eating habits (109,111). There are five categories of readiness, known as stages of change (113):

1. Pre-contemplation: not thinking about starting exercise or eating healthier
2. Contemplation: thinking about starting exercising or eating healthier within the next 6 months
3. Preparation: doing some exercise or eating healthy some of the time, but not regularly
4. Action: engaged in regular exercise or healthy eating practices for less than 6 months
5. Maintenance: involved in regular exercise or healthier eating habits for greater than 6 months

Studies have found that if the stage of change is matched with the intervention strategy, participants are more likely to adhere to the intervention, less likely to drop out, more likely to meet and exceed their goals, and more likely to maintain the behaviour changes in the long term (114,115). However, the model is not without criticism. Many of the positive results from using a stage-matched intervention do not last in the longer term (116). In addition, the participants that volunteer for any behaviour change study are likely more motivated than the general public to make a behaviour change, and therefore few are in a pre-contemplation stage after signing the letter of information to start the research study and most are likely in the preparation stage. Behaviour matched interventions are important for reaching out to a diverse population who may have a wide range of intentions. However, the TTM does not develop in much detail the experiences that people go through while staying involved and engaged in a behaviour change, or describe how to encourage and support someone in preparation and action stages to move towards the maintenance stage.

A behaviour change theory that has expanded upon the TTM stages of change and the social cognitive theory's emphasis of self-efficacy, is the Health Action Processes Approach (HAPA) developed by Schwarzer in 1992 (117). This theory separates behaviour change into two separate periods, a motivation phase and a volitional phase. In the motivation phase, a person can be considered in a stage of change 1, 2 or 3, and thought of as either a "pre-intender" or an "intender". Influencing his intention to make a behaviour change his task self-efficacy, his expected outcomes of the behaviour and perhaps also the personal risk he associates with acting or not on that behaviour. For example, 'Stuart' may not think he can eat many more fruits and vegetables, but if given the suggestion to replace pretzels with broccoli, he may agree that he can substitute one serving a day; this is his task self-efficacy. He may expect that replacing one serving of pretzels with a serving of broccoli may help lower their blood glucose levels. He may also expect that eating broccoli instead of pretzels will not satisfy his taste buds. Weighing these outcomes will influence his intention. If he knows that his brother has had a stroke, and that he himself has already been diagnosed with hypertension, he will likely be more willing to consider making that switch in snacks versus a person who does not think he is at risk of diabetic complications.

The volitional phase is where a person acts on his good intentions and then maintains the behaviour change, stage of change 4 and 5, also known as the "actor". As this appears to be the point where many people, especially participants who are motivated enough to volunteer for lifestyle intervention studies, are not able to move past, this is where lifestyle intervention research projects need to focus. To move from the motivation phase to the volition phase, HAPA theorizes that a person must have sufficient task self-efficacy, maintenance self-efficacy, recovery self-efficacy and he must have a plan. The plan should not only involve the details of how the behaviour will be carried out, but also problem solving for how to manage barriers that may hinder the plan. For example, Stuart may plan to eat his broccoli as a snack when he gets home from work instead of pretzels, but what happens when he runs out of broccoli, or he goes to a friend's house after work? Plans for deviations from Stuart's regular routine will influence how well Stuart sticks with his behaviour change. These plans will also help to build Stuart's maintenance self-efficacy, his confidence to continue a behaviour once he's begun.

Studies using HAPA as a motivation model have found support for the HAPA theory. A study conducted by Chiu and colleagues found support for HAPA backed dietary self-management program among a population of people with multiple sclerosis (118). A study conducted by Barg and colleagues found HAPA to be a useful framework for predicting physical activity among inactive middle-aged women (119). Likewise, Lippke and Plotnikoff, and Ochsner, Scholz and Hornung found that HAPA principles were beneficial in a population of people with T2D (120,121).

Indirectly, further support for the HAPA model can be found. Behaviour change strategies that involve goal setting and self-monitoring can help increase or maintain exercise (122–124). It is important to note that goal setting strategies that followed up with support for the participants and their goals was more effective (123). In Cholewa and Irwin's study, an online tracking system was used for self-monitoring and demonstrated success as a means of tracking physical activity to increase or maintain exercise levels (124). Mirroring the conclusions drawn above regarding barriers to self-management and targeted education: T2D is a difficult disease to manage, and needs to encompass behaviour theories and multiple behaviour change strategies in order to be effective. Strategies like goal setting frameworks that involve feedback, making contracts, counselling about barriers, tracking behaviours, goal attainment and skill development should be part of comprehensive diabetes health care (123).

The different strategies and debates that surround effective delivery of primary and secondary prevention of diabetes do have some common ground: diabetes care must include tailored and practical education, effective and frequent communication between a patient and their primary care team and close monitoring, including blood glucose and blood pressure. Using behaviour change theories helps to structure and guide the strategies to ensure that building self-efficacy, goal setting and tangible problem solving is not left out of diabetes health care. These conclusion nicely echo the Canadian Diabetes Association's Best Practice Guidelines for effective diabetes care (5).

2.4 Current Research Directions For Improving Diabetes Care

Although the above-noted activities and strategies have had remarkable success in reducing diabetic complication risks, knowledge translation from these programs into feasible treatment plans in family practice has been problematic. Most of the research projects that yielded the greatest health outcomes involved lifestyle interventions that are very intensive and require a large time and resource investment by health care providers, thus making them unsustainable in Canada's current health care system (100,125–127). Despite some research pointing to the cost-effectiveness of these lifestyle intervention programs (21,128), in an overburdened health care system and fractured funding system it is difficult to make these programs a reality (129). Self-monitoring in particular is time consuming and tedious to discuss in a typical health care appointment, but recent advances in communication technology have made monitoring behaviours easier (130). Online and mobile tools, coined "mHealth" (131), hold potential for lowering the time cost to clinicians and also increasing the number of people who can access the monitoring programs (39,132). Given the realities of primary health care in Canada, this review will now consider the ways modern technology can transform programs and guidelines into usable and relevant interventions for patients and health care providers (133,134).

2.4.1 **Internet.**

Many internet and electronic management systems have reported improved diabetes care (122,135–137). For example, Trief and colleagues found that web-enabled computers which allowed users to upload their blood glucose and blood pressure so that health care providers could monitor, counsel and formulate self-management plans and goals with patients improved diabetes self-efficacy and glycaemic control (138). Another electronic health system was used to teach people with early diagnosed T2D about the disease and to help them develop self-care activities and improve their biomedical outcomes (139). Research results led Kelley and colleagues to conclude that patients are likely ready and capable of using electronic health systems to improve their care (139). In their research, the electronic health system was comprised of electronic educational materials, interactive tools to communicate with clinicians, tools for the patient to capture health information and the capability for patients and clinicians to monitor health information. Results also suggest that internet based learning resources can increase patient self-efficacy towards self-care, thereby predisposing them to carry out self-care behaviours, which could lead to better outcomes (139).

In contrast, recent study results presented by Wakefield and Koopeman at the 2012 HIMSS Conference (140) of people with diabetes and hypertension who manually uploaded their blood pressure and blood glucose readings onto a web-portal found no improvement in blood pressure and blood glucose control (141). While Kelley and colleagues' study results implied that use of the electronic health system could affect self-care behaviours directly, which could in turn, affect health directly, Wakefield and Koopeman found no beneficial changes short term through internet monitoring and brief feedback without addition educational material (140–142). Taken together, these findings support the argument for tailored education stated earlier: patients require specific knowledge tailored to their situation and resources to improve their diabetes self-efficacy perception, in order to improve the likelihood of these patients performing self-care activities (141,143). Corroborating this, a comprehensive review of internet interventions for promoting chronic illness self-management by Bull and colleagues observed that tailored interventions were superior, and successful interventions included collaborative goal setting and feedback during initiation and maintenance of the intervention (144).

2.4.2 mHealth.

Using mobile phones with internet, known as smartphones, for managing diabetes care has gained momentum due to smartphones' relatively low cost, convenience of use, and their increasing transcendence among generations and ethnicities (137,145–147). The advantage of a smartphone for diabetes management is that measurements using the phone can be taken any time and any place without needing a computer, and if Bluetooth® wireless technology and 3G or 4G networks are used, the mobile phone technology allows for an automatic transfer of data (148).

There have been several remote mobile phone studies with lifestyle interventions for T2D conducted in the United States, Europe and Asia (38,147,149,150). These studies have shown that the mobile phone can support diabetes monitoring and self-care (151,152). One example in particular used mobile phones and included data analysis to deliver personalized education (153). This study demonstrated some of the still largely untapped potential of mobile phones to enhance self-management outcomes (153).

Another example of a successful intervention using mobile phones was the 'diabetes phone' study in Korea, which had comparable success to the internet-based glucose monitoring system (154). Patient satisfaction with the 'diabetes phone' and adherence to medical advice was similar between the technology interventions, and better than traditional education interventions. Istepanian and colleagues evaluated the impact of using a mobile phone to intensify the delivery of care for T2D (155). The phone was used to record and monitor blood pressure and blood glucose levels and found a significant fall in mean systolic blood pressure and a trend towards lower HbA_1c. Other studies monitoring blood pressure and smartphones have found similar results (39,156,157).

In Canada, only a few studies have examined mobile monitoring for the management of prediabetes and T2D. The results have been mixed, likely due to varying degrees of following best practice guidelines (39,148,158). In Seto and colleagues' recent review of mobile application (app) interventions in Canada and the UK, three studies were examined that used an app to monitor blood pressure, in Toronto and Chapleau, Ontario and in South London, UK (148). The latter two interventions also monitored blood glucose using a wireless Bluetooth® glucose meter that was synced with the app. The overall conclusion was that HbA_1c did not improve with monitoring, however, the two studies faced a number of difficulties throughout their implementation due to changes in research staff and difficulties with the technology, making it hard to draw any solid conclusions from these results. In contrast, a systematic review of the use of cell phones in health promotion strategies found that of the ten studies that looked at cell phones and HbA_1c, nine reported significant improvements in the blood glucose control (159). In addition to improved diabetes-related health outcomes, knowledge, self-efficacy and better adherence to protocol scores were increased in subjects who practiced self-management behaviours (158).

2.4.3 **Data mining.**

Reviews of research done on mobile phones as tools in health care have concluded that smartphone functionality has not yet been exploited to its full potential (160). Data mining in particular is an area that, while having been used in others fields to discover trends and predict future outcomes, has yet to be really utilized in health care, let alone diabetes. Data mining is a process of using statistical analysis in order to discover patterns and trends in a data set, which in turn are used to build predictive models. Because the smartphone makes data simple to collect, its potential as a tool to collect the large amounts of data needed for mining may be the link that can turn measured data into guidance and actionable feedback delivered to the user at the time he or she needs it most. Current research has only started to discuss and test data mining for diabetes care (161–165). Data mining is limited by the quality of data collected, and needs an initial bank in order to run. In addition, data mining can discover trends that are only a result of random variation, and therefore needs a sufficiently trained and vigilant team to observe the outcomes and decipher between useful and nonsense results, which may explain why it has been under-utilized, as interdisciplinary teams are needed to understand data mining results. Only one study has published outcomes for data mining among a small

T2D population (163), while one other has been done in a type 1 diabetes population (153) and a protocol has recently been published with proposing to use data mining to discover trends and send recommendations for people with type 1 diabetes (165). While some of the challenges with data mining in health care are still being sorted out, it remains an exciting field to deliver tailored and targeted information to individuals in a manner that has not been possible in the past.

2.5 Future Directions

mHealth initiatives have shown promise of being effective at enabling management of prediabetes and diabetes (147,150,152,166). However, barriers have also been encountered in the implementation of these interventions, namely design flaws and high operating costs (155,156,158,166). Researchers suggest that future developments in mobile monitoring should focus on combining simple apps with familiar mobile phone technologies and should focus on permitting sufficient interaction with care providers (147,167). This echoes previous research that emphasizes the importance of communication in any diabetes health care strategy (103,104). In addition, apps should be developed using behaviour change theory, and leverage mobile technologies to provide just-in-time, interactive and adaptive interventions to help people make positive lifestyle choices (132,168). For example, using real-time alarm software and automatic response algorithms based on the patient's data along with performing data mining could help provide instant, tailored feedback (168).

A systematic review of apps currently available on online markets found that the most common features were diet, insulin and medication recording, data synchronization and communication, and tools for weight management (158). A concurrent literature review from Choumutare and colleagues found that in research apps, the most prevalent features were personal health record or web server synchronization, insulin and medication recording, diet recording, data export and communication. Noticeably lacking was diabetes education or apps built on evidence-based recommendations. Despite a wide body of literature on the use of mobile devices and diabetes interventions using the internet and mobile phones, present knowledge about good practice in designing health care integrated apps seems limited (158,169).

Patient perspective is essential to understanding the benefits of an intervention program for patients, and necessary in order to improve the program, increase patient engagement in their care, and maintain behaviour change. Especially important to consider is patient intention along with task, motivation and recovery self-efficacy change before and after the intervention (91,170). In a systematic review and meta-analysis of web-based interventions on patient empowerment, participants reported significant positive change in empowerment after the interventions, as well as self-efficacy in regards to disease specific scales (171), and thus similar results should be measured and seen in a well-developed mHealth study.

Self-efficacy has been a strong theme in this review, therefore it is important to build task, maintenance and recovery self-efficacy strategies in order to ensure a successful diabetes intervention. Task self-efficacy for self-monitoring using a mobile phone may not be difficult to come by, because mobile phones are becoming ubiquitous in Western culture. For example, participant feedback in a study using mobile phones to monitor hypertension was enthusiastic; participants liked the idea of having a physician review and act on their data if their blood pressure was too high, most were comfortable with using a blood pressure cuff because they already did some monitoring of blood pressure outside their physician's office, and they believed a monitoring system would give a better picture of their overall health than they currently had (156). Another review reported a similarly promising finding, the majority of patients involved with mobile interventions found apps convenient and easy to use (132). These results suggest that mobile phones apps are a feasible tool for diabetes health care as long as it is designed for the target population, and users are given sufficient training about how to use the app.

2.6 Conclusion

The increasing availability and use of mobile phones, and the groundwork research of how diabetes care, self-management education and behaviour change theories can be applied to current technologies provide a solid platform for the SMART Study. The lessons learned from the internet and mHealth tools outlined above and the framework of diabetes best practices were the base for the SMART Study research team to build an app designed to enhance primary health care. The app promotes healthy behaviour change by building each users' self-efficacy, encouraging self-monitoring and goal setting, strategies can help a person reduce their risk of developing diabetes or its complications. The app uses data mining to send tailored feedback to users and alerts to the health care team; communication strategies that have been shown to help people with prediabetes and T2D to succeed in self-management and overcome some of the barriers to healthy living. The app provides a venue for communication between the health care team and their patients, while avoiding some of the high health care provider costs and time commitments that have traditionally come hand-in-hand with personalized feedback. It is possible, using the app, to collect and analyze large volumes of health data through data mining, and the results can be presented to users and their health care team to inform them if blood glucose is under control or how daily lifestyle choices are affecting blood glucose levels. Building on the research that has already been conducted and explored above, the SMART Study advances understanding of how an app and data mining can be used in conjunction with the health team to provide primary and secondary prevention for T2D.

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Chapter 3

3 DESIGNING GLUCOGUIDE™

Self-management of health is a task that health care practitioners seek to teach their patients presenting with prediabetes and T2D. However, this is no small task. As discussed in the previous chapter, the interplay of behavioural, psychological, social, environmental and structural factors that influence daily living make achieving blood glucose control very difficult. Best practices outlined in the 2008 Clinical Practice Guidelines from the CDA advise a combination of self-management education, nutrition therapy, physical activity, obesity management and pharmacologic management should be used to achieve blood glucose control (1). In addition, these tools should be tailored to the individual's treatment recommendations, readiness for change, learning style, ability, resources and motivation. These best practices, informed by many successful intensive lifestyle interventions among people with prediabetes and T2D are worthy goals, and yet almost impossible for a primary care physician in Canada to deliver given their limitations in knowledge, time and resources (2–4). In addition, because blood glucose influences are multifactorial, the behaviours that must be undertaken to achieve control are far more complex than the often simplified explanations discussed in most clinical setting such as "eat less carbohydrates", "lose 5-10 lbs", or "keep track of your blood sugar".

It is due to the complex nature of this chronic disease that as an interdisciplinary team we developed a tool that could simplify the task of improving blood glucose control. We had three goals:

- to follow best practice guidelines
- to inform health care decisions tailored for each individual
- and most importantly, to provide support for people living with prediabetes and T2D given their unique situations.

Our vision for this tool was a smartphone application (app) that could be accessed by patients and their health care teams when and where they needed it most. Making a mobile health application was ideal because it is accessible, available, and through data mining we have the capacity to learn and tailor our message for each individual.

Below, we will outline the results of our research among scholarly articles, grey papers and the diabetes community. Along with this we will describe the system we designed, GlucoGuide™. We will outline some of the problems and solutions we encountered, including feedback we received from our pilot tests among 10 people diagnosed with prediabetes or T2D. This paper will be of interest for people interested in designing health apps promoting behaviour change, as it described the lessons we learned and suggestions for future development.

3.1 Background

This idea of an individual approach for complex chronic disease is not a new concept, yet in the past has been quite costly for health care providers due to the enormous amounts of time required of health care teams (5–8). However, with advances in machine learning and data mining, along with network and smartphone functionality and availability, the realization of these ideas into tangible tools with a more feasible economic costs to patients and health care providers has become a reality. While patient monitoring is one of the least developed mHealth initiatives (9), it is quickly gaining momentum. Within the last 5 years the number of apps available for download on iTunes and the Android Play Store has exploded (10,11).

The scientific community has been critical of the current mobile health apps for T2D on the market, due to the lack of apparent research or theoretical backbone to their creation, and most importantly a lack of regulation of these applications that could potentially lead to misinformation or health risk. Unfortunately, even among applications used for scientific research, finding a theoretical behaviour change model behind the development and process of the app is rare (10–13). A recent meta-analysis and systematic review found moderate benefits for using apps for behaviour change (13), while another review postures that apps are more successful when built on behaviour change theory (12).

3.2 Design

Several research groups have conducted needs assessments and user focus groups among people interested in using a smartphone app to monitor and manage their prediabetes or T2D (14–20). These results provide a clear path for developers looking to build an app that will be well received by their intended prediabetes and T2D users. The results that shaped the design of our app are summarized here along with descriptions of how we interpreted and integrated the results into GlucoGuide™.

Developers of apps for T2D have described many ideas and lessons learned, which further informed our development of an appealing, functional app (10,11,13,17,21–24). Developers stressed the importance of pilot testing for learning about the highlights and problems with the app itself and with the training required to teach others to use the app (14,22). Our pilot test is described in detail in the next two chapters. Developers also recommended matching technology to the participants (14,25), which influenced our decision to allow participants to choose the tool that they would like to use (a paper journal or the GlucoGuide™ system) in this pilot study.

3.2.1 Intuitive design, user friendly functions.

App-tester participants tend to prefer a simple display on their phone screen with graphics and some text (19). Several participants who tested out the various apps expressed frustration using the smartphone (14,15), a point that we addressed in our protocol by having adequate training and help for the smartphone and other health monitoring devices. We also tried to make the phone as user-friendly as possible, by showing simple graphics, large menu buttons, along with smaller buttons accessible for more technology-savvy users (Figures 1-4). We also settled on four basic metrics we wanted to have participants record: diet, blood glucose, blood pressure, and step count.

Participants wanted control over the data they uploaded. This includes the ability to enter unique data, such as new food items, and edit previously entered data (18). This was particularly important for the diet entry component of the app, as it required more effort from the users and had greater potential for entry error. After several revisions we came up with a simple interface that allowed participants to enter food, remove food, review the calorie summary and macronutrient breakdown of the entry and adjust the time of the meal, if they needed to enter a meal they had eaten earlier in the day (Figure 2). Micronutrients were not calculated or recorded, as developers recommended not having detailed food information (17). Users of our app can also look through their previously

Figures 1-4: Screen Shots from the GlucoGuide™ Smartphone Application

Figure 1. Main Menu in the GlucoGuide™ Smartphone Application

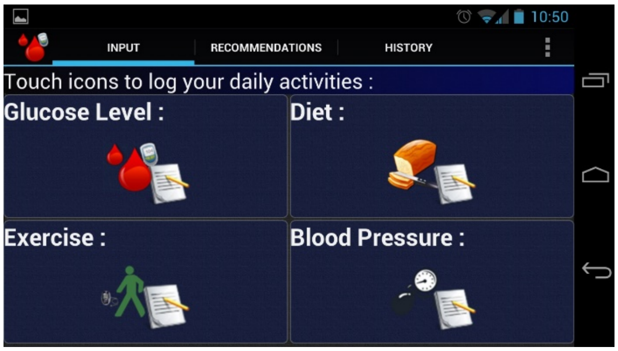


Figure 2. Diet Entry Screen in the GlucoGuide™ Smartphone Application

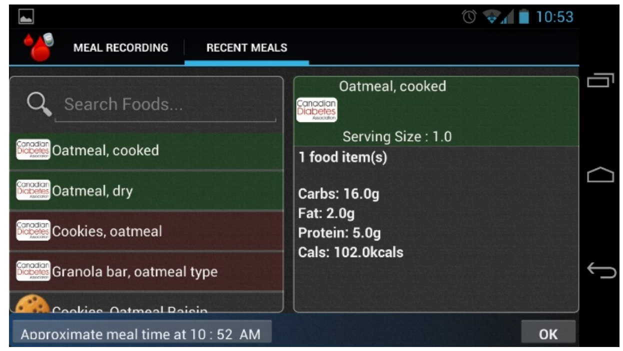


Figure 3. Blood Glucose Entry Screen in the GlucoGuide™ Smartphone Application

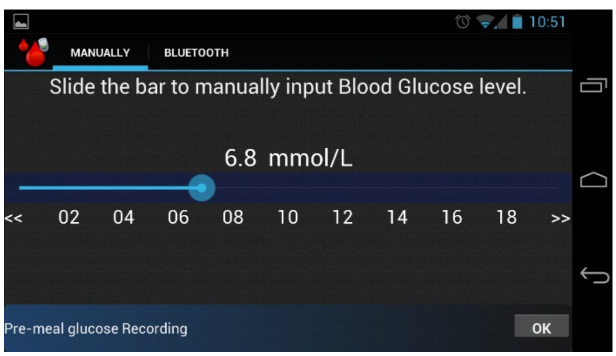
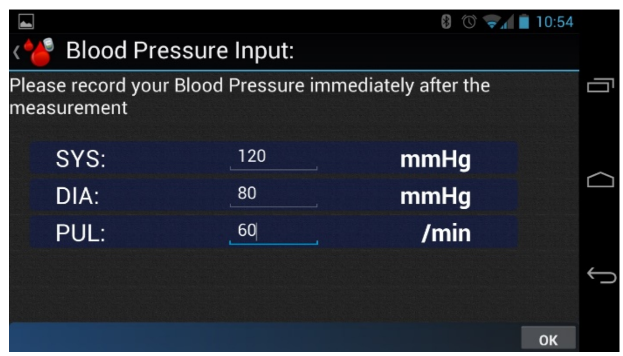


Figure 4. Blood Pressure Entry in the GlucoGuide™ Smartphone Application



entered meals and select one of these, so they not need reenter their coffee snack every day, thereby reducing redundancy and increasing ease of use. These features were noted in participant reviews to be features they would like in an app (18), but are still not widely available in apps currently available on the market (21).

3.2.2 **Accessibility.**

Interestingly enough, participants interviewed about having the option of a web-based program or a mobile app usually preferred both, or a mobile app rather than a web-based program alone (14,15,18). Based on these results, we built a web-portal interface for users, but we did not push our participants to use the web-portal. Instead, if someone was interested in learning more, we would provide the information for accessing their results on line (Figures 5 and 6).

Figures 5-6: Screen Shots from GlucoGuide™ Web Portal

Figure 5. Sign-in Page for the GlucoGuide™ Web Portal

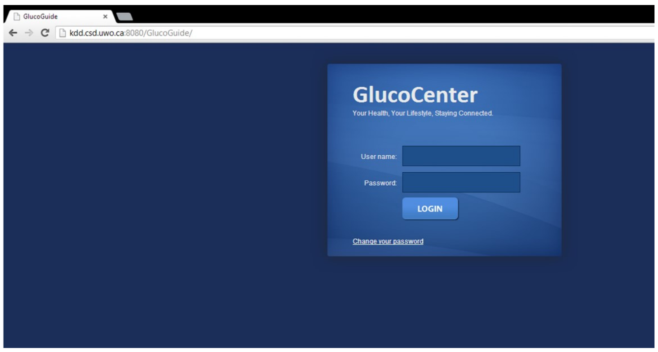
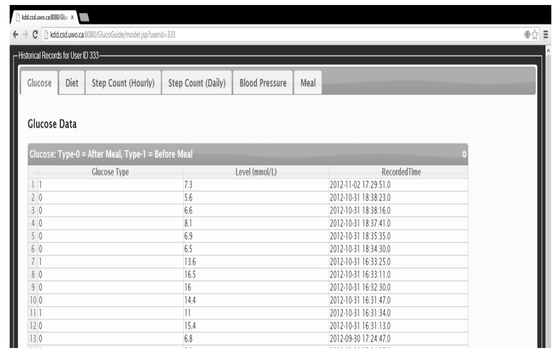


Figure 6. Screen Shot of Blood Glucose Data in the GlucoGuide™ Web Portal



3.2.3 **Built on established behaviour change theory.**

Developers noted specific features that should be carefully considered for incorporation in future app development, including messages tailored for the individual to enhance management self-efficacy (15,17). And as noted above, while research has found that lifestyle interventions are more successful when they are based on behaviour change theory, it is often left out. One specific example of an app incorporating strategies for building management self-efficacy was tested by 15 sedentary adults (20). The participants found goal setting and problem solving to be appealing aspects of a physical activity promoting app. The participant support of these features suggests that building an app using behaviour change theory may appeal to users, and will be welcomed rather than a feature that is solely pushed upon them from experts.

Due to these findings, we decided to build our application using the TTM (26), which has been time tested as a successful model for determining individual readiness to change physical activity levels and healthy eating behaviours (27,28). We also decided to use the HAPA (29) to inform our implementation and evaluation of the app, as it advances some of the ideas of the TTM in an attempt to describe what influences a person's ability to continue or relapse once beginning a new behaviour. This model has been shown to distinguish among levels of intention and volition for people with T2D (30), and suggests specific strategies for helping encourage healthy behaviours among these different levels. Since HAPA extends the TTM by looking deeper at the differences between an intention and action, it can therefore be used for planning and evaluating behaviour change interventions for people who are highly motivated, but not yet carrying out their good intentions.

We incorporated these theories by first determining which stage of change each participant perceived himself or herself to be at, and then working through goal setting and overcoming barrier exercises at clinic meetings. The stage of change, goals and barriers were recorded and used to formulate individually-tailored messages that were sent back to participants by the research team, as a means of building self-efficacy as well as continuing communication and triggering compliance to the self-management behaviours the SMART Study participants set as goals.

3.2.4 **Simple, automatic data upload.**

One theme that we found repeatedly was the need for simplicity and low user effort (14–17,20). However, one review noted that while automation should be included as much as possible, there should be options for manual operation by patients in order to allow users increased control over the functions of the phone (15). Another study noted that participants found the act of recording and reviewing records of eating habits was inherently rewarding (18). Manual operation requires mindfulness on the part of the user to recognize and keep track of whatever metric is being recorded, and that act in itself encourages healthier behaviours (31,32).

While we initially tried to incorporate as much participant hands-off data collecting as possible, differences in technology did not allow us to syncronize the blood glucometers and blood pressure monitors wirelessly with the smartphones. Bluetooth® pedometers collected hourly totals of steps taken. However, the pedometer needed some attention on the part of the user to get the data transmitted from the pedometer to the phone. This was done by pressing several buttons on the pedometer and phone and using a docking station at the participant’s convenience. On the other hand, the effort required to enter blood glucose levels and blood pressure was minimal; users selected the data they wanted to upload and then used a sliding scale for blood glucose and guided boxes for blood pressure to enter the readings from the screen (Figures 3 and 4).

3.2.5 **Personalized feedback.**

Several participants groups reported that personalized feedback from their health care teams would be an important feature of any app promoting healthy eating and physical activity (14,16,17,19,20). As Årsand described in his recommendations for developers, the reward for inputting data should be more valuable to the user than the cost of entering the data, and the reward should be immediate once the data is entered (17). To respond to this, our team decided to use the power of data mining to simplify the large amount of data uploaded by users, find trends between the data and generate automatic recommendations. This was the most innovative part of this system. Data mining is the application of statistics to data to elucidate trends and associations is a relatively new concept in health care. While it has been used by business for recognizing marketing opportunities for some time, it has only started to appear in health care (33–37).

Simply, the idea is that by using a participant’s uploaded data in an algebraic equation with the participant’s blood glucose level as the outcome, data mining can assign values for cofactors for a set of uploaded variables (i.e. step count, carbohydrates, proteins, fats) and relate these to the particpant’s blood glucose. The value of a variable’s cofactor indicates the strength of that variable on the individual’s blood glucose, so that we have a more tailored and direct plan to improve that individual’s blood glucose control. An example equation that could be generated for a participant is shown below.

$$Blood\ Glucose = 0.32 * Carbohydrates + 0.03 * Fats + 0.001 * Protein - 0.2 * Step\ Count + 67$$

The largest cofactor is associated with carbohydrates and the second largest cofactor is associated with step count. Therefore, to impact blood glucose levels, we would recommend to the above participant that she try decreasing the amount of carbohydrates she eats at meal time and try increasing her step count. A message is automatically generated by the GlucoGuide™ system and left in the portal ready to review by our research health care team, where it can also be edited if needed. Once approved, the message is sent to the user. An example message would be

> Based on your uploaded data, we've noticed that your blood glucose levels are most related to steps you taking, and the amount of carbohydrates you eat. To improve blood glucose control, try adding 1,000 steps to your after dinner routine, and reducing your carbohydrate intake at dinner. For example, replace 1 cup of pasta (40 grams of carbohydrates) at dinner with 1 cup of cooked spaghetti squash (10 grams of carbohydrates).

The cofactors may change each time data mining is run, as a result a participant uploading new data. This would affect the feedback and personalized behaviour tips. This feature is the cornerstone of the GlucoGuide™ system, and sets the system apart from previous behaviour change interventions for prediabetes and T2D.

We have left the message under the control of the health care provider to send rather than sending it automatically so that the health care provider could approve that the information and message produced by data mining was appropriate (38), and because participants in review groups commented that without being tied to the health care providers, some automated messages could end up being irrelevant and patronizing (16). We also provide trend lines of the data uploaded so that users can review their data themselves in a visual mode, a feature reported by participants as useful (16).

3.3 Lessons Learned

GlucoGuide™ Messages. A total of 124 messages were sent out throughout the 12 weeks of the study to the 10 people enrolled in the smartphone group. The health care team received 327 alerts for data uploaded that triggered high or low thresholds. In addition, 27 phone calls and 411 emails were sent to participants to follow-up alerts, troubleshoot for the smartphone, and book follow-up appointments. The most common problem with the system was syncing the Bluetooth® pedometer with the phone. Due to the number of steps and buttons to select that were required for synchronizing to occur, participants had trouble remembering the order and thus had trouble uploading this step count data. The Bluetooth® pedometers also used up battery power quickly, and this resulted in pedometers being unable to record or transmit step counts. The training program and battery life are two aspects that we had not expected to cause problems, but in the future are aspects we will pay attention to.

All participants who pilot tested the app (10) reported that the time required to enter their data took less than 20 minutes per day. The most time-consuming data recording function was diet entry. Initially a few programming errors prevented users from accurately recording their data, which caused some frustration and aggravation. The concerns from pilot testers throughout the study were mainly centered on the diet entry, likely because it did require the most effort and had the greatest potential for problems. Our pilot testers also frequently commented on the variety of food available in the food database. Our food database was taken from a free online source based in the United States along with a nutrient file from the CDA. While some of the foods were Canadian, the American food database had a much larger number of food items, and therefore most of the fast food items that appeared in the search bar were linked with American food chains. Our pilot testers wanted more Canadian restaurant-food options.

Other suggestions included turning the blood glucose sliding scale into a single number entry, an option to add notes such as “flu today” with the diet entry, finding a way of decreasing menu input time, allowing previous day entry for data, and allowing opportunities to record other forms of physical activity beyond step count, such as swimming. These suggestions will all be considered in future releases of the GlucoGuide™ app.

3.4 Future Development

We are currently working to improve the intuitive functioning of the food system. By changing the breakdown of macronutrients in the display, simplifying the food options and ensuring Canadian content, we hope to have a more user friendly, faster-entry diet function. We are also working to make the system recognize frequently chosen foods, and push these to the top of the search bar for ease of use. Many of the other technical issues experienced in the pilot test have already been resolved; such as the troubles with unique food item entry and pedometer connectivity and wireless upload troubles. As well, the recommendations are now more visible to the users so that they can easily view any feedback sent to them by their health care team, and are aware when a new message has come to them.

We are also working to improve the quality and method of messages sent to participants. Some pilot testers found the messages were not impactful, so in order to build on the strength of the system we want to involve more user information to make the messages more tailored while continuing to be based on HAPA principles. We are also working on finding the best schedule for sending messages to users. This may be an individual preference that we can build in to the app (16).

3.5 Conclusion

Self-management for prediabetes and T2D is important for lowering the risk of developing diabetic complications. One tool that may encourage self-management is a smartphone application that not only allows users to track their health data but also to send this information to their health care team and receive feedback messages from their health care team. Our system, GlucoGuide™ aims to do this by following the CDA's best practice guidelines, and using data mining for analyzing users' health data in order to send tailored and actionable messaging to GlucoGuide™ users. By incorporating evidence-supported methods, expert advice, and the needs and feedback from our target audience we continue to strive to deliver a system that will encourage self-management, thereby helping reduce the risk of diabetic complications for people living with prediabetes and T2D.

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Chapter 4

4 PROGRAM EVALUATION PLAN

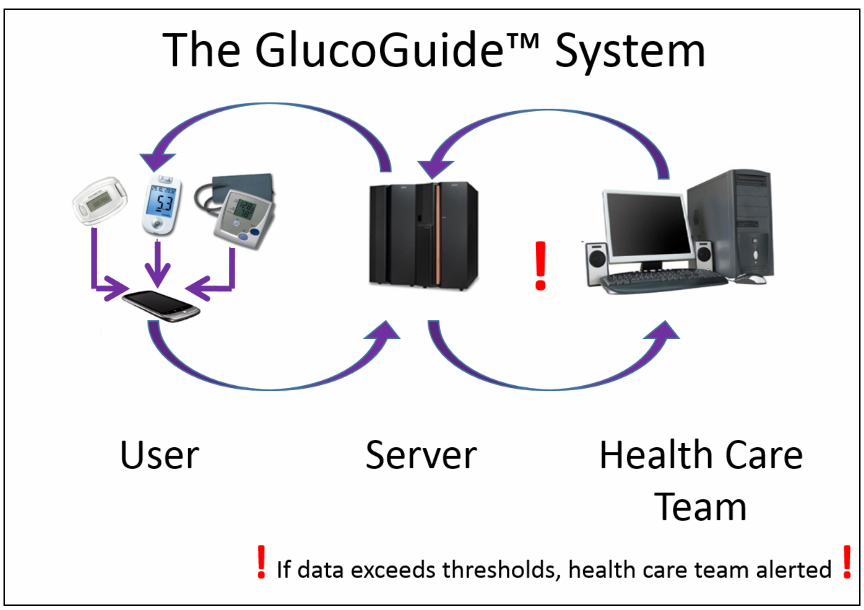
Smartphone applications (apps) are a promising tool for aiding people with prediabetes and T2D to adopt and maintain healthy behaviours. However, these applications need a rigorous evaluation to determine whether the tool enhances outcomes when combined with a lifestyle intervention. The GlucoGuide™ system is a smartphone app, web portal and data mining protocol that was built following the CDA's Best Practice Guidelines (1) at the University of Western Ontario. The system was designed to supplement a lifestyle intervention program for people with prediabetes and T2D. It was tested for feasibility and utility through a 12 week pilot study, which compared a lifestyle intervention combined with the GlucoGuide™ system to a lifestyle intervention combine with a paper journal. The following chapter will describe our detailed plan for evaluating the GlucoGuide™ system.

4.1 Background

Smartphones are a tool that can be used to encourage people to follow the recommendations from the CDA. Smartphones have increasingly become a part of modern life in the western world. They have the potential to enhance and compliment primary care by providing care outside of the office for people who are looking to increase or sustain healthy behaviours. While popular consensus is that using smartphones can improve healthy behaviours (2–4), current research has not shown consistent definite improvements for people who use mobile technologies (5–11). While many different types of lifestyle and smartphone linked lifestyle interventions have been tested in the United States and Korea, these interventions have been less investigated here in Canada (5,12). In addition, recent meta-analyses and systematic reviews of these interventions have indicated mixed results (2,13–15). There is speculation that some of these initiatives fail due to a lack of established behaviour change theory informing the programs, as well as disregard for evidence-based best practice guidelines (11,15,16). However currently, these applications lack detailed evaluations describing why or why not they produced the hypothesized beneficial results. Clearly a more in-depth evaluation of where these programs are and are not producing results is needed.

GlucoGuide™ is an innovative answer to previous smartphone-aided lifestyle interventions because it allows its users to upload health data (blood glucose levels, blood pressure, step count, diet) onto a secure database using the GlucoGuide™ app. The database not only collects the health data, but also alerts the user's health care team when blood pressure or blood glucose levels exceed set thresholds (for example, if systolic blood pressure goes above 160 mmHg). The collected health data allows the GlucoGuide™ system to run algorithms which determine aspects of the uploaded data that may be having more of an influence on the blood glucose levels. The results are reported to the user's health care team, and the team can then relay the information to the individual using the app (Figure 7).

Figure 7. Illustration of the Components of the GlucoGuide™ System



Because this is a multi-faceted approach to improving diabetes care, a detailed evaluation plan of the app is warranted to examine if and how the intervention is supplemented by GlucoGuide™. This evaluation plan is guided by causal and logic models specific to the program and built on well-supported behaviour change models in order to ensure all aspects of the program are considered and included in the evaluation. We decided to use a quaisexperimental design for a pilot study of the GlucoGuide™ system, to test the system's functionality and efficacy among a group of people with prediabetes or T2D living in London, Ontario.

A detailed program evaluation study has not yet been done to evaluate the processes of how a smartphone app combined with a lifestyle intervention may affect people making behaviour change. The use of a compartor group using a paper journal will allow identification of changes in participants that are unique to the group using the GlucoGuide™ system. A 12 week study will produce results while technology is still current and the knowledge is useful for developers of health care and behaviour change apps.

4.1.1 Theory-backed lifestyle intervention and GlucoGuide™ system.

The GlucoGuide™ system has been built to complement the SMART (Smart technology to Monitor type 2 diabetes and Achieve health goals through Record keeping and Tailored feedback) lifestyle intervention, an intervention based on the Staged Nutrition and Activity Counselling study (SNAC) (16). The SNAC study protocol was successfully used by family doctors to counsel patients with prediabetes and pre-hypertension, resulting in significant changes in fitness (estimated VO_2max), blood pressure, blood lipids (triglycerides and LDL), BMI, weight and waist circumference, as well as feelings of self-efficacy in regards to eating a Mediterranean-style diet (17). As a new addition to the program, the GlucoGuide™ system is hypothesized to be a feasible and usable supplement to the SMART lifestyle intervention program. The app was developed to meet CDA best practice guidelines and builds upon successes of similar lifestyle research for people with prediabetes and T2D (18,19) while addressing the areas that have been found to be lacking in current market apps for diabetes health care as described in the previous chapter.

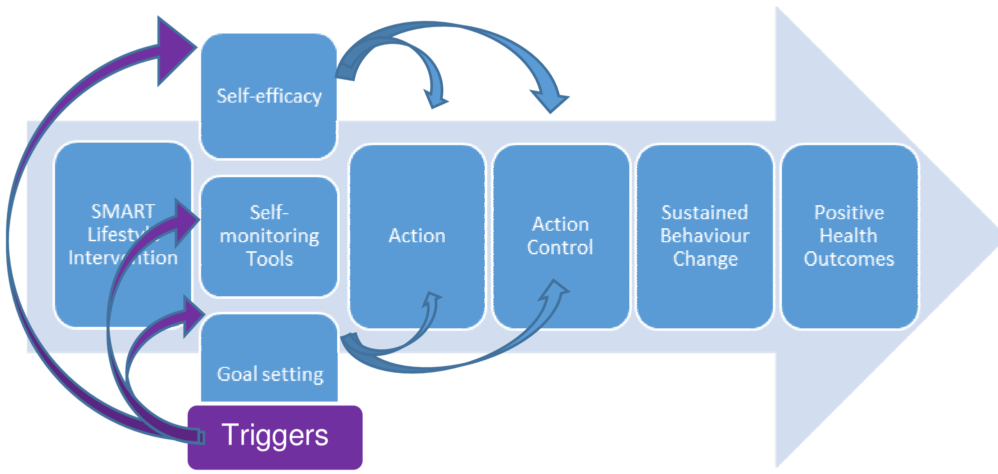
Behaviour change theory factored heavily into the development of the GlucoGuide™ system as well as the evaluation plan. The SNAC study was based on the Transtheoretical Model (TTM) (20), a model that recognizes different people may be at different stages of readiness for making a change in their behaviour, also known as different stages of change. The model proposes that if a behaviour change intervention meets each person at the stage of change he or she is at, the intervention will be more successful at encouraging a person to move to the next stage than if a blanket intervention is delivered to all people regardless of their stages of chage.

The TTM has found support among lifestyle interventions for physical activity and healthy eating, including the SNAC study (17,21–23). However, it is limited in its scope for this project, as most people volunteering for participation in the SMART Study are already in similar stages of change. The theory does not breakdown the steps that bring a person from having an intention of making a behaviour change to acting and sustaining this behaviour change. The HAPA theory is a behaviour change theory that builds upon the TTM, and describes some of the steps that can potentially move a person from intention to action, and maintenance of the behaviour change. The HAPA theory is described in more detail in Chapter 1, and a schematic of both the HAPA and TTM theory is included in Appendix 1.

We used the TTM and HAPA behaviour change theories to build our causal and logic models, which have helped shape our evaluation of the GlucoGuide™ system. Ultimately, the GlucoGuide™ system acts as a “trigger” for the action and action control steps of HAPA within the SMART lifestyle intervention. The system can send reminders to GlucoGuide™ users to practice self-monitoring, build self-efficacy by sending encouraging messages when goals are met, and give tips to help users with goal planning and overcoming barriers (Figure 8).

Figure 8. The SMART Lifestyle Intervention and GlucoGuide™ System Causal Model

Intentional Phase   Volitional Phase



The purple box and arrows indicate how the GlucoGuide™ system is hypothesized to enhance the SMART lifestyle intervention by sending messages regarding self-efficacy, self-monitoring and goal setting between scheduled clinic visits. This causal model guided the development and the evaluation of the GlucoGuide™ system.

This causal model (Figure 8), shaped our logic model (Appendix 2) and helped to determine our outcomes. While a decreased risk of diabetes complications is our end goal, our timeline of 12 weeks did not allow enough time to determine a reduction in diabetic complications, as these complications develop over much long time periods. Therefore, our primary outcomes for this study looked for positive health outcomes: an increase in physical activity (step count), a decrease fasting blood glucose (FBG) levels, and a decrease in blood pressure.

In addition to measuring our primary outcomes, we used the steps of the causal model to guide our secondary outcomes. These helped us fully understand the process that individuals using the GlucoGuide™ system experienced and adopted. We controlled for external factors by comparing the results to similarly sized group that was solely involved in the SMART lifestyle intervention and recorded their health data using a paper journal.

Each link of the causal model is described in more detail below along with an explanation of how it was measured.

Self-efficacy. Self-efficacy was measured through reliable, validated questionnaires measuring self-efficacy for physical activity and self-efficacy for eating a Mediterranean-style diet (24). Self-efficacy activities took place at each clinic visit (focused on one or two of the three HAPA self-efficacy specific aspects: task, maintenance or recovery, based on the participant's self-identified stage of change for physical activity and the Mediterranean-style diet). Activities such as reviewing and praising accomplishments were intended to build task self-efficacy, while discussions about ways to overcome barriers and identifying new opportunities for action were intended for increasing maintenance self-efficacy (25).

Self-monitoring. It has been noted that for many novel mobile phone apps adoption is high for the first month but then its use quickly diminishes (15). We looked at adherence to the self-monitoring schedule to measure the use of the tools, measured by the number non-repeated uploads per week compared to the number of requested uploads for each of the four health markers (see Appendix 3, Table 1 the for monitoring schedule).

Plans for Goals. Goal setting is a component of the intervention, driven by the participant's intentions. The goals the participants set, along with a simple Yes or No for completion of the goal setting sheet (Appendix 4) was recorded if participants took part in this step of the causal model.

Triggers. The number of triggers sent to participants was recorded for each month of the intervention.

Action. Behaviour change was assessed through the change in daily step count and healthy eating targets that each participant identified as their healthy living goals set each month with the research team's Kinesiologist. Lifestyle behaviours were also assessed by comparing 7-day Physical Activity Recall Questionnaires from baseline and after 12 weeks of the intervention (26), and by comparing 3-day food logs from baseline and the last month of the intervention, and scoring them according to the Canadian Healthy Eating Index (27).

Action Control. Action control refers to the ability of participant to overcome challenges and barriers that may come in the way of healthy behaviour plans. While more difficult to measure, changes in health status items such as sickness, vacation, injury, increased demands at work and emotional difficulties were recorded in the case report files. The week after the change in health status was compared with the average 1, 2, 3 and 4 weeks after the change in health status to see if recovery occurred.

Sustained Behaviour Change. Sustained behaviour change was measured by examining the time series data of step count and diet to evaluate if behaviour changes persisted for the duration of intervention.

Positive Health Outcomes. Clinical measures of clinic blood pressure, estimated VO_2max, and the Borg scale for perceived exertion, weight and waist circumference were measured and compared for all clinic visits. Time series data of home blood pressure, FBG and 2 hour postprandial blood glucose were also examined. In addition, HbA_1c, a longer term reflection of blood glucose control was measured and compared between baseline and the end of the intervention.

4.2 Evaluation Protocol

(See Appendix 5 for a comprehensive checklist).

At each visit all participants participated in a step exercise test (STEP™) (28) to measure estimated VO_2max. Following the SMART protocol, participants discussed their diet based on the past month's food record brought in to their office visit. Anthropometric and laboratory tests were performed at these visits, and involved three blood pressure measures using the BP-Tru™, height and weight measured without shoes and in the clothing worn by participants using the Health Scale RGT.B-200-RT, and waist circumference using a simple tape measure and following the Canadian Society of Exercise Physiologists standards (29). Blood samples for fasting blood glucose and HbA_1c were collected at the baseline and 3 month visits and analyzed by a local laboratory. In addition, the questionnaires assessing decisional balance for physical activity and healthy eating (24), self-efficacy for physical activity and diet (24), baseline physical activity (26) and technology experience (19) were completed by participants at the baseline and 3 month visits.

Participants were monitored for their intention regarding physical activity and healthy eating at each office visit (24). Goal setting took place at each clinic visit, based on the participant's experience, current intentions and abilities. Goal setting consisted of using the STEP™ results, Canadian Healthy Eating Index scores (27), Canadian Society of Exercise Physiology activity guidelines (30) and the Mediterranean diet Pyramid (31), along with action and coping planning. Action and coping planning was an interactive activity between the Kinesiologist and the participants and used goal setting sheets that helped guide the participant to identify specific details of how the participant planned on reaching her goals along. The sheet also prompted participants to identify barriers that they would likely encounter along the way of reaching her goals, and to brainstorm alternative actions to handle these situations (see Appendix 4 for the goal setting sheet). Self-efficacy activities, to increase task, maintenance or recovery self-efficacy depending on the individual's needs also took place throughout the clinic visit.

4.2.1 **Statistics.**

Statistical calculations were made using IBM SPSS 2.0. Comparisons between groups were made with Student's unpaired two-tailed *t* tests. Statistical significance were considered to be present at the 5% level ($p \leq 0.05$). Differences between V_0, V_1, V_2 and V_3 along with time series data for weekly records were analyzed for each variable using multivariate analysis of variance (MANOVA). Partial eta-squared (η^2_p) was used to display the variability accounted for in the treatment effect, unique to this study interaction. Trigger feedback was used by the GlucoGuide™ development team to enhance usability, but will not be evaluated formally.

4.3 Assumptions, Strengths And Limitations In Evaluation

The assumption that all participants in the GlucoGuide™ program entered the program with some level of intention (the first section of HAPA) was tested by using a stage of change questionnaire for Physical Activity and a Mediterranean-style of eating (24). In addition, participants perceptions of outcome expectancy for physical activity and following a Mediterranean-style diet were measured using the Decisional Balance for Physical Activity and the Decisional Balance for Healthy Eating (24). These measures were repeated at the end of the intervention, to see if there were any changes in participants' responses. Additionally, as the smartphone played a significant role, the self-efficacy of the participants for using the smartphone and other self-monitoring devices (use, comfort, ease of use, perception and burden) was assessed through a simple Technology Experience Scale (19) at baseline and 12 weeks.

Because the GlucoGuide™ program is a multi-faceted approach to improving self-management for people with prediabetes and T2D, a detailed program evaluation intended to ensure each part of the intervention is carried out and measured. While the use of a quasi-experimental desgin reduced the strength of the evidence collected, the benefits of having users that were able to choose their intervention ensured a more engaged participant pool. The short time frame of 12 weeks only gave us a short-term sample of how the app may influence behaviour and health outcomes, yet it also reduced the time, cost and effort required, thereby allowing efficient work while still giving us a snapshot of how the smartphone affects behaviour change and health outcomes. The compartor group using a paper journal allowed identification of changes in participants that are unique to the group using the GlucoGuide™ system. Results from this short-term evaluation allow us to start modification and refinement of the GlucoGuide™ system quickly while the technology is still current.

4.4 Conclusion

The detailed plan outlined above describes the theory, measures, assumptions and limitations involved in evaluating the GlucoGuide™ system. The evaluation results are discussed in the next chapter, and the SMART study project adds to the small but growing literature surrounding smartphone applications for behaviour change that leverages data mining for health care. The focus of this evaluation plan was to break down the specific steps we believe needed to take place in order for the GlucoGuide™ system to enhance the SMART lifestyle intervention. This was important to do in order to determine the feasibility and utility of the GlucoGuide™ system within the SMART lifestyle intervention. The evaluation allowed for an in-depth look at how the intervention and app itself worked in day to day life, and if the TTM and HAPA behaviour change theories applied to the GlucoGuide™ program were supported by what was observed among participants. A detailed program evaluation study has not yet been done to evaluate the processes of how a data mining smartphone app combined with a lifestyle intervention may influence people with prediabetes and T2D interested in making behaviour change. We believe this evaluation plan will be able to inform future research, and encourage more behaviour change theory based designs and evaluations for health care apps.

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Chapter 5

5 THE SMART STUDY

Diabetes has reached pandemic prevalence worldwide. In Canada alone, approximately 9 million people are diagnosed with prediabetes or T2D (1). People with prediabetes or T2D have chronic elevated blood glucose levels (EBG), and without intervention EBG can lead to devastating complications (2). Repeatedly, early interventions that stress lifestyle modifications such as healthy eating and regular physical activity has been shown to markedly reduce the risk of developing diabetic complications and even delay the onset of diabetes (3–5). Consequently, the CDA has outlined these behaviour changes as very important in their best practices for managing EBG (6).

Smartphones applications (apps) are a tool that have received recent interest by researchers as they hold potential to facilitate behaviour change, by encouraging health self-management, and thereby following CDA recommendations. The appeal of the smartphone is its potential to enhance and compliment primary care by providing support outside of the physician's office. While popular consensus is that using smartphones can improve healthy behaviours (7–9), current research has not shown consistent or definite improvements for people who use mobile technologies (10–17). In addition, recent meta-analyses and systematic reviews of these interventions have indicated mixed results (7,18–21). However, the large difference in how evidence-based practice guidelines and behaviour change theory have informed current apps may be the reason that there is discrepancy between outcomes in current app studies (16,20).

Our team of interdisciplinary researchers at the University of Western Ontario designed and implemented a pilot study a system that incorporated CDA's best practice guidelines, and held the potential to provide personalized support for people living with EBG given their unique situations. This system, GlucoGuide™, involved data mining, a web portal and a smartphone application. The system was built to supplement the SMART (Smart technology to Manage type 2 diabetes and Achieve health goals through Record keeping and Tailored feedback) lifestyle intervention. This intervention was based on the Staged

Nutrition and Activity Counselling Study, which combined evidence-based behaviour change theory, goal setting, self-monitoring, feedback and clinic follow-up (22,23). Following the protocol from this study ensured that evidence-based best practice guidelines were followed and the project was informed by well-supported behaviour change theory. The methods and results of a 12-week pilot test with the GlucoGuide™ system are described below along with a discussion of the implications for future research for behaviour change apps for people diagnosed with prediabetes or T2D.

The study was approved by the Health Science Research Ethics Board of the University of Western Ontario as well as the Clinical Research Impact Committee at the Lawson Health Research Institute at St. Joseph's Health Care, London at Parkwood Hospital. Written informed consent was obtained from all participating individuals, and the study was conducted in conformity with the Declaration of Helsinki. The study took place from July 2012 to May 2013.

5.1 Methods

Seventeen participants were recruited in London, Ontario through local family practice health teams, prediabetes workshops held at Brescia College, the Diabetes Education Centre at St. Joseph's Hospital and through strategically placed posters. Participants were enrolled in the 12 week quasi-experimental study after passing the inclusion and exclusion criteria and signing the Letter of Consent. Participants were included if they met the follow criteria: a diagnosis within the past 2 years of T2D or prediabetes, age between 18 and 80 years, and self-recognition of leading a sedentary or low active lifestyle, which was confirmed using the 7-day Physical Activity Recall Questionnaire (24). Participants who had difficulties understanding English, were taking more than 2 diabetes medications, were suffering from severe mental disease or malignant disease, or were abusing drugs were excluded from participation in the study. To ensure participant engagement, participants were given a choice of how to record their data (25). Upon enrollment, participants were presented with two intervention options, using the GlucoGuide™ system or using a paper journal for logging their health data. Participants were fitted as best as possible into the intervention option of their choice. All participants were involved in the lifestyle intervention.

5.1.1 The SMART lifestyle intervention.

Volunteer participants met with a Kinesiologist to discuss healthy eating and physical activity goals. To determine the intensity at which the participants should be training at, the participants performed a submaximal exercise test (STEP™) by stepping up and down 2 steps 20 times, from which an estimation of maximal exercise capacity (VO_2max) was determined (26). The calculated maximal exercise capacity was used to determine a physical activity training heart rate prescription for each participant, and approximates between 70-85% of their maximal aerobic capacity. Participants set a daily target step count as well. The Canadian Healthy Eating Index (27), Mediterranean-style diet guidelines (28), and the CDA's Best Practice Guidelines (6), were used to evaluate current eating practices and recommend healthy food choices. Each person's healthy lifestyle program was built upon the participant's current level of activity and diet, his or her abilities and his or her resources. The goal was for participants to eventually reach 10,000 steps per day (29) and follow a Mediterranean-style diet, which has demonstrated beneficial results for people with EBG (30). However, the individual had a key role in setting the goals and step targets. Participants met with the Kinesiologist every four weeks to review physical activity and healthy eating goals and barriers and plan for the next month.

Goal setting was an interactive activity between the Kinesiologist and the participant and used goal setting sheets to help guide the participant to identify the specific details of how the participant planned on reaching his or her goals along with barriers that he or she would likely encounter along the way. The sheet also asked the participant to brainstorm alternative actions to handle these situations and to focus on personal strengths that would allow the participant to accomplish these tasks, building self-efficacy, in order to increase goal maintenance and overcome barriers or relapses.

5.1.2 GlucoGuide™ system.

Smartphone supplementation.

The GlucoGuide™ system was designed to further supplement the SMART lifestyle intervention. Participants who used the GlucoGuide™ system were asked to monitor their health by recording their step count, blood pressure, blood glucose and diet in the app. Using blood pressure cuffs, blood glucose meters and pedometers, along with a food diary, the app asked users to input their health data in to the GlucoGuide™ smartphone application. This data was then uploaded and transmitted to a central database where it was analyzed by the system and our computer science team. Data outside of set thresholds such as systolic blood pressure greater than 180 mmHg, or blood glucose less than 4.0 mmol/L automatically triggered alarms that alerted the research team to follow-up with the participant. Data was also analyzed through data mining algorithms to determine which components of a person's lifestyle, are affecting blood glucose levels the most. From these results, personalized feedback was sent back in real-time to the participant, with specific, actionable recommendations of how to improve that specific marker. In addition, notes of congratulations and encouragement for reaching a target or reminders to upload data were also sent through the system to the individual's GlucoGuide™ app. Trigger messages that were sent to participants included:

> Step goal achieved again! Fantastic!
>
> We're missing your latest step counts, do you need a reminder of how to upload them? …[further instructions to record steps]
>
> You are making great healthy choices! Remember to reward yourself - decide what kind of reward would work best for you: maybe it is a new pair of running shoes, or some time for reading a good book. Use the reward you choose to treat yourself when you've reached a goal.
>
> Based on your uploaded data, GlucoGuide™ has found that your fat intake is linked to your blood glucose levels. To improve your blood glucose levels try eating foods with less saturated fat at meals. Ideally fat should make up 30% of our total calories that we eat each day. Lighten up on fats. For example, decrease the amount of butter, oil, salad dressing, cream cheese, sour cream and other fats you use. They're loaded with calories and some have unhealthy saturated fat.

Behaviour change theory.

The SMART lifestyle intervention was built upon the TTM (31) and HAPA (32). These models which informed the development and evaluation of the intervention. The GlucoGuide™ system provided a means of increasing communication between the health care team and participants, by providing reminders to record health data, alerts when health data met critical thresholds, and feedback on uploaded data with actionable recommendations specific for the individual. All of these messages were considered "triggers" that would further compliment the SMART lifestyle intervention by encouraging participants to carry out the behaviours they had set in the clinic visits, either by prompting goal planning or building self-efficacy.

5.1.3 Paper journal and GlucoGuide™ training.

The paper journal participants were given a blood pressure monitor, a blood glucose meter, a log book and a pedometer. Participants who chose GlucoGuide™ received a blood pressure monitor, a blood glucose meter, an Android phone and data plan and a Bluetooth®-enabled pedometer. Each participant was trained to use the tools they were given to record their health data, and instructed on the frequency and detail of their recording. Paper journal participants were given written documents to bring home with them to reference in the event that they needed a reminder or had a question about the use of the devices and recording protocol. GlucoGuide™ participants were emailed a PDF with information about using the devices and the recording protocol.

5.1.4 Self-monitoring.

All participants were asked to record their diet for the first week, along with their blood glucose before and 2 hours after meals for breakfast and dinner. They were also asked to record their blood pressure before breakfast and dinner. Step count was also recorded each day. After the first week, participants were asked to focus on dinner alone, recording their food intake at dinner, blood glucose before and 2 hours after dinner, blood pressure before dinner, and step count for the day. This was repeated each month. A sample month can be found in Appendix 3.

5.1.5 Primary and secondary outcomes.

Primary outcomes for this pilot test were changes in step count and clinic blood pressure, from baseline (V_0) to 3 month (V_3) visits. Secondary outcomes included height, weight, estimated VO_2max and waist circumference which were collected at each clinic visit. Blood samples for fasting blood glucose (FBG) and glycated hemoglobin (HbA_1c) were collected at the baseline and 3 month visits and analyzed by a local laboratory. In addition, validated questionnaires assessing quality of life (33), physical activity recall (24), decisional balance for physical activity and diet (34), self-efficacy for physical activity and diet (34), diabetes empowerment (35), along with a technology experience survey (36) were completed by participants at the baseline and 3 month visits. The health data (diet (27), home blood pressure and home blood glucose) recorded by participants were also analyzed for changes over the 3 month study.

5.1.6 **Statistics.**

Statistical calculations were made using IBM SPSS 2.0. Comparisons between groups at baseline were made with Student's unpaired two-tailed *t* tests. Statistical significance was considered to be present at the 5% level ($p \leq 0.05$). Differences between clinic visit data and weekly averages of home health data were analyzed for each variable using a repeated measures analysis of variance (split-plot ANOVA). Partial eta squared (η^2_p) was used to display the variability accounted for in the treatment effect, unique to this study interaction.

Multiple imputation was used to deal with a missing post-intervention FBG value determined to be missing completely at random due to laboratory error. Multiple imputation was chosen as the use of multiple random error substitutions prevents over-fitting. Five data sets were created using IB SPSS Statistics 20 Data Editor, and modelled using the data collected for age, weight, sex, FBG and HbA_1c from baseline and the final visit. These variables were chosen for modeling because of their expected close relationship with the post-intervention FBG. Multiple imputation was also used for weekly averages of blood glucose, blood pressure and step counts, after confirming that there was no relationship between missing data and participant age, sex, intervention, estimated VO_2max, HbA_1c and FBG using regression analysis, except for the missing data for the blood pressure weekly averages in week 12. Therefore, this data was excluded from the final analysis.

5.2 Results

The study sample of 17 adults included 7 men (41%), 1 person in an ethnic minority group (6%) and 4 individuals with less than a college degree (24%). The average age of the participants was 62 years (±8). At baseline, men had a mean weight of 105.8 kg (±19.6) and a BMI of 35.1 kg/m^2 (±6.4). Women had a mean weight of 90.0 kg (±19.9), and a BMI of 34.3 kg/m^2 (±6.3). Demographic information is summarized in Table 1.

Table 1. Demographic Characteristics of the SMART Study Participants at Baseline

Characteristics	GlucoGuide™ Group (n = 10)	Paper Journal Group (n = 7)	Total (N = 17)
Age, years (SD)	61 (6)	65 (10)	63 (8)
Male sex, %	40.0 %	43.9%	41.2%
Minority Ethnicity	0	14.3%	5.9%
Less than college education	10.0%	43.9%	23.5%
BMI, kg/m^2 (SD)	34.7 (6.4)	35.6 (4.3)	33.4 (8.8)

*significant difference between groups at baseline

Fourteen people (10 of the GlucoGuide™ group and 4 of the Paper Journal group) agreed or strongly agreed with feeling comfortable using the technology packages (including smartphone, blood glucose monitor, blood pressure monitor and pedometer) before being trained how to use them, even though only 4 participants strongly agreed with having previous experience with all the tools. Most participants used electronic devices in their daily lives, with all participants using at least two forms of modern technology (TV, Radio, PC, internet, cell phone, MP3 player or a game system), and an average of 4 to 5 of these items used daily. As was expected, the confidence expressed for using the self-monitoring tools (using a Likert scale of 1-5) was significantly greater for the group who chose to use the smartphones ($F=5.413$, $p<0.05$, $\eta^2_p=0.294$). Among other baseline characteristics only diastolic blood pressure was found to be significantly different ($t= -2.214$, $p<0.05$) (Table 2).

5.2.1 Self-monitoring.

There was a significant difference in adherence to the protocol for the two groups (Table 3). Despite having received the same instructions on the frequency of uploading data, the participants who chose to use the paper journal recorded many more data points than the people who used the smartphone application, with the intervention accounting for 29.9% of the error variation ($F = 6.399$, $p<0.05$, η^2_p=0.299). In addition, both groups decreased in their adherence to protocol over the 12 weeks ($F = 3.950$, $p<0.05$, η^2_p=0.208).

Table 2. Primary Outcomes: Average Characteristics of the SMART Study Participants at Baseline (V0) and Final Visit (V3)

Characteristics	Visit	Total (N = 17)	GlucoGuide™ Group (n = 10)	Paper Journal Group (n = 7)
Systolic Blood Pressure	V0	130 (16)	132 (16)	126 (16)
	V3	129 (20)	124 (14)	138 (25)
Diastolic Blood Pressure	V0	80 (9)	84 (8)**	75 (8)
	V3	78 (10)*	80 (9)	75 (11)
Fasting Blood Glucose	V0	6.19 (1.32)	6.22 (1.51)	6.14 (1.09)
	V3	6.11 (1.14)	6.14 (1.35)	6.06 (0.95)
Daily Step Count	Month 1	5700 (3866)	4744 (2561)	7067 (5131)
	Month 2	5805 (3234)	5029 (1986)	6913 (4420)
	Month 3	5909 (4047)	4350 (2083)	7690 (5120)

*significant decrease over time, **significant difference between groups

5.2.2 GlucoGuide™ messages.

A total of 124 messages were sent out throughout the 12 weeks of the study to the 10 people enrolled in the smartphone group. The health care team received 327 alerts for data uploaded that triggered high or low thresholds. In addition, 27 phone calls and 411 emails were sent to participants to follow-up alerts, troubleshoot for the smartphone, and book follow-up appointments.

5.2.3 Self-efficacy and quality of life.

Diet self-efficacy significantly increased over the course of the intervention for both groups ($F=7.118$, $p<0.05$, η^2_p=0.322) (Table 3). In addition, perceived downsides of following a Mediterranean-style diet significantly decreased from the beginning to the end of the intervention (F=9.363, p<0.05, η^2_p=0.384), while the perceived positive benefits of following a Mediterranean-style diet stayed the same (F=0.719, p>0.05). A similar trend was seen in physical activity self-efficacy (F=4.054, p=0.065), however the trend was not statistically significant. The overall mental health metric in the SF-36 significantly increased for both groups as they continued through the study (F=6.293, p<0.05, η^2_p=0.296). Significant positive results were found when participants rated how their health was compared to a year ago, using the Transition metric of the SF-36 (F= 4.845, p<0.05, $\eta^2_p = 0.244$). Diabetes specific empowerment for managing psychosocial aspects of the disease (using the Diabetes Empowerment Scale) also significantly increased for both groups in the study (F=6.237, p<0.05, η^2_p = 0.294).

5.2.4 **Clinic results.**

Clinic diastolic blood pressure significantly decreased over the 12 weeks for both groups (F=3.009, p<0.05, η^2_p=0.158). Importantly, the significantly higher diastolic blood pressure seen in the GlucoGuide™ group at the beginning of the study was not evident at the final visit (p>0.05). Additionally, the fitness rating (four categories from poor to excellent) based on the estimated VO_2max increased over the 12 weeks (F=3.357, p<0.05, η^2_p =0.173). Clinic and weekly systolic blood pressure, FBG and daily step count averages did not significantly change over the twelve weeks (p>0.05).

5.2.5 **Partial Effect Sizes.**

Effect sizes for comparisons of groups, and averages over time have been reported in Tables 4 and 5. These are important to consider because of the small sample size involved in this pilot study. For example, the variance due to the intervention accounted for 10.2% of the observed variance, similar to the variance for healthy eating self-efficacy (9.9%) (Table 4). The intervention accounted for roughly 15% of the variance observed due to error and interaction for people’s responses to setting and achieving diabetes goals (Diabetes Empowerment Scale) as well as for people’s response to their

Table 3. Secondary Outcomes: Average Characteristics of the SMART Study Participants at Baseline (V0) and Final Visit (V3)

Characteristics	Visit	Total (n = 17)	GlucoGuide™ Group (n = 10)	Paper Journal Group (n = 7)
Weight, kg (SD)	V0	97.4 (21.4)	100.6 (19.0)	92.8 (25.1)
	V3	95.5 (21.4)	98.7 (20.0)	91.0 (24.7)
Waist circumference, cm (SD)	V0	113 (12)	114 (9)	112 (16)
	V3	112 (13)	113 (10)	111 (17)
HbA_1c, % (SD)	V0	6.5 (0.7)	06.6 (0.9)	6.3 (0.5)
	V3	6.2 (0.4)	0.062 (0.4)	6.2 (0.5)
VO_2max, mmol/L (SD)	V0	30.4 (8.0)	31.3 (5.7)	29.1 (10.8)
	V3	34.0 (7.5)	34.6 (8.2)	33.2 (6.9)
VO_2max Rating, (SD)	V0	3 - Good (1)	3 - Good (1)	2 – Fair (1)
	V3	3 - Good (1)	3 - Good (1)	3 - Good (1)
Canadian Healthy Eating Index: Adequacy (SD)	V0	40.7 (8.7)	39.3 (8.0)	42.7 (9.9)
	V3	n/a	n/a	32.7 (9.5)
Canadian Healthy Eating Index: Moderation (SD)	V0	22.5 (5.8)	21.5 (6.0)	23.9 (5.6)
	V3	n/a	n/a	26.1 (7.5)
Canadian Healthy Eating Index: Total Score (SD)	V0	63.3 (7.1)	60.9 (8.0)	64.2 (5.6)
	V3	n/a	n/a	58.8 (6)
Home Systolic Blood Pressure, mmHg (SD)	Month 1	122 (5)	122 (5)	124 (6)
	Month 2	121 (7)	120 (7)	122 (6)
	Month 3	122 (5)	122 (5)	124 (6)
Home Diastolic Blood Pressure, mmHg (SD)	Month 1	77 (7)	79 (5)	73 (8)
	Month 2	76 (6)	78 (4)	72 (7)
	Month 3	77 (7)	79 (5)	73 (8)
Home Evening Fasting Blood Glucose, mmHg (SD)	Month 1	6.5 (0.9)	6.6 (1.0)	6.4 (0.6)
	Month 2	6.4 (0.7)	6.3 (0.7)	6.4 (0.9)
	Month 3	6.3 (0.7)	6.1 (0.7)	6.5 (0.7)
Home Evening 2-hour Postprandial Blood Glucose, mmHg (SD)	Month 1	7.5 (0.7)	7.6 (0.7)	7.3 (0.6)
	Month 2	7.8 (1.5)	8.1 (1.8)	7.4 (0.7)
	Month 3	7.6 (0.7)	7.6 (0.8)	7.6 (0.7)
Protocol Adherence, % (SD)	Total	68 (16)	61 (14)*	78 (13)

n/a – errors in collecting data prevented an analysis of the GlucoGuide™ group diet

*significant difference between groups

self-efficacy to do physical activity. The outcomes of physical health and mental health totals within the Quality of Life SF-36 questionnaire were also found to be significantly different between GlucoGuide and Paper Journal groups.

Table 4. Effect Sizes for Differences Between the GluocGuide™ and Paper Journal Groups for the SMART Study

Measure	**F-ratio**	η^2_p
Clinic Systolic Blood Pressure	0.034	0.002
Clinic Diastolic Blood Pressure	2.806	0.159
Clinic Fasting Blood Glucose	0.023	0.001
Weight	0.425	0.028
Waist circumference	1.939	0.102
HbA_1c	0.298	0.019
VO_2max	0.060	0.004
VO_2max rating	0.709	0.045
Stage of Change for Physical Activity	0.392	0.025
Stage of Change for Mediterranean-style diet	0.090	0.006
Diabetes Empowerment Scale – Managing the psychosocial aspects of the disease	2.195	0.128
Diabetes Empowerment Scale – Assessing dissatisfaction and readiness to change	0.835	0.053
Diabetes Empowerment Scale – Setting and achieving diabetes goals	2.776	0.156
Technology Evaluation Survey – Comfort Level	4.240	0.220
Technology Evaluation Survey – Current Use	0.078	0.005
Physical Activity Self-Efficacy	2.738	0.154
Healthy Eating Self-Efficacy	1.643	0.099
Physical Activity Decisional Balance	0.007	0.000
Pros to Physical Activity	0.002	0.000
Cons to Physical Activity	0.086	0.006
Mediterranean-style diet Decisional Balance	0.004	0.000
Pros to a Mediterranean-style diet	0.542	0.034
Cons to a Mediterranean-style diet	1.341	0.082
SF36 – Physical Health Total	26.193	0.636*
SF36 – Mental Health Total	20.613	0.579*
SF36 – Transition	0.027	0.002
Adherence to protocol	42.662	0.299*

*significant difference ($p<0.05$) between groups

Effect sizes that were notable for the study, regardless of intervention, over time (Table 5) include weight, waist circumference, HbA_1c and VO_2max. These effect sizes were similar to those seen in the results that found significance over time, such as clinic diastolic blood pressure and VO_2max rating.

Table 5. Effect Sizes for Differences Over Time for the SMART Study Participants

Measure	**F-ratio**	η^2_p
Clinic Systolic Blood Pressure	0.107	0.007
Clinic` Diastolic Blood Pressure	3.009	0.158*
Clinic Fasting Blood Glucose	0.041	0.008
Weight	1.905	0.094
Waist circumference	1.809	0.107
HbA_1c	2.676	0.151
VO_2max	2.751	0.171
VO_2max rating	3.357	0.173*
Stage of Change for Physical Activity	6.472	0.288*
Stage of Change for Mediterranean-style diet	0.285	0.018
Diabetes Empowerment Scale – Managing the psychosocial aspects of the disease	6.237	0.294*
Diabetes Empowerment Scale – Assessing dissatisfaction and readiness to change	0.253	0.017
Diabetes Empowerment Scale – Setting and achieving diabetes goals	0.0459	0.030
Technology Evaluation Survey – Comfort Level	4.779	0.242*
Technology Evaluation Survey – Current Use	54.982	0.786*
Physical Activity Self-Efficacy	2.466	0.141
Healthy Eating Self-Efficacy	7.118	0.322*
Physical Activity Decisional Balance	0.680	0.043
Pros to Physical Activity	0.745	0.047
Cons to Physical Activity	0.012	0.001
Mediterranean-style diet Decisional Balance	5.492	0.268*
Pros to a Mediterranean-style diet	0.872	0.055
Cons to a Mediterranean-style diet	9.363	0.384*
SF36 – Physical Health Total	0.656	0.042
SF36 – Mental Health Total	6.293	0.296*
SF36 – Transition	4.845	0.244*
Adherence to protocol	3.950	0.208*

*significant difference ($p<0.05$) over time groups

5.3 Discussion

This pilot study tested the functionality and efficacy of the GlucoGuide™ system by comparing health outcomes between participants who used GlucoGuide™ and participants who used a paper journal during a 12-week intervention in a quasi-experimental design. In both groups, there were some significant changes at the end of the 12 week study, including: decreased diastolic blood pressure, increased overall fitness rating, improved self-efficacy for eating a Mediterranean-style diet, improved ability to manage the psychosocial aspects of diabetes and improved overall mental health. Interestingly, these findings in mental health and self-efficacy for following a Mediterranean-style diet may be linked; Muñoz and colleagues have previously reported that following Mediterranean-style diet led to improvements in mental health (37).

In addition, the average FBG levels throughout the study were well controlled within CDA target ranges (fasting: 4.0 to 8.0 mmol/L; postprandial: 5.0 mmol/L to 10.0 mmol/L) and the average blood pressure met the CDA's recommendations of less than 130 mmHg systolic and 80 mmHg diastolic (6). Overall, these results suggest that the GlucoGuide™ system is both feasible and effective as an aid for diabetes management, and it is a good alternative to a paper journal.

In the causal model we developed for the SMART lifestyle intervention and GlucoGuide™ system (Appendix 6), self-efficacy is a critical construct influencing healthy lifestyle outcomes. The significant improvements in the SF-36 Mental Health score and managing the psychosocial aspects of diabetes cannot be overlooked. Diabetes has close links with depression, which can perpetuate unhealthy behaviours and increase cardiovascular complications (38,39). An improvement in participants' perceived ability to manage their disease and their overall mental health are very important outcomes in any lifestyle intervention program for people with prediabetes or T2D.

The participants were given an opportunity to choose their intervention group because this is more reflective of a "real world" situation in which some people prefer to use technological devices more than others (15,25). It also allowed comparison of the two groups at baseline. Although both groups were similar in their experience with every day electronic devices (PC, cell phone, radio etc.) it is important to notice that the people who chose to use GlucoGuide™ expressed significantly more confidence in using the technology tools involved in the study. This supports our hypothesis that task self-efficacy would influence a participant's selection of the smartphone or the paper journal for self-monitoring. A disadvantage of this method of intervention allocation is that it could not be randomized or double-blind, and this increases the possibility for bias to occur during data collection.

Adherence to the health data recording protocol was difficult for both groups, but adherence was significantly poorer in the GlucoGuide™ group compared to the paper journal group over the last 4 weeks of the study. This may have resulted due to several programing errors that were discovered during participant use of GlucoGuide™, some of which decreased or hindered participant data entry. This was particularly a problem for the diet entry function of GlucoGuide™, which limited any analysis of this data. While every attempt was made to remedy the problem as quickly as possible, these programing errors created frustration among participants and led to a further decrease in adherence to protocol. Twice the university server shut down, which also decreased the ability for participants to upload data and for the Kinesiologist to send back trigger messages to the participants' phones. Even though participants were encouraged to record their data as best as they could, the inability to follow the protocol may have caused discouragement and decreased task self-efficacy which may explain the drop off in adherence. Fixing all software problems with GlucoGuide™ may greatly improve adherence to the recording protocol in future use of the app.

While poor adherence to self-monitoring programs is not an unusual finding (40), researchers need to continue to search for ways to make adhering to protocol simpler and more appealing. One exciting idea is using the smartphone's camera to take before and after meal photos that can be processed by the server to identify foods, estimate serving sizes and calculate caloric intake (41). While many logistics such as food and camera position, and accurate food recognition need to be further explored, the possibility is exciting. Another idea is to utilize voice recognition software for quicker entry, an area we have started exploring but have not formally tested yet. Other research evaluating theories of how technology can mediate adherence beyond motivation are currently being conducted (42), which will add more to the discussion not only of adherence, but also to our understanding of behaviour change theory and our development of strong causal models.

Considering the causal model, the intervention did not appear to promote the maintenance of new behaviour change (Action Control), as there was no significant improvement in clinical measures except diastolic blood pressure or step count from baseline. However, the targets set by CDA for blood pressure and blood glucose levels were met for the groups, and clinical measures did not significantly decrease, which suggest that perhaps ongoing healthy behaviours were continued. A one month self-monitoring lead-in before any SMART intervention or GlucoGuide™ system use begins may be an important addition to future protocols to better measure participant's daily behaviours before receiving any counselling or trigger messages. The disruption in the ability to send trigger messages to the GlucoGuide™ group may explain why there was no significant difference found between the GlucoGuide™ group and the paper journal intervention groups. Future research with GlucoGuide™ should examine whether the addition of increased trigger messages that concentrate on building self-efficacy and reminding participants of their goals will enhance healthy behaviour change and improve clinical outcomes through increasing mindfulness outside of clinic visits.

Changing a behaviour is a complex interaction between environment, psychological and physical factors, and making more than one behaviour change at the same time likely increases this complexity. Little research has been done to examine the complexities and strategies for making multiple behaviour changes. While behaviour change models break down the hypotheses about making a single behaviour change, we do not know if these models work as well when making multiple behaviour changes. Perhaps working on making two behaviour changes at the same time aids in carrying forth change by strengthening a person's resolve, while it may also detract by drawing a person's focus in multiple directions. It may be that in a population of people with prediabetes and T2D, healthy eating changes should be a focus before adding in physical activity, but it may also be the converse. And perhaps it solely depends individual's self-efficacy for the order or the decision to make multiple behaviour changes at the same time. This is an area that needs further study.

The results presented in this paper will guide further development of the GlucoGuide™ smartphone application and its target audience. For example, the partial effect sizes for some of the non-significant findings were similar to those observed for outcomes that were significant, which suggests that perhaps a larger sample size may result in more outcomes with significant findings than those observed in this pilot study. The findings here will guide future primary outcome measures for GlucoGuide™ system research, as well as sample size calculations. In addition, further investigation is needed to understand why the protocol adherence dropped off significantly in the final month of the study, and how to make the application more engaging to encourage continued use and maintenance of healthy lifestyle behaviours. The use of TTM and HAPA behaviour change theory to frame our causal model and system helped to develop and evaluate the steps of the lifestyle intervention and GlucoGuide™. The reason GlucoGuide™ was not able to enhance the lifestyle program more than the paper journal may be due to insufficient trigger messages. Guided by the causal model, these messages should focus on promoting self-efficacy and encouraging goal planning.

The recruitment for the GlucoGuide™ group saturated first, indicating that the GlucoGuide™ tool was the more popular choice. This did not appear to be affected greatly by age, as there was not a significant difference in age between the two intervention groups, despite poorer adherence to protocol by the GlucoGuide™ group. If an increase in adherence to protocol is seen, perhaps a difference in outcomes between groups may be seen. These are promising results for future endeavours using smartphone apps, and may help inform app developers of their target audience. The transcendence of the smartphone among people irrespective of socioeconomic status and location may make the smartphone a viable option for people unable to receive or participate in a face-to-face lifestyle intervention. We would like to explore if the GlucoGuide™ system can be developed to be implemented on its own without monthly clinic visits. As we continue to investigate ways of providing primary and secondary prevention of diabetes, one subpopulation of Canada that the GlucoGuide™ system could possibly support are those with prediabetes and T2D living in remote and rural locations with limited health care who are not able to make monthly visits to see their health care team, yet could download the app and thereby start receiving tailored information and feedback about their health and how to manage their prediabetes or T2D.

5.4 Conclusion

The GlucoGuide™ system was found to be feasible and usable, and as comparable as a paper journal when combined with the SMART lifestyle intervention. Using CDA best practice guidelines and evidence-based behaviour change theory to develop and evaluate the GlucoGuide™ system yielded a number of interesting findings. Except for a few differences in quality of life questionnaires, and initial diastolic blood pressure, no data was found to differ between the two groups. However, there were some significant changes over time for both groups of participants, including time to complete the fitness test, participant overall fitness rating, improved self-efficacy for eating a Mediterranean-style diet, managing the psychosocial aspects of diabetes and overall mental health. These results reflect a benefit of the lifestyle program for people with prediabetes and T2D, irrespective of the tool participants selected. The potential for the smartphone to transcend socioeconomic status may mean that in the future a system like GlucoGuide™ can reach populations in Canada with prediabetes and T2D who would not otherwise receive the health care the desperately need, helping to stem the prevalence of diabetes in Canada by providing primary and secondary prevention of diabetes.

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ETHICS APPROVAL

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Robert Petrella
Review Number: 18759E
Review Level: Delegated
Approved Local Adult Participants: 24
Approved Local Minor Participants: 0
Protocol Title: Smart technology to Manage type 2 diabetes and Achieve health goals through Record keeping and Tailored feedback
Department & Institution: Schulich School of Medicine and Dentistry\Family Medicine, University of Western Ontario
Sponsor:
Ethics Approval Date: March 08, 2012 **Expiry Date:** November 30, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Western University Protocol		
Letter of Information & Consent		2012/03/07
Advertisement		

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The UWO HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signature

Ethics Officer to Contact for Further Information

Janice Sutherland ([illegible])	✓ Grace Kelly ([illegible])	Shantel Walcott ([illegible])

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The University of Western Ontario
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APPENDICES

Appendix 1. Behaviour Change Theory Figures

Figure 1. Transtheoretical Model: Stages of Change

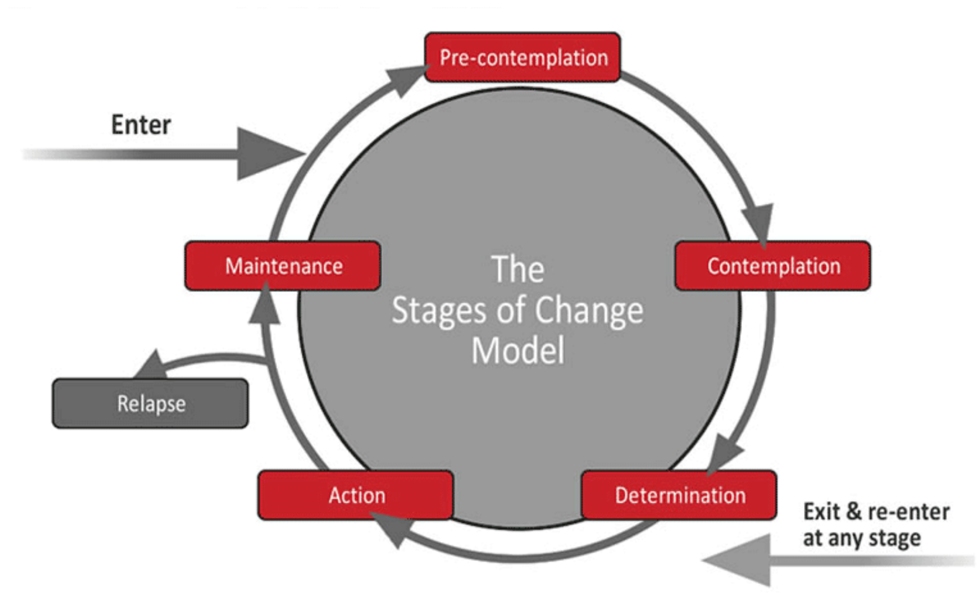
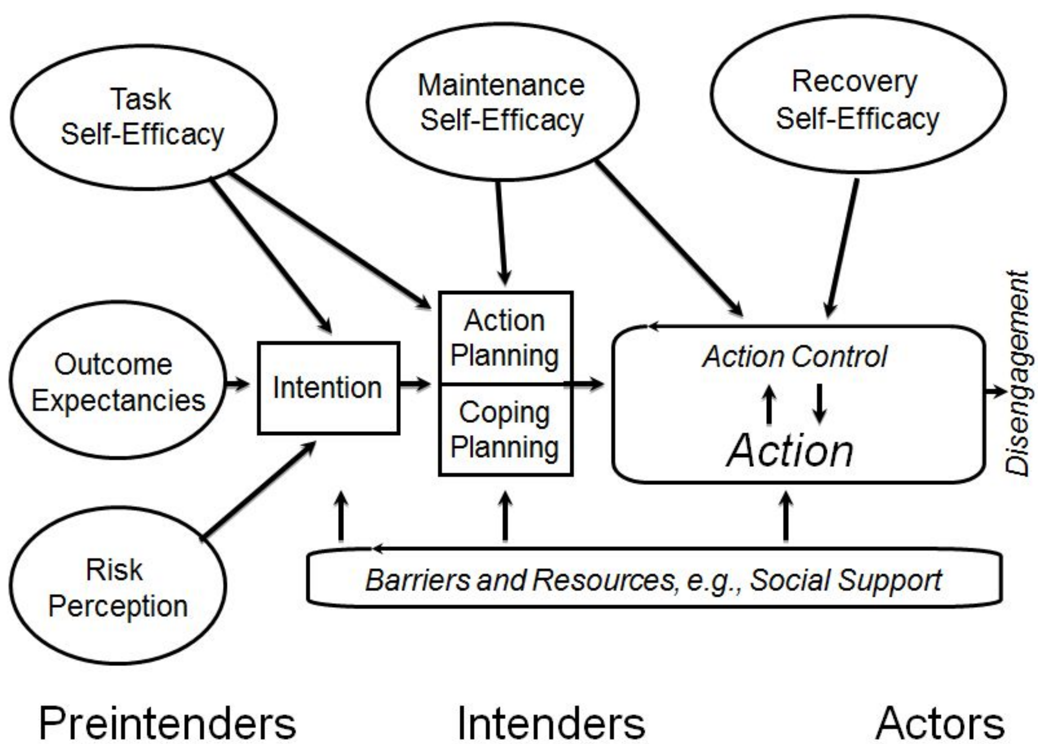
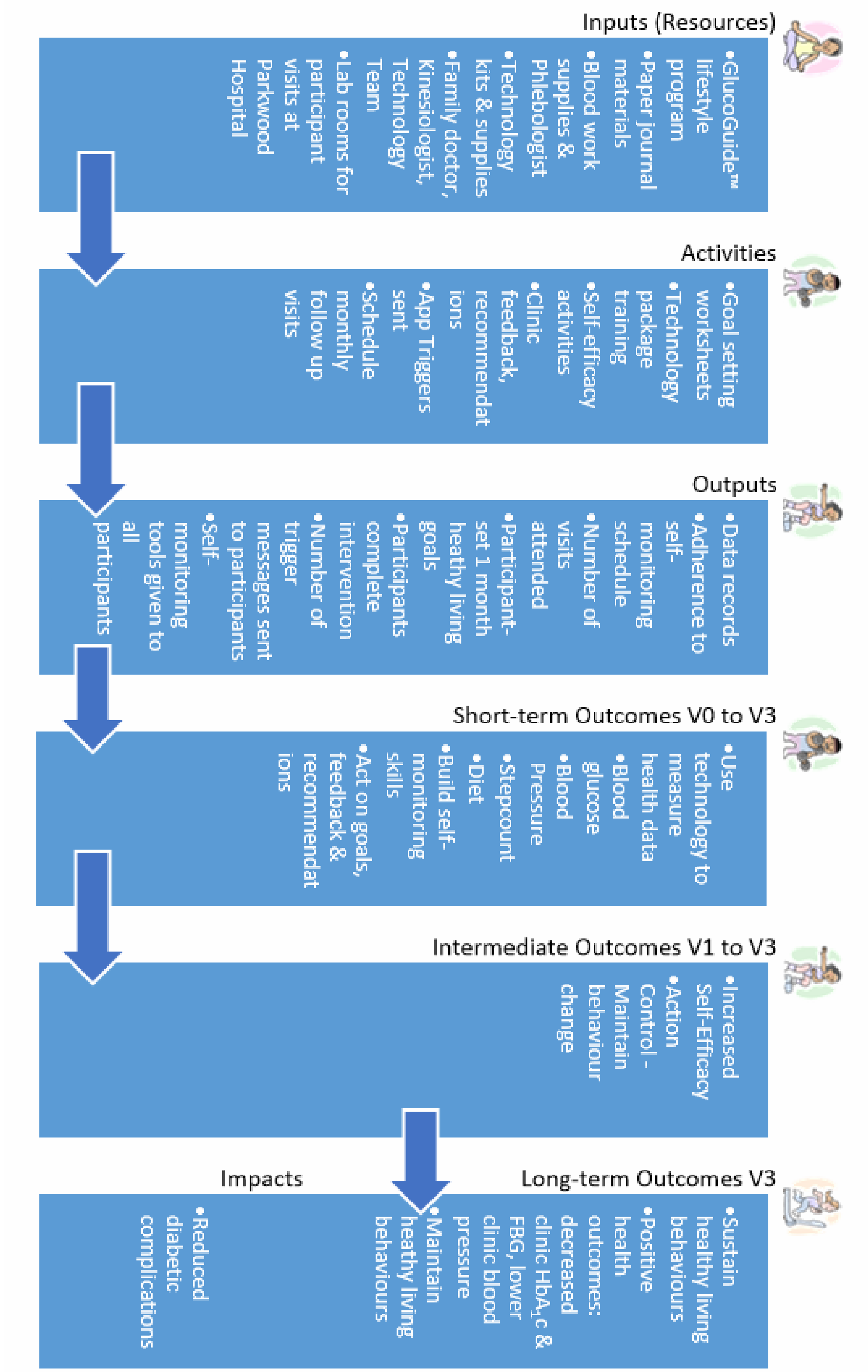


Figure 2. Health Action Processes Approach



Appendix 2. Logic Model for the SMART Lifestyle Intervention and GlucoGuide™ System



Appendix 3. Self-monitoring Schedule

All participants will be asked to record their diet for the first week, along with their blood glucose before and 2 hours after meals for breakfast and dinner. They will also be asked to record their blood pressure before breakfast and dinner. Step count will be recorded for each day. After the first week, participants will focus on dinner alone, recording their food intake at dinner, blood glucose before and 2 hours after dinner, blood pressure before dinner, and step count for the day. A sample month is outlined below.

May 2012
V_x = visit number, i.e., V_0 = baseline, V_1 = first follow-up visit, etc.
Diet = all food and drink consumed that day
Dinner = all food and drink consumed at dinner time, or, between blood glucose testing
PA = step count, BG = blood glucose, BP = blood pressure,
#x = the number indicates the frequency of testing per day, if no number is indicated it was only recorded once per day

S	M	T	W	T	F	S
		1 **V_o**	2 Diet, PA, BG 4x, BP 2x	3 Diet, PA, BG 4x, BP 2x	4 Diet, PA, BG 4x, BP 2x	5 Diet, PA, BG 4x, BP 2x
6 Diet, PA, BG 4x, BP 2x	7 Diet, PA, BG 4x, BP 2x	8 Diet, PA, BG 4x, BP 2x	9 Dinner, PA, BG 2x	10 Dinner, PA, BG 2x, BP	11 Dinner, PA, BG 2x	12 Dinner, PA, BG 2x, BP
13 Dinner, PA, BG 2x, BP	14 Dinner, PA, BG 2x, BP	15 Dinner, PA, BG 2x	16 Dinner, PA, BG 2x	17 Dinner, PA, BG 2x, BP	18 Dinner, PA, BG 2x	19 Dinner, PA, BG 2x, BP
20 Dinner, PA, BG 2x, BP	21 Dinner, PA, BG 2x, BP	22 Dinner, PA, BG 2x	23 Dinner, PA, BG 2x	24 Dinner, PA, BG 2x, BP	25 Dinner, PA, BG 2x	26 Dinner, PA, BG 2x, BP
27 Dinner, PA, BG 2x, BP	28 Dinner, PA, BG 2x, BP	29 **V_1** Dinner, PA, BG 2x	30 Diet, PA, BG 4x, BP 2x	31 Diet, PA, BG 4x, BP 2x		

Appendix 4. Goal Setting Worksheet

Physical Activity and Healthy Eating Card

Date: ________________
Participant: ____________

VO_2max Score: ____________________ VO_2max Rating: __________________________

VO_2max is a measure of your cardiorespiratory fitness. It is a score of how well your heart, lungs and muscles work together. The higher your VO_2max is, the more aerobically fit you are. You can become fitter by increasing your aerobic physical activity; some examples of aerobic physical activity includes walking, running, or snow shovelling the driveway.

Training Heart Rate (bpm): __________ Training Heart Rate (10 seconds): ____________

In order to improve your fitness, it is important to check your heart rate during physical activity. This training heart rate has been prescribed specifically for you based on your STEP test results. The easiest way to check your pulse it to count how many times you feel your heart beat in 10 seconds.

Physical Activity

Target Daily Step Count:

Types of Aerobic Exercises:

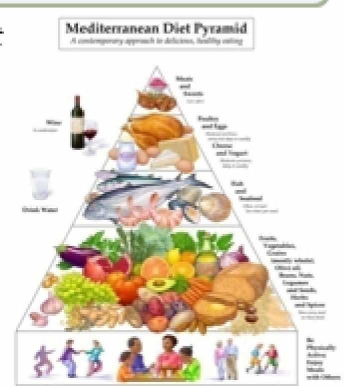
Target Aerobic Frequency:

Types of Resistance Training Exercises:

Healthy Eating Recommendations

Here are some ways to eat a more Mediterranean-style diet

- Increasing fish intake to at least 2 – 3 times per week
- Increase fruit and vegetable intake
- Replace any oil, margarine, butter you are currently using with Olive Oil.
- Choose low fat dairy products
- Choose wholegrain breads and cereals
- Try and include some legumes in your diet



Appendix 4. Goal setting worksheet, Page 2

Participant Goals/Barriers/Solutions

Write down 2-3 physical activity or health related goals that you want to achieve. They should be specific, measureable and attainable.

For each goal, identify how you can achieve that goal, and the strengths & resources you already have that will help you achieve that goal. For example, perhaps you have great friends that you enjoy walking with, or perhaps you like cooking new recipes.

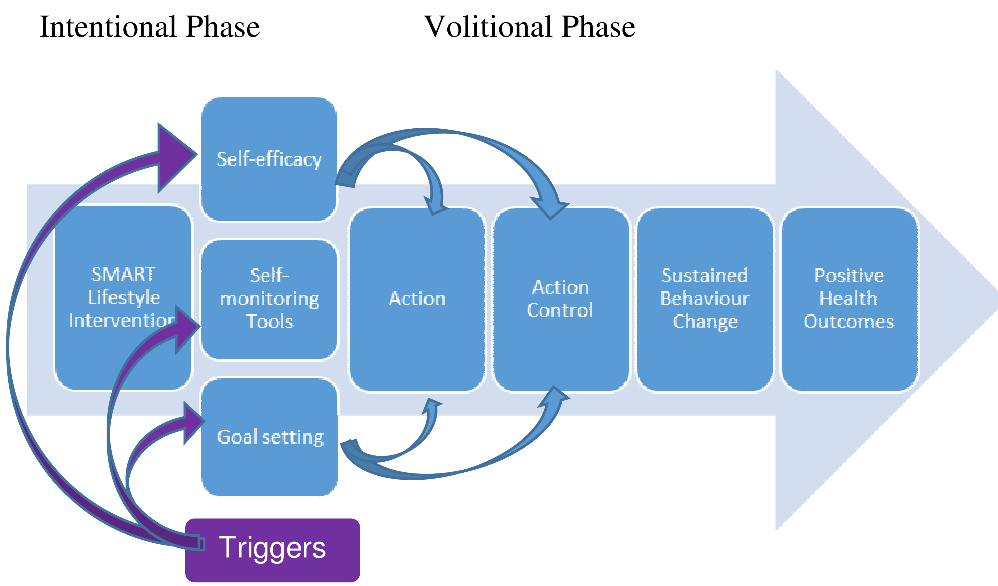
For each strength identify barriers that could prevent you from reaching your goal. Barriers can be things that you cannot control, such as the weather, or things you can control such as feeling too tired. For example you might overcome bad weather by choosing to walk up and down the stairs in your home.

Goal 1 ________	**Strengths** ________	**Barriers & Solutions** ________
Goal 2 ________	**Strengths** ________	**Barriers & Solutions** ________
Goal 3 ________	**Strengths** ________	**Barriers & Solutions** ________

Appendix 5. Evaluation Measures and Activities Schedule

Phase	Measure	V0, Baseline	V1, 4 wks	V2, 8 wks	V3, 12 wks
Enrollment	Letter of Information	X			
	Inclusion/Exclusion	X			
	Letters of Consent	X			
Baseline Assumption Measures	7-Day Physical Activity Recall (Sallis et al., 1985)	X			X
	Technology Experience Survey, Part 1 (Stuckey et al., 2011)	X			
	Technology Experience Survey, Part 2 (Stuckey et al., 2011)				X
	Perceived Outcomes measured: Decisional Balance for Physical Activity, Health Eating (Atkin et al., 2005)	X			X
	Intention measured: Stage of Change - Physical Activity, Diet (Atkin et al., 2005)	X	X	X	X
Activities	Technology Training	X	X		
	STEP™ Test (Petrella et al., 1998)	X	X	X	X
	CHEI Diet Assessment (Garriguet, 2009)	X	X	X	X
	Goal Setting / Action and Planning Coping	X	X	X	X
	Self-efficacy Activities (Schwarzer, 2008)	X	X	X	X
	Monthly Follow-up Scheduled	X	X	X	
Outputs	Goal Setting Worksheets completed	X	X	X	X
	Adherence to self-monitoring protocol measured		X	X	X
	Number of visits attended / enrolled participant				X
	Monthly goals recorded	X	X	X	
	Trigger feedback				X
Outcomes	HbA_{1c}, FBG	X			X
	Anthropometric and Clinical Measures Blood Pressure, Waist Circumference (McGuire & Ross, 2008), Height, Weight	X	X	X	X
	Self-Efficacy Scale - Physical Activity, "Mediterranean-style Eating" (Atkin et al., 2005)	X			X
	Action measured (Diet, Step Count change / month, 3-day food records)	X	X	X	X
	Action Control reviewed and measured	X	X	X	X
	Sustained behaviour change measured (baseline to V3)				X

Appendix 6. The SMART Lifestyle Intervention and GlucoGuide™ System Causal Model



The purple box and arrows indicate how the GlucoGuide™ system is hypothesized to enhance the SMART lifestyle intervention by sending messages regarding self-efficacy, self-monitoring and goal setting between scheduled clinic visits. This causal model guided the development and the evaluation of the GlucoGuide™ system.

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Schuurman, J., Luo, Y., Ling, C., Petrella, R. (2013).The SMART Study: A pilot project examining tools for self-management among diabetes and prediabetes. Abstract, Oral and Poster presentation, Aging Rehabilitation and Geriatric Care and the Faculty of Health Science Symposium, London Ontario, February 1, 2013.

Schuurman, J., Luo, Y., Ling, C., Petrella, R. (2012). The SMART Study: A pilot project investigating mobile health and traditional methods of delivering a lifestyle intervention. Abstract and Poster presentation, Diabetes Research Day, London Ontario, November 13, 2012.

Morrison, S. & Schuurman, J. (2012). Misguidance in Diabetes Nutrition: Food Labeling & Agency Recommendations. Health Science Inquiry. 3(1):80-81.