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Examining the Feasibility of Delivering a Multi-Component Virtual Lifestyle Medicine Program for Adults with Type 2 Diabetes

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Abstract

BACKGROUND: The virtual delivery of lifestyle medicine programs (e.g., via web-conferencing platforms) can increase program accessibility for adults living with type 2 diabetes (T2D). **PURPOSE:** To assess the feasibility of virtually delivering a multi-component group-based lifestyle medicine program that uses wearable technologies and exercise prescriptions in an adult population with T2D. **METHODS:** This was a six-week, single-cohort feasibility study. The virtual lifestyle medicine program included live-video delivery of group education classes, one-on-one exercise counselling phone calls, flash glucose monitors, wearable activity monitors, and exercise prescriptions. Several feasibility outcomes were assessed including recruitment and retention rates, acceptability (e.g., exit survey), and adherence (e.g., group education class attendance). Data are reported descriptively. **RESULTS:** Ten participants with T2D were recruited (60% female, 50 ± 15 (SD) years, mean A1c 6.7 ± 0.5 %). Recruitment and retention rates were 29% and 80%, respectively. Most participants (89%) were 'satisfied'/'very satisfied' with the program. There were 3.2 ± 2.6 technology 'issues' reported per person, mostly related to study data transfer. Participants attended 83% and 93% of group education classes and one-on-one exercise counselling phone calls, respectively. **CONCLUSION:** The virtual delivery of a multi-component group-based lifestyle medicine program for adults living with T2D is feasible, however, several study protocol and interventions refinements are recommended before conducting a larger trial.

Keywords

Type 2 Diabetes, Virtual Care, Self-Management, Wearables, Activity Monitor, Continuous Glucose Monitor, Exercise Prescription, Physical Activity, Lifestyle Medicine, Nutrition, Group Education

Summary for Lay Audience

To address common barriers to self-management education in populations with type 2 diabetes, effective delivery of virtual group lifestyle medicine programs is needed. This was a six-week, single group study that assessed the feasibility of delivering a virtual group lifestyle medicine program that used wearable glucose monitors and activity monitors (i.e., FitBit Inspire 2™), and provided personalized exercise prescriptions for patients with type 2 diabetes. This study was conducted through a specialized primary care clinic in London, Ontario. Adults (≥18 years) with type 2 diabetes who owned a smartphone, had Internet access, and were medically cleared to exercise, were included. During a two-week baseline and six-week intervention, participants wore wearable glucose monitors and FitBit Inspire 2™'s. Virtual group education classes (via a videoconferencing platform) and one-on-one exercise counselling phone calls (with an exercise specialist) were delivered bi-weekly, on alternating weeks. Virtual group education classes covered content such as low carbohydrate nutrition topics, how to interpret and use glucose data to make nutrition and exercise decisions, why and how to exercise, and learning coping/problem solving skills. Data (n=10 participants) reported an 80% retention rate at follow-up, 3.2 ± 2.6 mean technology issues per person, high participant satisfaction (89%), and intervention adherence rates of 83% and 93% for group and phone call check-in attendance, respectively. Several opportunities for refinement were found to help inform a pilot study. This work may lead to better, more accessible virtual group education for patients with type 2 diabetes and reduce healthcare worker burden.

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Chapter 1

1 Introduction

1.1 *Background*

In 2020, an estimated 3.77 million (10%) Canadians were living with diagnosed type 1 or type 2 diabetes mellitus (T2D), where T2D made up about 90-95% of all cases (Diabetes Canada, 2021a). The prevalence is expected to increase approximately 30% by 2030 (Diabetes Canada, 2021a). In general, adults living with T2D have higher rates of morbidity (e.g., cardiovascular disease hospitalizations) and mortality (e.g., all-cause mortality; Hux et al., 2003; LeBlanc et al., 2019). Better T2D self-management and glycemic control can slow disease progression as well as decrease the risk of complications (e.g., neuropathies; Imran et al., 2018). Those living with T2D experience many challenges that are related to self-management, including: (a) demanding treatment regimens, (b) increased family burden, (c) higher levels of mental and emotional strain, (d) financial burden, and (e) decreased quality of life (Gonzalez et al., 2016; Harding et al., 2019; Houlden, 2018; Nicolucci et al., 2013). More accessible T2D self-management solutions are needed to help address some of these challenges and decrease disease burden (Banbury et al., 2018; Horigan et al., 2017; Powers et al., 2015).

1.2 *Self-Management*

Diabetes self-management is often described as a ‘full-time’ job (Gonzalez et al., 2016), with healthcare-related decision making, symptom monitoring (e.g., hypoglycemia), and treatment regimens (e.g., insulin injection) required multiple times a day, every single day (Chodosh et al., 2005; Gonzalez et al., 2016; Sherifali et al., 2018). Aspects of T2D treatment regimens generally belong to four main ‘pillars’ of diabetes self-management, including: (a) regular glycemic monitoring (Berard et al., 2018), (b) medication adherence (Khunti et al., 2017), (c) proper nutrition (Sievenpiper et al., 2018), and (d) sufficient physical activity/exercise (Colberg et al., 2010; Colberg et al., 2016; Marçal et

al., 2020; Sigal et al., 2018; Warburton & Bredin, 2017; Zhao et al., 2020). In particular, the evidence-base is growing to support exercise as a daily cornerstone of treatment (Sigal et al., 2018). Unfortunately, under the current circumstances, the COVID-19 pandemic (including stay-at-home orders, a generalized fear of infection, etc.) has led to decreased physical activity levels and increased sedentary behaviours in the general population globally (Marçal et al., 2020) and possibly in those with T2D as well. Another consequence of the COVID-19 pandemic has been rising levels of anxiety and depression amongst those living with T2D (Marçal et al., 2020), which has been previously shown to limit the quality of chronic disease self-management (Grenard et al., 2011). Before the COVID-19 pandemic, this clinical population often demonstrated sub-optimal treatment adherence and glycemic control (Coons et al., 2017; Polonsky & Henry, 2016). The added pressures of the COVID-19 pandemic are expected to exacerbate the low treatment adherence issue, leading to poorer glycemic control and increased rates of T2D complications (Marçal et al., 2020). Now, almost more than ever before, adults living with T2D need accessible self-management supports (Aberer et al., 2021; Sauchelli et al., 2021).

1.3 *Self-Management 'Boosters'*

The T2D self-management literature suggests that diabetes self-management education (DSME), theory-based interventions, and technologies (e.g., wearable activity monitors, smartphone applications [apps], etc.) may promote health behaviour change and improve glycemic outcomes (Gonzalez et al., 2016; Kirk et al., 2019; Kooiman et al., 2018; Liao et al., 2020; Lystrup et al., 2020; Patel et al., 2015; Shan et al., 2019; Sherifali et al., 2018; Shigaki et al., 2010; Sigal et al., 2018; van Ommen et al., 2017; Williams et al., 2004). DSME is a collaborative and interactive process between patients and providers that helps patients learn the knowledge and skills needed to better manage their T2D (Chodosh et al., 2005; Sherifali et al., 2018). When grounded in behaviour change theory, DSME has shown to be more efficacious (Ntoumanis et al., 2020; Sheeran et al., 2020). Self-determination theory (SDT), a global theory of human motivation (Ryan & Deci, 2000b), has previously informed effective DSME interventions (Karlsen et al., 2018; Liu et al., 2018; Williams et al., 2009) and been applied in exercise-based interventions

(Koponen et al., 2018; Sigal et al., 2018; Silva et al., 2010). SDT offers a framework for developing health behaviour interventions by nurturing intrinsic motivation through the satisfaction of three basic psychological needs: autonomy, relatedness, and competence (Ryan & Deci, 2000b, 2017). Evidence suggests that behaviour change techniques (BCTs) can be used to support these psychosocial needs and help patients internalize the motivation to engage in self-management practices (Michie et al., 2013; Ntoumanis et al., 2020). BCTs are the "active ingredient" components in an intervention that have previously shown observable, reproducible results that are designed to alter causal processes that regulate behaviour (Michie et al., 2013). For example, the incorporation of specific BCTs (i.e., enhanced self-monitoring or goal setting) have been linked to increased feelings of self-efficacy in adult populations with T2D (Fredrix et al., 2018; McSharry et al., 2020; McSharry et al., 2016).

Virtually delivering group education classes has the potential to create feelings of social relatedness as well as offer an inclusive environment that one-on-one sessions cannot (Cliffe et al., 2021; Jiwani et al., 2021; Ryan & Deci, 2017). As well, it can increase opportunities for peer learning and acknowledgement of feelings from and by, clinicians and peers, which can assist in the development of autonomy and relatedness (Ryan & Deci, 2017; Williams et al., 2004). Wearable technologies (particularly when used in a DSME environment) can be beneficial for building intrinsic motivation as well. Wearable technologies such as flash glucose monitors (FGMs; i.e. FreeStyle® Libre, Abbott Laboratories Ltd., Illinois, United States) and wearable activity monitors (e.g., FitBit Inspire 2™, FitBit Inc., San Francisco, California) can support increased feelings of self-efficacy for diabetes self-management behaviours by providing positive performance feedback (e.g., biofeedback) and optimal challenges (e.g., scalable physical activity goals; Ryan & Deci, 2017). Wearable technologies can also support autonomy by providing patients with increased opportunities for treatment-related choices (e.g., selecting their own physical activity goals; Ryan & Deci, 2017) and social-connectedness (such as sharing experiences using tracked data (e.g., 'I can't believe what happened to my blood glucose after I went for a walk.'; Kooiman et al., 2018; Lystrup et al., 2020; Michaud et al., 2021; Rollo et al., 2016; Shan et al., 2019; Sherifali et al., 2018; Sigal et al., 2018; van Ommen et al., 2017). T2D self-management, therefore, may be improved

with DSME that is grounded in health behaviour change theory and that leverages virtual group education classes and wearable technologies (Gonzalez et al., 2016; Whelan et al., 2019).

1.4 *New Virtual Possibilities*

As a result of the COVID-19 pandemic, methods of virtual care are being used at unprecedented rates (e.g., virtual patient/provider group videoconferencing platforms such as Zoom or WebEx®, etc.; Zhang et al., 2021). Virtual care is an all-encompassing term and is defined as, "any interaction between patients and/or members of their circle of care, occurring remotely, using any forms of communication or information technologies, with the aim of facilitating or maximizing the quality and effectiveness of patient care." (Jamieson et al., 2015, p. 5). Methods of delivering virtual care can address common self-management barriers (e.g., time intensive treatment tasks such as taking public transit to medical appointments) and increase access to timely T2D support and education (Gonzalez et al., 2016; Horigan et al., 2017; Robinson et al., 2018; Zgibor & Songer, 2001). Previous evidence has shown that the virtual delivery of DSME (with or without the use of wearable technology) may be as effective as face-to-face delivery and can result in positive health behaviour changes (Komkova et al., 2019; Li et al., 2020; Ward et al., 2018; Wolever et al., 2010). There has been a rapid transition to virtual care across many jurisdictions around the world in response to the COVID-19 pandemic (Aberer et al., 2021; Zhang et al., 2021). This response presents an opportunity to examine and improve the virtual delivery of DSME programs (Aberer et al., 2021). What once was a less common, alternative medium is (for now and for many) the standard of care (Aberer et al., 2021; Iyengar et al., 2016). Necessity certainly does breed innovation.

1.5 *Virtual Lifestyle Medicine*

Little is known about the feasibility of virtually delivering multi-component group-based lifestyle-focused DSME (or "lifestyle medicine programs"). To date, virtual lifestyle medicine programs have primarily been delivered in human resource-intensive, one-on-one formats (Kato et al., 2020; Majithia et al., 2020; Michaud et al., 2021; Wayne et al.,

2015; Wolever et al., 2010; Zheng et al., 2020), potentially limiting program scalability and sustainability (Marzolini et al., 2021). As well, while many virtual lifestyle medicine programs in T2D settings include an exercise component, most appear to lack *individualized* exercise prescriptions which may limit behaviour change potential (Kato et al., 2020; Li et al., 2020; Liao et al., 2020; Majithia et al., 2020). A recent focus group study by Jiwani and colleagues (2021) examined the acceptability of a multi-component virtual lifestyle medicine program that included group education and wearable monitors (n=18; older adults living with overweight/obesity and T2D aged 72 ± 5.4 years). However, despite promising results, a broader range of feasibility (e.g., recruitment rate, intervention adherence, etc.) and health behaviour/outcome metrics are needed to refine these virtual interventions, and ultimately establish their efficacy. Aligning with the ORBIT Model for Developing Behavioral Treatments for Chronic Diseases (Czajkowski et al., 2015), our clinically significant question (and marker of change) defined by ORBIT *Phase* 1a: "*What is the effect of a* multi-component (e.g., wearable technology, exercise prescriptions) virtual lifestyle medicine program *on A1c in adults with T2D*?". As well, a behavioural risk factor (exercise), potential candidates (adults with T2D), and intervention components and their targets (i.e., step count prescriptions and change in daily step count) were delineated in advance for the purpose of this. In order to prepare for a proper *Phase III* efficacy trial, the primary objective of *this* study, therefore, was to assess the feasibility of delivering a multi-component virtual lifestyle medicine program for adults with T2D. This preparatory research (ORBIT *Phase Ib*) will help set the stage for a pilot randomized controlled trial (RCT) that tests the impact of virtual vs. in-person delivery of a multi-component lifestyle medicine program.

Chapter 2

2 Literature Review

2.1 *Type 2 Diabetes Mellitus: Prevalence and Burden*

"Diabetes mellitus is a heterogeneous metabolic disorder characterized by the presence of hyperglycemia due to impairment of insulin secretion, defective insulin action or both" (Punthakee et al., 2018, p. S10). More specifically, T2D is a chronic disease, characterized by the inability to produce a sufficient amount of insulin, or when the body does not efficiently use the insulin that is produced (Punthakee et al., 2018). T2D is diagnosed as having glycated hemoglobin (A1c) levels of ≥6.5 mmol/L and either a) a fasting plasma glucose level of ≥ 7 mmol/L or b) two separate two-hour oral glucose tolerance tests of ≥11.1 mmol/L (Punthakee et al., 2018). According to Diabetes Canada (2021a), it was estimated that one in three (29%), or about 11 million, Canadians were living with diabetes (Type 1, Type 2 diagnosed or undiagnosed) or pre-diabetes (a T2D precursor diagnosed as having an A1c of 6.0-6.4 mmol/L) in 2020. Specifically, there were roughly 3.77 million (10%) Canadians with diagnosed Type 1 or Type 2 diabetes in 2020, where is T2D made up 90 to 95% of that population. In Ontario alone, 4.5 million people were living with diabetes or pre-diabetes in 2020. These all-inclusive Canadian and Ontarian prevalence statistics are expected to increase to 13.5 million (32%) and 5.47 (33%) million, respectively, by 2030. In 2019, Canada ranked ninth globally in largest diabetes-related total (direct and indirect costs) healthcare expenditure at $12.3 billion USD for those 20-79 years old (International Diabetes Federation, 2019). In 2020, diabetes cost the Canadian health care system an estimated $3.01 billion USD in direct costs (e.g., hospitalization, medication, home care, outpatient care like dialysis; Diabetes Canada, 2021).

The burden of diabetes is not just realized by the large-scale burden on our healthcare system resources and economy, but also on an individual level. All-cause mortality rates are double for Canadians living with diabetes, compared to those living without (LeBlanc et al., 2019). Diabetes can shorten one's lifespan by 5 to 15 years and triples the risk of

cardiovascular disease hospitalization (Public Health Agency of Canada, 2011), and is linked to 30% of strokes, 40% of myocardial infarctions, and 70% of all non-traumatic leg and foot amputations (Hux et al., 2003). Every day, people with diabetes face difficult realities due to increased risks of many health complications (including early death), decreased quality of life, greater family burden, as well as financial, emotional, and mental strains (Gonzalez et al., 2016; Harding et al., 2019; Houlden, 2018). A daily diabetes treatment regimen and frequent medical appointments can be burdensome and time consuming (e.g., one to two hours per day; Gonzalez et al., 2016; Nicolucci et al., 2013). Diabetes self-management is directly and indirectly related to individual-level financial burden as well. Canadians with T2D spend an estimated $1,200-$1,900 CAD out-of-pocket each year on oral medications, in addition to other medical supplies (e.g., glucometer, glucometer strips, etc.; Diabetes Canada, 2021). Time spent driving to health appointments, in addition to increased time on disability (i.e., 15% longer than people without diabetes) can also result in financial losses (Diabetes Canada, 2018; Gonzalez et al., 2016). The human burdens and strains stated here are not an exhaustive list, but do illustrate some of the wide-ranging impacts of this debilitating chronic disease.

2.2 *Management of Diabetes*

2.2.1 **Optimizing Type 2 Diabetes Care.**

Management plans and support decisions should be made collaboratively between those living with T2D and their healthcare team in order to optimize diabetes outcomes such as glycemic control (Sherifali et al., 2018). Practitioners must consider individualization as there are many aspects that play into treatment decisions (Sherifali et al., 2018). For example, several social determinants of health influence both an individual's ability to engage in healthy behaviours and their T2D disease management/progression (Houlden, 2018). These determinants include, but are not limited to socio-economic status, ethnicity, environment (e.g., unsafe neighbourhood, no sidewalks), education level, income, food security, social connectedness, community resources, childhood development, and social stigmas (Diabetes Canada, 2018; Houlden, 2018). Examples of social stigmas related to diabetes can be (a) people assuming that the cause of T2D was the fault of the person's

behaviours; (b) persons with T2D reporting claims of discrimination against T2D; and/or (c) persons with T2D feeling embarrassment or are ashamed to let people know they have diabetes (Diabetes Canada, 2018; Horigan et al., 2017). To optimize T2D management and minimize health inequities, these social determinants of health along with culture, health beliefs, as well as ability/readiness for health change, must be considered when individualizing T2D management plans (Diabetes Canada, 2018; Sherifali et al., 2018). Overall, it is evident that there are a multitude of factors required to properly manage each person's unique journey with T2D. Therefore, patients require individualized treatments and knowledge/skills training that incorporate care around medical, emotional, and behavioural topics of diabetes self-management.

2.2.2 Type 2 Diabetes Mellitus: The Role of Self-Management.

Chronic disease self-management can be defined as the active participation in self-monitoring of symptoms, making informed treatment decisions, and/or performing complex activities needed for self-care (Chodosh et al., 2005; Sherifali et al., 2018). When it comes to T2D self-management specifically, it is often described as an 'around the clock, full time job' that requires a certain level of health literacy and numeracy, as well as decision-making and problem-solving skills to achieve optimal glycemic control Diabetes Canada, 2018; Gonzalez et al., 2016; Sherifali et al., 2018). Optimal glycemic control is essential to the management of T2D and is associated with slowing the progression of T2D and decreasing T2D-related microvascular (e.g., neuropathy) and macrovascular (e.g., stroke) complications (Imran et al., 2018). Other outcome goals of successful T2D management include increased quality of life, treatment self-efficacy, and long-term functional capacity (Berard et al., 2018; Diabetes Canada, 2018; Sherifali et al., 2018).

According to Diabetes Canada's most recent *Clinical Practice Guidelines* (2018) and the ABCDES of Diabetes Care Guide (Diabetes Canada, 2021b), T2D self-management includes the following: glycemic control monitoring, regular exercise, decreased sedentary time, healthy eating, weight management, medication adherence, foot care, mental health management, and regular surveillance of T2D complications (which may include self-awareness and regular screening for neuropathy, retinopathy, gum disease, or

chronic kidney disease, etc.). Other guideline targets such as a blood pressure of <130/80 mmHg, cholesterol targets LDL-C of <2.0 mmol/L, drugs to reduce cardiovascular risks, smoking cessation, management of stress, and mental health (or other barriers that can prevent optimal targets) also need to be addressed (Diabetes Canada, 2021b).

2.2.3 ***Type 2 Diabetes Mellitus: Management Pillars.*** Overall, proper medication adherence, nutrition, exercise, and glycemic monitoring should be highlighted as they play as key diabetes management pillars and should be considered as a front-line treatment rather than as a second-line defense, as these have the largest effects on glucose control, such as lowered A1c levels (Berard et al., 2018; Colberg et al., 2010; Colberg et al., 2016; Marçal et al., 2020; Sievenpiper et al., 2018; Sigal et al., 2018). Controlled A1c levels, or levels ≤7% are linked with significant reductions in macrovascular and microvascular risks (Imran et al., 2018). A1c targets of ≤6.5% can result in risk reduction for retinopathy and chronic kidney disease (Imran et al., 2018). A1c targets should be individualized and will vary, depending on other health conditions, goals and age (Imran et al., 2018).

2.2.3.1 ***Medication Adherence.*** Medication adherence for people with T2D is an important element in managing the progression of the disease and can result in reduced mortality, hospitalizations, and healthcare costs (Khunti et al., 2017; Kirkman et al., 2015). Despite benefits of optimal T2D control with regular medication adherence, many fail to maintain regularity in taking medication (Gonzalez et al., 2016). In some cases, non-adherence may be related to having to take multiple medications or certain medications causing unwanted side-effects or requiring calculations, titrations, and/or multiple doses (Lipscombe et al., 2018). Out-of-pocket costs, younger age, recent diagnosis, or multiple medications can also threaten medication adherence (Kirkman et al., 2015).

2.2.3.2 ***Nutrition.*** Nutrition is a key player in reducing overall A1c. Studies have reported that nutrition therapy can result in 1-2% reductions in A1c levels (Sievenpiper et al., 2018). Additionally, proper nutrition, timing of meals, and low glycemic index food can assist in lowering glucose variability throughout the day (Sievenpiper et al., 2018).

High glucose variability is linked to increased cardiovascular risks and microvascular complications (Ceriello, 2020). Nutrition should be individualized and meet the preferences of the patient to create long term, sustainable habits that are adhered to (Sherifali et al., 2018; Sievenpiper et al., 2018).

2.2.3.3 ***Physical Activity: A Cornerstone of Type 2 Diabetes Management.*** There is overwhelming evidence to suggest that higher physical activity levels have greater protective effects against all-cause mortality and the incidence/mortality risks among patients with several non-communicable diseases (Warburton & Bredin, 2017; Zhao et al., 2020). These include cardiovascular disease, multiple types of cancers, chronic respiratory tract diseases, T2D, hypertension, ischemic heart disease, and strokes (Warburton & Bredin, 2017; Zhao et al., 2020).

Overall, higher physical activity levels, as well as engagement in aerobic and resistance exercise, are critical to controlling and slowing T2D progression and the development of co-morbid conditions (Sigal et al., 2018). Benefits include decreases in A1c, systolic blood pressure, triglycerides, waist circumference, depression and anxiety symptoms, as well as increases in glycemic control, quality of life and immune responses (Bull et al., 2020; Chudyk & Petrella, 2011; Gupta et al., 2020; Myers et al., 2013; Umpierre et al., 2011). In general, exercise has a contraction-mediated glucose uptake effect, distinct from the insulin-mediated pathways (Colberg et al., 2010; Khayat et al., 2002). In those with insulin resistance (i.e., T2D) this is particularly beneficial, as a person can increase skeletal muscle glucose uptake (without the need for endogenous insulin) and subsequently decrease current glucose levels (and several hours post-exercise; Colberg et al., 2010).

In order to best achieve these benefits, the most recent Diabetes Canada Clinical Practice guidelines (Sigal et al., 2018) and American Diabetes Association (ADA) guidelines (Colberg et al., 2016) recommend a minimum of 150 minutes or more of moderate to vigorous physical activity each week, with no more than two consecutive days without aerobic exercise (i.e., walking, jogging, cycling, swimming, etc.) or resistance training. Aerobic exercise of higher intensities (Liubaoerjijin et al., 2016) or longer than 150

minutes of moderate to vigorous physical activity (Umpierre et al., 2011) have been found to be associated with greater reductions in A1c, compared to less intense exercise or 150 minutes or less of moderate to vigorous activity, respectively (Colberg et al., 2016; Sigal et al., 2018). Resistance training alone is beneficial for diabetes because it can increase insulin sensitivity (Jorge et al., 2011). Three sets of approximately eight repetitions utilizing major muscle groups at a frequency of three times per week (Castaneda et al., 2002; Dunstan et al., 2002) or more (Cauza et al., 2005; Durak et al., 1990) have shown the greatest improvements in A1c (using free-weights or machines; Sigal et al., 2018). The combined effects of engaging in both aerobic and resistance exercise training result in significant improvements in A1c, compared to either aerobic or resistance training alone (Pan et al., 2018; Sigal et al., 2007). One RCT including 251 adults with T2D reported that training in either aerobic or resistance training 3 times per week for 22 weeks resulted in a mean (95% confidence interval [CI]) reduction in A1c of -0.51% (-0.87 to -0.14) and -0.38 % (-0.72 to -0.22), respectively, when compared to a control group (Sigal et al., 2007). However, combined effects of resistance and aerobic training compared to either aerobic or resistance training alone, resulted in a further mean reduction in A1c of -0.46% (-0.83 to -0.09) and -0.59% (-0.95 to -0.23), respectively (Sigal et al., 2007). Although physical activity does come with increased risk of hypoglycemic or cardiac events, typically the benefits of physical activity outweigh the negatives (Bull et al., 2020), and there is low risk of adverse events with low- to moderate-intensity physical activity engagement (Colberg et al., 2016).

On the lightest end of the physical activity spectrum, is sedentary behaviour, a behaviour indicated by any waking activity in a seated, lying or reclining position (≤1.5 METs) (Tremblay et al., 2017). Physical inactivity, in contrast, is another distinct behaviour. Physical inactivity is defined as “an insufficient physical activity level to meet present physical activity recommendations (Trembley et al., 2017, p.10). High sedentary time is linked to increased risk of early mortality in the general population and those with diabetes, even after controlling for moderate to vigorous physical activity levels (Sigal et al., 2018). Both Diabetes Canada Clinical Practice Guidelines (Sigal et al., 2018) and the ADA (Colberg et al., 2016) recommend to decrease and break up daily sedentary behaviour, replacing it with standing or light physical activity every 20 to 30 minutes.

Evidence shows that interrupting prolonged bouts of sitting with light and/or moderate physical activity has positive effects on glucose, post-prandial glucose, insulin and triacylglycerol levels, and waist circumference in many different populations, with the greatest benefits to sedentary people with T2D (Dempsey et al., 2016; Dunstan et al., 2012; Healy et al., 2008; Loh et al., 2020). Dempsey and colleagues (2016) conducted a three-armed crossover RCT in an inactive sample living with overweight/obese and T2D and compared the effects of uninterrupted sitting, sitting plus three-minute bouts of light walking, and simple resistance activities (i.e., half-squats, calf raises), every 30 minutes on metabolic outcomes. Both three-minute bouts of activity types resulted in significant decreases on the incremental areas under the curve for glucose, insulin, and C-peptide levels. Only simple resistance activities significantly decreased triglycerides. This style of activity, in populations that are sedentary, physically unable to, unwilling to, or struggle with adhering to exercise, can be used as a practical steppingstone towards increasing activity (Colberg et al., 2016; Dempsey et al., 2016).

2.2.3.4 ***Glycemic Monitoring.*** Glycemic monitoring is crucial to preventing abovementioned complications of sub-optimal glycemic control related to T2D. Glycemic monitoring is typically completed by both testing A1c every three months and self-monitoring of blood glucose (with frequency individually prescribed by physicians; Berard et al., 2018). Continuous or flash glucose monitoring can also be used to self-monitor glucose levels (Berard et al., 2018). Self-monitoring requirements of glucose varies from person to person, depending on type of diabetes, insulin or other anti-hyperglycemic medications, numeracy and literacy skills, and hypoglycemic awareness (to name a few; Berard et al., 2018). When combined with structured education and behaviour change programs, glycemic monitoring can result in improved glucose levels and frequency of hypoglycemia (Berard et al., 2018). Glycemic monitoring can also be used to support behaviour change when it comes to nutrition choices and participation in exercise, utilizing biofeedback as a learning experience and positive reinforcement (Berard et al., 2018; Ryan & Deci, 2000b).

2.2.4 Sustaining Type 2 Diabetes Management with Education.

DSME can be defined as a systematic intervention of facilitating knowledge, skills, and

abilities required to actively participate in self-monitoring of symptoms, make informed treatment decisions, and/or perform complex activities needed for self-care (Chodosh et al., 2005; Sherifali et al., 2018). DSME should: be based on evidence-based standards; address patient preferences, needs, goals and experiences; support problem solving skill development; and be fostered by patient-healthcare team collaboration and interaction, with the end goal of independent and effective, sustained self-care (Al-Khawaldeh et al., 2012; Powers et al., 2015; Sherifali et al., 2018). These educational opportunities should also cover topics about, and how to (i.e., behaviour change techniques), implement proper nutrition, physical activity and glucose monitoring (Sherifali et al., 2018).

Despite benefits of DSME, people with diabetes may experience personal barriers to attending DSME sessions. For many, socioeconomic status can play a large factor such as lack of reliable transportation (e.g., unable to afford a personal vehicle) and/or financial costs of attending (time taken off work, potential need to hire help for child supervision; Horigan et al., 2017; Zgibor & Songer, 2001). Time can also be a large barrier, due to the inability to travel far distances (e.g., no vehicle, rural location) or take time off work (Horigan et al., 2017). Mental health, psychological disorders/factors (i.e., depression, anxiety, borderline personality disorders), and emotions may also play into a role in barriers to attendance (such as heightened anxiety about condition, denial, shame, fear of excessive demands, and negative feelings towards groups or diabetes education) (Gonzalez et al., 2016; Horigan et al., 2017; Robinson et al., 2018). Thus, virtual delivery of group education sessions may address some of these barriers (e.g., remove need for travel, cutting down on overall time needed for in-person attendance, etc.). Although technology provides the potential to leverage efficient delivery of DSME for both patients and clinical practice settings (i.e., video conferencing delivery), there is potential for further marginalization of disadvantaged populations with limited resources (due to socioeconomic status, access to internet, national healthcare policies/insurance plans etc.; Faghy et al., 2021; Kang et al., 2021). This marginalization has only been exacerbated by the COVID-19 pandemic (Misra & Bloomgarden, 2020). It is important to note that not all persons may benefit from a virtual delivery of education sessions (Maddison et al., 2019). Method of delivery should be determined via patient preference to maximize attendance rates (Maddison et al., 2019). Current evidence suggests that technologies that

support Internet (or "web-based") DSME interventions (Arens et al., 2018), smartphone DSME interventions (smartphone health apps or SMS text messages) (Li et al., 2020), and wearable technologies may assist in supporting diabetes self-management (e.g., glucose monitoring; Kamei et al., 2020; Majithia et al., 2020; Sigal et al., 2018; van Ommen et al., 2017) and result in improved glycemic control (Sherifali et al., 2018). Therefore, utilizing these tools in addition to traditional DSME practice can maximize accessibility and meet patients' needs/preferences.

2.3 *Wearable Devices: A Boost for Diabetes Self-Management?*

Wearable devices (such FGMs and wearable activity monitors) have the ability to increase capabilities and self-efficacy in diabetes self-management (Sherifali et al., 2018; Sigal et al., 2018; van Ommen et al., 2017) and can be useful in facilitating behaviour change (Patel, Asch, & Volpp, 2015). Wearable devices have been linked to lower A1c levels (Quinn et al., 2011; Veazie et al., 2018), indicating general improvements in diabetes self-management. They have become more user friendly, prevalent, and affordable, which presents an opportunity to make diabetes care more inclusive and effective (van Ommen et al., 2017). The ability to share medical and lifestyle data (i.e., glucose levels, step counts, meals etc.) with healthcare practitioners either remotely (synchronous or asynchronous) or at an appointment can greatly benefit DSME and increase motivation, improve feedback accuracy, and allow healthcare practitioners to reinforce behavioural changes (Michaud et al., 2021; Rollo et al., 2016).

Wearable Activity Monitors. Wearable activity monitors (e.g., FitBit® or Apple watch®, or Garmin®) have risen in popularity globally (Lamkin, 2016), which may suggest that many people are interested in taking control of their health if it is made accessible to them. Wearable activity monitors can be described as, "any device designed to be worn on the user's body, using accelerometers, with or without altimeters or other sensors to track the wearer's movements and/or biometric data, and with or without the possibility to upload activity data to an online application that shows trends over time" (Davergne et al., 2019, p. 759). Several studies have found increases in physical activity and/or step counts when using wearable activity monitors as a form of self-monitoring in

healthy populations (Brickwood et al., 2019; Goode et al., 2017; Lynch et al., 2020) people living with overweight/obesity (de Vries et al., 2016; Fawcett et al., 2020), and people with T2D or other metabolic diseases (Kirk et al., 2019; Kooiman et al., 2018). One meta-analysis (n=28) investigated the effects of a wearable device on physical activity levels in adult populations with cardiometabolic diseases (45% of studies with samples with T2D and 28.6% with overweight/obesity) (Kirk et al., 2019). Meta-analyses found statistically significant changes in the intervention group for steps per day (MD = 2592 steps/day; 95% confidence interval [CI]: 1689-3496) and moderate to vigorous physical activity (MD = 36.31 min per week; 95% CI: 18.33-54.29). Wearable activity monitors track daily step counts, minutes of physical activity and offer hourly reminders to move amongst other features. For example, FitBit®, can offer reminders or "nudges" to break sedentary behaviour (e.g., "Almost there! Keep moving to get your 250 steps for this hour"). Nudges have been used successfully in interventions involving people with T2D (Kullgren et al., 2017). The FitBit® and Apple Watch® models often feature an animation to celebrate when the daily step goal is achieved, offering positive reinforcement to further behaviour change (Bandura, 1998).

2.3.1 **Wearable Glucose Monitors.** Continuous glucose monitoring and flash glucose monitoring are still relatively new, though are increasing in popularity. As of 2019, the continuous glucose monitor (CGM) market was valued at 4.24 billion (Market Study Report, 2020). Currently, there is only one FGM on the market, which is the FreeStyle® Libre (Abbott Laboratories Ltd., Illinois, United States). Both CGMs and FGMs are small, wearable disk-like interstitial glucose sensors that can be worn on the skin (usually the upper arm) for 7 to 10 days or 14 days, respectively (Beck et al., 2017; Edelman et al., 2018; Diabetes Canada, 2020a; Heinemann & Freckmann, 2015). There are differences between CGM and FGM. CGMs require finger-prick calibration and can send continuous information to linked apps or readers, as well as provide alerts about out-of-range glucose levels (Berard et al., 2018). The FGM requires no finger-prick calibration and requires a person to actively scan ("flash") the sensor once at least every eight hours to transmit the past eight-hours' worth of data (in 15-minute increments) to a smartphone or reader (Berard et al., 2018; Diabetes Canada, 2020a). Further, these

technologies can reduce self-management barriers, such as the traditional painful finger-stick blood samples, which has lower adherence than CGM/FGM, and result in poor glycemic outcomes (Shan et al., 2019). These sensors offer timely, individualized feedback that has shown to significantly reduce A1c levels and glycemic variability and increase self-monitoring frequency, treatment satisfaction, and quality of life compared to traditional self-blood glucose monitoring (Aberer et al., 2021; Berard et al., 2018; Cosson et al., 2009; Evans et al., 2020; Hermanns et al., 2019; Shan et al., 2019). Hereafter, FGMs will primarily be referred to, as this was the sensor used in this intervention (though CGM evidence will also be referred to as needed).

2.3.2 **Wearables Supercharged?** The combined, complementary use of FGMs and wearable activity monitors can be used as an instant-biofeedback mechanism can counteract people's tendency to prefer immediate over delayed gratifications (e.g., using positive biofeedback that displays immediate effects of physical activity on glucose levels verses the promise of lower cardiovascular risks in 25 years from daily exercise) (Liao et al., 2020; Rabin & O'Donoghue, 1999). Likewise, instant biofeedback from CGM and FGMs has the potential to help participants draw stronger links between lifestyle health behaviour choices (i.e., food and exercise) and patterns in their glucose responses (Allen et al., 2008; Liao et al., 2020; Whelan et al., 2019). The combined educational experience of utilizing both FGM and wearable activity monitors may also help participants to develop a deeper understanding of their self-management behaviours (Hermanns et al., 2019). It may increase perceived feelings of control over and confidence in, managing their chronic disease (Hermanns et al., 2019). This may be explained in part by of the social-cognitive theory, which states that task performance outcomes are linked to beliefs of self-efficacy and perceived control (Bandura & Wood, 1989). As well, according to SDT, positive performance feedback enhances levels of competence (Ryan & Deci, 2000a). Increased confidence in abilities (self-efficacy) and perceived control (fostered by evidence of change from biofeedback) are suggested to

result in successful diabetes management and improved glycemic control (Gonzalez et al., 2015; Gonzalez et al., 2016).

2.3.3 **The Smartphone Hub.** Often, wearable monitors are linked with associated smartphone apps or Internet accounts. Diabetes-related smartphone health apps offer comprehensive features, including health education, skill building, glucose monitoring, weight management, dietary intake tracking, health coaching and/or automated responses, and peer support groups (Koot et al., 2019; Shan et al., 2019). These features can increase patients' diabetes knowledge, social connectivity, and management self-efficacy, resulting in glycemic outcome improvements (Kebede & Pischke, 2019). Previous interventions have successfully used smartphone apps, with or without the incorporation of wearable technologies, in in-person or virtual DSME interventions (Arens et al., 2018; Hilmarsdóttir et al., 2020; Khanh et al., 2020; Staite et al., 2020).

2.4 *Theory-Based Diabetes Self-Management Interventions*

When it comes to achieving optimal diabetes management outcomes, behaviour is the lynchpin (McSharry et al., 2020). Behaviour change theories, such as SDT, provides a framework that identifies key factors to target behaviour change that can be used to inform diabetes care delivery and intervention content development (McSharry et al., 2020). Additionally, SDT and other theories can explain/evaluate the efficacy of diabetes health-behaviour targeted interventions (Halvari et al., 2017; McSharry et al., 2020; Shigaki et al., 2010) and other health behaviour changes (e.g., physical activity, smoking cessation, healthy eating etc.) in other populations (Sheeran et al., 2020). One review of systematic reviews and meat-analyses (n=8) investigated the efficacy of theory-based interventions on adult health behaviour changes activity (Dalgetty et al., 2019). This review reported that two of the meta-analyses concluded that interventions that specifically used SDT were associated with greater efficacy for interventions targeting diet or physical activity (Dalgetty et al., 2019). The Diabetes Canada's *Clinical Practice Guidelines* (2018) specifically recommend informing exercise interventions with theory, and mention the SDT, in order to increase exercise engagement (Sigal et al., 2018).

Emerging evidence suggests that SDT-informed health behaviour change interventions can be supplemented with use of specific BCTs in populations with T2D, such as goal setting and self-monitoring (Fredrix et al., 2018; McSharry et al., 2020; McSharry et al., 2016; Ntoumanis et al., 2020)

It is well known that the main goal of health behaviour change is long-term maintenance. In general, autonomous motivation is a key factor for long term behaviour change, as well as for increased healthy behaviour engagement, persistence, and overall well-being (Ryan & Deci, 2000b; Ryan et al., 2008). Among patients with T2D, studies have found that levels of autonomous motivation and perceived competence can modulate diabetes self-management behaviours (Williams et al., 2004) and predict medication adherence (Williams et al., 2009). Higher levels of autonomous motivation for diabetes self-management activities are related to higher frequencies for diet and blood glucose testing (Shigaki et al., 2010) and decreased A1c levels (Williams et al., 2004).

Autonomous motivation for health behaviour changes can be supported using the SDT. SDT is a general theory of motivation (Figure 1). Under the health-related behaviour change lens, SDT focuses on the processes of personal and contextual motivational

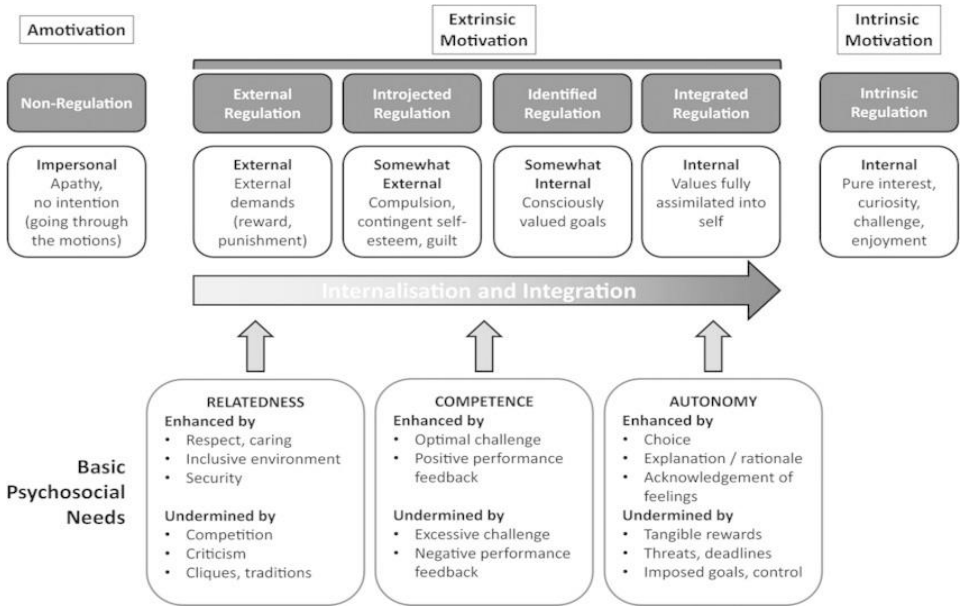

Figure 1. An adaptation of Ryan and Deci's Self-Determination Theory (p. 1010) (Cook & Artino, 2016)

factors behind health behaviour initiation all the way to sustained engagement (Ryan & Deci, 2017; Ryan et al., 2008). In the health domain, personal factors such as *types* of motivation and psychological needs have been specifically targeted in experimental interventions. One of the strengths of SDT is that it offers flexible processes (i.e., autonomy, relatedness, competence) that can be targeted in any health behaviour change intervention (Fortier et al., 2007).

Motivation is a multifaceted concept; it can be distinguished into different types of regulatory styles when considering the underlying factors that result in engaging in a behaviour (Ryan & Deci, 2000b). Motivation lies on a continuum of self-determination (or autonomy; Ryan & Deci, 2000b). On one end there is amotivation, where there is no motivation to engage in, and no regulation of, the behaviour. On the other, there is intrinsic motivation, where actions are done out of enjoyment and pleasure and intrinsically regulated; Ryan & Deci, 2000a, 2000b, 2017). In the middle of the spectrum lies extrinsic motivation. Extrinsic motivation can be an array of regulatory styles based on levels of self-determined autonomy (Ntoumanis et al., 2020; Ryan & Deci, 2017). First, external regulation is the least self-determined extrinsic motivation; a person will engage in the behaviour passively, typically to appease external demands or to satisfy a reward contingency (Ryan & Deci, 2000a). Introjected regulation is the second type of extrinsic motivation. This internalized regulation is still heavily controlling, as people act to satisfy contingent self-esteem (i.e., self or other's approval) and/or to avoid guilt or anxiety (Ryan & Deci, 2000a). Identified regulation is the third extrinsic motivation, where there is a conscious valuing and endorsement of behaviours and their outcomes form these motivations (Ryan & Deci, 2000a, 2000b). Lastly, integrated regulation (the most self-determined of external motivation) occurs when behaviours are acted on when there is alignment with core values and identity, and the person accepts self-regulation (Ryan & Deci, 2000a, 2017).

The process of internalization and integration of health-related behaviours explain the progression of increasing levels autonomous motivation (through various regulation styles) (Ryan & Deci, 2000a). Notably, there is no specific sequence of progression (Ryan & Deci, 2000a). SDT recognizes that different life experiences and factors may

place people in different stages of motivation levels initially and can move either "forward" or "backward" in self-regulation (Ryan & Deci, 2000a). Though, generally people progress towards higher levels of intrinsic motivation and internal regulation (Ryan & Deci, 2000a).

SDT also focuses on three key psychological factors: need for autonomy (a sense of control or choice of a behaviour), competence (a sense of mastery, feeling competent or confident), and relatedness (sense of belonging, accepted by, connect with others) (Ntoumanis et al., 2020; Ryan & Deci, 2017; Ryan et al., 2008). SDT posits that in any healthcare environment, it is critical that a person experiences feelings of both autonomy and competence in order to foster internalization and integration of health-related values and skills (Ryan et al., 2008). These processes can lead to increased self-regulation, enhanced adherence, and sustained healthy behaviour engagement (Ryan & Deci, 2000b; Ryan et al., 2008). A sense of relatedness is also a key aspect to internalization: a person is more likely to adopt values and behaviours promoted by figures that they trust and feel connected with (Ryan et al., 2008). Interventions that target increasing psychological needs satisfaction will modulate levels of perceived confidence and autonomous motivation, which in turn fosters self-determined motivation and increases healthy behaviour engagement (Halvari et al., 2017; Ng et al., 2012; Ntoumanis et al., 2020; Ntoumanis et al., 2017; Shigaki et al., 2010). Overall, since T2D is a chronic disease, motivation to engage with the lifelong journey (or process) may be more important in diabetes self-management treatment, rather than a specific treatment or outcome goal (Shigaki et al., 2010), and consequently, should be targeted.

2.5 *A Call to Action for Diabetes Management*

On March 11, 2020, the World Health Organization declared the COVID-19 virus outbreak as a global pandemic. The COVID-19 virus has now infected over 167.5 million people worldwide (as of May 24, 2021; worldometers.info/coronavirus). Populations with non-communicable diseases, such as those with T2D, are at increased risk of more severe cases of, and mortality from, a COVID-19 infection (Apicella et al., 2020). Fortunately, good glycemic control is linked to lower mortality rates and disease complications

(Stefan et al., 2021; Zhang et al., 2021). As part of the measures taken to limit the spread of the COVID-19 virus, many people are staying home and pausing usual activities. Evidence shows that glycemic control in people with T2D has significantly deteriorated as a result (Marçal et al., 2020). This metabolic deterioration is likely attributable to increased stress and anxiety levels, decreased physical activity levels, increased sedentary behaviour, and unhealthy eating patterns (Marçal et al., 2020). Longer or more extreme forms of isolation are expected to futher exacerbate the detrimental effects of physical inactivity and deconditioning (Marçal et al., 2020). Increasing amounts of literature are supporting the urgency and clinical importance of making physical activity as one of the cornerstone practices for COVID-19 infection severity and risk management for people with T2D (Faghy et al., 2021; Marçal et al., 2020), along with general diabetes progression (Sigal et al., 2018). Many community and clinical-based DSME programs have had previous success in assisting with an uptake of healthy behaviour changes (physical activity and nutrition) resulting in promising glycemic, cardiometabolic, and weight loss outcomes (Castillo et al., 2010; Wayne et al., 2015; Wing & Look Ahead Research Group, 2010). Although, traditional DSME has been typically offered in-person or mostly in person, current literature suggests that DSME and support delivered through a virtual platform may be a feasible alternative for both those with T2D and educators (Clement et al., 2018; Sherifali et al., 2018). The need for accessible, effective virtual delivery of DSME has never been more important than during this pandemic, and heavy demands for rapid innovations in technology, healthcare and interventions may offer an accelerated path towards the future of a promising virtual diabetes care setting.

2.6 *Virtual Care*

The “new normal” in the COVID-19 pandemic has sparked a revolution in the healthcare world, offering unparalleled opportunities for quick real-world application and testing of new technologies, type of care, and interventions (Agarwal et al., 2021). As a result, virtual patient/provider group videoconferencing platforms (i.e., Zoom, WebEx etc.,) and virtual care technologies are being adopted and used at unprecedented rates, thereby increasing the demand for rapid improvements, creations of, and supply for innovative digital health technologies (Agarwal et al., 2021). Systems offering automated decision-

making software, remote-monitoring technologies (such as wearable monitors), multiple medical devices (i.e., insulin pens, FGMs, etc.), and rapid data analytics can be used to optimize virtual and face-to-face diabetes care (Cafazzo, 2019; Phillip et al., 2021).

With the increased need for virtual consultations (delivered off-site using multiple types of technology) due to COVID-19, the literature has become even more saturated with multiple terminologies that can overlap each other (i.e., eHealth, telehealth, telemedicine, uHealth, mHealth, remote monitoring etc.). The umbrella term of "virtual care" has been chosen to refer aspects of previous and current published literature related to diabetes care. Virtual care is an all-encompassing term and is defined as, "any interaction between patients and/or members of their circle of care, occurring remotely, using any forms of communication or information technologies, with the aim of facilitating or maximizing the quality and effectiveness of patient care." (Jamieson et al., 2015, p. 5). According to Jamieson et al. (2015), virtual care does not refer to specific technology, actors (e.g. patients, physicians), or data. Virtual care can for example include, remote monitoring or patients, secure electronic messaging, teleconsultations, or videoconferencing visits.

2.6.1 Slow Traction, Inertia Laiden: Barriers to Virtual Delivery.

Previous studies have tested testing multiple mediums of delivering both general diabetes care and DSME virtually, typically though either teleconsultation (most often), smartphone health app, or Web-based app interventions (Bergenstal et al., 2021; Kooiman et al., 2015; Kato et al., 2020; Lystrup et al., 2020). Additionally, many researchers have attempted to incorporate technologies such as wearable activity monitors, Bluetooth weighscales, and/or apps to manually input steps, glucose readings, and/or food (Shan et al., 2019). Though often, at the time of trial completion, and even more so, publication, many of these technologies were already replaced with bigger and better versions, and thus quickly irrelevant (Cafazzo, 2019). Multiple articles have - reported inertia in the movement to a fully integrated, virtual diabetes care model, despite large amounts of evidence for potential for improvements in standards of care and multiple patient outcomes (Aberer et al., 2021; Cafazzo, 2019; Phillip et al., 2021). This has been attibuted to several factors. One, there have been issues with extreme lack of interoperability between third-party wearables, electronic health records, diabetes

technology platforms (creating data “silos”; Zhang et al., 2021), and type of data being transferred (e.g., cut and paste method; Phillip et al., 2021). Two, there have been insufficient patient and healthcare practitioner infrastructure, insufficient healthcare practitioner reimbursements systems, patient insurance coverage (Phillip et al., 2021), and/or regulatory limitations with data sharing (Aberer et al., 2021). Three, patient or healthcare practitioners may lack self-efficacy or technological skills, well as the time, effort, or literacy required to learn them (Cafazzo, 2019; Zhang et al., 2021). Finally, there is the potential for extra burden on patients (Rollo et al., 2016), challenge with clinical trial to real-world implementation, and the potential for workforce burn out due to its time-consuming nature (such as continuous monitoring, multiple data input, data saturation, or patients’ reliance on healthcare practitioners for support and interpretation etc.; Agarwal et al., 2021; Sim & Lee, 2021). The increased demand for comprehensive virtual care technology in response to the COVID-19 pandemic has opened up an opportunity to accelerate this inertia-laiden, pre-existing transition towards use of virtual diabetes care delivery (Agarwal et al., 2021; Zhang et al., 2021). Already, the COVID-19 pandemic virtual care transition has influenced workflows and technology infrastructure, as well as national/provincial healthcare reimbursement policies in a positive direction (Zhang et al., 2021).

Virtual Diabetes Self-Management: Always Evolving. Previous virtually delivered diabetes management interventions, with or without wearable technology, suggest promise of positive results in healthy behaviour changes (i.e., increased physical activity) and glycemic outcomes, and in some cases, larger improvements compared to traditional face-to-face (Komkova et al., 2019; Li et al., 2020; Ward et al., 2018; Wolever et al., 2010). Recently, a meta-analysis investigating the effects of wearable devices used in virtually delivered health interventions in chronic disease populations (cardiac diseases, T2D, and chronic obstructive pulmonary disease) was conducted (Kamei et al., 2020). A T2D sub-analysis reported a significantly higher number of participants with a weight loss of >2% from baseline weight (a risk ratio of 2.2; 95% CI 1.38 to 3.5; $p=0.0009$; $I^2=0\%$) to three months when using a wearable activity monitor with a virtually delivered DSME program (specifically interventions using goal setting),

compared to a wearable activity monitor alone. The authors of another meta-analysis reported that the addition of remote feedback from wearables into standardized treatments led to small to moderate increases in physical activity levels (which may be particularly useful when direct supervision is not possible; Kongstad et al., 2019). A large meta-analysis on 55 RCT's described improvements in A1c levels (Hedge's g= -0.48, p <0.001) with virtual delivery which included either device-based remote monitoring and/or any method of virtual consultation, compared to traditional face to face diabetes care delivery (Su et al., 2016). Of the included RCTs, 22 significantly favoured the virtual delivery groups, one the traditional delivery, and 32 reported no significant group differences in reducing A1c ($p<0.05$). A recent meta-analysis pooling data from 15 RCTs (from 2000 to 2017), reported modest decreases in A1c (a mean difference (95% CI) of -.30% (-0.31 to -0.29%)) from virtual delivery compared to usual care (Michaud et al., 2021). Subgroup analyses revealed that studies that included both remote monitoring with automatic submission and real-time feedback as a part of the virtually delivered programs, can result in greater decreases in A1c (a mean difference (95% CI) of -0.61 (-0.65 to -0.56) and 0.77 (-0.82 to -0.72]), respectively. Their results demonstrate the combination of remote monitoring technologies into lifestyle supportive, virtual DSME programs can be beneficial and can potentially lead to decreased A1c levels. It is worth commenting that the teleconsultations were likely one-on-one treatment, as none of the descriptors in the narrative tables described any group-based interventions (Michaud et al., 2021).

2.6.2 **Identifying Gaps in the Literature.** More intensive interventions combining remote monitoring, behavioural counselling, and lifestyle medicine have also shown promise in their feasibility and glycemic control outcomes (Gal et al., 2020; Hermanns et al., 2019; Hickman et al., 2021; Hilmarsdóttir et al., 2020; Jiwani et al., 2021; Kato et al., 2020; Kooiman et al., 2018; Majithia et al., 2020; Rawstorn, Gant, Meads, et al., 2016; Taylor et al., 2019; Wada et al., 2020; Whelan et al., 2019; Whitehouse et al., 2020). However, as technology continues to rapidly advance, there remains many identified barriers of clinical implementation and gaps in the literature. Barriers of clinical implementation can be related to high levels of patient reliance on healthcare practitioner continuous monitoring (Majithia et al., 2020) or the time consuming nature of one-on-one

counselling with healthcare practitioners (Kato et al., 2020; Wolever et al., 2010). Particularly in the virtual DSME literature, there remains a lack of structured exercise prescriptions and/or exercise experts (Jiwani et al., 2021; Kato et al., 2020; Majithia et al., 2020). For example, a study conducted by Kato et al. (2020) between August 2016 to January 2017, offered a relatively comprehensive, six-month remote exercise therapy program to 53 men (mean age 54.4 ± 6.0 years) that combined Bluetooth wearable activity monitors, sphygmomanometers, and body weight scale data onto an automatically transmitted platform. Although the combined data platform was novel, the study had some limitations. This study lacked a seminal part of diabetes self-management: glucose monitoring. As well, there were bi-weekly 20-minute individual food and nutrition coaching sessions led by a public health nurse. Over the course of 6 months, this type of protocol could potentially create undue workload when dealing with many patients. The public health nurse provided one nutrition and exercise goal to be achieved until the next appointment based on individuals' transmitted data. However, assigned goals have shown to decrease intrinsic motivation (Ryan & Deci, 2000b). Lastly, a nurse, although knowledgeable in general exercise guidelines, could potentially not be able to provide specific counselling or prescriptions to best optimize treatment outcomes, unlike an exercise specialist (e.g., Registered Kinesiologist or Certified Exercise Physiologist; Sigal et al., 2018).

Another pre-post single arm study with 594 participants (mean age 53.0 ± 8.4 years, 62.3% female) investigated participants' attitudes towards use of CGMs and linking the use of CGM to changes in A1c (Bergenstal et al., 2021). The intervention was a novel, comprehensive virtual diabetes clinic that combined a smartphone app, remote personalized lifestyle coaching (including health coaches, certified diabetes care and education specialist) and CGMs. Glucose data from the CGMs were all reviewed by a care team and used as a coaching tool to help patients associate glucose levels with lifestyle choices (i.e., nutrition, exercise) to help optimize glycemic levels. At the 10 ± 4.0 month follow up period, there were significant reductions in A1c: -0.6% ± 1.5% ($p<0.001$). Specifically, in insulin and non-insulin users with a baseline of A1c ≥8%, a reduction of -1.5 ± 2.1% and -2.0 ± 1.7% (both $p<0.001$) was found, respectively. Overall, it was also feasible to train participants to apply the CGMs over a completely

virtual setting and was accepted by patients (4.5/5 mean satisfaction score). A few limitations are noted. There appears to be a heavy reliance on interpretation and guidance from practitioners by patients and only used one-on-one sessions. This could add considerable amount of workload to practitioners, such as needing to both review data in advance and constantly with patient and may create a dependence and/or low patient ownership of T2D management. The intervention lacked wearable activity monitors, which have considerable impact with self-monitoring and motivation to increase physical activity (as previously mentioned; Brickwood et al., 2019; de Vries et al., 2016; Goode et al., 2017; Lynch et al., 2020; Kirk et al., 2019; Kooiman et al., 2018). Although there were health coaches as a part of this program, no specific exercise prescriptions or exercise specialists were explicitly mentioned in this study.

Overall, workforce burnout and lack of staff or funding is a large concern for sustainability of virtual care practices (Marzolini et al., 2021). Group education can address some of these issues by offering the ability to target multiple patients at once, and can be beneficial in increasing feelings of relatedness, social connectedness, and peer learning (Deci & Ryan, 2015; Ryan & Deci, 2000b). Additionally, exercise specialists should be included when working with chronic disease populations (who may also have co-morbidities) and can help guide exercise prescriptions more effectively when working with patients, compared to nurses or physicians (Colberg et al., 2016). Evidence suggests that virtually delivered exercise cardiac rehabilitation programs can be at least as effective as in person programs (Rawstorn, Gant, Direito, et al., 2016). One 12-week RCT offered completely virtual, real-time one-on-one cardiac rehabilitation exercise intensive sessions (using electrocardiogram and accelerometry monitoring devices) as a part of a theory-based, behavioural change cardiac rehabilitation program (Maddison et al., 2019). Results deemed their comprehensive remote delivery as an effective, cost-efficient alternative delivery model. Therefore, a more intensive exercise delivery for a population with T2D has the potential to also be feasible.

To the author’s knowledge, there is only one study to incorporate a completely virtual delivery of an intensive lifestyle medicine intervention that use FGMs and wearable activity monitors for a T2D population (Jiwani et al., 2021). A focus group study

conducted by Jiwani and colleagues (2021) included 18 older adults living with overweight/obese and T2D (mean age 72 ± 5.4 years, 56% female), reported on the participants' experiences of a six-month pilot intervention. The pilot was a completely virtual, group-based lifestyle medicine intervention that incorporated use of FGMs (FreeStyle® Libre) and wearable activity monitors (FitBit® monitor). The authors reported high levels program acceptability, retention (90%), participant-reported increases in diabetes self-management knowledge and behaviour, and quality of life. The study occurred during the midst of the initial phases of the COVID-19 pandemic and provided information on how the intervention helped participants cope with social distancing measures and disruptions to routines when it came to exercise and nutrition behaviours. As well, they report themes of increased self-awareness of exercise and nutrition behaviours and their link to health outcomes (which for some, lead to increased feelings of competence). Unfortunately, as this was a comprehensive qualitative synthesis, there were no basic quantitative outcomes reported (e.g., change in steps, glycemic outcome) which are needed to move forward with a larger study. This program also lacked the crucial feature of exercise specialist expertise and individualized exercise prescriptions. Overall, evidence continues to build to support the development of comprehensive technologies integrated into virtually lifestyle medicine programs. However, there remains little evidence available on multi-component interventions that deliver virtual, group-based lifestyle medicine programs that offer exercise prescriptions, especially in populations with T2D.

Chapter 3

3 Methodology

3.1 *Study Design*

To assess the feasibility of delivering a virtual multi-component group-based lifestyle medicine program, a six-week single cohort feasibility study was conducted between November 2020 and March 2021. Following *Phase Ib* (Treatment Refinement) of the ORBIT model (Figure 1), the aim of this study was to define critical treatment components (e.g., self-monitoring) and assess study acceptability (e.g., recruitment rates, participant satisfaction), adapting the protocol as necessary (Czajkowski et al., 2015). Methods to optimize treatment (i.e., testing different modes of program delivery) and todetermine clinical relevancy on behaviour/physiological outcomes were also investigated (Czajkowski et al., 2015). The study was registered at clinicaltrials.gov (Identifier number: NCT04498819) and approved by Western University's Health Science Research Ethics Board (REB # 116071; Appendix A).

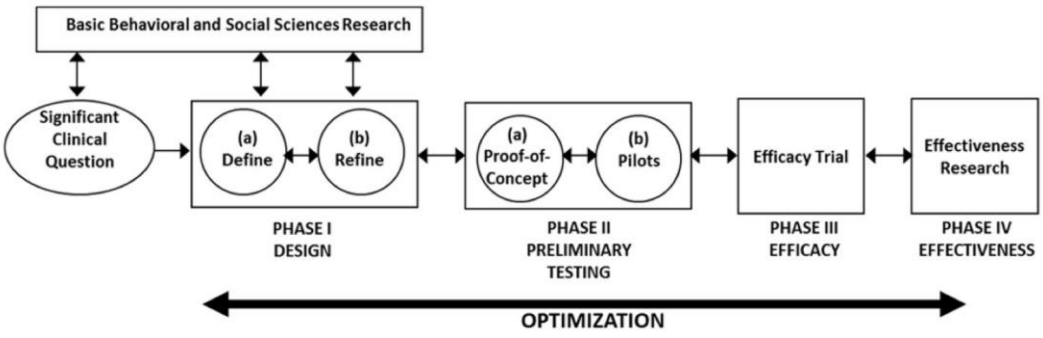

Figure 2. The ORBIT Model for Behavioural Treatment Development (p. 19) (Czajkowski et al. 2015).

3.2 *Setting and Study Sample*

The study was conducted at a London, Ontario diabetes outpatient clinic (the Primary Care for Diabetes Support Program, hereafter referred to as the 'diabetes clinic'). This multidisciplinary diabetes clinic serves approximately 3000 patients at any given time, with six to eight new patient referrals per week from London and surrounding areas (Reichert et al., 2014). Adults (≥18 years old) who were new patient intakes, medically diagnosed with T2D, able to communicate in English, and physician-cleared to exercise were recruited. This study sought to recruit a convenience sample of 15 to 20 participants, a sample size used in similar studies (Dack et al., 2019; Jiwani et al., 2021; Taylor et al., 2019; Whitehouse et al., 2020). Patients had to have access to the Internet and a smartphone (i.e., iPhone 7 iOS of 12.2 or higher or Android (operating system 5 or higher) to allow for FitBit® and LibreView smartphone app compatibility) to be eligible to participate. Participants were excluded if they had an active or recent case of a foot ulcer(s), unstable health conditions limiting exercise, were pregnant, or had an unstable psychiatric disease that would limit participation in group education classes.

3.3 *Recruitment*

The full recruitment procedure is described in Appendix B. Briefly, all new patients at the diabetes clinic were encouraged by physicians and nurse practitioners at their initial intake appointment to attend a physician-led one-hour general lifestyle medicine class, per usual care (in person and virtually, depending on Ontario COVID-19 pandemic restrictions at the time). Upon completion of this one-hour class, prospective study participants were recruited by a diabetes clinic physician to participate in this feasibility study. Recruitment occurred between November 1, 2020, and January 31, 2021. Patients expressing interest in the study were given a Letter of Information to review (Appendix C). Concurrently, prospective participants were medically screened for safe exercise participation using a modified version of the Physical Activity Readiness Questionnaire (PAR-Q; Appendix D) previously used by the diabetes clinic (Freehan et al., 2018). Those deemed eligible to participate in the study were then sent an email containing a copy of the four baseline questionnaires (for advance review) and a video tutorial on how

to use the WebEx® video communication platform (Cisco© Systems, Inc., San Jose, California). The WebEx® platform is Health Information Protection and Privacy Act (HIPPA) compliant. The informed consent process occurred via WebEx® or telephone (according to participant preference), at which time technology eligibility requirements were confirmed. Participants provided informed consent with their digital signature via a secure, individualized REDCap (Harris et al., 2008) link. REDCap is a secure, web-based database and online questionnaire program that was used to store study data. Patients who did not wish to participate in the study continued to receive usual care (i.e., follow-up appointments with primary care provider).

3.4 *Lifestyle Medicine Program*

3.4.1 **In-Person Programming.** Before the implementation of COVID-19 physical distancing measures, the diabetes clinic offered an optional in-person lifestyle medicine program for their patients living with T2D. This 12-week program was delivered bi-weekly in a semi-structured group format by a multidisciplinary clinical team, including: Certified Diabetes Nurse Educators (CDNEs) (who are registered nurses), nurse practitioners, registered dieticians, and/or physicians. Their group education class structure typically followed: (a) individuals viewing their bi-weekly FreeStyle® Libre glucose patterns (discussing the impact of sleep patterns, food intake, medication adherence) and (b) general food (e.g., glycemic index or meal preparation) or behaviour change (i.e., self-monitoring activity) topic discussions. This evidence-based program used motivational coaching techniques (e.g., client discrepancy discerning, expressing empathy, rolling with resistance etc.) (Markland et al., 2005) to promote healthy living behaviours with a particular focus on lower carbohydrate diets (Sievenpieper et al., 2018). The program also offered general advice to increase physical activity and reduce sedentary behaviour (e.g., “Your goal is to get 150 minutes of exercise each week.” or “Reduce your daily sitting time.”).

3.4.2 **Virtual Programming.** The intervention is a modification of the existing aforementioned in-person lifestyle medicine program. The virtual version of this multi-component group-based lifestyle medicine program shared many of the in-person program treatment components (i.e., glucose monitors, bi-weekly classes) (Figure 3) and is summarized using the BCT Taxonomy (see Table 1). This taxonomy is used to identify

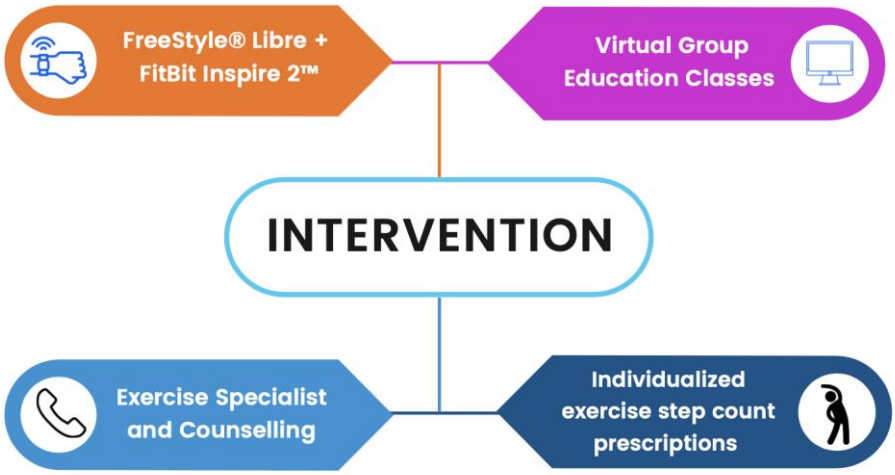

Figure 3. A summary of key intervention components.

"active ingredient" intervention components by standardized labels and definitions (Michie et al., 2013). There were some key differences between the in-person and virtual programs, and they are noted next. First, the program was offered almost entirely virtually (i.e., bi-weekly group education classes via WebEx® videoconferencing platform). Next, wrist-worn wearable activity monitors, the Fitbit Inspire 2™, were loaned to participants. There were group technology orientation classes to assist with set up of the FreeStyle® Libre and FitBit Inspire 2™ and ongoing technology assistance was provided throughout the study. Third, physical activity education was given roughly equal emphasis (vs. nutrition education only) during the bi-weekly group education classes, with more problem-solving skill development included (e.g., developing exercise mindfulness; see below for general topics covered and Appendix E for BCT-related topics covered). As well, the intervention used the self-determination theory as the framework for certain intervention components. Last, instead of only offering general advice to increase physical activity, an exercise specialist (a kinesiology graduate and certified personal trainer; Canadian Society of Exercise Physiology, under physician

supervision)) provided participants with individualized exercise prescriptions. The exercise specialist provided bi-weekly 10 to 15-minute one-on-one check-in phone calls to provide exercise counselling (e.g., review daily step count goals, facilitate action planning; Gillison et al., 2019; Schroe et al., 2020) The one-one-one phone call check-ins with the exercise specialist was intended to increase individualization of advising, agreeing on plans, and assisting with advice/resources, as some participants may be less likely to want to share their plans with the class (Vallis et al., 2013).

Table 1. Identifying notable components of the virtual lifestyle medicine program, using the behaviour change techniques (BCTs) taxonomy.

Intervention Components		
BCT		*Intervention Component*
Number	*Label*	
1. Goals and Planning		
1.1*	Goal Setting (behaviour)	Prompted participants to set goals at end of classes and during exercise counselling calls. E.g., "what kind of food or activity goal would you like to set for this week?"
1.2	Problem solving	Encouraged identifying barriers.
1.4*	Action planning	Encouraged detailing the specifics of how they were to achieve their set goal or step count goal.
1.5	Review behaviour goals	Encouraged asking self, "What went well, what didn't? Do I need to scale back or make it more challenging?"
2. Feedback and Monitoring		
2.2*	Feedback on behaviour	Email summaries and phone discussions informed participants about previous weeks' activity. E.g., "You hit 9/14 days of your step count goal! I noticed you hit over 10,000 steps on 4 days last week."
2.3*	Self-monitoring of behaviour	Provided the FitBit Inspire 2™ to track daily step counts, hourly movement goals (and exercise minutes, if desired).
2.4	Self-monitoring of outcome(s) of behaviour	Provided the FreeStyle® Libre to participants so that they may see the immediate effects of exercise and food choices on glucose.
2.6	Biofeedback	Using FreeStyle® Libre glucose readings as a learning tool to understand personal glucose responses to exercise and food, with the goal of increasing healthy behaviour adaptations.
7. Associations		
7.1*	Prompts/cues	Using FitBit Inspire 2™ reminders to get 250 steps/hour.
8. Repetition and Substitution		
8.7*	Graded tasks	Individualized step count prescriptions. Creating "easy to perform" tasks, making step count goals increasingly difficult, but achievable.
10. Reward and Threat		
10.4	Social reward	Congratulating participants on an achievement, regardless of size of achievement. This was done via email or during one-on-one phone call check-in correspondence. E.g., "I saw that you hit 7000 steps on Tuesday, which has been your highest daily step count yet! Amazing!"
*BCT that was not used as a part of the in-person version of the lifestyle medicine program (i.e., 'new' BCT)		

3.4.2.1 ***Virtual Class Format.*** Class learning material was founded on Diabetes Canada Self-Management Education guidelines (Sherifali et al., 2018). Class topics and materials were inspired and supplemented from other programs and studies (Jiwani et al., 2020; Look AHEAD trial, 2008; Diabetes College™; Diabetes Canada; Duhigg, 2012). Group classes were planned to flow based on patient questions, comments, or concerns. The original aim was to not be didactic, but rather have a "conversation" led by patients' questions and answers, with guiding input from the CDNE or exercise specialist depending on the topic and question at hand.

A) Opener

After a quick icebreaker related to the previous week's theme, the CDNE congratulated participants on improvements in glucose readings from FreeStyle® Libre reports. This was followed by nutrition and glucose topics (taught by the CDNE), then exercise and coping strategies (taught by the exercise specialist). Each class participants were provided with a worksheet to fill in their new exercise prescription step goals, take notes, and create new goals and action plans.

B) Nutrition and Glucose Levels

This part of class was delivered previously at the diabetes clinic. Due to rolling intake, each class reviewed briefly what carbohydrates, fats, and proteins are, as well as ideas of meals that fall under a low carbohydrate diet. There were group discussion opportunities to problem solve examples of glucose responses after types of meals and review on how to understand glucose data (i.e., what numbers to look for, what arrow trends meant, and how to read/understand glucose summaries/trends available in the LibreLink app). The CDNE covered how to identify specific trends and fluctuations in daily patterns. As well, the CDNE emphasized how "good" glucose trends, caused by specific eating, exercise, stress, sleep, or medication at certain times of day, can be used to figure out how to improve other areas from other times of the day. Broad topics such as snacking, low carbohydrate habits, the glycemic index, healthy fats, fast

food, and holiday eating were covered. Topics were closed by discussing their old habits (related to the week's topic), a new habit to consider adopting, how to reward the habit, and types of strategies participants would consider using to implement these new habits. These practices are in line with recommendations from the Self-Management Education and Support 2018 Clinical Practice Guidelines: teaching how to properly self-manage their diabetes, incorporating problem solving and self-monitoring of health parameters, as well as numeracy sensitive materials into a comprehensive self-management education program to improve self-efficacy, numeracy and A1c (Sherifali et al., 2018).

C) Exercise

The exercise specialist led exercise discussions. Each week started out with brief safety reminders, followed by a review of aerobic exercise and incidental/light activity (the differences, recommended guidelines, and strategies on how to accumulate them (and progress independently)). Participants were strongly advised to exercise for a minimum of 5 to 10 minutes per bout, encouraging them to ideally progress up to a minimum of 150 minutes per week or 30 minutes per day, 5 days a week at a brisk walking pace at an RPE (or "Rating of Perceived Exertion") of 3-6 which elicits a moderate intensity (Sigal et al., 2018). Participants were strongly advised to not go more than two days without any aerobic activity to avoid any excessive decline in insulin action (Sigal et al., 2018). It was emphasized that the goal of the exercise education was to give knowledge and facilitate self-management skills needed to create and achieve individualized exercise goals, based on the individuals' needs and preferences (Sherifali et al., 2018). Strategies and recommendations were discussed on how to accumulate their step counts: through exercise minutes (walking) and light physical activity (messaged as: "movement throughout the day"). In class (and in one-on-one phone call check-ins), participants were encouraged to make a goal on how they could accumulate their steps (e.g., how long the bouts will be etc.), and they were advised to record them in their workbooks. These basic, recommended strategies and information on exercise accumulation and progression were based off the Diabetes Canada (Sigal et al., 2018) and *Exercise and Diabetes: A Clinician's Guide to*

Prescribing Physical Activity (Colberg, 2013), published by the American Diabetes Association. Sedentary behaviour guidelines were sourced from Diabetes Canada (Sigal et al., 2018) and the Canadian Society of Exercise Physiology's 24-hour Movement Guidelines. Other exercise topics covered were sedentary behaviour, strength training, exercising and glucose responses (i.e., walking after a meal to decrease blood glucose), behaviour substitution (e.g., replacing sedentary behaviour for light physical activity), and exercise mindfulness/monitoring of emotional consequences.

E) Coping and Problem Solving

The exercise specialist covered coping and problem-solving topics in relation to exercise adherence, such as: working against negative thoughts, holiday guilt, mindfulness, goal setting, action planning, barrier identification and problem solving, tracking progress/self-monitoring of behaviours, building on success and failures, relapse prevention, using social support, and prompts/cue to initiate behaviours (Duhigg, 2012; Look AHEAD material, 2008; Jiwani et al., 2020).

F) Goal Setting and Action Planning and Closure

Participants would be sent off with encouragement for the next two weeks. Facilitators emphasized at the end of each class that participants had a fresh start or "clean slate" to the next two weeks (Dai et al., 2014). Additionally, a small task would be encouraged related to the type of coping or problem-solving skills discussed that day. Participants would be prompted to reflect on the class discussion and their past two-weeks' experiences. They were encouraged to set a new food or activity goal (could be the same as the previous week) and evaluate their confidence in achieving that goal, identify and solve how to overcome barriers using a provided worksheet. This activity involved the patient in their own care (Clement et al., 2018) thereby increasing autonomy, self-efficacy, self-control and engages the participant in implementation intentions (Bandura, 1998; Deci & Ryan, 1985).

3.4.2.2 ***Self Determination Theory.*** Autonomy was enhanced by offering the choice of how to accumulate their individualized step count goal and discussing how exercise and nutrition choices immediately effect glucose levels (rationale/explanation). Autonomy can also be undermined by imposed goals. The aim of the step count goals was to provide a measurable motivator and to help participants gauge their activity. Competence was enhanced by using an adaptive goal setting approach (optimal challenge), as it has shown to be appropriate for increasing and/or creating manageable goals for participants (Adams et al., 2013). This was to avoid continuous increases in step count goals unlike other 'static' interventions that do not consider variability in daily life contexts/events and within person variability (Adams et al., 2013). The use of lower number offered more opportunity to work on consistency and ability to achieve their goal, thereby increasing competence and thus increasing levels of intrinsic motivation (Deci and Ryan, 2000). Positive feedback regarding the previous two-weeks' activities was always given by the exercise specialist when sending the new prescription via email to the participant, regardless of improvement (e.g., "You got 9/14 days of your step goal, which is amazing! This week, with your new step count goal, think of an activity goal that can help you try to consistently achieve this step count each day"). Relatedness can be fostered with environments that are inclusive, respectful and caring. The intervention included a large group component, in order to increase sharing of experiences/struggles and strategies in a welcoming atmosphere. As well, all healthcare leaders (CDNE, exercise specialist, physician) sought to create a positive atmosphere (e.g., finding positive outcomes, regardless of participants' behaviours).

3.4.2.3 ***Exercise Prescriptions.*** The daily step count goal was generated by using whichever number was lower, either: a) the previous two-week's daily step count mean or b) two-week step count median. When participants' step counts were below 10,000 steps there would be an additional 500 steps added onto the mean or median. If above 10,000 (Tudor-Locke et al., 2011), no increases were prescribed on top of the mean or median, but rather, participants were encouraged to focus on creating goals to be consistent around their prescribed goal. Participants were encouraged to accumulate their step count goal through activity throughout the day and through moderate-vigorous exercise. Participants were asked to change step count goals on their FitBit® app.

Participants were encouraged to interrupt their prolonged sitting with frequently (every 20 to 45 minutes, under an hour) with 2-3 minutes light-intensity physical activity (Dunstan et al., 2012; Dempsey et al., 2016; Healy et al., 2011; Paing et al., 2019). Strategies were discussed and provided to assist with implementation. As well, they were encouraged to decrease overall daily sedentary time (Sigal et al., 2018). To give participants daily feedback and reminders to get up and move every hour, participants were advised to achieve their hourly movement goals (defined as an hour with 250 steps or more, defined and measured by the FitBit Inspire 2™) or 2 to 3 minutes of light physical activity.

3.5 *Study Protocol*

Two study protocols (i.e., 'open' and 'closed' protocols) were implemented in response to evolving provincial COVID-19 physical distancing policies. In the 'open' protocol, the technology orientation class was held in-person at the diabetes clinic (with the goal of increasing technology uptake and ease of participation). This protocol was in place from November 23, 2020, to December 25, 2020. On December 26th, the province of Ontario implemented stricter physical distancing policies ("lockdown") and so the 'closed' protocol was adopted, with the technology orientation class offered virtually on WebEx® instead. After the technology orientation class, the protocols were identical. See the study flowchart in Figure 4 below. For a more detailed protocol description, see Appendix G. See the participant study handbook given to participants at the technology orientation session in Appendix H.

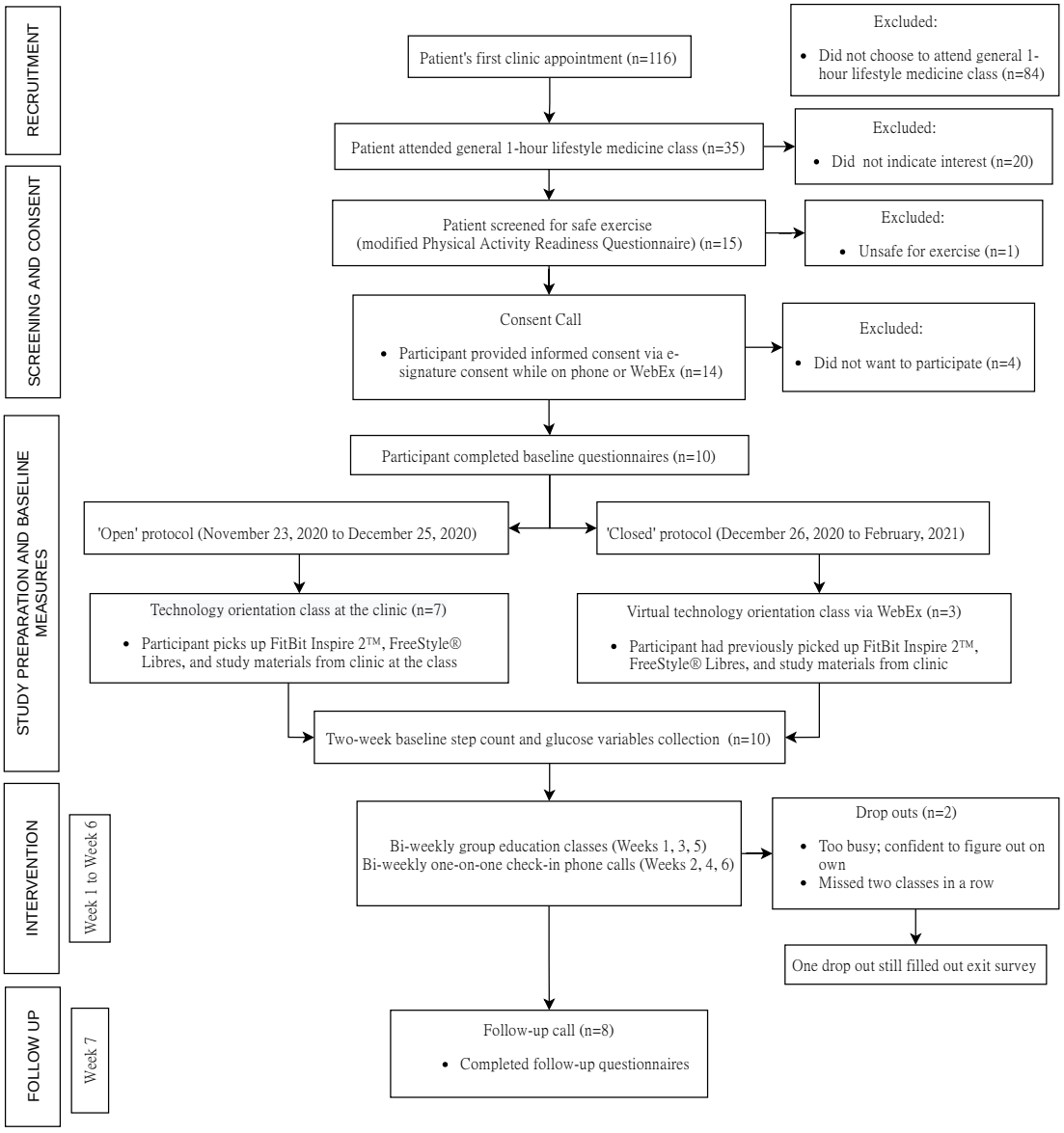

Figure 4. Flowchart of Protocol Timeline

3.6 *Data Collection*

After providing consent, participants completed four baseline surveys: (1) a socio-demographic survey (Appendix I), (2) a technology use survey (Appendix J), (3) the Stanford Self-Efficacy Scale (Lorig et al., 2001; Ritter & Lorig, 2014) (Appendix K), and (4) the five-item Problem Areas in Diabetes Scale (PAID-5; McGuire et al., 2010; see Appendix L). Survey, other measurement tool, and technology equipment descriptions can be found in Appendix M. These were completed with the help of the study researcher

via the WebEx® platform or telephone. Baseline physiological data were extracted from the diabetes clinic's electronic medical records by the investigating physician (Appendix N) and stored in REDCap. These data included sex, full date of birth, height, weight, insulin-usage and other medications, other comorbidities, year of T2D diagnosis, and blood pressure. One day prior to the group education classes, participants were reminded via email to export their FitBit Inspire 2™ data from the online desktop website (https://www.fitbit.com) and asked to share the data via a secure file transfer website, https://filesafe.lhsc.on.ca. FitBit Inspire 2™ data was sent in order to both collect data and update bi-weekly step count prescriptions. On the day of the class, new individualized step count prescriptions were provided via email and participants were instructed to replace their FreeStyle® Libres (which need replacing every two weeks). At follow-up (week 7), participants completed the Stanford Self-Efficacy scale and PAID-5 scale over the phone with a researcher. Additionally, the participants completed an exit survey (Appendix O) via an individualized link from REDCap.

3.7 *Outcomes*

To inform the development of a future pilot RCT, several feasibility outcome variables were collected (a summary is provided in Table 2 below). First, recruitment rate was calculated (i.e., proportion of participants providing informed consent compared to those who attended the initial one-hour general lifestyle medicine class). The total number of new patient intakes and number of those attending the initial one-on-one intake prior to the one-hour general lifestyle medicine class are also reported. Retention rates were defined as a) proportion of consenting participants completing baseline assessments, b) proportion 'dropping out', and c) proportion completing follow-up assessments.

Participants missing two or more bi-weekly group education classes in a row were considered 'dropped out'. Intervention acceptability was assessed using exit survey responses. Acceptability was also assessed by the mean number of patient-reported technology issues per person. Technology issues were recorded when participants reported a technology issue in class, on the phone, or via email. Intervention adherence was measured in several ways, including: proportion of consenting participants attending

bi-weekly educational classes (out of 3) and one-on-one phone call check-ins (out of 4), number of timely FitBit Inspire 2™ data submissions (out of 3), percent of valid days with FitBit Inspire 2™ data ([number of valid days/total days in program]/number of participants), and the bi-weekly mean percent of 'active time' of the FreeStyle® Libre.

Table 2. Primary and secondary study outcomes.

Primary outcomes	**Secondary outcomes**

• Recruitment rate
• Retention rate
• Intervention acceptability
  o Mean number of technology issues/person
  o Exit survey responses
• Intervention adherence
  o Percent of valid days with FitBit Inspire 2™ data
  o Mean 'active time' of FreeStyle® Libre
  o On-time FitBit Inspire 2™ submissions
  o Group education class and one-on-one phone call check in attendance
	• Bi-weekly daily step counts means
	• Bi-weekly daily sedentary time means
	• Exercise prescription adherence
	• Bi-weekly glycemic variables means
	  o Estimated glycated hemoglobin (A1c)
	  o Time in target
	  o Coefficient of variation
	• Self-management task self-efficacy (Stanford Self-Efficacy Scale)
	• Diabetes related-distress (PAID-5 scale)

Data was considered submitted if sent on time (within one day before or after group education class). A valid day was defined as a day with ≥500 daily steps recorded on the FitBit Inspire 2™ (Kooiman et al., 2018). 'Active time' is the mean percent of total glucose data captured in 24-hour period every two weeks by the FreeStyle® Libre. The FreeStyle® Libre requires at least one scan every eight hours to collect the past eight hours of data).

Additionally, several secondary outcomes were assessed to determine whether virtual lifestyle medicine programming holds promise and warrants further study. First, daily step counts and total daily sedentary time were measured using the wrist worn FitBit Inspire 2™. The FitBit Inspire 2™ was only released on September 25, 2020, and thus has not yet been validated. An older, similar model, the FitBit Charge ™ has been validated, however, shown to have slight overestimation in steps per day (1432 steps/day) and underestimation in sedentary minutes (-25 minutes) in comparison to an ActiGraph GT3X accelerometer (Mikkelsen et al., 2020). Bi-weekly daily step count means (i.e., steps per day) and total daily sedentary time (i.e., minutes) were collected at the end of the baseline period, as well as weeks 2, 4, and 6**.** Second, exercise prescription adherence

was measured using the equation: [(# of step count goals achieved ± SD)/(# of valid days collected by the FitBit Inspire 2™ ± SD)]. Number of daily step goals achieved every two weeks are also reported. Third, to assess glycemic control, bi-weekly daily 'time in glycemic target' and 'coefficient of variation' means were examined at baseline, week 2, 4 and 6. A1c levels are traditionally collected every three months. As this was a six-week study, A1c was measured using the bi-weekly average estimated A1c reading from the end of baseline, week 2, 4, and 6. Finally, two diabetes-related attitudes, (a) chronic disease self-efficacy and (b) diabetes-related emotional distress were measured using the validated Stanford Self-Efficacy Scale and the PAID-5, respectively. These two measures were completed at baseline and follow-up.

3.8 *Data Analysis*

Data analysis was performed using GraphPad Prism 9 (version 9.1.0; GraphPad Software, San Diego, California, USA). Group data is presented descriptively, rather than completing inferential statistics, given the feasibility nature of this study. Recruitment, retention, acceptability, intervention adherence, and exercise prescription adherence are presented in proportions and percentages ± standard deviation (SD). Technology issues are presented as a mean ± SD and using categorical counts. Bi-weekly step count, sedentary time, glycemic variables, and diabetes attitude results are presented as mean ± SD (95% Confidence Interval [CI]). As well, descriptive participant-level data for step counts, sedentary time and glycemic variables are provided.

Chapter 4

4 Results

4.1 *Study Sample*

Ten participants were enrolled in the study (60% female, 50 ± 15 years old; range 36 to 73 years). Sample socio-demographic and health characteristics are presented in Table 3. Mean duration of time with T2D was 2.6 ± 3.3 years. Notably, mean A1c at baseline was under 7% (A1c = 6.2 ± 0.49 %, range 5.7 to 6.7) and mean systolic blood pressure was over 130 mmHg (131 ± 16.7 mmHg). Due to the discovery of a misdiagnosis of Type 1 diabetes (20+ years misdiagnosis) for T2D, Participant #7's glucose data was removed from any glycemic measures, including baseline mean time with T2D and estimated A1c. Half of participants self-reported household incomes below $50,000 CAD per year, and most (70%) were not married. Baseline daily step count mean was 7103 ± 2900 (4874-9332. Five out of nine participants were not meeting the minimum recommended daily step count guideline of 7000 steps per day (Tudor-Locke et al., 2011). Seventy percent of participants self-reported being physically active for a minimum of 30 minutes per day, three days per week. All participants had easy access to unlimited wireless Internet, and 90% reported daily smartphone use (for more information regarding participant 'technology use' see Appendix P).

Table 3. Sample socio-demographic and health characteristics of participants.

≥50,001

4.2 *Primary Outcomes*

4.2.1 **Recruitment and Retention Rates.** During study recruitment, the diabetes clinic registered 136 new patients, but only 116 patients attended their initial clinician one-one-one intake session. Of the 116, 35 patients attended the one-hour general lifestyle medicine class. Fifteen patients expressed interest in participating in this feasibility study, and 10 were ultimately enrolled (29% recruitment rate; Figure 1). Reasons for non-participation (n=5) included work-time conflict, sick spouse, too busy, did not want to wear the FreeStyle® Libre (and be identified as diabetic), or felt exercise and nutrition were well-managed. One patient was scheduled for a coronary artery bypass graft during the study period and was excluded. All ten participants (10/10) completed the baseline assessments (100%). Twenty percent (2/10) of participants dropped out of the study (i.e., Participant #1 missed two bi-weekly group education classes in a row, Participant #8 withdrew from the study during week 5 citing too much time and felt confidence to figure out on their own, as reasons). Eight participants completed follow-up assessments (8/10; 80% retention rate). Of the three follow-up assessments, one of the dropouts (Participant #8) completed the exit survey only.

4.2.2 **Intervention Acceptability and Adherence.** Exit survey responses (Table 4) suggested that participants were generally satisfied with the virtual lifestyle medicine program with 88.8% agreeing with the statement, “Overall, I was satisfied with the program”. Participants indicated that the combined information from the FitBit Inspire 2™ and the FreeStyle® Libre (~44%) was most helpful in learning about diabetes management, compared to the FreeStyle® Libre (11%) or FitBit Inspire 2™ (0%) alone. However, others indicated they felt the group-based education classes were most helpful (~33%). Two-thirds of participants agreed or strongly agreed that their personal health information was safe, and privacy upheld. Other responses from the exit survey can be found in Appendix Q. Responses to the two open-ended exit survey questions regarding study ‘likes’ (e.g., monitoring activity throughout the day, guidance on eating/exercising, group input) and ‘dislikes’/areas for improvement (e.g., FitBit Inspire 2™ screen was too

small, advance notice of group education class curriculum, ability to mute participants in group) are provided in Appendix R.

Table 4. Select exit survey responses.

	Strongly Disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly Agree (%)
The option of using the FitBit to track my exercise was a great motivational tool	11.1	0	22.2	22.2	44.4
The option of using the Libre to track my glucose was a great motivational tool (e.g., eating, exercising)	11.1	0	11.1	22.2	55.6
I felt comfortable speaking in the group-based educational sessions	11.1	11.1	44.4	11.1	22.2
I had plenty of opportunity to ask questions during the group-based educational sessions	11.1	0	22.2	33.3	33.3
I felt encouraged by others in the group-based educational sessions	11.1	22.2	22.2	22.2	22.2
I would have liked to have a friend or family member join the group-based educational sessions	0	33.3	33.3	0	33.3
It was easy for me to join the group-based educational sessions	0	0	0	66.7	33.3
Throughout the study I felt like my personal health information was protected (e.g., my privacy was being upheld)	11.1	11.1	0	11.1	66.7
Overall, I would say this program helped me become more physically active than I was before	0	0	22.2	33.3	44.4
Overall, I was satisfied with the program	0	0	11.1	44.4	44.4

All participants reported at least one ‘technology issue’ (e.g., unable to access WebEx link; 3.2 ± 2.6 issues per person). In total, 32 issues were reported, including: difficulties sending exported FitBit Inspire 2™ data in (n=10), lost WebEx® link (n=6), FreeStyle® Libre falling off before the two-week timepoint (n=7), submitting the wrong Fitbit® data collection periods (n=4), problem synchronizing smartphone with the FitBit Inspire 2™ (n=3), and losing an item (e.g., the Fitbit Inspire 2™; n=2). One FitBit Inspire 2™ “malfunctioned”, where the exported FitBit® file showed step data collected, but no sedentary minutes were provided. Most participants (~78%) said they experienced technology issues 30% of the time or less. All participants agreed or strongly agreed that

it was easy to join the group education classes on the WebEx® platform. Intervention adherence was tracked using several variables. First, proportions of group education class and one-on-one phone call check-ins attendance were 83% and 92.5%, respectively. Participants had 93.8 ± 7.8% valid days of FitBit Inspire 2™ data during study participation. Participants collected 78.8 ± 19.2% of total FreeStyle® Libre data (which requires one scan every eight hours to collect eight hours of data). Participants, however, failed to consistently submit their FitBit Inspire 2™ data within one day of the group education classes (for exercise prescription purposes), with timely submissions only 53.3% of the time. By the end of the study, participants had sent in 98% of all FitBit Inspire 2™ data for data analysis. All adherence data are summarized in Table 5.

Table 5. Intervention adherence.

	Class Attendance[a]	Phone Attendance[b]	Timely FitBit Submission[c]	Percent of Valid Days (FitBit)[d]	'Active Time'[e]
Completers + Dropouts (n=10)	2.5/3 (83%)	3.7/4 (92.5%)	1.6/3 (53.3%)	93.9±7.8%*	78.8 ±19.2%
Completers Only (n=8)	2.88/3 (85%)	3.9/4 (96.9%)	2/3 (66.7%)	93.5±5.4%	80.8 ± 16.9%

Percent of Valid Days (FitBit) and 'Active Time' are presented as mean ± standard deviation %.
[a]Class Attendance = number and percent of group education classes attended;
[b]Phone attendance = number and percent of one-on-one check-in phone calls with exercise specialist attended;
[c]Timely FitBit Submission = the amount of bi-weekly FitBit Inspire 2™ data submitted on time, or within a day of a group education class;
[d]Percent of Valid Days (FitBit) = the group mean percent of (valid days captured / amount of total days participated in the study), where a valid day was defined as a day with ≥500 steps per day;
[e]'Active time' = the mean percent of total glucose data captured in 24-hour period every two weeks. The FreeStyle® Libre requires at least one scan every eight hours to collect the past eight hours data;
*n=9, Participant #1 did not send in any FitBit data to be included.

4.3 *Secondary Outcomes*

Several secondary outcome variables were assessed for the purposes of demonstrating intervention potential. On average, participants took 7103 ± 2900 (4874-9332) steps per day at baseline and 7515 ± 3169 (4866-10164) steps per day at the end of week 6. Regarding number of sedentary minutes per day, participants accumulated 837 ± 303 (775-899) and 975 ± 231 (925-1024) minutes per day at baseline and week 6, respectively. Exercise prescription targets (i.e., daily step count goals) were achieved roughly half the time (50 ± 16% of the time; 19.4 ± 6.0 daily goals met / 39.3 ± 9.3 valid days) by all participants, and 46.6 ± 15.7% of the time by the eight study 'completers'

(17.5 ± 7.4 daily goals met / 36.4 ± 8.8 valid days). Individual daily step count goal achievements can be found in Table 5. Individual mean glycemic measures (i.e., estimated A1c, time in target, coefficient of variation) are presented in Table 6 and group mean glycemic measures such as biweekly estimated A1c at baseline (6.2 ± 0.49% (5.7-6.7)) and follow-up (6.2 ± 0.61 (5.6-6.9)), or biweekly 'time active' at baseline (77 ± 22% (60-94)) and follow up (77 ± 20% (59-95)) in Appendix S. Baseline and follow-up scores for the Chronic Disease Self-Efficacy Scale (n=8) were 7.4 ± 2.0 (5.7-9.1) and 7.7 ± 1.7 (6.3-9.1), respectively. PAID-5 (diabetes distress) baseline and follow up scores (n=8) were 8.1 ± 3.3 (5.4-11) and 7.9 ± 2.7 (5.6-10), respectively.

Table 6. Bi-weekly physical activity outcome means, by participant.

Participant		Baseline		Week 1-2			Week 3-4			Week 5-6		
# ID[a]	Age[b]	Steps[c]	Sedentary Time[d]	Steps	Sedentary Time	Step Goal[e]	Steps	Sedentary Time	Step Goal	Steps	Sedentary Time	Step Goal
1	36	X	X	X	X	X	X	X	X	X	X	X
2	58	9729±2985 (6968-12849)	645±333 (338-953)	11158±3917 (8896-13419)	923±149 (820-1026)	8	9521±4002 (7103-11939)	831±190 (716-945)	3	8165±5222 (5150-11180)	1148±233 (1014-1283)	8
3	68	2114±663 (1743-2544)	945±225 (812-1084)	1790±585 (1452-2128)	850±201 (734-967)	1	1779±948 (1232-2327)	841±152 (753-928)	4	2103±746 (1672-2534)	843±144 (760-925)	8
4	68	9191±2794 (7503-10879)	406±93 (350-462)	8001±1800 (6962-9040)	683±80 (637-723)	2	9187±1654 (8232-10142)	680±74 (637-723)	10	8987±2203 (7715-10259)	678±74 (635-721)	6
5	43	6112±1762 (5057-7187)	1021±249 (871-721)	6154±1590 (5236-7072)	1136±159 (1044-1228)	4	5052±1526 (4129-5974)	1160±139 (1076-1244)	3	5487±1823 (4386-6589)	1215±46 (1187-1243)	7
6	42	8954±2569 (7348-10560)	788±71 (745-831)	8979±1890 (7887-10070)	794±145 (710-878)	5	10286±1279 (9547-11024)	797±75 (753-840)	13	10111±1744 (9104-11118)	795±74 (752-838)	12
7	73	11114±3595 (8942-13287)	830±234 (688-972)	13114±1736 (12111-14116)	1032±46 (1006-1059)	12	12484±1743 (11477-13490)	1053±35 (1033-1073)	4	12930±2619 (11418-14442)	1053±51 (1023-1082)	9
8	35	4877±1733 (3830-5924)	729±262 (562-895)	4355±1212 (3655-5055)	723±147 (638-808)	3	X	X	X	X	X	X
9	40	4721±2063 (3335-6107)	1090±278 (913-1267)	5113±1195 (4354-5872)	1218±58 (1181-1255)	10	5366±2177 (3693-7039)	1193±104 (1113-1273)	5	6511±2936 (4410-8611)	1123±197 (982-1264)	7
10	36	7115±2622 (5354-5872)	1115±146 (1017-1213)	7570±2741 (5729-9412)	1155±101 (1087-1223)	7	6786±1999 (5578-7993)	Malfunction	4	6634±4062 (3728-9540)	1118±146 (1006-1230)	3
Total	50±15	7103 ± 2900 (4874-9332)	837±303 (775-899)	7359 ±3485 (4680-10038)	941±232 (897-986)	5.8±3.7	7558±3449 (4674-10441)	915±216 (866-965)	5.8±3.7	7515±3169 (4866-10164)	975±231 (925-1024)	7.5±2.6

Numbers presented as mean ± SD (95% confidence interval);
[a]#ID = Participant ID number,
[b]Age = measured in years;
[c]Steps = average daily step count for two weeks, measured in steps/day;
[d]Sedentary Time = average daily sedentary time for two weeks, measured in minutes/day;
[e]Step Goal = number of prescribed daily step count goals achieved over the course of the two weeks (out of 14 days);
N/A = Participant that was improperly diagnosed with Type 2 diabetes; N = No estimate provided; Libre cannot provide an estimated A1c when sensor activity < 50%; X = Participant did not send in data/drop out; Malfunction = step data was collected, but sedentary minutes were not available on the exported FitBit file

Table 7. Bi-weekly glycemic outcome means, by participant.

# ID[a]	Baseline			Week 1-2			Week 3-4			Week 5-6		
	Est. A1c[b]	CV[c]	'Active Time'[d]	Est. A1c	CV	'Active Time'	Est. A1c	CV	'Active Time'	Est. A1c	CV	'Active Time'
1	NE	23.2	34	NE	34.7	35	X	X	X	X	X	X
2	6.0	19.4	99	6.0	26.7	94	6.2	20.2	99	6.3	17.3	98
3	NE	16.4	52	6.7	17.6	67	6.4	15.3	64	6.3	17.8	70
4	6.1	27.9	83	6.0	26.6	85	5.8	30.1	88	5.8	30.8	81
5	7.0	29.9	89	7.0	33	94	7.3	28.5	83	6.9	32.1	77
6	5.6	14.4	97	5.6	12.8	98	5.5	11.9	100	5.3	13.5	90
7	N/A	N/A	95	N/A	N/A	100	N/A	N/A	100	N/A	N/A	100
8	6.2	29.3	89	6.2	28.3	87	6.5	29.5	93	X	X	X
9	6.7	23.4	87	7.0	23.3	84	7.4	21.4	88	6.8	22.6	86
10	5.8	20.6	66	5.7	24.3	50	6.2	29	56	NE	30.4	37

All numbers are presented as percentages;
[a]# ID = Participant ID number;
[b]Est. A1c = estimated glycated hemoglobin via FreeStyle® Libre;
[c]CV = coefficient of variation;
[d]'Active time' = the mean percent of total glucose data captured in 24-hour period every two weeks (the FreeStyle® Libre requires at least one scan every eight hours to collect the past eight hours data);
N/A = Participant that was improperly diagnosed with Type 2 diabetes; NE: No estimate provided; Libre cannot provide an estimated A1c when sensor activity < 50%.

Chapter 5

5 Discussion

5.1 *Main Findings*

This is one of the first studies to investigate the feasibility of virtually delivering a multi-component group-based lifestyle medicine program in a population with T2D. Overall, the protocol was generally feasible and well-accepted by participants (i.e., ~88% satisfied with overall program with relatively low rates (<30% of the time) of technology issues). Notably, nearly 100% of FitBit Inspire 2™ data were collected (albeit not 'on time'), and FreeStyle® Libre 'active time' approached 80% over 8 weeks (where a minimum of 70% capture is considered ideal). Offering virtual lifestyle medicine programming with contemporary technologies may prove possible and appears to be promising for clinical practice. Comparisons to similar studies, protocol recommendations for future trials, and study implications are provided next.

5.2 *Comparisons to similar studies*

5.2.1 **Recruitment.** In terms of recruitment, there was a 29% recruitment rate (10 out of 35 patients). Similar 12-week feasibility studies with different clinical populations (i.e., adults and older adults with T2D, liver transplant patients, adults with overweight/obesity), have reported a range of recruitment rates—from 21% to 65% (Baillot et al., 2017; Hickman et al., 2021; Taylor et al., 2019; Zheng et al., 2020). One six-week, three-armed pilot RCT study that included adults with high risk of developing T2D or prediabetes recruited 77.6% of eligible participants (n=45; aged 56 ± 8.7 years; Whelan et al., 2019). Ninety people, or 32% of potential participants were ineligible for Whelan et al.'s study because of incompatibility between the iPhone and Libre (though since has been resolved). In the present study, no potential participants were excluded due to lack of sufficient technology or access to internet. As the present diabetes clinic traditionally manages patients with lower incomes (Reichert et al., 2014), it is promising

that there was no limiting technology or cost-related barriers to participating (though, this may be due to selection bias).

5.2.2 **Retention Rates.** Of the ten who signed up, 80% of participants completed the study. Other similar studies ranging from six weeks to six months incorporating multiple self-monitoring technologies have demonstrated 90-100% retention rates (Jiwani et al., 2021; Whelan et al., 2019; Zheng et al., 2020). One six-month RCT compared the use of FreeStyle® Libre (control) (n=108; aged 47 ± 13.6 years) to the FreeStyle® Libre plus an educational program in a sample with T2D on intensive insulin therapy (n=108, aged 44 ± 13 years). Interestingly, the control group retained 96.4% participants (5/108) and the intervention group a lower rate, at 88.9% (96/108) (all lost to follow-up). Examining the reasons for dropouts in the present study (i.e., time commitment, viewed as not valuable, loss to follow-up), it seems unlikely that the virtual delivery would have been the mediating factor for withdrawal like in previous studies (Dasgupta et al., 2017; Tomlinson et al., 2020).

5.2.3 **Acceptability.** Acceptability was measured by number of technology issues per person and participant exit survey responses. Overall, the findings of this study suggest the protocol and methodology to be acceptable. There were a low mean number of technology issues per person (3.2 ± 2.6 issues per person). Whelan et al. (2019) reported a total of 262 FreeStyle® Libre replacements were supplied to participants (n=45), due to misplacements or faulty sensors during their six-week intervention. Replacing 262 sensors over a very short period is costly, thus proper placement and prevention education should be identified. The present study only reported seven FreeStyle® Libres falling off prematurely, and usually occurred within three days or less of sensor replacement. In terms of using the videoconferencing platform, there were no reported issues with hearing or lag issues with the video group educational classes in this study, which is encouraging for future virtual delivery. In contrast, other videoconferencing lifestyle medicine program group education classes have reported audio/video lags or drops in calls 20-25% of the time or reported Internet instability issues (Cliffe et al., 2021; Hickman et al., 2021; Tomlinson et al., 2020). Exit survey responses shed light on some aspects of intervention acceptability, such as opinions about

the FitBit Inspire 2™ and FreeStyle® Libre usefulness and group classes experiences. Almost half of participants (44%) reported the combined biofeedback from the FitBit Inspire 2™ and FreeStyle® Libre was the most helpful in learning how to best manage their diabetes. Interestingly, 35% of participants felt the FreeStyle® Libre was most motivating in increasing physical activity, followed by the group education classes (25%) and FitBit Inspire 2™ (25%). This could indicate that there may be value in combining FGM and wearables for learning (Gonzalez et al., 2016; Liao et al., 2020) and treatment satisfaction (Gal et al., 2020; Hermanns et al., 2019; Wada et al., 2020). As well, multi-component interventions could be more likely to satisfy multiple individuals' needs with a wider range of accessible resources. Most participants on the exit survey agreed or strongly agreed (67%) that "the option to use the FitBit Inspire 2™ was a great motivational tool". These responses are in line with participants experiences from previous studies using a FitBit® (Jiwani et al., 2021; Kooiman et al., 2018; Maher et al., 2017).

5.2.4 **Intervention Adherence.** Group and phone call check-ins had averaged mean attendance rates of 83% and 93%, respectively. A 12-month non-randomized trial comparing the video delivery of (a) one-on-one counselling sessions with an endocrinologist (every three months) (n=33; 56.7 ± 9.4 years) and (b) group DSME with a certified diabetes educator (every three months for two hours) (n=36; 56.5 ± 6.7 years) in rural community patients with advanced T2D provides context for the present findings (Nyenwe et al., 2020). At least 40% of participants in each group missed at least one appointment. Sub-analyses revealed those who attended less than 50% of classes were more likely to be younger, which is similar to previous evidence (Adams et al., 2013; Kirkman et al., 2015) and what the present study suggests as well. Other attendance rates of virtual lifestyle medicine programs using videoconferencing to deliver classes have widely ranged from 52-95% (Baillot et al., 2017; Hickman et al., 2021).

In the present study, data presented with and without dropout participant data displayed a 94% rate of valid days of FitBit Inspire 2™ data over the course of the study. One three-month lifestyle program combining multiple self-tracking technologies in an older adult sample with T2D, reported 85.2 ± 19.7% valid days of FitBit® data (Zheng et al., 2020),

whereas Whelan et al. (2019) reported 95% of valid days of data were collected during their six-week feasibility study.

Four participants had their lowest ‘active time’ of FreeStyle® Libre (the total percent of data captured) in study weeks five and six, which could potentially indicate the start of an often-cited phenomenon in digital health intervention referred to as “non-usage attrition”, as previously described (Eysenbach, 2005). However, group means of ‘active time’ hovered at 77% at both baseline and follow-up. In contrast, Whelan and colleagues (2019) noted a continuously decreasing ‘active time’ of the FreeStyle® Libre, having 87.6% in the first week and dropping to 82% by the sixth week. Zheng et al. (2020) (who utilized multiple health monitors including a FitBit® and a nutrition tracking app) noted consistent high engagement levels with their technologies up until week 6 and then noticed a trending decline for the next six weeks. Given the small sample of this study, this non-usage attrition claim is speculative. Regardless, since non-usage attrition is common in this context (Eysenbach, 2005) strategies for preventing or minimizing it should be considered moving forward (e.g., eliminating user ‘friction’, drawing to new program features as time passes, etc.), as higher engagement (scans) with the Libre® FreeStyle is associated with better A1c (a future primary outcome) and decreased time in hypo- and hyperglycemia (Dunn et al., 2018).

5.2.5 **Physical Activity Outcomes.** Overall, there does not appear to be any trends when examining group mean daily step counts from baseline to follow-up. Some participants’ individual bi-weekly mean step counts trended upwards, and some down. Individual daily step goal achievement also varied, though group means number of daily step count goals achieved were trending upward over time (which could suggest increased daily step count consistency). Individuals with downward step count trends may have been subject to the ‘Hawthorne Effect’ (when people behave differently when they know they are being watched/monitored; Landsberger, 1957), either during the baseline period or the initial two intervention weeks. However, it is also possible that Ontario’s COVID-19 pandemic transition from partial to full lockdown restrictions during the study (on December 26th, 2020) left some people with either decreased opportunity or motivation to continue to be active. Additionally, this study was conducted

during the winter in Canada; winter seasons have previously shown decreased steps compared to warmer seasons (Clemes et al., 2011). In contrast to the current step count data, one 12-week self-monitoring eHealth intervention utilizing FitBit® monitors reported significant increases in steps per day (a mean increase 1255 ± 1500 steps per day; ($p<0.01$) from baseline (5978 ± 2982 steps per day) (Kooiman et al., 2018). Meta-analyses have reported increases of 2000 or more steps per day over periods of 6 to 12 months (Dasgupta et al., 2017; Qiu et al., 2014; Vaes et al., 2013)). Nonetheless, this study was not powered to determine statistically significant changes, nor primarily targeted change in daily step counts as the goal was to assess the feasibility of using steps for bi-weekly exercise prescriptions and data collection.

Participant baseline mean daily sedentary behaviour time was roughly 14-15 hours per day. In contrast, current evidence suggests that in the general population, the average Canadian adult aged ≥ 35 years accumulates about 9.5 to 10 hours per day (Prince et al., 2020). Sedentary time may have also trended upwards over the course of the intervention, though this study was not powered to draw firm conclusions in this regard (baseline period: 837 ± 303 (775-899) minutes per day; weeks 5-6: 975 ± 231 (925-1024) minutes per day). Given that these data were either collected with some COVID-19 restrictions or under total "lockdown", these higher (and potentially rising) levels seem to be matching up with claims of predicted increases in sedentary behaviour during the COVID-19 pandemic (Marçal et al., 2020). Regardless, this is particularly concerning as higher and longer periods of sedentary behaviour are strongly linked to increased risks of insulin resistance, heart attacks, Alzheimer's/ dementia, and all-cause mortality (Dempsey et al., 2016; Dunstan et al., 2012; Healy et al., 2008; Loh et al., 2020). This type of behaviour should at minimum be targeted more heavily and emphasized more to this population, especially as targeting sedentary behaviour can be a great method to ease people into increasing physical activity (Colberg et al., 2016; Dempsey et al., 2016) and has shown decreases in A1c and weight (Dempsey et al., 2016; Dunstan et al., 2012; Healy et al., 2008; Loh et al., 2020).

5.2.6 **Diabetes Related Attitudes.** Breaking down the specific categories in the Stanford Self-Efficacy Scale suggest levels of emotional distress may have decreased

during the study, though again, firm conclusions must not be drawn (8.4 to 7.75, range 1-10). As well, general self-efficacy scores demonstrated a small increase, and particularly the lower end of the 95% confidence interval (7.4 ± 2.0 (5.7-9.1) to 7.7 ± 1.7 (6.3-9.1). This may indicate that those with lower self-efficacy may have benefitted more, as well as the intervention having influence on competence levels, though a larger study is needed to confirm these claims. In the PAID-5 scale, participants appear to have reported lower levels of "feeling scared when thinking about living with diabetes" and "worrying about the future and the possibility of serious complications". This downward trend indicates potential acceptability of our intervention as well, as participants may feel more confident and knowledgeable as a result of the intervention and thus have fewer concerns and/or fears. Interestingly, "feeling that diabetes is taking up too much of your mental and physical energy every day" scores may have increased for some. Theoretically, it is possible that if participants had not previously been engaging in self-management practices and had increased involvement, both the learning curve and added effort may have increased mental strain. Other virtual interventions using CGMs or FGMs have reported no significant changes in psychological well-being, depression score, empowerment, self-efficacy, hypoglycemia worry (Hermanns et al., 2019), or perceived stress (Taylor et al., 2019), yet some have reported significant decreases in management distress, emotional burden and behavioural burden (Gal et al., 2020; Hermanns et al., 2019).

5.3 *Protocol Refinements*

5.3.1 **Recruitment and Sample Characteristics.**

Several opportunities were identified to improve the study protocol, and the intervention specifically (Table 8). First, the number of people recruited compared to the number of new patient intakes that were seen during the recruitment period (10 vs. 116) was relatively low. Post-recruitment, a lack of clinical referrals to the general lifestyle medicine class was identified as one possible explanation. This could be addressed in part by giving clearer instructions to clinicians in the future. Second, T2D appeared to be generally well-controlled in the current sample with baseline estimated A1c of 6.2% (below the typical

7% target for most adults), which limits the generalizability of these results (Pillay et al., 2015). If a similarly well-controlled sample were to be recruited in a future study, this could impact results (i.e., limited room for improvement; Pantalone et al., 2020; Wada et al., 2020). Additionally, both insulin and non-insulin users were included in the current

Table 8. Key intervention and protocol refinement recommendations.

Description of Study	**Current Protocol**	**Optimization for Future Studies**
Recruitment	Low referrals to the one-hour general lifestyle medicine class by clinicians from diabetes clinic.	Clearer instructions for clinicians.
Sample	Well controlled diabetes (baseline estimated A1c = 6.2%). Both insulin and non-insulin users included.	Consideration of type of sample; controlling for important diabetes related sample covariates (i.e., medications, insulin, baseline A1c. Sub-analysis of insulin users vs. non-insulin users.
Technology	1. Multiple issues with study data submissions due to a relatively complex protocol (i.e., downloading a FitBit™ excel file from desktop/laptop and uploading to a secure file sharing website). 2. Sound feedback issues.	1. Providing option to email/text in screenshot of two-week FitBit® step count summary or implement automatic data upload to server. 2. Ensure class facilitator mute capabilities.
Group Class Dynamics	1. Low participant participation in group discussions, led to more didactic class format. 2. Difficulty "reading the room" when phoning onto the call. 3. Rolling intake format	1. a. Provide one-page content summaries to review prior to class for content familiarization (increase ease of discussion); provide small homework assignments to re-enforce learning and encourage more meaningful conversations. b. Emphasize the importance of sharing and peer learning 2. Ensure participants are participating via the video platform (camera on or off). 3. Remove rolling intake, have set start and end dates for programs.
Exercise Prescription and Physical Activity Outcomes	Step count prescriptions only. Participants provided choice on "how" to accumulate the steps (with advice from exercise specialist).	1. Offer participants choice of type and frequency of a preferred exercise (to supplement or replace step count goal); offer specific prescriptions for minutes of walking (to help achieve step count goal); increase frequency and automation of personalized feedback. 2. Consider tracking change in physical activity intensities levels using research-grade accelerometer.
FreeStyle® Libre	Potential decrease in engagement with FreeStyle® Libre	Create short booster sessions with specific topics, to encourage further exploration of personal data and shared experiences.
A1c = glycated hemoglobin		

sample. Current evidence and clinical practice support the use of CGM in insulin users (Beck et al., 2017; Haak et al., 2017; Yaron et al., 2019); yet, the efficacy, let alone the practical, cost-effective use of the CGM or FGM in non-insulin users remains controversial due to limited supportive evidence (Allen et al., 2008; Diabetes Canada, 2020a, 2020b; Lipscombe et al., 2018; Robertson et al., 2020; Wada et al., 2020). According to some, non-insulin users should be provided an opportunity for earlier lifestyle choice adaptations (reducing the potential need to use insulin), in addition to increasing the evidence on efficacy of FGMs in this population (Wada et al., 2020). Inclusion of sample characteristics such as degree of glycemic control and/or insulin usage should be considered in the design of future trials (e.g., block randomized control design, include as co-variates in analyses, etc.; Balducci et al., 2019), especially when using FGMs (Pantalone et al., 2020).

5.3.2 **Technology Issues.** There were relatively low mean numbers of reported technology issues per person, and most were related to study-related data submissions (14 total). Data submission issues may have been related to the complex study protocol/procedures, which had to follow ethics-mandated secure data transfer and involved the inclusion of FitBit® Excel file for data collection (and was complex for some participants). This complex protocol also may have resulted in suboptimal Fitbit/Libre submission rates (~53%). This matter was addressed early in the study by providing the option to send in a smartphone screenshot of the two-week FitBit® app summary as an alternative option. Moving forward, this is a critical issue that needs to be addressed to increase clinical practicality and reduce participant burden (such as automatic data upload to a server for clinician viewing; e.g., Kato et al., 2020) or at minimum, data submission via email (Michaud et al., 2021). Overall, it was valuable to have a technology support person on hand to resolve issues quickly, as has been previously recommended (Aberer et al., 2021).

5.3.3 **Group Class Dynamics.** Exit survey feedback identified several areas for protocol refinement as well. For example, there were varying responses about participant's level of comfort speaking during the group education classes. Virtual group environments via video can prove to be difficult for members to assess body language

and feel others' emotions, in addition to leaving plenty of opportunity for miscommunication and negative experiences (Parks, 2020). The original protocol planned for semi-structured classes, that were primarily non-didactic (led by participants) to increase relatedness and peer learning. This proved to be challenging as many open-ended questions (e.g., "what type of physical activity goal do you want to set for the next two weeks?") did not stimulate as much discussion as intended. Perhaps this could be attributed to (a) not being able to 'read the room'/participants being shy or not comfortable speaking in public, (b) not wanting to disclose health goals due to feelings of embarrassment or vulnerability, or (c) low familiarity with the education topic. For example, exit survey responses revealed requests for advance review of group education class material, so that they could be familiar with the topic and easily engage in discussion. Although the slideshow files were sent one day in advance, either participants did not look at them beforehand or the slides may have been too dense or long to review. In the future, a course package that includes comprehensive questions to solidify the previous class discussion, as well as content (e.g., one page summary) for the next class could be provided. Issues with sound feedback during group calls were identified. This was exacerbated when one of the participants was calling in by the phone. In the future, having facilitator muting capabilities is highly advised to ensure a better experience for everyone (Connor, 2018). As well, whenever possible, encourage participants to attend the video call (even if the individual has their video off) to be able to see others and "read the room" better is recommended, in order to increase group cohesion (Connor, 2018). Other recommendations to increase group cohesion are to avoid rolling in-takes.

5.3.4 **Physical Activity Data Collection.** Additionally, although only daily step count data was collected for this study, Fitbit® monitors are capable of tracking minutes of physical activity at different intensities (though additional data is required to do so, including participant weight/height). Measuring levels of physical activity intensities (e.g., moderate to vigorous intensities) may provide additional insight on change in exercise behaviours in the future (O'Brien et al., 2018).

5.3.5 **Self Determination Theory.** The self-determination theory can be used to target health behaviour change (Halvari et al., 2017; McSharry et al., 2020; Shigaki et

al., 2010), and a stronger application in the current context may yield better results (e.g., better attendance, larger daily step count increases, greater reductions in A1c). Although the intervention sought to target the three psychological needs and in doing so increase intrinsic motivation, these psychological outcomes were not measured. For future studies, a fidelity check to ensure the intervention is appropriately targeting the three needs and shifting motivation intrinsically is needed. The Behavioural Regulation in Exercise Questionnaire (BREQ-3), for example, is used to assess types of motivations for exercise on the motivation continuum and is recommended for future studies (Markland & Tobin, 2004; Wilson et al., 2006). The use of step count prescriptions to elicit change in daily step counts were perhaps not sufficient. It is possible that participants: (a) did not want a step count goal only but needed a more specific exercise prescription that included type, time, and/or intensity of aerobic exercise, (b) did not fully comprehend how to accumulate steps through exercise, or (c) were simply not motivated by a daily step count goal. Step count goals may have imposed an unwanted goal, which have shown to decrease intrinsic motivation (Ryan & Deci, 2000b). To increase autonomy, future studies should consider offering participants the choice of type and frequency of a preferred exercise, for instance, to supplement the step count goal, or to fully replace the step count goal (Halvari et al., 2017). As well, offering participants the option to receive recommended prescriptions for minutes of walking (to help achieve step count goal) may also increase levels of autonomy. Lastly, providing increased levels of positive performance via automated personalized feedback (e.g., automated SMS texts; Hochberg et al., 2016) may increase levels of competence (Ryan & Deci, 2000a). To increase competence levels further, the FreeStyle® Libre should be leveraged more heavily to increase feelings of knowledge and control over diabetes progression. Participants found the FreeStyle® Libre to be the most helpful with increasing physical activity (37.5%) and helped guide food (100%), physical activity (~78%), and medication (~33%) decisions. To further leverage and stimulate (or at least maintain) individual engagement with the FreeStyle Libre sensor, short group “booster” topic-specific, guided sessions could be beneficial; thereby, not only learning interpretation basics, but having participants interact with, and share their data as a group (fostering both competence and relatedness). Lastly, a stronger application of self-determination theory may lead to even greater

increases in feelings of social relatedness. As mentioned, group discussions proved difficult to facilitate, for several reasons. For the third group-education class, a fun group icebreaker was implemented. These appeared to be well received and may have promoted participant engagement during the session, however no data were collected to quantify this statement. Creating questions in advance to prompt discussion to compliment lesson material (e.g., “Does anyone feel scared to exercise?”) or having assignments to prepare and feel comfortable to engage for more in-depth group discussions (e.g., preparing to share glucose trends after eating something that made their glucose spike, or exercise etc.) could be used. This could help increase group cohesion to foster better conversations that may lead to increased opportunity for peer learning, motivation (e.g., “If they can do it, I can do it”; Jiwani et al., 2021)), and feelings of competence and relatedness. In order to support increase group cohesion, other strategies can include adding in a group name (group environment distinctiveness), group collective goals (e.g., collaboratively creating a group goal to attain X amount of distance during the program), or increasing group problem solving activities (Estabrooks et al., 2008; 2012)

In summary, refinement to the data submission protocol to decrease barriers (i.e., time, frustration, effort), offer exercise choice and increase performance feedback frequency, implement small engagement FreeStyle® Libre boosters, and increase group engagement, may prove to be useful in intervention adherence and engagement, and possible long-term study retention.

5.4 *Strengths and Limitations*

This study was novel, as it is one of the first studies to evaluate the implementation of a multi-component virtual group lifestyle medicine program for adults with T2D. A large strength of this study was the strong alignment with the ORBIT model (Czajkowski et al., 2015). Many of the participants were of lower incomes, which can further support the feasibility of this type of program (as technology ownership could have been a limiting factor). As well, this study was very successful in collecting all study related data virtually (~100% of FitBit data, 79% of FreeStyle® Libre data). Lastly, this study was

positioned to capitalize on the COVID-19 pandemic, as we were able to test this setting in a “real world” clinical setting, ultimately adding to the ecological validity of this study.

However, this study has limitations that must be considered when interpreting the results. First, baseline data was extracted from the most recent records available on the electronic medical record. Therefore, not all baseline physiological data measurements were completed at the same time relatively to the study start date, and some data were missing. Second, this study had a small sample and was conducted over short period of time (six weeks). These issues were due, in part, to COVID-19 related physical distancing policies that delayed project initiation. However, other studies testing the virtual delivery of lifestyle medicine programs report similar sample sizes (Baillot et al., 2017; Burkow et al., 2018; Tomlinson et al., 2020; Zheng et al., 2020). Second, while health behaviour change interventions in this field are typically 12-weeks or longer (Kooiman et al., 2018; Peacock et al., 2020; Umpierre et al., 2011; Yang et al., 2020; Zheng et al., 2020) this current study was only six weeks in duration. A longer study may have yielded different results. Third, this was an uncontrolled, single group cohort study. More engaged, healthy diabetes clinic patients may have volunteered to participate in this study (‘self-selection bias’) as is often reported in similar studies. The characteristics of this small, potentially more engaged/healthy sample may have affected the feasibility outcomes reported here. (Mardanian Dehkordi & Abdoli, 2017). Fourth, despite individualized exercise prescription playing an important intervention role, cardiorespiratory fitness (a key cardiovascular disease risk factor) was not assessed. Moving forward, utilizing validated tests such as the six-minute walk test or a step test should be considered (Hansen et al., 2013; Lee, 2018). Fifth, a daily step count of 500 steps or more was a considered a full day worth of data (‘valid day’; Kooiman et al., 2018). Looking ahead, an updated definition of ‘valid day’ may include the time between the first and last daily step recorded, with the valid days counted if at least 8-10 hours between first/last count (either via self-report or heart rate data). As well, previous evidence suggests wrist-worn accelerometers can inflate step counts compared to hip-worn monitors (Mandigout et al., 2019). Thus, FitBit®-related data should be interpreted with caution. Sixth, this study was non-blinded. The research trainee/author collecting and analyzing data was also the exercise specialist, which may introduce observer bias to data interpretation (Mahtani et

al., 2018). Lastly, the mostly discrete response format of the exit survey could only provide so much insight (vs. for example, focus groups; e.g., Jiwani et al., 2021, ORBIT Phase I recommendations, Czajkowski et al., 2015). Important participant insight/feedback may not have been captured.

5.5 *Implications and Future Directions*

This study is one of the first studies to deliver an almost completely virtual lifestyle medicine program in a group setting while simultaneously utilizing FGMs, wearable activity monitors, and individualized exercise prescriptions. In general, this intervention package (if shown to be efficacious in future studies) may address a number of low DSME attendance barriers, increase program accessibility, and better equip people living with T2D to self-manage their chronic condition (Sim & Lee, 2021). This study suggests that a virtual lifestyle medicine program can be feasibly delivered in a clinical, real-world setting, even amidst a global pandemic. Multiple participants were reached at once, which required less clinician time/resource and provided the opportunity for peer learning and increased feelings of social relatedness (not otherwise possible in one-one-one virtual appointments). One consideration of this program is its institution-level feasibility. Although not assessed in this study, future work should evaluate time usage of staffing (i.e., reception, healthcare practitioners) and resources such as wearables or technology platforms, spent in running the program. However, an end goal of a this type of program is to have a fully developed program that no longer needs fine-tuning and thus requires significantly less work. Providing FreeStyle® Libres free-of-charge and/or loaning FitBit Inspire 2™ monitors may be costly, and begs the question, ‘should clinics be investing in expensive health technologies to support self-management?’. Although these costly tools may likely prove to be more efficacious in a high-risk, high-cost populations, researchers and clinicians should consider whether to indeed promote relatively high-cost health technologies in lower-risk patient groups (e.g., non-insulin dependent). In real-world settings, not everyone will have access or can afford to use FGMs, as they are only covered in some Canadian provincial healthcare systems, and in some instances only by insurance companies if the person is using insulin (Diabetes Canada, 2020a, 2020b). As well, not everyone is going to own or be able to afford a FitBit® (or other wearable

activity monitor; Patel et al., 2015), nor continue to wear them long term. One consumer report revealed that half of an adult sample (n=6223) claimed they stopped using their wearable, and one third of these stopped within six months of owning one (Maddox, 2014). Therefore, programs should also consider leveraging smartphones as a cheaper (or second choice) alternative as they have demonstrated reasonable accuracy as a daily step count monitoring tool (if worn on their person, e.g., in pant pocket; Bonn et al., 2018; Patel et al., 2015; Sullivan & Lachman, 2016). Finally, it must be acknowledged that virtual participants in DSME might not be for everyone. Offering these types of virtual options should likely be done to compliment rather than replace existing services (Maddison et al., 2019).

Aligning with *Phase Ib* of the ORBIT model (Czajkowski et al., 2015), the protocol was adapted as needed. Any changes needed were mostly related to optimizing delivery and content for classes. This study exhibited a successful adaptation of the lifestyle medicine program (including a new mode of delivery) previously delivered at the diabetes clinic (*Phase Ib*). Moving forward, with increased confidence in the intervention package discussed and refined here, the next step is to move onto a proof-of-concept test (IIa) or a pilot feasibility trial (IIb) to determining if clinical significance is possible and further refine the protocol if necessary. A fixed treatment protocol outline and creation of an intervention delivery manual are necessary for rigorous and quality delivery. A small, specific sample should be chosen using criteria previously discussed, prior to a larger more generalizable sample in Phase III. Testing the efficacy of virtual delivery against in-person delivery in a primary clinical endpoint, such as A1c (Phase IIb), prior to moving to final the Phase III efficacy trial is recommended.

5.6 *Conclusion*

The results of this study show that it is feasible to conduct a study that delivers a virtual group-based lifestyle medicine program that uses wearables and individualized exercise prescriptions. However, several refinements to the protocol are needed prior to moving forward to a pilot trial (e.g., better data transfer, increased options for exercise prescriptions, etc.). Future research is warranted to determine the efficacy of this style of

delivery modality and multi-component intervention in improving physical activity and glycemic control outcomes.

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Appendix A

Western Research

Date: 31 August 2020

To: Dr. Sonja Reichert

Project ID: 116071

Study Title: Virtually Delivered Lifestyle Program Integrating Wearable Technology and Exercise Prescriptions in Patients with Type 2 Diabetes (STAND-VAT): A Feasibility Study

Application Type: HSREB Initial Application

Review Type: Full Board

Meeting Date: July 07, 2020

Date Approval Issued: 31/Aug/2020 19:25

REB Approval Expiry Date: 31/Aug/2021

Dear Dr. Sonja Reichert

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
Data Collection Log	Other Data Collection Instruments	17/Jul/2020	2
Participant Information	Other Data Collection Instruments	17/Jul/2020	2
PAID-5	Other Data Collection Instruments	20/Jun/2020	2
Demographics	Other Data Collection Instruments	04/Jun/2020	2
Tech Survey	Other Data Collection Instruments	19/Jun/2020	2
V2. PCDSP Physical Activity Assessment Form	Other Data Collection Instruments	03/Oct/2019	2
Stanford Self-Efficacy Scale	Other Data Collection Instruments	20/Jun/2020	2
STAND-VAT Class Handout	Other Participant Material(s)	20/Jul/2020	2
Using Your FitBit: Hourly Movement	Other Participant Material(s)	21/Jun/2020	2
Participant Expectations	Other Participant Material(s)	21/Jun/2020	2
Using Your FitBit: Setup	Other Participant Material(s)	21/Jun/2020	2
HOW TO EXPORT YOUR DATA Handout	Other Participant Material(s)	21/Jun/2020	2
Exercise FitBit Handout	Other Participant Material(s)	21/Jun/2020	2
Exercising Safely	Other Participant Material(s)	21/Jun/2020	2
Telephone Script	Telephone Script	20/Jun/2020	1
Exit Survey	Other Data Collection Instruments	23/Jul/2020	2
Recruitment Email	Email Script	20/Jul/2020	2
End of Study Letter V3	End of Study Letter	19/Aug/2020	3
LOIAndConsent_VirtuallyDeliver	Online Survey	20/Aug/2020	1
STAND_VAT Feasibility Protocol	Protocol	20/Aug/2020	3
Consent form V4	Written Consent/Assent	26/Aug/2020	4

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western

Appendix B

Recruitment

Routinely, after their initial intake, all new patients at the diabetes clinic are to be referred by their healthcare practitioner to a one-hour general lifestyle medicine class. From November 2020 to late December 2020, Ontario was under COVID-19 yellow and red restrictions (ten and five people indoor gatherings, respectively), during which the diabetes clinic held these lifestyle medicine classes in person (while also offering simultaneous online attendance as an option as well). As of December 26th, 2020, Ontario entered a complete COVID-19 lockdown (grey restriction; no group meetings) and the classes moved entirely virtual. All virtual classes were held using the WebEx® video platform. As such, participating patients had to have access to technology (in line with technology inclusion criteria) that enabled WebEx® participation. At the end of the one-hour general lifestyle medicine class, patients were invited to participate in the study.

Appendix C

Letter of Information and Consent: Open Protocol

Study Title: Virtually Delivered Lifestyle Program Integrating Wearable Technology and Exercise Prescriptions in Patients with Type 2 Diabetes (STAND-VAT): A Feasibility Study

Principal Investigator: Sonja M. Reichert, MD MSc CCFP. Assistant Professor, Department of Family Medicine, Western University.

1. Introduction and Invitation to Participate

As you have type 2 diabetes and participated in the one-hour Lifestyle is Medicine education class you are being invited to participate in our research study.

2. Purpose of the Letter

The purpose of this letter is to provide you with the information that is required for you to make an informed decision about participating in our study. We invite you to read this letter closely.

3. Background and Purpose of this Study

The St. Joseph's Primary Care Diabetes Support Program (PCDSP) has offered an in-clinic group program called STAND for people interested in learning more about exercise and nutrition as one type of treatment for type 2 diabetes for the last few years.

Due to COVID-19 restrictions, the program will now be delivered virtually starting in September. Virtual care delivery (i.e., video healthcare appointments) is becoming more common and can decrease travel time and other hassles. Additionally, wearable technology (e.g., FitBits) are now often used in remote healthcare monitoring. However, we do not know if it is feasible to incorporate supervised exercise programming and wearable activity monitors into the clinic's STAND program.

We will offer you the use of activity monitors (a FitBit). We also hope to understand if we can coach you virtually to use this wearable technology and if it affects your confidence in your diabetes management and exercise behaviours. You are being asked to participate because the information collected from your experiences and responses in this study will help us decide if virtual delivery of the STAND program is something we can offer again in the future, and if so, how to improve it.

4. Study Design and Procedures:

If you choose to participate in this study, you will need to first be eligible and medically cleared by a PCDSP nurse practitioner or doctor before participating in this study. The total time you will be involved with the study will be a one-week preparation, two-week

baseline, six-week intervention, and one follow up week immediately after the intervention finishes. The follow up testing and questionnaires will occur one week **after** the **six weeks** of the intervention.

During the intervention, you will be required to attend the program's virtual 1-hour group classes every two weeks (at a prearranged time). The following is a description of additional features of the study (on top of the normal diet/exercise counseling (which includes wearable glucose monitors, FreeStyle Libre sensors (Abbott)) you would usually receive for six weeks through the regular STAND program at the PCDSP if you chose not to participate in this study).

To begin, the clinic will have already provided you this Letter of Information and four short surveys to review. A study investigator will video call you to review any questions you have, then you will confirm your consent to participate via REDCap. REDCap is a secure, online data collection platform; you will be send the link via email to access the consent page. On the same call (if you agree to participate), you will answer the survey questions the Master's student.

The day of your **in-person** orientation class, you will receive your FitBit along with any other STAND related items, including your FreeStyle Libre. During the class, one of the researchers and clinic staff will teach you how to set-up and use your FitBit, along with other parts of the normal STAND program. You will wear the FitBit and your FreeStyle Libre every day after this orientation class until the program completes. Two weeks after the orientation class, you will attend your first **virtual** STAND-VAT class. At the first class you will receive your first personalized step count goal. This program will be individually adjusted every two weeks.

You will be asked to send in your FitBit data and FreeStyle Libre glucose numbers to the clinic ***the day before*** each group class you attend (on Sunday). A PCDSP practitioner will review your glucose data, and the exercise specialist apart of this study (MH) will review your FitBit data. This information *may* be discussed during the 1-hour virtual STAND group session if you volunteer to do so and will be used to create a new bi-weekly personalized step count goal by the exercise specialist. Within one day of the class, you will receive a summary email about your new step goal.

For the six weeks of the intervention, one week after each class, you will be briefly contacted by telephone by the exercise specialist (MH) (these calls will end after 6 weeks). This call is to discuss how your exercise is going, confirm your exercising is safe, and if you have any technology or study questions. One week **after** sixth week of the intervention, you will answer two of the surveys you completed before the program started and an exit survey. The exit survey will ask you about your study experience and for any suggestions for improvement. These surveys will be done on a one-on-one video call with the Master's student. You will be required to return your FitBit to the clinic after the program finishes.

5. Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You also may choose to skip any survey questions that you do not wish to answer, by saying, "pass". You may leave the study at any time without affecting your care. We will give you any new information that is learned during the study that might affect your decision to stay in the study. Additionally, sharing exercise or glucose data with the rest of the class for learning purposes is completely voluntary. You may refuse to share data with the rest of the class without any consequence to your care and will be followed up with a Certified Diabetes Nurse Educator to make sure you understand your own data.

6. Withdrawal from the Study:

If you decide to withdraw from the study, the information that was collected during the study can be removed upon request. No new information will be collected without your permission. You reserve the right to delete your FitBit account if you wish. You, solely, hold your own access to your FitBit account.

7. Benefits:

You may not directly benefit from being in this study. However, you may benefit from this study in a few ways:

a) You will have the opportunity to self-monitor your current physical activity levels by using the FitBit.
b) You will receive personalized exercise programming with support from a coach and other peers to work towards your exercise goals.

Overall, the information learned from this study may be used to lead improved diabetes management strategies in the future, which can benefit other people with diabetes too.

8. Risks, Harms, or Inconveniences:

Expected risks or discomforts related with participating in this study include disruption of your personal time to complete the required needs of the study. We do not expect any severe risks, harms, or inconveniences, however there are a few you need to be aware of:

a) **Inconveniences**: You will need to send in FitBit data every two weeks. You will also be contacted every other week (on weeks without classes) by a researcher to discuss your exercise routine and technology experiences. You may experience technical difficulties (i.e. struggling to figure out your FitBit or how to send your data in), which may increase frustration and/or result in requiring more time than you anticipate. Please note that a clinic IT person or the Master's Kinesiology student will be available to assist you if you need help.
b) **Privacy:** There is always a possibility for privacy breaches. We have taken precautions using encrypted, password protected files and a research-grade data storage server. Our video calling platform is secure and uses encryption software. Like online shopping, teleconferencing/videoconferencing technology has some privacy and security risks. It is possible that information could be intercepted by unauthorized people (hacked) or otherwise shared by accident. This risk cannot be

completely eliminated. It is recommended that you use your home computer or personal device, and not a shared or work device to ensure privacy. For your FitBit account, we will put your email address, birth year, sex, and height/weight in order to get accurate feedback for us and you. Below, you will be asked to review and sign the Patient Acknowledgment and Consent Form FitBit® Activity Program.

c) **FitBit Data:** FitBit data shared with the study investigators will be used using the St. Joseph's Health Care (SJHC)'s secure patient file sharing platform. We will also ask for your email address, as it will be necessary to communicate with you occasionally using email i.e. to send you study questionnaires and study information. Please be aware that email is not a secure or confidential form of communication. As the message leaves SJHC, it is sent across the Internet, where it could be intercepted and read. For this reason, SJHC cannot guarantee the security of messages that are sent to and by us. We will not use email to communicate sensitive personal or health information. Email will NOT be used to communicate emergency or urgent health matters.

d) **Negative feelings**: As changing your lifestyle habits can be very hard, especially on top of daily self-management practices, the study has the potential to:
    a. cause feelings of distress or frustration (e.g., stress from learning to use new technology), or
    b. decrease confidence or feelings of disappointment about lifestyle changes (e.g., you finding you are not achieving your goals like you wanted). We will work with you to make your goals achievable. One of the researchers or exercise leader can always be reached if you are having difficulties with your prescription.

e) **Safety:** As with any exercise, you may be at risk for mild soreness (if you have not exercised in a while), developing a foot blister, and even hypoglycemia if you are taking medication that can cause hypoglycemia. Before starting the program, you will be medically cleared to ensure high levels of safety while participating in this study. We will also teach you how to exercise safely as a person with Type 2 Diabetes.

9. Confidentiality:

Special care will be given to protect your confidentiality. Identifying information (phone number, email address, names and date of birth), will be kept separate from our main study data and will be stored on a password protected, secure, research grade platform (REDCap). All other electronic study documents will be labeled with only your study number and will be encrypted, and password protected on the Western OneDrive; this data will be wiped after the study completes. All study-related information will be kept for 15 years after the study has been completed. Representatives of Western's Research Ethics Board and the Lawson Quality Assurance and Education Program may contact you or may access your study-related records to monitor the conduct of the research.

The information from this research project will be submitted, when the study ends, for publication in a peer-reviewed academic journal as well as presented at related conferences. You will not be named in any report, publication or presentation resulting from this study.

10. Costs:

You will not have to pay to participate in this study.

11. Rights as a Participant:

You do not waive any legal right by signing this consent form

12. Conflict of Interest:

Some of the clinicians are our study investigators. Thus, the doctor or nurse practitioner treating you may also be the practitioners in charge of this study. Participating in this study, however, will in no way jeopardize your care at PCDSP.

13. Questions About the Study:

If you have any questions regarding your participation in the study, please contact one of our co-investigators, Elizabeth Harvey (RNEC, MScN CNS/ Nurse Practitioner) at or Dr. Sonja Reichert (Co-Principal Investigator); or Dr. Marc Mitchell (Co-Principal Investigator) or Madison Hiemstra (Master's Student at Western University).

If you have any questions about your rights as a research participant or the conduct of this study, you may contact SJHC Patient Relations Phone at 519 646-6100, ext. 61234; email: patientrelations@sjhc.london.on.ca.

Patient Acknowledgment and Consent Form: FitBit® Activity Program

As part of my care at the Primary Care Diabetes Support Program, I understand that I may choose to participate in a fitness program/evaluation whereby I will wear a FitBit Inspire HR and share my activity details with my care team. This information will assist my care team in monitoring my activity and prescribing appropriate activity plans, remotely.

I further understand that if I choose to participate in this program, the FitBit hardware will be loaned to me on a temporary basis (12 weeks) and must be returned to my care provider at the end of this timeframe.

I understand that I must create a profile with FitBit at https://www.fitbit.com/en-ca/home, and will be responsible for reading, accepting, and following the FitBit Terms of Service and Privacy Policy. These terms include, but are not limited to, FitBit's license to use, copy, modify, reproduce, use publicly, etc. any photos, video, text, etc. that I choose to upload to my profile. The Privacy Policy outlines how FitBit collects, stores and uses your information. Please note that the Privacy Policy indicates that it uses encryption with many of its services, however no method of transmitting or storing data is completely secure. Additionally, FitBit is an international company and information you add to your profile may be stored in various locations, including those outside of Canada, which may not have the same privacy standards. I understand and agree that I will provide my care team with access to my activity log in order to facilitate and prescribe my activity plan. I have had the opportunity to ask any and all questions I may have and have had all questions answered to my satisfaction.

Letter of Information and Consent: Closed Protocol

Study Title:	Virtually Delivered Lifestyle Program Integrating Wearable Technology and Exercise Prescriptions in Patients with Type 2 Diabetes (STAND-VAT): A Feasibility Study
Principal Investigator:	Sonja M. Reichert, MD MSc CCFP. Assistant Professor, Department of Family Medicine, Western University.

1. Introduction and Invitation to Participate

As you have type 2 diabetes and participated in the one-hour Lifestyle is Medicine education class you are being invited to participate in our research study.

2. Purpose of the Letter

The purpose of this letter is to provide you with the information that is required for you to make an informed decision about participating in our study. We invite you to read this letter closely.

3. Background and Purpose of this Study

The St. Joseph's Primary Care Diabetes Support Program (PCDSP) has offered an in-clinic group program called STAND for people interested in learning more about exercise and nutrition as one type of treatment for type 2 diabetes for the last few years.

Due to COVID-19 restrictions, the program will now be delivered virtually starting in September. Virtual care delivery (i.e., video healthcare appointments) is becoming more common and can decrease travel time and other hassles. Additionally, wearable technology (e.g., FitBits) are now often used in remote healthcare monitoring. However, we do not know if it is feasible to incorporate supervised exercise programming and wearable activity monitors into the clinic's STAND program.

We will offer you the use of activity monitors (a FitBit). We also hope to understand if we can coach you virtually to use this wearable technology and if it affects your confidence in your diabetes management and exercise behaviours. You are being asked to participate because the information collected from your experiences and responses in this study will help us decide if virtual delivery of the STAND program is something we can offer again in the future, and if so, how to improve it.

4. Study Design and Procedures:

If you choose to participate in this study, you will need to first be eligible and medically cleared by a PCDSP nurse practitioner or doctor before participating in this study. The total time you will be involved with the study will be a one-week preparation, two-week baseline, six-week intervention. Please note, the follow up testing and questionnaires will occur **one week after the sixth week** intervention.

During the six-week intervention period, you will be required to attend the program's virtual one-hour group classes every two weeks (at a prearranged time). The following is a description of additional features of the study (on top of the normal diet/exercise counseling (which includes wearable glucose monitors, FreeStyle Libre sensors (Abbott)) you would usually receive for six weeks through the regular STAND program at the PCDSP if you chose not to participate in this study).

To begin, the clinic will have already provided you this Letter of Information and four short surveys to review. A study investigator will video call you to review any questions you have, then you will confirm your consent to participate via REDCap. REDCap is a secure, online data collection platform; you will be sent the link via email to access the consent page. On the same call (if you agree to participate), you will answer the survey questions.

The day **before** your first virtual group orientation class, you will drop by the clinic to pick up your FitBit and FreeStyle Libre. During the **virtual** orientation class, one of the researchers and clinic staff will teach you how to set-up and use your FitBit, along with other parts of the normal STAND program. You will wear the FitBit every day after this orientation class until the program completes. Two weeks after the orientation class, you will attend your first **virtual** STAND-VAT class. At the first class you will receive your first personalized step count goal. This program will be individually adjusted every two weeks.

You will be asked to send in your FitBit data and FreeStyle Libre glucose numbers to the clinic ***the day before*** each group class you attend (on Sunday). A PCDSP practitioner will review your glucose data, and the exercise specialist apart of this study (MH) will review your FitBit data. This information *may* be discussed during the one-hour virtual STAND group session if you volunteer to do so and will be used to create a new bi-weekly personalized step count goal by the exercise specialist. Within one day of the class, you will receive a summary email about your new step goal.

For the six weeks of the intervention, one week after each class, you will be briefly contacted by telephone by the exercise specialist (MH). This call is to discuss how your exercise is going, confirm your exercising is safe, and if you have any technology or study questions. During the seventh week of the intervention, you will answer two of the surveys you completed before the program started and an exit survey. The exit survey will ask you about your study experience and for any suggestions for improvement. You will also recomplete the two-minute fitness test. These surveys and fitness test will be done on a one-on-one video call with the Master's student and a physician present. **After the first six weeks** of the intervention, the telephone calls with the exercise specialist and glucose monitor supply will end. You will continue to attend classes and wear your FitBit, send in your FitBit data and receive exercise prescriptions. You will be required to return your FitBit to the clinic after the six weeks of the intervention ends.

5. Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You also may choose to skip any survey questions that you do not wish to answer, by saying, "pass". You may leave the study at any time without affecting your care. We will give you any new information that is learned during the study that might affect your decision to stay in the study. Additionally, sharing exercise or glucose data with the rest of the class for learning purposes is completely voluntary. You may refuse to share data with the rest of the class without any consequence to your care and will be followed up with a Certified Diabetes Nurse Educator to make sure you understand your own data.

6. Withdrawal from the Study:

If you decide to withdraw from the study, the information that was collected during the study can be removed upon request. No new information will be collected without your permission. You reserve the right to delete your FitBit account if you wish. You, solely, hold your own access to your FitBit account.

7. Benefits:

You may not directly benefit from being in this study. However, you may benefit from this study in a few ways.

a) You will have the opportunity to self-monitor your current physical activity levels by using the FitBit.
b) You will receive personalized exercise programming with support from a coach and other peers to work towards your exercise goals.

Overall, the information learned from this study may be used to lead improved diabetes management strategies in the future, which can benefit other people with diabetes too.

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B) Privacy: There is always a possibility for privacy breaches. We have taken precautions using encrypted, password protected files and a research-grade data storage server. Our video calling platform is secure and uses encryption software. Like online shopping, teleconferencing/videoconferencing technology has some privacy and security risks. It is possible that information could be intercepted by unauthorized people (hacked) or otherwise shared by accident. This risk can't be completely eliminated. It is recommended that you use your home computer or

personal device, and not a shared or work device to ensure privacy. For your FitBit account, we will put your email address, birth year, sex, and height/weight in order to get accurate feedback for us and you. Below, you will be asked to review and sign the Patient Acknowledgment and Consent Form FitBit® Activity Program.

C) FitBit Data: FitBit data shared with the study investigators will be used using the St. Joseph's Health Care (SJHC)'s secure patient file sharing platform. We will also ask for your email address, as it will be necessary to communicate with you occasionally using email i.e. to send you study questionnaires and study information. Please be aware that email is not a secure or confidential form of communication. As the message leaves SJHC, it is sent across the Internet, where it could be intercepted and read. For this reason, SJHC cannot guarantee the security of messages that are sent to and by us. We will not use email to communicate sensitive personal or health information. Email will NOT be used to communicate emergency or urgent health matters.

D) Negative feelings: As changing your lifestyle habits can be very hard, especially on top of daily self-management practices, the study has the potential to:

a. cause feelings of distress or frustration (i.e., stress from learning to use new technology), or
b. decrease confidence or feelings of disappointment about lifestyle changes (i.e., you finding you are not achieving your goals like you wanted). We will work with you to make your goals achievable. One of the researchers or exercise leader can always be reached if you are having difficulties with your prescription.
c. **Safety:** As with any exercise, you may be at risk for mild soreness (if you have not exercised in a while), developing a foot blister, and even hypoglycemia if you are taking medication that can cause hypoglycemia. Before starting the program, you will be medically cleared to ensure high levels of safety while participating in this study. We will also teach you how to exercise safely as a person with Type 2 Diabetes.

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The information from this research project will be submitted, when the study ends, for publication in a peer-reviewed academic journal as well as presented at related conferences. You will not be named in any report, publication or presentation resulting from this study.

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11. Rights as a Participant:

You do not waive any legal right by signing this consent form

12. Conflict of Interest:

Some of the clinicians are our study investigators. Thus, the doctor or nurse practitioner treating you may also be the practitioners in charge of this study. Participating in this study, however, will in no way jeopardize your care at PCDSP.

13. Questions About the Study:

If you have any questions regarding your participation in the study, please contact one of our co-investigators, Elizabeth Harvey (RNEC, MScN CNS/ Nurse Practitioner) at or Dr. Sonja Reichert (Co-Principal Investigator) or Dr. Marc Mitchell (Co-Principal Investigator), or Madison Hiemstra (Master's Student at Western University).

If you have any questions about your rights as a research participant or the conduct of this study, you may contact SJHC Patient Relations Phone.

Patient Acknowledgment and Consent Form: FitBit® Activity Program

As part of my care at the Primary Care Diabetes Support Program, I understand that I may choose to participate in a fitness program/evaluation whereby I will wear a FitBit Inspire HR and share my activity details with my care team. This information will assist my care team in monitoring my activity and prescribing appropriate activity plans, remotely.

I further understand that if I choose to participate in this program, the FitBit hardware will be loaned to me on a temporary basis (12 weeks) and must be returned to my care provider at the end of this timeframe.

I understand that I must create a profile with FitBit at https://www.fitbit.com/en-ca/home, and will be responsible for reading, accepting and following the FitBit Terms of Service and Privacy Policy. These terms include, but are not limited to, FitBit's license to use, copy, modify, reproduce, use publicly, etc. any photos, video, text, etc. that I choose to upload to my profile. The Privacy Policy outlines how FitBit collects, stores and uses your information. Please note that the Privacy Policy indicates that it uses encryption with many of its services, however no method of transmitting or storing data is completely secure. Additionally, FitBit is an international company and information you add to your profile may be stored in various locations, including those outside of Canada, which may not have the same privacy standards.

I understand and agree that I will provide my care team with access to my activity log in order to facilitate and prescribe my activity plan.

I have had the opportunity to ask any and all questions I may have and have had all questions answered to my satisfaction.

Appendix D

PCDSP Physical Activity Assessment Form

Patient Survey Date :			NP/MD Assessment		
Yes	**No**		**Yes**	**No**	
□	□	As a rule, do you **do less than** 30 minutes of moderate to vigorous exercise (such as brisk walk) **less than** 5 days per week?	□	□	BP > target 130/80?
□	□	As a rule, do you **do less than 10 minutes** per session of moderate activity , on some days of the week?	□	□	Hx of CAD or in need for vascular surveillance
□	□	As a rule, do you do muscle strengthening activities on **less than** 2 days a week?	□	□	Tx with Su/Insulin?
□	□	Has your doctor ever said that you have a heart condition or high blood pressure?	□	□	Hx Diabetes Retinopathy or >1 yr since last DEE?
□	□	Do you feel any discomfort in you your chest/shoulder/arm/back/neck or jaw with physical activity?	□	□	Foot Score >0?
□	□	Do you experience unexplained shortness of breath with minimal exertion?	**NP/MD Recommendations**		
□	□	Do you lose balance because of dizziness or have you ever passed out?	□	□	Requires Medically supervised exercise prescription
□	□	Has your doctor ever said that you have peripheral vascular disease (any calf pain with walking)?			
□	□	Have you experienced a stroke or a transient ischemic attack (mini stroke)?	Date:		Signature
□	□	Any Change in the above?			
□	□	Any change in the Above?			
□	□	Any change in the Above?			
□	□	Any change in the Above?			
□	□	Any change in the Above?			

03/10/2019

Appendix E

Group education class topics identified by the Behaviour Change Techniques Taxonomy (BCT) (Michie et al., 2013)

BCT Number	*BCT*	*Intervention Component*
1.2	Problem solving	Encouraged identifying barriers from previous experiences (and other behaviour changes) and the value of anticipating barriers prior to them occurring.
1.4	Action planning	Discussed the importance of action planning and how to do it.
2.4	Self-monitoring of behaviour	Discussed the importance of self-monitoring behaviours and methods on how (and provided some tools as well) to track their activity.
3.2	Social support (practical)	Discussed a) the benefit of social support when it comes to behaviour change b) how to identify those who support/don't support the person, and c) how to ask for support.
4.1	Instruction on how to perform a behaviour	Repetitive discussion on the *how* to achieve minutes of exercise and daily step count goals. Discussed how to start out and progress exercise, and how to individualize exercise habits to optimize exercise behaviour adoption and maintenance.
4.2	Information of Antecedents	Encouraged participants to become mindful of (a) certain triggers that result in habitual behaviours (and how to use the trigger while changing the habit sequence) and (b) mindful or recording about thoughts, self-talk before initiating behaviour performance (to understand what makes them successful in doing a healthy exercise or food behaviour).
5.4	Monitoring emotional consequences	Discussed being mindful and/or recording feelings after performing a behaviour (journal, phone notes, smiley faces on the calendar). E.g., monitoring their overall feeling (e.g., glad they did it). If negatively viewed, reflecting on the *why*. Encouraged awareness of the emotional aftereffects of exercise, so that they can use the memory of positive experiences to motivate them to engage in the behaviour again.
5.6	Information about emotional consequences	Discussed the mental health benefits of exercise and health food.
7.1	Prompts/cues	Discussed how to set up cue/triggers to initiate habitual sequences.
7.2	Cue signaling reward	Discussed the importance of choosing a reward that will make you want to develop a habit; how to make a reward the end point of a habit cycle.
8.2	Habit substitution	E.g., discussed replacing sedentary time with light physical activity or exercise strategies, or replacement of types of foods with low carbohydrate alternatives.
8.3	Habit formation	Discussed how rehearsal and repetition of behaviour leads to habit formation.
10.4	Social reward	Congratulated all participants on an achievement, regardless of achievement size. E.g., "Everyone's glucose levels are looking amazing! Tina, I see improvements in those morning spikes! Way to go!"
11.2	Reduce negative emotions	Advised ways to reduce negative emotions to help facilitate behaviours. Discussions focused on recognizing and addressing negative thoughts in relation to behaviour change.
13.1	Identification of self as a role model	Encouraged the class to share as many experiences and thoughts with others and the importance as to why sharing is important (as related experiences may motivate or set an example for others to try new healthy behaviours/strategies).
15.3	Focus on past success	Instructed participants to think about what has made them successful previously with exercising or eating healthy (or any behaviour change).
15.4	Self-talk	Instructed participants to talk back to their negative thoughts and to talk to positively to themselves. E.g., "I will feel refreshed after this walk."

Appendix F

Exercise Prescription: Aerobic Exercise

Participants received individualized aerobic exercise prescriptions created by the exercise specialist (with medical clearance from the investigating physician). New step count prescriptions were given bi-weekly via an official email stating their new daily step count goal. Additionally, the email contained positive feedback about the past-two weeks performance (e.g., “You got 9/14 days of your step goal, which is amazing! This week, with your new step count goal, think of an activity goal that can help you try to consistently achieve this step count each day”). If the goal achievement was low, other positive feedback was given.

This was a feasibility study that looked at remotely offering individualized exercise prescriptions utilizing a wearable activity monitor and did not test the efficacy of a step count prescription. Aerobic exercise was chosen for this study to increase safety, as opposed to resistance training, which is often new to many people and may require intensive guidance from an exercise specialist (Sigal et al., 2018).

An adaptive goal setting approach was utilized, as it has shown to be appropriate for increasing and/or creating manageable goals for participants (Adams et al., 2013). This approach was taken so that the step goals did not continue to rise if the participant was not similarly ramping up their step count (unlike other “static” interventions that do not consider variability in daily life contexts/events and within person variability that affect daily step counts and activity) (Bickel and Vuchinich, 2000; Adams et al., 2013). The Look AHEAD trial prescribed a reasonable 250-step goal increase each week over the course of the study, though the prescription was linearly static (increased regardless). This adaptive approach allowed individualized daily step count targets to be calculated using activity data from the previous two weeks.

Appendix G

Description of Protocol

Virtual Technology Orientation Preparation (only for 'closed' protocol)

The morning prior to the virtual technology orientation class, participants drove by the diabetes clinic to pick-up study supplies (FitBit Inspire 2™ device, four FreeStyle® Libres, and the study booklet) via curbside pick-up.

Technology Orientation Class (in person for 'open' protocol, on WebEx® for 'closed' protocol)

The technology orientation class helped orient and teach participants how to set up and use the program technology. First, a CDNE taught participants how to apply FreeStyle® Libre (for future applications) and understand the basics of data interpretation. Participants downloaded, created accounts for, and learned how to use the FitBit® smartphone app and FreeStyle® Libre's associated app, LibreLink. Participants linked their LibreLink account to the clinic's LibreView account. Participants were encouraged to keep push-notifications on for reminders to move every hour on their FitBit Inspire 2™. Procedures for downloading and exporting FitBit Inspire 2™ data and other study tasks were discussed. Participants were given instructions about their FitBit Inspire 2™, exercising safely, and participant study tasks via a pre-printed study booklet. As well, an email containing links to investigator-created video tutorials and other helpful videos posted on YouTube, was sent after class. Participants wore the FitBit Inspire 2™ and FreeStyle® Libre immediately thereafter and continued to wear it the rest of the virtual lifestyle medicine program. Participants received study supplies in-person at this class for OPEN protocol.

T2: Baseline Step Count and Familiarization

Participants wore their FitBit Inspire 2™ and FreeStyle® Libre's for two weeks, prior to the first group education class. This served as a baseline to collect step (informing their individualized step count prescription) and glucose data and to familiarize participants

with the technology. Participants were encouraged to try to remain in pre-study activity levels and behaviour. One week after the technology orientation class, the exercise specialist briefly called participants to encourage: timely glucose scanning, exploration of the LibreLink and FitBit® apps, and FitBit Inspire 2™ features, and clarify on study procedures.

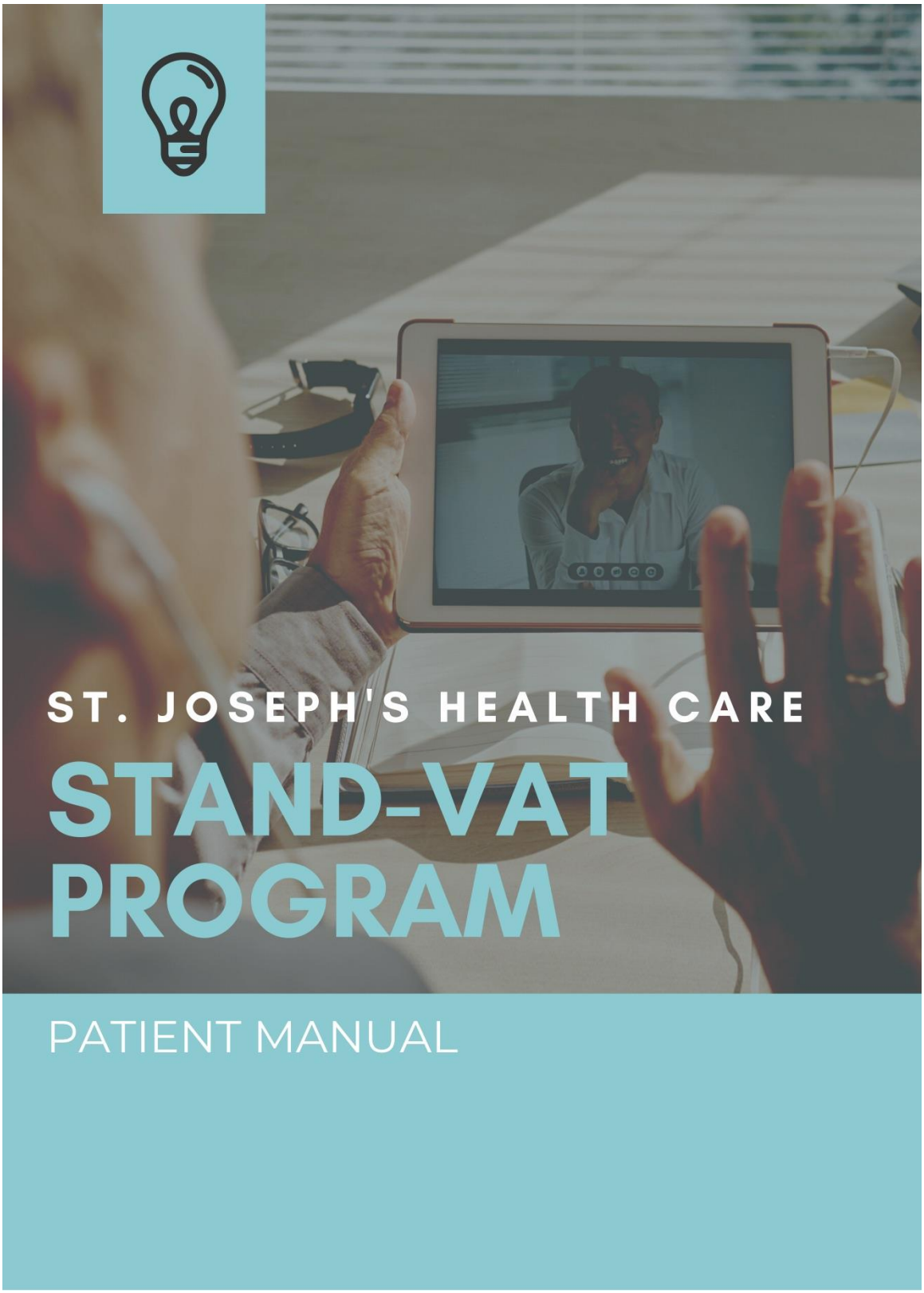
Intervention (Weeks 1 to 6)

During the six-week intervention, participants continued to receive normal or standard clinical care at the diabetes clinic as determined by their clinical team, in addition to the intervention. Participants attended group education classes and received a new exercise prescription on week 1, 3 and 5. One-on-one check-in calls were completed on week 2, 4 and 6.

Follow-Up

Participants completed the Stanford Self-Efficacy survey, PAID-5, and exit survey. Participants returned their FitBit Inspire 2™ devices to the clinic.

Appendix H



WELCOME

We're so glad you are part of the team.

CLINIC CONTACTS:

Clinic phone number:

Dr. Sonja Reichert, MD, MSc, CCFP
Position: Principle Investigator, Primary Care Physican

Dr. Marc Mitchell, PhD
Associate Professor, Western University
Position: Co-Investigator

Madison Hiemstra, BSc, CSEP-CPT
Master's Student
Position: Co-Investigator, Exercise Leader

TABLE OF CONTENTS

PARTICIPANT EXPECTATIONS

As you have agreed to participate in the STAND-VAT study (in the below items), we have broken down the activities required of you during the study period:

THE SET-UP WEEK

- Speak study investigator about the study and sent to participate, plus answer four short surveys and complete a 2-minute step test on a one-on-on video call.

TWO WEEKS BEFORE THE FIRST CLASS

- Attend your **orientation session (Monday)** to set up your FitBit Inspire HR, Libre Freestyle and their respective apps, as well as how to effectively engage in a group video format.
- Wear the FitBit Inspire HR and sync your data to the FitBit app (open your FitBit app) .
- Send in FitBit Data **ON SUNDAY BEFORE THE FIRST CLASS** to receive your individualized exercise prescription.
- Wear the Libre Freestyle glucose monitor and scan within every 8 hours with your phone app.

DAILY

- Sync your FitBit Inspire HR to the FitBit app and your Libre.
- Get those steps in!
- Record notes about your food and activity in the LibreLink app notes section.

BIWEEKLY

- On Sunday, one day prior (to the Monday group class), share your past two weeks FitBit data with the clinic by email (see instruction sheet for more detail).
- Make sure your Libre data is properly synced to the clinic (open the LibreLink app and have internet access).
- Attend bi-weekly video group classes through the WebEx platform; classes will be one-hour long.
- Replace your FreeStyle Libre on the day of the group class.

BIWEEKLY (on opposite weeks to the virtual group classes):

- Be available for a short weekly follow-up phone call to go over any medical changes, and talk about exercise or any concerns/needs/questions (5-10 minutes).

THE WEEK AFTER THE PROGRAM ENDS

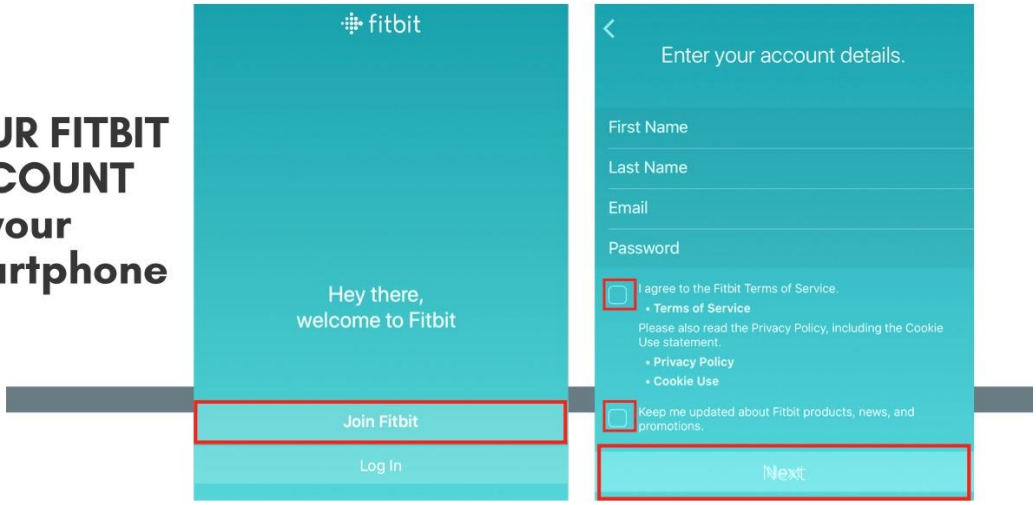
- On a one-on-one video call, re-complete two of the surveys (that you did before the study started)
- On the same call, complete an exit survey to review your experiences with the program and receive feedback on the phone AND re-complete the 2-minute step test.
- Return your FitBit Inspire HR to the clinic (in person).



SETTING UP YOUR ACCOUNTS

We recommend that you record your account username and passwords somewhere you will be able to find them if you need to re-login to your account at any point.

YOUR FITBIT ACCOUNT on your smartphone



YOUR LIBRELINK and LIBREVIEW ACCOUNTS

LibreLink app account

Download the app (give your phone permission to download)

2. Find the app on your home screen and click it, then click "Get Started Now"
3. Choose your country, accept the terms of use, and privacy
4. Enter your first name, last name and date of birth in the **Create New Account** page
5. Create an account – record username and password somewhere
6. Verify account (by checking your email that you used to create an account, click the "**verify**" button).

LibreView Account (desktop or laptop computer views) *_if you wish to view_

First: *Remember the email address and password you've chosen, as the same logins will be used when you set up your LibreView account)*

1. Head to http://libreview.com/
2. Use the same username and password you have for the LibreLink app
3. Click the rectangle with the squiggle in the upper left corner of the screen, bringing you to glucose history. From there, you will be able to access your glucose reports.

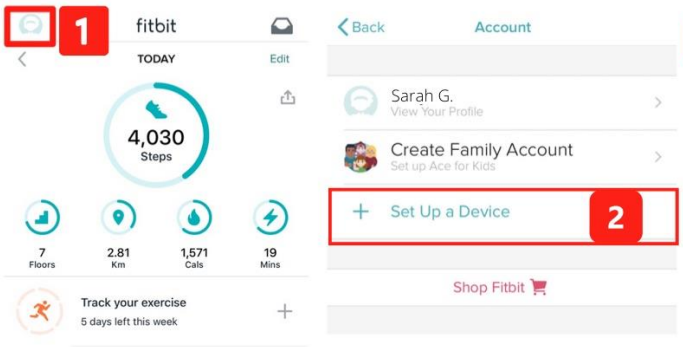
USING YOUR FITBIT: SET UP

1 CHARGE YOUR TRACKER

To set up Inspire 2, connect it to the charging cable. Your Inspire 2 can be charged with or without the watch straps on. Make sure it is plugged into a USB port on your computer or wall outlet.

2 CONNECT YOUR DEVICE

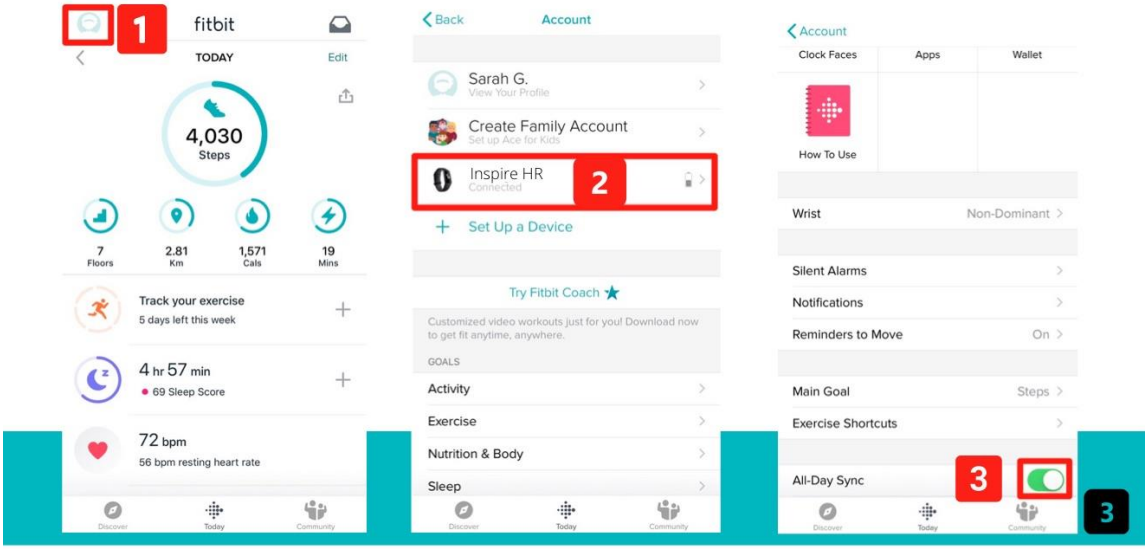
Next, download the app from the Google Play or Apple App Store. Create or log in to your Fitbit account and connect your tracker.



3 Follow on screen instructions to continue to set up. You may or may not be prompted to "update" the software on screen. Accept these changes.

3 AUTOMATICALLY SYNC

Next, create or log in to your Fitbit account and connect your tracker.



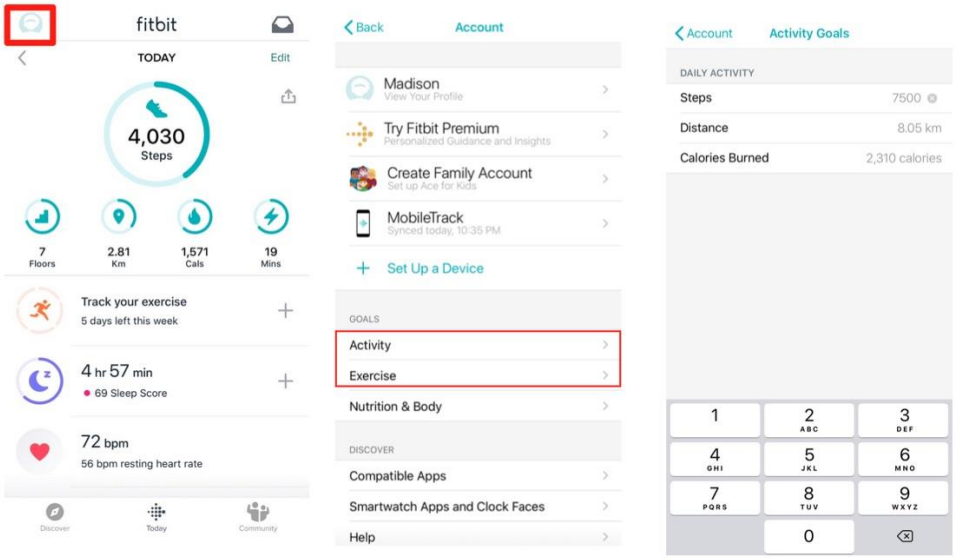
USING YOUR FITBIT: STEPS & EXERCISE

SETTING YOUR DAILY STEP GOAL

Every 2 weeks you may or may not need to update your step prescription.

To start, make sure you are on the Today Page

1. Click your account
2. Click on either Activity or Exercise
3. On the **Activity Goals page**, click **STEPS**. This should bring up a number pad to type your new step goal prescription in.
4. On your **Exercise page,** pick the **NUMBER** of days you want to make it a goal to exercise on! We want to shoot for at least 3 days per week, with no more than two consecutive days without exercise. Any exercise, no matter the length is EXERCISE!



HOW DO I START AND STOP AN EXERCISE ON MY FITBIT DEVICE?

1. On your tracker, open the Exercise app and swipe to find an exercise.
2. Tap the exercise to choose it. If GPS is available, an icon appears at the top as your device tries to connect.
3. Tap the play icon to start, or swipe up to set an exercise goal. If you set a goal, press the button to go back and tap the play icon.
4. Tap the middle of the screen to scroll through your real-time stats.
5. To pause or end your workout, press the button.
6. To resume, tap the play button.
7. Press the button again, and tap Finish to end the workout.
8. Swipe up to see your workout summary.
9. Press the sides of the FitBit to close the summary screen.
10. To see your GPS data, sync your tracker and tap the Exercise tile in the Fitbit app.

This was adapted from: https://fitbit.secure.force.com/articles/en_US/Help_article/1935#workouts

USING YOUR FITBIT: HOURLY MOVEMENT

WHAT'S MY HOURLY ACTIVITY GOAL ON MY FITBIT DEVICE?

To start, your goal is to take at least 250 steps per hour (which equals a few minutes of walking) from 9:00 a.m. - 6:00 p.m., 7 days a week. You can adjust the hours that you track your goal and receive reminders to move.

HOW DO I SEE HOW MANY HOURS PER DAY I MET MY HOURLY ACTIVITY GOAL?

On most devices, check your progress on your wrist in Fitbit Today button ( ).

1. From the clock screen, swipe up to open Fitbit Today button ( )
2. On the Hourly Activity tile button ( ) see how many steps you took this hour.
3. Swipe to see how many hours you met your goal today.

You can also learn more about your time spent moving versus sitting in the Fitbit app:

1. From the Today tab (button) in the Fitbit app, tap the hourly activity tile button ( ).
2. On the graph at the top, swipe left to see your longest stationary period (the single longest period of time you spent sitting) each day over the past week.
3. Tap Today to see your longest stationary period today and your 30-day average. The All Day Breakdown shows the percentage of the day you spent active versus inactive.

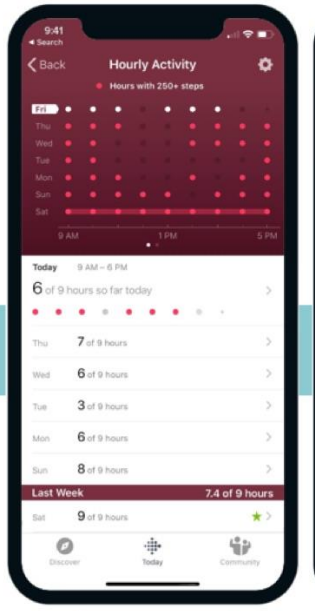


Figure 1

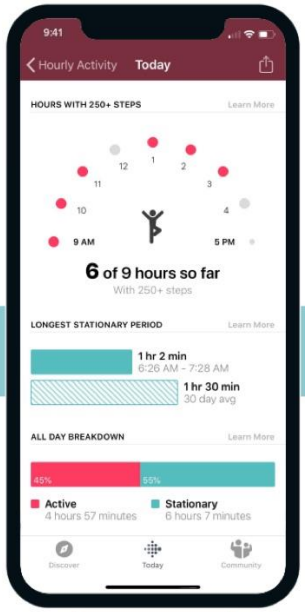


Figure 2

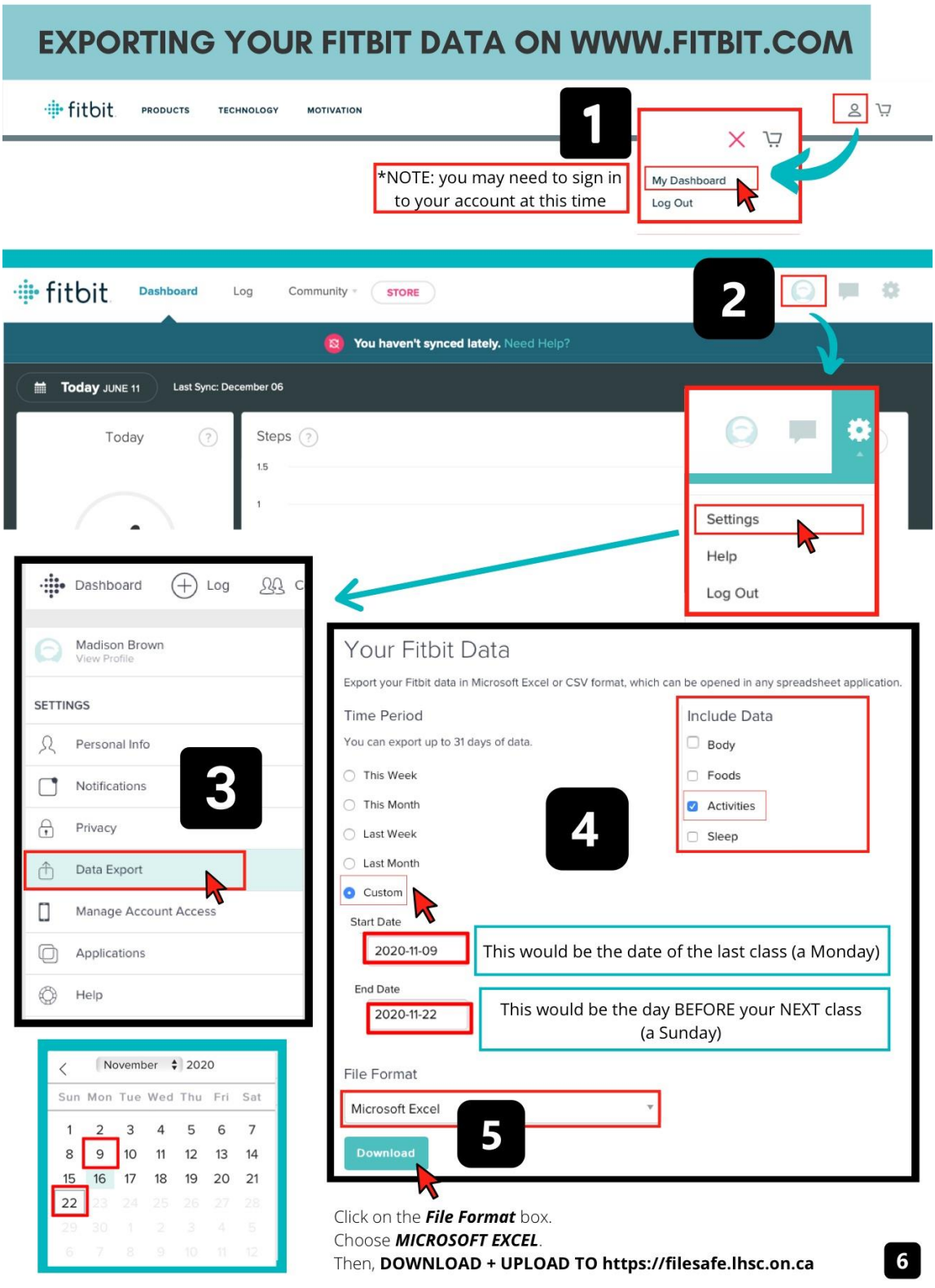
HOW CAN I CHANGE MY HOURLY MOVEMENT GOAL TIME FRAMES?

To change the 12-hour time period to achieve your 250+ steps, click the the upper right screen on your hourly activity screen (Figure 1).

WHAT ARE HOURLY MOVEMENT GOALS?

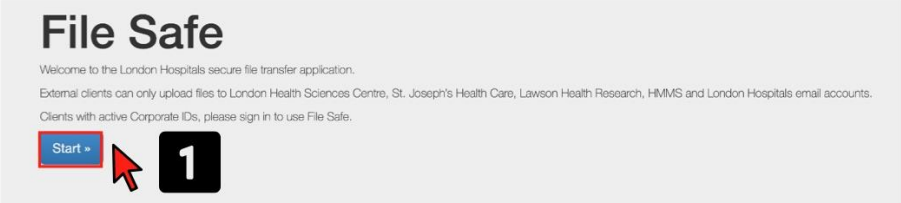
Hourly Movement goals are hours with 250 or more steps taken. Your Inspire 2 will remind you to get moving 10 minutes before hour is up to move around, limber up and get the blood flowing!

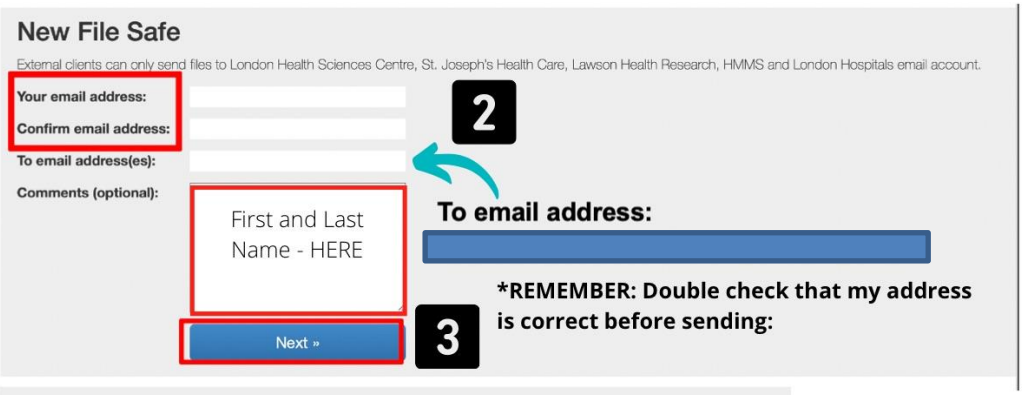
These instructions have been adapted from: https://help.fitbit.com/articles/en_US/Help_article/1878


EXPORTING YOUR FITBIT DATA ON WWW.FITBIT.COM
fitbit
PRODUCTS
TECHNOLOGY
MOTIVATION
1
*NOTE: you may need to sign in to your account at this time
My Dashboard
Log Out
fitbit
Dashboard
Log
Community
STORE
2
You haven't synced lately. Need Help?
Today JUNE 11
Last Sync: December 06
Today
Steps
Settings
Help
Log Out
Dashboard
Log
Madison Brown
View Profile
SETTINGS
Personal Info
Notifications
Privacy
Data Export
Manage Account Access
Applications
Help
3
Your Fitbit Data
Export your Fitbit data in Microsoft Excel or CSV format, which can be opened in any spreadsheet application.
Time Period
You can export up to 31 days of data.
This Week
This Month
Last Week
Last Month
Custom
4
Include Data
Body
Foods
Activities
Sleep
Start Date
2020-11-09
This would be the date of the last class (a Monday)
End Date
2020-11-22
This would be the day BEFORE your NEXT class (a Sunday)
File Format
Microsoft Excel
5
Download
November 2020
Sun Mon Tue Wed Thu Fri Sat
Click on the File Format box.
Choose MICROSOFT EXCEL.
Then, DOWNLOAD + UPLOAD TO https://filesafe.lhsc.on.ca
6

UPLOADING YOUR DATA ON FILESAFE.LHSC.ON.CA

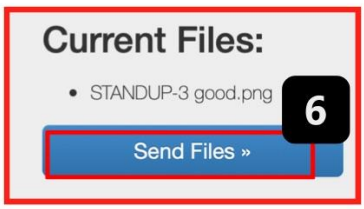
After downloading your Excel Document with your FitBit data, you need to **UPLOAD IT TO https://filesafe.lhsc.on.ca**





4 After clicking "**Choose File**" - go to (likely) your Downloads folder *(see either PC or Mac picture, depending on your computer)* and **click on** the Excel File you downloaded from FitBit. **Click "Choose"** at the right bottom corner of the file folder.

5 You should see your file name pop up and then click "**Add File**"



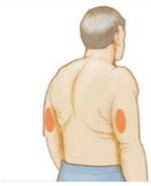
6 Click - **Send your Files**... and you're done!

7

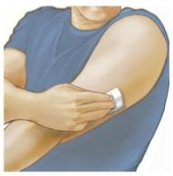
FREESTYLE BLOOD GLUCOSE READER SET-UP

This is the FreeStyle Libre Sensor. It is a flash glucose monitoring system that updates glucose results up to every minute and stores up to 8 hours of glucose readings in 15 minute intervals. It can be worn for a maximum of 14 days. *You will also be taught how to apply and remove this device from the back of your upper arm.

PART 1: GET READY

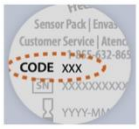


Select site on back of upper arm. Do not use other sites as these are not approved and may result in inaccurate glucose readings.
Note: Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.



Clean site with alcohol wipe. Allow site to dry before proceeding.

Peel lid completely off Sensor Park. Unscrew cap from Sensor Applicator.



CAUTION: Sensor codes must match on Sensor Pack and Sensor Applicator or glucose readings will be incorrect.

PART 2: PREPARE SENSOR APPLICATOR

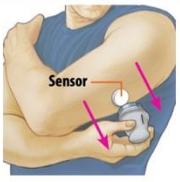
Line up dark mark on Sensor Applicator with dark mark on Sensor Pack. On a hard surface, press down firmly on Sensor Applicator until it comes to a stop.

Lift Sensor Applicator out of Sensor Pack.

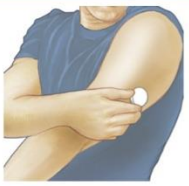
Sensor Applicator is ready to apply Sensor. **CAUTION**: Sensor Applicator now contains a needle. Do not touch inside Sensor Applicator or put it back into Sensor Pack

PART 3: APPLY SENSOR

Place Sensor Applicator over site and push down firmly to apply Sensor. **CAUTION**: Do not push down on Sensor Applicator until placed over prepared site to prevent unintended results or injury.



Gently pull Sensor Applicator away from your body.



Make sure Sensor is secure. Discard used Sensor Applicator and Sensor Pack according to local regulations.

If you have any more questions, check out their FAQ page: https://www.freestyle.abbott/ca/en/products/libre/faqs.html

EXERCISING SAFELY

Hypoglycemia

- If you use insulin or a sulfonylurea (i.e. Diamieron or Glyburide), you may be at increased risk of hypoglycaemia (**low blood sugar**) during exercise, however it is still relatively rare (2).
- ***What is hypoglycaemia?*** Hypoglycemia is glucose levels of <3.9-4 mmol/L.
  *However, it is possible to start exercising a 8t mmol/L but drop during or after exercise to 5 mmol/L, at which point you ***may*** experience hypoglycemia symptoms (1).
- You need to be monitoring glucose levels before, during and after exercise (and before driving after exercise) ***and*** **BE PREPARED** to treat hypoglycemia (1).
- Hypoglycemia is most often seen right after exercise, but can occur up to 12 hours after exercise completion (2).
- Consider recording how you feel before and after exercise, and watch your glucose levels to better understand the effects of exercise on your glucose levels especially during your first week of exercising (3).

RECOGNIZE YOUR SIGNS OF HYPOGLYCEMIA! (2)

- Sweating
- Headache, dizziness or nausea
- Trembling or tingling
- Extreme tiredness and paleness
- Hunger
- Blurred vision, drowsiness, confusion
- Difficulty concentrating
- Mood changes, like anxiety
- Palpitation or racing heart

Everyone experiences hypoglycaemic symptoms differently...so make sure you are paying attention and listening to you body!

THE 15:15 RULE

1. Consume 15g of carbohydrates
2. Wait 15 minutes
3. Check glucose again
4. Repeat if no change

TREAT: If glucose levels are <5.5 mmol/L BEFORE exercising (1)

EXERCISING SAFELY

EXERCISING IN COLD WEATHER

- Do not exercise outside in -10˚C weather.
- Wear layers and clothes for cold weather.
  - This will keep you warm and make exercise more comfortable.
  - The clothes closest to your skin should be moisture wicking "dry-fit" material, as sweat sticking to clothing can get cold.
  - Clothing material such as polyester or a ribbed shirt with wool/cotton blend works well.
- Find a route that is clear of snow and ice.

TAKING CARE OF YOUR FEET (1,6)

Foot Care

People with Type 2 Diabetes can experience nerve damage and foot ulcers. Foot care is important to avoid any necessary foot complications (1,6).

- Inspect your feet daily
- Wash your feet everyday, dry them very well especially in between toes.
- Moisturize feet if they are dry. If you have cracks on your feet, contact your doctor
- Always check for blisters
- ***DO NOT exercise if you have a sore or blister.***
- ***Buy good running shoes!!***
  - *If in doubt, speak to your Primary Care Diabetes Care Provider.*

SPECIAL NOTE:

If you feel dizzy, shortness of breath (that continues for longer than usual/or are unable to catch your breath, chest pain while exercising, STOP exercising and call your doctor and/or 911(4).

REFERENCES

1.Embil JM, Albalawi Z, Bowering K, Trepman E. 2018 Clinical Practice Guidelines Foot Care Diabetes Canada Clinical Practice Guidelines Expert Committee. Can J Diabetes. 2018;42:222-227. doi:10.1016/j.jcjd.2017.10.0202.
2.Yale J-F, Paty B, Senior PA. 2018 Clinical Practice Guidelines Hypoglycemia Diabetes Canada Clinical Practice Guidelines Expert Committee. Canadian Journal of Diabetes. 2018;42:S104-S108. doi:https://doi.org/10.1016/j.jcjd.2017.10.010
3. McMahon SK, Ferreira LD, Ratnam N, et al. Glucose requirements to maintain euglycemia after moderate-intensity afternoon exercise in adolescents with type 1 diabetes are increased in a biphasic manner. J Clin Endocrinol Metab. 2007;92(3):963-968. doi:10.1210/jc.2006-22633.
4. Sigal RJ, Armstrong MJ, Bacon SL, et al. 2018 Clinical practice guidelines: Physical activity and diabetes. Can J Diabetes. 2018;42(1):54-63. doi:10.1016/j.jcjd.2017.10.008
5. https://www.healtheuniversity.ca/EN/DiabetesCollege/Active/Safety/Pages/foot_care.aspx
6. https://www.healtheuniversity.ca/EN/DiabetesCollege/Active/Safety/Pages/cold_weather.aspx

STAND-VAT HANDOUT

1

MY NOTES

REFLECTION TIME....

1. Think about your past week or two, what went well with your action plan and felt good?

2. What didn't go well with your action plan, what challenges did you have or what got in the way?? Describe the problem.

2

STAND-VAT HANDOUT

DEFINE YOUR VISION from healtheuniversity.ca

Your vision is what you are working towards ultimately. Ask yourself, what do I want to feel like in the future and what do I want to do differently in the future? You can also think about what you hope to be doing in the future.

→

MY GOAL:

Your goals should help you achieve your vision

WHY MY GOAL IS IMPORTANT...

MY NEW STEP GOAL: _____

Is my goal SMART?

S PECIFIC
(simple, sensible, significant)

M EASURABLE
(meaningful, motivating)

A CHIEVABLE

R ELEVANT
(reasonable, realistic and resourced, results-based)

T IME BOUND
(time-based, time/cost limited, timely, time-sensitive)

12

STAND-VAT HANDOUT

3

READY, SET, ACTION!!! from healtheuniversity.ca

Create your action plan this week to achieve your step goal

- **What habit will you do and how**
- **When will do you do this habit?** i.e. After eating my lunch and dinner
- **Where will you do this habit?** i.e. the neighbourhood, at work, and the park at my house
- **Will you have someone with you to do this habit?** i.e. my spouse
- **How much and how often will you do this healthy habit over the next 2 weeks?** i.e. 20 minutes, 2 times per day for 5 days each week.

LIST PROBLEMS THAT MIGHT KEEP YOU FROM COMPLETING YOUR GOAL

and how you will address them!

-
-
-

HOW CONFIDENT ARE YOU IN YOUR ABILITY TO FOLLOW YOUR ACTION PLAN OVER THE NEXT TWO WEEKS?

0 1 2 3 4 5 6 7 8 9 10

not very confident — very confident

Appendix I

Socio-demographics Survey

1. **What do you consider to be your racial/ethnic background?** Please check ☑ one (1) of the following boxes:

1. Aboriginal (includes Inuit, Métis peoples of Canada, First Nations)
2. Arab (includes Egyptian, Kuwait, Libyan)
3. West Asian (includes Afghan, Assyrian and Iranian)
4. Chinese
5. Filipino
6. Japanese
7. Korean
8. South Asian (includes Bangladeshi, Punjabi, Sri Lankan)
9. Black (includes African, Nigerian, Somali)
10. Latin American (includes Chilean, Costa Rican, Mexican)
11. South East Asian (includes Vietnamese, Cambodian, Malaysian, Laotian)
12. White (Caucasian)
13. Other (**specify):**
14. Multiple cultural backgrounds (**specify):**

2. **What is your marital/relationship status?** Please check ☑ one (1) of the following boxes:

- ☐ Single
- ☐ Married or equivalent (i.e. common law; same sex)
- ☐ Separated or equivalent
- ☐ Divorced
- ☐ Widowed

3. **Which option best matches your <u>current</u> work status?** Please check ☑ one (1) of the following boxes:

- ☐ Employed full-time, that is, 35 more hours per week
- ☐ Employed part-time, that is, less than 35 hours per week
- ☐ Unemployed, but looking for work
- ☐ Student
- ☐ Retired
- ☐ Not in the paid workforce (homemaker, unemployed but not able to work e.g., due to disability, chronic illness, etc.)

4. **What is the <u>highest</u> level of education you have completed?** Please check ☑ one (1) of the following boxes:

- ☐ Less than high school (no certificates, diplomas or degrees)
- ☐ High school graduation certificate
- ☐ Trades certificate
- ☐ College certificate or diploma: a certificate from a community college, CEGEP, school of nursing, theological college or private college

- ☐ University: a certificate below the bachelor level, bachelor's degree, certificate above the bachelor level, master's degree, earned doctorate or a professional degree in medicine, dentistry, veterinary medicine, or optometry.

5. **What is your best estimate of the total income received by <u>all household members</u>, <u>from all sources</u>, before taxes and deductions, last year?** For example, if there are two (2) people living in your house, each making $30,000 per year ($60,000 total), you would select $35,001 to $65,000 below. Please check ☑ one (1) of the following boxes:

- ☐ Less than $25,000
- ☐ $25,001 to 50,000
- ☐ $50,001 to 75,000
- ☐ $75,001 to $100,000
- ☐ Greater than 100,000

6. **Do you own a car?** Please check ☑ one (1) of the following boxes:

- ☐ Yes, I own a car.
- ☐ No, but I have frequent access to borrowing a car.
- ☐ I do not own a car.

7. **What is your main method of transportation?** Please check ☑ one (1) of the following boxes:

- ☐ Vehicle
- ☐ Bike
- ☐ Bus
- ☐ Taxi
- ☐ Walk
- ☐ Scooter/Motorcycle

8. **In the past 3 months, have you been active for a minimum of 30 minutes/day on at least 3 days of the week?** Please check ☑ one (1) of the following boxes:

- ☐ Yes
- ☐ No

9. **In the past 6 months, have you been smoking or quit smoking? As well, are you frequently exposed to environmental tobacco smoke?** Please check ☑ the following boxes appropriate to your situation:

- ☐ Yes, I have been smoking or have recently quit smoking.
- ☐ No, I have not smoked or recently quit smoking in the past 6 months.
- ☐ I am exposed to frequent environmental tobacco smoke.

Appendix J

Technology Survey

Record ID	_____

Technology Experience

Do you use a cell phone/smartphone?	◯ Yes ◯ No
How frequently do you use your cell phone/smartphone?	◯ at least once a week ◯ one time per day ◯ 2 or more times per day
Which of the following things can you do with each of these technologies?	☐ take pictures ☐ access the internet (e.g. search for information e.g. Google) ☐ Video Chat (e.g. Skype, Zoom, Facebook messenger) ☐ Social media (e.g. Facebook, Twitter etc.) ☐ video with friends or family ☐ e-mail ☐ other apps ☐ None
If Apps used, for what (select all that apply):	☐ games ☐ Social media (e.g. Facebook, Twitter etc.) ☐ shopping ☐ music ☐ Health Tracking: nutrition ☐ health tracking: exercise/step tracker ☐ health tracking: blood glucose tracker
How is your cellphone/smartphone connected to the internet ?	☐ Unlimited Wi-Fi (wireless) ☐ Limited Wi-Fi ☐ Unlimited Mobile data (i.e. Minutes) ☐ Limited Mobile data (i.e. minutes) ☐ Other ☐ I don't know
Do you use a tablet?	◯ Yes ◯ No
How frequently do you use your tablet?	◯ at least once a week ◯ one time per day ◯ 2 or more times per day
Which of the following things can you do with each of these technologies?	☐ take pictures ☐ access the internet (e.g. search for information e.g. Google) ☐ Video Chat (e.g. Skype, Zoom, Facebook messenger) ☐ Social media (e.g. Facebook, Twitter etc.) ☐ video with friends or family ☐ e-mail ☐ other apps ☐ None

Confidential

If Apps used, for what:	☐ games ☐ Social media (e.g. Facebook, Twitter etc.) ☐ shopping ☐ music ☐ Health Tracking: nutrition ☐ health tracking: exercise/step tracker ☐ health tracking: blood glucose tracker
How is your tablet connected to the internet ?	☐ Unlimited Wi-Fi (wireless) ☐ Limited Wi-Fi ☐ Unlimited Mobile data (i.e. Minutes) ☐ Limited Mobile data (i.e. minutes) ☐ Other ☐ I don't know
Do you primarily use a laptop or desktop?	◯ laptop ◯ desktop ◯ no
How frequently do you use your [computer_use]?	◯ at least once a week ◯ one time per day ◯ 2 or more times per day
Which of the following things can you do with your [computer_use]?	☐ take pictures ☐ access the internet (e.g. search for information e.g. Google) ☐ Video Chat (e.g. Skype, Zoom, Facebook messenger) ☐ Social media (e.g. Facebook, Twitter etc.) ☐ video with friends or family ☐ e-mail ☐ other apps ☐ None
How is your [computer_use] connected to the internet?	☐ Unlimited Wi-Fi (wireless) ☐ Limited Wi-Fi ☐ Unlimited Mobile data (i.e. Minutes) ☐ Limited Mobile data (i.e. minutes) ☐ Other ☐ I don't know
Do you use wearable technology?	◯ Yes ◯ No
What kind of wearable technology?	☐ wearable glucose monitor ☐ activity tracker (i.e. fitbit) ☐ smartwatch
Which of the following things do you do with your wearable technologies?	☐ flash glucose monitoring ☐ step counting ☐ sedentary behaviour reminders ☐ heart rate ☐ other

Technology Self-Efficacy					
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I am very confident in my abilities to use digital technology	○	○	○	○	○
I often have difficulty whey trying to learn how to use a new software package, or online application	○	○	○	○	○
I always seem to have problems when trying to use digital technology	○	○	○	○	○
I find having a person showing me works best when I am learning how to do something new	○	○	○	○	○
I find working through it myself works best when I am learning something new	○	○	○	○	○
I need to have someone to call for help if I get stuck	○	○	○	○	○

Appendix K

Stanford Self-Efficacy Scale

Record ID _____

Stanford Self-Efficacy Scale

	not confident at all	2	3	4	somewhat confident	6	7	8	9	totally confident
How confident do you feel that you can keep the fatigue caused by your disease from interfering with the things you want to do?	○	○	○	○	○	○	○	○	○	○
How confident do you feel that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?	○	○	○	○	○	○	○	○	○	○
How confident do you feel that you can keep the emotional distress caused by your disease from interfering with the things you want to do?	○	○	○	○	○	○	○	○	○	○
How confident do you feel that you can keep any other symptoms or health problems you have from interfering with the things you want to do?	○	○	○	○	○	○	○	○	○	○
How confident do you feel that you can the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	○	○	○	○	○	○	○	○	○	○
How confident do you feel that you can do things other than just taking medication to reduce how much your illness affects your everyday life?	○	○	○	○	○	○	○	○	○	○

Appendix L

PAID-5

Record ID _____

*For the PAID-5, a total score of ≥ 8 indicates possible diabetes related emotional distress, which warrants further assessment

Instructions: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	not a problem	minor problem	moderate problem	somewhat serious problem	serious problem
feeling scared when you think about living with diabetes	○	○	○	○	○
feeling depressed when you think about living with diabetes	○	○	○	○	○
worrying about the future and the possibility of serious complications	○	○	○	○	○
feeling that diabetes is taking up too much of your mental and physical energy everyday	○	○	○	○	○
coping with complications of diabetes	○	○	○	○	○

Appendix M

Instruments Used

PCDSP Modified Physical Activity Report Questionnaire (PAR-Q)

The PAR-Q (Freehan et al., 2018) is a nine-item questionnaire that is used to assess a patient's medical safety clearance to exercise. It has been modified by, and is used as a part of, the in-person lifestyle medicine program at the diabetes clinic.

Stanford Self-Efficacy Scale

The Stanford Self-Efficacy Scale is a reliable, validated six-item questionnaire that assesses the self-efficacy to manage a chronic disease, including exercise (Lorig et al., 2001; Ritter & Lorig, 2014). Each question is ranked from 1 (not confident) to 10 (very confident). The final score is the mean of the scores, where higher scores mean higher self-efficacy (range 1 to 10).

Five-Item Problem Areas in Diabetes (PAID-5) Scale

The five-item Problem Areas in Diabetes Scale (PAID-5) is a valid and reliable short version of the PAID Scale, focusing on emotional distress related to diabetes (McGuire et al., 2010). Each question is ranked from zero (not a problem) to four (serious problem). The range is between 0 and 20. A total score of eight or greater indicates possible emotional distress and may warrant further investigation.

Technology Survey

This is a non-validated, descriptive tool that assesses current level of use of technologies (i.e., desktops, smartphones phones, wearable devices) and the personal functional use of the technologies. It also assesses a person's comfort and self-efficacy with using technologies related to the study. This survey was created by the diabetes clinic's staff input and investigators to describe participant's baseline characteristics.

Exit Survey

The exit survey collected data on participants' perceived levels: of program satisfaction, level of technology difficulties, privacy protection, and help for increasing physical activity. It also inquired about relationship of learning and motivation with the FreeStyle® Libre, FitBit Inspire 2™, and other aspects of the program. It covers the study's acceptability outcomes. The exit survey was informed by the study's primary feasibility outcomes and by a similar pilot study's focus group responses (Jiwani et al., 2020).

FitBit Inspire 2™

The FitBit Inspire 2™ is a wearable activity monitor containing a 3-axis accelerometer, optical heart rate monitor, and vibration motor. It was used to track step counts and minutes of sedentary behaviour. The device dimensions are 37 by 16 mm. The device is water resistant to 50 meters and has a battery life up to 10 days. It can store 7 days of detailed (minute by minute) motion data and saves daily totals for the past 30 days. It has a syncing range of 30 feet. The wearable activity monitor data is synced to the FitBit® app.

FitBit® Smartphone Application

The FitBit® app software (version 3.0+) was downloaded onto participants' phones (Android or iPhone) in order to upload and save physical activity data. The platform can also be accessed on a computer (if desired). The FitBit Inspire 2™ is automatically and wirelessly synced to computers and 200+ leading iOS and Android devices using Bluetooth LE wireless technology (FitBit Inc., 2020). To upload/sync data from the FitBit® app onto the main server, Internet connection is required. The app retrieves data from the FitBit Inspire 2™ and stores it on the participant's user account (investigators did not have access to any account data). The FitBit® app and FitBit Inspire 2™ display hourly goals of 250 steps or more and was set to read for a 12-hour range (the time range is customizable (e.g., 8:00am to 5:00pm)).

FitBit® Desktop Platform

Participants were asked to sync their FitBit® app to the Internet in order to make their step count data available on their FitBit® desktop platform. The platform is available on https://www.fitbit.com, where participants had to select “My Dashboard” to view their data. The diabetes clinic could not extract any data off the FitBit® site, rather the participant downloaded their own data. On the settings page, the data export option is available. Participants selected the time frame of a custom range of two dates to ensure the proper time frame two weeks were exported to a Microsoft Excel file. Participants uploaded this information to the secure file transfer website, https://filesafe.lhsc.on.ca.

WebEx®

WebEx® is a secure video conferencing and online meeting software that features end-to-end encryption. WebEx® offers specific healthcare platform options, such as high-quality video and audio for face-to-face consultations between patients and practitioners. Participants could join calls from a link sent from the diabetes clinic’s encrypted email. Participants could join from their desktop or smartphone WebEx® app.

Appendix N

Baseline Physiological Date (extracted from PCDSP EMR by Dr. Reichert)

1. Sex
   - ❑ Male
   - ❑ Female
2. Age : _____ years
3. Height (cm) : _____
4. Weight (kg): _____
5. Years since diagnosis : _____ years

6. Comorbidities (Select all that apply)
   - ❑ Cardiovascular
   - ❑ Psychatric
   - ❑ Peripheral Vascular
   - ❑ Renal
   - ❑ Visual

7. List of Cardiovascular Comorbidities :
   - ❑ CAD
   - ❑ Heart Failure
   - ❑ Angina
   - ❑ Atrial Fibrillation
   - ❑ Arrhythmia
   - ❑ CVD
   - ❑ CABG
   - ❑ HTN
   - ❑ PVD
   - ❑ Other: _____

8. List of Psychiatric Comorbidities :
   - ❑ Depression
   - ❑ Diabetes Depression
   - ❑ Anxiety
   - ❑ Bipolar
   - ❑ MDD
   - ❑ Misc.

9. List of Renal Disease
   - ❑ Chronic Kidney Disease
     - o Stage 1 (eGFR 90+)
     - o Stage 2 (eGFT 60-89+)
     - o Stage 3 (eGFR 30-59)
     - o Stage 4 (eGFR 15-29)
   - ❑ Other : _____

10. List of Visual diseases :
    - ❑ Cataracts
    - ❑ Retinopathy
    - ❑ Other

11. Blood Pressure (SBP/DBP) : _____
12. Last A1C measurement (%) : _____ Lab Records Date : _____
13. Last weight (kg) : _____
14. Last measured height (cm) :

15. Diabetes Medication
    - ❑ Insulin
      - o Type of Insulin :
        - ❑ Short Acting
        - ❑ Long Acting
      - o Insulin Dose (units per day) : _____
    - ❑ DD4
      - o DD4 Type : _____
    - ❑ GLP
      - o GLP Type : _____
    - ❑ Metformin :
      - o Metformin Type : _____
    - ❑ Sulfonlyurea
      - o Sulfonlyurea Type : _____
    - ❑ SGLT2
      - o SGLT2 Type : _____
    - ❑ TZD
      - o TZD Type : _____
    - ❑ Alpha glucosidase inhibitor
      - o AGI Type : _____

Appendix O

Confidential

Exit Survey

Exit Survey: The "STAND-VAT" Study

This survey asks you about your feelings towards various aspects of the "STAND-VAT" study you have so graciously participated in – please complete it to help us improve programming in the future.

For each question, choose the answer that best describes how you feel.

Exit Survey: The "STAND-VAT" Study

This survey asks you about your feelings towards various aspects of the "STAND-VAT" study you have so graciously participated in – please complete it to help us improve programming in the future.

For each question, choose the answer that best describes how you feel.

Reason for Participating: the MAIN REASON I signed up for the study was because	◯ I was told I would get a FitBit ◯ I was told I would get a Libre ◯ I was told I would receive an individualized exercise program ◯ I like participating in studies in general ◯ My doctor told me to ◯ I thought it might improve my health (e.g., reduce my medications, help me feel better, etc.) ◯ I was unable to participate in lifestyle programs/activities that I normally could participate in, due to COVID restrictions, and this offered an alternative. ◯ Other
If other:	_____
Which part of the study MOTIVATED you the MOST to increase your physical activity?	◯ FitBit ◯ Libre ◯ Individualized exercise prescription ◯ Group-based educational sessions ◯ One-on-one phone calls with the exercise specialist ◯ Other
If other:	_____

Confidential

Motivational Tools

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The option of using the FitBit to track my exercise was a great motivational tool.	○	○	○	○	○
The option of using the Libre to track my glucose was a great motivational tool (i.e. eating, exercising).	○	○	○	○	○

Motivational Tools – The use of my Libre guided my decisions about.... (SELECT ALL THAT APPLY):

- ☐ Food
- ☐ Exercise
- ☐ Medication
- ☐ None of the above
- ☐ Other:

(Select all that apply)

If other: _____

Learning tools

Learning tools: Which part of the program helped you LEARN the MOST about how to better manage your diabetes?

- ○ Information I got from my FitBit
- ○ Information I got from my Libre
- ○ The combined information from my FitBit and Libre
- ○ Group-based educational sessions
- ○ One-on-one phone calls with the exercise specialist
- ○ Other

If other: _____

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I felt comfortable speaking in the group-based educational sessions.	○	○	○	○	○
I had plenty of opportunity to ask questions during the group-based educational sessions.	○	○	○	○	○
I felt encouraged by others in the group-based educational sessions.	○	○	○	○	○
I would have liked to have a friend or family member join the group-based educational sessions.	○	○	○	○	○

Educational Tools: Most of the time, I accessed my group-based educational sessions on my...	◯ Desktop computer ◯ Laptop computer ◯ Cell phone (no Internet connectivity) ◯ Smartphone ◯ Tablet (e.g., iPad) ◯ Other
Technology: It was easy for me to join the group-based educational sessions.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
Technology: OVERALL, I experienced technology issues ____ of the time ((i.e. using the Libre, sending Fitbit data, joining video calls).	◯ 0% ◯ 10% ◯ 20% ◯ 30% ◯ 40% ◯ 50% ◯ 60% ◯ 70% ◯ 80% ◯ 90% ◯ 100%
Technology: Throughout the study I felt like my personal health information was protected (e.g., my privacy was being upheld)."	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
Overall, I would say this program helped me become more physically active than I was before.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
Overall, I was satisfied with the program.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
Briefly list the 1 or 2 things that you liked MOST about the program.	_____
Briefly list the 1 or 2 ways that you think the program could be improved.	_____

Appendix P

Technology Survey Results

Do you use a…	Yes	No
Cellphone/Smartphone	100%	-
Tablet?	70%	30%

Do you primarily use a laptop or desktop?	Desktop	Laptop	None
	40% (4)	50% (5)	10% (1)

How frequently do you use these technologies?	At least one time per week	One time per day	2 or more times per day
Cellphone/Smartphone	-	10% (1)	90% (9)
Tablet	14.3% (1)	28.6% (2)	57.1% (4)
Desktop	-	67% (2)	33% (1)
Laptop	40% (2)	20% (1)	40% (2)

How is your ___ connected to the internet?	Unlimited WiFi (wireless)	Limited WiFi (wireless)	Unlimited Mobile data (i.e., megabytes)	Limited Mobile data (i.e., megabytes)
Cellphone/Smartphone	100% (10)	-	20% (2)	20% (2)
Tablet	100% (7)	-	-	-
Computer/Desktop	100% (9)	-	-	-

Do you use wearable technology?	Yes	No
	40% (4)	60% (6)

What kind of wearable technology?	Wearable glucose monitor	Activity Tracker (e.g., basic FitBit)	Smartwatch (e.g., Apple or Samsung Watch)
	50% (2)	50% (2)	50% (2)

What can you do with your wearable technology?	Flash glucose monitoring	Step Counting	Sedentary behaviour reminders	Heart Rate	Other
	25% (1)	100% (4)	100% (4)	75% (3)	-

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Technology Survey Results continued…

Technology Self-Efficacy	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I am very confident in my abilities to use digital technology	-	-	10% (1)	50% (5)	40% (4)
I often have difficulty when trying to learn how to use a new software package, or online application	20% (2)	20% (2)	20% (2)	30% (3)	10% (1)
I always seem to have problems when trying to use digital technology	20% (2)	30% (3)	40% (4)	10% (1)	-
I find having a person showing me works best when I am learning how to do something new	-	-	10% (1)	30% (3)	60% (6)
I find working through it myself works best when I am learning something new	-	20% (2)	20% (2)	30% (3)	30% (3)
I need to have someone to call for help if I get stuck	10% (1)	10% (1)	20% (2)	30% (3)	30% (3)

Which of the following can you do with these technologies?	Take Pictures	Access the internet	Video Chat (e.g., Skype, Zoom, Facebook messenger)	Social media (e.g., Facebook, Twitter etc.)	e-mail	other apps
Smartphone (n=10)	100% (10)	100% (10)	100 % (10)	90% (9)	100 (10%)	60% (6)
Tablet (n=6)	100% (6)	100% (6)	83% (5)	100% (6)	100% (6)	83% (5)
Computer/Desktop (n=9)	44.4 (4)	100% (9)	66.7% (6)	77.8% (7)	100% (9)	44.4% (4)

Appendix Q

Other Descriptive Exit Survey Responses

Main Reason for Participating (n=9)	**Get a FitBit (%)**	**Get a Libre (%)**	**Individualized Exercise Prescription (%)**	**Thought it would improve health (%)**	**Participating in studies (%)**	**COVID-19 alternative opportunity (%)**	**Other (%)**
	0	11.1	11.1	55.6	11.1	0	11.1
Which part of the study MOTIVATED you the MOST to increase your physical activity? (n=8)	**FitBit (%)**		**Libre (%)**	**Individualized Exercise Prescription (%)**	**Group Education Classes (%)**	**1:1 Phone call with exercise specialist (%)**	
	25		37.5	12.5	25	0	
The use of my Libre guided my decisions about.... (SELECT ALL THAT APPLY) (n=9)	**Food (%)**		**Exercise (%)**	**Medication (%)**	**None (%)**	**Other (%)**	
	100		77.8	33.3	0	11.1	
Which part of the program helped you LEARN the MOST about how to better manage your diabetes?	**The combined information from the FitBit and FreeStyle Libre (%)**		**Information from the FreeStyle Libre (%)**	**Information from the FitBit (%)**	**Group education classes (%)**	**1:1 phone calls with exercise specialist (%)**	
	44.4		11.1	0	33.3	11.1	

Appendix R

Exit Survey Written Responses

Participants' brief responses providing feedback on program experience collected from exit survey (displayed in direct quotes).
Items liked about the program
• The group input and information on diet and exercise • Ability to understand more about diabetes. • Learning about carbohydrates really helped • Guidance on what to eat and how to exercise • Libre helped me to see what happens to my glucose level at different situations • I was able to see my movement level with Fitbit throughout the day. • One on one answers. • Updated information. • Liked the Libre and the step prescription. • Contact with clinic. • Keeping track. • Reading my glucose and seeing out reacts to my outcomes.
Things disliked/ (room for improvement) in the program
• More time to be in the program. • Advance notice of curriculum to be spoken about, just to make it clearer and help in conversation. • Print out of class material in advance; maybe homework to prepare for class. • The FitBit screen was too small, could not read when outside in bright light. • During the group session, it would be helpful if the facilitators can mute and unmute participants. • Exercise challenges. • Eating food together to see what is good/not good to eat (visual learners); to all check out the Libre's together as a group. • Privacy issues. Felt uncomfortable about practitioners commenting on other people's medication and how they are doing with their glucose patterns. • Small exercise videos to watch and try.

Appendix S

Bi-weekly group glycemic variable means.

Time	Mean Estimated A1c (n=8)	Mean Bi-weekly Time in Target (%) (n=9)	Mean Bi-weekly CV (%) (n=9)	Mean Bi-weekly 'Time Active' of FreeStyle® Libre (%) (n=9)#
Baseline	6.2 ± 0.49 (5.7-6.7)**	90 ± 9.0 (83-97)	23 ± 5.6 (18-27)	77 ± 22 (60-94)
Week 1-2	6.3 ± 0.56 (5.8-6.7)	89 ± 9.4 (82-96)	25 ± 6.9 (20-31)	77 ± 22 (60-94)
Week 3-4	6.4 ± 0.7 (5.9-7.0)	86 ± 14 (74-98)***	23 ± 7.1 (17-29)***	84 ± 16 (71-97)***
Week 5-6	6.2 ± 0.61 (5.6-6.9)*	89 ± 9.3 (81-98)**	24 ± 7.6 (16-31)**	77 ± 20 (59-95)**

All numbers were presented as mean ± SD (95% CI)
A1c = glycated hemoglobin; CV= Coefficient of variation
*n=6; **n=7; ***n=8; #: Participant #7 who did not have Type 2 Diabetes was included, as this would not skew any true glycemic data.

Curriculum Vitae

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University of Western
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Related Work Experience

Research Assistant
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Dillon, K., Hiemstra, M., Mitchell, M., Bartmann, N., Rollo, S., & Prapavessis, H. (2021). Validity of the occupational sitting and physical activity questionnaire (OSPAQ) for home-based office workers during the COVID-19 global pandemic: A secondary analysis. Submitted to Applied Ergonomics (under review: JERG-D-21-00353).

Virtual 10-minute Presentation: “Virtually Delivered Lifestyle Program Integrating Wearable Technology and Exercise Prescriptions for Patients with Type 2 Diabetes (STAND-VAT): Feasibility Study.” London Health Research Day 2021. London, Ontario, Canada on May 7 to May 18, 2021

Abstract Publication: Hiemstra, M. Spilsbury, S. Mitchell, M. Oh, P. (2020). Can Financial Incentives Promote Exercise Adherence Amongst Cardiac Rehabilitation Graduates? A 24-week Pilot Randomized Controlled Trial. *Medicine & Science in Sports & Exercise*. *52*(7S), 441. doi: 10.1249/01.mss.0000678696.60517.7b

Posted Presentation: Can Financial Incentives Promote Exercise Adherence Amongst Cardiac Rehabilitation Graduates? A 24-week Pilot Randomized Controlled Trial. American College of Sports Medicine’s 67th General Meeting. San Francisco, California on May 26-30, 2020 *(Cancelled).*