Influencing Behaviour to Improve Diabetes Self-Management: 
The Design and Evaluation of Mobile Health Applications

by

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for the degree of Doctor of Philosophy

Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Abstract
The global increase in the prevalence of diabetes along with the cost associated with complications is challenging traditional approaches to healthcare delivery. While the pervasiveness of mobile phones has resulted in a consumer-driven market for diabetes-focused mobile health applications (apps), the majority of these apps are not evidence-based or rigorously evaluated. The main objectives of this research were to design, develop and evaluate, a consumer-focused, behavioural app for the self-management of diabetes.

Following a knowledge translation framework, existing evidence around behaviour change theory, diabetes self-management, and mHealth was reviewed, and informed the conceptualization of the app features. The app was developed following user-centered design principles, where iterative feedback was obtained from patients throughout the process. The resulting intervention, bant2, was a consumer-focused app for the self-management of type 2 diabetes, focused on the contextualization of blood glucose readings with personalized lifestyle behaviours. While a 12-month randomized controlled trial (RCT) was designed to evaluate the impact of bant2 on clinical outcomes, findings from recent studies led to reconsider both the intervention the evaluation approach.

The bant RCT (n=96) and <30 Days study demonstrated that traditional evaluation of apps cannot keep pace with the rapidly evolving consumer expectations or technological landscape. The <30 Days study, a pragmatic evaluation of a consumer-focused chronic disease self-management app among 70,000 users, demonstrated how population-level data can power
robust evaluations of apps. Traditional RCTs are lengthy, high cost, do not consider practical implementation, and assume that all users require the same behavioural intervention.

Evaluation of mHealth apps need to shift focus to population-level approaches to enable the rapid optimization and scalability of diabetes self-management apps. The next generation of apps must also consider strategies that integrate with information systems to optimize the use of patient data, through approaches like precision medicine, to provide patients with dynamic, adaptive and personalized diabetes interventions.
I dedicate this work to my mother. Her spirit in times of struggle, and hope for a better tomorrow, inspire me every day.
Acknowledgments

I would like to express my gratitude for the immeasurable support I have received while pursuing this work.

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### Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
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<tr>
<td>BG</td>
<td>Blood glucose</td>
</tr>
<tr>
<td>CEEBIT</td>
<td>Continuous evaluation of evolving behavioural intervention technologies</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>DES-SF</td>
<td>Diabetes empowerment scale- short form</td>
</tr>
<tr>
<td>HCP</td>
<td>Health care provider</td>
</tr>
<tr>
<td>KTA</td>
<td>Knowledge-to-action</td>
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<tr>
<td>LDL</td>
<td>Low density lipoprotein</td>
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<tr>
<td>MOST</td>
<td>Multiphase optimization strategy</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>NPT</td>
<td>Normalization Process Theory</td>
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<tr>
<td>PHR</td>
<td>Personal health record</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>REB</td>
<td>Research Ethics Board</td>
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<tr>
<td>SCT</td>
<td>Social cognitive theory</td>
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<tr>
<td>SDT</td>
<td>Social determinant theory</td>
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<tr>
<td>SMART</td>
<td>Sequential multiple assignment randomized trial</td>
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<tr>
<td>SMBG</td>
<td>Self-monitoring of blood glucose</td>
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<tr>
<td>T1DM</td>
<td>Type 1 diabetes mellitus</td>
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<tr>
<td>T2DM</td>
<td>Type 2 diabetes mellitus</td>
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<tr>
<td>TTM</td>
<td>Transtheoretical model</td>
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Chapter 1

Introduction

1.1 Problem Statement

Diabetes mellitus is one of the most prevalent chronic diseases worldwide. It is estimated that more than 422 million are currently diagnosed with diabetes, with approximately 3 million in Canada (1,2). By 2030, the number of adults with diabetes will increase by 54% worldwide, representing an annual growth of 2.2% - double the growth of the total world adult population (1). An overwhelming number of individuals living with diabetes face the serious complications, resulting in hospitalizations, exhaustive use of resources, and a low quality of life. The estimated total cost of diabetes in Canada including secondary complications is $16.9 billion a year; approximately 10% of healthcare expenditures (1,3). Given the significant impact of diabetes, there is an urgent need to investigate methods of promoting and facilitating proactive self-management of diabetes, leading to improved outcomes and a lower burden of cost.

Diabetes is a chronic condition that places the burden of long term self-management on the individual affected. In addition to the medical challenges associated with diabetes, there are several challenges with self care, including deficits in knowledge, sustained motivation, and psychosocial factors (4,5). Although self-management training has long been acknowledged as a key component of the clinical treatment of diabetes, patients still lack the diabetes knowledge and ability to manage their condition on a daily basis (6). Generally, the diabetes training provided to patients is not customized or easily applied to real-world settings, leading to adherence levels as low as 37%, 35% and 78% for diet, exercise and medication respectively (7).

The majority of existing self-management tools are one-dimensional, and focus on tracking diabetes related measures, such as blood glucose readings (8). They do not provide frequent, personalized, or actionable feedback on the impact of daily lifestyle behaviours on glycemic control, or motivate positive behaviour change. It is hypothesized that the effective self-management of diabetes requires a
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personalized intervention that facilitates self-care activities, and provides context-specific feedback in order to motivate behaviour change. Of particular interest is the subgroup of patients with type 2 diabetes mellitus (T2DM), who require a behavioural intervention that contextualizes blood glucose readings with lifestyle behaviours, such as physical activity and weight maintenance.

Compared to traditional paper-based tools, mobile phones offer a unique opportunity to deliver highly personalized and dynamic behavioural interventions (9). While the pervasiveness of mobile phones has resulted in a competitive and consumer-driven market for mobile health (mHealth) applications (apps), the large majority of these apps are not evidence-based or rigorously evaluated (9,10) and consequently are not highly impactful in improving the overall health of the individual living with diabetes. The few interventions that are founded on evidence, typically required a third party healthcare provider (HCP) to deliver real-time feedback (e.g. the WellDoc System) (11). Therefore, the central research question of this thesis is:

*Can a consumer-focused mHealth app designed following user-centered and evidence based methods, elicit positive and sustained behaviour change, leading to improved diabetes self-management?*

*A second postulation is that automated feedback delivered through the mobile app would be as effective, less resource intensive, and more scalable than interventions involving HCP feedback.*

To investigate the central research question, the following aims were established:

I. Review existing evidence for the use of mHealth apps for diabetes self-management.
II. Understand consumer behaviours through the pragmatic evaluation of a behavioural mHealth app for the self-management of modifiable risk factors (e.g. lifestyle).
III. Develop a consumer-focused self-management app for T2DM that is founded on evidence, user-centered design, and theoretical frameworks, and applies previously underexplored novel approaches to behaviour change.
IV. Evaluate the effectiveness of behavioural mHealth apps on the self-management of diabetes through randomized controlled trials (RCT).
V. Assess the appropriateness of RCTs to evaluate consumer-driven mHealth apps.
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1.2 Thesis Outline

This thesis had three main objectives: (1) to understand the current landscape of diabetes self-management interventions and identify opportunities and challenges for consumer mobile health apps; (2) to follow a robust framework for the development of complex behavioural interventions, design a user-centered, behavioural, self-management diabetes app; and (3) to evaluate the effectiveness of diabetes self-management apps through randomized controlled trials.

The content presented in the chapters are based on the following five key publications:


In certain instances the content from the publications have been excluded or adapted to allow for readability and to reduce repetition. In chapters where this was relevant, the publications and associated modifications have been highlighted.

Chapter 2 discusses the importance of diabetes education and self-management. This chapter also provides an overview of the evolution of interventions, from paper-based to more sophisticated mobile apps, highlighting the challenges and opportunities of apps for the self-management of both type 1 and type 2 diabetes.

Given that the current demand and uptake of diabetes apps are consumer-driven, Chapter 3 explores the usage and engagement levels of <30 days, a consumer-focused chronic disease prevention app, downloaded by approximately 70,000 users. Chapter 3 presents the results of this evaluation, and provides additional insights around the behaviours and characteristics of particular demographic
Chapter 1- Introduction

subgroups, contributing to the overall understanding of how consumers interact with apps for the self-management of modifiable risk factors (e.g. lifestyle modification).

Chapter 4 presents the systematic design of bant2, a novel mobile app for the self-management of T2DM, focused on motivating diabetes self-care activities (e.g. structured self-monitoring of blood glucose) through personalized and context-specific feedback. This chapter discusses both the intervention development and the behaviour change frameworks used to guide the development of the app, as well as the evidence supporting the conceptualization of the features and algorithms.

Chapter 5 outlines the intended study design for the evaluation of bant2. The app was to be evaluated using an RCT (n=150) among patients with non-insulin requiring T2DM. Participants were to be randomly allocated to either the intervention arm (bant2 plus usual care) or the control arm (usual care). The primary outcome was the change in hemoglobin A1c, between groups, from baseline to 12 months.

While the bant2 RCT was underway, the 12-month RCT evaluating bant, the first generation of the app aimed towards the self-management of type 1 diabetes mellitus (T1DM) among adolescents, reached completion (Figure 1). As such, Chapter 6 summarizes the bant RCT findings, which focused on evaluating the effectiveness of the app on clinical outcomes (i.e. hemoglobin A1c) and self-care behaviours (i.e. self monitoring of blood glucose), and discusses the challenges of using an RCT to evaluate mHealth apps. The results of the bant trial led to the reconsideration of the bant2 RCT study design, and motivated an interim analysis on the overall engagement levels at the 3-month time point.

Chapter 7 discusses the results of this analysis and their implications on the evaluation of bant2.

Chapter 8 reviews the key findings of this thesis, explores how novel and modernized evaluation methods could address the challenges associated with mHealth research, and proposes an alternative evaluation approach for not only bant2, but also for future apps focused on the self-management of chronic disease.
Chapter 1 - Introduction

Figure 1. Timelines of the \textit{bant} and \textit{bant2} RCTs
Chapter 2

Background

2.1 Behaviour Change & Self-Management

The existing acute-care focused health care system does not meet the demands associated with the rapidly increasing prevalence of chronic disease (12). The role of the individual affected by (or ‘living with’) the chronic illness, previously understated, is central in the prevention, management, and maintenance of chronic disease (13). However, psychosocial factors, such as motivation, perceived susceptibility, readiness to change, and self-efficacy, can greatly influence the patient’s ability or desire to participate in the self-management of their health (13).

Self-management is founded on self-regulatory mechanisms, where through self-monitoring and proximal goal setting, individuals can motivate themselves towards behaviour change (13). These concepts are based on Social Cognitive Theory (SCT), which specifies optimal mechanisms for the translation of knowledge into practice through the following determinants: 1) knowledge of health risks and benefits, 2) perceived self-efficacy, 3) outcome expectations, 4) goals, 5) perceived facilitators, and 6) social and structural impediments to change (13). Targeting these determinants can enhance self-regulation by 1) enabling patients with the ability to devise self-regulation strategies through self-observation, self-judgment, and self-reaction, and 2) enable the development or problem-solving skills (14).

SCT has been used to guide the development of complex interventions for the self-management of chronic illness. Evidence from RCTs have demonstrated that interventions founded on SCT have led to improved outcomes for chronic conditions, such as asthma, arthritis, cardiac rehabilitation, weight lost, and diabetes (15–17). For example, Steed et al compared the theory of Self-Regulation and Social Cognitive Theory, and found that beliefs in seriousness and treatment effectiveness were not significant mediators of self-care, however, behaviour-specific self-efficacy, particularly for physical activity and self-monitoring of blood glucose, were mediators of behaviour change.
Chapter 2- Background

While SCT can guide the development of interventions focused on improving self-regulation and self-efficacy, it assumes that individuals are equally motivated to actually participate in self-management (14). Clark et al suggest that use of external factors, for example social reinforcement, to initially engage individuals in health behaviour interventions, eventually shift control towards the autonomous internal process (14). Self-determination theory (SDT) is focused on human motivation, and in addition to quantifying motivation, the theory also attempts to categorize types of motivation. Specifically, SDT explores the relationship between intrinsic and extrinsic motivations (18). In attempts to stimulate intrinsic motivation, many behaviorists have explored the use of tangible extrinsic rewards as a motivational strategy (19). While this concept of “rewarding” desired behaviours is common in the commercial industry, typically manifesting as loyalty programs, the sustained benefits and scalability of rewards to motivate healthy behaviours among communities remains elusive (20).

For type 2 diabetes, the American Diabetes Association prioritizes lifestyle behaviour modification as part of the top three objectives for improving diabetes care (21). However, individuals with diabetes have poor adherence to clinical recommendations for medication therapy and lifestyle changes, due to the lack of motivational support and self-management tools (11). Adherence levels to diet, exercise and medication recommendations have been has low as 37%, 35% and 78% respectively (11,22). As a result, less than half of all patients with T2DM are achieving the clinical targets for hemoglobin A1c (A1c) (6). Poor diabetes management increases the risk of micro and macrovascular complications, leading to hospitalizations, a low quality of life, and an increased burden of cost to the health care system.

Moreover, the lack of adherence stems from the inability of both health professionals and those affected by diabetes to understand how each care component contributes to overall glycemic control. Patient diagnosed with diabetes typically receive training and education that is generic, infrequent, and difficult to apply to real-world settings (11). Current diabetes training does not typically empower patients to (1) understand and apply guidelines, or (2) to understand the functional dynamics of glycemic control and be able to recover from exceptional situations (7). For example, many individuals do not relate increased exercise to better glycemic control, and therefore do not have the additional motivation to increase their levels of physical activity.

In addition to routine self-care, the ability to problem-solve and make decisions based on blood glucose levels can significantly reduce long-term complications (23). Overall self-care management refers to routine decision-making processes, and subsequent behaviors, performed in response to signs and symptoms. Self-care management includes five stages: (a) recognizing signs and/or symptoms, (b)
Chapter 2 - Background

evaluating signs and/or symptoms, (c) deciding to take action, (d) implementing treatment, and (e) evaluating treatment effectiveness (24). These skills, however, can only be formed through both lifestyle and knowledge modification (24). Fundamentally, patients with type 2 diabetes lack self-awareness and knowledge around how to overcome their individual barriers to diabetes control, impacting their perceived self-efficacy and motivation towards the adoption of behaviour change.

Self-monitoring, in certain situations or when accompanied by actionable outcomes, is a key component of self-management, enabling individuals to capture behaviours, recognize patterns, and undertake corrective action, facilitating improved self-efficacy (24,25). For patients with diabetes, improved self-efficacy has shown improved diet, levels of physical activity and overall self-management behaviours (25). Currently, patients with non-insulin requiring diabetes have no daily indication of their glycemic control. Although self-monitoring of blood glucose (SMBG) is an effective tool for insulin requiring patients, the role of SMBG for T2DM patients on oral agents is unclear due to the lack of demonstrated benefit (26). As a standalone intervention, SMBG has failed to demonstrate a significant decrease in A1c (reduction of 0.1%) at 12-month follow-up, in patients with a duration of T2DM >1 year (26). Although newly diagnosed patients have benefited from SMBG, the long-term value of SMBG as a standalone intervention has not been supported by evidence (26). We speculate that non-insulin requiring patients do not benefit from SMBG due to the lack of personalized structured education needed to derive the meaningful, actionable, information from the blood glucose readings.(8)

In contrast, structured SMBG and education have demonstrated significant reductions in A1c of up to 1.2% (27). This method requires the patient to perform SMBG on specific days in order to build a blood glucose profile (for example, record a 7-point SMBG profile for 3 consecutive days) (27). Structured SMBG can not only meaningfully reduce A1c, but it can also increase self-confidence and overall motivation (26,28,29). Therefore, structured SMBG coupled with education has the potential to empower patients with actionable knowledge which can be used to deal with blood glucose variability, and achieve glycemic control (8).

Although traditionally the clinician has carried the responsibility for treatment goals, plans and patient outcomes, this approach does not consider the patient’s priorities, capabilities and factors which may influence adherence to treatment. As such, there is a gap between what the clinicians recommend and what is actually being performed by patients with diabetes, leading to suboptimal outcomes (24). It is clear that behavioural self-management interventions can empower patients with the ability to proactively
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manage their diabetes, however, the design of these interventions requires a multifactorial approach, which has resulted in a wide diversity of approaches and strategies.

2.2 Overview of Diabetes Self-Management Interventions from 1980-2010

Self-management training has been acknowledged as a key component of the clinical treatment of diabetes since the 1930’s (6). Although many interventions have been developed and evaluated, there still exists a significant deficit of diabetes knowledge and skills amongst patients (6). It is thus necessary to extract the lessons of past research in order to generate progressive solutions.

A review of 74 RCTs from 1980 to 1999, concluded that diabetes self-management interventions with short follow-up lengths (<6 months) demonstrated improvements in knowledge levels, SMBG skills, glycemic control, and diet (6). The use of regular reinforcement or repetition also showed enhanced knowledge levels (6). Studies evaluating interventions that required a high level of interaction demonstrated high attrition rates, resulting in a final sample of participants who were likely already motivated. However, these studies did find improvements in problem solving, anxiety and quality of life, when an intensive intervention was used.

Furthermore, most studies demonstrated an improvement in self-reported dietary behaviours, however, few also illustrated a corresponding change in weight or glycemic control (6). The effect of the interventions on physical activity was more variable than diet, and it was unclear what factors led to improvements. Moreover, the studies that explored the relationship between SMBG and glycemic control among patients with T2DM, concluded that an increase in the frequency of blood glucose testing did not lead to improved glycemic control. This suggests that these patients were willing to test more frequently, but they were not able to use the readings to adjust their lifestyle and improve glycemic control. Therefore, the interventions (group sessions, phone calls, and clinical visits) from this time period were not able to demonstrate the effective self-management of diabetes resulting in improved clinical outcomes.

Diabetes self-management training approaches have evolved from being didactic to “empowerment” models, and from being one-dimensional to multifactorial. Majority of the studies from 2000 to 2010 focused on behaviour change aspects such as learning, planning, and practicing. The interventions that applied learning and/or planning methods showed mixed results, but the majority of studies that applied practicing methods demonstrated improvements in A1c (30). Similar to previous reviews, these studies
Chapter 2- Background

also showed an improvement in self-reported dietary behaviour but no change in clinical outcomes. While the multifaceted interventions focused on behaviour change did not influence an increase in physical activity levels, they did improve perceived knowledge of diabetes and quality of life. This generation of studies concluded that the most favorable results were achieved when interventions included both the “practicing” method and collaborative learning with care givers (30). Given that many of these studies showed a medium-to-large effect on both behaviour and clinical outcomes, this suggests that diabetes self-management interventions have the potential to improve glycemic control.

However, the underlying behaviour mechanism of physical activity and diet self-management need to be better understood. Lastly, the desired efficacy will only be achieved if the intervention is embedded in the daily life of patients, respects their individual habits, and provides them with reinforcement and social support over time (30).

2.3 mHealth Interventions

This section was reproduced from the following publication: Goyal S, Morita P, Lewis GF, et al. The Systematic Design of a Behavioural Mobile Health Application for the Self-Management of Type 2 Diabetes. Canadian Journal of Diabetes. Canadian Diabetes Association; 2015; 40(1): 1–10. To minimize repetition, certain sections of the publication were excluded.

Mobile phones have become a ubiquitous electronic tool in daily consumer transactions, such as communication, shopping, and even access to health related information, fundamentally transforming the way society interacts with the world around them. Recently, mobile phone-based telemedicine has proven to be an effective approach for information exchange and providing feedback between patients and their caregivers. However, they are heavily dependent on a third party health care provider (HCP) to facilitate real-time feedback (10,22,31). For example, the WellDoc study, a cluster randomized clinical trial with 163 patients with type 2 diabetes, demonstrated that a multifaceted mobile-phone system with third party feedback reduced A1c up to 1.9% in the intervention arm. (31) However, the involvement of the HCP in this study was critical for achieving the outcome, and the associated cost of this additional resource is of major concern in terms of access and long-term sustainability (7).

Mobiles phones are inherently personal communications devices with powerful computing and touch-based user interfaces. They can be used to deliver self-management tools that are embedded into the daily routine of individuals and facilitate habitual self-monitoring (10,30,33). However, in order to elicit
behaviour change, the design of mobile applications requires a thoughtful, patient-centered, and evidence-based approach (33). For example, Cafazzo et al conducted a randomized clinical trial (n=110) amongst hypertensive patients with type 2 diabetes, where in addition to standard care the intervention group received a mobile phone loaded with a self-management application and a wireless blood pressure cuff, and the control group received a regular blood pressure cuff plus standard care. At 12-month follow-up, the intervention group demonstrated a significant decrease in ambulatory systolic blood pressure of 9.1±15.6 mmHg, and the control group saw no change (34). The user-centered mobile system facilitated behaviour change amongst these patients without regular third-party HCP feedback or additional visits to their family physician (34). Similarly, we hypothesized that a well-designed mHealth intervention coupled with SMBG can also achieve improved clinical outcomes.

Although there is a growing body of research supporting the use of specific mHealth apps for diabetes self-management, the availability of hundreds of such apps makes it difficult to identify those with clinical relevance. Recent reviews of apps conclude that impact of mHealth on clinical outcomes compared to usual care remains uncertain (35). Nonetheless, there continue to be opportunities for mHealth to supplement traditional care, especially between healthcare provider visits, where patients can provided with in-situ feedback and personalized education (36).

The remaining sections were reproduced from the following publication: Goyal S, Cafazzo JA. Mobile Phone Health Apps for Diabetes Management: Current Evidence and Future Developments. QJM: Monthly Journal of the Association of Physicians. 2013 Dec; 106(12): 1067–9.

### 2.3.1 Insulin-Dependent Diabetes

Younger, and less experienced patients with type 1 diabetes (T1DM) struggle with the complex guidance involved, and ultimately fail to reach target A1c values (37). In addition to monitoring glycemic variability, the psychological stress related to fear of hypoglycemia, future complications and impact on general wellbeing, results in a significant burden of care for both the patient and their family caregivers. The paper tools currently available to patients permit them to log blood glucose, carbohydrates and insulin doses, but remain suboptimal largely due to (i) a high probability of erroneous manual data entry; (ii) inability to capture enough data need for healthcare care provider clinical decision making; and (iii) lack of real-time feedback and behaviour change motivation enabling patients to improve their ability to self-care (37).
Chapter 2- Background

For insulin requiring patients, the means to transfer blood glucose data wirelessly to a mobile phone can reduce errors and frustration associated with manual data entry, simplifying the daily task and potentially impacting adherence to self-monitoring. However, Chomutare et al. reveals that all of the apps commercially available required manual data entry, and only 62% of those found in the literature used wireless data transfer (10). Although wireless medical devices are becoming more readily available, proprietary restrictions and regulatory issues are hindering the use of them in the commercial market. A similar discrepancy is seen with the integration of personal health records in research-based apps compared to those commercially available.

While personal health records (PHRs) allow for secure and portable storage of personal health information as well as secure sharing between informal and formal caregivers, the majority of apps found on the market only allow for Excel data export. Although personalized feedback is a key construct of most self-care behavioural frameworks, only 20% of the apps assessed had an educational component, of which only 1/5 delivered personal feedback. Without embedded behaviour change strategies, mobile apps risk being simply an electronic form of existing paper-based tools, failing to empower patients with actionable self-care knowledge. Others apps have explored the use of automated algorithms and external incentives to influence behaviour change.

In a pilot conducted by Cafazzo et al., the use of a mobile app bant, led to a 49.6% increase in the frequency of blood glucose measurements at the end of a 12-week period (38). The app enabled users to wirelessly transfer blood glucose readings, review trends, receive automated feedback, and share information through Microsoft HealthVault. Furthermore, bant also rewarded positive behaviour with points, which users could redeem for iTunes rewards. These results further emphasize that mHealth apps can effectively engage patients, influence their behaviour positively, and potentially impact health outcomes (38).

2.3.2 T2DM and Lifestyle Management

The self-management of non-insulin requiring type 2 diabetes (T2DM) deemphasizes frequent blood glucose (BG) monitoring and focuses on the modification of lifestyle behaviours. Supporting these patients requires a multifaceted solution embedded with behaviour change mechanisms, where the patient is involved in their own care and is receiving regular feedback from their health care providers. Although telemedicine delivered through web and mobile phone systems overcomes geographical barriers, providing frequent follow-up and feedback to diabetes patients remains both challenging and costly (10).
Chapter 2- Background

Quinn et al. evaluated the effectiveness of the WellDoc system, a patient-coaching and provider clinical decision support system (31). The multimodal tool enables patients to wirelessly upload BG readings and other diabetes-related information, and receive real-time feedback either via the health care provider (HCP), caregiver or WellDoc research team. In a 1-year cluster-randomized clinical trial, the intervention group’s A1c decreased by 1.9% compared to the usual care group that decreased by 0.7%. Although third party feedback systems can reduce A1c, the involvement of the HCP is critical, and the reimbursement of this additional resource is of major concern. This solution’s dependency on the HCP or coach will be difficult to scale, and does not fully explore the advanced capability of personal devices and mobile applications to promote more autonomous patient self-management.

2.3.3 The Gap Between Research and the Marketplace

Most apps commercially available are not evidence-based and tend not to differentiate between T1DM and T2DM. Of the 137 apps identified by Chomutare et al, the top features were manual data recording, insulin and medication tracking, followed by data export and communication (10). By focusing on the simple logging of blood glucose readings, the significant and fundamental differences between the self-management of these conditions remain ignored.

Although the role of self-monitoring of blood glucose (SMBG) among T2DM patients on oral medications remains controversial, there is still some consensus that these patients could benefit from monitoring blood glucose when viewed in the context of their lifestyle behaviours (39). While there exist individual apps that allow users to objectively track physical activity, nutrition, weight and medications, few offer an integrated behavioural self-management tool targeted towards non-insulin requiring type 2 diabetes (10).

Although electronic versions of less efficient paper-based tools are trending, and telemedicine systems with health coaches are gaining momentum, the full potential of mHealth remains unrealized. To truly impact diabetes outcomes, the gap between evidence-based guidance and functionality of consumer apps needs to be addressed. Whether it is for patients with T1DM who need to adjust insulin doses according to carbohydrate intake, or for patients with T2DM who are struggling to reduce sedentary behaviours and improve their lifestyle, mobile applications can potentially address existing gaps in self-care while empowering patients with the ability to effectively manage their chronic condition.
Chapter 2 - Background

The consumer uptake of diabetes-related mobile apps indicates that these patients can be reached increasingly through these electronic tools. However, fully harnessing the capabilities of smartphones to deliver real-time feedback, diabetes education and secure data sharing remains largely underexplored. Even more compelling is the possibility of positively shaping behaviours, and guiding patients with chronic illnesses towards optimal mental, emotional and physical health and wellbeing.
Chapter 3

Pragmatic Evaluation of a Consumer Focused mHealth App

While the popularity of mHealth apps has increased over the last decade, with over 165,000 apps available for download on the Apple and Google Play Stores, the actual adoption, sustained engagement, and utilization of these tools remains elusive (40). Although the characteristics of users who download apps has been explored (e.g. younger demographic tend to download more apps), their engagement with consumer apps for the self-management of chronic disease remains under-reported (40,41).

Rai et al conducted a cross-sectional survey among 1,132 consumers in the US, evaluating demographics, acceptance, intentions and channel preferences for mHealth apps (42). The study found that health status was a predictor of mHealth usage, and those worried about their risk for chronic disease would more likely consider proactively using risk management apps (42). However, this study did not evaluate uptake or usage of apps based on the identified intentions and preferences. The <30 days study is one of the first examples of a population-level evaluation of an mHealth app, which evaluated how consumers engaged with an app focused on the self-management of modifiable risk factors (e.g. lifestyle modification). While the study focused on the identification and management of heart health risk factors, it shares the same underlying principal of motivating behaviour change around lifestyle, seen in diabetes management. Given that the demand for self-management apps is consumer-driven, it is imperative the design of diabetes apps considers how users interact with self-management tools in real-world settings.

The remaining sections of this chapter were reproduced from the following publication: Goyal S, Morita PP, Picton P, Seto E, Zbib A, Cafazzo JA. Uptake of a Consumer-Focused mHealth Application for the Assessment and Prevention of Heart Disease: The <30 Days Study, JMIR mHealth & uHealth, 2016; 4(1): e32.
Chapter 3- Pragmatic Evaluation of a Consumer Focused mHealth App

3.1 Introduction

Heart disease and stroke remain the leading cause of death and disability worldwide, and are responsible for almost 30% of all deaths (43). The majority of the world’s adult population has at least one modifiable risk factor for cardiovascular disease (CVD), such as obesity, hypertension, physical inactivity, poor nutrition, and tobacco and/or alcohol consumption (44). As with many chronic diseases, modifiable risk factors can be prevented by 1) identifying unhealthy lifestyle behaviors and 2) providing education and support to guide individuals towards behaviour change and subsequent lifestyle modification (45,46).

Although health risk assessments have been an effective approach for health promotion and risk projection, the increased awareness of risk does not necessarily translate into behaviour change (46,47). Existing paper and internet-based assessments are one-dimensional and do not provide patients with tools and education required to actively work towards reducing their cardiovascular risk on a day-to-day basis (48). For example, Heart Aware™, an Internet-based cardiac risk assessment deployed to 373,085 users, provided an overview of risk based on the information that users entered. However, it did not provide continued guidance or actionable knowledge to enable individuals to work towards reducing their risk (45).

While many workplace wellness programs do offer tools with components of self-education and counseling that target and effectively reduce chronic diseases, they are not scalable to larger community-based populations (49). These programs are typically adopted by large organizations that have the resources and infrastructure needed to successfully implement and maintain such programs. They do focus on developing capacity amongst community members which is necessary to support, implement, and sustain an effective preventative program (50).

Engaging individuals in risk factor identification and modification is crucial for preventing CVD. However, given the high prevalence of CVD, it is clear that current primary preventative actions are suboptimal (51). Technology, such as mobile phones, can enable people to gain access to health promotion resources and peers within their community (50). The increasing market penetration of mobile phones presents a unique opportunity to not only deliver an evidence-based dynamic health risk assessments, but also promote lifestyle modification interventions (52).

With this premise, we hypothesized that a dynamic risk assessment delivered as a mobile phone application (app), hosted by a reputable public not-for-profit organization, would promote uptake amongst
Chapter 3- Pragmatic Evaluation of a Consumer Focused mHealth App

community members. The Heart and Stroke Foundation commissioned the development and public deploy of <30 Days, a mobile CVD risk assessment and management app. The uptake was predicted to be influenced by incentives offered for downloading the mobile app. Usage data was collected at a population-level to provide insight on uptake and engagement levels.

The goal of this study was to assess levels of engagement in terms of number of challenges completed and duration of use, and to compare usage and uptake between the incentives group and the non-incentives group. We anticipated that the users from the incentives group would be initially attracted to the app, but would subsequently have lower levels of engagement than the non-incentive group.

3.2 Methods

The Heart and Stroke Foundation of Canada launched the app on the iTunes App Store and population-level usage data was collected over five months. Consent to analyze de-identified usage data for ‘research purposes’ was obtained from users in the form of an in-app mobile agreement. Aggregate data included information on download rates, usage, feedback, and demographics of users across the globe.

3.3 Mobile App Overview

The aim of the <30 Days app was to empower users with the ability to easily and effectively manage their heart health on a daily basis. Principles of user-centered design guided the conceptualization of the application, where feedback from end-users informed the concept and key features (53). In addition to the requirements gathered from users, constructs from the theory of planned behaviour were used to guide the overall structure and motivations of the app (54).

The resulting app was available for download in Canada, free of charge, on the iTunes App Store. Upon downloading the app, users had the option to either complete the risk assessment right away, or temporarily skip the risk assessment and preview the app content. If the user opted to browse the app first, they were only offered three sample challenges before they were required to complete the risk assessment in order to continue using the app. Upon completion of the risk assessment (Figure 2; Appendix, Table A), users were presented with a list of their modifiable risk factors, which they could prioritize (first, second and third) according to what they wanted to work on over the course of thirty days. The mobile app suggested simple daily activities based on identified risk factors, provided resources and
encouragement, and tailored content to individual’s risk profiles. When a user was presented with a challenge, they had the option to *skip* the challenge and browse for more options, or *accept* the challenge. If accepted, on the following day they would be asked whether or not they completed the challenge, at which point they could proceed to select their next challenge.

To promote the completion of at least one heart health challenge per day, the app included an achievements system in the form of badges and a progress review module that was presented every seven days. The Heart and Stroke Foundation also launched an incentive promotion for one month, where users were rewarded with *Air Miles*® points for downloading the app. Previous studies have indicated that positive feedback in the form of a rewards system can motivate users to participate in self-management behaviours, and potentially result in positive health outcomes (38,55,56).

Figure 2. Screen shots from the <30 Days app.

### 3.4 Data Collection

The primary data source for this evaluation was anonymized usage data, collected over five consecutive months. The data set consisted of responses to the health risk assessment and subsequent app usage, based on a unique installation of the app. Given that the risk assessment requires demographic and
Chapter 3- Pragmatic Evaluation of a Consumer Focused mHealth App

anthropometric data, it was possible to evaluate app usage based on demographic and at-risk subgroups. Feedback from users was received through both the iTunes App Store and the technical support emails. Consent was acquired from all users through the mobile license agreement presented in the app upon first use. The user group for this evaluation included all those that downloaded and used the app within the study time limits.

3.5 Data Analysis

Output files for data processing were created using SQL (Structured Query Language) queries to the <30 Days app database. In order to organize the data into a format that would permit specific statistical analyses in SPSS (SPSS, Inc., Chicago IL, USA), further data processing was performed in LabVIEW™ (National Instruments, TX, USA). The resulting data file was then ported into SPSS for statistical analysis.

Descriptive statistics helped identify usage patterns and the effectiveness of key features of the app. Independent t-tests and chi-square statistics determined differences between groups, such as male and female groups, and incentives and non-incentives groups. Between-subjects ANOVA was conducted to analyze differences between age groups and engagements levels. A Pearson correlation analysis was conducted to assess the relationship between factors identified in the risk assessment and engagement levels. A multiple regression analysis on the number of challenges completed by the users was conducted to better understand the effect of the numerous independent variables on the uptake of the app and engagement levels.

Lastly, a thematic analysis was conducted on the comments received from users, where comments were compiled, organized, and assessed for recurrent themes. Major themes pertaining to the usability and utility of the app were derived as critical feedback for improving the future versions of the app.

3.6 Results

Out of the 74,396 users that downloaded the app during the study period, 4,444 users installed the app but never launched it. Of the 69,952 users who downloaded and launched the app, 33.9% (23,727) were registered during the Air Miles® promotion period, of which 5.7% (3,957) users opened the app but did not complete the risk assessment. Altogether, 12,622 users never created a profile and consequently never
completed the risk assessment. As shown in Figure 3, the final data set used for this analysis consisted of the data obtained from 57,330 users.

The Air Miles® incentive attracted 41.4% of the total male users and 32.1% of the total female users that downloaded the app and created a profile \((n = 57,330)\), \(\chi^2(1) = 423.7, p < 0.001, \phi_{Cramer} = 0.086\), and engaged primarily users who were 31-70 years of years of age, \(\chi^2(8) = 586.1, p < 0.001, \phi_{Cramer} = 0.101\). On average, users in the incentives group completed slightly more challenges on the first 30 days of the intervention than in the non-incentives group, with 7.9 ± 0.13 and 6.1 ± 0.06 completed challenges respectively, \(t(28870) = -12.293, p < 0.001, d = 0.12, 95\% \ CI [-2.02, -1.47]\). Additional data shows that during the promotion period, the overall number of downloads per day increased from 326 to 1,186.

![Number of downloads which completed the risk assessment.](image)

### 3.6.1 Demographics

As shown in Table 1, the users were primarily female (73.9%), between the ages of 21 and 30 (59.4%), and Caucasian (69.2%). The uptake from the younger demographic was significantly higher than the older demographic, with only 8.8% of adults aged 51 years and older downloading the app compared to 59.4% of users aged 21 to 30 years. The average Body Mass Index for the males and females were 28.0 ± 5.2 and 26.9 ± 6.5 respectively, classifying the majority of users as overweight (BMI 25-30).
Table 1. Demographics of users who completed the <30 Days health risk assessment.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14,950 (26.1)</td>
</tr>
<tr>
<td>Female</td>
<td>42,380 (73.9)</td>
</tr>
<tr>
<td><strong>Age Group (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Under 20</td>
<td>14,842 (25.9)</td>
</tr>
<tr>
<td>21-30</td>
<td>19,200 (33.5)</td>
</tr>
<tr>
<td>31-40</td>
<td>11,464 (20.0)</td>
</tr>
<tr>
<td>41-50</td>
<td>6,782 (11.8)</td>
</tr>
<tr>
<td>51-60</td>
<td>3,777 (6.6)</td>
</tr>
<tr>
<td>61-70</td>
<td>1,125 (2.0)</td>
</tr>
<tr>
<td>71-80</td>
<td>116 (0.2)</td>
</tr>
<tr>
<td>81-90</td>
<td>13 (0)</td>
</tr>
<tr>
<td>91+</td>
<td>11 (0)</td>
</tr>
<tr>
<td><strong>Ethnicity/Race</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>39,700 (69.2)</td>
</tr>
<tr>
<td>Latin American</td>
<td>2,374 (4.1)</td>
</tr>
<tr>
<td>Chinese</td>
<td>2,091 (3.6)</td>
</tr>
<tr>
<td>South Asian</td>
<td>2,057 (3.6)</td>
</tr>
<tr>
<td>African Heritage</td>
<td>1,928 (3.4)</td>
</tr>
<tr>
<td>Other</td>
<td>9,180 (16.0)</td>
</tr>
</tbody>
</table>

3.6.2 Modifiable Risk Factors

The most prevalent risk factor was poor nutrition (87%), followed by lack of exercise (52%), stress (50%), excessive salt intake (30%), tobacco use (15%) and excessive alcohol use (10%). On average, women had slightly more risk factors (2.5 ± 0.01) compared to men (2.3 ± 0.01), t(26, 446) = -12.648, d=0.11, p < 0.001, 95% CI [-0.16, -0.12]. Analysis of variance showed a relatively small, but statistically significant difference of risk factors between age groups F(8, 57 321) = 142.55, p < 0.001, η2 = 0.02. More precisely, users in the 21-30 (2.6 ±0.01) and 31-40 (2.5 ± 0.01) age groups had a higher mean number of risk factors compared to those in the 61-70 (1.8 ± 0.3) and 71-80 (1.4 ± 0.9) age groups.
3.6.3 **Health Conditions & Nutritional Habits**

The risk assessment asked users to identify health conditions they may have, or health conditions of which they have a family history. Overall, 44.5% (25,511) of users reported having at least one of the listed conditions (depression, diabetes, heart disease, stroke, high blood pressure, high cholesterol, renal disease and sleep apnea), with 31% (17,839) of users reported having depression or anxiety, as showing in Table 2. A large percentage of users, 69.4% (39,793) to be exact, reported having a family history of diabetes or high blood sugar, heart disease, high blood pressure, high cholesterol, or stroke.

In terms of nutritional habits, the following percentage of users reported eating these foods 3 or more times a week: 45.3% (25,996) eat high fat foods, 30.6% (17,520) eat fast food, 24.2% (13,898) eat foods rich in omega-3, 42.3% (24,263) eat 5 or more servings of fruits and vegetables per day, and 18% (10,291) eat none of the above.

<table>
<thead>
<tr>
<th>Do you have any of the following conditions?</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression or anxiety</td>
<td>17,839</td>
<td>(31.1)</td>
</tr>
<tr>
<td>Diabetes or high blood sugar</td>
<td>1,978</td>
<td>(3.5)</td>
</tr>
<tr>
<td>History of heart disease</td>
<td>1,736</td>
<td>(3.0)</td>
</tr>
<tr>
<td>History of stroke</td>
<td>746</td>
<td>(1.3)</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>5,564</td>
<td>(9.7)</td>
</tr>
<tr>
<td>High cholesterol or triglycerides</td>
<td>4,847</td>
<td>(8.5)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>209</td>
<td>(0.4)</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>3,611</td>
<td>(6.3)</td>
</tr>
<tr>
<td>None of the above</td>
<td>31,819</td>
<td>(55.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do you have a family history of?</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes or high blood sugar</td>
<td>24,309</td>
<td>(42.4)</td>
</tr>
<tr>
<td>Heart disease</td>
<td>15,916</td>
<td>(27.8)</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>25,204</td>
<td>(44.0)</td>
</tr>
<tr>
<td>High cholesterol or triglycerides</td>
<td>16,678</td>
<td>(29.1)</td>
</tr>
<tr>
<td>Stroke</td>
<td>10,806</td>
<td>(18.8)</td>
</tr>
<tr>
<td>None of the above</td>
<td>17,537</td>
<td>(30.6)</td>
</tr>
</tbody>
</table>
3.6.4 Engagement Levels

A sub sample (n=52,431) of all users (n = 74,396) who downloaded, opened the app, created a profile, and had at least 30 days to use the app was selected for this part of the evaluation to ensure that all users had an opportunity to complete the challenges. As shown in Table 3, 47.6% (30,341) of users had ‘low’ levels of engagement, and 8.3% (5,273) of users had ‘high’ levels of engagement. The categorization and range of engagement levels were defined a priori by the Heart and Stroke Foundation, where a categorization of Very Low describes those who completed a profile but did not complete any challenges, and Low, Moderate and High, describe those who completed 1-14, 15-21 and 22+ challenges respectively.

Engagement was measured by looking at the number of challenges completed in the first 30 days of each user, according to the distribution presented on Table 3. One sample t-test indicated that engagement levels amongst female users (7.10 ± 0.07, n =38,494) was slightly higher than male users (6.73 ± 0.15, n = 13,937), t-test, t(52,429) = -2.509, p = 0.012, d=0.02, 95% CI [-0.648, -0.08]. Analysis of variance showed a small, statistically significant effect of age on engagement levels F(8, 52,422) = 55.10, p < 0.001, η² = 0.008, with older participants (e.g. >51 years of age) completing more challenges than younger participants (Table 4). The frequency of the virtual rewards (badges) offered to users through the app was also captured and Figure 4 illustrates that a higher percentage of individuals aged 50 to 70 years achieved rewards for consecutive use of the app over seven days (“Warming Up” badge) and completing the thirty day (“30 Day” badge challenge).

Table 3. User engagement levels measured by the number completed challenges in the first 30 days of the intervention (n = 52,431).

<table>
<thead>
<tr>
<th>Engagement Levels (challenges completed)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low (0)</td>
<td>14,546 (27.3)</td>
</tr>
<tr>
<td>Low (1-14)</td>
<td>29,991 (57.2)</td>
</tr>
<tr>
<td>Moderate (15-21)</td>
<td>2,635 (5)</td>
</tr>
<tr>
<td>High (22+)</td>
<td>5,259 (10)</td>
</tr>
</tbody>
</table>

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### Table 4. Number of challenges completed by age group (n=52,431)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Mean number of challenges completed in first 30 days</th>
<th>SD</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 and under</td>
<td>5.44</td>
<td>11.08</td>
<td>13,291 (25.3)</td>
</tr>
<tr>
<td>21-30</td>
<td>6.47</td>
<td>12.23</td>
<td>17,571 (33.5)</td>
</tr>
<tr>
<td>31-40</td>
<td>7.67</td>
<td>18.11</td>
<td>10,604 (20.2)</td>
</tr>
<tr>
<td>41-50</td>
<td>8.59</td>
<td>16.71</td>
<td>6,297 (12.0)</td>
</tr>
<tr>
<td>51-60</td>
<td>9.78</td>
<td>19.96</td>
<td>3,485 (6.6)</td>
</tr>
<tr>
<td>61-70</td>
<td>9.74</td>
<td>16.10</td>
<td>1,050 (2.0)</td>
</tr>
<tr>
<td>71-80</td>
<td>9.89</td>
<td>15.69</td>
<td>110 (0.2)</td>
</tr>
<tr>
<td>81-90</td>
<td>10.08</td>
<td>16.09</td>
<td>13 (0.0)</td>
</tr>
<tr>
<td>91+</td>
<td>19.80</td>
<td>36.59</td>
<td>10 (0.0)</td>
</tr>
</tbody>
</table>

**Figure 4.** Rewards achieved by users per age group.
As shown in Table 5, those who reported having health conditions, such as diabetes, heart disease, stroke, high blood pressure and high cholesterol, completed a higher number of challenges. A correlation analysis revealed a positive but weak correlation between the number of challenges completed and the number of personal conditions ($r = 0.025$, $p < 0.001$) and number family history conditions ($r = 0.041$; $p < 0.001$) reported.

The effect of several potential predictors on number of challenges was evaluated through multiple regression analysis. Due to the large dataset, the model was tested against 14 predictors: gender, age group, ethnicity, height, weight, all 6 risk factors; incentive/non-incentive info, number of conditions, and number of family histories. The assumptions of independence of errors, linearity, unusual points and normality of residuals, and homoscedasticity were met. Out of the predictors used in the regression, only gender, age group, ethnicity, five of the risk factors (all but alcohol), the presence of incentives, and the number of family histories predicted the number of challenges completed by the user, $F(14, 56,538) = 86.644$, $p < 0.001$, adj. $R^2 = 0.021$. The regression coefficients and standard errors for each of the predictors can be found in Table 6.
Table 5. Number of challenges completed based on health conditions identified

<table>
<thead>
<tr>
<th>Health Condition</th>
<th>‘Yes’ Average Number of Challenges (n)</th>
<th>SD</th>
<th>‘No’ Average Number of Challenges (n)</th>
<th>SD</th>
<th>t-value</th>
<th>Cohen d</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>6.97 (16, 112)</td>
<td>15.59</td>
<td>7.01 (36, 319)</td>
<td>14.25</td>
<td>t(52,429)= -0.25</td>
<td>-0.003</td>
<td>0.80</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7.87(1, 795)</td>
<td>14.32</td>
<td>6.97(50, 636)</td>
<td>14.69</td>
<td>t(52,429)= -2.56</td>
<td>0.60</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>History of Heart Disease</td>
<td>8.60(1, 581)</td>
<td>19.47</td>
<td>6.95(50, 850)</td>
<td>14.50</td>
<td>t(52, 429)= -4.42</td>
<td>0.11</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>History of Stroke</td>
<td>9.27(688)</td>
<td>21.33</td>
<td>6.97(51, 743)</td>
<td>14.56</td>
<td>t(52, 429)= -4.10</td>
<td>0.15</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>7.93(5, 079)</td>
<td>14.24</td>
<td>6.90(47, 362)</td>
<td>14.72</td>
<td>t(52, 429)= -4.76</td>
<td>0.70</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>High Cholesterol</td>
<td>8.24(4, 429)</td>
<td>22.19</td>
<td>6.88(48, 002)</td>
<td>13.77</td>
<td>t(52, 429)= -5.87</td>
<td>0.09</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Renal Disease</td>
<td>7.95(191)</td>
<td>14.63</td>
<td>7.00(52, 240)</td>
<td>14.68</td>
<td>t(52, 429)= -0.90</td>
<td>0.06</td>
<td>0.37</td>
</tr>
<tr>
<td>Sleep Apnea</td>
<td>7.40(3, 254)</td>
<td>14.78</td>
<td>6.97(49, 177)</td>
<td>14.67</td>
<td>t(52, 429)= -1.61</td>
<td>0.03</td>
<td>0.109</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Family History</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>7.25(22, 177)</td>
<td>16.05</td>
<td>6.81(30, 254)</td>
<td>13.58</td>
<td>t(52, 429)= -3.69</td>
<td>0.03</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>7.83(14, 533)</td>
<td>17.57</td>
<td>6.68(37, 898)</td>
<td>13.39</td>
<td>t(52, 429)= -6.24</td>
<td>0.11</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>7.83(9, 874)</td>
<td>16.19</td>
<td>6.81(42, 557)</td>
<td>14.293</td>
<td>t(52, 429)= -4.096</td>
<td>0.15</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>7.43(23, 063)</td>
<td>15.52</td>
<td>6.66(29, 368)</td>
<td>13.97</td>
<td>t(52, 429)= -5.94</td>
<td>0.05</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>High Cholesterol</td>
<td>7.69(15, 233)</td>
<td>17.69</td>
<td>6.71(37, 198)</td>
<td>13.24</td>
<td>t(52, 429)= -6.939</td>
<td>0.07</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
Table 6. Summary of the multiple regression analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SEβ</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>2.741</td>
<td>0.855</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>1.064</td>
<td>0.154</td>
<td>0.033**</td>
</tr>
<tr>
<td>Age Group</td>
<td>0.911</td>
<td>0.051</td>
<td>0.083**</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>-0.074</td>
<td>0.021</td>
<td>-0.015**</td>
</tr>
<tr>
<td>Height</td>
<td>0.006</td>
<td>0.004</td>
<td>0.007</td>
</tr>
<tr>
<td>Weight</td>
<td>0.002</td>
<td>0.002</td>
<td>0.005</td>
</tr>
<tr>
<td>Alcohol (Risk Factor)</td>
<td>0.233</td>
<td>0.199</td>
<td>0.005</td>
</tr>
<tr>
<td>Smoking (Risk Factor)</td>
<td>-0.761</td>
<td>0.171</td>
<td>-0.019**</td>
</tr>
<tr>
<td>Stress (Risk Factor)</td>
<td>0.641</td>
<td>0.126</td>
<td>0.022**</td>
</tr>
<tr>
<td>Exercise (Risk Factor)</td>
<td>-2.015</td>
<td>0.123</td>
<td>-0.071**</td>
</tr>
<tr>
<td>Salt (Risk Factor)</td>
<td>-1.174</td>
<td>0.132</td>
<td>-0.038**</td>
</tr>
<tr>
<td>Nutrition (Risk Factor)</td>
<td>-1.071</td>
<td>0.189</td>
<td>-0.025**</td>
</tr>
<tr>
<td>Air Miles (Incentive)</td>
<td>1.573</td>
<td>0.126</td>
<td>0.052**</td>
</tr>
<tr>
<td>Number of Conditions</td>
<td>-0.007</td>
<td>0.075</td>
<td>0.000</td>
</tr>
<tr>
<td>Number of Family Histories</td>
<td>0.315</td>
<td>0.043</td>
<td>0.033**</td>
</tr>
</tbody>
</table>

Note. * p < 0.05, ** p < 0.001; B = unstandardized regression coefficient, SEβ = Standard error of the coefficient; β = standardized coefficient

3.6.5 Analysis of Challenges

When presented with a daily challenge, users have the option either skip or accept the challenge, and then later mark it as complete or incomplete the following day. Though 93% of the accepted challenges were completed, a large majority (70%) of the challenges presented to the users for selection were skipped. Figure 5 provides a breakdown of the completion rates per risk factor. Although nutrition was the most prevalent risk factor, the challenges from this category had the highest skip rate (74.8%), with only 23.1% challenges completed. In contrast, 50.4% of the alcohol challenges were completed, with 46.9% of them skipped.
3.6.6 User Feedback

Over the study duration, a total of 37 user comments were received, with 24 comments submitted through the iTunes store and 13 comments through the technical support email. A large number of users (n=17) stated that the daily tips were a good way of incorporating attainable healthy changes into their daily routines and facilitating heart disease prevention. Another subset (n= 5) mentioned that the challenges were not applicable to them because the challenges were more focused on urban lifestyles rather than the rural setting.

3.7 Discussion

Our analysis of the <30 days usage data provided a number of insights on the uptake and effectiveness of a consumer friendly mobile app for the engagement of populations in the management of cardiovascular risk. Majority of users were female and from the younger demographic (21-30 years) group. However, the older user groups demonstrated higher levels of engagement and completed more challenges. The
skewing of the demographic towards younger adults was anticipated, and is characteristic of the population currently owning smartphones and downloading mobile applications (57,58).

However, the finding that the level of engagement increased with age was unique. The Pew Internet’s May 2010 survey showed that younger users not only download more apps, but also tend to be 50% more likely than users aged 50 and older to use them (57). In this case, it can be inferred that the older user groups were more committed to their health goals and were potentially more willing to participate in a daily self-management activities.

The multiple regression analysis suggests that gender, age group, ethnicity, five of the risk factors (all but alcohol), the presence of incentives, and the number of family histories are predictors of the number of challenges completed by a user, $F(14, 56,538) = 86.644, p < 0.001, \text{adj. } R^2 = 0.021$. The analysis also demonstrates that these variables only explain 2% of the variation in the number of challenges completed. The social phenomena around the use of apps for lifestyle modification are complex and multidimensional, consequently making it difficult to explain the large amount of variation. There may be other factors, such as the influence of the user’s environment, familial structure, socioeconomic status, and familiarity with technology, that could have affected the number of challenges completed and the resulting low R-squared value (59).

Furthermore, those who identified having a diagnosis or family history of health conditions would have higher levels of participation. This implies that individuals who are aware of their familial risk or are currently dealing with a health condition, may have a greater perceived susceptibility or risk and may be more inclined to use a risk management app, when compared to those who have not yet been exposed to health related problems (60). A recent review by Imes et al. found that both the awareness of family history and perceived personal risk are necessary predictors of change, and when coupled with interventions that are 1) founded in theoretic frameworks, and 2) provide lifestyle modification options, they can guide individuals at risk towards improved health behaviour change (61). Moreover, certain risk factors influenced number of challenges completed by an individual. Physical inactivity, nutrition, and salt and tobacco intake had a negative association, demonstrating that users who had these risk factors completed less challenges than users without these risk factors. Stress, on the other hand, had a positive association, and consequently users with this risk factor completed more challenges than users that did not have this risk factor. The negative association is counter intuitive, as one would expect that the presence of a risk factor would result in increased engagement with ones health.
Chapter 3- Pragmatic Evaluation of a Consumer Focused mHealth App

The incentives group demonstrated comparable engagement levels to the non-incentives group, which implies that a one-time monetary incentive could potentially trigger sustained motivation, and engage individuals in a short-term preventative intervention. The Air Miles® incentives increased uptake amongst the male and the older demographic, which brings to speculation the impact the reward form (cash, points, gift card, etc.) and vendors could have on attracting specific user demographics (62). For example, are the majority of Air Miles® consumers older compared to the iTunes App Store user base, who may be younger? While there is increasing evidence showing that financial incentives are more effective at changing behaviour than usual care, the effect of alternative incentive types on uptake from target populations with varying socio-demographic settings remains unexplored (38,56).

Poor nutrition, physical inactivity and stress were the most prevalent risk factors identified, coupled with the majority of users having a BMI between 25 and 30, suggests that being overweight was a predominant risk factor amongst the users.

Furthermore, the feedback received in the form of comments from the users expressed the need for challenges that were relevant to their situation and needs. For individuals who work in the service industry, for example, getting up from their desk and going for a walk may not be relevant. Also, the high frequency of challenges skipped, suggests that perhaps the challenges were not applicable to the user, forcing them to search for options. The individualization of content and selection of strategies based on personal preference can optimize engagement and have a significant impact on the effectiveness of the intervention (63,64). Offering customization by offering users the ability to tailored challenges based on their profile (age group, location, ethnicity, etc.) could increase the number of appropriate challenges shown to the users, resulting in higher engagement and motivation levels.

3.8 Limitations

The data obtained from both the risk assessment and the challenge completion rates were dependent on self-reporting, which could have influenced the overall accuracy of the data. Given that the app was only made available to iOS (iPhone, iPad, iPod Touch) users, the usage data does not fully represent all consumers, specifically Android users, who now represent a majority of the smartphone market (58). Smartphone ownership varies by socioeconomic background, and it was been shown that those who have higher levels of income and education are more likely to own iPhones (58).
3.9 Conclusions

While the younger population downloaded the app the most, it was the older population who demonstrated greater and sustained engagement levels. Behavior change applications have the potential to reach a targeted population previously thought to be uninterested or unable to use mobile apps. However, lifestyle modification and risk reduction tools must be useful, relevant, and integrated into daily routines, where the opportunity to achieve significant behaviour change is the greatest. Mobile devices may be an effective channel for the delivery of such interventions to populations in various settings. The development of behaviour change mobile applications should assume that older adults will in fact engage if the behavior change elements are suitably designed, integrated into daily routines, and tailored.

While incentives may be the stepping stone that is needed to guide the general population towards preventative tools and promote maintenance of positive behaviour change, the incentive type and its influence on specific user groups needs to be further explored. It is clear, however, that capturing population-level usage information offers tremendous insight on user behaviours and interactions. The possibility of expanding the data collection beyond a single intervention, and capturing data from peripheral devices and the environment, or even linking such findings with long-term outcomes, could better inform the development, delivery, and uptake of preventative tools.
Chapter 4

Systematic Design of a Behavioural mHealth App

The <30 days study illustrated the tremendous potential of consumer apps to effectively access and engage populations in the identification and management of modifiable risk factors (65). Contrary to common belief, this study also highlighted that, overall, older users (51 years and older) had sustained app engagement compared to their younger counterparts. This finding further reinforces the use of an app for the self-management of T2DM, a chronic illness that is common among a similar age group (66).

Furthermore, the majority of existing consumer apps for diabetes self-management are not based on previous evidence and knowledge, yielding suboptimal engagement levels and clinical outcomes (67). This chapter discusses the systematic design of a behaviour mHealth app for the self-management of T2DM, which included the identification of an appropriate theoretical framework for the development of complex chronic disease interventions, a scoping review of relevant literature, and the translation of knowledge into app features through the user-centered design approach.

This chapter has been reproduced from the following publication: Goyal S, Morita P, Lewis GF, et al. The Systematic Design of a Behavioural Mobile Health Application for the Self-Management of Type 2 Diabetes. Canadian Journal of Diabetes. Canadian Diabetes Association; 2015; 40(1): 1–10. To minimize repetition, certain sections of the publication were excluded.

4.1 Introduction

Currently, only half of the patients with T2DM are achieving a target A1c of <7% (66). Although self-management has long been acknowledged as a key component in the clinical treatment of diabetes, patients often lack the diabetes knowledge and skills necessary to manage their condition on a daily basis (6). The inability to fundamentally understand the impact of diabetes management activities on overall glycemic control leads to low levels of participation in self-care behaviours (4,5). This is particularly problematic for T2DM patients not treated with insulin, who are typically prescribed lifestyle modification and pharmacotherapy, as they have no daily indicator of glycemic control.
Chapter 4- Systematic Design of a Behavioural mHealth App

While SMBG is an essential component of insulin therapy regimens, its role amongst patients not treated with insulin has previously been unclear (26). However, recent studies have demonstrated that structured SMBG, an approach where the frequency and timing are predetermined, can significantly improve glycemic control and overall patient engagement (39,68,69). With the appropriate guidance and education, SMBG can improve self-awareness and motivate patients with T2DM not on insulin to participate in diabetes self-management activities (70).

While some patients may receive diabetes education, the training is generally infrequent, impersonal, and difficult to apply to real-world settings (7). As a result, patients are unable to 1) understand and apply guidelines to their individual and unique situations, and 2) understand the functional dynamics of glycemic control and recover from exceptional situations (7). These two factors can significantly impact diabetes self-management since, in addition to routine self care, the ability to problem-solve and make decisions based on blood glucose levels can significantly reduce the long-term complications for patients with diabetes (23).

The self-management tools currently available are didactic and do not provide patients with the personalized and actionable knowledge needed to participate in routine self-care (10). While the increasing prevalence of mobile phones has resulted in the publication of many diabetes apps, most are not evidence-based nor rigorously evaluated, and many rely on real-time feedback from a third party health care provider (10,11,31,33). We hypothesized that the effective self-management of non-insulin requiring T2DM requires a behavioural mHealth application that empowers patients with the ability to self-monitor, understand the impact of lifestyle behaviours on glycemic control, and adjust their self care based on contextualized data.

4.2 Framework for the Development of a Behavioural Intervention

The vast majority of existing mHealth applications not only lack any use of theoretical models for behaviour change, but also have no clinical evaluation to validate their approach (71). The limited use of frameworks in this field has resulted in mHealth technologies that are most often not intuitive, useful nor evidence based. In order to ensure that the mobile application is clinically relevant and rigorously evaluated, the design, development and evaluation of bant II will be guided by the Knowledge to Action (KTA) and Medical Research Council’s (MRC) blended framework for complex interventions, depicted in Figure 6.
Graham’s Knowledge to Action (KTA) model promotes the evidence-based and user-centric approach of knowledge implementation in a clinical setting (67). In the context of this intervention, the KTA model was used to translate diabetes education into actionable knowledge, in order to facilitate diabetes self care. The MRC framework for complex interventions, developed by the Medical Research Council in the United Kingdom, was used to support the design of both the intervention and the rigorous evaluation phases (72). Although these models were conceived separately, the blended model has previously successfully guided the methodological and user-centered design and evaluation of a multifaceted clinical tool (67). However, to our best knowledge, this is the first instance of this model being adapted for the design and evaluation of an mHealth intervention. This review presents the results of phase one of the KTA-MRC blended model, where we identified a guiding theory, reviewed the evidence, assessed barriers to use, modeled the process and outcomes and adapted the knowledge to the local context. Specifically, we discuss how the knowledge pertaining to specific aspects of T2DM self-management, such as SMBG, was assessed and translated into the key constructs of the application design.

![The KTA-MRC blended framework](image)

**Figure 6.** The KTA-MRC blended framework.
Chapter 4- Systematic Design of a Behavioural mHealth App

4.3 Theoretical Model for Behaviour Change

Patients with T2DM not treated with insulin require self-management tools that enable self-monitoring, provide actionable knowledge, and facilitate behaviour change. These concepts align with the constructs of the Social Cognitive Theory (SCT), a behavioural model commonly applied to the design of interventions intended for the self-directed management of chronic disease (54). Self-care mHealth applications based on SCT have previously demonstrated positive behaviour change, leading to improved compliance and health outcomes in randomized trials (17,73). The key constructs of the SCT can be categorized into five subgroups: 1) psychological determinants of behaviour, 2) observational learning, 3) environmental determinants of behaviour, 4) self-regulation, and 5) moral disengagement (54). These constructs emphasize the dynamic interaction of personal, behavioural and environmental factors that have the ability to alter human behaviour (54). Under the guidance of phase 1 of the KTA-MRC model, the Social Cognitive Theory was identified as the governing behaviour change theory for the intervention. The application design will drive self-efficacy through observational learning, self-regulation, incentive motivation and facilitation (54). Specifically, these will be achieved through self-monitoring, tailored feedback and structured education, social media and incentivizing positive behaviour with real-world rewards. Self-monitoring of blood glucose and lifestyle behaviours are at the core of the application, and the existing evidence for these approaches was first reviewed and then translated into mobile app features.

4.4 Context-Driven Self-Monitoring of Blood Glucose

The regular use of self-monitoring of blood glucose amongst T2DM patients not using insulin has previously been unclear. As a standalone intervention, SMBG demonstrated a non-significant decrease in A1c of 0.1% at 12-month follow-up in non-insulin requiring T2DM patients with a diabetes duration of longer than 1 year (26). It can be inferred these patients did not benefit from SMBG due to the lack of the personalized structured education needed to derive the meaningful and actionable information from the blood glucose readings (10). Due to the inability to interpret and make self-management decisions based on day-to-day SMBG readings, patients must rely solely on their physician visits where they may receive feedback based on quarterly A1c measurements.

More recently, an approach known as structured SMBG, shown in Figure 7, has demonstrated significant improvements in patient engagement and diabetes outcomes (39,68,69). This programmatic approach requires patients to take blood glucose measurements according to a defined schedule and adjust their diabetes care based on the patterns identified, guiding them towards better self-management (39). The
Structured Testing Program (STeP) evaluated the use of structured SMBG in a 12-month randomized clinical trial (n=483) and demonstrated reductions in A1c of up to 1.2% (27,74). Not only can this approach meaningfully reduce A1c, but it also increased self-confidence and overall motivation amongst the patients (39,75). SMBG coupled with the appropriate education has the potential to empower patients with actionable knowledge, which can be used to manage blood glucose variability and improve glycemic control (8).

**Figure 7. Staggered SMBG (74)**

Polonsky highlights four key aspects that need to be addressed in order to optimize the benefits seen from SMBG in T2DM patients not on insulin: 1) frequency and timing, 2) patient education, 3) clinician interpretation of data, and 4) efficient data collection approaches (70). The recent guidelines released by the International Diabetes Federation reflect these considerations, suggesting that structured SMBG in non-insulin requiring T2DM patients should only be used when patients and/or their clinicians have the skills and knowledge to adjust treatment goals according to the data obtained (74).

As such, bant II will utilize structured SMBG to help patients recognize patterns in lifestyle behaviours that may require modification, and reinforce education around the impact these behaviours can have on
overall glycemic control. As shown in Figure 8, goal setting and reminders will be used to guide the patients towards structured SMBG and promote paired testing (pre and post prandial blood glucose measurements). Using this information, the bant II will identify trends and walk users through teachable moments depicted in Figure 8, where they can reflect on possible causes and fixes for the trends triggered. Coupled with meal and physical activity data, the contextualized SMBG readings will be displayed to the patients in a way that enables the clear association between behaviours and glycemic control.

In order to reduce the barriers associated with manually recording blood glucose readings, we opted to interface with a Bluetooth-enabled blood glucose meter, which will allow patients to wirelessly upload their blood glucose readings directly to their mobile device running the bant II app. Similar to the study we conducted with the first version of bant amongst adolescents with type 1 diabetes, this automated approach facilitates fast and discrete transactions, reduces erroneous manual data entry, and decreases the burden on the patient when reporting data collected during self-monitoring activities (38). Although the use of wireless blood glucose meter appears to be a necessary feature to reduce barriers to use, a review by Chomutare et al. notes that 100% of the apps commercially available in 2011 relied on manual entry of blood glucose data, and only 62% of interventions used in literature had any form of wireless data transfer (10).

The blood glucose readings captured will be paired with related lifestyle information to provide real-time feedback and facilitate individualized education. Existing approaches and evidence around self-monitoring of physical activity levels, dietary intake and weight, informed the design and overall architecture of the bant II app.
Figure 8. Goals and teachable moments: a) Users can select SMBG or activity goals. b) Once the goal is selected, users can set reminders and plan their SMBG over the next 7 days. c) If the user triggers a string of consecutive high or low readings for a given context, they will be prompted to complete a trend review.

4.5 The importance of Physical Inactivity

While the benefits of physical activity are widely known, it continues to be the most prevalent (yet modifiable) risk factor for 51% of the Canadian adult population (76). Even a modest increase in physical activity, either aerobic or resistance training, can improve glycaemia and overall diabetes control (77). There is a growing body of research exploring the benefits of frequent breaks in prolonged periods of sedentary behaviour on glycemic control, specifically postprandial spikes (78,79). For example, reducing time spent in sedentary positions (sitting/lying) can moderate the pathological progression of type 2 diabetes (77,78). However, the benefits of reducing and breaking up long periods of physical inactivity on glycemic control remain underexplored in free-living settings (79).

To date, most interventions have not been able to effectively monitor lifestyle behaviours, such as diet, physical activity and weight, and influence a change in physical outcomes amongst patients with diabetes.
Chapter 4- Systematic Design of a Behavioural mHealth App

(30). This is largely because these interventions were not embedded into the daily routine of users and did not provide the structured personalized feedback needed to facilitate decision-making, and ultimately change behaviour. The combination of wireless peripheral devices and mobile applications offers an integrated platform, which has the potential to promote real-time self-monitoring of physical activity levels, weight and diet, provide tailored feedback and can ultimately guide patients with diabetes towards positive behaviour change (77).

Body-worn activity monitors are a user-friendly, unobtrusive, and a real-time approach of capturing ambulatory activity, specifically number of steps taken (80). Even though currently available wearable activity monitors do not accurately capture all forms of activity (swimming, cycling, etc.), walking is the most commonly reported form of activity amongst this population, and can be accurately and easily captured through these devices (80). Increases in the amount of walking has previously demonstrated improved body composition, A1c, lipid profiles and glycemic control in patients with T2DM (81). The Diabetes Prevention Program also previously demonstrated that achieving a minimum of 150 min/week of physical activity, which could take the form of brisk walking, was more effective than metformin in preventing type 2 diabetes amongst individuals with prediabetes (82).

Commercially available activity monitors offer wireless data transfer to mobile phones with companion applications that offer more advanced analytics compared to traditional pedometers. An even less disruptive approach is the use of the accelerometer in the iPhone itself to quantify the number of steps taken while walking with an accuracy as high as 94.1% (83). To our knowledge, there has only been one study that evaluated the use of the mobile phone as an activity-monitoring device amongst primary care patients. The randomized trial (n=90) evaluating the effectiveness of using an accelerometer-enabled mobile phone application to promote physical activity demonstrated a mean improvement of 1,029 (95% confidence interval 214 to 1843) steps per day from baseline to week eight (84). While technology such as pedometers can increase levels of physical activity amongst T2DM patients, a systematic review by Connelly et al. found that high attrition rates must be addressed by placing more emphasis on sustained patient participation (81,85).

To provide users a means to capture steps, bant II will support the wearable activity monitor Jawbone UP24 (Jawbone®, San Francisco, CA, USA), and the activity monitoring capability of the mobile phone itself. Both approaches will quantify sedentary periods and steps taken, and enable wireless data integration with the mobile app, where the data will be analyzed and displayed to the user. As shown in Figure 7, daily physical activity trends will be showcased alongside dietary intake and blood glucose readings to provide a holistic overview of potential factors that can influence glycemic control. Figure 7
Chapter 4- Systematic Design of a Behavioural mHealth App

depicts the trends page of the app, where the activity trends will be shown in the context of overall diabetes control, to further illustrate the impact a sedentary lifestyle can have on glycemic control and weight goals. The recommendation of 10,000 steps/day will be used to motivate users, by starting their goal at 5,000 steps and increasing the goal by increments of 500 steps as the users progressively achieve their step goals (82). Tudor-Locke et al. proposed a sedentary lifestyle index which considers <5,000 steps/day to be “sedentary” and >10,000 steps/day to be active (86). The application design will facilitate self-monitoring of steps and progressive goal setting to motivate patients towards increasing overall levels of physical activity.

Figure 9. Data entry and trends: a) Users may sync with the app with a wireless weight scale, blood glucose meter and physical activity monitor, and capture meal photos using the mobile phone’s camera. b) The daily readings are showcased on a timeline providing a snapshot of their day and the timing of their various activities. c) The trends page provides an overview of their glycemic control, physical activity levels, and weight trends.
4.6 Dietary Intake

In addition to decreased levels of physical inactivity, adherence to dietary recommendations is a key component of diabetes management and achieving metabolic goals. Nonetheless, most patients fail to comply due to lack of motivation, difficulty changing lifestyle behaviours, and not understanding the direct impact dietary choices have on glycemic control (17,70). Telemedicine delivered through mobile devices has enabled patients to receive real-time feedback on dietary patterns, caloric intake, and distribution of macronutrients (87,88). The feedback component of this approach relies on the patient to accurately capture their meal information and send this information to a health care provider for evaluation. Self-report approaches, such as electronic questionnaires, databases, and diaries, depend on an individual’s ability to recall the contents and portions of the food consumed, not only placing a burden on the user but also potentially reducing the accuracy of the record. Food photography is an approach that enables users to easily capture high quality records, without having to depend on memory recall or lengthy logs, potentially reducing the barriers of self-monitoring dietary intake (87,89). This approach can also account for the variability in dietary habits, staple foods, and preparations amongst communities and ethnicities, which has always been a challenge for other electronic methods such as food databases and recognitions systems (89).

The mobile phone’s camera can facilitate food photography in free-living conditions. Although there are studies evaluating the use of mobile phones for recording dietary intake, most are based on the Remote Food Photography Method in which the user captures food photos and sends them to a third party provider for interpretation (90). To date, the emphasis has been on the use of food photography to accurately detect food contents, rather than for the delivery of personalized education, facilitation of self-care and behaviour change.

In order to bring self-awareness to food intake and drive the association between dietary behaviours and glycemic control, bant II will promote meal photos through reminders and automatically associate the photos with the corresponding blood glucose reading context (e.g. breakfast). For example, if a user selects breakfast as a goal, then on their preselected goal days they will receive an alert thirty minutes before and two hours after their meal, reminding them to take their pre-prandial blood glucose reading, meal photo, and subsequently their postprandial reading. As shown in Figure 8, the respective pre and postprandial blood glucose readings will be linked to the appropriate meal photo, adding context to the measurements and facilitating the data analytics. The contextualized information will enable patients to draw a well-defined association between the meal characteristics and their resulting glycemic control, either reassuring them or motivating them to modify their behaviours to improve outcomes.
Chapter 4- Systematic Design of a Behavioural mHealth App

Figure 10. Meal photos and SMBG: a) The meal photos and corresponding paired blood glucose readings will be automatically associated based on meal context. b) A trend view enables patients to click through photos of a specific meal, for example breakfast, and see corresponding blood glucose levels. c) The weight readings will be trended over time illustrating weight gain, lost or maintenance.

4.7 Weight Management

Outside of bariatric and pharmacological approaches, weight reduction can be achieved through lifestyle interventions, such as improved nutrition and increased levels of physical activity. Weight loss amongst overweight and obese adults with diabetes can not only improve glycemic control, but also lower the risk of cardiovascular disease (88). Short and long-term, multicomponent, behavioural interventions, have previously demonstrated successful weight loss, however, these approaches require frequent in-person visits making them difficult to scale to the public at large (88,91).
Chapter 4- Systematic Design of a Behavioural mHealth App

Managing weight is a key component of achieving metabolic control, and will be included as a holistic approach to the overall management of diabetes. The application will encourage weekly weight measurements through reminders, and facilitate the wireless data transfer using the Bluetooth-enabled Wahoo (Wahoo Fitness, Altanta, GA, USA) weight scale. As shown in Figure 5c, the intent is to bring self-awareness to changes in weight and draw relationships with associated lifestyle behaviours, such as food intake and sedentary behaviours. Frequent self-monitoring of weight is an approach for preventing relapse and motivating lifestyle modification (92).

4.8 Incentivizing Behaviour Change

Patients who follow clinical recommendations, such as lifestyle modification and medication adherence, tend not to realize immediate benefits of their actions and may only see the positive effects of their actions after a few years or decades (93). Frequent reinforcement of positive behaviours through tangible monetary-based rewards has previously demonstrated significant health behaviour change (93). Incentivizing health related actions is based on behaviour economic principles, where the psychology behind understanding how economics impacts decision-making is studied (93,94).

Gamification, an approach that uses game mechanisms in non-game contexts, can be used to increase motivations and to deliver incentives, driving sustained behaviours over time (95). Reinforced behaviour change interventions have demonstrated improved outcomes for conditions ranging from substance abuse to diabetes management (53,54). For example, our mobile self care application bant for type 1 diabetes, developed with SickKids Hospital (Toronto, Canada), engages adolescents with type 1 diabetes to improve the management of their condition (96). It could be inferred that adolescents also do not witness the immediate benefits of self care activities, and as a result may struggle with achieving optimal glycemic control (93). The bant app, designed with iterative feedback from adolescents, their families, and clinicians, enabled the patients to automatically transfer their blood glucose readings wirelessly, collect experience points to redeem iTunes rewards, and to review both their positive and negative trends. In a 12-week pilot (n=20), the use of bant led to a 49.6% increase in the frequency of blood glucose measurements in twelve patients (96). Similarly, a game mechanism promoting positive behaviours will be integrated within bant II.

An obviously caveat is the long-term sustainability of the providing incentives to patients. The majority of interventions studied to date have demonstrated only short-term benefits, and as soon as the reinforcement is no longer present, patients discontinue the self care activities (93,95). However, the
intent of the proposed solution is to deliver adult-appropriate incentives through a game mechanism that initially motivates and engages users, reinforces positive behaviours, and leads to an improvement in the patient’s ability to self-manage T2DM (95). The ultimate goal is to not only motivate, but to also develop a sense of mastery amongst the patients, potentially reducing the dependency on the incentive itself.

*bant II* will reward users with points for positive behaviours, which can then be redeemed for tangible gifts like grocery coupons, reinforcing and immediately rewarding positive behaviour change (93). As shown in Figure 9, the actions associated with points include completing paired-testing and step goals, taking blood glucose measurements, capturing meal photos, measuring weight once a week, and resolving any trends triggered. It is anticipated that the mixture of frequently reinforcing immediate positive behaviours and trouble-shooting negative behaviours will improve a self-efficacy and result in sustained behavioural change (93).

**Figure 11.** Gamification and Social Media: a) Users can accumulate points for participating in diabetes self-care activities. b) The points accumulated through the application can be used to redeem tangible gift cards. c) A gated community will promote peer support and experience sharing.

### 4.9 Social Support & Information Sharing

While many have emphasized the importance of experience sharing amongst peers, both for clinical information and additional support, the majority of existing applications either fail to fully integrate with
social media platforms, or they simply do not include them in their solutions (8,97,98). This is a surprising reality, given the increasing use of social media for information-sharing, patient-centered management, and community-building (97). Patients with diabetes often do not have a support network, which can significantly hinder engagement in diabetes self care (99). Social media can facilitate connections to patients across geographical areas or even to patients in local communities (17). Building on the application design of bant, we will also facilitate peer communication through a closed-looped microblogging service, depicted in Figure 9.

To ensure the secure storage of the clinical data collected, bant II was integrated with TELUS Health Space (Microsoft HealthVault), an online personal health record (PHR) certified by the federal agency, Canada Health Infoway (38). The consumer-focused PHR will not only act as a data repository, but it will also enable data sharing with both formal and informal family members.

4.10 Conclusions

The design of bant II was governed by phase one of the KTA-MRC blended model, where a theoretical model was identified, existing evidence was reviewed, and barriers to use were assessed. Together this knowledge was translated into the key constructs of the application. The concepts were then modeled and adapted to the local context following the principles of user-centered design, ensuring that features of the software were informed by the needs of patients with type 2 diabetes. The resulting application, bant II, can enable patients with type 2 diabetes to self-monitor their physical activity, diet, and weight, identify patterns in glycemic control in relation to their lifestyle, guide them towards remedial decision-making, and ultimately improve their ability to self-manage. Phases two and three will involve a final usability session followed by a randomized trial amongst T2DM patients not treated with insulin and who are managed in a primary care setting. The primary outcome of the trial will be change in A1c from baseline to 12 months. Moreover, the goal of the study is to not only evaluate the effectiveness of a behavioural mobile application for diabetes self-management, but to also define the role of mobile applications as a complementary tool for the delivery of health care, and more specifically, tailored diabetes education. bant II has the potential to address a gap in the clinical management of type 2 diabetes patients, potentially preventing secondary complications and ultimately improving quality of life.
Chapter 5

Evaluation of an App for the Self-Management of Type 2 Diabetes

The design of *bant II*, a mHealth app for the self-management of T2DM, followed Phases 1 and 2 of the KTA-MRC framework, which included a review of evidence to inform the intervention features, and subsequent validation from end-users. As part of Phase 3 of the framework, this chapter presents the RCT design for the evaluation of *bant II*. The primary objective of this RCT was to determine the impact of the evidence-based and patient-centered app on the self-management of T2DM.

This chapter has been reproduced from the following publication: Goyal S, Lewis G, Yu C, Rotondi M, Seto E, Cafazzo JA. Evaluation of a Behavioral Mobile Phone App Intervention for the Self-Management of Type 2 Diabetes: Randomized Controlled Trial Protocol, JMIR Res Protocol 2016; 5(3): e174. In order to minimize repetition, the introduction was excluded, and results section of the manuscript was adapted.

5.1 Methods

The *bant II* study is a 12-month, prospective, multicenter, unblinded, parallel RCT in which 150 participants are randomly assigned to one of two groups: the control group receives current standard of care, and the intervention group receives the mobile phone app system in addition to standard of care. During the study period, all participants (intervention and control) attend quarterly clinic visits (standard care).

The primary recruitment strategy for this study is through self-referral at primary care and community practices throughout the Greater Toronto Area. This area includes sites that are situated in urban and suburban settings. The University Health Network Research Ethics Board (REB) approved the study (14-7978-AE). Local institutional REB approvals were also obtained from the following participating sites: St- Joseph’s Health Care Centre (#2015-010), Trillium Health Partners (#698), and North York General (#15-0038). For sites without an institutional REB, namely the Taddle Creek Diabetes Education
Chapter 5- Evaluation of an App for the Self-Management of Type 2 Diabetes

Program and LMC Diabetes and Endocrinology, approval was obtained from an Institutional Review Board (Pro00016415).

Randomization is being conducted at the patient level, using random block sizes of four and six to reduce the variance across the entire sample, with a 1:1 allocation ratio. Stratification is also conducted by recruitment site. The allocation envelopes contain a piece of paper with either control or intervention written upon it, as well as a random patient identifier. The study coordinator allocates each participant by taking the envelop on the top of the stack, and enrolls them into the appropriate study arm, as indicated.

5.1.1 Intervention

The participants randomly assigned to the intervention group will receive an iPhone 5s loaded with the bant II app, as well as a Bluetooth-enabled (a standard protocol for short distance wireless communication) Wahoo weight scale (Wahoo Fitness, Atlanta, GA, USA), Jawbone UP24 (Jawbone, San Francisco, CA, USA) wrist-worn activity monitor, and Jazz blood glucose meter (Agamatrix, Salem, NH, USA). We will also provide BluGluLe, a Bluetooth adapter that connects to the glucose meter and enables the wireless transfer of readings from the meter to the iPhone. The mobile app also enables users to capture meal photos using the built-in camera, and track medication adherence on a weekly basis. In addition to the wrist-worn activity monitor, steps could also be tracked through the mobile phone itself using the built in accelerometer.

The bant II app, shown in Figure 1, facilitates self-monitoring of lifestyle behaviors, and enables patients to correlate their lifestyle behaviors with their glycemic control through paired (pre- and post-prandial) blood glucose testing. Upon data capture, the app will assess the other data points in context, identify positive and negative behaviours based on the analysis, and facilitate remedial decision making. The app also enables patients to set goals and receive reminders, participate in a closed-gated social community, and accumulate points for positive behaviors, which can be redeemed for tangible gift cards (eg, groceries, gym membership). This app builds on a previous version of the bant app, which focused on engaging adolescents in the self-management of type 1 diabetes mellitus (T1DM). A 12-week pilot of bant demonstrated positive behavior change amongst the adolescents with T1DM.

We have ensured that all of the appropriate safeguards are in place to protect personal health information. For example, the iPhone requires a passcode to access the app, and the app itself requires a username and password. In the event that the device is lost or stolen, we can remotely wipe the device using mobile data
management software (Airwatch, Atlanta, GA). The bant II app is intended to provide guidance and facilitate diabetes self-management, and is not classified as medical device. Given that the app poses minimal risk to the patient, Health Insurance Portability and Accountability Act requirements do not apply.

5.1.2 Participants

The inclusion criteria for participants include: definitive diagnosis of T2DM, not treated with insulin, at least 18 years of age, a baseline glycated hemoglobin A1c (A1c) of 7.5% or higher, and English speaking.

Exclusion criteria include: inability to use a mobile phone (eg, due to vision problems) or to comply with home monitoring (eg, due to suffering from anxiety or depression), and duration of diabetes under one year. Participants who have had diabetes for less than one year are excluded because they typically demonstrate a higher adherence to self-care and have high levels of motivation (103).

5.1.3 Outcomes

The primary outcome measure is change in A1c from baseline to 12 months. Each recruitment site is provided with a DCA Vantage Analyzer (Siemens, Munich, Germany) point of care A1c device to reduce the variability in the A1c laboratory assays. As secondary end points, A1c measurements are also collected at 3-month intervals (3, 6, and 9 months). Clinical staff within the patient’s circle of care are conducting the point of care A1c tests.

Secondary outcomes include blood pressure (mmHg), weight (pounds), total cholesterol (mmol/L), Low Density Lipoprotein cholesterol (mmol/L), and weight at baseline, 3, 6, 9, and 12 months. The number of participants who achieve optimal glycemic control (A1c <7%), as well as the type and frequency of medication changes, will also be measured. Furthermore, validated instruments described in Table 7 are being used to collect and measure burden of disease and diabetes-related self-efficacy and self-care, pre-, mid-, and post-study.
Table 7. Validated instruments administered pre-, mid-, and post study.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Distress Scale (DDS)</td>
<td>The DDS is a 17-item instrument that assesses the emotional, physician-related, regimen-related, and interpersonal aspects of diabetes distress, and provides an indication of diabetes-related quality of life [13].</td>
</tr>
<tr>
<td>Diabetes Empowerment Scale (DES-SF)</td>
<td>The DES-SF is a 28-item (short form) instrument used to measure psychosocial self-efficacy of diabetes self-management. This tool focuses on (1) managing diabetes, (2) assessing readiness to change, and 3) willingness to set goals and change behaviors [14,15].</td>
</tr>
<tr>
<td>Summary of Diabetes Self-Care Activities (SDSCA) measure</td>
<td>The SDSCA is a 11-item instrument that assesses individual levels of diabetes self-care, focusing on general diet, specific diet, exercise, medication adherence, blood-glucose testing, smoking, and foot care [16].</td>
</tr>
<tr>
<td>The Mobile Application Rating Scale (MARS) App -User Version</td>
<td>The MARS is a 26-item instrument used to evaluate the quality, functionality, and overall satisfaction of the mobile app itself [17].</td>
</tr>
</tbody>
</table>

5.1.4 Sample Size

The sample size estimation was based on detecting a minimum reduction of 0.5% in A1c values. Given our inclusion criteria of A1c >7.5%, we anticipate that A1c levels will be highly clustered around 8.5 ± 1.0%. That is, standard deviation values between 0.75% and 1.00% were considered reasonable for the planned study. A minimum of 63 participants per group is necessary to detect a difference of 0.5% in A1c, at an 80% power with a one-sided 5% significance level in all anticipated cases. With a further 15% adjustment for potential dropouts, a final sample size of 150 subjects will be required for both group, with 75 participants in each study arm. All calculations were performed using the R software package, epibasix [18].

5.1.5 Recruitment Procedure

Physician Recruitment
Chapter 5- Evaluation of an App for the Self-Management of Type 2 Diabetes

The lead physician (or research administration staff) of the recruitment site is first approached by email regarding their interest in the study, and a 20-30 minute presentation is offered as a way to disseminate the study details and gauge interest across the site. If the lead physician is interested in participating, they contact the clinicians within their site, disseminate information regarding the study, and identify the clinicians interested in participating in the study. Upon receiving REB approval, a staff member at the participating site generates a list of eligible participants and has the list vetted by the respective physicians for appropriateness.

**Patient Recruitment**

The participating sites send invitation letters to eligible and appropriate participants, explaining the study goals and protocol. The letter invites participants to contact the study coordinator directly, either through email or phone call, if they are interested in participating in the study. Upon initial contact, the study coordinator describes the study and answers any of the patient’s study-related questions. If the participant is interested in participating, the coordinator will schedule an appointment with the respective clinic, and email or mail the patient the consent form in advance for review.

**5.1.6 Data Analysis**

The principal analysis strategy will be the use of linear mixed models in SAS (Cary, NC, USA) using the PROC MIXED procedure. This approach provides a simple method to incorporate baseline values and the correlation of each participant over time (using a random effect). This model is more powerful than the repeated measures *analysis of variance*, as it can easily examine differences between the RCT groups at all time points, and can accommodate potential confounders. Furthermore, although the A1c measurements will be made at 3-month intervals, our primary analysis will focus on A1c levels at the conclusion of the 12-month study. A contrast will be constructed to test this primary comparison among all possible pair-wise tests; no adjustments for multiple testing will be required. Subsequent adjustments will be made for potential confounding variables as necessary, such as baseline parameters that may vary between groups (e.g., age, sex).

Secondary contrasts will be used to examine differences from baseline for all other time points, however these will be of exploratory interest only. Moreover, we will use regression analysis to separate the contribution of the different intervention components (activity monitor, weight scale, SMBG, mobile app...
features), and determine their independent effects on the primary outcome at 12 months. This approach will identify which aspect of the mHealth intervention contributed to the change in A1c.

5.2 Discussion

SMBG is an essential part of managing glycemic control. However, for T2DM patients that are not treated with insulin, the standard approach of simply recommending SMBG without the appropriate guidelines and training will not facilitate behavior change [4]. Polonsky outlines four main considerations for SMBG amongst this specific population: (1) SMBG should be structured and performed regularly around key events (e.g., meals), (2) patients need to be provided with SMBG-related training, (3) clinicians must be able to view SMBG data and use it to inform clinical decisions, and (4) useful display of SMBG data to facilitate pattern identification [3]. To our knowledge, the bant II app is the first mobile app to facilitate structured SMBG, enable simple pattern and trend detection, and potentially facilitate communication between the patient and HCPs during clinic visits.

This RCT will evaluate the use of the bant II app as a self-management tool compared to standard care, over a period of 12 months. We anticipate that the use of the app will provide patients with a greater understanding of which aspects of lifestyle behaviors impact glycemic control, increase participation in self-care activities, and potentially improved diabetes outcomes. We also anticipate that along with higher levels of engagement, patients will initiate conversations with their HCPs, using the SMBG summary data displayed in the app as a reference during consultations. The sharing of such data may result in earlier treatment optimization and medication changes in the intervention group compared to the control group. A considerable limitation of the study is that the iPhone provided to the intervention group is likely to be a secondary device, potentially hindering the complete immersion of the app into daily routines.

At the time of the intervention design, there were no Bluetooth-enabled blood glucose meters available in Canada. In order to facilitate the wireless transfer of blood glucose readings to the app, and reduce burden and errors associated with manual entry, we had to develop a customized Bluetooth adapter [9]. Future studies should explore how apps can be installed directly on an individual’s personal devices, and explore ways to utilize off-the-shelf meters already familiar to consumers (and which meters are potentially reimbursable). These issues highlight the challenges of RCTs as an evaluation approach for mobile apps. Given the rapid evolution of technology (e.g., Bluetooth-supported devices), the mHealth interventions evaluated in trials are often no longer relevant once the lengthy trials have concluded several years later [19]. Furthermore, although recommended by Polonsky [3], we were not able to provide additional
education and skills training to providers. However, we anticipate that through use of bant II, patients will develop an understanding of glycemic control and self-management skills, leading to improved lifestyle management.

The results of this study will further our understanding of how an evidence-based behavior modification mobile app can guide patients in the self-management of their diabetes. Specifically, we will be able to assess how various features of the app influenced self-management behaviours. For example, how consumer-grade devices, such as wearable devices, facilitated chronic disease management, or how incentive mechanisms potentially motivate behaviour change. Most importantly, the study data will demonstrate how test strips are consumed when SMBG is performed in a systematic way, and the impact of immediate feedback on glycemic control and trends.

5.3 Conclusions

This RCT is one of the first to evaluate an evidence-based mobile app that focuses on facilitating lifestyle behavior change driven by contextualized and structured SMBG. The results of this trial will provide insight around the usage of mobile tools for diabetes self-care, effectiveness of consumer-grade devices for chronic disease management, the economic model of using incentives to motivate behavior change, and the consumption of test strips when SMBG follows a rigorously structured approach. The findings from this study will inform the next generation of diabetes education, guidelines for SMBG, and potentially inform health policy pertaining to strip reimbursements for T2DM patients that are not treated with insulin.
Chapter 6

Evaluation of an App for the Self-Management of Type 1 Diabetes

The design of bant II (also known as bant2) was founded on the first version of the app, bant, which focused on self-management among adolescents with T1DM (38). Both apps share a similar architecture; a standalone app with connectivity to Bluetooth enabled devices to enable the wireless upload of self-management data, and also both used a RCT to evaluate effectiveness. As such, the results of the bant RCT provided additional insights on the effectiveness of a standalone app on the self-management of diabetes, potential barriers to use, and the strengths and weaknesses of using an RCT to evaluate mobile apps, further informing the evaluation of the bant2 app.

This chapter has been reproduced from the following manuscript: Goyal S, Nunn C, Rotondi M, Couperthwaite A, Reiser S, Simone A, Katzmann D, Cafazzo JA, Palmert M. Randomized Controlled Trial of a Mobile app for the Self-Management of T1DM Among Adolescents. JMIR (In Press).

6.1 Introduction

Type 1 Diabetes Mellitus (T1DM) is among the most common chronic diseases affecting children, adolescents and adults, with an increasing worldwide incidence of approximately 3-4% a year. Optimizing blood glucose (BG) control is important for patients with T1DM, as improved control has been shown to reduce the incidence and severity of T1DM complications and diabetes-related mortality (104–107). However, achieving optimal control requires intensive self-management, which can be challenging for patients to achieve. Adolescents, in particular, struggle with optimizing BG control, with worldwide data indicating they consistently fail to meet their prescribed therapeutic targets (108,109).

Overall, the mechanism of insulin delivery (i.e. insulin pump or multiple daily injections) has limited impact on glycemic control among youth (110,111). Instead, factors such as self-care behaviours and
Chapter 6- Evaluation of an App for the Self-Management of Type 1 Diabetes

Educational models may have a more significant influence on their health outcomes (112). Given adolescents’ propensity for new technology, eHealth interventions may provide a unique opportunity to communicate with and motivate youth, and thereby improve diabetes management (113,114). Global survey data shows that teenagers adopt new forms of technology quicker and in a more immersive way than any previous generation. The mobile phone has become a primary communication tool for teens. In 2015, it was reported that 88% of American teens either owned or had access to a mobile phone, up from 45% in 2004 (115,116).

Recently, the use of mHealth apps as a tool for improved diabetes self-management has proliferated, as illustrated by the number of diabetes apps currently available for download on the iOS App Store and Google Play (40,117–121). While interest in this technology continues to rise, the clinical utility of these apps remains unclear (35). Only a limited number of diabetes apps have completed rigorous evaluation and to date, most studies have been conducted for the adult and/or T2DM population (31,122,123). It remains unknown how effective these apps are among adolescents with T1DM.

Furthermore, many of the existing apps require manual entry of BG values, and focus primarily on the display of diabetes-related data, such as BG readings, carbohydrate intake and insulin doses (8,35). A recent review observed as little as 5% of these apps utilize this information to provide users with personalized feedback, education or motivation (8,124,125). With clinical guidelines emphasizing the importance of individualized feedback and targeted education, failing to provide users with these features puts current apps at risk of simply mirroring paper-based tools, instead of being a means for behavior change and comprehensive self-management (1).

Therefore, the objective of this research was to design, develop, and evaluate, bant, an app aimed to assist adolescents with the self-management of T1DM. In 2010-11, a pilot version of bant was developed and evaluated through a 12-week pilot study (n=20) among adolescents with T1DM, aged 12-16 years, with hemoglobin A1c’s between 8-10%. Results showed an increase in daily SMBG by 49.8% (P=0.006) and a high reported level of satisfaction, with 88% of respondents stating they would continue to use the system (38). While utilization of bant led to improved self-management behaviours, the trial was not designed to assess effect on hemoglobin A1c (A1c). This study reports the results of a 12-month randomized controlled trial (RCT) conducted to assess the effectiveness of an updated version of bant as a self-management tool for adolescents with T1DM (Trial Registration: ClinicalTrials.gov NCT01899274).
6.2 Methods

Adolescents diagnosed with type 1 diabetes, between the ages of 11 and 16 years, were randomly assigned to 1 of 2 groups: (1) the *bant* (intervention) group; or (2) the treatment as usual (control) group, and followed for a duration of 12 months.

6.2.1 Ethical Approval

Prior to study initiation, protocol approval was obtained from all site-specific ethical review boards and/or committees (The Hospital for Sick Children (HSC) –#1000036524, University Health Network - #13-6237-BE, Trillium Health Partners (THP) – #619).

6.2.2 Enrollment

We recruited subjects from August 2013 to December 2014 from two Pediatric Endocrinology Centers in Toronto, Canada. The final study visit was completed in January 2016. Prior to study initiation, protocol approval was obtained from all site-specific ethical review boards and/or committees (The Hospital for Sick Children –#1000036524, University Health Network - #13-6237-BE, Trillium Health Partners – #619). Patients were eligible to participate if they (1) were diagnosed with T1DM (as defined by Canadian Diabetes Association guidelines (126)) for ≥ 1 year, (2) were between the ages of 11 to 16 years old, inclusive, at time of enrollment, (3) had been followed at the current clinic for ≥ 6 months, and (4) had two of their three most recent A1c readings (including the day of enrollment) between 8.0 – 10.5%. Given that *bant* was only offered in English at the time of recruitment, participants were excluded if they did not speak and understand fluent English. All subjects and parents provided written, informed consent prior to participation.

6.2.3 Sample Size

Sample size was determined based on a nominal two-sided type I error rate of 5% and 80% power. Estimates of standard deviation in A1c ranging from 0.50 % to 0.75 % were used to determine the minimum number of subjects required to detect a clinically relevant (≥ 0.5%) change in A1c levels. Standard deviation estimations were consistent with the *bant* pilot study which reported baseline standard deviation of 0.55% in A1c levels, and were also informed by longitudinal A1c variation over 9 months in
an independent sample of 13 patients. Final sample size of 92 subjects (46 per intervention arm) allowed for a potential 25% dropout rate.

### 6.2.4 Randomization

At enrollment, subjects were assigned equally to intervention or control arms using randomly allocated block sequences of 4-6 subjects. To ensure equal distribution between arms, randomization was stratified for treatment modality (insulin pump vs. insulin injection) as well as study center (The Hospital for Sick Children vs. Trillium Health Partners). The RCT was an unblinded, open label study, as both the participants and those delivering the intervention were aware of allocation based on whether or not the bant system was received. In addition, clinical outcomes were not blinded as they are part of a participant’s ongoing clinical care and diabetes monitoring regimen.

### 6.2.5 Intervention

The initial design of bant was informed by insights gathered through qualitative ethnographic interviews conducted with adolescents living with T1DM and their families. In addition to patient input, focus group sessions were held with clinical staff who had experience managing T1DM and chronic disease among adolescents. Feedback from these sessions, as well as input from human factors specialists, informed the development of the pilot version of bant, which was then evaluated among 20 adolescents for duration of 3 months. The initial user-centered design and testing of bant has been previously reported by Cafazzo et al (38). Upon the completion of the pilot trial, feedback was obtained from participants leading to further refinement of bant (Appendix B). It is important to note that the pilot version of bant was designed to incentivize more frequent SMBG, whereas the updated version of bant incentivized SMBG but also rewarded users for maintaining their BG within their target range. Figure 12 describes the key features of bant, and Figure 13 illustrates the system that the intervention group received.
### Figure 12. Description of bant’s key features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic Data Transfer</td>
<td>Blood glucose (BG) readings are wirelessly transferred from a Bluetooth enabled BG meter, using an adaptor (BluGlu), to bant.</td>
</tr>
<tr>
<td>Electronic Logbook</td>
<td>Display of current and past BG readings categorized by context (e.g. lunch) and displayed over multiple timeframes (e.g. one week, one month).</td>
</tr>
<tr>
<td>Trends</td>
<td>Display of percentage of readings in/out of target, per context, over various timeframes (e.g. over 30 days, 10% of breakfast reading were high).</td>
</tr>
<tr>
<td>Trend Wizard</td>
<td>Algorithm that detects and informs user of consecutive out-of-range readings for the same context (e.g. 3 consecutive high dinner readings). Prompts user to identify the likely cause of the trend and potential fixes.</td>
</tr>
<tr>
<td>Reward System</td>
<td>Rewards mechanism that awards points to encourage the following behaviours: 1) Taking up to 5 readings per day, 2) Getting readings in target range, 3) Avoiding out of range trends, and 4) Resolving any identified 3 days trends. Users could redeem their points for iTunes gift cards. bant also included a leaderboard for users to see where they ranked compared to their peers.</td>
</tr>
<tr>
<td>banter</td>
<td>A private social media community that allowed trial participants to communicate with each other.</td>
</tr>
<tr>
<td>Personal Health Record</td>
<td>Integration with TELUS health space, a secure personal health record which stored BG data and enables sharing with members of the care team.</td>
</tr>
</tbody>
</table>
6.2.6 Study Protocol

Adolescents who met the inclusion criteria and provided informed consent were randomly allocated to receive either usual clinical care (control group) or usual clinical care plus bant (intervention group). At baseline, those allocated to the intervention group received an iPhone 4S (Apple, CA, USA) loaded with bant, a One Touch Ultra Mini (Lifescan, CA, USA) blood glucose meter, and a Bluetooth adapter (BluGlu) that allowed for wireless transmission of data from the BG meter to bant. To facilitate independent use, all bant users received a standardized 1-hour tutorial at study enrolment, which included hardware setup, introduction to app features, username creation and troubleshooting steps for potential issues. During this time, bant users also created a TELUS health space (THS) account, which allowed for remote and secure storage/backup of their BG data. Control subjects also completed a baseline visit. However, they did not receive any study-related hardware from the research team. Both control and
intervention subjects received two movie theater passes in exchange for their effort and time during the baseline and all subsequent visits.

Baseline visits were followed by 3, 6, 9, and 12-month research visits, which coincided with participant’s standard quarterly clinic visits. During all research visits, qualitative and quantitative data were collected via semi-structured interviews, downloads of blood glucose meters and electronic chart review for all participants. Validated instruments were used to capture diabetes specific quality of life, self-care, and management. The Diabetes Quality of Life (DQOLY) (127) (128) and the Diabetes Family Responsibility Questionnaire (DFRQ) (129) were administered at 6 and 12-month visits, the Self Care Inventory (SCI) (130–132) was administered at all time points, and the Readiness to Change Survey (Appendix C-Participant Management Questionnaire) was captured only at baseline (104,133). Halfway between each follow-up visit, subjects in the bant group were contacted to ensure they were not experiencing any technical issues. At study end, the bant system was returned to research personnel.

### 6.2.7 Primary Outcome Measures

The primary outcome of the study was change in A1c from baseline to 12 months, between the intervention and control group. A1c was measured during routine clinical blood work and accessed by research staff through electronic chart review. The primary research site used a High Performance Liquid Chromatography (HPLC) assay (Bio-Rad Laboratories, Inc.) or an Enzymatic assay (Abbott Laboratories, Ltd.) to measure A1c, with internal quality control demonstrating excellent agreement among samples assayed by both methods (r>0.99). The secondary site measured A1c using a Point of Care (POC) immunoassay (DCA 2000+, Seimens Healthcare Ltd.) for all measurements.

### 6.2.8 Secondary Outcome Measures

#### 6.2.8.1 Hypoglycemic Events

Frequencies of mild and severe hypoglycemic events were assessed as secondary measures of glycemic control. A severe hypoglycemic event was defined as any episode which required the assistance of another individual and a BG reading below 2.8 mmol/L and/or subsequent reversal of clinical symptoms with intake of oral carbohydrate, glucagon injection or intravenous glucose (104). A mild hypoglycemia event was defined as a BG reading below 3.4 mmol/L.
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The frequency of severe hypoglycemic events was self-reported by subjects and/or their guardians during semi-structured interviews conducted at baseline and all follow-up visits. To capture the frequency of mild hypoglycemic events, the previous 50 days of BG readings were downloaded from all available (study and/or personal) blood glucose meters and/or insulin pumps during the subject’s clinic appointment. All downloads were completed by trained staff using the manufacturer-provided electronic downloading programs, specific to each blood glucose meter/pump brand. In cases where not all hardware was available, subjects estimated what percent of their total BG readings were on the devices they brought to clinic that day.

All individual readings <3.4 mmol/L were recorded as an individual mild hypoglycemic events, except for low BG readings taken within the same or consecutive hour timeslots. Grouping contemporaneous readings together and counting them as a single episode ensured that a singular hypoglycemic event was not recorded multiple times.

6.2.8.2 Self-Monitoring Blood Glucose

The average number of daily SMBG was measured using the 50-day BG meter and/or insulin pump printout(s). Each BG reading was counted individually, except when taken within the same hour, in which case readings were grouped. Readings taken over a 2-hour period in apparent response to an initial low (<4.1 mmol/L) or high (>18.0 mmol/L) were also grouped together. The average number of daily SMBG was calculated at baseline as well as each follow-up visit, and when warranted, was corrected for the percent readings available as estimated by participants.

6.2.8.3 Self-Initiated Adjustments

The number of self-initiated adjustments made to a subject’s T1DM insulin regimen was assessed during qualitative interviews conducted at baseline and all follow-up visits to determine if use of bant led to subjects attempting to adjust their insulin regimens more frequently. A self-initiated adjustment was defined as a change made to the prescribed treatment regimen that was initiated by the participant and/or their guardian(s) and implemented between clinic appointments. Changes made to the regimen by the diabetes care team during a routine clinic visit, were not included. Participants self-reported who (the
subject and/or their parent(s)/guardian(s)) was responsible for initiating the adjustment(s), as well as if the diabetes team had been contacted for input on the regimen change.

6.2.9 Validated Questionnaires

Validated instruments were used to capture quality of life, self-care and management data. The Diabetes Quality of Life (DQOLY) (127,128) and the Diabetes Family Responsibility Questionnaire (DFRQ) (129) were administered at 6 and 12-month visits; the Self Care Inventory (SCI) (130–132) was administered at all time points. The Readiness to Change Survey (Appendix C-Participant Management Questionnaire) was captured at baseline to help characterize the study population (133,134). All surveys were given to participants to complete independently during their research visit.

6.2.9.1 Satisfaction with bant

Overall satisfaction with bant was assessed via qualitative interviews conducted at 6 and 12-month visits. Using a 7-point Likert scale, ranging from 1 (Very Dissatisfied) to 7 (Very Satisfied), users were asked to rate overall satisfaction and satisfaction for 5 individual bant components: (i) Trend Wizard, (ii) The Leaderboard, (iii) Automatic BG Transfer, (iv) banter, and (v) iTunes Rewards. In addition to satisfaction scores, semi-structured interviews were conducted to gather qualitative feedback from bant users during their 6 and 12-month research visits. Users were asked to provide feedback on app features, content, and how bant influenced their overall T1DM management. They were also asked to list, in a free form text field, the three most and least helpful features of bant.

6.2.9.2 Usage Data

Mobile usage data was collected using a third party service, Flurry (Yahoo, CA, USA), which tracked 1) number of times users accessed bant, 2) how often they used certain features, and 3) the number of times a user wirelessly uploaded data from their blood glucose meter.
6.3 Statistical Analysis

Preliminary t-tests and chi-squared tests were used to determine if there were any statistically significant differences between the intervention and control groups for the primary and secondary outcomes and demographic characteristics at baseline. This step allowed us to ensure the comparability of both the intervention and control groups at baseline and ensure that we did not have any chance imbalances that may require further adjustment.

Subsequently, linear mixed models were used to determine if there were any statistically significant differences between the treatment and control groups for the above mentioned outcomes. As all outcomes of interest were continuous, a linear mixed model approach provides a simple method to assess treatment efficacy while adjusting for the correlation of each participant over time (using a random effect). Moreover, this approach is more powerful than a repeated measures ANOVA as it allows participants with missing values at one or more time point to contribute some information to the analysis, while a repeated measures ANOVA requires the availability of data at all time points for each participant (135). Each outcome was examined graphically to determine if the data were normally distributed. All outcomes were approximately normally distributed, with the exception of the number of mild hypoglycemic events, which appeared to be somewhat skewed. However, linear mixed models have the ability to assess data that is not normally distributed and remain robust, as long as a large sample size is present (136). As a result of the large sample size and graphical appearances of normality, this assumption appeared reasonable.

Secondary analyses relied on comparison between groups at the primary endpoint of 12 months using two-sample t-tests or chi-squared tests. Moreover, additional exploratory univariate regression analyses examined the impact of SMBG on clinical outcomes for those who were monitoring SMBG of \( \geq 5 \) per day at 12-months within both the intervention \((n=8)\) and control \((n=5)\) groups. Although this is a very small subgroup, it provides some insight into the potential role of bant in controlling diabetes for those participants who are engaged and actively monitoring their blood glucose levels. Due to small sample sizes, adjusting for other confounding variables was not possible. Additional exploratory analyses, including chi-squared tests, two sampled t-tests and regression analyses, were also used to evaluate the effectiveness of
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bant in subgroups based on insulin regimen (insulin pump vs. insulin injections) and baseline HbA1c levels (≥9.0% vs. <9.0%). Finally, usage and satisfaction data are also summarized for exploratory purposes. All statistical analyses were performed using SAS™ software Version 9.4 for Windows (SAS Institute Inc., Cary, NC, USA) Results were considered statistically significant at the p < 0.05 levels and all reported results are two-tailed.

6.4 Results

6.4.1 Study Population

Using the study inclusion criteria, eligible subjects were identified from clinical databases and enrolled sequentially until recruitment targets were met. Through this process, 199 eligible patients were identified; 42 patients declined to participate, 31 patients no longer met eligibility, and 34 patients were excluded for other reasons, including planning to change clinics within the study timeframe, having recently switched insulin regimens, and participating in another study with similar outcome measures. As shown by Figure 14, a total of 92 subjects were enrolled and randomized into the study.
Figure 14. Participant enrollment
### 6.4.2 Clinical Outcomes

There were no significant differences in HbA1c between the intervention and control groups over the duration of the 12-month trial \((P=0.99)\). Both groups demonstrated diminution in HbA1c up to the 9-month time point, after which both experienced a subsequent increase to pre-intervention HbA1c levels. This diminution speaks to study effects from the trial and demonstrates the importance of the control group. At trial conclusion, the intervention and control group displayed a mean HbA1c of 8.96 (±1.3) and HbA1c of 8.96 (±1.2), respectively (Figure 16).

**Figure 15.** Baseline characteristics of intervention and control groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Tx Group</th>
<th>Control Group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 46</td>
<td>n = 46</td>
<td></td>
</tr>
<tr>
<td>Gender (m/f)</td>
<td>21/25</td>
<td>20/26</td>
<td>1.0</td>
</tr>
<tr>
<td>Age at Baseline (yrs)</td>
<td>14.1 (±1.7)</td>
<td>13.9 (±1.5)</td>
<td>0.54</td>
</tr>
<tr>
<td>Age at Diagnosis (yrs)</td>
<td>7.1 (±3.6)</td>
<td>7.4 (±3.3)</td>
<td>0.71</td>
</tr>
<tr>
<td>Duration of T1DM (yrs)</td>
<td>7.1 (±3.2)</td>
<td>6.6 (±3.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>Insulin Regimen (pump/injection)</td>
<td>23/23</td>
<td>22/23</td>
<td>1.0</td>
</tr>
<tr>
<td>A1c</td>
<td>8.96 (±0.7)</td>
<td>8.92 (±0.6)</td>
<td>0.77</td>
</tr>
</tbody>
</table>
Between group analyses also showed no significant improvements in any of the pre-defined secondary outcomes between the intervention and control groups (Figure 17).
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<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Intervention</th>
<th>Control</th>
<th>P-Value (Between Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 12-mon</td>
<td>Baseline 12-mon</td>
<td></td>
</tr>
<tr>
<td>Mild Hypoglycemic Events*</td>
<td>10 ± 8.2</td>
<td>11.52 ± 10.7</td>
<td>8.49 ± 9.6</td>
</tr>
<tr>
<td>Severe Hypoglycemic Events**</td>
<td>0.23 ± 0.6</td>
<td>0.16 ± 0.4</td>
<td>0.41 ± 1.3</td>
</tr>
<tr>
<td>Self-Monitoring Blood Glucose*</td>
<td>3.98 ± 1.6</td>
<td>3.49 ± 1.8</td>
<td>3.55 ± 1.6</td>
</tr>
<tr>
<td>Number of Adjustments to Regimen**</td>
<td>1.85 ± 2.3</td>
<td>1.77 ± 2.7</td>
<td>2.08 ± 3.4</td>
</tr>
<tr>
<td>Self Care Inventory (SCI)***</td>
<td>35.73 ± 4.6</td>
<td>35.42 ± 5.0</td>
<td>36.07 ± 5.4</td>
</tr>
</tbody>
</table>

**Diabetes Quality of Life for Youth Questionnaire (DQOLY)** †

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>P-Value (Between Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of Symptoms</td>
<td>3.58 ± 1.7</td>
<td>3.33 ± 1.7</td>
<td>3.55 ± 1.8</td>
</tr>
<tr>
<td>Impact of Treatment</td>
<td>2.76 ± 2.3</td>
<td>2.53 ± 2.1</td>
<td>2.73 ± 2.0</td>
</tr>
<tr>
<td>Impact on Activities</td>
<td>3.00 ± 2.2</td>
<td>2.96 ± 3.0</td>
<td>3.04 ± 2.8</td>
</tr>
<tr>
<td>Parental Issues</td>
<td>5.13 ± 3.3</td>
<td>5.20 ± 3.6</td>
<td>5.12 ± 3.1</td>
</tr>
<tr>
<td>Worries about diabetes</td>
<td>6.83 ± 5.5</td>
<td>6.84 ± 5.8</td>
<td>6.51 ± 5.8</td>
</tr>
<tr>
<td>Health Perception</td>
<td>2.00 ± 0.7</td>
<td>1.96 ± 0.7</td>
<td>1.90 ± 0.6</td>
</tr>
</tbody>
</table>

**Diabetes Family Responsibility Questionnaire (DFRQ)** ‡

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>P-Value (Between Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Health Domain</td>
<td>12.76 ± 2.2</td>
<td>13.70 ± 2.4</td>
<td>12.53 ± 2.1</td>
</tr>
<tr>
<td>Social Presentation Domain</td>
<td>8.62 ± 1.6</td>
<td>8.86 ± 1.5</td>
<td>8.81 ± 1.5</td>
</tr>
<tr>
<td>Regimen Domain</td>
<td>13.90 ± 2.4</td>
<td>14.60 ± 2.1</td>
<td>13.61 ± 2.5</td>
</tr>
<tr>
<td>Total DFRQ Score</td>
<td>35.29 ± 4.9</td>
<td>37.16 ± 4.3</td>
<td>34.94 ± 4.6</td>
</tr>
</tbody>
</table>

* Average number over 50 days prior to study clinic appointment

** Average number between study clinic appointments (typically 90 days)

*** SCI - 14-item questionnaire using 6-point scale (1 to 5, and N/A option) to measure adherence to treatment recommendations. Overall score ranges from 10 to 50.

† DQOLY - 22-item questionnaire measuring Quality of Life (QOL), split across 6 subscales. Subscales use inverted 5 point Likert scale (0 to 4), with exception of Health Perception subscale which uses an Inverted 4 point scale (1 to 4). Higher scores associated with poorer QOL; possible subscale scores range from 1 to 4 (Health Perception), 0 to 12 (Impact of Symptoms, Impact of Treatment, Parental Issues), 0 to 28 (Impact on Activities) and 0 to 28 (Worries About Diabetes).

‡ DFRQ - 17-item questionnaire measuring adolescent/guardian interaction around care, split across 3 subscales. All subscales use 3 point scale (1 to 3). Higher scores are associated with increased adolescent involvement in care. Overall score ranges from 17 to 51; subscales range from 7 to 21 (General Health Domain), 4 to 12 (Social Presentation Domain) and 6 to 18 (Regimen Domain).

Figure 17. Secondary Outcomes Measures
6.5 Exploratory Analyses

Additional analyses were performed to identify potential relationships between measured clinical outcomes, both within and between the intervention and control groups. Figure 18 shows a significant relationship between increased SMBG and improved A1c in the intervention group at baseline, which strengthened over time, specifically when comparing 9 ($P=0.002$) and 12 month visits ($P=0.008$) to baseline. This relationship was not observed in the control group at any time point.
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**Figure 18.** Regression analysis for SMBG and A1c. Left) Intervention group. Right) Control group.
In further exploratory analyses, we identified a subgroup of patients with frequency of SMBG of \( \geq 5 \) per day at 12-months within both the intervention (n=8) and control (n=5) group. This threshold was chosen as it is a commonly recommended daily SMBG target in the Hospital for Sick Children diabetes clinic and this group represented a population of users who were actively engaged with daily SMBG at the end of the trial. No significant difference in daily SMBG was noted between the control subgroup (7.02±0.57) and intervention subgroup (6.32±0.45) at baseline \( (P=0.34) \). Similarly, at 12-months, there was also no significant difference in SMBG frequency among subjects in the control (6.24±0.57) and intervention (6.33±0.45) subgroups \( (P=0.90) \).

HbA1c did not significantly differ between the two subgroups at baseline (control vs. intervention group 8.84% ±0.27 vs. 8.40% ±0.21 \( (P=0.21) \), respectively). However, as shown in Figure 8, at the 6-month time point users in the intervention subgroup demonstrated a significantly lower HbA1c when compared to the controlled subgroup \( (P<0.001) \), a difference which persisted for the remainder of the trial (9-month \( (P<0.001) \), 12-month \( (P=0.008) \)). Furthermore, the *bant* subgroup demonstrated an overall improvement in HbA1c of 0.58% \( (P=0.02) \), while the parallel subgroup in the control arm experienced no significant change in HbA1c (decrease of 0.06%, \( P=0.84 \)).
In addition to the SMBG ≥5 subset, subgroup analyses were also conducted for insulin regimen (insulin pump vs. insulin injections) as well as baseline HbA1c levels (subjects with baseline HbA1c ≥9.0% vs. <9.0%); however, no statistically significant differences were noted.

### 6.6 bant Usage Data

To assess use of bant over the course of the study, engagement levels were established. Given that the app was designed to facilitate daily SMBG and self-management activities, the engagement threshold levels were based on the total number of days that a user wirelessly uploaded blood glucose readings to bant over 12 months. As shown in Figure 20, four levels of engagement (Very low, Low, Moderate, and High) were used, where the highest engagement level was defined by a data upload frequency greater than 3 out of 7 days.
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<table>
<thead>
<tr>
<th>Engagement Levels</th>
<th>Descriptions</th>
<th>Injections (n)</th>
<th>Insulin Pump (n)</th>
<th>Total (n)</th>
<th>% of all participants within each treshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low</td>
<td>Less than 1 of 14 days</td>
<td>9</td>
<td>8</td>
<td>17</td>
<td>36.96%</td>
</tr>
<tr>
<td>Low</td>
<td>Less than 1 of 7 days</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>28.26%</td>
</tr>
<tr>
<td>Moderate</td>
<td>Less than 3 of 7 days</td>
<td>5</td>
<td>7</td>
<td>12</td>
<td>26.09%</td>
</tr>
<tr>
<td>High</td>
<td>3 of 7 days or more</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>8.69%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>23</td>
<td>23</td>
<td>46</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Figure 20.** Engagement thresholds during the 12-month trial

**Figure 21.** Number of many times (measured as days per month) users uploaded BG data to *bant* across the study duration.
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Overall, usage of bant showed a significant interaction with SMBG \((P=0.03)\), with users in the high engagement group having a significantly higher frequency of SMBG throughout the trial than either low \((P=0.004)\) or very low engaged \((P=0.02)\) users. There were no significant associations between usage on any other clinical outcomes.

### 6.6.1 Satisfaction

Participants reported high levels of satisfaction with bant throughout the trial (figure 22). At 6 and 12 months, 79\% (30/38) and 76\% (34/45) of participants reported being “satisfied” or “highly satisfied” with bant, respectively. In addition, 96\% (43/45) of respondents reported that they would continue to use bant if it were available to them outside of the trial.

![Figure 22.](image)

**Figure 22.** Overall satisfaction with bant at 6 and 12-month time points.

Users were also asked to rank the features of bant according to their perceived usefulness in assisting with daily self-management of T1DM. Overall, the trending feature was ranked as the most useful component
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of *bant* by 45% (20/44) of respondents. This was followed by the logbook, which was ranked ‘most useful’ by 14% (6/44) and the app homepage (which displays current readings with respect to target range), which was ranked ‘most useful’ by 11% (5/44).

### 6.7 Discussion

The aim of this 12-month RCT was to evaluate the effectiveness of *bant*, a mobile health app for the self-management of T1DM among adolescents. Although satisfaction was high across the duration of the trial, with a defined subset of users regularly accessing and using *bant*, overall no significant improvements were noted in primary or secondary outcomes.

While primary clinical outcomes remained unchanged, a post-hoc, exploratory analysis provided additional insights. A significant and strengthening relationship between increased SMBG and improved A1c was observed exclusively in the intervention group (Figure 19), suggesting that *bant* users may have better utilized their SMBG data for the self-management of T1DM. This finding was reinforced by a subgroup analysis conducted on participants who were taking 5 or more SMBG a day at their 12-month visit. Users in this *bant* subgroup demonstrated significant improvements in A1c when compared to the parallel control subgroup, with a statistically and clinically significant decrease in A1c of 0.58% over trial duration. Thus, it is possible that for those users who were testing frequently, *bant* enabled better self-management of diabetes, resulting in an improved A1c, when compared to usual care.

To identify any factors that may have influenced overall trial results, several secondary analyses were conducted, including the characteristics of the study population and potential trial design artifacts. The current RCT purposefully targeted adolescents who were experiencing difficulty in managing their diabetes, as defined by sustained A1c values between 8.0-10.5%, who might benefit greatly from enhanced self-management skills and motivation. However, it is possible by extending the A1c inclusion range to 10.5%, subjects whose poor glycemic control was caused by multiple complex factors, requiring support beyond the scope of the *bant* features, were detrimentally included in the study. While the study was not powered to look at subgroups, secondary analysis was conducted on users with a baseline A1c ≥9.0% and A1c < 9.0%. The results showed no significant changes in glycemic control over trial duration within either subgroup, suggesting that baseline A1c was not predictive of *bant* effectiveness.

In addition, with equal numbers of subjects on an insulin pump versus insulin injections, it was also possible that insulin regimen may have impacted clinical outcomes. However, secondary subgroup
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analysis was conducted and showed no significant impact of bant on glycemic control, or any other clinical outcomes, in either pump or injector groups.

We also hypothesized that a poorly motivated subject population could have resulted in the lack of improvement in clinical outcomes. However, the Readiness to Change questionnaire data showed that, on average, the intervention and control groups were classified as being in the “preparation” stage of change, associated with individuals who are ready to implement a plan of action to improve their health outcomes (134). This observation, paired with the previously discussed subgroup results, suggests that the lack of significance found during primary analysis was likely not due to an inappropriate study population.

The bant usage data (Figure 21) indicates that for many of the participants, the regular use of the app extended beyond the average 3 to 5-week engagement period reported by other mobile app industries (137,138). This finding is in accord with the satisfaction data (Figure 22), and implies that future versions of bant may also be well used. However, over the 12-month trial duration only 34.79% of users (n=16) wirelessly uploaded BG data to bant, on average, once or more per week (Figure 20). Given that the key self-management features of bant require BG data, it can be inferred that usage of the app is dependent on users uploading data in the first place. There are two key factors which may have resulted in the low frequency of data uploads: 1) providing patients with a secondary mobile phone, and 2) the functionality of BluGlu.

Participants in the intervention arm were given bant on a study-provided mobile phone, rather than installing the app directly on their own personal devices. While this was intentional, ensuring that all participants had equitable access to the iOS app, recent data indicates that many of these adolescents likely already owned a mobile phone, and therefore the addition of the study phone may have added an unanticipated burden on the subject (115). A key strength of mobile health is the ability to capture data and provide feedback for users via their personal devices, which are embedded into their daily routines. Providing the intervention on an additional secondary phone may have defeated the concept of embedded health interventions, as it is likely that many participants may not have wanted, or be able, to carry two mobile phones for 12 months.

Interestingly, in the 2011 study (n=20) bant elicited significant increase in SMBG (38). It can be hypothesized that at this time there were lower levels of mobile device penetration among adolescents, and the novelty of having an iPhone would likely compel participants to use the device as a primary phone. Future studies should deploy mHealth apps directly onto personal mobile phones in order to improve usage and facilitate seamless integration into daily life.
Secondly, the RCT version of *bant* was developed before the emergence of Bluetooth enabled BG meters. As such, we developed our own adapter, BluGlu, to facilitate the wireless upload of data from BG meters to *bant*. However, this adapter was only compatible with the One Touch Ultra Mini (OTUM) BG meter. Throughout the study, a subset of participants continued to use additional BG meters, often of a different brand. Therefore, it is possible that asking participants to use an external adapter, which only worked with one particular BG meter, hindered the full integration of *bant* into their existing diabetes management routines. Over the duration of the RCT, several Bluetooth-enabled meters have come to the market, enabling a “plug and play” environment. A future consideration is to enable an open ecosystem so that users can have the option of using whichever wireless BG meter suits their specific needs; this flexibility, along with no longer needing an external adapter, may improve use mobile self-management platforms.

Another aspect that should be considered is the role of caregivers in the self-management activities adolescents perform using mobile tools. One of the key themes that emerged during the initial user-centered design of *bant* was the desire for adolescents to share their diabetes-related information with parents, peers and clinic staff (38). A recent literature review by Deacon *et al* suggests that mobile interventions that encourage data collection as well as clinician feedback may be more successful at decreasing A1c (139). *bant* included a feature that allowed users to store their data in TELUS health space, a secure personal health record that allowed them, if desired, to share their data with those within their circle of care. It was not possible to gather data around the use of this feature, however based on interactions with participants, it is likely that *bant* was used a standalone self-management tool. The next iteration of the *bant* should explore adding features that easily enable adolescents to receive feedback from caregivers and approaches that integrate the app into routine clinical care.

The study results illustrate the importance of rigorously evaluating mHealth apps, not only for understanding the impact on clinical outcomes and user engagement, but also for assessing the methods used to evaluate these tools. While traditional RCTs have been considered as the “gold standard” for evaluation of interventions, a recent review by Pham *et al* emphasizes that RCTs may not be best suited for the evaluation of rapidly evolving software interventions. Traditional RCTs are lengthy (average 5.5 years from enrollment to publication), high cost, and follow a rigid protocol that might not consider the sociotechnical, personal and social components of mHealth implementation (40). Perhaps more important, in the context of apps, they restrict the intervention to a static design, and limit the ability to dynamically tailor the intervention based on unique needs of individuals. Future evaluations of *bant* and other mHealth applications should consider use of alternative research methodologies or adaptive RCT study designs (40). For example, mPower, one of the first ResearchKit (Apple, CA, USA) enabled observational
Chapter 6- Evaluation of an App for the Self-Management of Type 1 Diabetes

mHealth iOS app trials, demonstrated a completely electronic and in-app consent, enrollment and study intervention, with 48,104 participants having downloaded the app within the first six months of the public launch (138). Participants completed questionnaires at predetermined time intervals, and used the native functionality of the mobile phone and its sensors to quantify Parkinson’s symptoms (e.g. tapping the screen to evaluate dexterity) (138). Additionally, The Sequential Multiple Assignment Randomized Trial (SMART) adaptive study design enables the identification of the most effective intervention component sequencing strategy, by evaluating outcomes at predetermined time intervals. In this case, we could allocate groups to specific combination of bant features, and based on the outcomes at a predetermined time point, alter the intervention according to feature sequencing protocol, allowing us to rapidly converge on optimal intervention designs based on unique patient trajectories (140). The Multiple Optimization Strategy (MOST) adaptive study design, ensures that the effectiveness of an intervention’s individual components and allows for incremental optimization of an intervention, prior to a full scale RCT (140).

Robust and scalable research methods, coupled with adaptive RCT study designs, have the potential to reshape mHealth research. These approaches can enable the rigorous evaluation of apps in a more timely manner, while facilitating the rapid and iterative development of an intervention -- keeping pace with the rapidly and continuously evolving mHealth landscape.

6.8 Conclusion

While adolescents are increasingly accessing technologies to support the self-management of T1DM, the impact of these tools on clinical outcomes remain unclear (141). Although this RCT found no changes in primary and secondary outcomes, exploratory analysis demonstrated improved A1c among bant users who tested more frequently. This suggests that these users gained insights around their SMBG data, which may have led to positive changes in their self-management behaviour. Overall satisfaction levels were high, suggesting that app users found utility in bant, specifically in features related to management of out of range blood glucose trends. The next iteration of bant will explore features that diminish barriers to use, enable deployment directly to personal mobile phones, are integrated into the daily clinical routine, and enable more frequent feedback from caregivers. Future evaluations of apps for diabetes self-management may also benefit from exploring methodologies that allow for more practical, scalable, and robust evaluation, given the challenges associated with rapidly evolving technology and consumer expectations.
Chapter 7

Three Month Data Analysis of the bant2 RCT

The bant RCT highlighted potential barriers to use of diabetes mobile apps in controlled studies, specifically, 1) the lack of integration into routine clinical care, 2) the impact of providing the app on a secondary study device, and 3) relying on an external Bluetooth BG meter adapter (BluGlu), with limited capabilities, to facilitate all data transfers. Given that these factors are also part of the bant2 intervention and trial design, a three-month within-group analysis was conducted to assess engagement levels, and determine if the existing RCT design is appropriate for the evaluation of bant2. In order to protect the integrity of the RCT itself, the analysis focused only on usage of the bant2 app and its components, and did not evaluate the primary or secondary outcomes. Given that the study followed rolling recruitment, at the time of the analysis n=15 patients were allocated to the intervention arm and completed 3 months of the RCT.

7.1 Methods

Throughout the study, usage data was collected using Google Analytics (Google, CA, USA), and personal health data (e.g., weight readings) was stored in individual PHR (TELUS health space) accounts. For this analysis, this data was assessed at an aggregate level to identify general trends and patterns in usage of bant2.

7.2 Results

7.2.1 Demographics

Table 8 shows the overall demographics of the intervention group. At 1-month, there was statistically significant difference in the mean usage between males and females, t(12.97)= 2.161, p=0.05, with females using the app 5.52 ± 2.55 days more, on average, than males (Table 9). There were no significant differences at the 2 and 3-month time points. There were also no statistically significant differences in usage for any of the other demographic factors.
### Table 8. Demographics of the intervention group

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>15</td>
</tr>
<tr>
<td>Age</td>
<td>54.87 ± 12.24</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>46.67% (n=7)</td>
</tr>
<tr>
<td>Male</td>
<td>53.33% (n=8)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>9</td>
</tr>
<tr>
<td>Black</td>
<td>1</td>
</tr>
<tr>
<td>South Asian</td>
<td>3</td>
</tr>
<tr>
<td>Filipino</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td><strong>Born in Canada</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53.33% (n=8)</td>
</tr>
<tr>
<td>No</td>
<td>46.67% (n=7)</td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
<td></td>
</tr>
<tr>
<td>High School</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>Trade</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>College/University Graduate</td>
<td>73.33% (n=11)</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td><strong>Living Situation</strong></td>
<td></td>
</tr>
<tr>
<td>Living with a partner and/or family members</td>
<td>8.00% (n=12)</td>
</tr>
<tr>
<td>Living with friends and/or room mates</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td>Living alone</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>Living Area</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>46.67% (n=7)</td>
</tr>
<tr>
<td>Suburban</td>
<td>53.33% (n=8)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Never been married</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>Married or living with a partner</td>
<td>8.00% (n=12)</td>
</tr>
<tr>
<td>Separated or divorced</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
</tr>
<tr>
<td>Homemaker</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>Fulltime</td>
<td>46.67% (n=7)</td>
</tr>
<tr>
<td>Part-time</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td>Retired for health reasons</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>Retired for non-health reasons</td>
<td>20.00% (n=3)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; $15,000</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td>$15,000-$29,000</td>
<td>6.67% (n=1)</td>
</tr>
<tr>
<td>$30,000-$49,000</td>
<td>13.33% (n=2)</td>
</tr>
<tr>
<td>$50,000-$74,000</td>
<td>33.33% (n=5)</td>
</tr>
<tr>
<td>More than $75,000</td>
<td>26.66% (n=4)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>6.67% (n=1)</td>
</tr>
</tbody>
</table>
Chapter 7- Three Month Analysis of the bant2 RCT

Table 9. Number of times users accessed the app by gender

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>1m</th>
<th>2m</th>
<th>3m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7</td>
<td>27.14 ± 4.70</td>
<td>21.00 ± 11.47</td>
<td>17.43 ± 14.45</td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>21.62 ± 5.18</td>
<td>18.75 ± 8.36</td>
<td>15.25 ± 15.25</td>
</tr>
</tbody>
</table>

7.2.2 Usage

Over the first 90 days of study participation, users (n=15) accessed bant2 an average of 58.21 ± 0.39 days. A linear regression established that time spent in the trial significantly predicted usage of bant2, F(1,88)=105.29, p <0.0005, and duration of participation accounted for 54.50% of the variability in usage. As shown by Figure 23, as time progressed, participants decreased their usage of bant2.

Figure 23. Number of active users during the first three months of the study
7.2.3 Engagement Levels

To further explore usage behaviours, a subgroup analysis was conducted on engagement users who accessed *bant2* on 12 or more days per month. Given that the objective of the *bant2* goals feature was to motivate paired SMBG a minimum frequency of 3 days per week, a minimum engagement of 12 days per month was selected as the threshold. Across the 3-month period, n=8 users accessed *bant2* on 12 or more days per month.

An ANOVA with repeated measures indicated that there was a statistically significant differences in *bant2* usage between engagement groups, F(1,13)= 39.904, p< 0.005, with the Engaged (n=8) and Non-Engagement (n=7) groups accessing *bant2* an average of 79 ± 12.86 days and 39.00 ± 11.46 days across the 3-month period (Figure 24).

![Figure 24. Engagement sub-group usage levels over three months](image-url)
7.2.4 Frequency of BG Readings Uploads

Table 10 demonstrates the average number of BG readings per week and number of BG readings uploaded per month. On average, users (n=15) wirelessly uploaded BG readings to bant2 on 43.53 ± 28.54 days over the 90-day period. The uploaded data indicated that users were taking an average of 8.14 ± 6.69 BG readings per week. A one-way repeated measures ANOVA indicated that there were no statistically significant differences in the frequency of BG reading uploads, F(2,28)=2.754, p=0.081, or in the number of SMBG over time F(2,28)=2.432, p=0.106.

Table 10. Average number of BG readings per week and uploads per month (n=15)

<table>
<thead>
<tr>
<th></th>
<th>1m</th>
<th>2m</th>
<th>3m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of BG readings per week</td>
<td>9.00 ±8.28</td>
<td>9.55 ±8.43</td>
<td>5.88 ±6.53</td>
</tr>
<tr>
<td>Average number of days with BG readings uploads per month</td>
<td>15.80 ±9.55</td>
<td>16.27 ±11.34</td>
<td>11.47 ±11.32</td>
</tr>
</tbody>
</table>

7.2.5 Frequency of Weight Readings Uploads

Over the 3-month period, users uploaded an average of 9.98 ± 9.17 weight readings per month (Table 11). A one-way repeated measures ANOVA indicated that there were no statistically significant differences in the number of weight measurements over time F(1.252,17.524) =0.47, p=0.881.

Table 11. Average number of weight readings per month (n=15)

<table>
<thead>
<tr>
<th></th>
<th>1m</th>
<th>2m</th>
<th>3m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of days with weight readings</td>
<td>10.13 ± 8.02</td>
<td>9.80 ± 10.57</td>
<td>9.66 ± 10.64</td>
</tr>
</tbody>
</table>

7.2.6 Food Photo Behaviours

Through the app, users had the ability to record meals by taking a food photo and/or entering a note in free text field (e.g. one chicken leg with mash potatoes). On average, users recorded a meal on 12.16 ± 0.78 days per month, with an average of 1.67 ± 1.04 records per day (Table 12). A one-way repeated measures ANOVA indicated that there were no statistically significant differences in the number of meal
Chapter 7- Three Month Analysis of the *bant2* RCT

records over time $F(1.258,17.608) =0.084$, $p=0.41$, or the number of readings per day $F(2.999,4.816) =0.623$, $p=0.43$.

As shown in Table 13, across the 3 months, the preferred food recording modality was food photos. On average, 67% of all recordings being photos only, 30% photo and a note, and only 3% consisted of solely a note.

| Table 12. Average number of food records per month |
|---------------------------------|--------|--------|--------|
|                                  | 1m     | 2m     | 3m     |
| Average number of days with food records | 12.40 ± 9.71 | 13.27 ± 11.26 | 10.80 ± 10.53 |
| Average number of food records/day | 1.75 ± 1.09 | 1.31 ± 1.32 | 1.94 ± 2.99 |

| Table 13. Type of modality used to record food data |
|---------------------------------|--------|--------|--------|
|                                  | 1m     | 2m     | 3m     |
| n                               | 11     | 11     | 10     |
| % Had a photo only              | 70%    | 66%    | 65%    |
| % Has a photo and a note        | 25%    | 32%    | 33%    |
| % Had a note only               | 6%     | 3%     | 2%     |

7.3 Discussion

Overall, the three-month within-group analysis of the *bant2* RCT demonstrated that based on the suggested frequency of paired testing (3 paired test with a meal photo per week), most users were engaged over the three months period. However, the regression analysis moderately predicted a decreased in usage over trial duration. While not statistically significant, there was also a decrease in the number of BG readings, suggesting that the limited BluGlu functionality may have impacted frequency of SMBG.

7.3.1 Recruitment Challenges

Over a recruitment period of 24 months, the study only recruited 29 participants. Recruitment was conducted at 7 sites, which included 5 primary clinics, 1 endocrinology clinic, and 1 diabetes education centre. The challenges faced with recruitment for the *bant2* RCT resemble those faced by others
conducting RCTs. For example, Thomas et al report an extended period of three years for the recruitment of 120 patients with T2DM into a prospective RCT, during which an additional site was included to accelerate recruitment, and a multitude of recruitment approaches (letters, phone calls, information sessions, radio advertisements, etc.) were exhausted (142). Overall, most publically funded RCTs struggle to meet recruitment targets, with 51% of trials reporting difficulty with recruitment (143).

Some of the recruitment challenges in the bant2 RCT could have been associated with restrictive inclusion criteria and characteristics of the recruitment sites. The inclusion criteria were limited to patients with T2DM not requiring insulin, who had an A1c of 7.5%-10%. The intention was to evaluate the usefulness of an app that supports context-based paired SMBG among a population for who the use of SMBG as a standalone has previously been demonstrated to be ineffective. However, upon searching the patient databases at the recruitment sites, there were few patients who met the inclusion criteria. We believe that this is likely because patients were initiated on insulin treatment if they remained uncontrolled for a sustained duration (144).

It is also possible that the populations at the recruitment sites, primarily situated in an urban setting, had an overall better diabetes status than those in suburban or rural communities (145,146). A study by Haven et al compared the difference in patient perceptions and utilisation of healthcare in urban versus rural settings and found that, in the USA, those in suburban settings reported the highest level of confidence in healthcare (147).

The findings of both this interim analysis and the bant RCT, coupled with significant recruitment challenges faced by the bant2 study, gave precedent to reevaluate the design of the bant2 evaluation.

### 7.3.2 Potential Study Redesign

Prior to the bant RCT results, the bant2 RCT redesign was focused on addressing the recruitment challenges by reducing the study duration and sample size. As such, the proposed study design changed the primary outcome from change in A1c (baseline to 12 months) to change in self-efficacy (baseline to 6 months), measured by the Diabetes Empowerment Scale Short-Form (DES-SF), between groups. Table 16 provides an overview of the original and proposed study designs. Given that the main objective of the study is to evaluate the impact of bant2 on the ability to self-manage diabetes, it seemed appropriate to use self-efficacy as a primary outcome measure. Any alternate choices for primary outcomes were limited to the measures that were already actively being collected.
Table 14. *bant II* RCT study redesign summary

<table>
<thead>
<tr>
<th></th>
<th>Original Study Design</th>
<th>Proposed Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Sample</strong></td>
<td>150</td>
<td>80</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>12 months</td>
<td>6 months</td>
</tr>
<tr>
<td><strong>Primary Outcome</strong></td>
<td>Change in A1c from baseline to 12-month, between groups.</td>
<td>Change in self-efficacy (DES-SF) from baseline to 6m, between groups.</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td>Baseline, 3m, 6m, 9m, 12m: Blood pressure (systolic and diastolic), weight, total cholesterol, LDL cholesterol, and hypoglycaemia.</td>
<td>Baseline, 3m, and 6m: Blood pressure (systolic and diastolic), weight, total cholesterol, LDL cholesterol, hypoglycaemia, and A1c.</td>
</tr>
<tr>
<td></td>
<td>Baseline, 6m, and 12m: Burden of disease (Diabetes Distress Scale), self-care (Summary of Diabetes Self-Care Activities), and user satisfaction (Mobile Application Rating Scale App User Version).</td>
<td>Baseline and 6m: Burden of disease (Diabetes Distress Scale), self-care (Summary of Diabetes Self-Care Activities), and user satisfaction (Mobile Application Rating Scale App User Version).</td>
</tr>
<tr>
<td></td>
<td>Secondary end points: Number of patients who achieve optimal glycemic control (A1c ≤ 7%) and medication changes.</td>
<td>Secondary end points: Number of patients who achieve optimal glycemic control (A1c ≤ 7%) and medication changes.</td>
</tr>
</tbody>
</table>

The DES-SF is a valid and reliable (α=0.84) 8-item short form instrument used to measure psychosocial self-efficacy of diabetes self-management (148). This tool focuses on assessing 1) diabetes management, 2) readiness to change and 3) willingness to set goals and change behaviours (149). More recently, the DES-SF has been used to evaluate the impact of mobile app interventions on diabetes related self-efficacy, and have demonstrated small to medium changes in the DES-SF score (*Arora* study found a change of 3.9 to 4.2; *Goh* study found a change of 4.1 to 4.23) (150,151).

Assuming the primary outcome is change in the DES-SF, the sample size estimation is based on detecting a minimum increase of 1.00 in the DES-SF mean score. A standard deviation of 1.5% was considered. A minimum of 35 adults per group is necessary to detect a mean score difference of 1.00, at an 81% power with two-sided 5% significant level. With a further 15% adjustments for dropouts, the final sample size of 40 subjects per group will be required.
Chapter 7- Three Month Analysis of the bant2 RCT

7.4 Conclusions

While the proposed study redesign met the goal of reducing the sample size and duration of the trial, it did not account for the challenges brought forward by the bant RCT or the challenges of the overall recruitment approach. Also, of the secondary measures collected, the DES-SF was selected as the primary outcome measure since it focused on patient empowerment. However, there is limited literature available on the use of DES-SF as a pre and post measure, and the sensitivity of this measure remains underexplored, making it a less powerful outcome measure when compared to A1c. As such, the existing bant2 RCT was repositioned as a 6-month feasibility pilot with the already patients recruited (n=29), informing the next iteration of the bant2 evaluation.
While diabetes can be managed through self-care, reducing secondary complications and improving overall quality of life, patients continue to struggle with self-management due to a lack of effective, accessible, and personalized tools. The existing diabetes clinical guidelines and education do emphasize the importance of behaviour change and self-management; however, they do not provide individualized tactics for enabling patients to improve self-efficacy (152).

For example, the recommendations for SMBG have been defined for both T1DM and T2DM. However, simply asking patients to measure BG will not lead to behaviour change. SMBG as a standalone intervention, provides only a one-time static value, and does not provide context around why and how the blood glucose value occurred, or any guidance around trends or patterns. For T2DM in particular, the influence of personal lifestyle behaviours, such as diet and physical activity, are a key part of the equation, and without this context, patient lack the actionable information needed to change their behavioural patterns.

Mobile devices have increasingly shown their potential to engage individuals in routine behaviours, such as social engagement, communication, and self-monitoring. The growing field of mHealth has demonstrated that while apps may be a way to access and engage patients in self-management, their sustained use, influence on behaviour change, and efficacy remained unclear (65,153).

Therefore, the central research question of this thesis was: Can a consumer-focused mHealth app designed following user-centered and evidence based methods, elicit positive and sustained behaviour change, leading to improved diabetes self-management? A second postulation was that automated feedback delivered through the mobile app would be as effective, less resource intensive, and more scalable than interventions involving HCP feedback. In order to address these questions, this thesis evaluated the use of consumer mobile apps, which were based on evidence, knowledge translation frameworks, behaviour change theory, and user-centered design principles, to elicit positive behaviour change of diabetes self-management. Through this research, key methodologic insights and challenges
regarding the use of knowledge translation frameworks for the design of complex self-management interventions, behaviour change strategies for diabetes self-management tools, and the evaluation approaches for behavioural consumer apps, were revealed. These findings emphasized that there remain many key aspects of the design of self-management consumer tools, such as clinical integration and consumer expectations, that are not considered when developing behavioural interventions. The evaluation of the self-management apps also highlighted that while traditional evaluation approaches such as RCTs remain the gold standard, conducting an evaluation on a behavioural app in isolation of the sociotechnical environment, clinical care, and individuals daily activities, fail to capture the complexities that may potentially enable mobile apps to fully meet their potential.

8.1 Knowledge Translation Frameworks

While there is increasing recognition that mHealth apps need to be informed by evidence and end-user feedback, the development of apps continues to occur without the guidance of knowledge translation frameworks. The resulting apps tend not to fully considered all aspects information technology systems, in terms of workflow, implementation, and patient experience (67).

The design of the bant2 app used the blended KTA-MRC framework to ensure that the complex intervention was founded on existing evidence, and followed a rigorous evaluation approach. However, given that bant2 was a self-management app, the phases of the framework, including the knowledge synthesis, end-user interviews, and tailoring of the intervention, were focused solely on the patient as the end-user. However, this method of using the KTA-MRC framework for the development of a mobile app ignored the larger environment within which the patient is embedded, potentially influencing the utilization of the developed tool. The evaluation of bant2 was also only focused the use of the app in isolation, with no consideration to how the app would integrate into clinical care. This is similar to the design and evaluation of bant, in which the evaluation design also did not consider the role of the app as part of routine clinical care. Isolating the intervention from the real-world implementation may facilitate evaluations with high internal validity, however, this approach, 1) does not fully facilitate the optimal use of the intervention, potentially hindering patient engagement, and 2) it does not consider whether or not the efficacy shown in clinical trials will translate to real-world implementation. When using the KTA-MRC framework to develop and evaluate self-management apps, it is imperative that the practical implementation considerations are included in not only in the conceptualization and design of the app, but also in the evaluation design.
### 8.2 Behaviour Change Strategies

The underlying construct of diabetes self-management apps is the improvement of self-efficacy through self-monitoring and actionable feedback, to motivate behaviour change. While the *bant* evaluation did not demonstrate any changes in diabetes related behaviours among adolescents with T1DM, for the subgroup of users who frequently conducted SMBG, *bant* may have enabled them to contextualize their BG data and change their self-behaviours, resulting in significant improvements in A1c (154). A similar group of frequent testers in the control group did not achieve improved A1c levels at the end of one year (154). Therefore, for those entering data, *bant* may provide additional context and support in the self-management of diabetes. However, strategies to motivate patients who are not engaged in self-monitoring need to be further explored.

The *<30 Days* study demonstrated that a one-time incentive may be an effective approach to initially engaging consumers in self-care interventions. The sustainability of this engagement was also surprising, where the users who downloaded the app during the incentive promotion period, actually completed slightly more challenges than those who downloaded the app without the presence of an incentive (65). Systematic reviews of health behaviour interventions conclude that financial incentives may be a useful component of the behaviour change approach, however evidence around their format, value, and timing, and the implications on intrinsic motivation once the rewards is removed, remain under investigated (20,155,156). While the use of financial incentives has been most explored for smoking cessation, weight loss, physical activity, the use of extrinsic rewards for the self-management of chronic conditions has been limited (157). In a review conducted by Ridder *et al*, a literature search between 2008 and 2014 revealed only three studies which used gamification to motivate diabetes self-care behaviours, one of which was the *bant* pilot with adolescents (158). While the strategy around gamification mechanisms for chronic disease self-management apps still needs to be established, there are examples of larger systems that have delivered incentive driven interventions, which may provide additional insights.

For example, Walgreens, a large drugstore chain in the United States, expanded their Balance Rewards program to offer members rewards for setting goals and inputting blood glucose and blood pressure readings in addition to lifestyle behaviours (153). Over 12 months, Walgreens enrolled 455, 341 users. However, even with an incentive program, there was significant attrition, with half of the users quitting the program within the first month. Nonetheless, this established program has the infrastructure to explore various individualized incentive schemes to motivate not only initial engagement, but also prolonged participation. For example, entering a blood glucose reading was associated with the same number of
points as entering in a weight reading, however, these two activities do not have the same level of burden on a user. As such, not only does the reward value of the activities need to be considered against the burden of the task, but also, the level of motivation of users should be considered when developing the incentive schemes.

Furthermore, similar to the <30 Days study and the bant2 interim engagement analysis, the Walgreens study also found that their users were mostly young (median age was 38.9) women (81%). A survey by the National Cancer Institute found that being younger and female were associated with the increased use of Web-based resource (153). Therefore, further strategies are required to engage older and male populations in both the prevention and management of chronic disease (153).

Furthermore, while the constructs of SCT (e.g. observational learning), provided a framework for the key self-management behaviours, and subsequent mobile app features of bant2, it did not consider the burden of chronic self-management. The Normalization Process Theory provides additional strategies to understand the “dimensions of treatment burden”, and facilitate the implementation, embedding and integration of interventions (159). The combination of the SCT and NPT constructs, provides a robust framework that considers not only key behavioural approaches but also strategies for implementation that minimize the burden of care.

### 8.3 Design Diabetes Self-Management Apps

Overall, it is clear that when apps follow user-centered design principals, high levels of satisfaction and usability, and uptake from diverse demographics, including the older group of consumers, can be achieved (65,154). However, the use of these apps to elicit sustained engagement and behaviour change remain elusive. There are a several themes that emerge when assessing the various diabetes apps developed to date: 1) There is suboptimal motivation to use apps for self-monitoring over long periods of time, 2) Apps assume a “one size fits all” approach with static feedback algorithms do not provide patients with engaging information, and may not evolve with the patient’s learning, 3) Failure to recognize that patients have consumer expectations when it comes to software on their mobile phone and peripheral devices, and 4) There is a lack of integration of mHealth self-management apps with clinical care for both feedback and bidirectional flow of data.
Recent advances in “big data” approaches, may address some of the above shortcomings. This approach, known as precision medicine, correlates various data sources, such as lab data, behavioural data, and genomics, to delivery personalized medicine (160). While the genomic, proteomic, and metabolomics profile captured can enable a clinician to determine the best medication, psychosocial determinants, captured through patient reported data, may also significantly influence the treatment path, particularly for behavioural interventions (160). mHealth apps have the potential to not only capture patient reported outcomes and objective measurements from connected devices (e.g. Bluetooth enabled continuous glucose monitors), but if integrated in to the clinical information system, can contribute to machine learning algorithms that will correlate data sets and delivery patients with hyper personalized care. For example, the data passively collected through a diabetes app (through connected devices and the mobile phone itself), such as activity levels, geolocation, blood glucose readings, food photos, heat rate, weight, blood pressure, when correlated with the patient’s various health data sets (e.g. lab data, medical history, genomics,), could provide highly personalized feedback to patients directly on their app. While the first examples of precision medicine are focused on providing clinicians with decision support, precision medicine could also provide patients with personalized glycemic management strategies, over the lifetime of disease management (161).

### 8.4 Moving Towards Robust Evaluation Approaches

The evaluation of mHealth apps continues to use traditional RCT designs to demonstrate efficacy, not only ignoring the complex sociotechnical and behavioural aspects of apps, but also resulting in lengthy and costly evaluations that are unable to keep pace with the rapid evolution of software (162). Even when the results of these studies show that the apps are effective; the technology used for the intervention at the time of evaluation would have likely become obsolete at study end, causing the findings to be less relevant or applicable.

The iterative design and evaluation of *bant*, the mHealth app for the self-management of T1DM among adolescents, is an example of how quickly technology, along with consumer’s expectations, evolve, and how traditional evaluation approaches lag. In 2010, funding was received to develop and pilot the first version of *bant*. In the 12-week pilot, teens (n=20) were provided with an iPhone 4S and the BluGlu adapter to enable wireless transfer of data from their BG meters to their mobile phones. The pilot demonstrated significant positive behaviour change, and the results were published in 2012 (102). Building on the findings of this trial and feedback from participants, the app was enhanced, and a 12-month RCT (n=92) was conducted, in which participants received the improved version of *bant* on an
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iPhone 4S along with BluGlu. The results of the RCT, published in 2017, did not demonstrate improvement in primary or secondary outcomes. It did however, highlight important barriers to use that may have impacted engagement levels, and more importantly, it brought into question the use of the traditional RCT study design to evaluate apps (154). From 2010 to 2017, bant underwent two development iterations, and was actually only used by 66 patients with T1DM (RCT intervention arm and pilot study). These timelines are similar to the duration of most RCTs, which take an average of 5.5 years from recruitment to the publication of results (162). By the end of this study, the iPhone hardware itself had incremented two significant generations, moving from the iPhone 4S to the iPhone 6. This emphasizes once again, the overall inability of mHealth to evolve at the same pace of its own ecosystem. Furthermore, in a consumer-driven mobile app marketplace, the failure to meet expectations of continuously evolving and high quality products and services, will likely negatively influence consumer behaviours and engagement level with mHealth apps.

There is a growing body of research that acknowledges the merits of RCTs but also seeks to explore evaluation designs that are equally as powerful, but more flexible and appropriate to the nature of software development (162). The <30 days study, was one of the first examples of how consumer demand and the mHealth market can be leveraged to recruit and collect data from approximately 70,000 patients, in under 6 months (65). While this study did not evaluate clinical outcomes, it did enable the rapid and comprehensive evaluation of the app in terms of user engagement and behaviours, facilitating a subsequent development iteration and release of an updated version of the app within the same year.

8.4.1 Real-World mHealth Research

The introduction of recent tools, such as Apple’s ResearchKit, an open sourced platform to enable smartphone research, are enabling population level and fully automated evaluations of mHealth apps, directly on individual’s personal mobile phones (163). ResearchKit not only greatly facilitates recruitment and electronic consent, but the collection of data. This includes data collection from sensors (e.g. accelerometers) and electronically administer validated questionnaires at desired frequencies. Recently, Apple partnered with Massachusetts General Hospital to launch GlucoSuccess, a ResearchKit enabled research study focused on providing T2DM patients with insights based on the data they collect through the app (e.g. physical activity through the embedded sensors). Within nine months GlucoSuccess’ initial launch, the app was used by 5,595 users across the USA (163). mPower, a ResearchKit app for the tracking Parkinson’s symptoms, recently reported that over 6 months of the initial app launch, 48,104 users downloaded the app across the country (Figure 25) (138).
Deploying research apps directly to the community also enables the use of off-the-shelf consumer devices (e.g. wearables) to capture and communicate health data directly with the apps, aligning with the current consumer-driven quantified-self movement (164). For example, bant2 followed the standard for Bluetooth communication protocol for blood glucose data, enabling any wireless commercial blood glucose meter conforming to the same standard to “plug-and-play” directly with the app. This not only leverages the existing consumer trends towards quantifying health behaviours, but it also reduces the burden of manual entry, prevents erroneous data, and also overcomes the barriers of using manufacture specific blood glucose adaptors (as seen in the bant RCT) (154).

![Figure 25. ResearchKit enabled mHealth apps. Left: GlucoSuccess, Right: mPower](image)

While the ResearchKit framework proposes an approach that is more robust, overcome geographic barriers, and offers “real-world” settings for evaluation, it also has important limitations. Given that the software library is more readily available on the iOS platform, there is a selection bias towards individuals with iPhones, who have previously been characterized as consumers belonging to a higher socioeconomic status when compared to Android users (58).
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Similar to traditional mobile apps, those supported with ResearchKit demonstrated similar engagement levels. The mPower study demonstrated engagement levels that were approximately 6 weeks, compared to traditional apps that tend to have engagement durations of 3 to 5 weeks (138,154). The ResearchKit supported apps to date have been limited to basic data collection and display, and have only begun to explore the opportunities to deliver highly personalized, behaviour driven, and dynamic self-management interventions. This framework is nascent, however, combined with more sophisticated research methodologies (e.g. factorial design), it has the potential to offer an evaluation approach that is just as rigorous as the tradition RCT, but a much more pragmatic and appropriate for mobile technology.

8.4.2 Alternative Evaluation Methods for Behavioural Health Interventions

Traditional RCT study designs fail to consider the complex behaviours and evolving needs of users in real-world settings (Goyal 2017). They are also lengthy, costly, and do not necessarily answer the practical questions required to progress the development of the mHealth field.

Pham et al describes three novel alternative strategies suitable for evaluation of mHealth apps, with the goal of converging towards an optimal intervention design: 1) Continuous Evaluation of Evolving Behavioral Intervention Technologies (CEEBIT), 2) Sequential Multiple Assignment Randomized Trial (SMART), and 3) Multiphase Optimization Strategy (MOST). The CEEBIT approach (Figure 26) is statistically powered to evaluate incrementally changing app versions, systematically eliminating inferior app versions, landing on the intervention design with the most superior outcomes (165). Interestingly, this method also includes a framework where consumer choice of the intervention variant can be included in the allocation process, considering those with preferences, versus those who have no preference who can then be randomized. The SMART method, has a similar branching method, however in this approach is based on evaluating a time-varying intervention, where different combinations of app components can be tested to tailor the intervention to the specific needs of subgroups, based on their outcomes at specific time points (140). The Multiple Optimization Strategy (MOST) evaluation framework ensures that the effectiveness of the intervention’s individual components is evaluated, incrementally optimizing the intervention, prior to a full scale RCT. It includes a screening, refining, and confirming phase, within which the app components are rigorously evaluated to ensure that the final draft contains the most potent app components. The MOST framework and factorial trial design could have been applied to the initial pilot of bant, in order to better understand component effectiveness and refine the intervention prior to performing a full scale RCT, however, the sample size was not adequately powered to do such an evaluation.
These evaluation approaches also have implications on the way software interventions are fundamentally architected. The \textit{bant}, \textit{bant} type 2, and \textit{<30 Days} apps were designed considering that users would receive all of the intervention components, making it difficult to assess individual component effectiveness. Also, in the \textit{bant} RCTs the intervention arm was compared to a usual care control arm. However, in order to gain a comprehensive assessment of app components effectiveness, the intervention arm would also have to be compared to various versions of the app.

While these alternative approaches may seem just as lengthy as the traditional RCT, using modern automated tools such as ResearchKit, can enable the rapid and modular evaluation of mHealth apps. Robust and scalable research methods, coupled with adaptive RCT study designs, have the potential to reshape and optimize mHealth research.

\subsection*{8.5 Evaluation Metrics}

While the ultimate goal of diabetes self-management apps is to improve clinical outcomes (i.e. A1c) and prevent secondary complications, there are still several unanswered questions around engagement, motivation, behaviour change, duration of use, and influence on self-efficacy. For example, while the

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{CEEBITApproach.png}
\caption{CEEBIT Approach to the systematic evaluation of behavioural health interventions (165)}
\end{figure}
bant pilot demonstrated improvements in the frequency of SMBG, it did not evaluate impact that actually had on self-awareness, or the perceptions around frequency of use or “dose”. Both bant for type 1 and type 2 diabetes were designed with specific frequency of use that was static (daily and 3 times a week respectively), and did not evolve as the users’ level of self-awareness changed over time. Furthermore, metrics that define engagement levels as number of times a behavioural app is used, fail to quantify the associated changes in self-awareness levels. For example, while engagement may decrease after 3 to 5 weeks, does that mean that users were applying no longer lessons learned through the app to their diabetes management? Looking again at the bant RCT subgroups, at 12-months users in the intervention group demonstrated improved A1c values even though their SMBG frequency remained the same, and their engagement levels were subpar. This suggests that these users may have in gained some actionable insight through the app that enabled them to improve their self-management over time. In addition to alternative research and evaluation methods, future studies should also consider metrics other than clinical outcomes (i.e. A1c over 12 months) to evaluate intervention effectiveness, integrated directly within the app (using tools like ResearchKit), especially while determining which app components are the most engaging and have the potential to drive improved self-management.

8.6 bant2 Proposed Study Redesign

Considering the challenges associated with both bant trials, along with the evolution of research and evaluation methods, bant2 has the opportunity to pivot its evaluation towards a much more suitable and practical approach. Figure 27 illustrates a potential study design where, assuming that bant2 has been designed modularly and has ResearchKit support, the recruitment process is conducted through the app store, directly with consumers. Upon downloading the bant2, users would be asked if they had a preference on receiving the consumer version of the app, or participating in a research arm of the application. Should they choose the consumer version, they would then have the option of selecting which features they would like to use. Through embedded analytics (e.g., Google analytics), we would then be able to evaluate engagement levels of different consumers based on their profile and unique preferences. If the user selects the research arm, they will then be asked to complete enrollment (via ResearchKit). Upon consenting into the study, the patients would be randomized following the SMART method, where different arms would receive different permutations of the app features (e.g. SMBG and food photos vs SMBG only). The arms would also be time-varying, where based on individual progress users could proceed down yet another branch of features. For example, if participants first started in the SMBG arm, and after 3 months they have not improved their overall BG control or have suboptimal engagement, then half of the sample may receive diet tracking, whereas the other half may receive some additional form of
insights. Similar to the <30 Days app and the ResearchKit studies, such as GlucoSuccess and mPower, it is anticipated that bant2 would have similar uptake, enrolling several thousands of patients in under a year. The proposed approach would enable an evaluation of engagement, component effectiveness, and behaviour change, in a real-world setting, directly with consumers, rapidly converging towards an intervention design that considers the diverse needs of individuals with diabetes.
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Traditional RCT
Full featured bant2

Rolling Recruitment
150 patients from multiple sites

Randomization
Intervention vs Usual Care

Evaluation
Static version of bant2

Results
Clinical Outcomes

1Y 2Y 3Y 4Y 5Y

Adaptive RCT
Modular bant2

Rolling Recruitment
30,000+ patients from across Canada

Evaluation
Pathway specific

Yes — CONSUMER BEHAVIOUR — User selected components

No — RIGOROUS EVALUATION — Randomization following factorial study design

Consumer Preference

Results
Clinical & Patient reported outcomes

1Y 2Y 3Y 4Y 5Y

Iterative development & evaluation

Figure 27. Comparison between traditional and an adaptive randomized controlled trial.
CHAPTER 9

Conclusion

The global increase in the prevalence of diabetes along with the cost associated with complications is one of the most significant challenges in healthcare delivery. Patients with type 2 diabetes have low adherence to clinical recommendations for medication therapy and lifestyle changes, leading to suboptimal glycemic control and a low quality of life. Patients with controlled diabetes can reduce their lifetime risk of renal failure by 87%, blindness by 72%, symptomatic neuropathy by 68%, and lower-extremity amputation by 67% (166). This impact is significant, and it is thus necessary to adopt new methods of enabling patients to effectively self-manage their diabetes, leading to improved clinical outcomes.

The central research question of this thesis was: Can a consumer-focused mHealth app designed following user-centered and evidence based methods, elicit positive and sustained behaviour change, leading to improved diabetes self-management? Five research aims were established and completed as part of this research: 1) Review of existing evidence for the use of mHealth apps for diabetes self-management, 2) Understanding of consumer behaviours through the pragmatic evaluation of a behavioural mHealth app for the self-management of modifiable risk factors (e.g. lifestyle), 3) Development of a consumer-focused self-management app for T2DM that is founded on evidence, user-centered design, and theoretical frameworks, and applies previously underexplored novel approaches to behaviour change, 4) Evaluation of the effectiveness of behavioural mHealth apps on the self-management of diabetes through randomized controlled trials (RCT), and 5) Assessment the appropriateness of RCTs to evaluate consumer-driven mHealth apps.

Through the review of the literature, design and evaluation of mHealth apps for diabetes self-management (Aims 1-4), it is clear that while apps continue to rapidly proliferate, their effectiveness towards enhancing the self-management of diabetes and improving clinical outcome continues to remain unclear. In comparison to the first generation of apps, there has been a rise in the number of developers paying more attention to the incorporation of existing evidence, behaviour change frameworks (e.g. Social Cognitive Theory), user-centered design processes, and evaluation. However, there remain significant
Chapter 9 - Conclusion

shortcomings such as; 1) There is suboptimal motivation to use apps for self-monitoring over long periods of time, 2) Apps assume a “one size fits all” approach with static feedback algorithms do not provide patients with engaging information, and may not evolve with the patient’s learning, 3) Failure to recognize that patients have consumer expectations when it comes to software on their mobile phone and peripheral devices, and 4) There is a lack of integration of mHealth self-management apps with clinical care for both feedback and bidirectional flow of data.

Furthermore, the findings of mHealth research seldom translate into products accessible by consumers. For apps focused on self-management, this is in part due to the use of traditional evaluation approaches that are lengthy, costly and do not necessarily mimic the way apps are used in real-world settings. As part of Aim 5, the appropriateness of RCTs for the evaluation of mHealth apps was assessed. Traditional RCTs, which can take as long as 5 years to complete, often yield results that are no longer applicable to the rapidly evolving mHealth app landscape. Both bant and bant2, highlighted the challenges associated with the development and evaluation of consumer mHealth apps for diabetes self-management. While these apps followed evidence-based frameworks and included behaviour change theories, the evaluation methods utilized did not inform the effectiveness of specific app components, and their impact on self-management behaviours. As a result, there is no clear guidance or evidence to support the inclusion or exclusion of specific app components in the future development of these interventions.

As shown by the <30 Days study, there is a tremendous consumer demand for self-management apps, which can be used to power robust development and evaluation of mHealth apps. Modern and automated research tools, such as ResearchKit, as well as adaptive evaluation approaches that support the time-varying assessment of app component effectiveness, can enable mHealth research to become more scalable, cost-effectives, and conducive to the iterative manner with which software evolves. The adoption of population-level and “big data” approaches will bring apps into the hands of patients much quicker, facilitating the collection of rich data (usage, engagement, behavioural, patient reported outcomes, etc.), and enabling the iterative improvement and development of the next generation of personalized, useful, and effective mHealth apps for the self-management of diabetes.
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# Appendix A- Heart Health Risk Assessment

## Table A The <30 days app risk assessment

<table>
<thead>
<tr>
<th>Question</th>
<th>Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unmodifiable Risk Factors</strong></td>
<td></td>
</tr>
<tr>
<td>What is your age?</td>
<td>(User selects age)</td>
</tr>
<tr>
<td>What is your ethnicity?</td>
<td>African heritage / Arab / Caucasian / Chinese / Filipino / South Asian (e.g. Indian, Pakistani) / Southeast/Asian (e.g. Vietnamese) / West Asian (e.g. Iranian) / Other</td>
</tr>
<tr>
<td>Do you have a family history of:</td>
<td>Diabetes or high blood sugar / Heart disease / High blood pressure / High cholesterol or triglycerides / Stroke / None of the above</td>
</tr>
<tr>
<td>Do you have any of the following conditions?</td>
<td>Depression or anxiety / Diabetes or high blood sugar / History of heart disease / History of stroke / High blood pressure / High cholesterol or triglycerides / Renal disease / Sleep apnea / None of the above</td>
</tr>
<tr>
<td><strong>Modifiable Risk Factors</strong></td>
<td></td>
</tr>
<tr>
<td>What is your height?</td>
<td>(User selects height)*</td>
</tr>
<tr>
<td>What is your waist measurement?</td>
<td>(User selects height)*</td>
</tr>
<tr>
<td>Do you eat the following 3 or more times a week?</td>
<td>High fat foods (e.g. fatty meats, donuts) / Fast food (e.g. hamburger, French fries) / Foods rich in omega-3 (e.g. cold-water fish such as salmon) / 5 or more servings of fruits and vegetables a day / None of the above</td>
</tr>
<tr>
<td>Are you moderately active for at least 3-60 minutes during 4 or more days of the week?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>How often do you feel overwhelmed by stress?</td>
<td>Very often / Not too often</td>
</tr>
<tr>
<td>What’s your salt intake like?</td>
<td>I love salt! / I limit my salt!</td>
</tr>
<tr>
<td>Do you smoke?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Do you drink more than 1-2 drinks containing alcohol a day, or more than 10 drinks a week?</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>
Appendix B- *bant* screen shots

The below screen shots provide an overview of the main pages *bant* as well as the trending features: a) home page, b) trends, c) *bant* book, d) rewards, e) *banter*, and f) the trending wizard.
Appendix C – Participant Management Questionnaire

The Transtheoretical Model (TTM) of behaviour change is an integrative model which uses defined stages (pre-contemplation, contemplation, preparation, action and maintenance) to explain how individuals modify their health behaviours (133,134). Using these TTM stages of change, we measured subject’s readiness to change their: 1) frequency of BG checks, and 2) frequency of self-initiated regimen adjustments.

All subjects were given the Participant Management Questionnaire (below) and asked to select 1 out of 6 statements that best described their thoughts around changing health behaviour. Statement 1 and 2 both corresponded to the pre-contemplation stage, with all other statements corresponding to the remaining 4 stages. In addition, using a 10-point Likert scale (with 10 being the highest score), subjects were also asked to rate how confident and motivated they were to make a change to each health behaviour. The Participant Readiness Survey was distributed to all subjects at baseline only.
Participant Management Questionnaire

Study Title: Assessment of an Electronic Self-Management Tool on Glycemic Control in Teens with Type 1 Diabetes

Unique Study ID –

Version Date: 11/06/2013

Question #1

Please read each of the following 5 statements about yourself. Check the box regarding the one statement that best describes how you think about checking blood sugars:

1) I have not even thought of checking my blood sugars more often.
2) I don’t believe that I need to check my blood sugars more often.
3) I might need to check my blood sugars more often, and I have been thinking about what to do about it.
4) I am ready to do something about checking my blood sugars more often, but haven’t yet.
5) I have actively been trying to check my blood sugars more often.
6) I have successfully made changes and now check my blood sugars more often.

For Question 2 and 3 circle one number. Please use the scale of 1-10, with 10 being the highest.

Question 2

How motivated are you to check your blood sugars more frequently?

1  2  3  4  5  6  7  8  9  10

Question #3

How confident are you that you can check your blood sugars more frequently?

1  2  3  4  5  6  7  8  9  10
Question #4

Please read each of the following 5 statements about yourself. Check the box regarding the one statement that best describes how you think about making changes to your diabetes regimen (insulin doses and/or diet):

1) I have not even thought of making more changes of my own to my diabetes regimen.

2) I don’t believe that I need to make more changes of my own to my diabetes regimen.

3) I might need to make more changes of my own to my diabetes regimen, and I have been thinking about how to do this.

4) I am ready to make more changes of my own to my diabetes regimen, but haven’t yet.

5) I have actively been trying to make more changes of my own to my diabetes regimen.

6) I have now made more changes of my own to my diabetes regimen.

For Question 5 and 6 circle one number. Please use the scale of 1-10, with 10 being the highest.

Question #5

How motivated are you to make more frequent changes of your own to your diabetes regimen (insulin doses and/or diet)?

1 2 3 4 5 6 7 8 9 10

Question #6

How confident are you that you can make more frequent changes of your own to your diabetes regimen (insulin doses and/or diet)?

1 2 3 4 5 6 7 8 9 10