ENHANCING DIABETES SELF-MANAGEMENT THROUGH MOBILE PHONE APPLICATION

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I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text, and a list of references is given.

I declare that the research included in this thesis was ethically conducted, with approval received for each component of the research from the James Cook University Human Research Ethics Committee. The following ethics approval codes relate to the research relevant to this thesis: H7087, H7285, H7716.

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Abstract

Introduction: Mobile phone applications (apps) offer a convenient, viable and easily accessible resource for patients to access on-going diabetes self-management education and support (DSMES). However, the lack of optimally consistent user engagement remains a significant and challenging limitation of app as tools for diabetes self-management (DSM). These limitations include lack of information on what constitutes standard/essential elements in the development process prior to use as intervention tools, high attrition rates, low engagement levels, sub-optimal educational components and poor consideration of mediating factors that are necessary for long-term behavioural changes. These knowledge gaps are pointers to the need for further improvements on diabetes apps in order to enhance their effectiveness in providing DSMES to patients. Therefore, this thesis aimed to: (1) Develop a framework on the essential elements required in the development of a DSM app, (2) Assess the perceptions of diabetes patients on the mediating factors of skills and self-efficacy for DSM, (3) Assess the perceptions of diabetes patients on the features and educational contents necessary for engagement with apps and ongoing DSM, (4) Develop a novel mobile app for DSMES and assess its usability among diabetes patients, and (5) Pilot-test the new app in order to ascertain its acceptability and feasibility in terms of retention, engagement and efficacy in promoting DSM.

Methods: Participant groups throughout the research reported in this thesis were people with type 1 or type 2 diabetes. The thesis involved three phases of research: i) Inspiration; ii) Development of intervention (an app) and usability testing; and (iii) Pilot testing of the intervention. The first phase comprised three evidence-based studies on the essential elements for developing diabetes apps. The three studies included a systematic review to derive an app development framework; patients' perceptions of their skills and self-efficacy for DSM; and their preferences for features and educational components in diabetes apps with recommendations on how to foster ongoing engagement.

Results from the first phase of the research informed the development of the app and a two-staged usability study, which was conducted to finesse the beta version of the app (second phase). The third phase involved a three-week pilot testing (single-arm repeated measure) of the beta version of the app to assess its feasibility for retention, engagement, efficacy on DSM behavioural change and acceptability by patients.

All primary studies in the three phases were conducted using a sequential explanatory mixed-methods study design, comprising quantitative online surveys and qualitative telephone interviews. All quantitative data were analysed using descriptive and appropriate inferential statistics. Qualitative data were analysed using thematic and concept-driven analyses.

Results and Discussion: The review findings highlighted the lack of consideration of the key elements of app development by app developers and researchers. The key elements identified were: inclusion of health behavioural theory, views of users and clinical experts, data security and privacy as well as pilot testings, for every diabetes app prior to use as an intervention tool in large-scale trials. There was a high correlation between skills set and self-efficacy ($r = 0.906$). Patients' skills set was a strong predictor ($R^2 = 0.82$) of self-efficacy, a necessary requirement for DSM. Common gaps were evident in identifying and managing the impact of stress on diabetes, exercise planning to avoid hypoglycaemia and interpretation of blood glucose patterns. The most preferred diabetes app features were visual analytics, food nutrient database, blood glucose trackers and personalised education. Recommendations on fostering better engagement with apps were improved functionalities on healthy recipes, actionable goals with reminders, ease of use, data consolidation, customised features, and certified reliable information sources. Specific educational topics of interest to patients were approaches to problem solving and basic guidelines for the management of diabetes.

A novel app (My Care Hub) was then developed following the pragmatic evaluation and use of the findings from the first phase of the research. Using the derived framework, the mediating

components of skills and self-efficacy, patients' preferred app features and educational components as well as their recommendations to improve engagement, My Care Hub aimed to monitor self-management activities, provide access to diabetes educational information and aid diabetes patients' motivation to engage in self-management. Results of the usability test revealed that the app was user-friendly, informative and provided motivation for DSM. Pilot testing of the app demonstrated significant correlations ($r=0.835$, $p=0.03$) between enhanced self-management skills and self-efficacy for long-term improved behavioural change and DSMES. Participants also reported high acceptability and retention rates; high levels of engagement with significantly increased self-management activities from pre- to post intervention time periods ($p<.01$) with an effect size of 0.24. Perceived benefits of the app included increased accountability, clarity of self-management activities/impact and improved awareness of blood glucose levels. Other benefits included highly educational function related to reinforcement of health providers' self-management recommendations, guidance on meal planning and mindfulness of calorie consumption. The inclusion of features and multi-functional components of visual analytics, blood glucose trackers, food nutrient data base and personalised education were highly effective in fostering better engagement with self-management apps, particularly among diabetes patients.

Conclusion: This research identified limitations of existing approaches to the development and effectiveness of apps for diabetes self-management and attempted to proffer a solution by using a systematic approach to explicate the design and development of a novel mobile phone diabetes app (My Care Hub) and evaluate its functionality. The study findings identified shared decision making between patients, clinical experts, researchers and app developers as essential in diabetes app development. Furthermore, consideration of educational reinforcement in the areas of healthy coping with diabetes stress, exercise planning to avoid hypoglycemia and interpreting blood glucose patterns could enhance self-management skills and self-efficacy in patients. In addition, it is important that apps have features to support healthy eating; blood glucose and physical activity monitoring; provide data analytics and educational contents in order to ensure that patients'

preferences are met. Finally, the reported benefits of My Care Hub provide both anecdotal and empirical evidence of support for its multi-feature functionality and comprehensive interventional role in DSMES. This provides a propitious prospect that the constructs of the models and approaches utilised in the development of My Care Hub will be relevant for the development of its future versions and long-term, larger-scale evaluation to further validate its promising results.

Thesis Publications

Peer – Reviewed Journal Papers with 2020 Impact Factor (IF)

1. Adu MD, Malabu UH, Callander E, Malau-Aduli AEO, Malau-Aduli BS (2018). Considerations for the development of mobile phone applications to support diabetes self-management: A systematic review. *JMIR Mhealth Uhealth.* 6(6):e10115. (IF – 4.301). https://mhealth.jmir.org/2018/6/e10115/

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List of Abbreviations

AD	Aaron Drovandi
AEOMA:	Aduli EO Malau-Aduli
ANOVA:	Analysis of Variance
App:	Application
BG:	Blood Glucose
BGL:	Blood glucose levels
BMA:	Bunmi Malau-Aduli
BP:	Blood pressure
CASP:	Critical Appraisal Skills Program
CHO:	Carbohydrate
COREQ:	Consolidated criteria for reporting qualitative research
DM:	Diabetes Mellitus
DSM:	Diabetes self-management
DSME:	Diabetes self-management education
DSMS:	Diabetes self-management support
DSMES:	Diabetes self-management education and support
EC:	Emily Callander
HCP:	Health Care Provider
IA:	Ian Aitkinson

ID:	Identification Number
IMBS:	Information Motivation Behavioural Skills Model
JBI:	Joanna Briggs Institute
JCU:	James Cook University
MCH:	My Care Hub Application
MDA:	Mary Damilola Adu
mHealth:	Mobile health
PRISMA:	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RQ:	Research Question
SD:	Standard Deviation
SV:	Sarai Viqar
T1D:	Type 1 Diabetes
T2D:	Type 2 Diabetes
TTM:	Transtheoretical Model
UM:	Usman Malabu
UK:	United Kingdom
USA:	United States of America
WHO:	World Health Organisation

Chapter ONE: General Introduction

1.1 DIABETES MELLITUS EPIDEMIC

Diabetes mellitus is considered as an epidemic because of its exponentially increasing prevalence (Bassett, 2005; Zimmet, 2017). International Diabetes Federation (IDF) estimates in 2019, indicated a global prevalence of 463 million adults living with type 1 or type 2 diabetes and predicted to reach 578 million in 2030 in the absence of any intervention. About 163 million adults with type 1 or 2 diabetes live in the Western pacific region which includes Australia (International Diabetes Federation, 2019), making it the fastest growing chronic condition across all ages in Australia. In 2014-2015, approximately 1.2 million (5.1%) Australian adults (18 years and above) had type 1 or type 2 diabetes equivalent to a 1.5 % increase over the 3.6% reported in 2004-2005. The majority (85%) of these cases were type 2 diabetes (Sainsbury et al., 2018; Australian Institute of Health and Welfare, 2019a). Specifically, adults living in areas with the greatest socio-economic disadvantage in rural/remote areas of Australia have three times the rate of diabetes as those living in areas of socioeconomic affluence (9% and 3% respectively) (National Rural Health Alliance International, 2011; Australian Institute of Health and Welfare, 2014). In 2011, diabetes was recognised as the 12th largest disease burden in Queensland, Australia, accounting for 2.4% of the total burden (Department of Health, Queensland Government, 2017). In 2018, there were 242, 061 registered cases of diabetes in Queensland, which equates to 4.8% of the population (Department of Health, Queensland Government, 2018).

People with diabetes are predisposed to major complications, resulting in hospitalisation, financial burden and could eventually lead to death. In Australia, diabetes contributed to 11% of all deaths in 2017 (Australian Institute of Health and Welfare, 2019b) and the health-care system attributed $2.7 billion of its total disease expenditure to diabetes care in 2015-16 (Australian Institute of Health and Welfare, 2015). This represented 97% increase from $1,507 million in 2008-09 (Australian Institute of Health and Welfare, 2008). Given the increasing prevalence of diabetes and its impact in Australia, there is an urgent need for improved methods to promote and facilitate proactive diabetes self-management necessary to prevent the development of complications and promote overall good health outcomes for patients.

1.2 DIABETES SELF-MANAGEMENT

Self-management of diabetes relied heavily on lifelong daily activities, which include behavioural changes and adherence to healthy lifestyles that are necessary for the reduction or prevention of complications (Shrivastava, Shrivastava & Ramasay, 2013). Patients self-manage by making choices and decisions to engage in therapeutic regimen behaviours. These include: healthy eating, physical exercise, monitoring of blood glucose, complying with medications, good problem-solving and healthy coping. Other steps include risk-reduction in the areas of smoking cessation, keeping medical appointments and limiting alcohol consumption (Shrivastava, Shrivastava & Ramasay, 2013). The absolute frequency or consistency in performing regimen behaviours relates to the level of self-management and is directly correlated with glycaemic control and improved health outcomes (Shrivastava, Shrivastava & Ramasay, 2013; Jarvis et al., 2010; Norris et al., 2002).

1.3 INTERVENTIONS TO IMPROVE DIABETES SELF-MANAGEMENT

Providing interventions to improve diabetes self-management is an integral component of IDF's global plan on managing diabetes (The International Diabetes Federation, 2003). Many countries including Australia have adopted the IDF's recommendations to improve patients' behavioural changes for self-management, including the imperative provision of Diabetes Self-Management Education (DSME) to patients (International Diabetes Federation, 2010; Australian Government Department of Health, 2015). The major aim of DSME is to develop the knowledge base and skills of patients on targeted self-management behaviours necessary for diabetes care (Mensing et al., 2006). The ultimate goal is an eventual reduction of the onset and/or advancement of complications (Jarvis et al., 2010) with consequential improvement in health status and quality of life. Although DSME had been previously shown to have positive effects on patient self-management behaviours, training had been generally infrequent (Siminerio, 2006) and the benefits declined one to three months after the intervention ceased (Norris et al., 2002). The unsustained benefits suggest that DSME does not in itself, guarantee long-term and sustainable self-management behaviours among patients. Therefore, patients require consistent and ongoing support to sustain their diabetes self-management behaviours in the long-term.

1.3.1. Ongoing Self-Management Education and Support

DSME promotes knowledge and awareness of the importance of self-management, however, it is typically provided as a formal but irregular program in an outpatient service conducted at a hospital/health facility (Powers et al., 2017). Conventionally, provision of DSME to patients occurs at diagnosis, annually, when a new complication sets in or during transition in care (Power et al., 2017). It is a short-term program with or without some degree of follow-up. This irregular approach is unable to sustain the level of self-management needed on a long-term basis due to the chronic nature of diabetes. Effective long-term management of diabetes requires programs that support the continued enhancement of self-management skills, behavioural strategies and metabolic improvement following DSME sessions. Therefore, it has been advocated that diabetes self-management support (DSMS) should be provided in addition to DSME on an ongoing basis (Powers et al., 2017). This ongoing support for patients sustains the self-management gains made during the DSME process. DSMS builds the resilience needed to overcome barriers, sustains coping skills for ongoing self-management demands and facilitates required behavioural changes for life transitions (Shrivastava, Shrivastava & Ramasay, 2013; Powers et al., 2017; Coyle, Francis & Chapman, 2013). DSMS can be delivered anywhere, at any time beyond and outside of formal health care facility. The type of support provided can be behavioural, educational, psychosocial or clinical (Hass et al., 2012) and could be delivered by a trained supporter: educator, pharmacist, peer, primary care practice staff etc. (Linda et al., 2013).

National standards for DSME and DSMS have been amalgamated and renamed diabetes self-management education and support (DSMES) to reflect the value of ongoing support and multiple services, which are essential for improved health outcomes in patients (Powers et al., 2017; Sherifali et al., 2016). DSMES is an ongoing process of facilitating knowledge, skills and ability necessary for diabetes self-care, as well as activities that assist a person in implementing and sustaining behaviours needed to manage his or her condition on an ongoing basis, beyond or outside of formal self-management educational training (Beck et al., 2019). DSMES has been recommended as a critical element of care for all people with diabetes (Powers et al., 2017). However, adherence to the guidelines has not been possible. For example, the guideline stipulate that patients should be offered structured DSME program at the time of diagnosis with a minimum of an annual update and review (Craig et al., 2011; Royal Australian College of General Practitioners, 2016). However, a national survey conducted in 2011 revealed that approximately half of Australian adults with type 1 or 2 diabetes had never received this intervention, nor ongoing DSMES (Peight et al., 2011). A similar survey was repeated in 2016 and reported no improvement (Ventura et al., 2016). Barriers to ongoing diabetes support in Australia have been attributed to under-resourced diabetes education (Kennedy & Dunning, 2017) and limited access to speciality care services and community resources (Speight et al., 2011; Manski-Nankervis et al., 2014; Dao et al., 2019). Barriers related to financial limitations, distance to health care and inadequate resourcing of speciality providers are particularly prevalent in rural/remote communities (Speight et al., 2011; Overland, Yue & Mira, 2001; Wan et al., 2008).

These barriers limit the necessary care required by patients and therefore pose as enormous challenges to policy makers on how to ensure ongoing support to all patients including those living in rural and remote areas. One potential avenue that has been explored in addressing the problem of accessibility of ongoing DSMES, is the use of mobile Health (mHealth) technology. mHealth is particularly feasible and important for reaching people in resource-poor settings with limited access to speciality providers and care but have connectivity to mobile phone networks (Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014; Källander et al., 2013).

1.3.2 Mobile Phone Applications for Consistent DSMES

mHealth interventions are typically behavioural change strategies operationalised for delivery using ''*computer devices that are intended to be always on or carried on the person throughout the day*'' (Riley et al., 2011). A major example of mHealth is the use of mobile phone application (app). This is a software program embedded in smartphones, with persuasive attributes intended to change users' attitudes or behaviours in a pre-determined way (Fogg 2002). App interventions have leveraged on the added-value that mobile phones are ubiquitous and valued by users (Patrick et al., 2008; Miller, 2012; Boschen & Casey, 2008), making it possible to deliver helpful behavioural change content to individuals as they go about their normal daily activities (Miller, 2012; Boschen & Casey, 2008; Preziosa et al., 2009; Kitsiou et al., 2017). Apps offer a convenient, viable and easily accessible resource for patients to access continuous DSMES outside the clinic environment. They are effective in improving patients' self-management behaviours and health outcomes in many part of the world (Kitsou et al., 2017; El-Gayar, 2013; Hou et al., 2016), including Australia (Kirwan et al., 2013).

1.3.3 Shortcomings of Mobile Apps as Self-Management Education / Support Tools and Possible Solutions

The lack of optimal user engagement with apps remains a significant challenge (Short et al., 2015; Eysenbach, 2005) because a significant proportion of app users disengage from repeat use, thus limiting apps as an effective DSMES tool. Quinn et al., 2011, utilised a mobile app intervention among people with type 2 diabetes and recorded 23.4% attrition rate at 12 months. A similar observation was made by Kirwan et al., 2013 in their evaluation of mobile app use in patients with type 1 diabetes, where 26.3% of the participants did not complete the study. Additionally, many of the currently available diabetes apps have little or no self-management educational component. A study found only 20% of apps had an educational component, of which only one-fifth delivered personal feedback (Chomutare, 2011). This denotes that fully harnessing the capabilities of mobile phones to deliver real-time feedback and diabetes education is largely under-explored. When a health tool is unable to meet patients' essential requirement, it is at risk of abandonment (Bickmore, Schulman & Yin, 2010), and can contribute to the high attrition and low engagement levels reported in diabetes apps usage. Therefore, further research is required to explore the main reasons for the high attrition rates and low engagement levels and to identity possible solutions.

Furthermore, most diabetes app interventions have only reported clinical efficacy or behavioural outcomes of the intervention without any explanation of the mediating factors underlying such results (Kirwan et al., 2013; Quinn et al., 2011; Rossi et al., 2010a; Berndt et al., 2014; Holmen et al., 2014). Nearly all the results of these studies range from none to low sustained effects of the intervention, which may be due to poor exploration of the necessary mediating factors. Constructs in behavioural theories are essential considerations in designing interventions because they can help developers and researchers to understand the causal effect of such behavioural interventions (Baranowski, Anderson & Carmack, 1998). This knowledge gap in the efficacy of existing diabetes apps intervention signifies the need for critical appraisal of the limitations and development of effective innovative changes that may result in improved ongoing self-management behaviours and sustained health outcomes for diabetes patients.

The limitations of apps as a tool for DSMES are related to lack of information on what constitutes standard/essential elements in the development process prior to use. Interventions rooted in poor consideration of mediating factors that are necessary for long-term behavioural changes can lead to limited success. Furthermore, high attrition rates and low engagement levels (Eysenbach, 2005) as well as sub-optimal educational components are common in most apps targeting diabetes self-management (Chomutare et al., 2011; Liang et al., 2011).

Despite the theoretical emphasis on the development of guidelines and adoption of evidence-based practice in the advancement of an effective suite of behavioural health interventions (Kohatsu, Robinson & Torner, 2004; Lhachimi, Bala & Vanagas, 2016), and to the best of our current knowledge, no guideline is available for diabetes apps development. The lack of standards and evidenced-based principles are responsible for the often reported non-replicable and low-quality health interventions (Glasgow & Emmons, 2007). This gap in the literature necessitates research that provides a framework on minimum standard requirements for the development of diabetes apps that serve as effective tools for DSMES.

The development of effective DSMES app interventions requires creative innovations that draw upon theoretical and evidence-based best practice. These are in addition to utilising systematic processes to help combat attrition and incorporate major mediating components (skills and self-efficacy) to foster improved patient engagement and behavioural health outcomes. In order to adequately self-manage diabetes, patients must acquire the necessary skills resulting from knowledge of the disease and adequate understanding of the interrelationships between various self-management activities and impacts on health outcomes (Persell et al., 2004). Skills is an essential pre-condition to self-efficacy, which is a prominent concept in self-management because successful self-management of any disease stems from a sense of confidence (self-efficacy) in one's self-management abilities (Sarkar, Fisher & Schillinger, 2006). A diabetic patient who has adequate sense of self-efficacy has better confidence in his/her ability to evaluate self-management performance. This could be in terms of diet adjustment, hypoglycaemia prevention or engaging in appropriate physical exercise (Beckerle & Lavin 2013; Yao, 2019). Therefore, incorporation of these strategies may provide remarkable improvements over existing diabetes app interventions with tangible long-term behavioural health outcomes for diabetic patients.

1.4 THESIS AIMS, RESEARCH QUESTIONS AND HYPOTHESES

1.4.1 Aims

Due to lack of guidelines for the systematic development of diabetes apps, high attrition rates associated with previous diabetes apps, low engagement of patients with ongoing self-management and inadequate educational components in diabetes app intervention, this thesis aims to:

1. Develop a framework/guideline on the essential elements required in a diabetes app development process prior to use, as an intervention for self-management in patients with type 1 or type 2 diabetes;

2. Assess the perceptions of people living with type 1 or type 2 diabetes on the mediating factors of skills and self-efficacy for diabetes self-management;

3. Assess the perceptions of people living with type 1 or type 2 diabetes on: (i) features and (ii) educational contents necessary for engagement with apps and ongoing diabetes self-management.

4. Develop a novel mobile app for diabetes self-management education and support and assess its usability among patients with type 1 or type 2 diabetes.

5. Pilot-test the new mobile app in order to ascertain its feasibility in terms of retention, engagement and efficacy in diabetes self-management as well as acceptability among patients with type 1 and type 2 diabetes.

1.4.2 Research Questions

Four research questions (RQ) were asked in order to address the thesis' aims. These are based on the premise that developing a new mobile diabetes app following a standard framework for an effective DSMES tool in addition to considering user needs on app features/functionalities and educational components will improve user' engagement and facilitate behavioural change in diabetes self-management. This is in the light of identifying, establishing and using mediators, which could foster improved patient' participation in self-management using the app.

RQ1: What are the necessary elements in an app development process to foster an effective diabetes self-management education and support intervention?

RQ2: To what extent do skills and self-efficacy stimulate behavioural change for self-management in patients with type 1 and type 2 diabetes?

RQ3: What are the preferences of patients with type 1 and type 2 diabetes as regards features and educational contents in apps that will foster retention and engagement with diabetes self-management activities?

RQ4: To what extent would a newly developed diabetes app stimulate improved diabetes self-management and acceptability among patients with type 1 and type 2 diabetes?

1.4.3 Hypotheses

In line with the afore-stated aims and research questions, it was hypothesised that:

1. A systematic review and evaluation of evidence from current literature on the impact of diabetes app intervention on patient health outcomes will assist in the establishment of guidelines that outline important considerations required for the development of effective mobile phone apps to support diabetes self-management.
2. Skills and self-efficacy are important mediating factors that stimulate behavioural change and improved self-management in people with type 1 and type 2 diabetes.
3. Needs analysis among patients with type 1 and type 2 diabetes will elucidate essential features and educational contents in apps to foster retention and engagement with diabetes self-management activities.
4. The newly developed mobile phone app will be an effective and acceptable diabetes self-management education and support tool.

1. 5 THEORETICAL FRAMEWORK

To adequately test the stated hypotheses, it is important to hinge the study on an appropriate health behavioural theory. Health-related behavioural change interventions may be more effective if grounded in an appropriate theory (Craig et al., 2008; Campbell et al., 2007). Theoretical models provide insights into underlying principles by identifying target mediators that are antecedents of behaviours, causal determinants of change and their mechanisms of action in an intervention (Hardeman et al., 2005). Theoretical models that are regularly utilised for planning and evaluating public health behavioural change interventions include the following: Social Ecological Model (SEM), Theory of Reasoned Action/Planned Behaviour (TPB), Health Belief Model (HBM), Transtheoretical Model (TTM), Social Cognitive Theory (SCT) (Glanz, Rimer & Lewis, 2008) and Information-Motivation-Behavioural Skills (IMBS) models (Fisher, Fisher & Harman, 2003). Each of these theoretical models specifies various concepts that can be influenced by behavioural change in an individual or population. In this thesis, the self-efficacy construct of the SCT model and the information and motivation constructs of IMBS model were blended to guide the development of the mobile app intervention.

1.5.1 Social Cognitive Theory (SCT)

The SCT is one of the most widely used conceptual frameworks for understanding and modifying health-related behaviours targeting the management of chronic diseases (Glanz, Rimer, Lewis, 2008; Newman, Steed, & Mullingan, 2004). As the corner stone of effective disease self-management interventions, the SCT has demonstrated positive behavioural changes resulting in improved health outcomes (Lyons et al., 2014; Cotter et al., 2014). It started as the Social Learning Theory where it was described as the link between behaviourism and cognitive approach. Unlike many other theories of behavioural change in health promotion, the SCT considers the unique ways in which individuals acquire and maintain behaviour. The current version (1998) of SCT posits a multifaceted causal structure in which self-efficacy beliefs operate together with knowledge of health risks and benefits, goals, outcome expectations, social and structural impediments to change and perceived facilitators of behavioural change (Bandura, 1998). Self-efficacy occupies a pivotal regulatory role in the causal structure of SCT and it is a core belief that directly leads to behavioural change (Bandura, 1998).

1.5.1.1. Self-efficacy

Self-efficacy refers to an individual’s thoughts and beliefs in his or her ability to perform specific actions required to attain preferred goals. The choice of what to do, effort to invest in such activities and how long to persevere in the face of barriers and experiences of failure are influenced by people’s judgement of their self-efficacy (Bandura, 1999). Self-efficacy is the belief in what one can do with whatever skills one has (Bandura, 1999) and it is one of the most widely used key constructs in health psychology for modifying health-related behaviours (Ashford, Edmunds & French, 2010). Improved self-efficacy is expected to increase an individual's move to a higher stage of behavioural change, decreasing the risk of relapse and it is a prerequisite for self-management (Bandura, 1999). In the context of diabetes, self-efficacy is a prominent concept with positive correlation with self-management. Self-efficacy is a key determinant for the adoption and maintenance of health related-behaviours and subsequent health outcomes when used as a guide to develop interventions for the management of chronic diseases including diabetes (Cotter et al., 2014; Avery et al., 2015; Tougas et al., 2015; Steel et al., 2014; Barlow et al., 2002). It has been shown to have a strong positive correlation with self-management of diabetes (Mishali, Omer & Haymann, 2011). Given the precedence of self-efficacy in diabetes related research, self-efficacy construct was utilised as an underlying mechanism to influence behavioural change effort for diabetes self-management in this study.

1.5.2 Information-Motivation-Behavioural Skills (IMBS) Model

Information-Motivation-Behavioural Skills (IMBS) model promotes evidence-based and user-centered approach of knowledge implementation in health related situations (Fisher, Fisher & Harman, 2003; Barlow et al., 2002; Fisher & Fisher, 1992; Fisher et al., 1996). It was originally developed in response to the HIV epidemic to predict HIV prevention behavior (Fisher et al., 1996; Fisher, Fisher & Harman, 2003). It was applied successfully in designing interventions that improved and predicted adherence to medication among individuals living with HIV (Fisher et al., 1996; Horvath, Smolenski & Amico, 2014) and diabetes (Mayberry & Osborn, 2014). The IMBS has a broad application potential in health promotion practice where it provides a framework for understanding and promoting disease preventive behaviours among populations (Fisher, Fisher & Harman, 2003; Fisher & Fisher, 1992). The model focuses on a set of informational, motivational and behavioural skill constructs (factors) associated with disease management. The model specifies that behavioural change occurs mainly as a result of changes in behavioural skills sequel to the effect of information and motivation interventions (Fisher, Fisher & Harman, 2003). Information and motivation influence behaviours independently, and in large part, indirectly through the model's third construct – the behavioural *skills* needed to perform self-management behaviours. IMBS has been used in diabetes cases where diabetes-educators and health promotion researchers have consistently found its strong correlation with behavioural outcomes. Information and motivation influences behavioural skills in diabetes patients and ensures that they have strategies necessary to perform the expected behaviours. This ultimately builds confidence (self-efficacy) in a patient's ability to perform his/her self-management behaviours (Gao et al., 2013; Jeon & Park 2018; Osborn et al., 2010). In this study, in addition to the self-efficacy construct of SCT, information, motivation and skills constructs of the IMBS model were also utilised.

1.5.3 SCT and IMBS Blended Model

In this research, the self-efficacy construct of SCT model (Bandura, 1999) and the information and motivation constructs of IMBS model (Fisher, Fisher & Harman, 2003) were blended to guide the development of the intervention. This is due to their precedence of use in technology-based behavioural change research (Poddar et al., 2010) and most importantly because they both identify significant constructs (mediators - skills and self-efficacy) needed for successful long-term maintenance of self-management behaviours required for improved health outcomes in people with chronic diseases including diabetes (Deakin et al., 2005; World Health organization, 2003).

Figure 1.1 shows a diagrammatic presentation of the SCT and IMBS blended elements for improving behavioural outcomes in diabetes self-management. DSMES intervention components related to information and motivation were utilised to enhance patients' skills and self-efficacy and consequently increase their self-management behaviours.

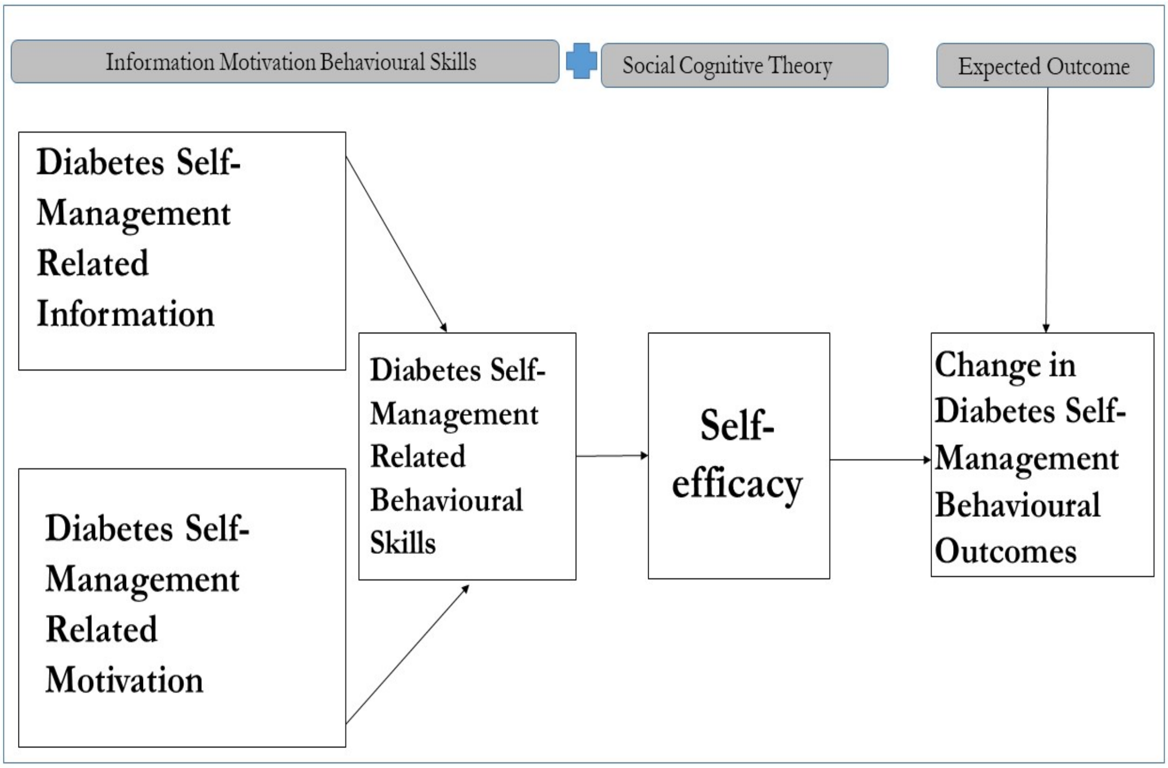


Figure 1.1: Framework for the blended SCT and IMBS elements for improving diabetes self-management behavioural outcomes.

1.6 METHODOLOGY

1.6.1 Research Design

This study utilised a sequential explanatory mixed-methods design approach using quantitative and qualitative data collection methods and analysis to address the research aims, questions and to test the postulated hypotheses. The results of both methods were triangulated to strengthen the research outcomes (Kennedy, 2009). Quantitative studies such as online surveys have the capacity to produce objective and statistically significant results. These can guide an effective intervention, although they lack the capacity to explore deeper underlying meanings and explanations of research findings due to limited responses (O'Leary, 2014). Furthermore, they overlook respondent experiences and perspectives and are unable to assess how respondents interpret questions asked (O'Leary 2014). Qualitative studies such as interviews are able to overcome these quantitative research limitations, particularly in gaining detailed understanding of respondents' opinions and perceptions about the effectiveness or ineffectiveness of an intervention. These studies however, are not focused on generalisability due to their small sample sizes and subjective nature of data generated (O'Leary, 2014). Triangulating results from both quantitative and qualitative approaches overcomes weaknesses presented by each research method and fosters improved understanding of the phenomenon of interest (Kennedy, 2009).

The mixed-methods approach was chosen in order to understand not only what patients preferred in an app to support their management, but also their perceptions on mediating factors for self-management. The outcomes of these studies were used to develop a new diabetes app as an intervention tool for DSMES. Thereafter, the efficacy of the intervention was assessed using a mixed method approach.

This research was conducted in three phases: Inspiration, app development and pilot testing. In all phases, quantitative data collection used online surveys using different validated tools to gather the perceptions of participants as appropriate to the aims of each phase of the study. Qualitative interviews were also conducted to build upon survey findings. Within each of the primary studies in each phase, a triangulation design was utilised to independently cross-validate internal findings between the online quantitative survey and qualitative interview components. This approach is widely used because it offers a comprehensive understanding through interpretations of convergent and divergent findings (Heale & Forbes, 2013). In addition, the qualitative components of the research were carefully designed based on the findings from the quantitative data, to explain the reason behind the observation from the quantitative data, thus deepening the understanding of the underlying phenomenon.

The research phases were sequenced and results of the preceding phase integrated into the next. The main limitation of the sequential method is the longer time lag and tendency for unexpected contradictory or divergence between the results in each phase. Nevertheless, divergent findings can provide a new and better explanation for the research question under investigation (Morse, 2003).

1.6.2 Key Participant Groups and Study Phases

There were three participant groups in this research: People without diabetes and diabetic patients with type 1 or type 2 diabetes.

Inspiration Phase: Participants involved in the first phase of the research were a multinational audience (USA, Asia, Australia and the United Kingdom) with type 1 or type 2 diabetes. This enabled the collection of a relatively generalizable dataset relating to patients' perspectives on preferences for app features that support diabetes self-management, recommendations for promoting engagements with such apps as well as specific educational information desired in apps. In addition, the data set inquired about common gaps in skills and self-efficacy as mediating factors for self-management in diabetic patients.

Development of Intervention and Usability Testing Phase: This phase involved the development of a new mobile phone app for DSMES and its usability testing. There were two sub-group of participants in the usability-testing phase - Australians who do not have diabetes and those who have type 1 or type 2 diabetes. Australian residents participated in this phase because one of the features in the newly developed intervention was aimed at reinforcing Australian clinical best practices related to the recommended blood glucose levels for patients with type 1 and type 2 diabetes. Participants who did not have diabetes were involved in the first stage of the usability testing because it assessed user interface and navigation issues of the newly developed intervention. Patients with diabetes took part in the stage 2 of the usability testing which included assessment of the app's value as a tool for supporting diabetes self-management.

Pilot Testing Phase: Phase 3 participants included people with type 1 or type 2 diabetes living in regional, rural and remote Northern Queensland, Australia. Participants in this phase were restricted to only Australian residents in rural and remote areas because of the higher prevalence of diabetes (6.7% compared to 4.7%) (Australian Bureau of Statistics, 2015), and shortage of health workers, hence poorer service availability for ongoing DSMES (Struber, 2004; Hussain et al., 2015). Therefore, rural and remote residents are the most needy of the new intervention for providing DSMES services. The preliminary efficacy of the intervention for diabetes self-management activities and acceptability by participants as a tool for DSMES were elucidated in this phase.

1.6.3 Analytical Techniques

Four primary methods were utilised in analysing the quantitative data in this research. Descriptive statistics including frequencies, percentages, means and standard deviations were used to analyse the demographic/health characteristics of participants and all dependent variables. Parametric tests including Pearson's Chi-Squared test, independent sample t-test and Analysis of Variance (ANOVA), were used to compute the relationships between dependent and independent variables within each study. Paired sample t-test for parametric repeated measures analyses and Wilcoxon Signed Rank test for non-parametric repeated measures analyses) were used to evaluate changes in pre and post intervention efficacy outcomes. Furthermore, Pearson's correlation analysis was used to measure the strength of association between two continuous variables, while multiple regression analysis was a predictive tool for estimating the contributions of different continuous independent variables on dependent variables in each study. All quantitative data were analysed using SPSS statistical software version 24 (IBM SPSS Statistics, 2018).

The primary method for analysing the qualitative data was inductive thematic analysis. This method was performed in line with Braun and Clarke's (Braun & Clarke, 2006) methodology of familiarization with the data, generating initial codes, organisation of codes into themes, reviewing themes, combination of themes into overarching themes that accurately depict the data and production of a report. This method allowed for easy approach to analysis while providing a rich and detailed account of the data (Braun & Clarke, 2006). Content analysis through objective, systematic and quantitative description of the manifest content of textual data (Hsieh & Shannon, 2005) was used for the open-ended survey in phase 2 of the research. In Phase 3, concept-driven analysis using a theoretical framework was utilised for the qualitative data from interviews. Concept-driven analysis involved iterative stages of labelling, classifying and organising data into main themes, concepts and categories in a theoretical framework (Ritchie et al., 2003). This method fostered understanding of participants' views and experiences in relation to the use of the new intervention. Qualitative data analyses were preformed using both Nvivo (version 11) and a Microsoft word processor (Microsoft word for Windows 2016).

1.6.4 Interpretation of Results

Triangulation of the overall dataset by integrating both quantitative and qualitative findings within every primary study in this research provided meaningful interpretation of the research results as a whole. Phase 1 study findings were integrated into the development of the new mobile app in Phase 2 of this research. Usability testing results of the new app were incorporated into re-designing and improving the quality of the app before moving onto Phase 3, where the resulting output from Phase 2 was pilot tested. Findings from Phase 3 were compared with previous findings from Phase 1 to identify both consistent patterns and unique results, especially relating to perceived factors for patients' engagement with an app and essential features necessary in an app to foster participation in self-management behavioural activities.

1.7 CONCEPTUAL FRAMEWORK OF THESIS

Figure 1.2 presents the conceptual framework of this research. It highlights the research questions and how they were answered by the 3 phases of the research.

<u>Phase 1: Inspiration</u>

As a first step of this research, a comprehensive literature review was conducted to provide a detailed background of type 1 and type 2 diabetes mellitus overview, the DSMES concept and the emergence of mobile apps as key tools for DSMES (Chapter 2-Part A). This was followed by a systematic review of literature to establish evidence regarding important factors and considerations in a mobile app development process to ensure its effectiveness as a DSMES tool (Chapter 2-Part B). The review focused on answering the first research question to know the necessary elements in an app development process in order to foster effective DSMES intervention.

Furthermore, the inspiration phase elucidated information on the understanding the mediating factors (skills and self-efficacy) that are important for improving diabetes self-management (Chapter 3). Prior to the commencement of the research reported in this thesis, a number of cross-sectional research reporting on skills and self-efficacy as mediating or enabling factors for fostering self-management in patients were identified (Persell, 2004; Aljasem et al., 2001; Johnston-Brooks, Lewis & Garg, 2002; Byers et al., 2016). However, most of these studies considered only a few aspects of diabetes self-management, type 1 (Johnston-Brooks, Lewis & Garg, 2002) or type 2 (Aljasem et al., 2001; Byers et al., 2016) diabetes alone, and rarely had an international audience. Therefore, this chapter contributed to answering the second research question aimed at establishing the relationship between skills and self-efficacy and knowing the extent to which they stimulate behavioural change for self-management in an international audience of patients with type 1 and type 2 diabetes. In addition, the inspiration phase answered the third research question aimed at exploring users' needs and preferences in app intervention for DSMES, offering recommendations to promote engagements with such apps and specific educational information desired in apps (Chapter 4).

Phase 2: Development of intervention

Findings from the inspiration phase were used to develop a new mobile phone app for DSMES (Chapter 5). In mapping information from the inspiration phase, it was found that a deliberate strategy used by health care givers to increase patients' self-efficacy involved self-monitoring of clinical and health behavioural activities (Steed et al., 2014; Hernandez-Tejada et al., 2012). Intervention targeting self-monitoring enhances self-efficacy, which in turn, positively impacts decision making for self-management behaviours (Cotter et al., 2014; Mishali, Omer & Heymann, 2011; Lalić et al., 2017; Cummings et al., 2011; Lorig et al., 2009; Gleeson-Kreig, 2006). This emphasises the importance of including self-monitoring elements in a behavioural health intervention.

From the systematic review (Chapter 2-part B), the use of health behavioural theory, user and clinical expert involvement, data security and privacy, and pilot testing were perceived as the most important factors to be included in a diabetes app development process to foster an effective intervention. Therefore, these considerations were followed in the second phase.

Phase 3: Pilot testing

The developed app was evaluated in subsequent chapters of this thesis (Chapters 6 and 7) to assess its capacity to retain and engage users. The efficacy of the intervention on diabetes self-management activities and acceptability by participants as a tool for DSMES were also elucidated.

Overall, both phases 2 and 3 of the study were aimed at answering the fourth research question on assessing the extent to which a newly developed intervention could stimulate improved diabetes self-management and its acceptability among end users with type 1 and type 2 diabetes.

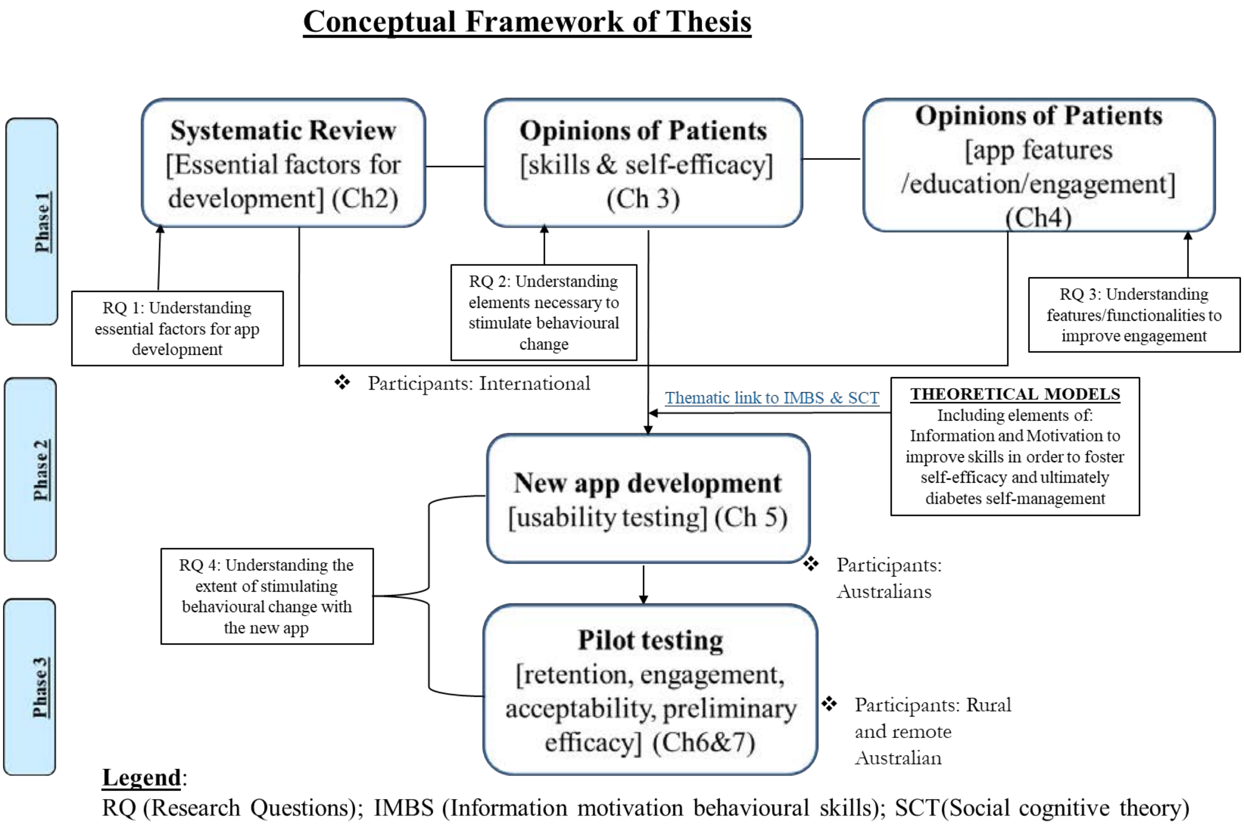


Figure 1.2. Illustration of the flow chart of research activities reported in this thesis

1.7.1 Thesis Outline

This thesis comprises of nine chapters, which taken together, aim to address the research aims, hypotheses and questions stated previously.

- Chapter 1 – General introduction gives an introductory background to prevalence of diabetes mellitus epidemic, existing knowledge gaps in mobile phone apps for diabetes self-management support interventions and the need for better user engagement. This chapter also discusses strengths and limitations of currently available apps for diabetes self-management, the theoretical conceptual framework for the development of a new diabetes app intervention, thesis aims, research questions, hypotheses, research design and methodology justification.

- Chapter 2 –Literature Review - is divided into two parts: Part A provides an overview of diabetes mellitus, its complications and interventions for self-management. It discusses the evolution of mobile apps as health intervention tools, highlighting barriers to successful use and improvement opportunities for self-management education and support in type 1 and type 2 diabetes. Part B is a systematic review that provides evidence of key sets of essential requirements in the process of developing an effective mobile phone app for DSMES. This chapter also answered RQ1.
- Chapter 3 reports the findings of an online survey and interviews of an international audience of type 1 or type 2 diabetes. It also answered part of RQ2 to establish empirical evidence for the relationships between patients' skills and self-efficacy including their mediating influence on diabetes self-management.
- Chapter 4 reports the findings of a combination of online survey and interviews of an international audience of type 1 or type 2 diabetes to gain in-depth understanding of patients' preferences of app features and educational content for inclusion in diabetes apps to foster engagement and improved self-management. The chapter answers RQ3. The data findings from this chapter informed the content development of a new mobile diabetes app presented in Chapter 5.
- Chapter 5 describes the process for the development and usability testing of a novel mobile app called 'My Care Hub', for self-management education and support of people with type 1 and type 2 diabetes. This study answered part of RQ4.
- Chapter 6 evaluates retention and participants' engagement with the newly developed app through pilot testing and contributes answers to RQ4.

- ❖ Chapter 7 assesses the preliminary efficacy of the new app for diabetes self-management and its patient acceptability as a DSMES tool. The findings contribute to answering RQ4.
- ❖ Chapter 8 discusses the overall findings of this research and implications of the findings for patients, health practitioners, patients and app developers.
- ❖ Chapter 9 draws an overall conclusion and makes recommendations for future research in the development and implementation of diabetes apps as self-management education and support tools.

1.8 SUMMARY

This chapter outlines the prevalence of diabetes mellitus and the need for ongoing self-management education and support in patients. It enumerates the current barriers to patients' ongoing access to DSMES. Furthermore, the potential use of mobile apps as tools for supporting patients in their self-management activities and the limitations of its effectiveness and adoption are highlighted. Theoretical models (Social Cognitive and Information Motivation Behavioural Skill Models) that underpin the current research, methodological framework and analytical techniques are also presented. The reasoning behind the design of a new intervention aimed at DSMES is also detailed. Finally, an outline of the thesis chapters and how they address the research questions is presented.

Table 1.1 Thesis Outline Chapter Details and Publication Status of Chapters*

Chapter (Abbreviated Titles)	Chapter Contents	Author Contributions	Submission Status
ONE: General Introduction	A brief introduction to the prevalence of diabetes mellitus in Australia, and the status of mobile phone apps intervention aimed at improving diabetes self-management. This chapter also discusses the strengths and limitations of current diabetes app interventions, and the theoretical background for the app intervention being evaluated in this thesis.	MDA wrote the introductory chapter, with UM, AEOMA and BMA reviewing each draft before approving the final version.	N/A
TWO **Part A: Literature review** **Part B: Systematic Review of Mobile Phone Apps for Diabetes Self-Management**	Part A provides an overview of diabetes mellitus and current literature on the evolution of mobile apps as diabetes self-management tools. It also highlights the barriers to the successful use and opportunities for improvement of diabetes apps. Part B is a systematic review investigating the essential requirements in developing mobile apps for effective diabetes self-management and education.	MDA wrote the part A of the literature review, with UM, AEOMA and BMA reviewing each draft before approving the final version. MDA designed and carried out the systematic search and quality appraisal, and wrote the manuscript drafts. BMA conducted quality appraisal checks. EC, UM, AEOMA and BMA reviewed each draft, and approved the final version.	Part A – N/A Part B - Published in *Journal of Medical Internet Research uHealth and mHealth*
THREE: Enablers and Barriers to Diabetes Self-Management	A mixed-methods study of an international audience on their perception of the enablers and barriers to diabetes self-management. Specific areas of skills and self-efficacy as enablers for diabetes self-management were evaluated to identify aspects, which require ongoing support.	MDA designed the study and wrote the ethics application. UM, AEOMA and BMA provided support on the study design and assisted in preparation of the ethics application. MDA and BMA analysed the data. MDA wrote the	Published in *Plos One*

		manuscript, while UM, AEOMA and BMA reviewed the final manuscript.	
FOUR: Users Preferences and Design Recommendations to Improve Engagement with Apps	A mixed-methods study of an international audience on their preferences for app features, educational contents and recommendations for improved engagement with apps.	MDA designed the study and wrote the ethics application. UM, AEOMA and BMA provided support on the study design and assisted in preparation of the ethics application. MDA and BMA analysed the data. MDA wrote the manuscript, while UM, AEOMA and BMA reviewed the final manuscript.	Published in *Plos One*
FIVE: The Development of Diabetes My Care Hub App to Support Diabetes Self-Management	A full report of the development process of a novel app called My Care Hub, aimed at the self-management education and support of people with type 1 or type 2 diabetes. This chapter also includes a two-staged usability testing of the app among Australian general population and diabetes patients.	MDA designed the app's concept. UM, AEOMA and BMA assisted with intellectual content in the app design. IA and SV developed the app's software. MDA wrote the manuscript, while UM, AEOMA and BMA reviewed the final manuscript.	Published in *Scientific Report*
SIX: User Retention and Engagement with My Care Hub App	A mixed-methods pilot testing of the novel app among type 1 and type 2 diabetes patients living in rural and remote areas of Australia. This is to evaluate participant's retention and engagement with the app.	MDA designed the study and wrote the ethics application. UM, AEOMA and BMA provided support on the study design and assisted in preparation of the ethics application. MDA, AD and BMA analysed the data. MDA wrote the manuscript, while UM, AEOMA, AD and BMA reviewed the final manuscript.	Published in *Journal of Medical Internet Research mHealth and UHealth*

SEVEN: Efficacy and Acceptability of My Care Hub App	A mixed-method pilot testing of the novel app among type 1 and type 2 diabetes patients living in a rural and remote area of Australia. This is to evaluate the preliminary efficacy of the app on diabetes self-management and its acceptability among the target audience.	MDA designed the study and wrote the ethics application. UM, AEOMA and BMA provided support on the study design and assisted in preparation of the ethics application. MDA, AD and BMA analysed the data. MDA wrote the manuscript, and UM, AEOMA, AD and BMA reviewed the final manuscript.	Published in *International Journal of Environmental Research and Public Health*
EIGHT: General Discussion	A discussion of the key findings of the research, including its novel contribution and practical implications within a broader context of diabetes self-management. It also outlines prospects for future research to enhance self-management education and support for patients with type 1 or type 2 diabetes.	MDA wrote the discussion chapter, with UM, AEOMA, and BMA reviewing each draft before approving the final version.	N/A
NINE: Conclusions and Recommendations	Final conclusions of the research and recommendations for patients, health professionals, researchers and app developers.	MDA wrote the conclusions and recommendations chapter, with UM, AEOMA, and BMA reviewing each draft before approving the final version.	N/A

*Chapters 2b – 7 are publication-based chapters in this thesis

Chapter TWO: Literature Review

Chapter Overview

This chapter has two sections (Parts A and B). Part A presents the epidemiological background of type 1 and type 2 diabetes mellitus. It also discusses the importance of DSMES and how technological devices especially apps play a key role in providing DSMES. Knowledge gaps in the use of apps as DSMES tools were identified and suggestions on filling these gaps provided.

Part B comprises the methodology and findings of a systematic review investigating developmental considerations adopted in randomised controlled trials that engaged mobile phone applications (apps) for diabetes self-management. This section of the chapter aimed to develop a framework/guideline on the essential elements required in a diabetes app development process prior to use, as an intervention for self-management in patients with type 1 or type 2 diabetes.

Part A: Review of Literature on Diabetes Mellitus, its Complications and Current Interventions to Improve Self-Management

2.1 DIABETES MELLITUS

According to the World Health Organisation (WHO), diabetes is ‘‘a metabolic disorder of multiple etiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both.’’ (World Health Organisation, 1999). Insulin is produced in the pancreas and facilitates glucose transport from the blood into cells for energy production. An absolute or partial deficiency in insulin secretion and/or ineffective utilisation by body cells over a prolonged period of time causes hyperglycemia - high blood glucose levels (World Health Organisation, 1999).There are mainly two type of diabetes: Type 1 and 2 diabetes.

2.1.2 Types 1 and 2 diabetes

Type 1 diabetes mellitus results from an auto-immune destruction of insulin-producing beta (β) cells by the immune system, eventually resulting in absolute deficiency in insulin secretion (World Health Organisation, 1999). The cause of auto-immune reaction has been attributed to genetic disposition triggered by changes in environmental risk factors (Vojdani, 2014). Type 1 diabetes requires lifelong treatment with insulin and is mostly diagnosed during childhood or adolescence (American Diabetes Association, 2017a), although in recent times, it is also diagnosed in adulthood due to late onset (Thomas et al., 2018).

Type 2 diabetes is characterised by relative insulin deficiency/malfunction in addition to insulin resistance, leading to hyperglycaemia. Insulin resistance induces increased insulin production by the β cells in an attempt by the body to maintain normal blood glucose balance, but consequently diminishes β cell mass and insulin (Kahn, Cooper, Del Prato & 2014). Type 2 diabetes, which is the most common type (accounting for 90% of all cases of diabetes) is progressive in nature and has a strong genetic propensity (Kahn, Cooper, Del Prato & 2014).

Generally, symptoms of marked hyperglycemia vary from polydipsia (excessive thirst), polyuria (excessive urine production), blurred vision to unexplained weight loss etc. (World Health Organisation, 1999). In some cases, patients presents with growth impairment and increased susceptibility to certain infections (Powers et al., 2015a). The severity of symptoms depends on the type of diabetes and duration of the disease.

2.1.3 Diagnostic criteria

Diagnostic criteria for both types 1 and 2 diabetes are the same; based on Fasting Plasma Glucose and the 75g Oral Glucose Tolerance Test with a cut point of 7.0mmol/L or 11.1mmol/L respectively (American Diabetes Association, 2017b), as shown in **Table 2.1**. In 2009, HbA1c with a cut-off point of 6.5% was introduced as a preferred diagnostic measure by the International Expert Committee, due to its strong evidence as a marker of chronic hyperglycaemia which reflects average blood glucose levels (BGL) over a 2- to 3- month period (The International Expert Committee, 2009). The measure was endorsed by WHO in 2011 (World Health Organisation, 2011a) and accepted by the Australian Diabetes Society in 2012 (d'Emden et al., 2012).

Table 2.1: General diagnostic criteria for diabetes mellitus (American Diabetes Association, 2017b).

Test	**Readings**
Fasting Plasma Glucose (no calorie intake for at least 8 hours)	≥126mg/dl (7.0mmol/L).
Oral Glucose Tolerance (2 hours post load of 75g anhydrous glucose	>200mg/dl (11.1mmol/L)
Glycated hemoglobin (HbA1c)	≥ 6.5% (48mmol/mil)

2.1.4 Complications of diabetes

Patients with diabetes risk developing acute and chronic complications when the condition is not well managed (American Diabetes Association, 2017a). Acute, life threatening consequences of uncontrolled diabetes are hypoglycaemia, diabetic ketoacidosis and hyperglycaemic hyperosmolar state (Fishbein & Palumbo, 1995; International Diabetes Federation, 2017). Chronic complications include damage to vital organs such as the eyes (retinopathy), kidneys (nephropathy) and nerves (neuropathy) as well as increased risk of heart disease, stroke and poor blood supply to the limbs (neuropathy) (Alberti & Zimmet, 1998; Papatheodorous et al., 2015). Globally, retinopathy affects 35% of people with diabetes and may result in severe visual loss. Also, patients have two to three fold increased rates of cardiovascular diseases (Papatheodorous et al., 2015). In Australia, a study which reported data on 2,731 adults with type 2 diabetes between 2000-2002 reported 13.8-16.5% of these populations had a foot complication (Harris et al., 2006). In a study from Australia's rural and remote Northern Territory, patients with diabetes were five times more likely to have foot infections and poorer diabetes control than other Australians (Commons et al., 2015). Diabetes complications are the leading cause of poor quality of life, pre-mature death and preventable hospitalisations. Diabetes complications accounted for 9% of all potentially preventable hospitalisations in Australia in 2013-14 (Australian Institute of Health and Welfare, 2015). Data from other rural and remote areas of Australia such as Queensland, indicate that in 2015-16, there were 184, 000 cases of potentially preventable hospitalisations with diabetes as the principal diagnosis and 25% of these cases were due to complications (Queensland Health Report, 2018). The hospitalisations were about 20% higher in inner and outer rural areas and 2.2 times higher in remote and very remote areas of Queensland (Queensland Health Report, 2018).

Complications from diabetes impose substantial financial burden on health care systems and national economies. In 2019, an annual global health expenditure of USD760 billion was spent on diabetes with a proposed estimate of USD825 billion by 2030 (International Diabetes Federation, 2019). In Australia, there is a direct annual cost of $9645 compared with $4025 among individuals with type 2 diabetes without complications (Colagiuri et al., 2002) and $16,698 compared to $3,468 among type 1 diabetes individuals without complications (Colagiuri et al., 2009). Besides the burden on nations and health care systems, diabetes complications pose significant economic impacts on patients and their families in terms of higher out-of-pocket health care payments, reduced productivity and increased absence from work (World Health Organisation, 2005).

Reducing the risk of complications, hospitalisations and associated financial implications are preventable and could be attained through optimal control of BGL. Specifically, Diabetes Australia guideline recommends a pre-prandial (fasting) BGL of 4 to 8 mmol/L and postprandial levels of <10 mmol/L in those with type 1 diabetes. For those with type 2 diabetes, 6 to 8 mmol/L and 6 to 10 mmol/L fasting/before meals and two hours after starting meals respectively, are recommended (Diabetes Australia, 2015; Deed et al., 2016). These targets may be adjusted for each patient based on the history of hypoglycaemia, age and onset of late complications. These recommended BGL could only be attained and maintained through regular self-management (UK Prospective Diabetes Study Group, 1998; Gæde et al., 2008).

2.2 SELF-MANAGEMENT

The concept of self-management was introduced into the healthcare system in the 1960s (Creer, Renne & Christian, 1976; Lorig & Holman, 2003), however, there exists heterogeneity in its application and understanding as well as a lack of consensus on definition (Ryan &Sawin, 2009; Jonkman et al., 2016). Self-management is often used interchangeably with self-care (Riegel et al., 2009), patient-centred care (Catalyst, 2017; Kuntz et al., 2014), self-regulation and patient activation (Kinney et al., 2015; Hibbard & Greene, 2013). Adding to the ambiguity of the concept is the use of the term self-management intervention programs, the process of self-management and the description of outcomes gained by engaging in self-management practices (Ryan & Sawin, 2009). Although, the concepts are related, definitions relevant to the current research are those delineating the uptake of responsibility for one's own behaviour and well-being, emphasising patient responsibility and acting in concert with health providers (Holman & Lorig, 2000; Bodenheimer et al., 2002). Self-management denotes patientcenteredness, where individuals are active participants in the management of their own disease for improved health outcomes and quality of life (Barlow et al., 2002). Self-management has the potential of an effective paradigm across the public health spectrum for disease prevention (primary), by establishing a pattern for healthy living early in life and providing strategies for disease mitigations and management in later life (secondary and tertiary). Therefore, the concept of self-management is integral to both the maintenance of wellness (Perera & Agboola, 2019) and the management of illness (Starfield et al., 2008; Grady & Gough, 2014).

2.2.1 Diabetes Self-Management

Traditionally, self-management of diabetes has been defined as a set of activities or actions related to healthy eating, being physically active, adhering to medications, self-monitoring of blood glucose (SMBG), foot inspection, problem solving, healthy coping and reducing risks such as smoking cessation and limiting alcohol consumption. Having a healthy lifestyle is crucial for people with types 1 and 2 diabetes, just like it is for the general population. The Australia Diabetes Guidelines targeting lifestyle for good health in diabetes (adopted from the American Diabetes Association, Standard of Medical Care) (American Diabetes Association, 2017c), emphasised increased physical activity, healthier eating and weight loss for those overweight or obese (Deed et al., 2016). Patients are discouraged from consuming foods containing saturated fat, refined carbohydrates and added sugar as much as possible because of their tendency to unnecessarily increase BGL and strain the metabolic system. Instead, consumption of green vegetables and other foods that are low in glycaemic index is advised (Deed et al., 2016, American Diabetes Association, 2017c). In addition to improved dietary recommendations, a minimum of 30 minutes' physical activity is a key component of patients' daily routine in order to help increase insulin sensitivity (Deed et al., 2016). Also, there is a growing body of research exploring the benefits of frequent breaks in prolonged periods of sedentary lifestyle on postprandial spikes and overall glycaemic control (Colberg, 2012;

Dunstan et al., 2012). Therefore, the importance of avoiding sedentary periods of more than 90 minutes is emphasised to patients (American Diabetes Association, 2017c).

For SMBG, it is essential for patients with type 1 diabetes to perform SMBG at least three times daily (American Diabetes Association, 2010; Manroa & Krupa, 2016) to detect asymptomatic hypoglycaemia and facilitate attainment of blood glucose goals (Deed et al., 2016; American Diabetes Association, 2010). There is debate over optimal frequency of SMBG for diet-treated patients with type 2 diabetes, but daily monitoring is important for those who use insulin or oral agents (Deed et al., 2016; Manroa & Krupa, 2016; American Diabetes Association, 2002). Nevertheless, studies have reported better glycaemic control with increased frequency of SMBG in both groups of patients (Evans et al., 1999, Welschen et al., 2005; Poolsup et al., 2009; Polonsky et al., 2011) due to improved ability to schedule lifestyle behaviours including physical activity, food and medication intake (American Diabetes Association, 2010). SMBG in patients promotes personal responsibility and allows for detection of blood glucose fluctuations. Furthermore, SMBG is an important tool for health providers to titrate blood glucose lowering agents (American Diabetes Association, 2010), problem solving and recommend lifestyle (activity, stress, nutrition) modifications for patients (Klonoff et al., 2008; Kirk & Stegner, 2010). For example, if the result of SMBG shows a consistent pattern of high pre-prandial levels, then medications that target liver output of glucose might be helpful. Postprandial glucose levels (two hours after eating) provide information related to the impact of food intake on blood glucose, hence, diet modification or medications such as mealtime insulin, may be helpful in such cases (Kirk & Stegner, 2010). Furthermore, lack of SMBG predicts hospitalisation for diabetes-related complications (Burge, 2001).

In relation to foot care, patients are recommended to wear footwear that fit, protect and accommodate the shape of their feet in order to prevent ulcerations. Also, patients are advised to regularly check and ensure that there are no signs of trauma, abnormal pressure or ulceration on their feet (Bergin et al., 2013; van Netten et al., 2018). Foot checking is essential for the prevention and early detection of diabetic foot ulcers caused by repetitive shear and pressure on the foot when peripheral artery disease or neuropathy is present (Bus et al., 2016). In relation to reducing risks, smoking caseation is encouraged in diabetes due to increased risk of cardiovascular diseases among patients who smoke (Haire-Joshu, Glasgow & Tibbs, 1999). Similarly, excessive alcohol consumption is discouraged in patients, especially those with type 1 diabetes, because it further increases the risk of hypoglycaemia and diabetes ketoacidosis (DKA) which are life threatening (Turner et al., 2001; Hermann et al., 2017).

2.2.2 Diabetes Self-Management Education and Support (DSME)

In 2006, the term DSME was defined as ‘‘*an interactive, collaborative, ongoing process involving persons with diabetes and diabetes educators*’’ (Mensing et al., 2006). This process includes: 1) Assessment of the individual’s specific education needs; 2) identification of the individual’s specific diabetes self-management goals; 3) education and behavioural interventions directed towards helping the individual achieve identified self-management goals and; 4) evaluation of the individual’s attainment of self-management goals’’ (Mensing et al., 2006). This definition was later revised in 2015 as ‘‘*the process of facilitating the knowledge, skill and ability necessary for diabetes self-care*’’ (Powers et al., 2015a). The definition was also adopted by the Australian Diabetes Educators who described the goal of DSME as a process to assist diabetes patients to better understand their condition, enable them make informed decision and increase their confidence in their self-management in order to improve their quality of life and reduce the risk of complications (Australian Diabetes Educators, 2015).

Often times, patients do not achieve the recommendations for their self-management due to lack of motivation, difficulty changing lifestyle behaviours and low understanding of the direct impact of lifestyle behaviours on glycaemic control and overall health outcomes (Rosenthal et al., 1998; Peveler et al., 2005; Polonsky et al., 2011; Kalra et al., 2013; Saleh et al., 2014; Bonger et al., 2018). A systematic review reported that the mean number of day patients adhering to their self-management behaviours were as low as 29.9%, 26.7%, 13%, 17.0% for diet, exercise, SMBG and foot care respectively (Mogre et al., 2019). Hence, the recommendation for diabetes self-management support (DSMS) to be provided in addition to DSME. DSMS are activities to support the individual with diabetes in order to implement and sustain coping skills and behaviours needed to self-manage their condition on a regular basis (Powers et al., 2015a). The type of support provided can include educational, behavioural, psychosocial, or clinical (Haas et al., 2012).

The need for DSMS originates from the work of Tang and colleagues (2005), who acknowledged the necessity to create a new generation of diabetes self-management support interventions that would reinforce and enhance self-management benefits that a patient achieves during DSME programs. Furthermore, DSMS is aimed at enhancing and sustaining self-management behaviours on a long term basis. Tang et al's (2005) work added self-management support to DSME to become diabetes self-management education and support (DSMES). This addition emphasises the need for ongoing support for patients in their diabetes self-management when they are outside of formal care programs (Haas et al., 2012). Traditionally, DSME is only provided by health professionals during appointments at clinics or hospitals, whereas ongoing DSMS can be provided within a variety of community-based settings (Power et al., 2015a).

The current Australian guidelines for the management of types 1 and 2 diabetes (Australian Diabetes Educators, 2015), are in line with updated recommendations in the ‘‘Position Statement for Diabetes Self-Management Education and Support’’ (Powers et al., 2017) and ‘‘Standards of Medical Care in Diabetes’’ (American Diabetes Association, 2019). These guidelines are in agreement with continuous DSMES for people with diabetes in order to increase their knowledge, skills and resilience required for ongoing commitment to self-management. DSMES are designed to address knowledge gaps, health beliefs, health literacy, emotional concerns and other factors that influence patients' ability to meet the challenges of self-management.

Through various modes of delivery, DSMES interventions have proven to improve behavioural change outcomes as evident in several reviews that reported improvements in physical activity (Norris, Engelgau & Narayan, 2001; Heinrich, Schaper & de Vries, 2010; Ricci-Cabello et al., 2014), diet (Newsman, Steed & Mulligan 2004; Norris, Engelgau & Narayan, 2001; Heinrich, Schaper & de Vries, 2010; Ricci-Cabello et al., 2014), blood glucose testing (Ricci-Cabello et al., 2014; Heinrich Schaper & de Vries, 2010) and foot care (Ricci-Cabello et al., 2014). The ultimate impact of those behavioural outcomes is the effect on glycaemic control. Many studies have reported the importance of DSMES for improved glycaemic outcome in the form of glycosylated haemoglobin (HbA1c) (Norris et al., 2002; Gary, 2003; Deakin et al., 2005; Steinsbekk et al., 2012; Tshiananga et al., 2012). Steinsbekk (2012) assessed 21 studies and found a significant decrease in HbA1c after 6-24 months. A meta-analysis of 34 RCT with a combined cohort size of 5993 patients, reported a significant effect on HbA1c with a moderate effect size of 0.51. However, the intervention effect reduced after six months (Norris et al., 2002). On the contrary, a meta-analysis by Gary and colleagues (Gary et al., 2003) reported a similar effect, but the intervention effects were sustained beyond six months. The results of these reviews denote an improvement in glycaemic control. However, discrepancies exist with regards to sustainability of the intervention effect.

The mode of delivery for studies in the above reviews ranged from individuals, in-persons, remotely or combined modes including nurse-led education, group meetings, etc. O'Hara et al., (2017) and Norris, Engelgau & Narayan (2001) found mixed results on HbA1c outcomes from both group-based versus individual interventions in people with type 1 or type 2 diabetes, respectively, thereby suggesting no clear evidence about the effects of delivery mode. However, a meta-analysis conducted a year later by Norris et al. (2002), found no differences related to the intervention delivery mode and yet, a positive impact on HbA1c, suggesting positive contributions from both group- or individual-based interventions. Similarly, a Cochrane review reported the benefits of individual mode of delivery only on type 2 diabetes participants who had a baseline HbA1c greater than 8%. Overall, the study found no significant difference in glycaemic control between individual- or group-based education (Duke, Colagiuri & Colaguiri 2009), thereby further confirming the equal effects of individual-and group-based interventions.

The most commonly used components of DSMES are education about the condition and its management, lifestyle advice and support, as well as psychological strategies for healthy coping. No component emerged as essential or optimal, but rather, a multi-component self-management strategy was advised (Fan & Sidani, 2009; Schaper & de Vries, 2010; Bolen et al., 2014; Sherifali et al., 2016; McBain et al., 2016). Research evaluating self-management interventions for 14 different chronic conditions highlighted the following core components: Education about the condition, practical self-management support, psychological strategies for life adjustments, self-management adherence and social support (Taylor et al., 2014). Another, meta-analysis found that the inclusion of an educational component in interventions produced statistically significant improvements in clinical outcomes (Ricci-Cabello et al., 2014). Furthermore, two reviews concluded that components that employed cognitive reframing techniques using regular reinforcements aimed at increasing motivation and changing behavioural attitudes, were the most effective; far better than those aimed at enhancing knowledge alone (Norris, Engelgau & Narayan, 2001; Ricci-Cabello et al.,2014). Therefore, education and feedback for motivation and behavioural attitudes have considerable effects on behavioural change. As such, DSMES approaches have evolved from training to empowerment and from one-dimensional to multi-component approach.

Regardless of the importance of DSMES, research has concluded that the number of persons with type 1 or type 2 diabetes accessing DSMES is low, partly due to economic, geographic and cultural barriers. In addition, patients have poor adherence to clinical recommendations for lifestyle changes, which has been attributed to lack of access to regular self-management education and support (Delamater, 2006). In Australia, a nationwide study found that only 25% and 17% of patients with type 1 or type 2 diabetes adhered to healthy eating plans and regular exercise, respectively (Ventura et al., 2016). Other studies reported that adherence to SMBG (Taylor, Fatima & Solomon, 2017) and foot care were sub-optimal (Perrin, Swerissen & Payne, 2009; van Netten et al., 2019). As a result, most patients are unable to achieve the clinical target for blood glucose control and HbA1c and are thus highly predisposed to developing diabetes-related complications (Speight et al., 2011; Ventura et al., 2016; Henderson et al., 2013). A possible way of overcoming these barriers and its subsequent impacts is through alternative settings such as the use of technology, especially those that could be embedded in the daily life of patients.

2.3 TECHNOLOGY FOR DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT (DSMES)

Technology can increase access to DSMES. Its ascendancy stems from the ability to provide new information and disease self-management programs to large populations that encourage behavioural change (Krishna, Boren & Balas 2009; Cole-Lewis & Kershaw, 2010; Oldenburg et al., 2015; Taj et al, 2019). Several concepts within the health technology space have emerged including telehealth, mHealth, eHealth, telecare and telemedicine. The terms encompass delivery of health care services at a distance using technologies and methodologies to enable remote care, improved health outcomes, health care services and health research (Wilson &

Maeder, 2015; Tuckson et al., 2017). mHealth is the applied concept for this research and has been defined as the practice of health care delivery supported by mobile devices, such as mobile phones, tablets, computers, personal digital assistants (PDA) and other wireless devices (World Health Organisation, 2011b). The concept of mHealth is considered to be a component of eHealth, which is health care delivered electronically, using mobile devices (Van Dyk, 2014).

2.3.1. mHealth

The emergence of mHealth stems from the enthusiasm of using mobile phones and other hand-held devices for healthcare. A key strength of mHealth is the ability to capture data and provide feedback to users through their personal devices, which are embedded into their daily routines, thus facilitating habitual self-monitoring (Chomutare et al., 2011; Nundy et al., 2014). Mobile phones are carried by persons, typically turned on, and suitable for bi-directional communication and on-demand access to resources (Proudfoot et al., 2011), hence their ability to facilitate point-of-care resources (e.g. decision support systems, remote consultation). Mobile phones have been further revolutionised into smartphones – mobile phones that can access the internet and run software applications (apps) (Poushter, 2016). Apps could be designed to be used by patients and health providers for behavioural prompts, reminders, continuous disease monitoring and self-management programs that extend beyond the confines of a physical clinic (Harrison et al., 2011; Luxton et al., 2011; Ben-Zeev, 2012). Apps could offer access to monitoring disease symptoms, information and communication with peers or health providers. In 2013, Martinez-Perez and colleagues reported in their review that diabetes led the list of the most common disease condition targeted by apps in scientific literature as well as in commercial stores

The use of apps as tools for DSMES has proliferated, as illustrated by the number of diabetes apps currently available for download on Google Play and iOS Store (Pham, Wiljer, Cefazzo, 2016; Huang et al., 2019; Izahar et al., 2017; Kordonouri & Riddell, 2019; Ubaid Ur Rehman et al., 2019; Arnhold, Quade & Kirch, 2014; Martinez et al., 2017). Therefore, as one of the prominent digital behavioural change interventions, apps could provide DSMES in a myriad of ways. These include: monitoring of blood glucose, physical activity, diet, medications, weight, push notifications and reminders/alerts, provision of education/information, analytics and graphical visualisation of data, goal setting, data export, communication with health professionals, synchronisation with health records, social networking, integration with research and news update (Chomutare, 2011; Arnhold, Quade & Kirch, 2014). Some apps allow for feedback and real-time data combined with predictive analytics of behavioural engagement on clinical outcomes, which are effective in self-discovery of the effect of self-management (Kaufman et al., 2016; Van Calster et al., 2019).

Overall, it is clear that diabetes apps can empower patients with the ability to proactively manage diabetes. However, there exists some limitations with apps as supporting tools for DSMES. These limitations include: 1) Lack of information on what constitutes standard considerations in the development of diabetes apps prior to use in trials; 2) poor exploration of mediating factors in diabetes apps to foster behavioural change and; 3) high attrition rates and low/absence of educational components in most apps.

2.3.2 Limitations in Mobile Apps for Diabetes Self-Management and How to Address Them.

a. Framework on standard consideration for diabetes app development:

While interest in the use of apps for DSMES continues to rise, to the best of our current knowledge, no systemic framework or guidelines on processes critical for an effective diabetes app are available. There is a general lack of explicit explanation among researchers and developers on the systematic elements that guide diabetes app development to foster an effective intervention. This gap suggests that research is needed to provide a framework on minimum standard considerations for diabetes app development prior to its use as an intervention in patients. Provision of standards will promote vigour, quality control and encourage a transparent and reproducible process of app development (Hoffmann et al., 2017). Such frameworks will provide a clearer understanding of the core elements that underline diabetes app development and inform guidelines that can be used consistently to ensure that such apps are fit for purpose - an effective tool for self-management education and support of patients.

b. Poor exploration of mediating factors in diabetes apps to foster behavioural change:

The role of mediating factors is central to the ability of patients' to desire or participate in self-management. This role had been poorly explored in previous diabetes app interventions. There exists a mediating framework between theoretical constructs and behaviour (Baranowski, 1998; Lewis et al., 2002). In behavioural theory, there is an assumption that interventions can target change in critical mediators of behavioural engagement and this will follow a causal chain resulting in behavioural change. Specifically, the independent variable (e.g. intervention) has an effect on outcomes (e.g. changes in diabetes behavioural management) via the mediator (Cerin & Mackinnon, 2009); MacKinnon et al., 2002).

Behavioural change models such as social cognitive theory (SCT) are frameworks for mediating constructs of behavioural change (Bandura, 1998). SCT has a history of supporting people to stay healthy through good self-management behaviours necessary for healthy living (Lyons et al., 2014). SCT has been reported by many studies to guide the development of complex interventions for self-management support of many chronic conditions including diabetes (Cotter et al., 2014; Avery et al., 2015; Tougas et al., 2015). Steed et al., (2014), noted in their evaluation of SCT and Self Determination Theory, that beliefs in seriousness and treatment effectiveness were not significant mediators of self-management, rather, behaviour specific self-efficacy for monitoring of blood glucose and physical activity had the most convincing and reliable evidence as a mediator of behavioural change. Likewise, a vast majority of evidence reveals that in patients with types 1 and 2 diabetes, improved self-efficacy improved the diets, levels of physical activity and overall self-management behaviours of such patients (Sarkar, Fisher & Schillinger, 2006; Qiu et al., 2012; Mohebi et al., 2013; Steed et al., 2014; Yao et al., 2019; Jiang et al., 2019; Alvarado-Martel et al., 2019).

Perceived self-efficacy enables an individual to succeed in challenging situations and this is the main basis for action. It begins with the perception of the existence of a problem followed by the belief that desired results can be achieved with one's action, thus creating an incentive to persevere (Bandura, 2004). This can greatly influence a patient's ability or desire to participate in self-management (Bandura, 2004). Self-efficacy underlines a person's ability to overcome temporary setbacks and relapses, and the extent to which a new behaviour is maintained (Bandura, 2004). The stronger the level of self-efficacy, the more likely behavioural change will be successful (Locke, 1997), therefore, it is a significant mediator for improved behavioural change.

While self-efficacy is a mediator for behavioural change, it assumes that if people lack the awareness and knowledge of how their lifestyle habits influence their health, they have little reason to pull themselves out of the bad habits they enjoy. Patients infrequently receive self-management training from health care providers and find it difficult to apply to real world settings (Delamater, 2006). Lack of adherence stems from the inability to understand how each care component or recommendation contributes to overall glycaemic control. For instance, many patients do not relate improved exercise to glycaemic control, and therefore lack motivation to increase their level of physical activity. The ability to problem-solve and make decisions based on BGL can significantly reduce long term complications (Siriwardena et al., 2012). Formation of these skills is through both lifestyle and knowledge modifications

(Hernandez et al., 2012). Poor knowledge and lack of these skills in patients impact their self-efficacy and motivation toward the adoption of behavioural change. Therefore, patient skills create the pre-condition for confidence (self-efficacy) to engage in healthy behaviours.

Apart from skills, self-monitoring is another mechanism that fosters improved self-efficacy in patients, because it enables individuals to capture their behaviours, recognise patterns and provides the motivation for behavioural change (Hernandez et al., 2012; Steed et al., 2014). Self-monitoring of blood glucose only has been found to be insufficient for behavioural change. However, self-monitoring of all essential behavioural activities including physical activities and diet, is the best behavioural change drivers, because it provides context around why and how blood glucose values come about. An addition of feedback to monitoring of behavioural activities will not only provide guidance around trends or patterns, but also provides awareness and information for corrective actions if required (Annesi, 1998; De Vries et al., 2008).

c. *High attrition and low engagement*

Although the popularity of mHealth has increased in recent times, the utilisation, sustained engagement and adoption of this tool all remain evasive, with evidence of reduced use over time, although patients reported improvement in self-management (Quinn et al., 2011; Kirwan et al., 2013). Given that the use of diabetes apps for self-management is user-driven, these findings suggest that it is imperative that the design of diabetes apps considers how patients interact with the tool in real world settings. The low level of acceptance of mHealth tools has been attributed to insufficient consideration of its usability requirements and preferences by users (Demidowich et al., 2012). Therefore, a critical solution to attrition and low engagement with app use is that of a shared decision-making between app developers and users, entailing needs analysis to confirm what appeals to patients and how to maximize their engagement with apps.

d. None / low educational component in app

Many of the existing diabetes apps lack self-management educational components (Chomutare 2011). With clinical guidelines emphasising the importance of educational support for patients, failure to provide users with this feature puts current apps at the risk of non-effectiveness instead of being a means to facilitate behavioural change and comprehensive self-management. Educational content in apps especially those targeting management skills and confidence, may consequently improve users' level of self-management necessary for improved health outcomes.

Part B: Considerations for the Development of Mobile Phone Apps to Support Diabetes Self-Management: A Systematic Review

2.4 ABSTRACT

There is increased research interest in the use of mobile phone apps to support diabetes management. However, there are divergent views on what constitute the minimum standards for inclusion in the development of mobile phone apps. Mobile phone apps require an evidence-based approach to development which will consequently impact on their effectiveness. Therefore, comprehensive information on developmental considerations could help designers and researchers to develop innovative and effective patient-centered self-management mobile apps for diabetes patients. This systematic review examined the developmental considerations adopted in trials that engaged mobile phone apps for diabetes self-management. A comprehensive search strategy was implemented across 5 electronic databases; Medline, Scopus, Social Science Citation Index, the Cochrane Central Register of Controlled Trials and Cumulative Index of Nursing and Allied Health Literature (CINALHL) and supplemented by reference list from identified studies. Study quality was evaluated using the Joanna Briggs critical appraisal checklist for trials. Information on developmental factors (health behavioural theory, features/functionality, pilot testing, user and clinical expert involvements, data privacy and app security) were assessed across experimental studies using a template developed for the review. A total of 11 studies (10 randomised controlled trials and 1 A quasi-experimental trial) that fitted the inclusion criteria were identified. All the included studies had the functionality for self-monitoring of blood glucose. However, only some of them included functions for data analytics (7/11, 63.6%), education (6/11, 54.5%) and reminder (6/11, 54.5%). There were 5/11 (45.5%) studies with significantly improved glycosylated hemoglobin in the intervention groups where educational functionality was present in the apps used in the 5 trials. Only 1 (1/11, 9.1%) study considered health behavioural theory and user

involvement, while 2 (2/11, 18.1%) other studies reported the involvement of clinical experts in the development of their apps. There were 4 (4/11, 36.4%) studies which referred to data security and privacy considerations during their app development while 7 (7/11, 63.6%) studies provided information on pilot testing of apps before use in the full trial. Overall, none of the studies provided information on all developmental factors assessed in the review. There is a lack of elaborate and detailed information in the literature regarding the factors considered in the development of apps used as interventions for diabetes self-management. Documentation and inclusion of such vital information will foster a transparent and shared decision-making process that will ultimately lead to the development of effective and user-friendly self-management apps that can enhance the health outcomes of diabetes patients.

2.5 BACKGROUND

Mobile apps refer to software installed on smart mobile devices that support medical and public health practices (Kay, Sanjo & Takane, 2011). These applications can deliver healthcare anywhere, subduing geographical and organisational barriers as well as time constraints (Akter & Ray, 2010; Thakkar et al., 2016). Their intended use is for diagnosis, self-management, mitigation, treatment or prevention of diseases such as diabetes (Silva et al., 2015). Self-management of blood glucose minimises the risk and health complications associated with the insidious and chronic nature of diabetes (UK Prospective Diabetes Study Group, 1998; ADVANCE Collaborative Group, 2008). Diabetes self-management (DSM) includes monitoring of glucose level, lifestyle modifications, medication management, prevention of complications and psychosocial care (American Diabetes Association, 2016). As a standard, diabetes self-management education is usually provided during outpatient visits; but it has been advocated that most patients require ongoing support to encourage and sustain behaviour at the level that can maintain good health (Funnell et al., 2009; Haas et al., 2014). Hence, the necessity for a regularly accessible form of diabetes self-management education and support (DSMES); which can be achieved with the use of mobile apps.

Although, mobile app is a field that has continually attracted the interest of researchers and has excellent prospects, both for the improvement of healthcare and economic interest (Free et al., 2013; de la Torre Diez et al., 2015), comprehensive information on its developmental considerations seem somewhat limited. Studies have reported gaps in the understanding of formal standards and evidence-based approaches employed in the development and evaluation of the mobile apps (Buijink, Visser & Marshall, 2013; Misra, Lewis & Aungst, 2013).

Considerations in Mobile Phone App Development

Presently, knowledge about the standard recommended practice for mobile app development for chronic disease management seems divergent and inconclusive. Some studies have reported the benefits of developing mobile app based on health behaviour and communication change theories (Webb et al., 2010; Riley et al., 2011). The main reason for using these theories is to adopt techniques and strategies to help patients embrace healthier lifestyles. Existing models/theories include transtheoretical model (Prochaska & Velicer, 1997), social cognitive theory (Bandura, 2004), self-determination theory (Ryan & Deci, 2000), social ecological theory (Bandura, 2004) and motivational interviewing (Miller & Rollnick, 2013). These theories have served as guards in designing diabetes management interventions.

Some authors are of the opinion that the development of healthcare tools for patient groups such as those with diabetes requires an understanding of current challenges and barriers to self-management (Arsand et al., 2010). This approach serves as an avenue for exploring users' needs at a specific time and envisaging what may evolve with time; which can help in visualising the use of the app as users' demands change (Yardley et al., 2015; Petersen & Hempler, 2017).

Chomutare et al., (2011) emphasised in their systematic review that good practice in designing mobile apps requires that inclusion of functionalities be anchored on evidence-based recommendations for the target groups. Furthermore, pilot testing with a target audience and incorporating feedbacks will aid identification of barriers to the usage of mobile apps and enhance the evaluation of its reliability, accuracy, usability, acceptability, and patient adherence (Thakkar et al., 2016). Ensuring the incorporation of evidence-based recommendations and pilot testing into app development for diabetes care will allow for accurate interfaces, interpretations, and evaluation of the effectiveness of the mobile app.

Data privacy and security whereby the users' information is securely managed is another major developmental consideration (Thakkar et al., 2016; Al-Taee et al., 2016). Emphasising the use of 'privacy by design' approach such as encryption and protocols for anonymous communication and authentication helps to deter unauthorised users from gaining access to patients' medical data (Gürses, Troncoso & Diaz, 2011; van Rest et al., 2014). Furthermore, it has been recommended that involvement of clinical experts and multidisciplinary health teams should be an integral part of the developmental and testing process of diabetes mobile apps to ensure that medical guidelines and clinical best practices are followed in the management of diabetes (Brandell & Ford, 2013).

The various views described above can be labeled as shared decision-making approach to the development of mobile app. Diabetes care and support using this approach in which patients, health care providers, researchers and app developers make health care decision together; taking into account specific evidence as well as specific needs and preferences of patients, has been recommended by various studies. This is seen to produce effective health outcomes (Kinmonth et al., 1998; American Diabetes Association, 2015; Inzucchi et al., 2015). Such an approach focuses on patient empowerment, ensuring a transition from a state where patients are only seen as the recipients of care to a position where they also have their opinion considered, and are allowed to make choices, thereby actively contributing to the decision-making process. Given that the organisational structure within the healthcare sector now recognises the patients' greater role in their healthcare, this trend should also result in a shift in the process involved in the development of mobile apps. Patient engagement strategies in app development may not necessarily refer to their involvement in the algorithm design but rather in the incorporation of procedures that meet patients' expectations through the consideration of their experiences, needs, reasons for engagement and satisfaction with the usage of the app.

Mobile apps have been proven to be a useful lifestyle modification tool for providing ongoing individual support for DSM and facilitating regular monitoring for improved health outcomes (Liang et al., 2011; Holtz & Lauchner, 2012; Nundy et al., 2014; Heinrich, Schaper & de Vries, 2015; Hou et al., 2016; Whitehead & Seaton, 2016). However, previous reviews have focused mainly on assessing the effectiveness of mobile apps to support DSM (Free et al., 2013; Hou et al., 2016; Liang et al., 2011; Whitehead & Seaton, 2016; Cui et al., 2016). A mixture of shared decision-making approaches that include developmental considerations such as health behavioural theories, user and clinical expert involvement, pilot testing and data security are essential. These approaches may help solve the problems of poor engagement experience and ineffectiveness of mobile apps (Yu et al., 2014).

The inclusion of robust, reliable and repeatable system design that involves end users early in the developmental consideration process will enhance ongoing support, which is crucial to sustaining progress made by patients in their DSM (Arsand et al., 2008). To the best of our knowledge, no other study has collated evidence on the factors taken into consideration in the development of such apps. This evidence will further aid the advancement of evidence-based development and evaluation of mobile apps for effective diabetes management.

This systematic review aims to evaluate the factors taken into consideration in the development of mobile phone-based apps used as self-management interventions in experimental trials of adults with diabetes. Also, the review compares these mobile app developmental factors with their impact on the key clinical outcome variable glycosylated hemoglobin (HbA1c). For this study, the developmental factors considered are categorised into the following: (1) Health behavioural change theory, (2) Features/Functionality (comprising documentation, analytics, reminder, and education), (3) Users involvement, (4) Clinical expert involvement, (5) Data security and privacy consideration, and (6) Pilot testing. These factors were considered based on extensive literature search and ingeminate brainstorming sessions among co-authors, with a focus to provide a guide on factors to consider in the development process of mobile app for diabetes self-management precluding the use of such apps in a full trial.

2.6 METHODS

This systematic review was conducted following the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement (Shamseer et al., 2015). Assessed developmental considerations are based solely on author reported descriptions directly available in the selected studies or referenced in another published article. For this review, we defined mobile phone applications as apps that are downloadable to mobile phones and take data inputs from users with a focus on improving one or more aspects of diabetes self-management domains.

2.6.1 Data Sources and Search Strategy

Published literature sources were identified by searching Medline, Cummulative Index to Nursing and Allied Health (CINAHL, EBSCOhost), Scopus, Social Science Citation Index and Cochrane Register of Controlled Trials (CENTRAL) databases. In order for search results to have the maximum possible coverage, the combination of the following terms and medical subject headings (MESH) were used during the search: (‘‘Type 1 diabetes mellitus’’ OR ‘‘Type

2 diabetes mellitus'' OR diabet* OR IDDM OR NIDDM) AND (''Mobile applications'' OR, Smartphone* OR ''app'' OR ''cellular phone'' OR ''mobile app'' OR ''portable electronic applications'' OR ''portable software application'' OR ''text messages''). Searches were done between 5th and 29th September 2017. Searches were supplemented by manual searching of reference lists of identified studies.

2.6.2 Selection Criteria

Selected studies were any randomised controlled trial (RCT), quasi-experimental study, or pre-post study evaluating the use of mobile apps for self-management in patients (≥ 18 years) with type 1 or 2 diabetes. Studies included were those that used mobile phone-based app intervention which allows real-time interaction between patients and the software. Such interactions include input from the user (which may/may not allow for reinforcement of personalised or general advice), goal setting, data analytics, decision support or reminders to improve DSM. Strict inclusion criteria were applied to streamline and capture only diabetes interventional studies. Therefore, to ensure review of fully functional apps used as an intervention for diabetes management, only trials that evaluated at least one glycaemia index of glycosylated hemoglobin ($HbA1_c$) or blood glucose levels as primary outcome were included. Selected studies were those published in the English language but not restricted to patients of any particular race.

Exclusion criteria included: (1) technological interventions not including mobile phone based app, for example systems which require patients to input data into a web-based server for review by clinician or researcher, (2) systematic reviews, meta-analyses, conference papers or letters, (3) pre-diabetes, gestational and secondary diabetes, (4) obesity, (5) software solutions mainly for insulin pumps only, (6) studies on mixed populations of adults and children, and (7) studies still ongoing that presented interim results only.

2.6.3 Data Extraction

The titles and abstracts of all identified references were reviewed by MDA. References that did not meet all of the inclusion criteria were excluded. The full-text article of all relevant references was retrieved and assessed. Data were extracted from each selected studies using an electronic form purposely developed for this review. All authors checked the extracted data for consistency. Discrepancies were resolved through discussion.

2.6.4 Quality Assessment

Assessment of study quality was performed by MDA in consultation with BMA. The quality was evaluated using Joanna Briggs Institute's pre-designed standardised critical appraisal tools (Aromataris et al., 2015). For the RCTs, the following criteria were considered: (1) true randomization of assignments, (2) allocation concealment, (3) blinding of outcome assessors, (4) intention-to-treat analysis, and (5) appropriateness of trial design. Criteria considered for the quasi-experimental trial included (1) clear description of cause and effect, (2) presence of a control group, and (3) pre- and post-intervention outcome measurements were assessed. For all studies, criteria included (1) details of similarity in baseline characteristics, (2) identical treatment for groups with the exception of intervention of interest, (3) degree and description of follow up, (4) similarities in group outcome measurements, (5) reliability of outcome (primary outcome of $HbA1_c$ or blood glucose levels), and (6) suitability of statistical analysis were evaluated. Blinding of participants and personnel were part of the quality criteria in the tools but were omitted and termed non-applicable since the nature of the intervention under study makes it difficult to achieve blinding. All criteria on the tools were scored on a 2 point scale: Yes (1 point) or no or unclear (0 points). When adding all quality criteria, the maximum obtainable scores was 11 for the RCTs and 9 for the quasi-controlled trials. Depending on the number of criteria met by each study, the quality of each study was graded as High ($\geq$7 points), moderate (4-6 points) or low (≤3 points). Disagreement were resolved through discussion among authors.

2.7 RESULTS

2.7.1 Selection of Studies

The initial search from the 5 databases identified 1203 articles which included 116 duplicates that were removed. Based on the review of the titles and abstracts, 53 articles were potentially relevant. The full text of these articles was retrieved for further examination, and their references were manually screened to identify articles that were not included in the original search. This process yielded 4 additional articles. After reading the full articles, 12 studies met the set inclusion criteria. The study by Quinn et al. (2011) and Quinn et al. (2016) reported on the same study population, with different group classifications The study by Rossi et al. (2009) and Rossi et al (2013) engaged the same app but in different study populations. Therefore, 11 RCTs and 1 quasi-experimental study were eventually included. An adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow-chart of study selection is shown in **Figure 2.1**.

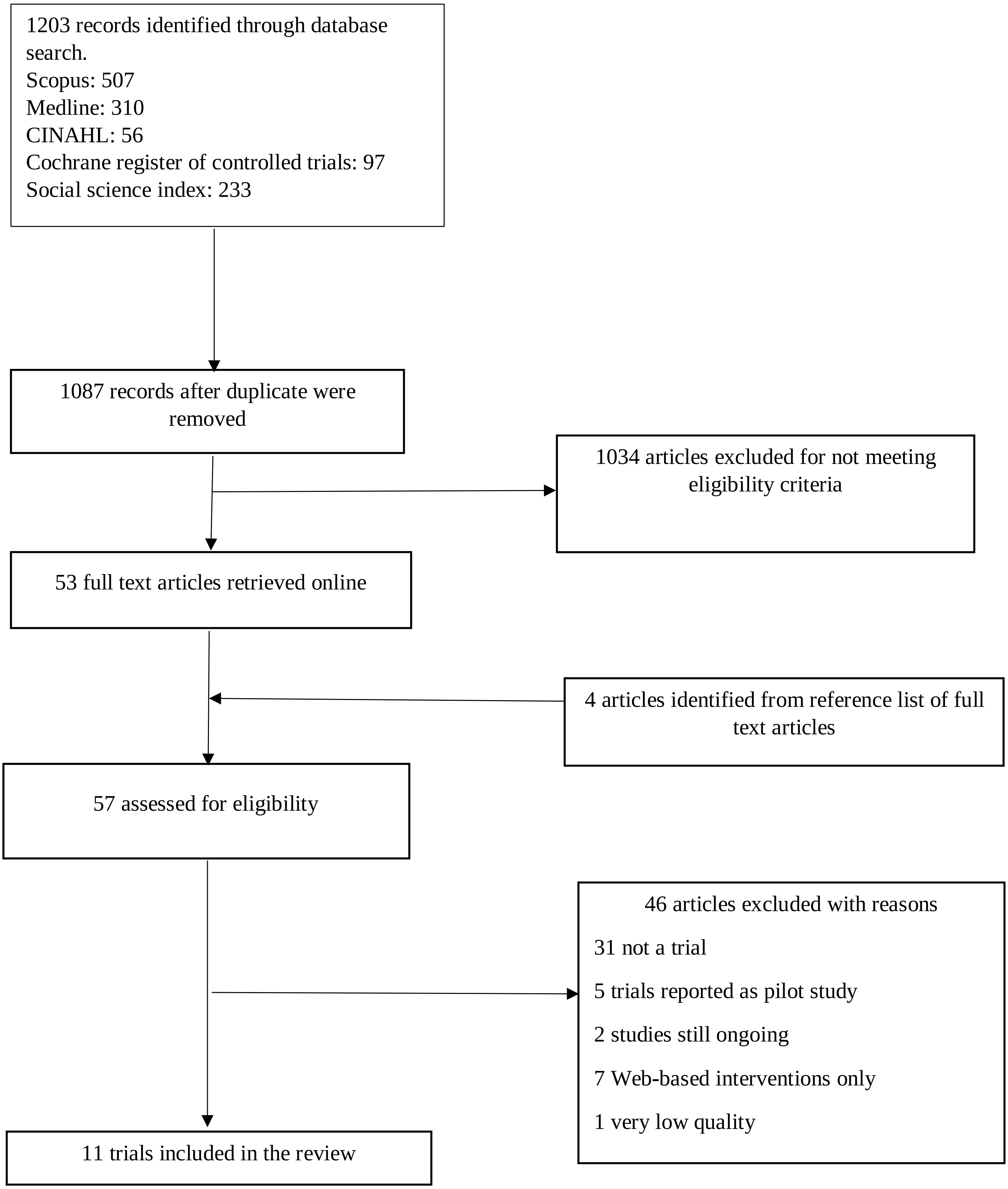


Figure 2.1: Flow diagram of the study selection process

2.7.2 Methodological Quality Assessment

There were 7/12 (58.3.6%) true randomisation trials (Istepanian et al., 2009; Rossi et al., 2010a; Charpentier et al., 2011; Rossi et al., 2013; Kirwan et al., 2013; Orsama et al., 2013; Waki et al., 2014). There were 2/12 (16.7%) trials with unclear evidence for their randomisation method as there was insufficient detail to make a judgment (Quinn et al, 2011; Quin et al., 2016). Allocation concealment was documented in only 1/12 (8.3%) study (Kirwan et al., 2013).

A total of 7/12 (58.3%) studies reported an intention-to-treat analysis of their data (Quinn et al., 2011; Quinn et al., 2016; Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Istepanian et al., 2009; Waki et al., 2014; Holmen et al., 2014). There was 1/12 (8.3%) study that reported the use of a linear mixed methodology, which allowed the inclusion of all randomised participants (Kirwan et al., 2013). A total of 9/12 (75.0%) studies had details of attrition with reasons for drop out balanced across groups (Quinn et al., 2016; Quinn et al., 2011; Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Kirwan et al., 2013; Orsama et al., 2013; Waki et al., 2014; Kim et al., 2014).

All studies had similar and reliable $HbA1_c$ measure. All studies, except 1/12 (8.3%) by Istepanian et al (2009), were judged to be appropriate in their statistical analyses and trial designs. Overall, 10/12 (83.3%) studies were graded as high quality because they met 7-9 criteria of the grading tool, 1/12 (8.3%) study met 6 of the criteria and was graded as moderate (Istepanian et al., 2009), and the last study (1/12, 8.3%) met only 2 quality criteria (Takenga et al., 2014), was graded as poor and removed from the review.

2.7.3 Characteristics of Included Studies

The 11 studies selected evaluated 9 mobile apps and were published between 2009 and 2016. A total of 10/11 (91.1%) studies were RCTs, while 1/11 (9.1%) was a quasi-experimental study (Kim et al., 2014). Participant numbers ranged from 54 (Waki et al., 2014) to 213 (Quinn et al., 2011). There were 4/11 (36.4%) studies which focused on type 1 diabetes (Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Kirwan et al., 2013), 6/11 (54.5%) studies were specific to type 2 diabetes while 1/11 (9.1%) study (Istepanian et al., 2009) involved both type 1 and 2 diabetes patients. Intervention duration for 8/11 (72.7%) studies ranged from 2 to 10 months, while the remaining 3/11 (27.3%) studies (Quinn et al., 2016; Quinn et al., 2011; Holmen et al., 2014) had their follow up period extended to 1 year. Study locations were from four geographic regions including Europe (6/11, 54.5%), Oceania (1/11, 9.1%), Asia (2/11, 18.2%) and America (2/11, 18.2%).

All studies had major interventions using a mobile app. A total of 2/11 (18.2%) studies had 2 intervention groups (Charpentier et al., 2011; Holmen et al., 2014) and another 2 studies had 3 intervention groups (Quinn et al., 2011; Quin et al., 2016). HbA1c was the primary outcome measure in all trials. A total of 5/11 (45.4%) studies reported a positive and statistically significant improvement in HbA1c in the intervention group (Quinn et al., 2011; Charpentier et al., 2011; Kirwan et al., 2013; Orsama et al., 2013; Waki et al., 2014). A total of 5/11 (45.4%) studies had $HbA1_c$ reduction in both the intervention and control groups (Quinn et al., 2016; Rossi et al., 2010a; Rossi et al., 2013; Holmen et al., 2014; Kim et al., 2014). While in 1/11 (9.1%) study, HbA1c remained unchanged between the intervention and control groups (Istepanian et al., 2009). A summary of these characteristics are shown in **Table 2.1**

Table 2.2 Study participants, methodological characteristics and quality (arranged from highest to lowest)

Author (s), Year	Study Design, Location, Type of diabetes, Total number of participants (N), Duration (in months), Attrition rate	Stated aim	Number of intervention group and details	Summary of HbA1c result	Scores/ Quality
Kirwan, 2013	RCT; *Australia*; Type 1 DM; N = 72; Duration = 6; Attrition = 19 (26.3%)	To examine the effectiveness of a freely available smartphone app combined with text message feedback from a certified diabetes educator to improve glycaemic control and other diabetes related outcomes in adults with type 1 diabetes	1 intervention group who received: (i) a freely available mobile app that allows users to manually enter BG levels, insulin dosages, other medications, diet and physical activities. (ii) One personalised SMS per week. ***Comparator***: Usual care	Significant HbA1c improvement in the intervention group [from mean 9.8% (SD 1.18%) to mean 7.8% (SD 0.75%)] compared to control [from mean 8.47% (0.86%) to mean 8.55 (SD 1.16)] after 9 month follow up. (*p*=.001)	10/ High
Rossi, 2013	Parallel group RCT; *Italy*; Type 1; *N* = 127; *Duration:* 6 months; *Attrition*: 15 (11.8%)	To compare the efficacy of the diabetes interactive diary versus usual care on metabolic control, hypoglycaemia and quality of life	1 intervention group who received: (i) a mobile app and attended a course on the usage. App was used to estimate CHO content in meals and prandial insulin doses were adjusted based on app algorithm. (ii) Education on hypoglycaemia (iii) BG meter	Non-statistically HbA1c reduction in both groups. Intervention [decrease of mean 0.41(SD 0.11)] and control [decrease of mean 0.48 (SD 0.11) (*p*=.73)	9/ High

Kim, 2014	Quasi experimental; *Korea*; *Type of DM:* Type 1; *N = 73*; *Duration*: 3 months; *Attrition:* 3(4.1%)	To assess the efficacy of the smartphone-based health app for glucose control and patient satisfaction with the mobile network system used for glucose self-monitoring	1 intervention group who received: (i) a mobile app to log BG data, which were automatically sent to the medical team for analysis to provide recommendations at least once a week. (ii) in the events of hypoglycaemia in participants or failure to record BG measurements, the medical team called such participant to change insulin dose or recommend an early visit to the hospital. ***Comparator***: Usual care	Non-significant improvement in HbA1c in the intervention group [from mean 7.7% (SD 0.7%) to mean 7.5% (SD 0.7%) (*p*=.077) and the control groups [from mean 7.7% (SD 0.5%) to mean 7.7% (SD 0.7%)] (*p*=.093)	9/ High
Charpentier, 2011	Parallel group RCT; *France*; Type 1; N = 180; Duration: 6 months; *Attrition*: 7 (3.9%)	To evaluate the efficacy of mobile app in improving metabolic control in poorly controlled patients with type 1 diabetes	2 intervention groups. (A). Both groups were provided with smartphone loaded with app, which can provide (a). bolus insulin dose based on logged, pre-meal BG, CHO, premeal BG and anticipated physical activity. (b). Plasma glucose targets. (c). Algorithm for the adjustment of CHO ratio and basal inulin doses. (B) Group 1 had a quarterly hospital visit. (c). Group 2 received teleconsultation every 2 weeks and a follow-up visit after 6-month. ***Comparator:*** Usual care plus the use of paper log book and attendance of two follow-up hospital visits.	The intervention group 1 (app only) had 0.67% improvement in HbA1c over the control group (*p*=.002) while the intervention group 2(app + teleconsultation) has a significant 0.91% improvement in $HbA1_c$ over the control group. (*p*=.002)	9/ High

Rossi, 2010[a]	Parallel group RCT; *Italy, England and Spain*; Type 1; *N* = 130; *Duration* = 6 months; *Attrition* = 11(8.5%)	To evaluate whether the use of mobile software intervention could be effective in improving metabolic control in type 1DM, while avoiding weight gain and reducing time devoted to education. Also, to investigate to what extent the mobile software could affect quality of life	1 intervention group who received: (i) a mobile app to log BG data and insulin dose. (ii) With logged information on physical activity, glycaemic target and specific events, the app can calculate and suggest most appropriate insulin dose and daily CHO intake. ***Comparator***: Usual care	Similar 0.5% reduction in HbA1c in both groups [Intervention: from mean 8.2% (SD 0.8%) to mean 7.8% (0.8) to mean 7.8% (SD 0.8) and control: from mean 8.4% (SD 0.7%) to mean 7.9% (SD 1.1)]. *p*=.68	9 / High
Waki, 2014	Parallel group RCT; *Tokyo*; Type 2; *N* = 54; *Duration* = 3 months; Attrition = 5 (9.3%)	To access the usability of a remote health monitoring system and especially its impact on modifying patients lifestyle and clinical outcomes	1 intervention group who received: (1) A smart phone with app. (ii) Glucometer, Bluetooth-enabled BP monitor, pedometer and scale. All devices were paired with a unique communicator that transmit the measured data through wireless network to a mobile app server. ***Comparator***: Usual care	Intervention group had significant improvement (0.4%) in HbA1c [from mean 7.1 (SD 1.0%) to mean 6.7 (SD 0.7%)] compared to 0.1% increase in HbA1c in the control group [Mean 7.0% (SD 0.9) to mean 7.19% (SD 1.1%)] (*p*=.019).	8 / High
Holmen, 2014	3 arms prospective RCT; *Norway*; Type 2; *N* =151; *Duration* = 12 months; *Attrition* = 31(21%)	To test whether the use of mobile phone based self-management system used for 1 year with or without health counselling by a diabetes specialist nurse for the first 4 months could improve HbA1[c], self-management and health-related quality of life with usual care	2 intervention groups. (A). One group received a mobile phone app only. (b) The other received an app plus health counselling via telephone by a diabetes nurse. ***Comparator:*** Usual care	HbA1c decreased in all three groups but no difference between groups. No specific data was reported	8 / High

Orsama, 2013	Parallel group RCT; *Finland;* Type 2; *N*=56; *Duration* =10 months; *Attrition* = 8 (14.3%)	This research involve the development and evaluation of a mobile telephone based remote patient reporting and automated telephone feedback system, guided by health behaviour change theory, aimed at improving self-management and health status in individuals with type 2 DM.	1 intervention group who received: (i) a mobile app for reporting BP, weight and physical activities. In specific cases BG meters was provided to those with high HbA1c values. (ii) Measuring device for BP, weight and physical activity (pedometer). (iii) Automatically generated health promotion information, motivation and behavioural skills feedback messages linked to patient remote self-reported health parameters. (iv) Participants had access to personal health records such a medication, laboratory data and personal care plan. ***Comparator***: Usual care	A significant 0.4% improvement in mean HbA1c in the intervention group [from -0.67% to -0.14% compared to 0.036% in the control group [from -0.23% to 0.30%] (*p*=0.03).	8 / High
Quinn, 2016	Cluster group RCT; *USA; Type 2*; *N* =118; *Duration* = 12 months; *Attrition* = Not reported; this was a subset analysis of Quinn 2011	To determine if there were differences in the impact of mobile intervention in younger adults (<55 years old) versus older adults (≥55 years) within the below 64 years old patient population. We were interested in understanding if there were difference for the cohort nearing 65 years old.	1 intervention group (with older and younger subgroup) who received: (i) a mobile app and HCP decision support. App allowed participants to log BG, CHO and medications. (ii) Automated real time education, behavioural and motivational messages in response to logged data. (iii) Logged data were intermittently reviewed by a diabetes educator with whom patients are allowed to have telephone conversation. (iv). Web portal to receive supplemental messages, access personal health records and communicate with HCP. (v) A mobile phone, 1 year unlimited data / service plan and the study app. (vi)Received electronic action plan on diabetes management every 2.5 month and pre-visit summary for physician office visit: ***Comparator***: Usual care	Decreased mean HbA1c in both groups. The intervention arm [older and younger patients] had HbA1c decline of 1.8% and 0.2% respectively while the control group [older and younger patients had HbA1c decline of 0.3% and 0.1% respectively]. (*p*=.0001)	7 / High

Quinn, 2011	Cluster RCT; *USA*; Type 2; N = 213; *Duration:* 12 months; *Attrition:* 50 (23.4%)	To test whether adding mobile app coaching and patient/provider Web portals to community primary care compared with standard diabetes management would reduce $HbA1_c$ in patients with type 2 diabetes	3 intervention groups: (A). Who all received: (i) a mobile phone, app, BG meter, one-year unlimited mobile phone data/service plan and web based portal. App allowed participants to enter BG, CHO consumed and medications. (ii) In response to logged data, participants received automated real time educational, behavioural and motivational messages. (iii) Received text messages on their portals as a supplement to automated messages. (iv) Feedbacks summaries of entered data and self-management action plan every 2.5 months, which also serves as pre-visit summary for patient's next visit to HCP. (B). In addition to the above; group 2 HCPs have access to a portal if they choose to review patients unanalysed data. (C). Group 3 HCPs have access to review patients analysed data on the web portal. ***Comparator****:* Usual care	Mean HbA1c decline in maximal treatment group of 1.9% and 0.7% mean HbA1c decline in the maximal intervention and control groups respectively. Significant HbA1c improvement was observed between the maximal intervention and control group only (*p*=.001). No significant changes between other groups	7 / High
Istepanian, 2009	Parallel group RCT; *London*; Type 1&2; *N* = 137; *Duration* = 9 months; *Attrition* = 50 (36.5%)	To evaluate m-health system against usual care	1 intervention group who received: (i) a mobile phone app (ii) 2 hours education on general diabetes care and self-BG monitoring (iii) BG meter. ***Comparator***: Usual care and received 2 hours education on general diabetes care and self-BG monitoring	There were no differences in mean HbA1c between the intervention and control groups: 7.9% and 8.2% respectively (*p*=.17).	6 / Moderate

BP: Blood pressure; BG: Blood glucose; CHO: carbohydrate; HbA1c: Glycosylated hemoglobin; HCP: Health Care Providers; RCT: randomised controlled trial

Details of the developmental factors considered in each of the reviewed studies and the resulting key clinical outcome ($HbA1_c$) are available in **Appendix 2.1** and **Appendix 2.2**.

Health Behavioral Theories: Only 1/11 (9.1%) study (Orsama et al., 2013) reported on health behavioural theories. Specifically, motivation behavioural skills model was used for the formulation of an automated personalised feedback message content of the mobile app.

Functions of mobile apps: It was apparent from the review that features of the mobile apps were diverse. However, documentation for self-monitoring of blood glucose (BG) either manually or through wireless transmission from BG meter was present in all studies. A total of 8/11 (72.2%) studies had mobile apps with capacity for diet management (Quinn et al, 2011; Quin et al., 2016; Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Kirwan et al., 2013; Waki et al., 2014; Holmen et al., 2014). Three studies incorporated blood pressure features in their mobile apps (Orsama et al., 2013; Waki et al., 2014; Kim et al., 2014). There were 7/11 (63.6%) studies which had a physical activity feature (Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Kirwan et al., 2013; Orsama et al., 2013; Waki et al., 2014; Kim et al., 2014) and 2/11 (18.2%) studies incorporated weight tracking feature (Orsama et al., 2013; Waki et al., 2014). There were specific features to log or calculate insulin dosages in mobile apps employed in the 4/11 (36.3%) studies with type 1 diabetes participants (Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011; Kirwan et al., 2013). A total of 2/11 (18.2%) studies reported a general medication log feature in their mobile apps (Quinn et al., 201l, Quinn et al., 2016).

With the exception of 4/11 (36.4%) studies, all others (7/11, 63.6%) had capacity for mobile apps to allow patients to analyse logged data. These 4 studies had their logged data transferred to a web/cloud storage and analysed by either the researcher or the health provider (Quinn et al., 2016; Quinn et al., 2011; Istepanian et al., 2009; Kim et al., 2014).

There were 6/11 (54.5%) studies that utilised mobile apps with an educational function. Half 3/6 (50.0%) of the studies provided education as a personalised real-time automated educational feedback specific to logged data (Quinn et al., 2011, Quinn et al., 2015; Orsama et al., 2013), while the other 3 provided a general information page (Rossi et al., 2010; Rossi et al., 2013; Holmen et al., 2014).

A total of 6/11 (54.5%) studies utilised a mobile app with reminder/alert function (Rossi et al., 2010a; Rossi et al., 2013; Istepanian et al., 2009; Kirwan et al., 2013; Orsama et al., 2013; Holmen et al., 2014).

Users' Involvement: There was only 1/11 (9.1%) study (Holmen et al., 2014) that clearly described users' involvement in the design of its mobile app. It reported an iterative design process involving 12-15 diabetes patients using the approach of focus group meetings, semi-structured interviews, usability testing, questionnaires and paper prototyping. This approach generated the design requirements and answers to research questions (Arsand et al., 2010).

Clinical Expert Involvement: There were 2/11 (18.2%) studies (Quinn et al., 2011; Quinn et al., 2016) which used the same mobile app and engaged the opinions of clinical experts in the field of diabetes during its development and design. The studies reported that the mobile app development involved an Endocrinologist and a Credentialed Diabetes Educator (Quinn et al., 2008).

Data Security and Privacy Considerations: Report on data security and privacy varied among the studies with limited elucidation of information in most cases. In 2/11 (18.2%) studies (Quinn et al., 2011, Quinn et al., 2016) the authors reported a real time capturing of self-monitored blood glucose data into a Health Insurance Portability and Accountability Act-compliant secured Web-based system (Quinn et al., 2008). In 1/11 (9.1%) study, measured data from participants were transmitted to a server. With each new measurement, the patient profile was updated allowing controlled access to patients' data and record history (Waki et al., 2014). Transfer of mobile app data into a secured central server was the only information provided by Charpentier et al., (2011).

Pilot Testing of Mobile Apps: A total of 7/11 (63.6%) studies provided information with regards to pilot testing. Of these, 2/11 (18.2%) (Quinn et al., 2011; Quinn et al., 2016) reported three months test running of the mobile app on 30 patients with type 2 diabetes with the aim of evaluating the impact on $HbA1_c$ and satisfaction of patients with the technology (Quinn et al., 2008). Likewise, 1/11 (9.1%) study (Charpentier et al., 2011) reported a 4-month open label observational pilot study on 35 type 1 diabetic patients with the aim of confirming if the use of the mobile app resulted in good control of post prandial blood glucose readings (Franc et al., 2009). Only 1/11 (9.1%) study (Waki et al., 2014) reported a one-month piloting on 11 type 2 diabetes patients to assess usability and impact of the mobile app on $HbA1_c$ outcomes and home blood pressure monitoring (Waki et al., 2012). In 2/11 (18.1%) studies (Rossi et al, 2010a; Rossi et al., 2013), 2 pilot programs were reported through a citation in another article. The first was with the use of a questionnaire to assess the feasibility and acceptability of the mobile app. The second was a 9-months follow up of 41 patients using the mobile app under routine clinical practice condition with the aim of investigating its effectiveness on metabolic control (Rossi et al., 2009). Lastly, 1/11 (9.1%) study (Holmen et al., 2014) reported a 12-month pilot testing on 12 persons with type 2 diabetes (Arsand et al., 2010).

2.8 DISCUSSION

Theoretical basis

Our review shows that most of the studies did not discuss consideration for health behaviour theories in their mobile app development. The lack of report on theoretical basis may be as a result of reliance on evidence-based guidelines that relates to the essential self-management activities in people with diabetes to predict good outcomes American Diabetes Association, 2008). While it is necessary for mobile apps to be guided by health behavioural theories, the current theories appear incapable of answering most of the questions likely to arise when mobile apps are employed as health interventions (Riley et al., 2011). Dunton and Atienza (2009) reported that current health behaviour theories have not been able to incorporate within-person differences, which allow for intra-individual tailoring of interventions. Borsboom and co-authors (2003) noted that between people theories do not imply, test or support causal factors valid at the individual level. Therefore, there is a need for more research into intra-individual non-static regulatory models, which can be incorporated in the development of mobile technology-based health behavioural interventions.

Functionalities of mobile apps

All the 11 trials reviewed in this study included mobile apps with documentation/monitoring component, where self-documentation of blood glucose readings was the most common. Only 3 studies used mobile apps that offer automated direct data transfer of blood glucose values from the glucometer or data from other measuring devices (Istepanian et al., 2009; Waki et al., 2014; Kim et al., 2014). This corroborates the report by Demidowich et al., (2012) where only four of the 42 mobile apps studied offered direct data input from glucometer. Data entry is often perceived as a persistent burden in chronic disease management (Arsand et al., 2008). Therefore, it is imperative that data entry in mobile apps be as spontaneous as possible, requiring little time and effort to use (Jensen & Larsen, 2007). Mobile App developers should prospectively consider including an interface between the app and biomarker measuring devices, which allow users to automatically log measurements. Such interface may include Bluetooth, which enables portable electronic devices to connect and communicate wirelessly (Haartsen, 2017). The success of using this interface was demonstrated in the studies by Waki et al., (2014) and Holmen et al., (2014).

Data analytics as an app feature was included in only 7/11 (63.3%) studies. A consumer-directed software such as mobile app is better incorporated with functions that enable users to enter, analyse their health parameters and view graph trends and statistics. This can improve the patient's ability to observe the impact of their lifestyle and behaviour on health indicators, access trends and even predict health outcome measures (Winters-Miner, 2014). Additionally, decision-making and problem-solving skills of patients can be improved when mobile apps include visualisation techniques such as colour-coded charts or graphs, which indicate when biomarkers, food carbohydrate component and physical activity are out of recommended range (Breland, Yeh & Yu, 2013). It is essential that analytic functions be dynamic, easily accessible and able to project trends to predict individual improvement in self-care activities, which may invariably lead to better health outcomes (Preuveneers & Berbers, 2008; Li & Fernando, 2016).

Despite the emphasis by published guidelines for the need for ongoing patient education (American Diabetes Association, 2016), very few studies used mobile apps that have education as a functionality. This finding is corroborated by another review where the authors confirmed personalised education as an underrepresented feature in diabetes mobile apps (Chomutare et al., 2011). Patients may have difficulty consulting with their diabetes educators or other health care professionals, due to lack of time, financial constraints, and other limitations. Hence, an app with an educational component can supplement healthcare provider diabetes education and reinforce information about the importance of self-management and complication prevention. This can serve as an avenue for continual patient empowerment to successfully deal with the disease. However, it is essential that the personalised educational feedback and advice provided in mobile apps are accurate. This is especially true for those that are automatically generated because monitoring mobile apps pose serious harm to the patients if they fail to function as intended (Barton, 2012).

A total of 6/11 (54.5%) studies reported using mobile apps with reminder function either in the form of prompting to measure missed blood glucose readings or alerts for appointments scheduled for the assessment of complication Quinn et al., 2011, Quinn et al. 2016; Istepanian et al., 2009; Kirwan et al., 2013; Waki et al., 2014; Holmen et al., 2014). They are sometimes referred to as 'push technology'; which enables messages to be delivered without any effort on the part of the recipient (Klasnja & Pratt, 2012). Such reminders can be in the form of text message, alarm, email, automated voice call or image message. Other review has illustrated the benefits of an alarm reminding patients to carry out their health activities (Benferdia & Zakaria, 2014). Another study revealed improvement in treatment adherence as patients get fascinated using reminders to handle their healthcare activities (Wohlers et al., 2009).

Users' involvement

Similar to an earlier review by El-Gayar et al., (2013) on the adoption of user-centered design principles in mobile apps, only one study (Holmen et al., 2014) documented inquiry into users' expectations and perceived needs in the app developmental phase. Users' involvement in design process increases the success rate of computerised system usability (Abras et al., 2004), as it is essential to understand the reasons for use and user requirements (Bevan, 2009; Goldberg et al., 2011). In contrast, a design process lacking the involvement of users in the design loop will fail to recognise the particular odds and problems in the use of the intervention (Höök, 2004). Design processes can use research tools such as questionnaires, focus group discussions and personal interviews. These help to seek users' requirements, preferences, understand current challenges and barriers to self-management and subsequently incorporate the findings into the design process. Incorporation of feedback during app design process can help in producing a more user-friendly application and encourage long-term user engagement.

Clinical experts' involvement

Many of the apps reported in the studies reviewed were designed without the involvement of healthcare professionals, and this observation is supported by an earlier review (Arnhold, Quade & Kirch 2014). Involvement of health professionals in diabetes mobile app development can assure the quality of health information and support provided by such apps (Boulos et al., 2014). This is especially important in mobile apps involving advice on insulin dosing. It has to be mentioned that the 3/11 (27.2%) studies in this review which used mobile apps to assist participants in calculating insulin dosage failed to report whether clinical experts were involved in the development of these apps, even though $HbA1_c$ levels in the intervention groups were not significantly lowered compared to the control groups (Rossi et al., 2010a; Rossi et al., 2013; Charpentier et al., 2011). This finding highlights possible issues with the effectiveness, efficiency, and relevance of these mobile apps to users' health security. Insulin overdose in people with diabetes can result to severe hypoglycemia and coma while under-dose can cause diabetes ketoacidosis; both can have fatal consequences (Seaquist et al., 2013; Wolfsdorf et al., 2013). Participation of health professionals in the development of diabetes mobile apps may decrease the likelihood of such fatal occurrences and protect consumers from incorrect and misleading information. Furthermore, clinical expert involvement in diabetes mobile app development will foster avoidance of legal implications surrounding noncompliance to regulatory and medical standards that relate to digital health services especially those which empower people to track, manage and make decisions about their health (United State Department of Health and Human Services, 2000; Australian Government, Federal Register of Legislation, 2016).

Data security and privacy

Information on data security and privacy considerations in mobile app development were lacking in many of the trials in this review. Late consideration of privacy and security are app developers' errors that cannot be underestimated. Medical data breaches resulting from failed security attract huge financial implications (such as costs associated with a pecuniary penalty, potential liability claim, lost brand value, responding to lawsuits, negative press statements and essentially loss of patients' and health care providers' trust) for non-compliant organisations (United State Department of Health and Human Services, 2000; Australian Government Federal Register of Legislation, 2016). Studies have revealed that some users are concerned about the privacy of their personal health information stored on an electronic device (Chhanabhai & Holt, 2007; Zurita, Nohr & Medinfo, 2004). Procedures to maintain health data privacy and security to avoid data breaches must, therefore, be considered during mobile app design. Encrypted storage, which ensures logged data are protected against malicious attack is a security approach to protecting health data on mobile apps (Kumar & Lee, 2012). Furthermore, the privacy of users' information can be ensured through user authentication or enforcement of password requirements (Kumar & Lee, 2012), and this can protect users' health data in case of mobile phone loss.

Pilot testing

There were 5/11 (45.5%) studies that failed to report on pilot testing of their apps before use in the trial. A previous study also reported that most health apps do not offer patients ample opportunity for feedback on the level of satisfaction and usability of the product (Arsand et al., 2012). The importance of pilot testing mobile apps cannot be overemphasised. Apart from serving as an avenue for testing the impact of the app on behavioural outcome or glycemic control, pilot testing can assess its user-friendly capacity and adherence for use as a self-management tool.

Developmental factors considered in mobile apps and the key clinical outcome (Glycosylated Hemoglobin)

Appendix 2.1 and **Appendix 2.2** show an overall evaluation of the developmental factors considered in the design of the mobile apps used in the reviewed studies and the resulting clinical outcome (ie, glycosylated hemoglobin-$HbA1_c$). **Appendix 2.2** highlighted 5/11(45.5%) studies that had intervention groups with significantly improved HbA1c. A comparison of these 5 studies showed that educational functionality was present in all. For example, 3/5 (60.0%) studies provided the educational information directly through the mobile app (Quinn et al., 2011; Orsama et al., 2013; Waki et al.,2014) while 2/5 (40%) provided additional text messaging or teleconsultation (Charpentier et al, 2011; Kirwan et al., 2013). It is likely that the similar outcomes observed in these studies were partly due to similitude in the provision of self-management education to participants, as digital tools with decision support features such as education have been proven to have the capacity to enhance self-management outcomes (Greenwood et al., 2017). This finding demonstrates the importance of consistent and ongoing provision of self-management education to people with diabetes. Diabetes education and diabetes management are inseparable because every patient would benefit from education in self-management. Therefore, in addition to other essential functionalities in mobile apps that support diabetes care, the inclusion of education functionality will provide the recommended ongoing support to promote the importance of self-management, build patient skills and confidence for behavioural change, increase motivation for self-management and ultimately improve glycemic control (Powers et al., 2015a; d Brunisholz et al., 2014).

Furthermore, 3/5 (60%) studies with significant improvement in $HbA1_c$ reported on pilot testing of their mobile apps before use in the full trial (Quinn et al., 2011; Charpentier et al., 2011; Waki et al., 2012). It is possible that excellent efficacy observed in these studies was due to pilot testing. Among other reasons, an essential aim of pilot testing a technology is to establish its usability. Usability testing of a mobile app examines end users' satisfaction and has been identified as one of the factors that determine its efficacy and success of users' engagement with it (Hornbak & Law, 2007).

Implications for practice and future research

Much work is needed to address challenges limiting the documentation and the implementation of developmental factors in the design of mobile apps for diabetes management. The use of mobile phone interventions in which the developmental design are not explicitly documented is likely to result in a non-replicable app with significant levels of wasted resources. Therefore, future work is required to promote the development of evidence-based apps research and clinical use. These mobile apps should focus on integrating functions to core diabetes self-management practices and primarily with the provision of self-management education. Additionally, integrating theories of health behavioural change, users, and clinical experts' involvement while ensuring data privacy and security are essential factors to be considered in the development of future mobile apps.

Limitations of this review

There are limitations to be considered when interpreting and extrapolating the findings of this systematic review. The results of this review were dependent on the terms used in the search strategy and the efficiency of the search engines used. An attempt to overcome this limitation was ensured by choosing common terms and combination of terms usually used in the literature review on mobile health applications. This review considered only trials that were reported in the English language with strict inclusion criteria and so the number of articles that met the study criteria was small, and this limits the ability to generalise the findings. Also, the process of extracting the data presented some risk of error and uncertainty because some studies were not explicit about their developmental considerations, and it is easy to miss or misunderstand some development description either reported directly within the article or referenced.

However, to avoid this occurrence, the authors ensured that the assessment process involved independent verification and all pitfalls that might invalidate the findings were avoided. Despite these limitations, this review provides valuable information to future researchers and developers of mobile apps for DSM on the necessary factors to consider during app development.

2.9 CONCLUSION

This systematic review has presented the crucial steps that need to be taken in mobile app development to support effective self-management for people with diabetes. Most of the studies in this review offer a limited and non-expository degree of information on the factors considered in the development of the apps employed.

The main stakeholder in diabetes management is the patient. Shared decision-making between diabetes patients, researchers, health-care professionals, and app developers can result in improved management. Therefore, this should be the basis for the development of mobile apps for diabetes support. Shared decision-making can be achieved through the process of patient and clinical expert involvement, ensuring data security and privacy, pilot testing and integration of core functions that support all aspects of the activities as indicated by evidence-based guidelines. Continual integration of these processes during app development (before actual use in clinical trials) will ensure that specific needs of diabetic patients are met in the finally developed app, and this will ultimately improve diabetes support, self-management and clinical outcomes for the patients.

Overall, the systematic review in this chapter addressed the first aim of the thesis by providing a framework/guideline on the essential elements required in a diabetes app development process prior to use as an intervention for self-management by type 1 or type 2 diabetes patients. These findings highlight the need for primary studies that explore health behavioural change mediators for self-management, diabetes patients' educational needs, app feature preferences and opinions on how to improve ongoing engagement with apps. These were addressed in Chapter 3 and 4.

Chapter THREE: Enablers and Barriers to Effective Diabetes Self-Management: A Multi-national Investigation

3.1 ABSTRACT

The study aimed to identify the common gaps in skills and self-efficacy for diabetes self-management and explore other factors, which serve as enablers of, and barriers to, achieving optimal diabetes self-management. The information gathered could provide health professionals with valuable insights to achieving better health outcomes with self-management education and support for diabetes patients. International online survey and telephone interviews were conducted on adults who have type 1 or type 2 diabetes. The survey inquired about their skills and self-efficacy in diabetes self-management, while the interviews assessed other enablers of, and barriers to, diabetes self-management. Surveys were analysed using descriptive and inferential statistics. Interviews were analysed using inductive thematic analysis. Survey participants (N=217) had type 1 diabetes (38.2%) or type 2 diabetes (61.8%), with a mean age of 44.56 SD 11.51 and were from 4 continents (Europe, Australia, Asia, America). Identified gaps in diabetes self-management skills included the ability to: recognise and manage the impact of stress on diabetes, exercise planning to avoid hypoglycemia and interpreting blood glucose pattern levels. Self-efficacy for healthy coping with stress and adjusting medications or food intake to reach ideal blood glucose levels were minimal. Sixteen participants were interviewed. Common enablers of diabetes self-management included: (i) the will to prevent the development of diabetes complications and (ii) the use of technological devices. Issues regarding: (i) frustration due to dynamic and chronic nature of diabetes (ii) financial constraints (iii) unrealistic expectations and (iv) work and environment-related factors limited patients' effective self-management of diabetes. Educational reinforcement using technological devices such as mobile application has been highlighted as an enabler of diabetes self-management and it could be employed as an intervention to alleviate identified gaps in

diabetes self-management. Furthermore, improved approaches that address financial burden, work and environment-related factors as well as diabetes distress are essential for enhancing diabetes self-management.

3.2 BACKGROUND

Diabetes mellitus is a major public health problem with rapidly increasing prevalence. In 2017, the global prevalence of diabetes among people aged 20-79 years was 425 million, mainly comprising type 1 or type 2 (International Diabetes Federation, 2017). Diabetes is one of the top 10 global causes of mortality. In 2015, it was responsible for 1.6 million deaths, indicating a 60% increase in 15 years from less than 1 million in 2000 (World Health Organisation, 2018). International audits have found that regimen adherence is less than optimal in both types 1 and 2 diabetes patients (Peyrot et al., 2005). As a consequence, the majority of these patients are at risk of serious health complications that endanger life (International Diabetes Federation, 2017; Papatheodorou et al., 2015) and impose great economic burden on affected individuals and the health care system (International Diabetes Federation, 2017).

Consistent engagement in diabetes self-management (DSM) has been found to be correlated with the attainment of health outcomes. These are in relation to good blood glucose control, fewer complications (International Diabetes Federation, 2017;Viswanathan et al., 2005) improved quality of life (Povey & Clark-Carter, 2007; Chen et al., 2015) and reduction in diabetes-related death risks (UK Prospective Diabetes Study Group, 1998). The term "self-management" refers to day to day activities or actions an individual must undertake to control or reduce the impact of disease on their health and wellbeing (Clark et al., 1991) in order to prevent further illness (Barlow et al., 2002). DSM actions involve engagement in recommended behavioural activities such as healthy eating, medication adherence, being active, monitoring, reducing risks, problem-solving and healthy coping, which are all necessary for the successful management of the disease (Tomky et al., 2008). Level of adherence to DSM differs in patients, which implies that decision-making processes for self-management are influenced by various factors, which could serve either as enablers or barriers.

Enablers of Self-Management

Enablers of self-management are mechanisms or factors that foster the ability of patients to undertake their recommended self-management regimen. Such factors are diverse and they include effective social support with assistance and encouragement from family members (Maillet et al., 1996; Chlebowy et al., 2010) or peers who have diabetes or close relative familiar with its management (Fisher et al., 2012). Likewise, individual resolution to prevent or reduce the risk of developing diabetes complications (Maillet et al., 1996; Cagle et al., 2002) helps with the determination to engage in self-management. Studies have also noted positive decision making about DSM as a result of effective health care provider-patient communication (Nagelkerk, Reick & Meengs, 2006), characterised by trust, respect and shared decision-making in planning health goals (Paterson & Thorne, 2000; Cooper, Booth & Gill, 2003). In addition, patient support with the use of health technological interventions such as mobile phone applications (Hunt et al., 2015) and self-management education (Atak, Gurkan & Kose, 2008; Haas et al., 2012) facilitate efective diabetes management. Individual factors, particularly higher educational level (Chlebowy, Hood & Lajoie, 2013; Al-Rasheedi, 2014) and gender (Carter, 1998) also contribute to patients' ability to care for their diabetes.

More importantly, adequate self-management skills (Persell et al., 2004) and self-efficacy (confidence) (Aljasem et al., 2001) to perform these skills are major enabling factors for engagement in DSM. This is because skills and self-efficacy operate in tandem to foster full engagement with self-management. Self-management skills result from knowledge about the disease (Persell et al., 2004), and understanding the interrelationships between different self-management activities and their impact on health outcomes (Herschbach et al., 1997). On the other hand, self-efficacy refers to ‘‘one’s belief in his/her own innate ability to perform specific tasks required to reach a desired goal’’ (Bandura, 1999). Unless people believe they can produce desired effects by their action, they have little incentive to act (Bandura, 1998), regardless of other enabling factors which may be available to them. In diabetes management, patients’ level of self-efficacy is influenced by their level of skills for self-management. Hence, patients with adequate skills and efficacy have more likelihood to adhere to prescribed behavioural regimen necessary to attain optimal health (Persell et al., 2004; Morowati-Sharifabad et al., 2007; Johnston-Brooks, Lewis & Grag, 2002; Aronson et al., 2018). Acquiring skills and efficacy for DSM are ongoing learning processes (Persell et al., 2004; Haas et al., 2012). While some skills and efficacy are easily acquired, others are often difficult to attain. Further research is therefore needed to adequately identify gaps in diabetes patients’ skills set and self-efficacy levels for self-management of their health issues. Information on identified gaps will guide health care providers in their development of educational support programs that foster self-management among diabetes patients.

Barriers to Self-Management

Non-adherence to recommended DSM regimen is influenced by barriers encountered by patients. These barriers make managing the disease more difficult. Only few studies have examined patients’ perceived barriers to general DSM from a global perspective. An international study identified diabetes related distress as a major factor responsible for poor adherence to self-management in patients (Peyrot et al., 2005). Local studies reported that difficulty in making lifestyle changes (Byers et al., 2016) and inadequate health care system communication interface (Jones et al., 2014) were related to poor DSM. In addition, financial constraints resulted in patients’ inability to access diabetes clinical supplies and eat in line with appropriate dietary recommendations (Hunt, Pugh & Valenzuela, 1998; Schoenberg & Drungle, 2001; Campbell et al., 2017). Other studies have examined barriers to some specific areas of DSM. Nagelkerk et al., (2006) and Ghimire (2017) reported that patients' lack of knowledge of a specific diet plan and perceived belief in social unacceptability of healthy behaviours hindered healthy eating and participation in physical exercise. Furthermore, depressive symptoms and personal belief about medication were observed to be associated with lower adherence to diabetes medications (Chao et al., 2005).

The empirical and conceptual research findings mentioned above are not exhaustive because only a few have an international focus (Peyrot et al., 2005). Additionally, the studies are mostly focused on barriers to self-management in patients with type 2 diabetes only (Hunt et al., 1998; Schoenberg & Drungle, 2001; Jones et al., 2014; Cheng et al., 2016; Ghimire, 2017; Aronson et al., 2018), older populations (Schoenberg & Drungle, 2001), those from low income background without indicating the type of diabetes the respondents had (Gazmararian, Ziemer & Barnes, 2009) or few areas of DSM (Ghimire, 2017; Chao et al., 2005; Cheng et al., 2016). The above limitations in previous studies emphasise the need for further and detailed exploration of factors serving as barriers to self-management in both types 1 and 2 diabetes patients. This will provide strategies that adequately address such challenges and foster better adherence to self-management for better health outcomes in both patient groups.

Study Aims

There is diversity in the level of self-management between patients. The ability to self-manage diabetes is influenced by various factors that can either serve as enablers or barriers. However, to the best our knowledge, global perspectives on the crucial enablers of self-management in terms of skills and self-efficacy, among types 1 and 2 diabetes patients is relatively scarce. Likewise, studies on other enablers and potential barriers to general DSM as perceived by these patient groups is scanty in the published literature. There is special interest in elucidating this information from an international perspective because issues encountered in self-management by both patient groups are likely to include common experiences and challenges. Identifying these commonalities could provide health professionals with an in-depth understanding of patients' experiences and help guide the development and enhancement of intervention strategies to improve patients' self-management of diabetes. Therefore, this study aimed to: i) identify the common gaps in skills and self-efficacy for self-management among individuals with type 1 or type 2 diabetes; ii) examine factors associated with self-management skills and self-efficacy; iii) explore other factors which serve as enablers of, and barriers to, achieving optimum DSM.

3.3 METHODS

3.3.1 Recruitment Procedure

A maximum variation purposive sampling technique was employed in recruiting participants aged ≥ 18 years who have type 1 or type 2 diabetes. Participants were recruited globally using diverse recruitment strategies. The aim of this sampling method was to obtain a mix of participants with diverse experiences and identify common patterns that cut across the population sample with regards to the subject of interest (Palinkas et al., 2015). Officially approved advertisement for the study was placed on various health organizations' websites. These websites included Diabetes UK and Diabetes Australia. In addition, the advertisement was placed in local digital newspapers, Twitter and Facebook pages focusing on diabetes support. Data collection was conducted between November 2017 and June 2018. There was no limit to sample size in order to capture the maximum number of people with type 1 or type 2 diabetes. The study requested participants' socio demographic characteristics of age, gender, educational level and geographic location. Details of the recruitment strategy and participants' characteristics have been fully described in our previous publication (*currently chapter 4 of this thesis*) (Adu et al., 2018b).

3.3.2. Study Design

A sequential mixed methods approach was used; comprising quantitative and qualitative data collection methods (Creswell et al., 2003). The quantitative phase of the study involved a cross sectional survey and data analysis. This was followed by qualitative telephone interviews of a subsample of the participants in order to provide a more complete and comprehensive understanding of the results which were integrated into the data interpretative phase (Creswell et al., 2003). Quantitative data were obtained through an online survey that focused on assessing participants' self-reported skills and self-efficacy (confidence) as part of the factors that enable DSM. Qualitative data were collected through individual telephone interviews, which further explored additional factors that serve as enablers and barriers to DSM.

Quantitative measures – Survey

The survey questions were divided into two parts. First, the following health characteristics which were likely to influence skills and self-efficacy for DSM were assessed: type of diabetes, duration of diagnosis and whether participants had recently received (within the previous 12 months) diabetes self-management education (DSME) from a member of their health care team.

Second, novel LMC Skills, Confidence and Preparedness Index (SCPI) tool was used to assess skills and self-efficacy in core behaviours central to DSM such as healthy eating, blood glucose monitoring, being active, healthy coping, medication adherence, problem solving and reducing risk (Tomky et al., 2008; Mbuagbaw et al., 2017). The SCPI tool had been previously validated, where its construct validity for different ages, ethnicity, gender and level of education was established (Aronson et al., 2018). Additionally, the validity of the tool for use in different settings is established by the fact that, as a new tool, the questions reflect the currently recommended self-management regimen for diabetes patients, and this has not been fully explored by previous tools (Mbuagbaw et al., 2017). It has excellent readability and reliability. Permission was obtained to use the tool. The SCPI tool consists of three subscales: skills, confidence and preparedness. The skills subscale was used to assess perceived ability to perform the self-management activities mentioned above. The confidence subscale was used to assess self-efficacy in being able to perform the skills. The preparedness scale was not used in this study because this subscale assesses the readiness of patients to implement behavioural changes following an educational session; which was not applicable in the present study.

The skills and confidence domains consist of nine (9) and eight (8) items respectively. Two of these items focus on skills and confidence to use insulin. These skills were adapted to accommodate participants who have type 2 diabetes but do not use insulin/other medications as part of their treatment regimen. All items were rated using a visual analogue scale, with scores between 1 and 10. Each of the items in the domains produced its own score out of 10. The total score was the mean score in each of the subscales, where higher scores denoted better skills and confidence. The scoring process is not affected by demographic factors such as age, gender, level of education or ethnicity (Mbuagbaw et al., 2017), hence, its' applicability for use in study populations with diverse social and health characteristics. The instrument was administered in English Language.

Qualitative measures – Phone interviews

Through the online survey, all participants were invited to participate in an individual telephone interview. They were requested to indicate interest by providing their best contact number and availability. A single independent resource person (male) who is an experienced researcher in qualitative studies conducted all interviews. The interviewer was trained on the aims of the study and the interview guide by MDA. The guide (see **Appendix 3.1**) was then pilot tested between the interviewer (AD) and MDA before actual use. Additionally, MDA was present in the first three interviews to ensure appropriateness of data collection. While the interviews were used to reflect on the interview guide, no changes were made to the guide afterwards. There was no interaction or previous relationship between MDA and the participants. The interviewer was located in a private office at James Cook University, Townsville, Australia. Prior to the commencement of the interview, each respondent was asked if they were located in a comfortable place for an interview, and were briefly presented with the general idea of the study and key diabetes self-management activities. The interviewer did not have prior relationship with the participants. Each interview was audio recorded and lasted between 7 and 20 minutes, with an average duration of 12 minutes. Data saturation was achieved through recurring explicit ideas (Guest, Brunce & Johnson, 2006) after completing the 14th interview. However, the interview was conducted for the remaining two participants who had indicated interest in order to ensure that no main idea was unintentionally discarded. Repeat interviews were not required and due to the remoteness of the study participants, there was no post interview debriefing. The semi-structured interview guide was developed by the research team. Topics covered in the interview included open ended questions and probes to facilitate discussion.

Ethics and Consent

The study procedures (registration number: H7087) were approved by James Cook University's human research ethics committee. The protocol detailed information on the ethical obligations of researchers toward participants engaging in online research activities. Essentially, these obligations included confidentiality, anonymity, scientific value, maximising benefits, minimizing harms, and informed consent (Hewson & Buchanan, 2017). All these obligations were strictly adhered to during the research process. Furthermore, as part of the application process for advertisement of the study on the website of health organisations, the ethics approval document was made available to the appropriate and designated officials of these organisations. All prospective study participants were provided with the study information along with the privacy policy prior to the survey. Therefore, participants were informed about the use of their answers for analysis under anonymity. Informed consent was implied by submission of the online survey, while all telephone interviewees provided verbal consent.

3.3.3 Data Analyses

IBM SPSS (Version 23) was used for quantitative data analysis. Cronbach's alpha of the subscales of measure used in this study was acceptable (0.92 and 0.91 for skills and confidence scales respectively). Participants' demographics and health variables were presented using descriptive statistics. Items in the skills and self-efficacy domains were reported as means and standard deviations (SD). For the purpose of explaining and discussing the results, scores were graded as high ($\geq$ 7), moderate (4-6) or poor ($\leq$ 3). Mean scores were calculated for demographic and health variable subgroups. Bivariate analyses were performed using Independent sample t-test and Analysis of Variance (ANOVA) to test the relationship between participants' subgroups and level of skills and confidence. Specifically, t-test was used for variables with two categories (i.e. type of diabetes, received DSME or not, gender) while ANOVA was used for variables with three or more categories (i.e. educational status, duration of diagnosis, geographic location, age range). Effect sizes were calculated using Eta squared values to show the magnitude of difference in mean scores between categories within each variable. Pearson correlation coefficients were used to estimate the strength of association between skills and self-efficacy scores. Additionally, multiple regression analysis was used to estimate the contributions of the different independent variables to participants' reported skills levels. Significant variables in the bivariate analysis were included in the regression. In all statistical analysis, values were considered statistically significant at $p < 0.05$ (two tailed).

For qualitative data analysis, audio recordings were transcribed verbatim by an independent professional transcriber and reviewed by MDA for accuracy. The transcripts were uploaded into a qualitative data analysis software (QSR Nvivo 11). Emerging themes were identified using in-depth inductive thematic analysis (Braun & Clarke, 2006) undertaken in six steps. These include: (i) Re-reading of data line by line to ensure familiarization (ii) identification of patterns within data and organization into codes (iii) grouping of initial codes through constant comparison to identify emerging themes (iv) grouping and review of identified themes into general themes (v) refining themes and (vi) selection of representative quotes to support themes (Braun & Clarke, 2006). The first coding and generation of themes was done by MDA. In order to enhance result credibility and validity, raw data transcripts, coded data and themes were independently reviewed by BMA. Data were cross-checked in a consensus meeting and there was 90% degree of congruence between both authors' coding, themes and classifications. Discrepancies were resolved through discussion and mutual agreement. Both MDA and BMA have experience in qualitative research methods. UM and AEOMA checked the quotes and themes to ensure consistency. Key themes were reported along with relevant quotes affixed with an assigned number code and the type of diabetes the respondent has (for instance P3, T2D). The final manuscript was subjected to COREQ checklist for consolidated criteria for reporting qualitative research (Tong, Sainsbury & Craig, 2007).

3.4 RESULTS

3.4.1 Socio-Demographic and Health Characteristics

A total of 217 complete responses to the online survey was received. Respondents were located in four geographic regions; namely, Europe (35%), Australia (34.6%), Asia (29.5%) and America (0.9%). The mean age of respondents was 44.65 ± 14.0 years (range 18-76 years) and 56.7% of them were females. More than half of the respondents had type 2 diabetes (61.8%)

and had received DSME in the previous 12 months prior to the study (64.1%). About half of them were diagnosed in the last 5 years (52.5%) while 20.3 % were diagnosed 6-10 years ago and the remaining 27.2% over 10 years. Over half of the respondents (56.2%) reported having a minimum of bachelor's degree, 20.3% completed high school, while 18.9% completed technical college and 4.6% attained other forms of education.

A total of 31 respondents (14.3%) expressed interest to participate in the telephone interview. However, about half of them declined at time of interview or never responded to phone calls, leaving a final respondent number of 16 individuals who were interviewed. The participants were mostly males; 56.2% (9/16), had type 1 diabetes; 62.5% (10/16) and lived in Australia; 87.5% (14/16), with age ranging from 26 to 61 years [mean age of 44.56 (SD 11.51).

3.4.2 Diabetes Self-Management Skills and Self-Efficacy (Confidence)

Table 3.1 shows the mean scores for each of the items across the skills and self-efficacy domains. Scores were highest in the skills for knowing the appropriate time to check blood glucose levels in order to reflect either the impact of meals consumed ($\bar{x}$ = 7.81 ± 2.33) or medications/physical activities ($\bar{x}$ = 7.47 ± 2.37). In addition, participants possessed a high ability to recognise the effect of missed physical activity or excess carbohydrate consumption on their health ($\bar{x}$ = 7.35 ± 2.35). The lowest scores were in the areas of skills for: identifying and managing the impact of stress on diabetes ($\bar{x}$ = 6.88 ± 2.43), exercise planning to avoid hypoglycemia ($\bar{x}$ = 6.88 ± 2.48), and interpreting blood glucose patterns ($\bar{x}$ = 6.84 ± 2.58).

In relation to participants' self-efficacy levels, the highest scores were in confidence to reduce risk by preventing and monitoring diabetes complications ($\bar{x} =$ 8.08 ± 1.85), and using blood glucose results to plan for meal intake ($\bar{x} =$ 7.22 ± 2.06). Participants scored lowest in their confidence for healthy coping with stress ($\bar{x} =$ 6.72 ± 2.28) and adjusting medications or food intake to reach targeted blood glucose levels ($\bar{x} =$ 6.87 ± 2.62).

There was a strong positive correlation between the scores in the two domains, $r = 0.906$, $p<0.001$, where higher levels of perceived skills were associated with higher levels of perceived self-efficacy. Coefficient of determination (R^2) indicates that level of skills explained 82% of the variation in respondents' scores on self-efficacy.

Table 3.1: Participants Skills and Self-efficacy (confidence) Ratings to Perform Diabetes Self-Management

SKILLS	Mean	SD
I am able to portion out and choose foods that have the minimal balance between carbohydrates, proteins and vegetables to keep my blood sugar in target	7.23	1.97
I know how my diabetes insulin and medication works in my body and at what time of the day I should check my blood sugar(BS) to make sure my dose is correct (*For T2D not controlling with insulin and medication*: I know how my diet and physical activities impact my BS and at what time of the day to check my BS to make sure they are in target)	7.47	2.37
If I eat too much carbohydrate, or do not engage in my regular physical exercise, I know how my body will react and the steps to take to get it back on track	7.35	2.35
When I am planning to exercise, I know what changes I need to make to avoid low blood sugar before, during and after exercise	6.88	2.48
I know when to check my blood sugar if I wanted to see how my body reacted to a meal	7.81	2.33
When I am sick, I know what to do differently with my medications, fluids intake, food intake, blood sugar testing and when to go to the hospital	6.91	2.67
I know how to identify stress in my life and how it can impact my diabetes management and overall health	6.88	2.43
When I look at my blood sugar in my meter or in my log book in a given week, I could explain to my diabetes educator or doctor what my blood sugar pattern is	6.84	2.58
I know what the ABCs (A1c, Blood Pressure and Cholesterol) of diabetes are, what my targets are and how they impact my diabetes	7.00	2.54
Average score on skills	7.15	1.97
SELF-EFFICACY		
I feel confident that I can plan meals and snacks effectively in a way that it will not raise my blood sugar unnecessarily above my targets	7.22	2.06
I am confident that I can implement stress management techniques in my lifestyles	6.72	2.28

I am confident that at the next time I am eating out in my home, I will be able to plan and select the foods that best keep my blood sugar under control	7.06	2.34
I am confident that I can plan ahead for what to do and how to react either before, during or after exercise to avoid a low blood sugar	6.92	2.4
I am confident that I can choose a healthy physical activity for myself and include it in my schedule	7.16	2.26
I am confident that I can adjust my insulin or medication doses on my own, to reach the target blood sugar levels *(For T2D not controlling with insulin and medication*: I am confident that I can adjust my meals and levels of physical activities on my own to reach the target blood sugar levels)	6.87	2.62
I am confident that I can commit to preventing and monitoring my diabetes complications such as seeing my eyes doctor at least once in a year and checking my feet on daily basis	8.08	1.85
I am confident that I can use my blood sugar results to make changes to my diet and/or insulin to help keep my blood sugar in target	7.00	2.54
Average score on confidence	7.17	1.81

A1c: Glycosylated hemoglobin; T2D: Type 2 diabetes mellitus

Relationship between participants' characteristics and levels of skills and self-efficacy

Table 3.2 shows the relationship between demographic and health characteristics and the levels of skills and self-efficacy for DSM in participants. All demographic characteristics except geographic location, gender and age, were significantly associated with perceived skills and self-efficacy.

Participants who had type 1 diabetes had higher levels of skills compared to those with type 2 diabetes, t (215) = 17.41, p< 0.001, eta squared = 0.123. Additionally, receiving DSME within the past 12 months prior to participating in the study had a moderate but significant association with level of skills, t (215) = 2.01, p = 0.045, eta squared = 0.018. There was a significant difference in duration of diabetes diagnosis, F (4, 215) = 5.59, p<0.001, eta squared = 0.095. Skill scores were significantly higher in the >15 years (M=8.28, SD=1.22) when compared to <1 year (M=6.28, SD=1.82), 1-5 years (M=6.98, SD=2.08) and 6-10 years (M=6.97, SD=2.14) of diabetes diagnosis. There was no significant difference for those with 10-15 years of diagnosis (M = 7.00, SD = 1.58). In addition, level of educational qualification significantly influenced the level of skills, F (4, 215) = 7.87, p<0.001, eta squared = 0.132. Skill scores were significantly higher among postgraduate degree holders (M = 7.76, SD =1.12) in comparison to high school (M=6.13, SD = 2.21) and technical school (M = 6.43, SD = 2.25) certificate holders. No significant difference was observed when compared to those with bachelor's degree (M = 7.76, SD = 1.53).

For self-efficacy (confidence), type 1 diabetes participants had higher confidence levels compared to their type 2 counterparts, t (215) = 5.46, p = 0.02, eta squared = 0.051. Furthermore, confidence score was significantly associated with duration of diagnosis, F (4, 215) = 3.23, p = 0.013, eta squared = 0.057. Confidence was significantly higher in the >15 years (M=7.95, SD=1.30) when compared to <1 year (M=6.50, SD=1.68) only. Furthermore, level of educational qualification significantly influenced confidence level, F (4, 215) = 6.77, p <0.001, eta squared = 0.11. Participants with postgraduate degree had significantly higher confidence (M = 7.71, SD =1.55) in comparison to those with high school (M = 6.42, SD = 1.98) and technical school (M = 6.47, SD = 2.11) certificates. No significant difference was observed for those with bachelor's degree (M = 7.48, SD =1.39).

Multiple regression analysis identified the simultaneous contributions of time since diagnosis, type of diabetes, educational qualification and receiving DSME within 12 months prior to the study on participants' level of skills. These variables predicted 22% of the variation in level of skills F (2, 216) =14.815, p<0.001, R^2 =.218. All variables, except receiving DSME, were statistical significant at p <.05.

Table 3.2: Summary of t-test or ANOVA and Post Hoc results on mean scores by participants' characteristics

	Skills			**Self-Efficacy**		
Variables	**mean ± SD**	***F* or *t* statistics, *p*-value**	**Effect size**	**mean ± SD**	***F* or *t* statistics, *p*-value**	**Effect size**
Type of Diabetes		t(215)= 17.41,*p*<0.001	0.123		t(215)=5.46, *p*=0.02	0.051
Type 1	7.95 ± 1.35			7.66 ± 1.47		
Type 2	6.66 ± 2.12			6.87 ± 1.93		
Duration of diagnosis (years)		*F* (4) = 5.59, *p*<0.001	0.095		*F* (4) = 3.23, *p*=0.013	0.057
<1	6.28 ± 1.82			6.50 ± 1.68		
1-5	6.98 ± 2.08			7.12 ± 1.86		
6-10	6.97 ± 2.14			6.96 ± 2.15		
10-15	7.00 ± 1.58			7.20 ± 1.27		
>15	8.28 ± 1.22			7.95 ± 1.30		
Received DSME in the previous 12 months		t(215)= 1.89,*p*=0.045	0.018		t(215)=1.48, *p*=0.141	0.01
Yes	7.35 ± 1.77			7.31 ± 1.66		
No	6.79 ± 2.23			6.93 ± 2.03		
Educational status		*F* (4) = 7.87, *p*<0.001	0.132		*F* (4) = 6.77, *p*<0.001	0.113
High School	6.13 ± 2.21			6.42 ± 1.98		
Technical College	6.53 ± 2.25			6.47 ± 2.11		
Bachelor Degree	7.47 ± 1.65			7.48 ± 1.39		
PG degree[b]	7.76 ± 1.53			7.71 ± 1.55		
Others[c]	8.40 ± 1.12			8.18 ± 1.46		
Gender		t(215)=-1.18,*p*=0.238	0.006		t(215)=-0.43, *p*=0.665	0.001
Male	6.97 ± 1.93			7.11 ± 1.76		
Female	7.28 ± 1.99			7.22 ± 1.85		

Geographic location		*F* (3) = 3.14, *p*=0.124	0.005		*F* (3) = 3.22, *p*=0.145	0.004
Australia	7.11 ± 2.01			6.96 ± 1.87		
Europe	6.73 ± 2.40			6.91 ± 1.94		
America	6.99 ± 2.11			6.77 ± 2.10		
Asia	7.16 ± 2.10			6.76 ± 2.13		
Age		F (4) = 1.46, *p*=0.215	0.027		F (4) = 1.48, *p*=0.211	0.027
18-29	6.95 ± 1.78			6.88 ± 1.80		
30-39	7.60 ± 1.52			7.52 ± 1.58		
40-49	7.06 ± 2.16			7.01 ± 2.02		
50-59	6.74 ± 1.98			6.81 ± 1.64		
60-69	7.12 ± 2.42			7.39 ± 2.05		

[a]DMSE: Diabetes Self-Management Education

[b]Post Graduate

[c]Others: Professional qualifications, graduate diploma

3.4.3 Other Enablers and Barriers to Diabetes Self-Management

Other enablers of self-management

Two major themes were identified as factors, which could facilitate diabetes self-management. These were patients' determination to prevent the development of complications and the use of health technological devices or software.

Theme 1 - Determination to prevent diabetes complication*:* The decision to regularly engage in self-management was fostered by participants' resolution to prevent the development of diabetes complications. Participants ensured that they engaged in the necessary lifestyle behavioural activities due to their determination to maintain better quality of life and thereby avoid what was observed in their peers who had already developed some form of diabetes complications:

''I see a lot of other people who already have diabetes talking about their diabetes on social media. Looking at others who are worse off than me and the problems they struggle with, I guess is keeping me in check saying, hell no, I'm not going down that path''. [P6, T2D]

Furthermore, the determination to prevent diabetes complication was expressed by refusal to purchase certain foods which participants believed could increase the risk of progressing type 2 diabetes management into requiring the use of insulin injection:

*''It's just the fact that I don't want to get to the stage of having injections many times a day…. I have to remind myself of that always. I'm quite happy to walk past some chocolate….knowing fully well that whilst I might enjoy a ** (name of a chocolate brand), …. then I get an injection at the end, which I don't want, which mean I will leave (name of a chocolate brand) alone''.* [P3, T2D]

Respondents acknowledged that having good knowledge and problem solving skills in diabetes has proven useful to aid their self-management. Awareness of how foods impact their health was reported as highly essential:

''I think having knowledge of the foods and the type of foods and diet and portion sizes are very important. Also, I found understanding what hypo or hyper, and understanding how my body reacts and how I can resolve that has been very useful in managing my diabetes.'' [P15, T1D]

Theme 2 - Use of health technological software and devices*:* Participants mentioned the use of mobile technological devices specifically, smart phone application (apps), insulin pump and continuous glucose monitors (CGM) as supporting tools which have enhanced their DSM.

2. 1 Apps**:** Some of the participants use smart phone apps to record their blood glucose data. They noted that having access to such previously stored data on their phones gave them insight into the best self-management strategy, which had assisted in adequate glycemic control:

''I have been diagnosed for a long time and back in the days I used to write it on a note book. But in these days, I record it using a smart phone app, which allows me to search. So it allows me to access the data quickly and make a sort of best guess for now based on what happened in the past. If it's not working, as it has done recently, I can go back to strategies that I might have been using years ago, that seems to work then ''. [P14, T1D]

Reminder feature in apps were found useful to give alert for recurring tasks such as taking medications thereby improving medication-taking behaviour especially during busy schedules:

''I'm only kind of new to this (newly diagnosed), so I am actually looking for ways to remind myself of the tablets (medication) am meant to be taking. When I get really busy I forgot..so my app pings at me a certain time of the day…just to kind of prompt me'' [P3, T2D]

Also, motivations and encouragements were received through the use of app especially in the event of unstable blood glucose control. Participants stated that whenever their blood glucose level fluctuated and differed from the prescribed limits despite all efforts to stabilise it, looking at good data previously stored in apps provided an assurance that their blood glucose levels will not always be unstable:

‘‘Sometimes it is simple as realizing it’s not all terrible. Being able to flip back on my smart phone. If you’ve had a rough four or five days, it can feel like it’s a long time since you’ve seen numbers that felt like relatively stable or in range. You can get disheartened but if you can just check back and see, actually no, it’s fine because two weeks ago it was all right, so I’ll be able to get back to that again. So having access to that sort of information storage allows me to be a little bit more relaxed when inevitable things start to wobble and go adrift again’’. [P14, T1D]

2. 2 Insulin pump and CGM**:** Participants with type 1 diabetes reported the use of insulin pump or continuous glucose monitor (CGM) as external aids which made it easier for them to manage and effectively monitor their health. In this regard, one participant stated that:

‘‘With the insulin pump, I find it easier to manage. Also, I’ve got the CGM and I can see what my sugar is on the screen all the time….you know that changed my life’’. [P1, T1D]

Participants also indicated that use of insulin pump provided additional support and relief from pains experienced while using needles:

‘‘I’m quite a thin bloke…… and have no body fat so inserting needles really hurt. My insulin pump definitely helps. So the best way I’ve managed my diabetes is through the insulin pump’’. [P12, T1D]

3.4.4 Barriers to Self-Management

In spite of the factors that foster effective self-management of diabetes, the key themes that emerged from the interview indicated that people with diabetes encountered diverse challenges in performing their self-management due to the: i) dynamic and chronic nature of diabetes; ii) financial constraints iii) work and environment related factors; and (iv) unrealistic expectations

Theme 1 - Dynamic and chronic nature of diabetes*:* The most common complaint reported by participants was the dynamic and chronic nature of diabetes and how these attributes make DSM require multiple needs. Participants felt there were many reasons including environmental conditions, which may demand an adjustment in their self-management even within short time periods. They believed the constant requirement to modify needs of the condition denoted certain things they were not doing right in their self-management and they always had to put in great effort to meet up with their health requirements:

''Because I live with type 1 diabetes I have to do a complete insulin replacement, which involves balancing for activity, ambient temperature, stress levels, insulin sensitivity of my body. It could be so much easier if you could just work out what your insulin to carb sensitivity portion is, work out how to behave around exercise, work out correction factors and that would be all. But no, my experience is that that's it for a week and then your basal requirement would have changed. Then the weather get warmer, you may need to re-evaluate your insulin sensitivity and carb ratio. So it's just- you are never getting it right and you're just always constantly trying to play catch up''. [P14 T1D]

Likewise, the effects of self-management on diabetes outcome was referred to as a system which could not be automatically controlled. Participants described how similar behavioural activity such as eating the same diet over time could impact their health differently.

‘‘It is a dynamic disease. I mean what works today doesn’t work tomorrow. You can eat something today and you can be okay, eat something tomorrow and it can be completely different. So you can never just put it on a cruise control and away you go’’. [P2, T1D]

The weariness about the never-ending need for self-management because diabetes is a lifetime disease was expressed:

‘‘The biggest thing that fazes me is just the fact that it’s something that you have to do 24 hours a day, seven days a week and nothing ever going to change that’’. [P4, T1D]

Participants were sometimes unwilling to undertake their self-management because they felt it is not a permanent cure for the disease, diabetes is chronic, so what is the point?

‘‘..Probably my mind frame, in just getting yourself down to the fact that it’s never going to..I’m always going to have it. So you sort of question what’s the point (of management)? It’s hard to comprehend’’. [P11, T1D]

The presence of other diabetes related complications or health problems such as neuropathy and depression in some participants limited their ability to actively engage in behavioural activities especially physical exercise or healthy eating:

‘‘Physical exercise is difficult…Yeah, I have peripheral neuropathy of the leg, a collapse in the foot and yeah, problems with the other foot’’. [P10, T2D]

‘‘Nutrition is something that is hard to keep on top of. I suffer from a major depressive disorder, so I have a lot more trouble following my optimum diet’’. [P7, T1D]

Theme 2 - Financial burden*:* The difficulty in meeting the financial cost for some diabetes medical tests and other treatment requirements was also identified as a barrier. Participants voiced out the financial burden they experienced by citing the need to pay for some clinical tests and diabetes supplies which are not covered by their health insurance such as the glycosylated hemoglobin (HbA1c) test and continuous glucose monitor. They expressed the desire to receive more support from the government:

‘‘I manage my diabetes fairly closely and I pay for HbA1c, you know …the financial cost is quite large. In Australia, our health system’s pretty good but you still have to pay for a lot of equipment which the government doesn’t seem to agree necessarily. Continuous Glucose Monitor should be government funded for over 21s for Christ sake’’. [P2, T1D]

Another participant based in the United Kingdom (UK) stated:

‘‘I don’t have unimpeded access to Continuous Glucose Monitor (CGM). I mean..the situation of health care in UK is that it’s (CGM) not often funded by National Health Service (NHS) apart from people that are in quite profound need. I don’t get that assistance... So that’s a challenge and access issue’’. [P14, T1D]

Theme 3: Work and environment-related conditions

<u>3.1 Occupation</u>**:** Job requirements especially those involving a lot of travelling serves as deterrent to maintaining a healthy diet. Participants stated that the inability to get healthy choices of foods in most restaurants or public places when unavoidably required to eat out due to travelling long distances to fulfill their job requirements:

‘‘My work requires a lot of travelling. If you are actually going to eat something that is actually not good and could put you in the circumstance where you know… Like I had a 16 hour travelling the other day and everywhere I turned, I couldn’t touch any of it. I had some but I had to acknowledge that it was not what I really needed to eat’’ [P3, T2D]

Work related stress was also reported as a hindrance to attaining optimal blood sugar levels:

‘‘With me personally, it’s stress. I’m an electrician, and I’m full time employed, so stress gets me. When I get stressed, my blood sugar level goes downhill’’ [P13, T1D]

3.2 Weather condition: Participants find it difficult to engage in physical exercise in hot weather conditions:

''..*Exercise is something I have trouble getting around to doing. Like during the summer, the heat hits me big time. So I'm loving the cooler weather we're starting to have because I can start to work a bit more, but during the heat, I cannot do it*''. [P2, T1D]

Theme 4- Unrealistic demands: Unrealistic expectations and advice about self-management from family or friends especially those not diagnosed with diabetes could be a hindrance to effective care. Participants' found such wrong advice irritating as evident in the following comment:

''*You know I don't think a lot of non-diabetic actually get to know how much it can take to actually manage a high or a low (Blood sugar) potentially. You know, you get comments from people that you're low and they know you are diabetic saying, oh, should you be eating that? Well, I'm going to say this nicely, you want me to die now or not or to go into coma? Because I need to eat this. They go oh, you didn't need to say it like that. You go well, stop asking a stupid question that you don't know anything about*''. [P4, T1D]

Additionally, discrepancy between patients and their health professionals' (HP) perception of care could be a barrier to self-management. Participants felt that some recommendations from HPs were contrary to their opinions on what their DSM should entail:

''*My doctor doesn't feel I need to be using a glucose meter to monitor my sugar levels and the diabetes educator doesn't think I need to be on any sort of diet, even though I've had increases in diabetes medications*''. [P10, T2D]

3.5 DISCUSSION

To the best of our knowledge, this is the first mixed-methods study that has investigated the enablers and barriers to general self-management among a multinational audience of people who have type 1 or type 2 diabetes. Most importantly, our findings emphasise the consequential impact of currency of exposure to DSME (within the previous 12 months), duration of diagnosis, level of educational qualification and use of technological devices on self-management skills and self-efficacy, regardless of geographical location or ethnicity. This implies that provision of ongoing self-management education/support through the use of mobile phones may help address the various difficulties (including time/financial constraint, diabetes distress, and limited access to care providers) encountered by patients and foster adherence to recommended self-management activities, which are necessary to prevent the risk of developing diabetes complications. Furthermore, this study presents in-depth understanding of the experiences of diabetes patients and provides useful insights to health professionals and researchers on how to improve the frequency and quality of self-management support provided to diabetes patients to achieve better health outcomes.

Skills and self-efficacy for diabetes self-management

The overall skills score was found to be high and many participants reported good level of ability for self-management. This is specifically in the area of accurate monitoring to assess the impact of diet, medication or physical activities on blood glucose levels. Similar findings were observed in a previous study (Persell et al., 2004). Accurate monitoring of blood glucose in relation to foods consumed and physical activities are important because they predict good outcomes in diabetes management (Shrivastava, Shrivastava & Ramasay, 2013).

Even though, the participants in this study scored high in their ability to monitor blood glucose, their capacity to interpret their blood glucose patterns over time was only moderate. Although, self-monitoring of blood glucose is important to assess glycemic pattern, accurate interpretation of these patterns is highly important to ensure effective management of glycaemia related problems encountered in diabetes management (Glasgow et al., 2007). More emphasis should be laid on glucose pattern management during DSM educational sessions in order to expatiate patients’ skills on effective monitoring and interpretation of blood glucose data and the resulting health implications.

Participants in this study possessed lower skills related to planning for physical exercise in order to avoid hypoglycemia and adjusting medication to reach targeted blood glucose levels. This result corroborates previous findings (Basu et al., 2014). Ability to manage and make appropriate adjustment to multiple regimens often determine success with other core areas of DSM and glycemic control (Glasgow et al., 2007). For instance, studies have reported that due to the fear of hypoglycemia, patients have resorted to unhealthy behaviours (such as reducing or eliminating medication dose, inappropriate food choices and /or avoidance of physical activities) that increase glucose levels (Perlmuter et al., 2008). Diabetes patients have an increased risk of developing hypoglycaemia particularly when treated with insulin or insulin secretagogues (Permulter et al., 2008). Hence, they should be provided with regular refresher courses and continuous training on blood glucose levels awareness and strategies to balance exercise, which could promote glycemic control and adherence to self-management.

Healthy coping strategies to identify and manage the impact of stress on diabetes management may be a difficult aspect of diabetes care because the participants in this study scored lowest in this area for both the skills and self-efficacy domains. All forms of stress either physical or mental, negatively impact blood glucose levels in those with diabetes (Pouwer, Kupper & Adriaanse, 2010) and it is a potential obstacle to attaining effective self-management and optimal health outcomes (McEwen, 1998). Patients’ understanding of dimensions of diabetes related stress is a clinically important factor and forms of stress that are potentially modifiable should be prioritised to guide clinical and educational interventions. This can include regular educational information on the impact of stress on health of diabetes patients and suggestions to reduce it.

Contrary to the findings of a previous study (Toljamo & Hentinen, 2001) that reported people with type 1 diabetes as having poorer self-management; our study participants who had type 1 diabetes scored higher than those with type 2 diabetes in skills and self-efficacy to care for their diabetes. Additionally, there was a significant positive relationship between the duration of diabetes and both skills and confidence for self-management. Patients with type 1 diabetes are typically diagnosed at an early age that may correspond to longer duration of diabetes. This pattern might have afforded them prolonged and regular exposure to health education, which is a significant predictor of successful DSM (Haas et al., 2012).

Overall, the strong correlation between the level of skills and self-efficacy found in this study strengthens the body of evidence supporting this link (Aronson et al., 2018). This pattern may be related to high level of education among most of the study respondents as also observed in a previous study (Schillinger et al., 2002). Patients who possess higher skills usually have higher perceived level of efficacy and are most likely to actually engage in their self-management (Persell et al., 2004; Aronson et al., 2018). Building patients' skills and confidence in their ability to self-manage diabetes is therefore imperative. Regular encouragement, which could either be provided verbally or through other means of contact (e.g text messages through phones or emails) could be beneficial to patients (Yoon & Kim, 2008). While for those with limited educational backgrounds, the use of clear and simple communication styles when providing diabetes education to them will be essential to foster their skills and confidence (Schillinger et al., 2002).

Other enablers of self-management

Based on the results of the interviews, the most commonly perceived factor that fostered regular self-management was the will to prevent the development of diabetes complications. This result corroborates previous findings (Maillet et al., 1996; Koch, Kralik & Taylor, 2000) and indicates that the participants in this study took responsibility for their choices and respective consequences. Discipline and proactive approaches to self-management are essential to reducing or preventing the development of diabetes complications. Regular reinforcement of education and motivation of patients could provide in-depth information about the disease and foster the will to mitigate its' clinical course.

Furthermore, our study findings confirm those of other studies that the use of mobile technologies such as smartphone applications (Hunt, 2015), insulin pump (Ghazanfar et al., 2016) and continuous glucose monitor (Burge et al., 2008) could enhance DSM in patients. Technology interventions have positive impact on diabetes outcomes such as adherence to self-management activities, glycosylated hemoglobin and diabetes self-efficacy (Hunt, 2005). Therefore, health professionals could recommend the use of mobile health technologies to patients who are capable of using them as they benefit from them.

Barriers to self-management

The lack of enthusiasm towards regular self-management due to the chronic and dynamic nature of diabetes is not entirely unexpected. This phenomenon could be referred to as diabetes distress which is the emotional stress resulting from living with diabetes and the ‘‘burden of relentless management’’ (Pandit et al., 2014). High diabetes distress results in sub-optimal diabetes management and compromised quality of life (Peyrot et al., 2005; Balfe et al., 2013). Diabetes distress is common among patients and impacts on their self-management and health outcomes. Therefore, the importance of providing appropriate regular support to all patients in this regard cannot be overemphasised. Health professionals could ask patients at every consultation about how they are coping with diabetes, encourage them to express their diabetes-related issues causing distress and offer encouragement and suggestions on ways to deal with it on a daily basis.

For many of the respondents in this study, the need to meet up with job requirements especially frequent travelling makes adherence to healthy eating difficult. Additionally, work related stress impacts greatly on their blood glucose levels. These findings echo the results by Chao et al. (2005) Recommendations to patients to engage in creative planning and social support are strategies to help address this barrier. Social support from families are essential. Families should be encouraged to attend educational training sessions with patients so as to offer appropriate support which can assist patients to make healthy food choices and decisions regarding their diabetes management (Maillet et al., 1996; Chlebowy, Hood & Lajoie, 2010).

Furthermore, financial burden associated with diabetes could be a hindrance to self-management especially those associated with out-of-pocket expenditure for medical needs. Campbell et al., (2017) observed that the predominant area of management where patients experience financial burdens are medications, diabetes supply and healthy food. People with diabetes require regular self-management and clinical monitoring to prevent the development of complications and foster optimal health outcomes; hence the associated financial demand. Health care providers could inform patients about resources available to them to buffer financial constraints that limit adherence to treatment plans. Such resources may include referring patients to specific social programs or compassionate relief programs to support financial burdens and enable easier access to necessary services.

Differences in patients' and health care professionals' (HCP) views of what constitutes the best approach to care was also identified as a barrier to DSM. This may be due to gaps in the way treatment recommendations were communicated to patients. Often times, HCPs' view of good care are based on adhering to stipulated biomedical care model, structured communication and central decision making (Van Keer et al., 2015), whereas patients perceived quality health care is how the scientific knowledge of HCPs' aligns with their own experiential knowledge and personal preferences (Pomey et al., 2015). Therefore, patients are always seeking exhaustive information about their diagnosis and treatment (Pomey et al., 2015). There is responsibility on the part of HCP's to advice and educate their patients on different treatment options and the reasons they are placed on a particular option and not the other. This patient centered-approach will empower patients and foster their health outcomes.

Integration of findings and recommendations for future interventions

The survey results show that many patients have limited capacity for healthy coping strategies to identify and manage the impact of diabetes related stress. This finding was confirmed in the interviews where diabetes distress was reported as a major barrier to self-management. Given that stress is a potential contributor to chronic elevated blood glucose levels, it is essential for health care professionals to assist patients with identifying approaches to reducing diabetes distress. Additionally, increased access to providers through expanded clinic hours could be a means of easing the burden of diabetes diagnosis (Gazmararian, Ziemer & Barnes, 2009).

The quantitative data also showed that higher educational level was the strongest predictor of better self-management skills in patients and this was affirmed by the highly skilled interviewees who identified the use of technological devices as an enabler to their DSM. This corroborates that higher educational level is a good predictor of eHealth usage (Kontos et al., 2014). In addition, in accordance with previous literature (Lim et al., 2011), good overall self-efficacy level observed in the survey might have influenced the positive report on the usefulness of technology in diabetes management. Therefore, given that use of health technologies provides both short and long term health improvements in diabetes patients (Kaufman et al., 2016), active use should be encouraged where necessary especially among patients who are educated and have the ability to engage with them. Furthermore, it is important to device avenues to improve patients' self-efficacy in their ability to manage the disease as this could increase their likelihood of engaging with technology for their self-management (Dou et al., 2017).

The interviews revealed that determination to prevent the development of complications is one of the major enablers to DSM. This might explain the overall high score in skills and self-efficacy observed in the survey. Therefore, we suggest that educators could focus on improving patients' skills and self-efficacy for DSM thereby raising patients' awareness of the negative effect of diabetes. This approach could in turn stimulate the patients' determination to engage in their self-management and thereby reduce the risk of developing complications.

A unique perspective from the qualitative results revealed that patients and HCPs have divergent views/opinions about what should constitute patient care. It is therefore, imperative that HCPs ensure that patients understand the reasons for the recommended treatments and engage them in shared decision making which is essential for patients' satisfaction and engagement in self-management practices (Heisler et al., 2002).

Lastly, it has been advocated that people with diabetes should receive self-management education and support in an ongoing and consistent manner (Powers et al., 2017), but the reality of facilitating face-to-face diabetes education between patients and HCPs on an ongoing basis is low due to limited human and organisational resources. Health behavioural treatments and therapies such as DSMES could be provided to patients on an on-going daily basis outside the clinical setting through the use of Ecological momentary interventions such as mobile technologies (Heron & Symth, 2010). Apart from the fact that apps were opined by patients to enable self-management in this study, the World Health Organisation (WHO) also confirmed that the use of mobile technologies (such as apps) can support the attainment of health outcomes which could transform health service delivery globally (World Health Organisation, 2011b). Considering that apps are cost effective avenues for providing ongoing delivery of care to patients outside the clinical environment (Iribarren et al., 2017), DSM educational messages could be developed and integrated into apps for patients. Such information should be targeted at improving patients' skills and self-efficacy capacity for effective self-management.

Strengths and limitations

The strength of this work is that it provides a multinational picture of skills and confidence for self-management in people with type 1 or type 2 diabetes. Such an elaborate and international approach to assessing the capacity and confidence levels for self-management is scanty in the literature. In addition, the data identified a number of factors serving as enablers and barriers to DSM emanated from patients' perspectives and their lived experiences. Therefore, the results are tenable to provide immense insights into improved strategies for supporting patients in their self-management.

There are some limitations to this study. Firstly, the reliability and validity of the quantitative tool used have not been previously demonstrated at multinational/multicultural levels, and this may limit the interpretation of our findings. Although, in a previous study (Aronson et al., 2018), the construct validity of the scale was tested among type 1 and type 2 diabetes patients who were from different ethnic backgrounds (Asians, Caribbeans, Caucasians etc.) but living in the same regional location. The study reported that the scale was not influenced by ethnicity. Secondly, the small sample size/groups for the survey, which mainly comprised of participants from three continents may limit the generalisation of our findings to other settings. Thirdly, the quantitative data was self-reported and therefore susceptible to bias, which may not reflect participants' actual skills and confidence levels for self-management. Hence, under or over reporting could result in inaccurate identification of common gaps in skills and confidence requiring intervention. Nevertheless, self-report can be made more reliable when questions are asked in non-judgmental manner as obtains in the SCPI tool used in this study. Lastly, the small number of interview participants is also acknowledged and the interview sessions were brief because additional compensation was not offered to interviewees. Short interview duration was utilised to foster increased participant numbers as long interview may not be justifiable for participants' time involvement in the study. Nevertheless, literature has shown that the anonymity of telephone interview reduces the interviewer bias, which makes the interviewing setting more calming and forthcoming, thus fostering a more accurate and truthful data collection (Musselwhite et al., 2007).

3.6 CONCLUSION

This study identified the common gaps in the skills and self-efficacy of people with type 1 or type 2 diabetes mellitus as well as other perceived enablers of, and barriers to, self-management in this population. Diabetes health care stakeholders may consider strategies for regular educational reinforcement in patients in order to foster healthy coping with diabetes stress, exercise planning to avoid hypoglycemia, interpreting blood glucose patterns and adjusting medications or foods to reach the targeted blood glucose levels. Furthermore, designing of interventions that capitalise on how to improve patients' desire to reduce the progression of diabetes and the use of relevant technological devices could enhance DSM. Improved approaches to address diabetes distress, financial burden, discrepancy between patients and their health professionals' perception of care as well as work and environment related factors are essential to foster improved self-management in patients. Finally, attention should be paid to type of diabetes, level of education and duration of diagnosis when counselling patients on diabetes self-management. Consideration of these areas of educational reinforcement and interventions could enhance self-management in patients and consequently improve their health outcomes.

This chapter addressed the second aim of the thesis and provided empirical evidence of skills and self-efficacy as mediating factors for diabetes self-management.The findings from this study guided the development of the DSM interventional app that is presented in Chapter 5.

Chapter FOUR: Users' Preferences and Design Recommendations to Promote Engagement with Mobile Apps for Diabetes Self-Management: Multi-national Perspectives

4. 1 ABSTRACT

Mobile phone applications (apps) offer motivation and support for self-management of diabetes mellitus (diabetes), but their use is limited by high attrition due to insufficient consideration of end-users perspectives and usability requirements. This study aimed to examine app usage and feature preferences among people with diabetes, and explore their recommendations for future inclusions to foster engagement with diabetes apps. The study was conducted internationally on adults with type 1 or type 2 diabetes using online questionnaire (quantitative) to investigate usage and preferences for app features that support diabetes self-management (DSM) and semi structured telephone interview (qualitative) to explore suggestions on fostering engagement and specific educational information for inclusion into diabetes apps. Survey and interview data were analysed using descriptive / inferential statistics and inductive thematic analysis respectively. A total of 217 respondents with type 1 diabetes (38.25%) or type 2 diabetes (61.8%), from 4 continents (Australia, Europe, Asia and America) participated in the survey. About half of the respondents (48%) use apps, mainly with features for tracking blood glucose (56.6%), blood pressure (51.9%) and food calories (48.1%). Preferred features in future apps include nutrient values of foods (56.7%), blood glucose (54.8%), physical exercise tracker (47%), health data analytics (42.9%) and education on DSM (40.6%). Irrespective of the type of diabetes, participants proposed future apps that are user friendly, support healthy eating, provide actionable reminders and consolidate data across peripheral health devices. Participants with type 1 diabetes recommended customised features with news update on developments in the field of diabetes. Nominated specific educational topics included tips on

problem solving, use of insulin pump therapy and basic guideline for the management of diabetes. The study has highlighted patients' perspectives on essential components for inclusion in diabetes apps to promote engagement and foster better health outcomes.

4.2 BACKGROUND

Mobile phone applications (apps), are extensively used to provide support for diabetes self-management (DSM) (Chomutare et al., 2011, Arnhold, Quade & Kirch, 2014). These apps include features for tracking blood glucose, calories in diet, body weight, as well as reminders for medication intake or health appointments (Rao et al., 2010; Chomutare et al., 2011; Tran, Tran & White, 2012). There is strong evidence suggesting that the use of apps encourages adherence to management therapy, improves glycaemic control, which subsequently prevents or delays the onset of diabetes complications and enhances patients' quality of life (Liang et al., 2011; Goyal & Cafazzo, 2013; Scheibe et al., 2015). However, despite the proven effectiveness and investments into the technological processes of app development, their use as an intervention for diabetes mellitus (diabetes) management, have been limited by high attrition rate (Istepanian et al., 2009; Quinn et al., 2011; Holmen et al., 2014), evidenced by reduced user engagement over time. The low level of adoption and use of apps has been attributed to insufficient consideration of end users' preferences (Chomutare et al., 2011; Holtz & Lauckner, 2012) and the factors for engagement. (Arsand & Demiris, 2008).

Trends in users' preferences for features and engagement with apps to support diabetes management

There are limited studies that have explored patients' use, feature preferences and recommendations that could improve engagement with diabetes apps. Recent surveys found that although many people with diabetes own a smartphone, only a few of them used apps to manage their diabetes (Kayyali et al., 2017; Dobson et al., 2017). The major reason for non-use was that patients were unaware of the existence of apps that could support their care (Dobson et al., 2017). Additionally, there are diverse patients' views about the essential features in apps to support diabetes management. A survey found that features for data recording, social coaching, reminder and remote collaboration with health care professionals were appealing to people with diabetes (Kayyali et al., 2017). Other studies have reported carbohydrate counter, blood glucose and physical activity tracking as the most commonly preferred app features by diabetes patients (Lithgow, Edwards & Rabi, 2017; Boyle et al., 2017). However, most apps were unable to meet up with patients' needs because diabetes education which is a crucial and evidence-based requirement for diabetes management is often lacking in the currently available apps (Chomutare et al., 2011; Boyle et al., 2017).

Moreover, to be an effective self-management support tool, app must continuously capture the attention of users and stimulate users' interest to actively engage with it. Engagement indicates the degree of interaction a user has with the technology within a given time span or the overall length of time from the onset use of a technology to when the user totally lost interest in the usage (Bickmore, Schulman & Yin, 2010). Engagement with health technologies including apps is a dynamic process comprising of different stages, namely: point of engagement, period of engagement, disengagement and reengagement. Therefore, users' engagement is multifaceted in nature and may change within a short or long periods of time (O'Brien & Toms, 2008). User's engagement can either be measured during a short session or long-term use of a technology. It is important to note that the ultimate goal of mobile apps usage for patients with chronic diseases is to foster their ongoing and regular participation in their self-management activities. Where participation in those activities may be reflected in the frequency of tracking or monitoring of the activities using an app hence denoting the extent of their engagement with the app. Nevertheless, patients may participate in management activities and not track with an app (non-usage) (Kayyali et al., 2017) even when apps are present on their mobile devices, which may be due to several reasons. Since health technologies are voluntary use systems, the extent of engagement with them is determined by the users' perceived quality of experience, ongoing benefit of usage (Lalmas, O'Brien & Yom-Tov, 2014), consideration of viable alternatives to using the technology and decrease in perceived costs (Bickmore, Schulman & Yin, 2010). Furthermore, Studies have reported that mobile health apps which are able to adequately meet patients' self-management needs and have clear evidence of data privacy will motivate users engagement with the technology (Woldaregay et al., 2018; Torous et al., 2018).

Low engagement is not unique to diabetes apps alone, but rather to all computerised behavioural therapeutic interventions that support the management of chronic diseases or health promotion (Dennison et al., 2013; Bender et al., 2014; Conway et al., 2016; Taki et al., 2017). Engagement with mobile apps is negatively affected by factors such as lack of motivation or commitment to change health behaviours (Dennison et al., 2013) and knowledge in managing the targeted behaviour. Once knowledge is attained, it is likely that participants' interest in app use will reduce (Guertler et al., 2015; Taki et al., 2017). Moreover, sub-optimal usability has been stated as a reason for low engagement with apps (Mallenius, Rossi & Tuunaunen, 2007; Demidowich et al., 2012). Optimal usability in apps could be achieved through simplicity, reduced time consumption and customised users' experience (Juarascio et al., 2015). To date, there is little or no clear evidence as to why engagement with diabetes apps remains low. Tatara et al., (2013), in their study on long-term engagement with a mobile self-management system for people with type 2 diabetes reported perceived sense of mastery over diabetes and experiences of problems with the app as factors for declining motivation to continuous use of app.

The few studies described above have shown that diabetes patients have different needs and requests for health care technology development (Holmen et al., 2017) and there is limited understanding of the factors which could foster engagement with apps to support diabetes.

Moreover, these studies have been limited to single countries and current app users alone. A critical step to knowing what appeals to end users and maximising app engagement is shared decision-making, whereby app developers involve targeted end users in the process of developing the content and features of apps (Arsand & Demiris, 2008; McCurdie et al., 2012). Hence, it is important to build upon previous research by examining the perception of a diverse range of people with diabetes; that is both current users and non-users, residing in diverse locations, about the usability and functionality of diabetes apps to support their health-care and factors for usage over time.

Study Aims

Thus, the aim of this study was to involve individuals with type 1 and type 2 diabetes in guiding the development of future mobile apps for DSM. The specific objectives were: (1) to assess the use and preferences for potential features in apps, which could support the health management needs of individuals with type 1 or type diabetes. (2) Seek recommendations on components and motivators that could foster long term use of apps (3) Assess specific educational topics desired in apps to support DSM. We hypothesised that diverse multinational respondents comprising of adults with type 1 or 2 diabetes (both users and non-users of apps) would recommend the necessary design components and strategies to maximise engagement with apps to support the self-management of diabetes. Getting this insight would provide an effective approach to the design and development of an evidence-based and highly functional app that best meets the identified needs of people with diabetes.

4.3 METHODS

4.3.1 Study Design

The study employed a mixed methods design, combining quantitative and qualitative data to explore patients' perceptions and the results were integrated in the data interpretation phase

(Creswell et al., 2003). Information was sought globally from adults aged ≥ 18 years who have type 1 or type 2 diabetes. Users and non-users of apps were included in the study to obtain balanced and un-biased findings.

Quantitative approach

Data were collected through an online survey conducted between November 2017 and June 2018. The study was advertised using multiple outlets, including Townsville Bulletin digital newspaper, Diabetes Australia and Diabetes UK websites as well as various diabetes support groups on Facebook and Twitter. Through these advertisements, a link was provided where potential participants were directed to the Survey Monkey page containing information about the study. Consenting participants could subsequently click on the survey link and submit their responses. As an incentive to encourage participation, a chance to enter a draw to win one of 6 US$50 e-gifts card was offered to respondents. This recruitment procedure yielded an inadequate response rate particularly from Asia and Europe, hence the need for another approach. More targeted respondents were recruited from Asia and Europe, and were offered an additional incentive ($US 5) for their participation.

Instrument

Through a systematic review, an overview of the frequent features currently available in mobile apps to support DSM as well as the gaps in literature were obtained (Adu et al., 2018a). This review guided the development of the study questionnaire, which comprised two sections (see **Appendix 4.1**). The first section inquired about basic demographic and health characteristics of the respondents. The second section comprised 3 questions aimed at elucidating preferences and perceived importance of various features in apps that could be utilised by patients with type 1 and type 2 diabetes, regardless of the use of insulin as part of the management therapy. The first question that was on a dichotomous scale (Yes or No) inquired about the current use of apps to manage diabetes. Those who indicated ‘No’ were requested to specify reasons for non-use while those who answered in the affirmative were asked to specify the features available in such apps. The second question assessed participants’ preferences on a list of app features and allowed multiple responses. The third question evaluated the perceived usefulness of various app features to support diabetes management. These features were rated on a 10-point scale with ‘‘1=least useful and 10=most useful’’, so that higher rating indicates greater perceived usefulness. Descriptors for intermediate points within the range were excluded to avoid clustering of scores around a preferred descriptor. App was defined as any program downloadable to a smart phone, which is used to support any aspect of diabetes management to foster improved health outcomes for the user. It could either be lifestyle oriented such as those for tracking diet and exercise or patient oriented for blood glucose or blood pressure monitoring. The instrument was reviewed among a diverse team of researchers with expertise in survey development in order to ascertain its readability and ease of understanding, and was revised based on feedback obtained. The instrument readability was further accessed with the Flesch Kincaid readability test (Flesch, 1948) producing a reading score of 61.8, indicating the instrument is well comprehensible, consistent with standard English that is easily understood by an eighth or ninth grade level student or one who has attained 13 years of age or above (Flesch, 1948). The instrument was administered in English Language.

Qualitative approach

Semi-structured telephone interviews were conducted with a subset of participants who responded to the questionnaire. To recruit participants for the interviews, a final question was added to the questionnaire asking for interest in a telephone interview aimed at further exploration of opinions on the use of apps to support DSM. Interest was indicated by providing a phone number and suitable contact time. No additional incentive was offered to interview participants. A standardised text message was sent to all phone numbers provided to confirm interview schedules. All interviews were conducted in June, 2018 by a resource person who was independent of the research team (designated as the interviewer, who is a male researcher with prior experiences in qualitative research and interview facilitator). The interviewer (AD) was trained on the aims of the study and the interview guide by MDA. Additionally, a pilot session of the interview was conducted between AD and MDA. The interviewer had no prior relationship with the participants and the interview sessions was conducted in a secure, private room at the James Cook University, Australia. Prior to the commencement of each interview session, participants were asked if they were in a location that was convenient for the interview. Interviews were conducted in English and MDA was present during the first three interviews to listen to the interactions between the participants and the interviewer and to ensure appropriate data acquisition. There was no previous relationship or interaction between MDA and the participants. Data saturation was achieved at the end of the 12^{th} interview, that is, the information was deemed sufficient as there were no new response patterns identified by the interviewer at this point. However, interview sessions with all consenting respondents (16) were completed in order to allow rich documentation and to ensure no point was accidentally missed. Repeat interviews were not required. Given that participants' location to the research site was remote, we were unable to return data transcripts to participants for comments.

The interview questions (See **Appendix 4.2**) were developed and iteratively reviewed by the research team. The notion behind the development of the questions was to seek recommendations on components and factors which patients considered important to continually stimulate their interest in the regular use of apps. Based on the fact that health technologies are voluntary use systems, therefore, the extent of engagement with them is determined by users' perceived quality of experience, ongoing benefit of usage (Lalmas, O'Brien & Yom-Tov, 2014), and consideration of viable alternatives to using the technology (Bickmore, Schulman & Yin, 2010). Furthermore, the development of questions on specific educational topics which could be incorporated into diabetes apps was informed by these reasons: (i) gaps in the literature which shows that most of the currently available diabetes apps are lacking in educational component (Chomutare et al., 2011; Izhar et al., 2017, Adu et al., 2018a) and (ii) the ability of apps to meet self-management needs (diabetes education fosters self-care); which could subsequently motivate users' engagement with apps (Woldaregay at al., 2018).

Ethical considerations and consent

Approval for the study was granted by the Human Research Ethics Committee of the James Cook University (H7087). Submission of the survey responses implied consent to participate in the quantitative phase of the study while verbal consents were obtained for the telephone interviews and recordings.

4.3.2 Data Analyses

Quantitative data analysis was done using SPSS version 23 (IBM, Armonk, New York, US). Continuous variables were reported as means and standard deviations (SD) while categorical variables were reported as percentages. Chi squared test for independence and ANOVA were used for group comparisons involving categorical and continuous variables respectively. Statistical significance was set at $p < 0.05$

For qualitative data analysis, each interview was digitally recorded and the duration ranged from 7 to 20 minutes. Audio files were professionally transcribed by an individual with privacy certification and reviewed for completeness. Raw data files were imported to QSR Nvivo 11 for open coding and analysis. Emerging themes were identified using an inductive thematic analysis approach in order to ensure rich description of the data set (Braun & Clarke, 2006). The thematic data coding followed six phases as described by Braun and Clarke (2006). (1) Familiarising with the data through reading and re-reading the transcripts to make meaning of participants' responses; (2) generation of initial codes; (3) initial coding to identify emerging themes; (4) review of identified themes; (5) refining theme names and (6) documenting the findings and presenting illustrative quotes from participants' responses to support each theme. All phases of the thematic coding were completed by MDA. To establish the trustworthiness and credibility of the data, BMA was involved in phases 2-6 of the thematic analysis. Data were cross-checked in a consensus meeting; there was an 80% agreement between both researchers and discrepancies were resolved through discussion and mutual agreement. Both MDA and BMA have prior methodological training and experiences in conducting qualitative research. The remaining two researchers also checked the codes and themes to ensure consistency. Illustrative quotes were appended with a combination of number code and the type of diabetes the respondent has (for example ''P4, T1D''). Quotes which included marketed names of apps were not reported verbatim for commercial reasons. The final manuscript was reported according to the COREQ criteria for reporting qualitative research (Tong, Sainbury & Craig 2007).

4.4 RESULTS

4.4.1 Participant Characteristics

A total of 245 respondents attempted the survey. Twenty-eight responses were excluded due to missing data (19) or ineligibility where the type of diabetes was not stated (9), leaving a total of 217 complete responses for the analyses. Participants' mean age was 44.65 (SD 11.51) and ranged between 18-76 years. They were predominantly type 2 diabetes (61.8%), females (55.7%) and were diagnosed with diabetes within the previous 1-5 years; (40.1%). Further demographic and health details are provided in **Table 4.1**.

Table 4.1. Demographic and health characteristics of survey respondents

	Study Participants (N=217)	
Characteristics	**n**	**%**
Gender		
Male	94	43.3
Female	123	56.7
Age (Years)		
18 - 29	27	12.4
30 - 39	64	29.5
40 - 49	41	18.9
50 - 59	46	21.2
60 - 79	39	18
Education		
High School	44	20.3
Technical College	41	18.9
Bachelor Degree	60	27.6
Post Graduate degree	62	28.6
Others	10	4.6
Continent		
Australia	75	34.6
Europe	76	35
Asia	64	29.5
America	2	0.9
Employment Status		
Employed	148	68.2
Unemployed	36	16.6
Retired	33	15.2
Type of Diabetes		
Type 1	83	38.2
Type 2	134	61.8
Duration of Diagnosis (Years)		
< 1	27	12.4
1-5	87	40.1
6-10	44	20.3
11-15	16	7.4
> 15	43	19.8

For the telephone interviews, initially 31 respondents indicated interest to participate by providing phone numbers on completion of the survey. However, due to subsequent decline, only 16 respondents participated in the phone interviews. Respondents were predominantly males; 56.2% (9/16), Australian residents; 87.5% (14/16) and have type 1 diabetes; 62.5% (10/16). Their ages ranged from 26 to 61 with a mean of 44.56 (SD 11.51) years old.

Use and non-use of apps.

Less than half of the participants (106/217, 48.8%) used apps to support their health management, where blood glucose tracker (60/106, 56.6%), blood pressure tracker (55/106, 51.9%) and food calorie counter (51/106, 48.1%) were the mostly used features. The remaining 51.2% (111/217) of the respondents did not use apps to care for their diabetes. Major reasons for non-use were ‘‘lack of awareness’’ (52/111, 46.8%) and ‘‘disinterest’’ (37/111, 33.3%) in the use of apps (See **Table 4.2** for details).

Influence of participant characteristics on the use/non-use of apps.

App use was significantly influenced by demographic/health characteristics. Individuals more likely to use apps tended to be younger (p=0.00), have type 1 diabetes (p=.002), resident in Asia (p=0.00), employed (p=0.001) and have higher educational level (p=0.00) than their counterparts in their respective demographic domains.

4.4.2 Preferences for app features and perceived usefulness

When asked to indicate the features they would prefer in a new app for DSM, major participant inclinations were towards apps with information on nutrient value of foods (56.7%), blood glucose tracker (54.8%), physical activity tracker (47%) and visual analytics to view trends in health status indicators (42.9%). Furthermore, interests were expressed in apps that provide either general education on diabetes self-management (40.6%) or personalised education in response to logged blood glucose data (40.1%).

Participants’ ratings of perceived usefulness of app features to support diabetic’ health management were highest for blood glucose tracker (mean 8.35 [S.D 2.03]), food nutrient counter (mean 7.73 [SD 2.32]) and fitness/exercise monitor (mean 7.37 [S.D 2.29]). Apps for social networking among people with diabetes (mean 5.96 [S.D 2.99]) had the lowest rating. (See **Table 4.2** for details).

Table 4.2. App use, preferences and perceived usefulness of app features to support diabetes management

Variables	n	%
Usage of app [N=217]		
Yes	106	48.8
No	111	51.2
Features in currently used apps [n =106]		
Blood pressure tracker	55	51.9
Blood glucose tracker	60	56.6
Food calorie counter	51	48.1
Fitness/exercise monitor	50	47.2
Body weight monitor	35	33
Transfer of health data to doctor	20	18.9
Reminder (e.g take medication, BG[a] monitoring)	38	38.6
Others[b]	10	9.4
Reasons for not using app [n=111]		
Not interested	37	33.3
Lack of awareness	52	46.8
Do not have a smart phone	12	10.8
Lack of access to the internet	8	7.2
Expensive	10	9
Missing	10	9
Preferred features / functions if offered a new app [n=217]		
Food nutrient composition	123	56.7
Blood glucose tracker	119	54.8
Body weight tracker	79	36.4
Physical exercise tracker	70	32.3
Task reminder	70	32.3
General education on diabetes self-management & complication prevention	88	40.6
Personalised advice /education in response to logged BG data	87	40.1
Visual Analytics (view trends of logged data)	93	42.9
Data export to Doctor or other health team members	75	34.6
Social networking among people with diabetes	54	24.9

Apps feature ratings	Mean	SD
Blood pressure tracker	6.64	2.7
Blood glucose tracker	8.35	2.03
Fitness and exercise monitor	7.37	2.29
Body weight monitor	6.93	2.45
Task reminder	6.71	2.56
Export of data to health care team (e.g doctor)	6.91	2.7
Social networking	5.96	2.99
Food nutrient composition	7.73	2.32

[a]Blood glucose

[b]bolus insulin dose calculator, heart rate monitor, apps for continuous glucose monitors

Influence of participant characteristics on preferences for app features

App feature preferences were not influenced by type of diabetes. Affirmative response rate for each of the suggested app features varied between 25-48/83 (30.1-57.8%) for those with type 1 diabetes and 28-76/134 (20.9-56.7%) for those with type 2 diabetes. The most commonly preferred feature by all participants was food nutrient composition (56.6%, 47/83 for Type 1 diabetes and 56.7%, 76/134 for Type 2 diabetes). Also, 54-123/217 (24.8-56.7%) of all respondents had an inclination towards each of the various suggested features, irrespective of diabetes type.

4.4.3 Recommendations to Foster Long-Term Engagement with Diabetes Apps

Four themes emerged from the interview based on recommendations to foster long-term engagement with diabetes apps. The themes include: (1) improved functionalities (exciting and new recipes, actionable goals with convenient reminder), (2) certified and reliable information sources (social networking, research and news update), (3) consolidated and customised features, (4) ease of use. The themes and subthemes are reported below with representative quotes.

Theme 1: Improved functionalities

Subtheme 1.1 - Exciting and new healthy recipes: Participants commonly advised that essential attributes which could foster their engagement with apps that support healthy eating was for such apps not to offer just suggestions on suitable food recipes for people who have diabetes, but that the recommended recipes are also delectable:

"Some ideas about recipes to brighten up my day, because turning food into just fuel I think is just terrible. Although, we do have to kind of trim off some lavish recipes, but that doesn't mean it has to be eating cardboard". [P3, T2D]

Some participants want healthy eating support by apps to include assistance with shopping:

"I was thinking like- just look up something. If you are in the supermarket and you decide what you're going to buy, if I haven't prepared my menu, it would be nice not just to rely on memory all the time and be able to look up something (in the app), like something different to make". [P8, T2D]

Additionally, many participants felt that when apps provide nutritional information not only on various conventional foods but also on rare foods, this could stimulate their continual use.

"The aspect with just kind of having all available, so more not so common foods and you can virtually put any product in (the app) and it will split out the nutritional table". [P9, T1D]

Subtheme 1.2 - Actionable goals with convenient reminders: Most of the participants said, they would be highly attracted to engage with the use of apps for their self-management if its' reminder feature can be complemented with actionable instructions on how to accomplish behavioural goals of DSM.

"My anxiety and stress levels are high around the time of my menstrual period, so I find my sugar levels difficult to manage around that time…So if an app could connect to my CGM and

sort of warn me about those days. So if those could be tracked and I could be given a reminder thing like, okay, you need to cool down, you need to go for an extra session of meditation, or you need to run a little bit more during this time, that would be helpful". [P11, T1D]

A participant who identifies as a software developer gave specific examples of how apps could provide actionable reminder.

"Actionable knowledge that nudges me on the key items which helps me to succeed. For example, I've been messing around with the idea of building an app that geofences the bad places that you shouldn't eat. I mean first of all, geofence every single [Name of an American fast food company], so right from the moment you walk into them, it pings up and say you don't really want to be here…ordering this food, this is a bad thing, at this time". [P3, T2D]

"*It can be listen, I've looked at the number of steps that you walked and you need to do… go for a walk at lunch time otherwise, you're not going to do and you know you that you've got to do something active for at least 30 minutes a day to help your diabetes*". [P3, T2D]

Nevertheless, some participants commented that in the event that a user is unable to immediately review a behavioural data prompted from an app, it is necessary that users are able to turn off such prompting to attend to it at a more convenient time.

"*Because you don't always want to be nagged by these things. Sometimes that sort of prompting-I mean there are apps that will automatically remind you, if you had a low blood glucose they might go, they might check back in and they might remind you in half an hour, or you might be able to set an optional reminder, to check again and make sure it is resolved. But you don't want any of that functionality to be so hard wired that you can't turn it off, because sometimes it's not convenient just at the moment. You know you might be in a meeting or you just never want to be nagged like that*". [P14, T1D]

Theme 2: Certified and reliable information sources.

Subtheme 2.1 - social networking: In multiple instances, participants, particularly those who have type 1 diabetes, emphasised that interfacing of apps with social forums would be appealing. They would like to make social connections using apps, through which they can access role model narratives of stories from other individuals who had overcome salient obstacles in DSM. Participants believed that social networking in apps could serve as a motivator for long-term engagement as well as an opportunity to receive information on problem-solving.

"*I think personal experience would be a massive thing. If I could sit down and read someone else's story and how they've gone from what I'm at now, like with minimal control, to being on top of it. It would be awesome to hear from someone that's done it, to give me a belief that I can do it. An app could be the only way to sort of get that connection ".* [P12, T1D]

Participants further explained that apps linked to certified information sources would equally serve the similar purpose of providing a platform for accessing problem solving techniques in diabetes management.

"For apps to be able to make connections to other information sources will be good. So if for example, that you-it was a logging app and it could be seen that the frequency of low blood glucose had increased this month…., may be you may be directed out to resources that might help someone think about why that is. You know, either, peer-to-peer resources or respected kind of academic resources on ways to manage whatever the challenge is". [P14, T1D]

Subtheme 2.2 - Research and news update: Many participants with type 1 diabetes requested that apps should serve as a resource for news update on ongoing developments in diabetes management. The participants want an app to function as a platform to seek out information whether in form of recent research, technology, medication or treatments which could further improve diabetes care.

"Good information on the latest technology or when the next pump is going to be approved. Am constantly looking for something that is going to make it (diabetes management) easier. It can go in there (into an app) and it's going to tell me what's waiting for FDA approval or what's the latest thing". [P1, T1D]

"In particular, the latest research and things they are implementing in recent times. So the latest news on use of medications and even new treatments would be fabulous (in an app)". [P7, T1D]

Theme 3: Consolidated and customised features

Subtheme 3.1 - Data consolidation: Consolidation of data from peripheral health devices used by patients into a single app was also an important consideration. Participants frequently mentioned that getting merged data would provide a unified record view.

"So it's got to be integrated completely into the health data in the phone. It can't be a stand-alone. It's got to be sharing data with everything else, so that if I look at my consolidated health chart collected by the app, say, how much I drank and may be the total sugar count I've consumed, I kind of want to see the (combined) data collected". [P3, T2D]

Also, participants' felt that when data are consolidated, clear meaningful outputs will be provided which will remove the barrier of deciphering the relationship between the data provided on each of the various health devices.

"*Well, it's actually linking all the information together. I'm on a Continuous Glucose Monitor. I'm on a pump and I have the Fitbit. Trying to link all these three things together is impossible.*

What I would like is for all the information to correlate with each other and be able to see it potentially on a single page". [P4, T1D]

Some participants noted that non-interdependency of data from various health devices is difficult to manage especially for people with low education and may discourage their use of app.

"*You know, you've got products like (''name of app'') and (''name of app'') for booking doctors' appointments. So I've got the (''name of app'') managing my CGM, I've got insulin pump managing my insulin injections and telling me how much carbs I've had to how much I need. Then, I've got different system to manage doctors and different systems to manage my carb counting. So, it's complex and if you're not literate enough to be able to use your phone in that way, then it's a big negative. So you could have that integrated solution*". [P2, T1D]

Subtheme 3.2 - Customised features: Participants with type 1 diabetes stated that the ability of apps to adapt to changes in users' requirement could encourage adoption and enhance engagement. Participants indicated that they would like to engage directly with specific functionality they desire to use per time without interruption by other functionalities which may be present in the same app.

"*I think the thing to bear in mind is management and management strategies vary significantly from person-to-person. If you have an app that's got 15 functions, each individual person might really only use six or seven of these. For example, I've got no interest in calorie at all and some other things and someone might be really interested in keeping track of their blood pressure. Again it's not something am particularly interested in. So the fact that it (the app) supports that is great but for me I'd want to be able to turn that entry thing off on the screen so I haven't got to keep scrolling past stuff am never going to be using. So, it's the tailorability, it's making it flexible really"*. [P14, T1D]

Additionally, inability of apps to adapt to the needs of a user could serve as a barrier to usage.

"Less amount of clicking stuff you've got to do on the app, I suppose would be beneficial. I like getting my tester out and all that stuff. Then having to go into an app where I'd have to go through 30 different things to find what I'm looking for would be more of a hindrance than what it would be to not just use it at all". [P12, T1D]

Theme 4: Ease of use - Several of the participants pointed out that simplicity of usage and limited time consumption by apps are major determinants for their engagement with the app. For example, a participant explained his view on these facts by giving reasons for abandoning a specific app for the other:

"I was formerly using (''name of app''). I just couldn't get it so I stopped using it. So the one I use now (''name of app'') as a carb counter is just a bit easier to use and not too time consuming". [P1, T1D]

Apps' ability to save and display previously logged data will also limit the time requirement for use:

"Apps that remembers what you have put it,…because you will probably find that we eat a lot of same foods all the time but having to re-enter that in as a new-entry every single time is a bit of pain".[P2, T1D]

4.4.4. Specific Educational Topics Desired in Future Apps to Support Diabetes Self-Management

Three major topics emerged from participants' responses to the question on areas of diabetes management, which may be embedded as educational information into apps. The topics were approaches to problem solving, basic guidelines for the management of diabetes (transitioning from paediatric to adult care, signs of acute and chronic complications of diabetes) and the use of insulin pump therapy.

Theme 1 - Approaches to problem-solving: Majority of the participants proposed that apps should provide information on specific steps to take in response to challenges posed in the self-management of diabetes. Specifically, respondents expressed their desire for apps to offer education on possible strategies for problem resolution when logged blood sugar data are out of the clinically recommended range.

"I think you need to potentially---if someone puts in low blood sugar or a high blood sugar, you need to give directions on what they need to do…whether you need to have more insulin or if you are low, you need to have 15g of carb.. just pointers like that would potentially help people's management longer term". [P4, T1D]

Furthermore, automating the problem solving suggestions, with the inclusion of information on the health consequences of blood glucose levels per time was recommended by respondents as echoed in the quotes below.

Just putting in whatever the blood sugar reading might be, and it could come back with ways to help me with that". [P8, T2D]

"Let's say I did a pinprick (blood sugar) test and I had a reading that was odd, I would like to see what the implications of that is". [P8, T2D]

Theme 2 - Basic guidelines for the management of diabetes mellitus

Subtheme 2.1- Transitioning from paediatric to adult care: Participants with type 1 diabetes indicated that the inclusion of information to augment their knowledge of self-management during the transitioning phase from paediatric into adult diabetes care would be helpful. Participants find this phase of life to be difficult, thus, they mentioned that providing encouragement/teaching for self-management skills via an app may help to answer some of the mind-boggling questions they have about their management.

"I think mainly, issues when you become a bit older. So, it's just that middle section, I found it quite difficult going through transition, so from probably about 18 until about 30. So information as you leave adolescence into adulthood. Also, going into pregnancy, there are a lot of questions I've kind of like asked out of curiosity to my endocrinologist about pregnancy, which I was quite shocked at the answer". [P9, T1D]

Subtheme 2.2 - Signs of acute and chronic complications of diabetes: Many participants noted that apps having information on the signs of acute and chronic complications of diabetes would further create awareness about the disease and the importance of self-management.

"I think it would definitely be beneficial to have (information) on the problems and complications. Like what problems you will face before you face the major complications, so you sort of know what to look out for and what to be aware about". [P12, T1D]

The importance of the reliability of all provided information in apps was also emphasised.

"From a lot of people that I've spoken to, everyone get different information from different doctors…doctors have got medical view which they must pass across and they've got their own personal view. So I would say, it's got to come from the Australian standard, you know medical view of diabetes". [P6, T1D]

Theme 3 - Use of insulin pump therapy: Provision of guidance on insulin pump therapy through apps was highlighted by many participants with type 1 diabetes. The participants enunciated that having adequate knowledge on how to set a pump to deliver the right amount of insulin (especially bolus rate) could be challenging. Therefore, they expressed that having information on the use of insulin pump therapy in apps would be beneficial to foster the attainment of a stable blood glucose levels.

"Something like (when to deliver boluses on insulin pump). I mean, it's potentially something that is quite hard to do…even when you have a pump before a meal is actually not really good

thing to do because your insulin starts working at the same time you are eating. If you dose 15 minutes or 30 minutes before you eat, you then don't get a peak because you've got your insulin working at the same time as the food is being digested. That sort of stuff- long-term for a person with diabetes, I think is critical so you are not going up…you are not doing the rollercoaster". [P4, T1D]

It was further stated that guidance on physical exercise and insulin dose adjustment when using a pump therapy would be helpful. Participants want apps to provide direction on administration of basal insulin relative to glycaemic levels in order to reduce or prevent hypoglycaemic events.

"So my experience about 6 months ago was that I started exercising and after 15 minutes of crunches I hit a 3 from 10 sugar level. I had my pump disconnected at that point. So I've been a little scared to get back to that. So in this scenario, it would be helpful if I sort of then put my sugar level in (an app), when I've exercised last or how am feeling at this point and I'd get at least an idea of whether I should continue to use the pump or disconnect it altogether". [P11, T1D]

4.5 DISCUSSION

A mixed methods study (online survey and telephone interviews) was conducted with a diverse pool of participants who have type 1 or type 2 diabetes. The online survey focused on obtaining information about the use and preferences for app features, which could support DSM. The interviews provided recommendations on how to foster long-term engagement with apps that support diabetes management and the educational topics, which could be included in such apps.

App use and preferences

Statistics on current app uses (48.8%) and mostly used app features (food calorie counter, blood glucose and blood pressure tracker) are in congruence with previous studies (Lithgow, Edwards

& Rabi, 2017; Conway et al., 2016). Monitoring of blood glucose and blood pressure are important to attain diabetes management goals. Therefore inputting these data into apps may encourage personal reflection and reveal out-of-range values in need of urgent treatment.

The current study also echoes the findings of previous surveys which reported that usage of apps was mostly seen among individuals with type 1 diabetes, those of younger age, high educational level (Boyle et al., 2017) employed and resident in Asia (Guertler et al., 2015). These observations confirm that socio-demographic characteristics of individuals especially the age, level of education and income status have a strong influence on their digital health use (Lustria, Smith & Hinnant, 2011; Kontos et al., 2014; Carroll et al., 2017). Additionally, eHealth literacy (the potential to accurately interpret health data obtained from mobile health devices) has a direct correlation with the aforementioned socio-demographic characteristics (Cho, Park & Lee, 2014), thus, may also be responsible for the app usage trends observed among the sub-groups in this study.

Contrary to the findings of other studies on app use among people with diabetes (Shibuta et al., 2017; Kayyali et al., 2017), a larger proportion of the respondents in this study do not use apps, primarily due to lack of interest and awareness. Given that most patients with chronic diseases often regard regular tracking of their health as an additional burden (Ancker et al., 2015), it is unsurprising that lack of interest was a major reason for not using an app. It is therefore important that apps are unambiguous, provide clear information on the specific health benefits for patients and at the same time are intuitive enough to stimulate interest in usage. Furthermore, since the use of apps offer great potential to support DSM, clinicians may promote and create awareness about apps to patients through their unique role of providing health recommendations to their patients (Gagnon et al., 2015).

Interestingly, the type of diabetes participants had did not influence their choice of app features. Preferences and ratings were highest for information on nutrient content of foods and capacity to track blood glucose. This result is expected since healthy eating and regular monitoring of blood glucose are important self-management domains for people with type 1 and type 2 diabetes in order to ensure healthy life (Shrivastava, Shrivastava & Ramasamy, 2013). Due to the direct impact of food on blood glucose levels, monitoring carbohydrate and calorie intake is imperative to maintain optimal glycemic control (Franz et al., 2010). Therefore, people with diabetes may benefit from apps that help with nutritional tracking in order to assess the impact of foods on blood glucose levels. Another app feature highly preferred by the participants was visual analytics that could present behavioural and health data progress in a graphical format. This feature increases the level of awareness and encourages accountability for self-management behaviours (Winters-Miner, 2014; Giroux et al., 2014) and provides support for healthy lifestyle decisions (Garabedian, Ross-Degnan & Wharam, 2015).

Recommendations to foster long-term engagement with Apps

Ye and colleagues (2018) reviewed about 1050 apps from the Google play and iTune stores and observed that more than 70% of these apps were designed to support healthy eating mainly with components for 'carbohydrate count' and 'diet tracking'. The present study shows that participants advocated for more comprehensive diet management features in future apps, comprising of nutrient data base of both the common and rare foods, and recipes for tasty foods which are suitable for people with diabetes. Patients' access to ideas on diverse food varieties via an app, will prevent monotonous dieting and subsequently may foster motivation to maintain a healthy diet and keep track of foods eaten and at the same time boost engagement with the app.

As voiced by the participants, future diabetes apps could include reminders for self-management behaviours which are accompanied by advice on realistic actionable steps to attain those behaviours. App developers could ensure that the proposed actions are simple and instinctively written in plain language, because these are the key factors to attaining health literacy (Stableford & Mettger, 2007). Additionally, in such suggested steps, users should be able to find what they need, understand what they find and act on it (United State Government, Plain Language Action and Information Network, 2010).

Participants with type 1 diabetes recommended the inclusion of community/social forum in apps and this is worth considering by app developers. Type 1 diabetes is usually diagnosed at a younger age, its management could be quite complex, and requires lifelong daily health commitments. Providing social support for type 1 diabetes patients may improve treatment adherence by encouraging optimism, which can mitigate the stress of living with the illness and accompanying depression (DiMatteo, 2004). App developers could design apps that offer peer interactions among individuals who share common health experiences (Heisler, 2007). Such social networking features may foster a sense of connection, serve as an essential social support system for patients to be more aware of the importance of DSM and learn new practical and effective ways for health maintenance. Nevertheless, it is important that patients who use social support features in health apps are reminded not to rely heavily on advice from other users or substitute such information for regular check-ups with their health care providers.

Furthermore, consolidation of data from peripheral devices into app (as proposed by participants), if done appropriately eliminates redundancy and provides data portability. Although in reality, meeting this need will be difficult and may face some challenges particularly when data streaming are from health devices developed by different companies. Such challenges will include which developer will be responsible for the accuracy, reliability, security and compliance with privacy regulation of the consolidated data. This may be the reason why data has remained confined to their respective platforms and integration with other health devices has been very limited (Chiauzzi, Rodarte & DasMahapatra, 2015).

Earlier studies on the use of smartphone apps for health-care have reported ease of use and simplicity as strong determinants of technology acceptance (Kayyali et al., 2017; Crane et al., 2017) and our study corroborates this finding. Hence, in order to maximise patients' uptake and long-term engagement with app resources, app developers need to facilitate easier maneuvering through apps menus as a means of reducing the burden of time consumption on users (Rao et al., 2010).

Customisation of apps in an adaptable way to match the interests, needs or habits of their respective users was another key point raised by the type 1 diabetes participants in this study. This proposition might have been influenced by participants' awareness of the highly individualised demand for self-management of type 1 diabetes (Smith & Harris, 2018). Customising apps features such as personalised alerts modified to users' specific needs and preferences may promote the required behavioural change (Klein et al., 2017) and engagement with the app (Juruascio et al., 2015).

Educational topics in future apps

Problem solving may be a difficult area of diabetes management hence the suggestion by many participants for the inclusion of tips on problem solving in diabetes apps. Problem solving in diabetes management is a learned behavioural process comprising a set of potential solutions to problems, selecting the most appropriate solution, applying the solution and evaluating its effectiveness (Hill-Briggs, 2003). Problem solving is the foundation upon which patient attainment of the remaining self-management behaviours (For example, healthy eating, monitoring, reducing risk) are built (Mulcahy et al., 2003). Also, there exists a direct correlation between problem solving and improvement in glycosylated hemoglobin (HbA1c) level (Hill-

Briggs & Echemendia, 2001; Glasgow et al., 2007), therefore it is important that patients receive additional support in this area. The support will involve development and incorporation of diabetes specific problem-solving measures into apps. Nevertheless, it should be noted that in some situations, apps may not be able to provide effective support to resolve health dilemma in people with diabetes because there may be too many variables in the decision making process needed to address certain challenging areas of self-management, therefore requiring direct interaction between a patient and the clinician or diabetes educator (Ye et al., 2018). Moreover, meeting this particular patients' desire should be handled with caution as diabetes management is uniquely complex, so the use of a single problem solving idea to serve all patients may not be feasible or applicable to some areas of diabetes management.

Personalised or general education is currently available in only a few diabetes apps (Chomutare et al., 2011; Izahar et al., 2017), and participants of the current study, requested for its inclusion in apps. There is ample evidence that patients retain little of the education provided at clinic visits (Kessels, 2003). Since, mobile devices have become ubiquitous in educational settings, they can give expanded opportunities for users to access health information anywhere or double check knowledge (Wallace, Clarke & White, 2012; Payne, Wharrad & Watts, 2012). Embedding apps with education and behaviour change techniques can complement instructions provided face to face by health care team members. However, apps that focus on provision of diabetes education should consider the medical accuracy of their content.

Practical implications

Patients' recommendations observed in this study demand thoughtful considerations from designers and developers to build mobile apps that best meet the identified patient preferences and propositions. Based on the findings of this study, apps with features on documentation (blood glucose and physical exercise log), reminders (with actionable notifications), advisory (educational information), analytics (view trends in behavioural and health data indicators) and comprehensive nutritional data base are proposed to strengthened the functionality of apps and foster long-term engagement and better health outcomes for people with diabetes. In addition, it is recommended that the educational information in these apps are related to problem solving and basic guideline for DSM.

Meeting the recommendation for future apps to include a data consolidation system across several peripheral health devices will require careful consideration of existing privacy regulations as this is one of the factors contributing to a lag in data interoperability (Chiauzzi, Rodarte & DasMahaptatra, 2015). Furthermore, the concept of providing a link to social support groups also warrants consideration especially if the app is targeted at people with type 1 diabetes although, social support can also promote self-management behaviours in those with type 2 diabetes. Lastly, it is important to ensure ease of use and limited time consumption in the developed app in order to further promote engagement.

It is imperative to evaluate the functionality of developed and operational apps based on experimental pilot studies and large randomised controlled trials (RCTs), which are essential next steps to ascertain patient engagement with the app. This will offer the opportunity to investigate if user engagement can be guaranteed if they (users) are provided with apps that offer the type of features they 'ask' for. These experimental studies should aim to integrate app interventions seamlessly into the daily routine of end-users so that app usage is not perceived as an extra chore.

Strengths and limitations

Firstly, this study was able to quantitatively characterise the social and health demographic profiles of adults with type 1 or type 2 diabetes in relation to their use of apps and feature preferences. Secondly, through a qualitative approach, it provided information on educational topics which could be included in apps to support DSM, in addition to ways to foster adoption and engagement with such apps. To the best of our knowledge, obtaining the information described above in a single study has not been attempted before. Thus, by using a mixed method design which offers the opportunity to comprehensively address the research questions and provide a clear picture of how to meet the research goal; this study fills important knowledge gaps, adds to the body of science and provides direction for future development of functional apps for DSM. The reliability of the study findings is further strengthened by the fact that participants were asked to indicate their preferences and provide recommendations for a future diabetes app and not on an already developed app. This affords them the convenience to give their candid opinion without the agitation of negatively criticising the work of a developer/investigator.

The findings of this study should be interpreted with the following limitations. Firstly, due to the cross-sectional nature of data collection which was done at one point in time, it is possible that people with diabetes may vary their preferences and recommendations for future diabetes apps over time especially due to evolving nature of digital technology. Secondly, generalisation of the findings to other settings might be limited due to the sample size/groups, which mainly comprised of participants from three continents whose responses might have been influenced by cultural or geographic differences. The inclusion of more participants especially from other continents might have led to the emergence of other results. Thirdly, it is worth noting that the quantitative part of this study did not access the differences in preferences of participants based on the use/non-use of insulin as part of their treatment regimen. Participants' preferences for app features may be influenced by their treatment therapies. Fourthly, more themes and topics may have emerged if the interview duration was longer. Given that no additional compensation was offered to interviewee, short interview duration was utilised to foster increased participant numbers as long interview may not be justifiable for participants' time involvement in the study''. Nevertheless, literature has also shown that telephone interview sessions are usually shorter than face-face interviews. Additionally, even when data saturation was observed at the 12th interview, all the 16 respondents were interviewed to ensure no point was accidentally missed. Lastly, the survey responses were based on self-report and therefore may be subjective to responder's bias.

4.6 CONCLUSION

This study will serve as a useful guide for researchers and developers of future apps aimed at diabetes self-management because it highlights the importance of involving end users in the process of developing the content and features that appeal to them. Perceived importance and preferences were higher for app features that could support healthy eating, blood glucose and physical activity monitoring; provide data analytics and diabetes education. Recommendations to foster long-term engagement with diabetes apps have been described via four themes: improved functionalities (exciting and new recipes, actionable goals with convenient reminder), certified and reliable information sources (social networking, research and news update), consolidated and customised features, and ease of use. Additionally, patients are interested in apps embedded with educational information on problem solving techniques, use of insulin pump therapy, signs of diabetes complication and prevention as well as transitioning from paediatric into adult care.

Overall, this chapter addressed the third aim of this thesis by highlighting the perceptions of type 1 and type 2 diabetes patients in relation to features and educational contents in apps that will foster retention and engagement with diabetes self-management activities. The results of this chapter provide evidence of the unmet app feature needs and support the development of a novel app that best meets these needs. These results were prioritised and utilised in the design of the novel mobile diabetes app in Chapter 5.

Chapter FIVE: The Development of My Care Hub Mobile-Phone App to Support Self-Management in Australians with Type 1 or Type 2 Diabetes

5.1 ABSTRACT

Non-adherence to self-management poses a serious risk to diabetes complications. Digital behavioural change interventions have the potential to provide education and motivate users to regularly engage with self-management of diabetes. This paper describes the development of My Care Hub mobile phone application (app) aimed at supporting self-management in people with type 1 or type 2 diabetes. The development of My Care Hub involved a comprehensive process of health behavioural change identification, end users' needs, expert consensus, data security and privacy considerations. The app translation was a highly iterative process accompanied by usability testing and design modification. The app development process included: (1) behaviour change strategy selection; (2) users' involvement; (3) expert advisory involvement; (4) data security and privacy considerations; (5) design creation and output translation into a smartphone app and (6) two usability testings of the app prototype version. The app features include self-management activities documentation, analytics, personalised and generalised messages for diabetes self-management (DSM) as well as carbohydrate components of common foods in Australia. Twelve respondents provided feedback on the usability of the app. Initially, a simplification of the documentation features of the app was identified as a need to improve usability. Overall, results indicated good user satisfaction rate.

5.1 BACKGROUND

More than 1.1 million Australians have type 1 (12%) and type 2 (85%) diabetes (Australian Institute of Health and Welfare, 2019c). Poorly controlled diabetes increases the risk of chronic complications (Alberti & Zimmet, 1998). Diabetes self-management education (DSME) and support are effective interventions to assist patients navigate through decision making processes for participation in self-management activities necessary for improved glycemic control (Henrich, Schaper & de Vries, 2010) and reduce the risk of developing complications (Powers et al., 2015b). Self-management support could be educational, behavioural, psychosocial or clinical (Haas et al., 2012). Providing ongoing support to patients could mitigate disease related distress, improve adherence to recommended self-management activities and consequently enhance health outcomes (Norris et al., 2002; Haas et al., 2012) but this practice has proven difficult in a real-world context (Kennedy et al., 2014). Provision of self-management support through the use of smartphone may help address health system level limiters which impact negatively on the frequency and quality of self-management support patient receives. Such limitations include time constraints, limited access to care providers (Wilkinson, Whitehead & Ritchie, 2014) and partial cost reimbursement by third party health insurance (Piette, 2007).

Smart phone is a ubiquitous technological device with more than 2 billion users worldwide (Statista, 2019a) and over 16% of 6 billion mobile subscriptions are smartphone subscriptions (MobiThinking, 2014). In Australia, the growth in smartphone usage has been sporadic. There is approximately 84% smartphone users among the entire population of mobile phone users in 2018, which is an increase from 74% in 2014 (Statista, 2019b). Most smart phone functionalities are aided by apps (software that are designed to run on smartphones), which could complement highly developed health care technologies and serve as supporting tools in many chronic disease management (Kay, Santos & Takane, 2011). Various apps have been developed to enhance self-management of diabetes (Quinn et al., 2011; Kirwan et al., 2013; Kim et al., 2014; Holmen et al., 2014; Waki et al., 2014). However, most apps have no reference to health behavioral change models or scientific evidence-based theories (Waki et al., 2014; Quinn et al., 2011; Kim et al., 2014). Additionally, considerations of target users' preferences (Waki et al., 2014; Quinn et al., 2011) and data privacy input (Norri et al., 2002;

Kim et al., 2014), are minimal or totally absent in apps. Furthermore, some lack educational information, which is a crucial component of diabetes care, to foster coping skills for ongoing self-management in patients and improved health (glycaemic) outcomes (Kim et al., 2014; Holmen et al., 2014).

Objective

Emerging evidence support the use of smartphone apps for DSM (Quinn et al., 2011; Kim et al., 2014; Waki et al., 2014). However, there remains paucity of information in relation to the description of the development processes and design of smartphone apps interventions, leaving unanswered questions about how to productively leverage apps for DSM (Adu et al., 2018a). Adequate description of the development of interventions could decrease waste in health research and enhance better organised synthesis of study results (Hoffmann et al., 2017; Adu et al., 2018a). Vivid explanation of study process will promote wider dissemination of research findings and improve the rigour and quality control of published research (Munafò, 2016). In addition, explicit reporting of intervention development can allow external scrutiny of its plausibility when later used in trials and help evaluators and policy makers decide which context to prioritise for future replication (Moore et al., 2015).

On the other hand, assessing usability occupies a central part of app development (Zaid, Jamaludin & Wafaa, 2012). A well designed app with high usability positively influences users' engagement (re-use rates) (Eysenbach, 2005). Conversely, poor usability is associated with low effectiveness and engagement (Eysenbach, 2005; Whitlock & McLaughlin, 2012). To the best of the authors' knowledge, there is no published full report of the systematic development of a diabetes smartphone app targeting Australian population before use in trials. Therefore, this paper reports a full description of the development and usability testing process of an app named ‘‘My Care Hub’’ prior to use in a pilot trial. My Care Hub was developed as an app to best meet the needs of type 1 and type 2 diabetes patients in the provision of preferred features and diabetes educational contents which could foster incremental knowledge gain, skills, self-efficacy and motivate patients to actively engage with self-management activities.

5.2 METHODS

An initial systematic review (Adu et al., 2018a) by the authors highlighted the importance of five essential factors that needed consideration in the diabetes app development before actual use in a Randomised Controlled Trial (RCT). Specifically, the factors included involvement of users and clinical experts, health behavioural change theory employed, data security and privacy considerations, and pilot testing (Adu et al., 2018a). In practice, these steps overlap and are iterative. Herein, we describe how these steps were considered in the development of My Care Hub. The process of pilot testing is excluded because it is beyond the scope of the present paper. Additionally, this paper describes the features and functionalities available in My Care Hub and the usability testing of its prototype. All activities conducted during the pre-development, development and testing stage of the app are described.

Ethical Consideration

This study was approved by the James cook University Human Research Ethics Committee (H7087, H7285). Informed consent was obtained from all participants involved in the usability testing of My Care Hub. All methods were performed in accordance with the relevant guidelines and regulations.

5.1.1 Stage 1: Pre-development

Users' involvement

A user centered design process was utilised in the development of My Care Hub. An iterative process addressing people's needs and the enabling infrastructure to meet those needs constitute the central focus of a user centered design approach (The International Organisation for Standardisation, 2010). People with type 1 or type 2 diabetes were the primary target users of My Care Hub, hence their involvement in the development process, in order to gather information and ideas for appropriate design and educational content of the app. We performed a need analysis study among a multinational audience of people with type 1 or type 2 diabetes using a mixed methods study design (*currently chapter 4 of this thesis*) (Adu et al., 2018b). The study elucidated diabetes patients' app feature preferences and explored their recommendations for inclusion to promote engagement with My Care Hub diabetes app. The result indicated that both patient groups desired apps that featured documentation (blood glucose and physical exercise), advisory information (educational), analytics (view trends in behavioural and health data indicators), reminders (with actionable notifications) and food nutritional database. Furthermore, patients desired educational information on approaches to problem solving when blood glucose data were out of the clinically recommended range. Basic guideline information for DSM was perceived to be highly beneficial. Full details of the findings of the needs analysis study have been published (Adu et al., 2018b).

Health behavioural change theory

Maximising the potential efficacy of health behavioral change interventions in humans requires an understanding of the theoretical models or mechanisms that underpin such behavioral changes (Davis et al., 2015). An extensive literature search of behavioural change theories (Michie et al., 2008) was adopted to make informed decision in the development of My Care Hub. This provided the opportunity to identify the best interventional techniques (and the underlying theories) that are likely to be effective in a DSM app. The first technique considered was self-monitoring; an important intervention that fosters adherence to self-management and driven by self-efficacy construct of the social cognitive theory (Bandura, 2001; Bandura 1998). Self-efficacy refers to confidence in a person's ability to take action required to implement situation specific behaviours in order to attain specific goals (health outcomes) (Bandura, 1999). Self-efficacy forms the ‘‘major basis for action’’, occupies a pivotal regulatory role in the causal structure of self-management and perseverance to continue even when barriers are encountered (Bandura, 1999. Hence, improving self-efficacy through task related activities such as self-monitoring increases the confidence and persistence towards accomplishing the task (Barling & Beattie, 1988). On this basis, it *was* decided that My Care Hub should provide users with a platform to create daily entries and monitoring of their health behavioral activities.

Although self-monitoring is an important feature in behavioural interventions, patients' adherence to self-monitoring alone is often low, especially when not accompanied by another intervention which could further enhance self-efficacy (Mishali, Omer & Heymann, 2011). High attrition rates when self-monitoring activities are the only intervention features in diabetes apps have been reported (Kirwan et al., 2013; Holmen et al., 2014; Guertler et al., 2015). Therefore, sole-reliance on self-monitoring features in an app may limit its effectiveness and use to only those who are personally motivated to self-monitor regularly. Consequently, it was considered important to include other essential interventional features such as provision of information and feedback in My Care Hub.

Components of educational information and feedback in health behavioural interventions are best developed using Information-Motivation-Behavioural Skills (IMBS) model (Fisher et al., 2011; Fisher, Fisher & Harman, 2003). The IMBS model has several constructs pertaining to patient adherence to recommended health behaviours. Primarily, the self-management information needs to be easily actionable in order to enhance optimal care. In addition, the information should provide basic knowledge about the relevant medical condition and effective management strategies. Users also need to be provided with encouraging and motivational feedback and recommendations in order to boost their confidence and enhance their ability to achieve desired health behavioural changes (Bandura, 1994; de Bruijn, 2010). Reinforcing healthy behaviour significantly improves self-efficacy for participation in self-management activities (Williams & French, 2011). Furthermore, inclusion of behavioural skills which ensure patients are provided specific strategies on how to perform the adherence behaviours (diabetes self-management activities - e.g. choosing appropriate foods, problem solving for low/high blood glucose) are important to enhance effective self-management. Lastly, IMBS model indicates that strategies aimed at increasing patients' knowledge are prerequisites for behavioural change but not sufficient enough to sustain the change (Mazzuca, 1982). Therefore, such information should be coupled with motivation to increase the possibility of adherence.

The IMBS constructs were employed in the development of three educational information modules embedded in My Care Hub. These modules were: general information on diabetes management, automated feedback in response to logged blood glucose and carbohydrate contents of foods. These modules were aimed at improving patients' knowledge, skills, self-efficacy and provide specific directions for fostering patients' adherence to ongoing self-management.

Data security and privacy considerations

Several security features and privacy policies in the design and development of mobile health apps (Morera et al., 2016) were followed. Authorization and authentication of users to assess the app was controlled, whereby the first user interface after the app download is a login screen. The screen requires a user to enter an assigned unique username (email address) and password in order to gain access to the app features. Authentication verifies user session handling for future research and ensures that the server is not vulnerable to injection attacks (Lin & Chen, 2007; Osawaru & Habeeb, 2014). Protection of data transfer from My Care Hub to cloud storage was ensured through encryption that makes the data illegible, unusable and indecipherable to unauthorised persons (Osawaru & Habeeb, 2014). My Care Hub was built on a proprietary personal health (PHR) platform using Firebase (Moroney, 2017) and it has no connection or interaction with third party health information systems. In accordance with the ‘‘Australian Privacy Principle’’ (Office of the Australian Information Commissioner, 2014), the services of an independent legal firm was employed to develop a comprehensive legal document pertaining to legal agreement, terms of use and privacy policy. The document describes how My Care Hub manages personal information, data collection, usage and storage. The legal document was incorporated into My Care Hub app for easy accessibility by users.

Expert advisory group

An expert advisory group comprising diabetes educators, endocrinologists, health researchers and app developers worked as a team to make decisions regarding My Care Hub. Implications of the users’ needs analysis study findings (Adu et al., 2018b) and effectiveness of identified health behavioural change interventions were discussed by the team. Results were prioritised, adjusted and refined before a final agreement on the selection of My Care Hub features, design and content in order to meet the requested needs of users as much as possible.

5.2.2. Stage 2: Design and Translation of Pre-Development Output into a Smartphone App

1. Development of My Care Hub Prototype

App developers within the eResearch Team at James Cook University (JCU), Queensland, Australia developed the prototype. The purpose of the app was to serve as a tool for monitoring self-management activities, providing access to information and aiding motivation to engage with DSM. These purpose were adequately met by providing opportunity to users to monitor and track their core health behaviours (weight, physical activities and carbohydrate contents of the foods consumed) and vitals (blood glucose); and have easy access to three streams of diabetes educational information: (i) an overview of diabetes management, (ii) problem solving related and motivational feedback on logged blood glucose data, and (iii) information on carbohydrate contents in foods. To ensure that the app is usable by both types 1 and 2 diabetes patients, the feedback took into consideration the different recommended blood glucose values.

Initially, a visual skeletal framework of the app was created and subsequently used to develop the prototype. The framework comprised features, educational content, lay out, and interfacing of the app functionalities. The app was developed in Java in order to run on Android Platform. The resulting prototype was thoroughly examined and tested to ensure that all specified requirements were incorporated into the app for optimal functionality.

2. Features and Functionalities of My Care Hub

My Care Hub contains the following features: selection of type of diabetes, My Info, documentation, View insights, Carbs in foods and educational tips. Description of each of these features are provided below and a screen shot of the features in My Care Hub are provided in **Figures 5.1a-d and 5.2a-d** below.

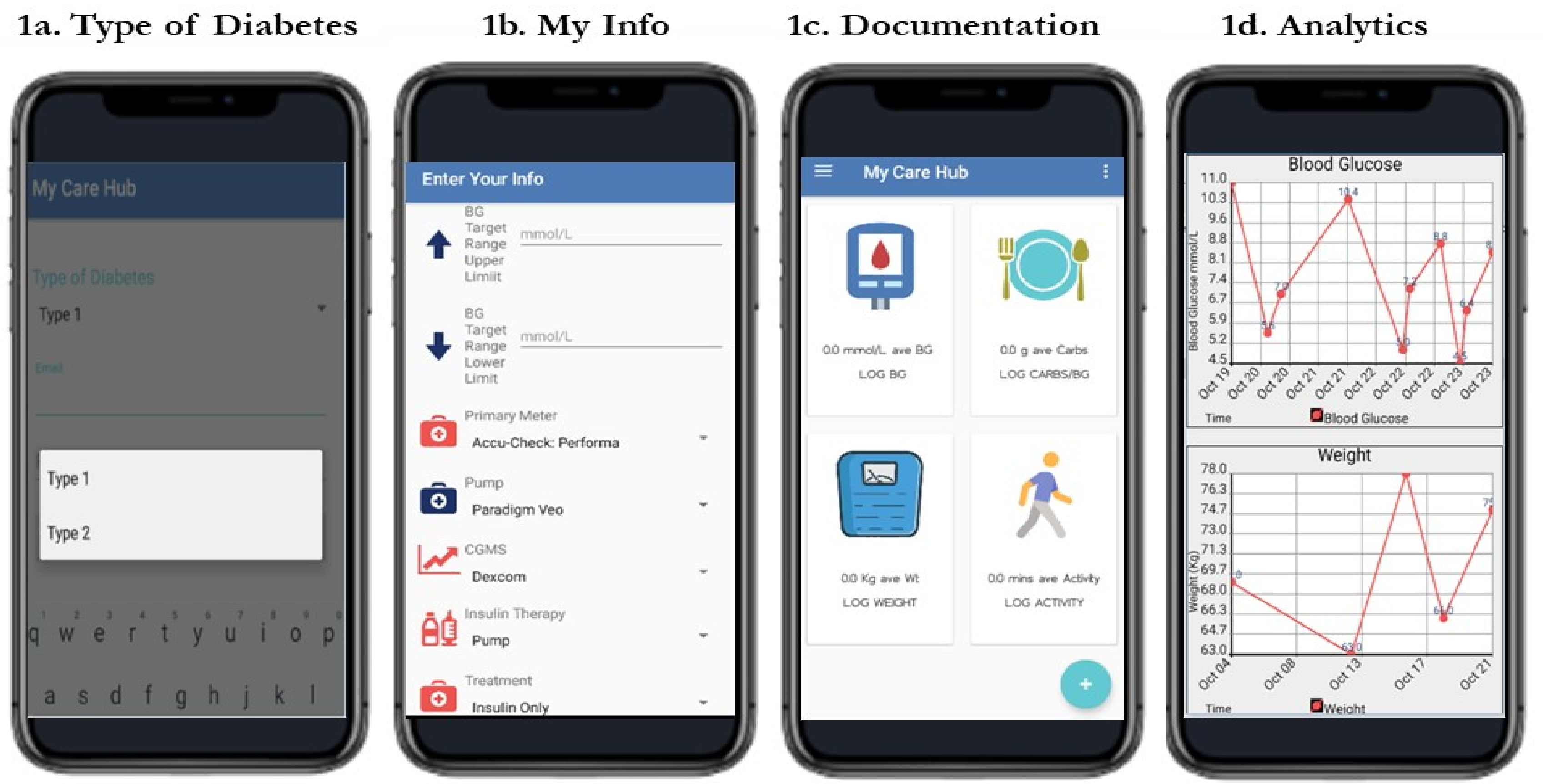


Figure 5.1a-d: My Care Hub Screen Shots

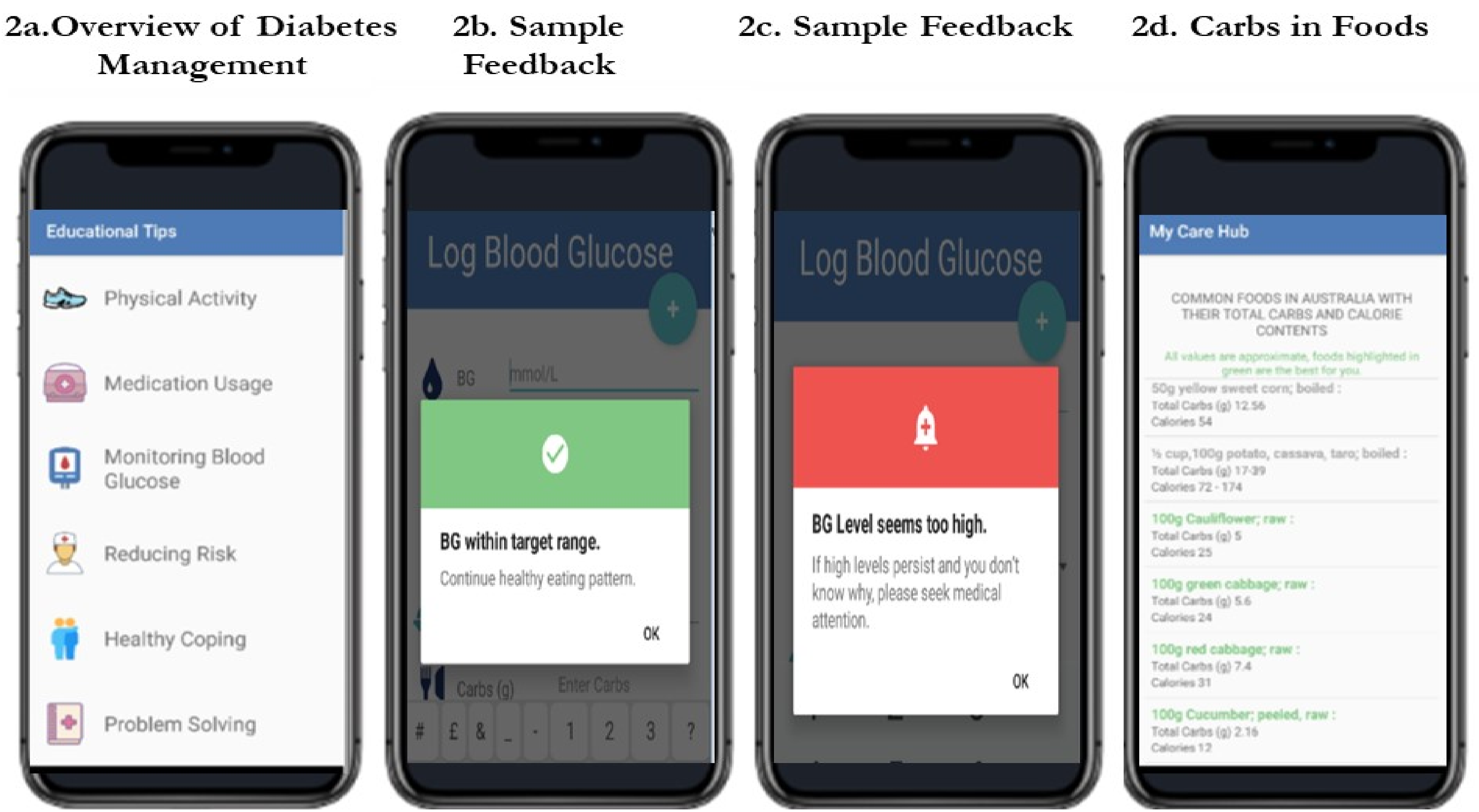


Figure 5.2a-d: My Care Hub educational modules screen examples

Type of DM: This feature is displayed after the user has downloaded, installed and registered the app on their smart phone. The user is then required to choose the type of diabetes they have (**see Figure 5.1a**) in order to determine the type of feedback to be received when blood glucose data are logged.

My Info: This feature gives the user the choice to set up a profile to document their treatment details. Users can indicate their treatment specifics such as recommended blood glucose targets (upper and lower), types of medication (oral only, oral plus insulin, insulin only or none) and types of blood glucose meter, insulin pump, continuous glucose meter, if applicable. Profile set up may also include personal details such as gender and height (see **Figure 5.1b**).

Documentation: The home screen of My Care Hub (**Figure 5.1c**), displays all its documentation features for logging of self-management activities including blood glucose, body weight, physical activities and carbohydrate content of foods consumed. The actual date and time of logging is automatically set and users have the option to record the activity location. For the blood glucose (BG) interface, the type of BG data measured (either fasting or post hours post breakfast, lunch or dinner) can be selected from a drop menu and saved.

View insights: This analytic feature provides users with graphical display of all data logged through the documentation features (**Figure 5.1d**). It also takes the average of all data logged into each of the documentation features over a period of seven days and displays the mean on the homepage in form of summary feedback. This enables patients to visualise trends in lifestyle activities (especially physical activity and carbohydrate content of foods) and observe the impact on blood glucose levels over time (Winters-Miner, 2014), thus fostering the ability to adjust their self-management strategy accordingly.

***Educational modules*:** My Care Hub comprises three educational modules:

a. Overview of diabetes management: The app contains textual information on the seven essential self-management activities for people with diabetes. These activities predict good health outcomes: lifestyle modifications (healthy eating and improved physical activity), monitoring of blood sugar, complying with medications, good problem-solving skills, healthy coping skills, and risk-reduction behaviours (such as smoking cessation and reduction in alcohol intake) (Tomky et al., 2008) (see **Figure 5.2a**). The messages were designed to be action-oriented, create awareness about associated benefits and provide engagement suggestions. The messages were written in plain language to enable users find, interpret and act on findings (Stableford & Mettger, 2007). **Table 5.1** depicts examples of app messages under each of the vital self-management activities.

Table 5.1: Examples of app messages

Category	Message
What is diabetes?	Diabetes results from inherited and/or acquired deficiency in insulin production or by the ineffectiveness of the insulin produced.
	In a diabetic state, insulin function is impaired, therefore the body needs conscious help to manage blood sugar by eating right, exercising, taking medications appropriately and reducing stress.
Health food choices	Stay motivated to eat healthy. When new foods are eaten, testing of blood sugar before and 2 hours after the first bite is recommended in order to see the effect of the food on the blood sugar.
	Vegetables are rich in fibre, make you comfortably full, have vitamins for healthy immune system and most likely not spike your blood sugar level.
Physical activity	Exercise improves bone strength, keeps the heart and blood vessels healthy and lowers insulin resistance.
	Exercise does not have to involve the whole day. You can split it up into 10 minutes, 3 times a day at a convenient period for you.
	If you are on insulin and planning for prolonged exercise, if your blood sugar level is below 6mmol/L, it is advisable to eat an extra carbohydrate.
Medication usage	Some diabetes medicines can lose effectiveness if they are old or stored improperly. For example, insulin should not be frozen or exposed to extreme heat.

	If you often forget to take your medications, setting a reminder or alert may help you.
	Do not inject insulin on moles or scars because it slows absorption rate and limit insulin effectiveness.
Monitoring blood glucose	Some of the important times to test blood glucose include before breakfast (fasting), 2h after a meal, before rigorous exercise, before bed, when you are not feeling well.
	Regular testing of blood sugar improves confidence to look after diabetes, give a better understanding of the impact of food intake, medication, exercise and other factors such as stress and illness on blood glucose.
Reducing the risk of complications	Keeping appointment with the eye/foot doctor, endocrinologist and other health care team is a great way to detect on time any complication development.
	Smoking increases the risk of developing acute and chronic complications in diabetes mellitus.
	Keep your foot healthy by checking regularly for any changes, washing daily and wear shoes that fit properly. In the occurrence of unexplainable blisters, cuts or openings, it is best to consult your doctor immediately.

b. Feedback: My Care Hub includes an algorithm that provides automated feedback messages in response to logged blood glucose (BG) data. It assesses if the logged BG data are within or outside the clinically recommended range and provides appropriate encouragement or advice. This feature was founded on relevant evidence-based literature and Diabetes Australia recommended BG level guidelines (Diabetes Australia, 2015) for appropriate and accurate feedback. For people with type 1 diabetes; 4-8mmol/L at fasting and < 10 mmol/L 2 hours postprandial BG levels were recommended. Fasting levels of 6-8 mmol/L and 2 hours postprandial levels of 6-10 mmol/L were endorsed for people with type 2 diabetes.

A range of evidence-based, motivational, health promotional and behavioural skills information were developed as feedback on BG levels recommended for both type 1 and type 2 diabetes. Decision based system rules were programmed into the app to ensure that users receive semi-individualised feedback based on their logged data. The system is controlled by the indicated type of diabetes, value of BG (whether within or beyond the clinically recommended range) and the period of BG measurement (either fasting or 2 hours postprandial). Once BG data are logged, the app delivers a brief feedback. If the BG is within the clinically recommended range, the app delivers messages to encourage the patient to continue with regular self-management. Such messages include: ‘‘Excellent; BG within target range, continue your medication as prescribed’’, and ‘‘Excellent, BG within target range, continue with healthy eating’’). It has been demonstrated that providing motivation and encouragement after attaining a goal can enhance self-efficacy (William & French, 2011) which in turn, facilitates health behavioural changes in disease control (Holloway & Watson, 2002). If the logged BG are outside normal range, the app offers suggestions related to problem solving for low or high BG as deemed appropriate. For instance, if logged BG is less than 4 mmol/L, sample feedback includes: ‘‘BG levels seems too low, this may occur when medication is not balanced with food and physical activities’’, and ‘‘you are at risk of hypoglycemia; treat immediately’’. If BG values are extremely aberrant to the normal range (over 15 mmol/L), messages such as ‘‘if high levels persist and you don’t know why, seek medical attention immediately’’ are triggered. Messages are unidirectional and displayed using colour labels, where green, orange and red indicate ‘‘ideal’’, ‘‘not ideal’’ and ‘‘extremely low or high’’ BG levels, respectively (see **Figures 5.2b and 5.2c**).

(c) Carbohydrates in foods: This feature comprises textual information about carbohydrate and calorie components of common foods in Australia sourced from the Australian Food, Supplement and Nutrient database (AUSNUT 2011-13) (Asutralian NewZealand Food Standards, 2019). Some commonly available foods were selected for this database and organised under four main groups: fruits and vegetables; eggs and meat; diary; and legumes and grains. Portion sizes and approximate carbohydrate and calorie content were provided for each food item. For example, 1 slice (40g) of whole wheat bread contains 20.56g of carbohydrates and 111 calories. Foods with low glycaemic index were displayed in green colours as healthier models for consumption by those who have diabetes (Rizkalla et al., 2002) (see **Figure 5.2d**).

Functionalities and features for future research: To facilitate future research, export of the logged data into a cloud storage for all documentation features, date and time of log-ins were enabled for downloading as comma-separated value files into our database for subsequent statistical analysis. Furthermore, the app platform offers analytics of users' logged data and includes cloud and in-app messaging features to allow for push notifications. These features will provide additional educational messages for future research.

5.3.3. Stage 3: Usability Testing

Usability testing of My Care Hub was done in two stages:

1) Members of the public who do not have diabetes were randomly selected for early testing strategy to ascertain the technical performance of the app and to identify any navigation issues when downloaded on various android phones. The app's functionality and aesthetic usability testing by users was over a period of 7 days. Using convenient and snow balling sampling methods, twelve participants (app testers) were individually contacted and provided with information about My Care Hub and the ultimate aim of its development. The primary inclusion criterion was access to an android phone since the app was developed on an android platform only. Specific tasks required of the app testers included app download and registration; daily log-ins of random numbers into the documentation features (no limit was set to the amount of data to be logged into the app) and a read through the educational information about DSM embedded in the app. Tasks further include observation of the automated feedback messages in response to each logged BG, examination of the graphical outputs of all the documentation features and general browsing of the app. Any data crash or lag time in the app response during

launching and usage, screen "swiping", using the slide out keyboard and apps touch screen buttons were also monitored. Each tester was contacted via email and provided with a unique user-name, password and app download instruction. Only testers who signed into and used the app were provided with a link to the online survey questionnaire items adapted from the mobile app rating scale (Stoyanov et al., 2015) (see **Appendix 5.1).** Testers were asked to rate the app's functionality (performance, ease of use, navigation, gestural design) and aesthetics (layout, graphics, visual appeal of the analytic display). In addition, open-text-comment boxes were provided to gather information related to any concern or observations during the testing period. The results from this first stage of usability testing was used to improve the app prototype before the second stage was completed.

2) The second stage of testing recruited participants who had diabetes from the diabetes center of a tertiary hospital in Queensland, Australia, and through snow balling. Participants were asked to use My Care Hub and provide feedback using a questionnaire. In addition to functionality and aesthetics of the app, they also provided feedback on their satisfaction using measures that included perceived usefulness of the app to motivate participation in, and increase awareness of, diabetes self-management, intention to use, perceived ease of use and accuracy of the educational components of the app. Furthermore, they were asked if they would recommend the app to people with type 1 or type 2 diabetes and give an overall rating of 1-5 with ''1= one of the worst apps I have ever used'' and ''5 = one of the best apps I have ever used''.

Results

Demographic and health characteristics

Of the 12 testers without diabetes, only eight (8) signed into the app. In the second stage of testing, 6 individuals with type 1 or type 2 agreed to test the app, but only 4 signed in. Time constraint was cited by the 6 people who withdrew from the testing as reason for non-participation. Feedback was provided by the remaining 12 participants (8 non diabetes + 4 with diabetes) who downloaded and used the app. The mean age of participants was 43.08 ± 14.02 years (range 28-76 years) and 58% of them were women. More than 75% were married and had obtained an educational level of first degree or higher. Of the four participants who have diabetes, three of them had type 2, one of them was diagnosed less than 5 years ago, while the remaining 3 had been diagnosed over 5 years. None of them reported hypoglycemia unawareness. Three of the four participants reported that their recommended range of fasting blood glucose was 4 to 7 mmol/L, with a postprandial of 5 to 9 mmol/L. The remaining one participant who had type 2 diabetes did not provide any information on this.

Usability result

In stage one of testing, all participants but one, were able to easily learn the use of the app following instructions provided via email. This one participant expressed an initial difficulty in operating the app by providing free text comment in the survey. Locating and learning how to use the documentation features took time, hence the suggestion to include a video recording of the instructions in addition to the already developed instruction manual for future users. Although, it was only one participant that indicated difficulty in using the app, it meant 13% of the participants had potential usability issues in relation to layout and ease of use. Therefore, based on the results of the first stage usability testing, minor modifications were made. In the prototype, accessing the documentation features required users to tap on a menu bar located on the top left corner of the app's homepage (which may not be apparent to users). The current version provides an improvement with an additional access via the app's homepage through direct taping on the icons of the documentation features.

In the second stage of testing using individuals with type 1 or type 2 diabetes, all the four participants were able to use the app easily. Across all participants (12), majority were satisfied with the performance of the app in terms of how fast the app features and components work (50% chose ‘‘perfect/timely response’’, 41.7% ‘‘mostly functional’’, 8.3% ‘‘app work overall, slow at times’’). Several participants were able to navigate between app screens and features easily (66.7% ‘‘perfectly logical and clear screen flow throughout’’, 25% ‘‘easy to use’’) and felt that interactions across all tabs in the app were consistent and spontaneous (41.7% ‘‘perfectly consistent and spontaneous’’, 50% ‘‘mostly consistent and spontaneous’’). Many participants were satisfied with the arrangement and size of icons/contents in the app (66.7% ‘‘mostly clear’’, 33.4% ‘‘professional, simple, clear and logically organised’’) and the quality of graphics was high/very high. With regards to the general visual appeal of the app and the analytic feature, 83.3% participants chose very high/high level of visual appeal for both domains. The app was given a five and four-star rating by 8.3% and 91.7% respondents respectively.

Among the four participants with diabetes, 75% of them strongly agreed that they saw value in the educational content of the app as it was relevant and likely to raise awareness of the importance of DSM. 75% strongly agreed that the app is likely to increase motivation of people with diabetes to engage in self-management activities. Furthermore, 75% noted that they would recommend My Care Hub to people with type 1 or type 2 diabetes and that they can continue to use it if granted continual access to the app.

5.3 DISCUSSION

This paper follows the principle of intervention development study report which details ‘‘the rationale, decision making processes, methods and findings from the inception of the intervention to the usability testing prior to full trial or evaluation’’ (Hoddinott, 2015). To the best of the authors' knowledge, My Care Hub is arguably the first DSM app aimed at Australian population with type 1 or type 2 diabetes to have reported / documented a systematic and transparent approach to its development based on empirical and theoretical framework of health behavior change theories, involvement of users and clinical experts, data security and privacy considerations (Adu et al., 2018a).

Behavioural theory is critical to the development of health behavioural change interventions (Campbell et al., 2007) because interventions grounded in theory are more effective at modifying behavior (Michie et al., 2008; Craig et al., 2008). Health behavioural theories predict how applying an intervention will drive change in underlying behavioural mechanisms or technique (mediating construct) that will in turn, drive behavioural change (output) (Michie et al., 2008). Majority of currently available diabetes app are lacking in health behavioural content (Cowan et al., 2013; Adu et al., 2018a), which may be an early indication of the low potential of such apps to influence behaviour long-term (Craig et al., 2008). My Care Hub is grounded in two major theories of behavioural change: Social cognitive theory (Bandura, 1998) and Information-Motivation-Behavioural Skills model (Fisher, Fisher & Harman, 2003; Fisher et al., 2011). Diverse constructs were employed within these theories; hence, giving My Care Hub the potential for effectiveness when eventually used as an intervention in trials.

Specific features and educational content in My Care Hub were chosen based on users' needs and preferences (Adu et al., 2018b). This is an added strength of the app which is often lacking in many health apps that are developed without considering the needs of the end users or guidelines for the management of such diseases (Chomutare et al., 2011; Holtz & Lauckner, 2012). Development of an intervention to meet the actual needs and demands of targeted users assures the feasibility of the product (International Organisation for Standardisation, 2010). Previous reports show that only few diabetes mobile apps incorporate elements of clinical best practices established by diabetes professionals (Bradell & Ford, 2013). Blood glucose level guidelines recommended by Diabetes Australia were consulted during the development of feedback messages provided in My Care Hub in order to ensure clinically sound information is provided to the patients. Providing relevant feedback is an important strategy to stimulate reflection in patients about their blood glucose goal and to engage them in healthy behaviours necessary for optimal health outcomes (Lie et al., 2018).

Data privacy and security in mobile health interventions are vital to intervention development, relevance and acceptance of such technology (Wilkowska & Ziefle, 2012), therefore, health apps must be protected from security breaches. This was ensured in My Care Hub. The multi-stage usability evaluation method applied to My Care Hub have better propensity to capture the complete usability of a technology in comparison to a single method (Georgsson & Staggers, 2016; Cho et al., 2018). First stage of testing revealed important changes to the app design in order to improve the ease of access to user interface. Similar to our findings, participants in studies assessing the usability of mobile apps for DSM had commented positively on the performance and ease of navigation of the app (Georgsson & Staggers, 2016; Booth et al., 2016). Furthermore, good level of satisfaction reported by our participants in relation to the app graphics, layout and visual appeal has also been reported in previous studies (Georgsson & Staggers, 2016; Schmocker, Zwahlen & Denecke, 2018). End users saw value in the app as a tool to support DSM and expressed interest in continuing to use the app in the future.

Strengths and limitations

The strengths of this study include a full description of the development process of My Care Hub - an app aimed at the Australian population with type 1 or type 2 diabetes as opposed to the reports of only efficacy and effectiveness of diabetes apps within RCTs in the published literature (Adu et al., 2018a). In our systematic review of previous RCTs using a diabetes app as an intervention, none of the studies provided detailed information about their developmental process (Adu et al., 2018a). The need for full description of the intervention development strategy, including detailed explanation of how important factors of health behavioural theories, users and clinical expert involvement, data security and privacy were used to guide the development process has been met in our current study. Not only is the use of two distinct approaches to usability testing unique in providing effective development guide and strategies for future apps, the results from both phases also allow for identification of pertinent issues from a general and targeted populace of app users. Usability testing of the app at this stage and not later during feasibility testing is essential for identifying improvement needs prior to full studies to secure future engagement with My Care Hub by patients with diabetes.

A limitation of this study is that the participants in the usability study may not be representative of the target population due to low sample size. Nonetheless, studies have shown that large sample sizes are not required in usability studies, as they do not propose inferential results. Therefore, the number of participants involved in the usability testing of My Care Hub in this study, may have been sufficient to identify usability issues in the app, which may occur under conditions of regular use (Macefield, 2009). Another limitation is that only some of those who initially agreed to test the app eventually did so. This may have introduced selection bias wherein only participants interested in the use of an app downloaded and signed into it and provided feedback. It is possible that we could have drawn different conclusion if all the initial participants had used the app. However, in reality, research outcomes are not free of either opinion or bias because they are highly subjective (Six & Macefield, 2016). In addition, although, the app needs analysis results indicated that patients will like an app that reminds them of their self-management activities, currently My Care Hub app does not have this feature. This is because upon prioritisation and consideration, we felt inclusion of a reminder feature might further increase the complexity of the app. In its' present version, the app entails a variety of features, therefore an addition of reminder feature (which ideally will be needed for each of the diabetes specific tasks) will increase the app's complexity. Studies have reported a significantly negative correlation between number of app features and ease of use (Arnhold, Qualde & Kirch, 2014). Nonetheless, upon ensuring that the app remains user friendly, inclusion of a reminder feature is a possible consideration for our future research. Lastly, given that no data was collected about the specifics of participants' android smartphone configurations, we were unable to assess the influence of such configuration on their responses to My Care Hub usability testing.

Future research

Future research includes pilot testing of My Care Hub as a key step for optimising an intervention before its evaluation in full trials (Eldridge et al., 2016). This pilot testing will provide valuable information on users' engagement, retention, acceptability and preliminary efficacy (Feeley et al., 2009) as well as the development of future versions of the app (if required) and design of future trials (Day, Bench & Griffiths, 2015).

My Care Hub is currently only available for Australians on Android operating system. The decision to make the app Australia-specific was based on the differences in the guidelines for recommended blood glucose levels between countries. There was the need to focus resources on developing a native app that could as much as possible provide a better user experience instead of including additional country specific requirements. My Care Hub presents a proof of concept and can be developed for other nations in order to reach a wider proportion of users, but there will be the need to modify the Australia-specific features of the app before it could be used elsewhere.

5.4 CONCLUSION

Detailed explanation of My Care Hub development was provided for future researchers to learn and understand the development process. My Care Hub has the potential to benefit Australians with types 1 and 2 diabetes in monitoring self-management activities. The app provides easy access to educational information and supporting tools, which could enhance knowledge, skills, self-efficacy and motivate patients to perform self-management activities to improve glycaemic control. An app such as My Care Hub developed based on the needs and preferences of its intended users maximises the potential to enhance self-management.

Essentially, this chapter addressed the fourth aim of this thesis by providing a full description of the novel app (My Care Hub) development. Usability testing results showed the app is user-friendly, intuitive and navigation was simple and easy to use. These results informed the final version of the app in the pilot testing stage (Chapters 6 and 7).

Chapter SIX: User Retention and Engagement with a Mobile App Intervention to Support Self-Management in Australians with Type 1 or Type 2 Diabetes (My Care Hub): Mixed Methods Study

6.1 Abstract

Mobile health apps are commonly used to support diabetes self-management (DSM). However, there is limited research assessing whether such apps are able to meet the basic requirements of retaining and engaging users. This study aimed to evaluate participants' retention and engagement with My Care Hub, a mobile app for DSM. The study employed an explanatory mixed methods design. Participants were people with type 1 or type 2 diabetes who used the health app intervention for 3 weeks. Retention was measured by completion of the post-intervention survey. Engagement was measured using system log indices and interviews. Retention and system log indices were presented using descriptive statistics. Transcripts were analysed using content analysis to develop themes interpreted according to the behavioural intervention technology theory. Of the 50 individuals enrolled, 42 (84%) adhered to the study protocol. System usage data showed multiple and frequent interactions with the app by most of the enrolled participants (42/50, 84%). Two-thirds of participants who inputted data during the first week returned to use the app after week 1 (36/42, 85%) and week 2 (30/42, 71%) of installation. Most daily used features were tracking of blood glucose (BG; 28/42, 68%) and accessing educational information (6/42, 13%). The interview results revealed the app's potential as a behavioural change intervention tool, particularly because it eased participants' self-care efforts and improved their engagement with DSM activities such as BG monitoring, physical exercise and healthy eating. Participants suggested additional functionalities such as extended access to historical analytic data, automated data transmission from the BG meter, and periodic update of meals and corresponding nutrients to further enhance engagement with

the app. The findings of this short-term intervention study suggested acceptable levels of participant retention and engagement with My Care Hub, indicating that it may be a promising tool for extending DSM support and education beyond the confines of a physical clinic.

6.2 INTRODUCTION

Mobile health (mHealth) apps offer a unique opportunity to deliver health promotion interventions to reach any population due to their ubiquitous nature (Payne et al., 2015; Zhao, Freeman & Li, 2016), with some developed specifically to support diabetes management (Chomutare et al., 2011; Arnhold, Quade & Kirch, 2014). However, these mHealth interventions suffer from low participant retention (Eysenbach, 2005; Kirwan et al., 2013) and non-usage attrition (Eysenbach, 2005; Kelders et al., 2012). Therefore, interventions that are more engaging are required to address these concerns (Short et al., 2015; Yardley et al., 2016) through user-centered and iterative approaches that integrate input from users and other relevant stakeholders in app design and development. This approach is necessary to provide interventions that meet user requirements and ensure greater retention, uptake, engagement, and sustainability (Arsand & Demiris, 2008; Yardley et al., 2016).

Retention

Inadequate participant retention is a major methodological challenge experienced by many mHealth app interventions (Murray et al., 2009). Low retention rates and lower statistical power threaten outcome validity (Eysenbach, 2005) and serve as a major reason for premature trial termination (Kasenda et al., 2014); hence, pilot studies are important before conducting large-scale studies. The evaluation of participant retention levels enables researchers to assess the relevancy and tendency for sustainable implementation of intervention ideas (Bowen et al., 2009). In addition, the assessment reveals any required research methodology modification in preparation for future large-scale research (Bowen et al., 2009).

Engagement

An effective mHealth intervention requires not only retention but also continuous and active engagement by users, as lack of engagement leads to study dropout and dampening of the treatment effect (Eysenbach, 2005; Murray et al., 2009). User engagement refers to interaction, experience, perceived usefulness, and desire to use the intervention repeatedly over a long period of time (Lalmas, O'Brien, Yom-Tov, 2014; O'Brien & Cairns, 2016). The degree to which users engage with a health app signifies their willingness to invest time, attention, and emotion into the use of the technology to satisfy and eventually achieve their pragmatic needs (such as self-management) (Lalmas, O'Brien & Yom-Tov, 2014). Measurement of users' engagement can be long- or short-term in nature with short-term measurement reflecting initial adoption of the intervention and the tendency of apps to successfully engage users in the long-term (Lalmas, O'Brien, Yom-Tov, 2014). Although, there are various approaches to measuring engagement with apps, system usage data and user-reported interactions with the system using specific techniques such as questionnaires and interviews are the most relevant in the context of short-term measurement (Lalmas, O'Brien, Yom-Tov, 2014; Wiebe et al., 2014; Yardley et al, 2016).

System usage is measured through the collection of non-invasive data on the frequency of access to the app, push notifications opened, and average time spent per usage (Burby, Brown & Commitee 2007; Perski et al., 2016). This provides information on user participation with specific target behaviours and frequency of access to the corresponding app features (Heerwegh, 2003; Stern, 2008). On the other hand, user-reported approaches reveal users' experiences related to behavioural engagement with the intervention (Lalmas, O'Brien, Yom-Tov, 2014; Weibe et al; 2014). This is necessary to assess intervention tendency to foster achievement of behavioural goals when used over a long period.

Behavioural Engagement Framework

Rate of use alone is not a sufficient indicator of engagement with a mHealth intervention (Yardley et al., 2016). There must also be an assessment of engagement with the behavioural goal of the intervention to ascertain the intervention's potential as an effective tool to support behavioural change. One possible way to achieve this is by assessing users' engagement with the process of achieving behavioural change. Behavioural change is fostered by intervention components that motivate users to achieve a behavioural goal [in this case, diabetes self-management (DSM) behaviours (Yardley et al., 2016)]. Assessing engagement in behavioural change process requires the use of models and frameworks that reveal the relationship between factors in a system for the realisation of a defined (Cole-Lewis, Ezeanochie & Turgiss, 2019).

Within the field of mHealth engagement, models and frameworks provide a richer understanding of the core components that influence user engagement to achieve the behavioural goal of the intervention (Cole-Lewis, Ezeanochie & Turgiss, 2019). The concept of behavioural engagement is complex and includes the extent to which users interact with the intervention. Major considerations include the quality of users' experience with the technology (O'Brien & Tom 2008), and if they have engaged with it as needed (Kelders et al., 2012) or as intended (O'Brien & Tom 2008). The behavioural intervention technology (BIT) model by Mohr et al., (2014) describes the full range of components that must be available in a technology to influence engagement with behavioural change and its potential as an effective intervention to attain a behavioural goal.

The BIT framework (Mohr et al., 2014) was utilised in this study as it describes the theoretical components necessary in the conceptualisation of mHealth and instantiates the necessary components for its implementation. The theoretical level covers the overall goal (*why*) or reason for mHealth development and *how* specific aims related to the goal could be achieved through the required *behavioural change strategies*. Each strategy is instantiated by *elements*:

features (*what*) available in the intervention. In addition, the *characteristics (technic)* of the intervention affect *how* an element is displayed to the users as well as their perception about the intervention. Finally, the *workflow (pattern of use)* describes *when* and under what conditions BIT interventions will be delivered. Therefore, the BIT model explains that achieving an intervention goal is fostered through relationships between the components *of aims, behavioral change strategies, elements, characteristics, and pattern of use* of the intervention (Mohr et al., 2014). We used this model to interpret our qualitative findings, allowing for an open approach to the concept of behavioural engagement, focusing on exploring the tendency of My Care Hub as an intervention tool for diabetes behavioural engagement.

Study Context and Objectives

Owing to poor retention and engagement with previous diabetes apps, we performed an initial study to explore user needs and preferences to foster engagement with a diabetes app (Adu et al., 2018b), which was used to develop a new app called My Care Hub (Adu et al., 2020a). Patients with diabetes who interacted with a prototype of My Care Hub reported that it was easy to use and that the educational contents were valuable in raising awareness about the importance of DSM and increased motivation to engage in self-management activities (Adu et al., 2020a). Although the usability of the app was satisfactory, it was unclear if My Care Hub has the potential to retain and engage users and if its components meet the requirements of a supporting tool to foster engagement with DSM.

Therefore, this study aimed to examine levels of user retention and engagement with My Care Hub in a short-term single-arm pilot trial. Retention was measured through completion of follow-up surveys, and engagement with the app was assessed in 2 areas: (1) system usage data and (2) qualitative feedback from users on behavioural interactions with the intervention. We expect that the app's contents and features (Adu et al., 2020a), which were developed based on results from our previous study on users' needs (Adu et al., 2018b; 2019) would result in high participant retention and greater engagement during the short trial period. Understanding these factors is critical in identifying areas where intervention design may need improvement and inform plans for future trials of mHealth interventions such as My Care Hub.

6.3 METHODS

This study received ethics approval from the James Cook University Human Research Ethics Committee (reference #H7716). Participants were informed about the study aims, and consent was implied by survey submission. Verbal consent was obtained for telephone interviews.

6.3.1 Study Design and Sample Size

This study utilised a sequential explanatory mixed methods design with quantitative surveys and qualitative interviews. This design captures both the engagement with technology and the process of behavioural change by triangulating the results of multiple measures (O'Brien, Cairns & Hall, 2018). This provides information about how users react to the contents and design of the intervention and offers an explanation for why users interact with the intervention in a particular way (Yardley et al., 2016). This study was conducted from August to October 2019, where each participant was given 3-week access to the app. Following this period, participants filled out a survey and were invited to participate in a telephone interview to better understand their interaction with the app.

The study used a maximum variation purposive sampling tailored to recruit participants who showed interest in the study within the time available. This sampling method is appropriate for an implementation feasibility assessment as related to this study (Leon, Davis & Kraemer, 2011). The components of the pilot testing that relate to retention and engagement with the app are presented in this paper.

6.3.2 Recruitment and Eligibility

Participants were recruited through a single invitation email sent to patients registered with the Australian National Diabetes Service Scheme. Email invitations were limited to patients who have type 1 or type 2 diabetes and live in North Queensland, Australia. North Queensland has a relatively high prevalence of diabetes (Queensland Health Report, 2018) and socioeconomic disadvantage, which can affect accessibility to regular diabetes support services (Australian Institute of Health and Welfare, 2020). Therefore, the use of mHealth interventions to provide DSM support may be essential among this population. Other eligibility criteria included ownership of an Android-operating smartphone, having a current recommended blood glucose level (BGL) target of 4 to 10 mmol/L (Diabetes Australia, 2015), and being aged 18 to 65 years. The upper age limit was chosen because of the less stringent glycaemic recommendations for many older adults who are above 65 years. Patients were excluded if pregnant or currently using an app with an educational component to support their diabetes management.

6.3.4 Enrolment and App Orientation

Participants enrolled through the Web by completing an eligibility screening form, providing consent, and completing the baseline survey, which entailed questions regarding socio-health demographics, email address, and residential postcode. Participants were emailed a unique code to enable them to download My Care Hub from Google Play store of any android-powered phone, an app manual, and a 5-min video explaining how to install the app, features, and functionalities. Participants could contact MDA for assistance with technical difficulties or for study clarification. It was emphasised that there was no limit to the frequency of use of My Care Hub as participants could engage with it at a level they considered useful and desired. My Care Hub is intended to be a stand-alone intervention. Therefore, push notifications (aimed at improving patients' awareness about diabetes distress and potential ways to reduce its impact on their self-management) were sent from the app during the first 2 weeks of the intervention and withheld in the third week to see the achievable level of engagement with the app with or without push notifications. Throughout the study period, no log-in reminders or calls were made from the study researchers to participants.

6.3.5 Intervention Overview

A detailed description of the development of My Care Hub and the methods of usability studies have been previously published (Adu et al., 2020a). In brief, the goal of My Care Hub is to provide support and education that facilitate positive behavioural change in DSM. The app was specifically designed for type 1 diabetes patients with standard Australian BGL recommendations of 4 to 8 mmol/L for fasting and <10 mmol/L 2-hour postprandial, and for type 2 diabetes patients with recommended fasting BGL of 6 to 8 mmol/L and 2-hour postprandial levels of 6 to 10 mmol/L. The app incorporates multiple functions and features to foster engagement with the app within 3 broad categories: *documentation*, *analytics*, and *education*.

In *documentation features,* users can manually input data for tracking BGL, physical activity, the carbohydrate content of foods eaten, and body weight. *Analytic features* provided a graphical output of each documentation feature, thus offering users the ability to visually inspect their logged data over time. *Education* was provided through four main features. First, users can review a variety of actionable textual information related to healthy food choices, self-monitoring of BGL, medication, reducing risk, healthy coping, problem solving, and physical activities. Second, users can look up information related to carbohydrate and calorie content of common foods in Australia (categorised under fruits and vegetables, egg and meat, dairy, grain and legumes). Third, the BGL feature provided immediate tailored feedback to every inputted data, driven by a decision-based system. The system is controlled by the value of logged BGL (either within or beyond the standard range), type of diabetes, and the indicated period of BGL measurement (either fasting or 2 hours postprandial). Messages were health-promoting and motivational information aimed at supporting behavioural skills building for self-management practices. Finally, the app provided education through daily push notifications aimed at improving awareness about diabetes distress and encouraging patients to focus on potential ways to reduce its impact on their self-management. Push notifications were terminated at the end of the second week. Sample screenshots are provided in **Appendix 6.1**.

6.3.6. Post-Intervention Data Collection

At the end of the study, participants were sent an email (with 1 reminder email sent to non-completers), which directed them to the post-intervention survey on the acceptability of the app and its preliminary efficacy (*results will be reported in future publications*). Through this survey, participants were also invited to participate in individual telephone interviews to further understand their perception of the app. Participants who completed the post-intervention survey were awarded an electronic gift (e-gift) card worth Aus $40 (US $25.07). All telephone interviewees were contacted within 3 weeks of completing the survey and awarded an additional Aus $20 (US $12.53) e-gift card.

6.3.7 Measures

Retention was assessed using the following indicators of study completion per protocol: number of participants enrolled, number of participants who used the app during the intervention period, and completion rate of the post-intervention survey.

Engagement with My Care Hub was measured using participants' app usage log and verbal feedback. App usage data were extracted from the app's activity database. The following time frames were considered: (1) date of log-in into the app to 2 weeks of use when the daily push notification was administered (referred to as week 1 and week 2) and (2) data during the third week (referred to as week 3) after the termination of push notifications. Key metrics collected from the database included app use (number of active users, frequency of daily access to app), data logs/time spent (for BGL, exercise, food activity, and weight), and number of opened notifications. Metrics were presented using an adapted version of the Frequency, Intensity, Time, and Type (FITT) principle index (Barisic, Leatherdale & Kreiger, 2011; Short et al., 2018). This index explores multidimensional domains of usage data, which provides greater insight into interaction with a mHealth app. Event count in the app was available for active (documentation features) and passive (viewing of educational screen) app features. Data had to be logged/saved in the documentation features before it could be counted as an active event as the app discarded data not logged after 30 min of inactivity. Users had to exit from an educational screen before it was counted as a passive event, and no maximum count per user was stipulated. This implies that the total count of passive events could be higher if a screen was viewed more than once. The FITT index used in this study is as follows:

1. Frequency index (F_i)*:* This subindex is an attention proxy that provides information on how often a participant uses the app. It recognises the number of users who return to use the app and active app users in each time period.
2. Intensity index (I_i): This subindex denotes the proportion of users who interact with each feature in the app. In total, 2 metrics were used in the assessment of I_i. These are the frequency of daily use of app features (I_{i1}) and number of push notifications opened versus the total sent (n=14) in 2 weeks (I_{i2}). In addition, intensity also measures the proportion of app features used out of the total available features.
3. Type index (T_y): This provides information on the form of engagement based on actions performed by users using the available app features. In this study, the type of action was categorised as *active* denoted as T_{ya} (use of documentation features for self-monitoring), and *passive* (T_{yp}), reading information on educational contents in the app).
4. Time index (T_i): This measures the duration of engagement, which signifies attention to the app as a function of daily event duration with each app feature.

6.3.8 Interviews

Interviews were conducted using a semi-structured interview guide (see **Appendix 6.2**) that explored behavioural engagement with the app through questions on patterns of use, perceived ease of use, perceived usefulness of app features enabling motivation for continued engagement with DSM, and recommendations on how the app could be improved.

Interviews were conducted by AD, who is well experienced in qualitative research. The interview guide was pilot tested between MDA and AD before actual use. The interviewer was located in a private office at James Cook University, Australia, while participants were asked if they were in a comfortable location before commencement of the interview. The first 3 interviews were used to reflect on the guide, although there were no resultant changes. Data saturation was achieved as judged by no emerging new information (Guest, Bunce & Johnson, 2006) after completing the 15th (of 17) interview. Interviews were audio recorded, and none of the participants had a previous relationship with any of the authors.

6.3.9 Data Analysis

Descriptive statistics were calculated for all quantitative variables. Baseline characteristics comparison between those who completed the study and those who did not were done using a Pearson chi-square test. All statistical analyses were performed using SPSS version 23.

Interviews were completed in an average of 15 min (range 9-30 min). Participant responses were transcribed verbatim by 1 researcher (AD). In this analysis, a combination of data and a concept-driven strategy was applied. Initially, inspired by the work of Schreier (2012), MDA and AD independently used a data-driven strategy to obtain an overview of the data, and then similar text segments were selected and sorted using coding. Coded segments were grouped to identify recurring themes from the data. Themes were compared between the 2 authors, discussed with BMA and agreement was reached about the main themes. Subsequently, the themes were analysed by applying a concept-driven strategy in accordance with the BIT framework (Mohr et al., 2014) to assess behavioural engagement with the intervention. The BIT components in the My Care Hub app that could potentially enhance behavioural engagement were identified ad described. These components overlap and diverge within the identified themes, which are presented using representative quotes affixed with an assigned number code and the type of diabetes the respondent has (for instance, respondent 3 with type 1 diabetes; P003, T1D and respondent 4 with type 2 diabetes; P004, T2D). The conduct and reporting of the interviews followed the consolidated criteria for reporting qualitative research (Tong, Sainsbury & Craig, 2007).

6.4 RESULTS

6.4.1 Participant Characteristics

Participant demographics and health characteristics are shown in **Table 6.1**. Participants were predominantly male (31/50, 62%), had type 2 diabetes (36/50, 76%), and aged between 20 and 64 years (mean 49.12, SD 12.34 years). On average, the recommended BGL in enrolees was as follows: for fasting, 4.58 (SD 0.78; range 4-6 mmol/L), and for 2-hour postprandial, 7.01 (SD 1.02; range 6-10 mmol/L). Most participants were diagnosed as having diabetes in the last 5 years (27/50, 54%), and an equal proportion rated their health status as being fair or good (20/50, 40%). Most had a technical college education or higher (39/50, 78%) and were employed (31/50, 62%). Only a few had previously used a health app to manage diabetes in the past (16/50, 32%). The linking of participants' postcode to the Australian Standard Geographical Classification System (Australian Government Department of Agriculture, 2019a) indicates the geographic location of the majority to be rural (37/50, 74%).

Of the 22 participants who indicated an interest in participating in the interview, only 17 were contactable within 3 call attempts. Most were males (12/17, 71%), had type 2 diabetes (13/17, 77%), and had been diagnosed for an average of 6 years (range 1-17 years). Overall, participants were between the ages of 36 to 64 years (mean 51.58, SD 11.31), except for one who was aged 20 years.

6.4.2 Retention

Of the 4984 patients who were emailed an invitation to participate in the study, 79 (1.59%) completed the eligibility form. Low response rate may be due to lack of access to an android phone to download the app, which is the main eligibility criterion as stated in the email invitation. Subsequently, only 84% (67/79) of those who responded met all the inclusion criteria and were provided access to download the app. Some participants (17/67, 25% of those eligible) failed to log in to the app, resulting in 50 enrolled participants (75% of eligible participants). Most enrolees (43/50, 86%) activated the app within the same day (range 0-5 days) of having access to it. One participant logged out of the app on the second day of installation stating that it did not meet her requirement. At the end of the study period, 41 of the enrolled participants completed the study per protocol by providing feedback about the app using the post-intervention survey (retention rate: 41/50, 82%). Reasons for non-completion of the study protocol were not recorded. In assessing baseline characteristics associated with retention, only employment status emerged as a significant predictor, with those unemployed being less likely to complete the study than those who were employed (50.0% versus 14.7%, respectively; P=.02). The full details of the demographic variables and comparison between those who completed the study and those who did not are shown in **Table 6.1.**

Table 6.1: Participant Characteristics

Characteristics	Baseline (n = 50)	Completers (n=41)	Loss to follow up (n=9)	
		Frequency (% within group)	Frequency (% within group)	*P* value
Gender				.75
Male	31	25 (81)	6 (19.4)	
Female	19	16 (84)	3 (15.8)	
Age (Years)				.82
Mean±SD		49.29±12.74	48.67±11.25	
18-29	5	4 (80)	1 (20)	
30-39	6	5 (83)	1 (17)	
40-49	12	10 (83)	2 (17)	
50-59	15	11 (73)	4 (27)	
60-65	12	11 (92)	1 (8)	
Type of diabetes				.81
Type 1	15	12 (80)	3 (20)	
Type 2	35	29 (83)	6 (17)	
Type 2 medications or not (n=35)				.32
None	2	1 (50)	1 (50)	
Oral drugs alone	33	28 (85)	5 (15)	
Oral and insulin	1	1 (100)	0 (0)	
Duration of diagnosis (years)				.92
≤ 5	27	23 (85)	4 (15)	
6-10	10	8 (80)	2 (20)	
11-15	9	6 (67)	3 (33)	
≥ 16	4	4 (100)	0 (0)	
Education				.59
High school equivalent	17	12 (71)	5 (29)	
Technical college	10	9 (90)	1 (10)	
First degree	11	10 (91)	1 (9)	
Post graduate	8	7 (88)	1 (13)	
Missing	4	3 (75)	1 (25)	
Ethnicity				.87
Caucasian/White	47	38 (81)	9 (19)	
Missing	3	3 (100)	0 (0)	
Employment				.02[a]
Unemployed	8	4 (50)	4 (50)	
Part/Full time Employed	34	29 (85)	5 (15)	
Retired	8	8 (100)	0 (0)	
Living Environment				.26
Remote	13	12 (92)	1 (8)	
Rural	37	29 (78)	8 (22)	
Usage of Smart Phone (Years)				.42
1-5	13	11 (85)	2 (15)	
6-10	28	24 (86)	4 (14)	
> 10	9	6 (67)	3 (33)	
Previous use of health apps to manage diabetes				.93

Yes	16	13 (81)	3 (19)	
Never	34	28 (82)	6 (18)	
Rating of health Status				.38
Poor	1	1 (100)	0 (0)	
Fair	19	14 (74)	5 (26)	
Good	21	17 (81)	4 (19)	
Very good	9	9 (100)	0 (0.)	

[a]$P < .05$

6.4.3 App Engagement

Most (42/50, 84%) enrolled participants logged data into the app at least once (during week 1 of installation) with the frequency index showing that they actively used the app on an average of 11 of the 14 days in the first 2 weeks when push notifications were sent (range 2-14 days; week 1 average: 5.2 days, week 2 average: 4.8 days). This reduced to an average of 4 of 7 days (range 2-5) in week 3: average 3.8 days. Furthermore, all participants who logged in to the app used it during week 1, and most returned to use the app after week 1 (36/42, 85%) and week 2 (30/42, 71%) of installation. With regard to the intensity index related to daily use of each app feature (I_{i1}), most participants used features for tracking their BGL (28/42, 68%) and accessing educational information (6/42, 13%) more frequently. The feature with the least daily use was tracking the carbohydrate content of foods (2/42, 2%). All 14 push notification messages during the first 2 weeks (1 per day) sent were published, and on average, 57% (24/42) of participants opened this notification within 24 hours, after which they were automatically deleted. None of the app features were unused. The type index (T_y) shows active and passive actions with the My Care Hub. The average frequency of BGL data log per participant in week 1 was 10.85 (SD 9.32; range 1-36), which reduced to 6.75 (SD 7.75; range 1-24) in week 2 and 5.67 (SD 6.05; range 0-22) in week 3. Physical activity logs showed a mean of 4.48 (SD 3.64; range 0-15) in week 1 compared with 2.97 (SD 2.93; range 0-11) in week 2 and 1.69 (SD 1.70; range 0-7) in week 3. Average passive engagement per participant on occasions of viewing screens alone in week 1 was 26.5 (SD 2.51; range: 9-32), 17.55 (SD 7.39; range 7-26) in week 2, and

14.4 (SD 6.13; range 6-24) in week 3. The time index (T_i) revealed that, for all events of participants' visit to the app, an average daily time of 3.56 min (range 1.37-7.48 min) was spent. More time was spent on BGL activity (2.2 min) and accessing the educational tips embedded in the app (1.35 min). **Table 6.2** summarises the app functions and features, their purposes, usage and engagement.

Table 6.2: My Care Hub Sections and Engagement Indices (N=42)

Functions/Features	Elements	Purpose	User Engagement	
			Percentage of daily users (I_{i1})[a] n (%)	Average time spent per user per day (T_i)[c]
Documentation				
Blood glucose activity (T_{ya})[d]	• Blood glucose log • Type of blood glucose • Automatic Feedback (as part of education)	• Monitoring and tracking of blood glucose values over time • Gain knowledge to support self-management practices	29 (69)	2m 2s
Physical activity (T_{ya})[d]	• log of time spent on physical activity • Calories used • Place	• Monitoring of physical activity behaviour over time	4 (10)	0m 7s
Food activity (T_{ya})[d]	• Record food intake • Log of carbohydrate content of food	• Monitoring and tracking of food intake and their carbohydrate content over time	1 (2)	0m 17s
Weight log (T_{ya})[d]	• Body weight log	• Body weight assessment over time	2 (5)	0m 22s
Analytics (T_{yb})[e]	• Graphical display of data log into each documentation feature	• Keeping track of trends in lifestyle activities and observe impact on blood glucose levels over time	3 (6)	0m 20s

Education				
Textual screens for management tips and food choices (T_{yb})[e]	• Information on behaviours in DM management • Information on average carb and calorie content of common Australian foods	• Assess current knowledge on diabetes self-management • Review carbohydrate content of foods in order to make healthy choices.	6 (13)	1m 35s
Push notifications (T_{yb})[e] and (I_{i2})[b]	• Messages on diabetes distress	• Create awareness about diabetes distress and ways to reduce it impact on self-management	24 (57)	Not captured[f]

[a]Intensity index for frequency of daily use

[b]Intensity index for number of push notifications opened

[c]Time index

[d]Type index for active app use

[e]Type index for passive app use

[f]Not captured due to limitations of system usage tracking data base

6.4.4 Interview Results

Different themes emerged from the data with interconnection among the themes over the course of My Care Hub usage. Overall, the results suggest that the use of the app has the potential to ease the effort in aiming for improved self-management and for better awareness of BGLs. In addition, participants provided their recommendations for extra functionalities that may further enhance engagement with self-management behaviours. We present our findings in relation to themes related to components of the behavioural intervention model (Mohr et al., 2014) used for this study, which are outlined in **Table 6.3.**

Table 6.3: Summary of Behavioural Intervention Technic (BIT) model as adapted to My Care Hub (MCH) Intervention

	BIT[a] Components		Details in MCH[b]
Theoretical			
	Why	Broader goal: Self-management education and support	aims:
			Improved blood glucose - long term impact
			Increase physical activity
			Healthy eating
			Decreased diabetes stress
	How	Behavioural change strategies	Elements/Strategies
			Documentation/Analytics:
			Accountability
			Clarity of self-management activities and impact
			Improved awareness of BG[c] levels
			Mindfulness of calorie consumption
			Feedback response:
			Reinforced HP's[d] recommendation
			Informative
			Carbs in Foods:
			Guidance on meal planning
			Knowledge provision and reinforcement
			Educational Tips:
			Knowledge reinforcement

Instantiation			
	What	Elements (app features)	Documentation (Logs) / Analytics Feedback response Carbs in Foods Educational Tips screen Push notifications
	How (Technic)	Characteristics	Aesthetic: Beautiful Ease of use: Simple and straight forward Few difficulties
	When	Pattern of use	User defined: Type of diabetes Established self-management routines Frequency: Daily Partly with reasons

[a]BIT: behabioural intervention technology
[b]MCH: My Care Hub
[c]BG: Blood Glucose
[d]HP: Health Provider

Pattern of use ('When')

User defined

Patterns of app use depended on users' type of diabetes and self-management routines, with most participants using the app multiple times per day, where those with type 1 diabetes input their BGL any time it was measured:

> *"I use it multiple times per day, basically any BGL I took I enter it at any time I took it."* [P001, T1D]

In contrast, participants with type 2 diabetes described that the frequency of usage depends on the self-management activity carried out on that day.

> *"I used it at least once a day. if I had done exercise, then I was putting in an exercise and blood test virtually every day. On every second day I was using it to stick in weight but the exercise was done at a different time."* [P005, T2D]

Conversely, some participants were only able to use the app infrequently because of issues such as limited internet access or multiple competing interests:

> *"I didn't use it fully, because at the moment I am having a problem with my internet, so I didn't get a chance to watch the video that comes with it."* [P012, T2D].

> *"I used it a few times to start with, but then I stopped pretty much because I was juggling between doing a lot of writing, doing a course, and was having other things to do."* [P003, T1D]

<u>Characteristics of the App (*How*)</u>

Simple and straightforward

Participants described the design as:

> *"Very well crafted and well put together, really easy to use."* [P007, T2D],

and could be used even by the elderly who may not be too proficient in using mobile technology:

> *"I would even say that like an older person in their 60s or so, once they get an idea of how to use it properly, would have no worries using it if they were in that way inclined."* [P012, T2D]

App difficulties

Some participants found a few aspects of the app difficult:

> *"There was one for the activities you had to put in what calories you might have burned off and I didn't have a clue how I was going to find out that information.* [P013, T2D]

> *I had a problem figuring out how to put dates in it, but I think it does it itself, so yeah."* [P008, T2D]

<u>Goal (*Why*), Elements (App Features; *What*), and Behavioural Change Strategies (*How*)</u>

The goal of developing My Care Hub was to enhance engagement with DSM activities such as improved BG, increased participation in physical exercise, and healthy eating. Participants identified multiple elements (features) that support this overall goal. They also described the perceived benefits (mechanism of action) of each of the elements that encouraged their interaction with it, and toward achieving an improved DSM. The commonly mentioned features are noted below, as well as reasons why participants found the features engaging.

Documentation/Analytics

Accountability

Participants mentioned that the documentation element strengthened the sense of responsibility to keep up with routines in DSM:

> *"I liked the activity log, because it gives you accountability, when did you go to the gym, how long were you there, what did you do."* [P014, T2D]

Clarity of self-management activities and impact

Participants explained that visualisation of logged data using *analytics* encouraged their interaction with My Care Hub. They noted that the feature provides better clarity on their level of self-care:

> *"Just the tracking of my fitness, exercise and my blood sugars, it is much better for me seeing it in a graph, makes it really clear how you are going."* [P006, T2D]

The feature also hinted at some participants to consult their physician for medication review or consultation if their BGLs were not in the recommended range:

> *"I liked the graphs…that was what gave me the red flag…maybe I have to see the doctor to have my medications changed."* [P010, T2D]

Improved awareness of blood glucose levels

Participants noted that although they have a BG meter that provides BG measurement history, having the graphical output of their BGL in My Care Hub further improved awareness of any fluctuations in BGLs:

> *"It was quite good to see longitudinal things, obviously on my blood monitor I can see by just hitting the back key what the previous readings are.., But to see it in a graphical linear form was really good. It showed me where my blood sugar was, if I went up and down."* [P005, T2D]

Mindfulness of calorie consumption

The analytic feature enabled participants to pay attention to daily calorie intake or carbohydrates consumed:

> *"I liked that idea of putting it all in and seeing how your graphs went up and down, and it sort of kept you a bit more mindful of how many calories or carbs you are eating during the day."* [P013, T2D]

Feedback Response

Reinforced health provider's recommendation

Feedback received in response to logged BGL is an element that reinforced the doctor's recommendation about participants' BGLs. A participant with hypoglycaemia unawareness noted that his doctor suggested continuing using the app to serve as an alert in the event of low BGL:

> *"It is one thing that made me maintain my BGLs. I tend to be what my doctor calls hypoglycaemia insensitive. So, he suggested that I stick with the app because it reminds me to do regular BGL tests to make sure that I am not dropping too low."* [P007, T2D]

Informative

Feedback feature serves as an alert about a potential problem in users' BGLs:

> *"I got confirmation that was somewhat reassuring. I mean if it was out and higher, it just alerts you to a potential problem that you may or may not be aware of."* [P005, T2D]

It aided decision making for improved self-management:

> *"If my levels were over the target range, it gave me very helpful ways to reduce the blood glucose level back into the range."* [P007, T2D]

Carbohydrate Components in Foods

Guidance on meal planning

Participants valued the *carbs in foods* feature as it provided information about the average carbohydrate and calorie contents of foods. Participants perceived they were better supported in their choice of appropriate foods to eat and avoid exceeding their recommended daily amount of carbohydrate intake. It also provided guidance on food planning:

> *"I try to stay between 20 and 50 grams a day, so the carb counting feature was very useful because then you can make an informed decision on what you are going to put on your plate, and you can plan out your week."* [P009, T2D]

Knowledge provision and reinforcement

Participants who had difficulties knowing the carbohydrate content of foods found this feature useful through outlining the best foods for consumption to ensure proper health management:

> *"I have a lot of trouble with how much carbohydrate is in one food but it (app) sort of gets you to realise okay then I have got to check on that."* [P004, T2D]

Furthermore, engaging with the *carbs in foods* feature reinforced knowledge and served as a reminder about carbohydrate content in foods:

> *"There is so much to take in, like reading labels, it is so much to take in. So I found it (app) quite interesting that it is a bit more set out with carbs and how much is in it, and some of them are low and you thought it would be high. Just reinforcing the information because I just can't remember everything."* [P014, T2D]

Educational Tips

Knowledge reinforcement

Educational tips were also acknowledged as a tool for knowledge reinforcement and fostered the use of the app. Participants found information on 7 essential ways to manage diabetes quite useful and reflective:

> *"It is useful, I have got a couple of books, and there is a lot of information, and whilst I may have read it, I am not sure I can regurgitate it."* [P005, T2D]

> *"It was just interesting to read it and think about it."* [P014, T2D]

In addition, participants felt that the element provided more comprehensive information in comparison with the feedback element:

> *"That (educational tips) was more useful than the little hint things (feedback messages) yeah… I think it probably covered it (all information) fairly thoroughly."* [P006, T2D]

<u>Recommendations to further improve engagement with the app</u>

Participants' recommendations were majorly based on extended functionality in the app including automated data transmission, more historical analytic data, feedback on physical activity, and update on food list and corresponding nutrient contents.

a. Automation of data input: Some participants found the manual recording of BGL, physical activity and carbohydrate content of foods consumed as burdensome and expressed that addition of Bluetooth, which could automatically extract data from BGL meter would not only encourage users' engagement with My Care Hub but also improve BGL monitoring. *"It is just the Bluetooth thing to me encouraged me to do blood samples as well without having to write them down manually."* [P003 T1D]

Furthermore, the desire for My Care Hub to automate tracking of time spent on physical activities and equivalent calorie expended was expressed. *"For exercise, if the app could automatically tell you that you have walked 5km, or you have done 30 minutes of exercise and that equals burning so many calories..that would be great."* [P016, T2D]. In addition, it was recommended that MCH should have features to calculate the calorie content of composite dishes. *"for someone like me being a lazy fella it is just easier if I can just click on apple and select small apple or large apple and it just tells me. And I think okay I had this much wholegrain bread, some meat, and an apple and it will tell me what I have consumed in calories for lunch."* [P016, T2D]

b. More analytic histories: Participants suggested extended historical data access and believed this would provide further opportunity to study patterns in self-management activities and have long-term data that could be reviewed by their health care providers. *"If you could scroll back and had a look at everything you put in to see if there is a pattern, or if you could scroll back and go back through those graphs. Because you couldn't scroll back any more than whatever was shown on the screen. Also, if there was an option, where you could print out those graphs and take it to your GP when you go for your next check-up and you could show them what is going on."* [P013, T2D] *c. Information update*: It was suggested that the ‘‘Carb in Foods’’ feature needed more food list and varieties of composite dishes. *"Probably just a greater level of information in the carbohydrate and food section, a broader range, just more information, fish meals, chicken, beef, you know."* [P007, T2D]. Participants suggested this information could be provided in monthly updates because users’ awareness of finding new information in the app on a regular basis could foster fresh interest in using the app. *"if there were more foods that would be good. If some of those changed you know like update once a month…a bit more refreshed, just to make things a bit different once a month like because once you have read this you wouldn’t keep reading it every day or once a week, once you have read it."* [P014, T2D]

d. Feedback on physical activities: The idea of providing motivational feedback in the app, especially when users achieve certain levels of physical exercise, was raised. This behavioural change strategy in My Care Hub is presently limited to the BGL documentation, presumably, participants want an extension of it to the physical activity documentation. *"Maybe a little bit of an achievement, like if I have exercised maybe it..oh great you have done this much for today, so good job well done. So, some positive reinforcement yeah. Because I know a lot of people struggle, my dad has type 2 diabetes and he struggles with exercise. Like some encouragement yeah, so for older people I guess, good job well done you have done 10 minutes of walking or something like that."* [P004, T2D]

6.5 DISCUSSION

The My Care Hub mobile app intervention was intended to encourage ongoing participation in DSM activities. This paper reports the levels of participant retention and engagement (usage and behavioural aspects) with the technology over a 3-week pilot study. The findings of the study revealed an acceptable level of participant retention with the intervention, where the majority completed the study per protocol. Furthermore, participants reported that the intervention eased and improved their effort in participating in self-management activities.

Thus, suggesting the app's potential as a tool for DSM support and education. Nevertheless, a larger sample and longer-term studies are required to establish these claims.

Participant retention

The retention rate was relatively high, with more than three-quarters (82%) of participants completing the study per protocol, which is similar to previous short-term pilot studies of diabetes app interventions (Agarwal et al., 2019a; Koot et al., 2019). This indicates that participants were highly motivated and willing to participate in their self-management activities. However, some other pilot studies on DSM support programs reported higher retention than this study. For example, Dick et al., (2011) reported 0% attrition over 4 weeks, whereas Kim et al., (2016) reported only 3% loss to follow-up over a 3-month pilot testing. Such findings are expected because the studies (Dick et al., 2011; Kim et al., 2016) were conducted in controlled settings where participants' recruitment took place in health care facilities, whereas our study utilised Web-based recruitment. Participants are likely to be more committed to the studies when recruited from their care facility and with the knowledge of their care physician (Newington & Metcalfe, 2014). In contrast, studies such as ours that recruited participants through the Web may experience a quick loss to follow-up due to a less structured environment (Eysenbach, 2005; Murray et al., 2009). Future studies with My Care Hub might consider recruitment from a structured setting as a further strategy to improve participants' retention.

Retention was not influenced by participant characteristics measured, with the exception that unemployed participants were less likely to complete the study, which was contrary to the results of a previous mHealth study (Jahangiry et al., 2014). Reasons for this discrepancy are unclear, although despite this difference, 50% of unemployed participants were retained in this study, which is relatively high for Web-based interventions. Future research with My Care Hub will explore reasons for higher attrition among unemployed participants and the use of empirical strategies to improve their retention rates.

Intervention engagement

Users in our study actively used the app for 11 of 14 days (11/14, 79%) in the first 2 weeks, where they all used the app at least once during the first week and 85% returned to use the app during week 2 and 71% during week 3. To put these rates into perspectives, we refer to studies of Faridi et al., (2008) and Kim et al., (2016) who found that 53% and 38%, respectively, of participants used the app for a portion of the 12 weeks intervention duration, where in some cases, there was up to 33% of completely inactive participants (Faridi et al., 2008). In comparison, our app frequency usage rate can be interpreted as reasonable. However, mobile-based interventions differ widely in terms of population, features, settings, and techniques used to foster engagement. For example, although our intervention was self-directed and we did not utilise reminders for self-management or data entry, the above-mentioned studies used face-to-face intervention orientation (Faridi et al., 2008; Kim et al., 2016), automated reminders for diabetes management (Faridi et al., 2008), and physician review of adherence (Kin et al., 2016). These disparities may have been a major influence on usage, thus making direct comparison with other app-based interventions difficult. However, the sharp reduction in app usage during week 3, where only 71% retuned to use the app without the push notifications reveals the role of push notification as a feature that could further stimulate users' engagement with apps (Freyne et al., 2017) especially those with content containing insights into how to overcome barriers to achieving health goals (Bidargaddi et al., 2018) as provided in this study. Nevertheless, some users find push notifications intrusive and annoying, especially when too frequent, thus limiting engagement with the intervention (Danaher et al., 2015). Hence, health apps should be built in ways that patients can customise and review when they see notifications or adjust the timing to suit the selected period of specific self-management tasks such as physical exercise or blood glucose monitoring.

The intensity of usage showed that participants interacted more with features for monitoring of BGL and physical activities, which are in congruence with previous studies (Waki et al., 2012; Kirwan et al., 2013). This was confirmed in the interviews where participants mentioned that these documentation features improved accountability for their self-management activities. This may be due to patients' understanding of the importance of these self-management activities for optimal health outcomes. Another explanation might be because the documentation features were accompanied by analytics that foster improved awareness of BGLs, accountability, and better clarity of self-management activities, as mentioned in the interview. These behavioural strategies in the documentation and analytic features might have encouraged personal reflection among participants, hence the increased intensity of usage.

The active time spent on the documentation features demonstrated that the duration of app usage necessary to generate consistency is a parameter that depends on individual users (Vehi et al., 2019). This was reflected in the interviews where the pattern of use was denoted by users' decision on sequence and DSM routine. This result reveals the advantage of a multicomponent intervention such as My Care Hub, which offers users the opportunity to embrace it in ways most relevant to their needs (Mohr et al., 2010). A user can bypass a feature that they feel does not apply to them, potentially increasing engagement with more relevant areas in relation to their needs. Therefore, the diverse elements available in My Care Hub represent an advancement over many existing diabetes app interventions that consist of only a single element that requires participants to complete a predefined behavioural program (Guertler et al., 2015).

Although the My Care Hub system log recorded participants' passive usage of the education textual screens, there are no standard measures to compare these data with similar diabetes-focused interventions. However, the interviews indicated that participants appreciated this feature as an important element that provided knowledge reinforcement as a behavioral strategy for DSM. Nonetheless, the app system was unable to capture whether participants were actually reading and comprehending the embedded information or simply clicking them. An approach to address this limitation is to incorporate eye-tracking technology (dos Santos et al., 2015) or tailored quizzes (Patel et al., 2009) into My Care Hub to measure cognitive responses and knowledge acquired through engagement with each information screen. These measures would need to determine if success or failure of a user to acquire knowledge is due to the intervention component delivery mode, users' engagement with the information, or some other intrinsic factors exclusive to the user.

Generally, engagement indices were initially high but decreased in subsequent weeks. Previous studies using mHealth interventions over short- and long-term periods have identified similar trends (Guertler et al., 2015; Dennison et al., 2013). This finding was expected, as this study was a real-life pragmatic pilot testing of an app, prone to non-use or infrequent use because users prefer to engage with apps periodically (Dennison et al., 2013). In addition, non-usage attrition with mHealth could be due to other reasons such as lack of self-motivation or commitment to change health behaviours (Dennison et al., 2013) and satisfactory attainment of knowledge or skills in managing the disease (Guerlter et al., 2015).

Participants' perceptions related to behavioural change strategies in My Care Hub derived from documentation, feedback response, calories in foods, and education tips features are consistent with the needs analysis study conducted as part of the predevelopment phase of the app (Adu et al., 2018b). Both type 1 and type 2 diabetes patients expressed a strong interest in these elements because of their ability to not only foster engagement with an app but also provide benefits for self-management behaviours. This reinforces the notion that benefits derived from an intervention strongly affect users' experience and, hence, engagement with the technology (O'Brien & Toms, 2008). As these elements are targeted toward self-monitoring of behavioural activities and the provision of educational information to support those activities, the perceived behavioural change strategies may be an indicator that the app has the tendency to support users to achieve their behavioural goals. Nevertheless, further long-term studies are required to establish this claim.

Perceived ease of use of mHealth positively affects continuance in intention to use (Cho, 2016). The presentation and characteristics of a technology determine the way users can optimise the elements to achieve their aim and overall behavioural goal (Mohr et al., 2014). If users enjoy their experience in a digital behavioural intervention, exposure to the behavioural change component will be improved and may subsequently influence behaviours (Cole-Lewis, Ezeanochie & Turgiss, 2019). These were reflected in our study as participants expressed their opinion about the simplicity of My Care Hub and perceived it as uncomplicated and effortless to use. Even when engagement is a purposeful choice and evolves from how people choose to obtain value from their experience, it has to be enabled by the technology and, thus, impacts long-term interaction with such technology (Lalmas, O'Brien & Yom-Tov, 2014).

The educational component of the app was informed by our previous study, which shows that information on basic guidelines for the management of diabetes and approaches to problem solving in diabetes were highly desired by both type 1 and type 2 diabetes patients (Adu et al., 2018b. However, once that knowledge is obtained, there is a tendency for a drop in participants' rate of use of the app (Taki et al., 2017). This highlights that apart from developing an app to meet end-user requirements and perceived relevance to diabetes management, mHealth developers need to consider ongoing novel strategies that will keep participants engaged. Novelty is also a main contributor to app engagement because it prevents boredom (O'Brien

& Tom, 2008; Webb et al., 2010). The downward trend in engagement indices may be explained by a lack of novelty in the app throughout the study period. Hence, future long-term research with My Care Hub must consider ongoing novel strategies that will keep participants engaged. Such strategies may be achieved by considering the suggestions raised by participants in this study. These include periodic information updates on meals and their corresponding nutrient values. Other suggestions on extended functionality in accessing more historical data, automated data transmission, and feedback on physical activity performance are also potential future improvements of My Care Hub, as they have been proven to have an effect on behaviour (Webb et al., 2010).

Strengths and limitations

A mixed methods study design was used to evaluate patient engagement with My Care Hub, which is a strength of the study compared with previous studies that have arbitrarily classified engagement as high or low based on frequency of use (Guertler et al., 2015) or overall adherence to the intervention (Sieverink et al., 2017). The unique contribution of this paper is threefold. First, retention with My Care Hub indicates its potential as a relevant behavioural change intervention tool for patients with diabetes in rural or remote environments with poorer access to specialist health care services. Second, participants' engagement based on interaction with multiple intervention elements was measured using the FITT metrics. The use of this measure reveals the level of user engagement with each intervention feature, thus providing results that are beneficial to inform future enhancements of My Care Hub. Although FITT is commonly used in physical activity research (Barisic, Leatherdale & Kreiger,2011) to the best of our knowledge, this is the first study to use this measure to assess users' engagement with a multi-component DSM app. Adjusting the index to measure engagement with the intervention in this study was possible because behaviour metrics and physical activities were measured. The use of FITT as a measure provided results that could broadly serve as a reference to evaluate other diabetes mHealth interventions before the execution of a full-scale trial. Third, due to the short intervention period of this study, we employed a theoretical and conceptual framework to confirm the components of BIT present in My Care Hub, as an analogue to measures of behavioural engagement with the app. Therefore, the framework served as a predictive device to evaluate the app's suitability as a behavioural change intervention tool. This approach supports a more comprehensive assessment of engagement than most existing short-term pilot studies, which lack theoretical foundations. The use of this framework provides guidance on aspects of mHealth interventions to ensure the development of a meaningful tool that could improve patient engagement with healthy behaviours (Mohr et al., 2014).

This study has some limitations that should be taken into account when interpreting the findings. The short intervention period is acknowledged. However, 3 weeks is the minimum time required for anyone to form a behavioural habit (Middelweerd et al., 2014), and multiple components as found in our intervention are potentially effective techniques to achieve behaviour change (Vernooij, Willson & Gagliardi, 2015). Furthermore, participant recruitment was restricted to a single source, and the sample size was small, thus limiting the sample diversity and generalisability of the results. In addition, the requirement that eligibility includes access to both an Android smartphone and an active email account may imply that the findings may not be generalisable to all smartphone users. In addition, because of the need for our app to comply with the Australian privacy policy and best practice on users' confidentiality, we were unable to include programming codes within the app that could capture users' personal profiles such as age, gender, browser, connection speed, etc. Having this information could provide an opportunity to assess different levels of engagement between those who completed the study and those who did not. In addition, we would have been able to assess if app use was moderated by users' profile. Despite these limitations, considering the promising results further research with a larger sample and over an extended period of time is necessary.

6.6 CONCLUSION

This study provided a comprehensive understanding of participant retention, technology usage, behavioural change process, and engagement with My Care Hub app during a short trial period. Retention was high, although further strategies may be required to further sustain retention when the app is used in long-term trials. The system log indices of FITT of engagement reveal a reasonable level of technology usage during the intervention period. The BIT model employed to measure behavioural change and engagement suggests that My Care Hub could be a behavioural change intervention tool to support self-management behaviours in people with type 1 or type 2 diabetes. Information obtained through the use of multicomponent measures of engagement in this study provides rich and useful data regarding the strengths and weaknesses of My Care Hub and areas requiring improvement to foster increased engagement, sustainable long-term use, and effective health behavioural intervention.

Overall, this chapter contributed to addressing the fifth aim of this thesis by reporting the pilot testing of the novel mobile app in order to ascertain patients' levels of retention and engagement with the app.

Chapter SEVEN: Efficacy and Acceptability of My Care Hub Mobile App to Support Self-Management in Australians with Type 1 or Type 2 Diabetes

7.1 ABSTRACT

Regular access to support and education is required for ongoing participation in diabetes self-management, which is essential for maintenance and improved health outcomes. Patients living in rural areas are the most disadvantaged in accessing such support and education, making mobile app interventions a potential avenue to target these specific populations because of its relatively low cost and easy accessibility. The aim of this study was to evaluate the preliminary efficacy and user acceptance of My Care Hub mobile app - developed to provide evidenced-based support and education on diabetes self-management (DSM). Using a mixed-methods pre-post trial design, efficacy and acceptability of My Care Hub were measured among people with type 1 or type 2 diabetes after 3 weeks of intervention. The primary outcome measure was levels of involvement with DSM while the mediating factors were skills and self-efficacy for DSM. In addition, general user acceptance was measured using a questionnaire, and telephone interviews were conducted to elucidate information on participants' perceptions of the app's impact on their DSM and interest in future use. Paired t-test, Wilcoxon-signed ranked test and regression analysis were applied to quantitative data while qualitative data were thematically analysed. Fourty-one participants completed the pre- and post- study questionnaires and 17 participants were interviewed. Statistically significant improvements were observed between pre and post intervention measures: DSM activities (4.55 ± 1.14 versus 5.35 ± 0.84; p =0.001); skills (7.10 ± 1.99 vs 7.90 ± 1.67; p =0.04) and self-efficacy (7.33 ±1.83 vs 8.07 ± 1.54; p =0.03). Multivariate analysis showed that self-efficacy had the strongest, though not significant influence on DSM. The ratings of each items in the acceptability-measuring tool were above 3

on a 5-point Likert scale. Interview findings revealed that the app reinforced knowledge and provided motivation to participate in DSM activities. The study suggested a positive impact of My Care Hub on diabetes self-management and acceptability by patients. To confirm these promising results, further large scale and long-term studies are required.

7.2 INTRODUCTION

Diabetes self-management education and support (DSMES) is an ongoing process beyond the formal self-management training, that facilitates the knowledge, skills and ability necessary for lifestyle behaviours that assist patients to manage their condition (Sherifali, Jones & Mullan, 2013; Beck et al., 2018). This is essential to prevent or reduce the risk of developing complications thus fostering improved short- and long-term health outcomes (Shrivastava, Shrivastava & Ramasamy, 2013). Currently, there are complex interplays between barriers and ongoing support for diabetes patients. Barriers include economic, geographical and time constraints for patients, and workforce shortages required to support patients beyond irregular diabetes self-management education classes by health professionals (Brown et al., 2002; Al-Azri et al., 2011). In Australia, patients living in rural and remote areas are more severely impacted by these barriers (Smith, Humphreys & Wilson, 2008), leading to significant gaps in service delivery, accessibility (Thomas, Wakerman & Humphreys, 2014), and lower health outcomes (Phillips, 2009). The Australian Institute of Health and Welfare, (2019d) defines rural as any area outside Australia's major cities, and a significant proportion of Australians with diabetes live in these rural areas (National Rural Health Alliance, 2011). Health system limitations in rural areas highlighted the key role that mobile health (mHealth) interventions such as applications (apps) play in the provision of ongoing DSMES to patients.

Numerous apps aimed at improving self-management activities exist for patients with type 1 or type 2 diabetes. However, many diabetes apps lack explicit description of the development process and design (Adu et al., 2018a), as well as educational components that enhance patients' knowledge for behavioural change (Chomutare et al., 2011; Adu et al., 2018a). There is also limited consideration of users' preferences, which is necessary to improve usage of the intervention and behavioral engagement in self-management (Arsand & Demiris, 2008; Woldaregay et al., 2018). Furthermore, there has been poor integration of the mediating factors that underpin reported self-management (behavioural) or clinical outcomes in studies using diabetes app interventions (Rossi et al., 2013; Holmen et al., 2014; Berndt et al., 2014; Quinn et al., 2016). Factors including knowledge of DSM skills and self-efficacy (confidence) are important mediators for behavioural change outcomes (Persell et al., 2004; Sarkar, Fisher & Schillinger, 2006). Thus, integration of these factors into interventions could foster patients' engagement with DSM. Adequate self-management skills are provided through knowledge about the disease and understanding of the relationship between various self-management behaviours and resulting health outcomes (Aronson et al., 2018). Self-efficacy, on the other hand develops patients' confidence to perform these behaviours and to overcome barriers that prevent achievement of behavioural goals (Wu et al., 2007).

Previous studies have reported linear positive association between levels of DSM skills and self-efficacy and participation in specific self-management behaviour such as diet control, monitoring of blood glucose (Wang et al., 2012), physical exercise (McAuley et al., 2011; Alemdag, 2018), foot care (Perrin, Swerissen & Payne, 2009) as well as overall self-management behaviours (Wu et al., 2007; Fang, Yu & Tao, 2013; Huang et al., 2014; Yao et al., 2019). This implies that participation in self-management behaviours is an end-product of an individual's management skills and confidence to perform the behaviour. Therefore, a diabetes mHealth intervention aimed at behavioural change should target patients' improvements in the mediating factors of skills and self-efficacy, which could consequently trigger improved diabetes self-management behaviours.

Researchers have also indicated a positive association between acceptability of a technology and improved levels of self-management (Harrison et al., 2014; Hirani et al., 2017). The content and quality of mHealth technology have implications for its acceptability (Sekhon, Cartwright & Francis et al., 2017) which is an antecedent of users engagement and a key consideration for implementation into practice (Kim, 2015).

Drawing on this background, a new diabetes app intervention called My Care Hub was developed to provide evidenced-based support and education to foster self-management behavioural change in Australians with Type 1 or Type 2 diabetes (Adu et al., 2020a). My Care Hub provide multiple features and functions targeting the mediating factors of skills and self-efficacy in patients in order to foster improved behavioural change. These features/functions include: (i) an electronic diary and analytics to self-monitor behavioural activities such as blood glucose, physical activities, food intake and weight; and (ii) various educational modules.

Study Aims

This study reports the preliminary efficacy of My Care Hub. The primary outcome measure is diabetes self-management behaviour pre- and post-intervention. Determinants factors that underpin the process of the primary outcome include changes in diabetes management skills and self-efficacy. In addition, we assessed the acceptability of the app among patients. We posit that the use of My Care Hub in this short-term trial would be acceptable and foster modest improvement in diabetes self-management behaviours due to improvement in skills and self-efficacy.

7.3 MATERIALS AND METHODS

The study procedures were approved by the Human Research Ethics Committee of the James Cook University (reference #H7716). Participants were informed about the study aims and the use of their de-identified data for analysis. Informed consent was implied by submission of an online survey while verbal consent was obtained for all telephone interviews.

7.3.1 Study Design

Details of the study methodology have been fully described in a previous publication (Adu et al., 2020b). In brief, this pilot study (conducted in August to October 2019) employed a mixed-method sequential explanatory design, where participants accessed the intervention over a three-week period and communicated their perceptions through surveys and interviews. The quantitative phase involved a single-arm repeated measures design entailing assessment of (1) preliminary efficacy of the intervention through measures of DSM activities, skills and self-efficacy where data were collected online before and after the intervention and (2) the app's acceptability. The qualitative phase involved telephone interviews with a subsample of participants and it was aimed at gaining more insight into the role that My Care Hub played in their DSM during the intervention period.

Participants were recruited via an email circulated to people interested in research who were registered with the National Diabetes Service Scheme, Australia. The inclusion criteria were (a) diagnosed with type 1 or type 2 diabetes, (b) aged 18-65 years, (c) live in North Queensland (a rural/regional part of Australia), (d) have a current recommended blood glucose level (BGL) target of 4 -10 mmol/L, (e) not pregnant, (f) able to perform activities of daily living, (g) have an android smartphone, and (h) not currently using an app which provides educational support related to DSM. To minimise response bias, a three-staged selection process was used: (i) all invited prospective participants were provided a link to the study information page containing details of the study focus and eligibility; (ii) those who indicated interest and gave consent were directed to the screening questions to confirm that they met all eligibility criteria; (iii) only those who met all the eligibility criteria were then directed to fill the pre-intervention survey which examined participants' demographic characteristics and health profile as well as their DSM, skills and self-efficacy levels. A total of 50 participants were enrolled into this study, which is sufficient for a preliminary efficacy study (Lancaster, Dodd & Williamson, 2004).

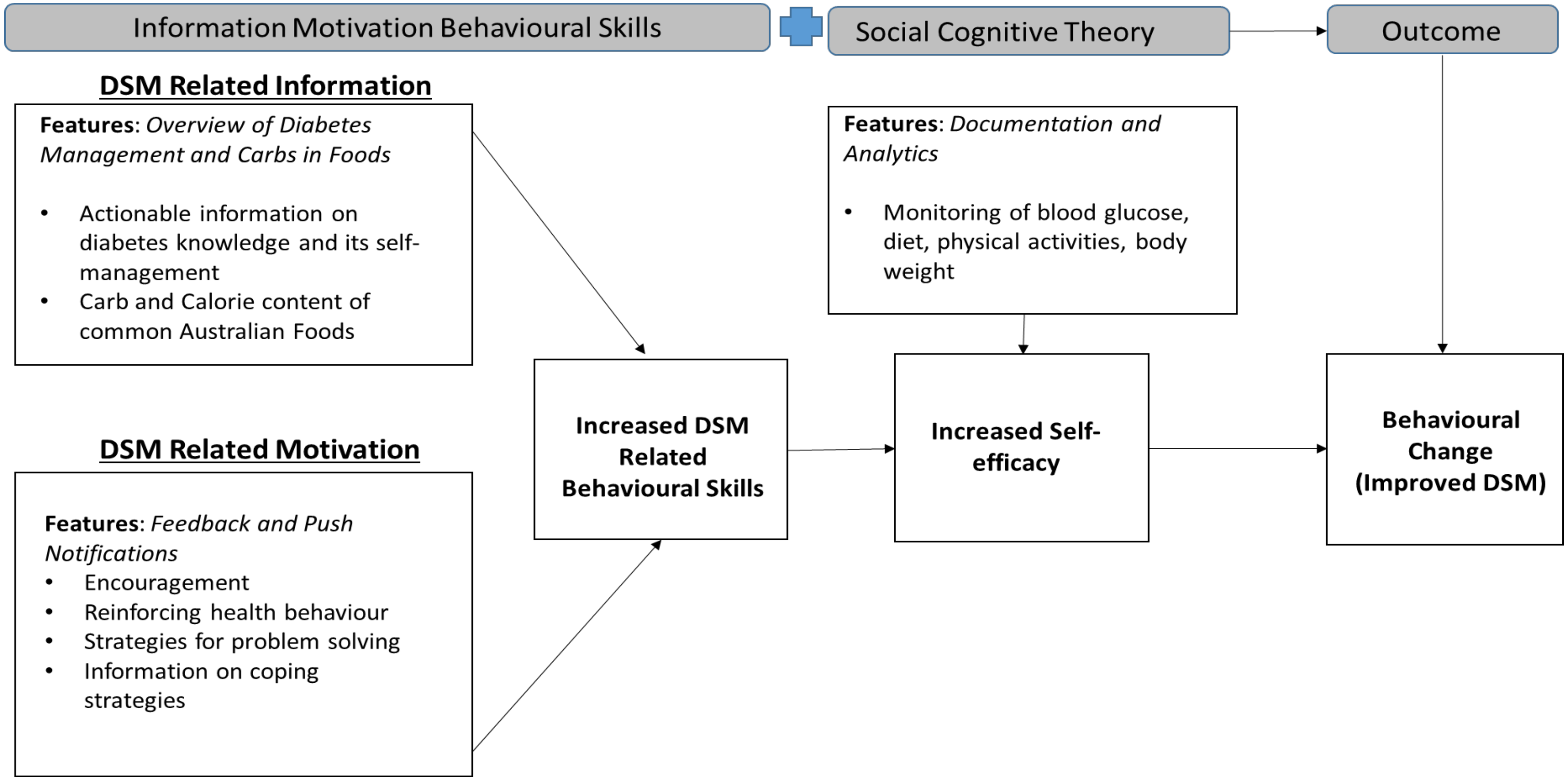
After filling the pre-study survey, participants were emailed a unique username and password to access the app and its user manual. Participants were provided with technical support to tackle any problems with the app and respond to queries.

7.3.2 Intervention

As outlined in the My Care Hub development protocol (Adu et al., 2020a), the app was specifically designed for those who have type 1 diabetes with recommended BGL of 4-8mmol/L-fasting and <10 mmol/L-2 hours postprandial, and fasting levels of 6-8 mmol/L and 2 hours post prandial levels of 6-10 mmol/L for those with type 2 diabetes. The self-efficacy (confidence) construct of the social cognitive theory (Bandura & National Institute of Mental Health, 1998) and the information, motivation constructs of the Information Motivation Behavioural Skills (IMBS) model (Fisher, Fisher & Harman, 2003) were the two underlying health behavioral change theories employed in the development of My Care Hub. In the context of this study, the blended concepts of the theories provided mediators for behavioural change. We hypothesised that diabetes self-management behavioural change is mediated by an individual's self-efficacy, which is related to their level of skills to undertake specific tasks required to reach a desired goal (diabetes self-management).

In relation to the framework described above, ''Documentation'' and ''Analytic'' features to monitor BGLs, physical activities, food intake were provided in My Care Hub as techniques to facilitate self-efficacy and consequently improve DSM in patients. Furthermore, the app's educational modules were developed using the three constructs of IMBS: Information, Motivation and Behavioural Skills. The IMBS model postulates that behavioural change occurs as a results of changes in skills sequel to effect of ‘information’ and ‘motivation’ interventions. Features on ‘‘overview of diabetes management’’ and ‘‘carbs in foods’’ provide information on diabetes and its self-management. Specifically, actionable ‘information’ on lifestyle modifications (healthy eating and physical activity), monitoring of BGL, complying with medications, good problem-solving skills, healthy coping skills, and risk-reduction behaviours (such as smoking cessation, alcohol intake reduction and foot care) for DSM (Shrivastava, Shrivastava & Ramasamy, 2013) were inputted into the app. In addition, the app contains ‘information’ on approximate equivalent carbohydrate and calorie content of common foods in Australia based on portion sizes of each food.

In relation to ‘motivation’, this was targeted using the ‘‘Feedback’’ and ‘‘Push notification’’ features in the app. Logged BGL data were automatically evaluated following the Australian Diabetes care guideline’s targeted values: optimally for people with type 1 diabetes, BGL 4-8 mmol/L before breakfast and <10 mmol/L 2 hours after each meal; for people with type 2 diabetes, BGL 6-8 mmol/L before breakfast and 6-10 mmol/L after each meal. The feedback feature determines if each data item satisfies guideline requirements or not and then provides feedback in the form of motivational encouragement, advice on lifestyle modifications or reinforcing health behaviours as applicable. Lastly, push notifications were provided to strengthen healthy coping necessary for improved engagement in DSM activities (Hood et al., 2015). Notifications provided messages related to diabetes distress, the importance of acknowledging it if experienced by participants and its’ potential impacts. Participants were then advised to identify realistic goals and focus on them in order to alleviate the distress, which consequently impact their DSM and health outcomes. Examples of actionable goals were provided in order to foster comprehension and engagement. Short, simple text notifications were sent at 12:30pm once daily during the intervention period. Long and frequent notifications may be perceived by patients as intrusive and annoying and might limit the opportunity for engagement with the intervention (Danaher et al., 2015). Although push notifications on apps can provide intervention content to users in a way that can be relatively difficult to ignore (Danaher et al., 2015), we took steps to increase the probability that all participants viewed the messages in order to equalise this intervention dosage. Hence, message sets sent in the first week were reshuffled and resent in the second week. This technique ensured that participants viewed messages - if a particular message was not opened in the first week on a specific day, it is likely it will be opened in the second week when sent on a different day. **Figure 7.1** illustrates the conceptual framework for the development and evaluation of the efficacy of the My Care Hub, which was informed by the mediating constructs of social cognitive and IMBS models.



Legend: Interventions on diabetes self-management information and motivation were provided in order to increase participants' skills for self-management aimed at fostering self-efficacy and consequently improved diabetes self-management behaviours

Figure 7.1: Conceptual framework for My Care Hub based on blended IMBS and SCT models.

7.3.4 Instrument and Data Collection

Baseline demographic and health characteristics reported by participants include age, gender, employment status, educational level, health care practitioner's recommended fasting and 2-hour post-prandial BGLs, duration since diagnosis and self-perceived health status.

Measures of primary outcome and mediators for preliminary efficacy

The primary outcome was frequency of involvement with DSM activities while mediating factors were diabetes management skills and self-efficacy. Improvement in each of the outcomes was defined by a statistically significant increase between pre- and post- intervention scores. The measuring tool (questionnaire) consisted of two sections, where section one measured the DSM activities using 10 items from the Summary of Diabetes Self-Care Activity (SDSCA) questionnaire (Toobert, Hampson & Glasgow, 2000). The SDSCA items covered five DSM behavioural domains: BGL monitoring (2 items), healthy eating (4 items), regular physical activities (2 items) and foot care (2 items). Participants were asked to recall their activities for the last seven days and state the number of days they performed the behaviours, after which the mean scores across each activity domain was calculated. Section two of the survey collected data on skills and self-efficacy for managing diabetes using the LMC skills, Confidence and Preparedness Index (SCPI) tool (Mbuagbaw et al., 2017). Only 17 items in the SCPI tool which addressed perceived skills (9 items) and self-efficacy (8 items) were relevant and used in this study. Participants were asked how they perceived their ability and confidence to perform diabetes related activities on diet, exercise, taking medications, managing stress, monitoring blood glucose and complications. Items were rated on a 10-point scale where higher values denoted better skills and self-efficacy. The scales have good internal consistency. In the current study, Cronbach alpha for the skills and self-efficacy items were 0.89 and 0.88 respectively.

Measures of acceptability

Post-intervention, participants also rated their experience with the app using a set of 18 relevant items adapted from different tools (Brooke, 1996; Venkatesh & Davis, 2000; Brooke, 1996; Lund, 2001). On a scale of 1 (strongly disagree) to 5 (strongly agree), participants rated their agreement with a series of statements about the app's acceptability. These are related to ease of use, intelligibility, satisfaction, perceived value, intention and behaviour towards recommendation.

Interviews

Within 3 weeks of participants indicating interest, semi-structured interviews were conducted by a single researcher (AD) who is well experienced in qualitative research. A semi-structured interview guide was developed for the study, and elucidated information on participants' perceptions of the app's impact on their DSM and interest in future use. The guide was pilot tested by MDA and AD, and the first three interviews were used to reflect on the guide, which was found appropriate for data collection in its original form. There was no prior relationship between the participants and any of the researchers. Each interview was audio-taped and transcribed. Data saturation was achieved after completing the 14th interview. However, interview sessions with all consenting respondents (17) were completed in order to allow for rich documentation. Repeat interviews were not required and there was no post interview debriefing. The conduct and reporting of the interviews followed the consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury & Craig, 2007).

7.3.5 Analysis

All quantitative data were analysed using SPSS version 23. Descriptive statistics was used to present participants' demographic characteristics. Outcome measures (pre-and post-intervention data) and acceptability of the intervention were reported using means and standard deviations (SD). Paired sample t-test and Wilcoxon signed-rank test were used to evaluate changes in the outcomes over 3 weeks for the normally distributed and non-normally distributed variables respectively. Effect sizes were calculated using Eta squared values to show the magnitude of changes in outcomes pre and post intervention. In addition, multiple regression analysis was used to estimate the contribution of the mediating factors to participants reported overall DSM levels post intervention. All mediating factors which increased (either significantly or not) from pre to post intervention were included in the regression. Two-tailed with $p < 0.05$ were considered statistically significant.

Audiotaped interviews were transcribed verbatim and coding of text fragments based on content was performed by two researchers MDA and AD independently. Consolidation of codes and grouping into themes was achieved through discussions with BMA. Findings are supported with illustrative quotes.

7.4 RESULTS

7.4.1 Demographics and Health Statistics

Of the 50 participants initially enrolled, 41(82%) completed the study, including filling in the post-study survey. Participants were predominantly male (61%), aged between 20-64 years (mean, 49.29 years [SD 12.74] and were Caucasians (92.7%). Most of the respondents were residents in rural areas of North Queensland (70.7%), had a technical college education or higher (78%) and were employed (70.7%). Most had type 2 diabetes (71%), rated their health status as ‘good’ or ‘better’ (63.4%) and were diagnosed with diabetes in the previous 5 years (56.1%). Participants reported their recommended fasting BGL: mean 6.03 ± 1.35; ranged 4-8 mmol/L and 2 hours postprandial: mean 7.53 ± 1.23; ranged 6 -10mmol/L.

7.4.2 Outcomes

Table 7.1 shows the total mean scores of the DSM domains and mediators: knowledge of diabetes management skills and self-efficacy. At baseline, self-reported adherence to daily dietary recommendations, engaging in physical exercise and BGL monitoring were generally performed five days a week while foot check was the lowest at about 3 days a week. The total mean score across all DSM domains was 4.55±1.44. Comparison between pre and post intervention scores shows that adherence to diet, monitoring of BGL and overall DSM significantly improved over time (p=0.04, eta squared = 0.1; p = 0.04, eta squared = 0.2 and p = 0.001, eta squared 0.24 respectively). In relation to skills and self-efficacy, significantly higher scores were observed in both of these factors after the intervention ($p < 0.05$ for both factors with an overall small effect size of 0.11).

Table 7.1: Observed mean and standard deviations for the outcome measures

Outcome	Baseline, Mean (SD)	Post intervention, Mean (SD)	P	Effect size
Diabetes self-management				
Diet	5.13 (1.10)	5.54 (0.90)	0.04*	0.10
Physical activity	4.48 (2.16)	5.35 (2.27)	0.09	0.07
Monitoring of BGL[a]	5.16 (2.81)	6.80 (1.95)	0.04*	0.20
Foot check	2.87 (1.86)	3.51 (1.79)	0.18	0.05
Overall	4.55 (1.14)	5.35 (0.84)	0.001*	0.24
Skills and self-efficacy				
Skills	7.10 (1.99)	7.90 (1.67)	0.04*	0.23
Self-efficacy	7.33 (1.82)	8.07 (1.54)	0.03*	0.25
Overall	7.27 (1.83)	8.00 (1.55)	0.04*	0.11

*p < 0.05
[a]BGL: Blood glucose levels

7.4.3 Relationship between Mediating Factors and Diabetes Self-Management

Positively strong significant correlations were found between skills and self-efficacy (r = 0.835, $p < 0.001$), where those with high level of skills have high self-efficacy. In addition, self-efficacy was weakly correlated with diabetes self-management (r = 0.285, $p = 0.07$).

Multiple linear regression analysis was conducted to examine the variables that predict DSM. After establishing the assumptions of multiple linear regression, analysis identified the simultaneous contributions of skills and self-efficacy on participants' level of DSM. These variables predicted 8% of the variation of DSM [F (1, 41) = 1.590, p = 0.218, R = 0.08]. While both factors did not have a significant relationship with DSM, the result shows that self-efficacy has the strongest influence on DSM (β = 0.478). Details are shown in **Table 7.2.**

Table 7.2: Influence of mediating variables on diabetes self-management

Determinant Variables	*B*	*SE*	*Beta*	*t*	*P*
Diabetes management skills	-0.15	0.144	0.298	0.1.38	0.306
Self-Efficacy	0.26	0.157	0.478	1.664	0.105
Constant (α) = 4.428					

$R^2 = 0.079$; Adjusted $R^2 = 0.29$

7.4.4. Acceptability

As presented in **Table 7.3**, overall mean ratings for all of the items were above 3 on the 5-point scale; suggesting that participants were satisfied with the app's ease of use and educational content. They noted that the app facilitated improved awareness, and stimulated their interest in DSM activities and assented that My Care Hub could serve as a DSM support tool. Participants also expressed interest in future use of the app if continually available and would recommend it to a friend or family with similar health condition.

Table 7. 3: Participant acceptability ratings of My Care Hub (N = 41)

Survey item	Mean	SD
Ease of use / intelligibility / satisfaction		
I feel confident using the app	4.2	0.68
I am satisfied with how easy it is to use the app	3.9	0.83
I felt comfortable using the app	4.02	0.76
I found the educational tips embedded in the app easy to understand	4.07	0.65
I found the immediate feedback provided after my BG log easy to understand	4.15	0.73
The messages displayed through push notification were easy to understand	4.17	0.59
Overall, I am satisfied with the app	3.68	1.04
Total	4.02	0.75
Value		
The daily messages (push notifications) increased my awareness of the importance of engaging in my self-management activities	3.59	1.14
The app features could stimulate my interest to continually participate in my self-management and record the activities	3.56	1.16
The app support my self-management such as tracking of BG, provide an idea of the carb content of my food	3.8	1.03
The daily messages (push notifications) motivates me more to pay attention to managing my diabetes	3.46	1.14
I found the immediate feedback received after logging my BG helpful for my self-management	3.61	1.16
The notifications motivates me to do my self-management activities (e.g exercise, healthy eating, BG monitoring)	3.41	1.16
My Care Hub app could serve as a self-management support tool for people with diabetes	4.05	0.87
Total	3.64	1.09
Intention for use and recommendation		
If I have continual access to the app, I will use it frequently	3.46	1.23
I think I would like to use the app more frequently	3.49	1.23
I could recommend the app to family and friends who have my type of diabetes	3.66	1.15
If I were to proceed with the program, I want to receive fewer push notification messages	3.02	1.01
Total	3.4	1.16

7.4.5. My Care Hub's Impact on Diabetes Self-Management and Interest in Future Use

An in-depth understanding of the quantitative findings in relation to My Care Hub's impact on participants' DSM abilities during the intervention period was elucidated through the interviews. Three major themes emerged from the interviews: ''Reinforced knowledge'', ''motivation for self-management'' and ''continuity''.

Reinforced knowledge: Participants perceived that the educational messages in My Care Hub reinforced their knowledge about diabetes and self-management of the condition.

''*I did have some knowledge as I have been to a dietician. But with the app. It is always good to have that little message to reinforce you each day to watch out for things that you shouldn't have too much of.*'' [P014, T2D]. *''It sort of helped me and remind me of watching the diet. High blood glucose level is a reflection of what you consume. It reminded me in that regard to be careful of what I eat.''* [P009, T2D].

The messages also prompted reflection on how best to handle events/situations. *''It clarifies the information I already know because this is a sort of disease that you can't see. It is eating away in the background there and the app lets you look at it from a different way other than just pricking your finger three or four times a day and prick again and it is still high. With the app, I kind of try to keep it under control.''* [P011, T2D].

A few participants reported that apart from the app reinforcing their knowledge, they also gained new information related to the effect of diabetes distress on blood glucose. *''Some of it was new information. It was quite interesting to know how stress affects diabetes and your sugar. I have a bit of stress every now and then. That information is something I had never thought about.''* [P016, T2D].

When asked about the advantage of promoting this intervention to a larger population, participants reported that the app would particularly improve the knowledge of people newly diagnosed with diabetes as a result of its educational information component: *''especially people who are new to diabetes could get a lot of information from it (My Care Hub). It would help them a lot to sort out what they are doing and what is going on.''* [P008, T2D]. *''People who are new to diabetes, like after attending a couple of courses, it could help them to understand a lot more.''* [P10, T2D].

Motivation for self-management: Participants described that the app provided motivation to care for themselves and encouraged participation in different aspects of their self-management. *''Yes, it increased my motivation. I do my blood test and I weigh myself regularly and I was going out to a do a reasonable amount of exercise.''* [P005, T2D]. Some participants mentioned that My Care Hub gave them some degree of control on managing their condition. *''For once it was about doing something for me, giving information to me and giving me I would say a degree of control…what I stick in my mouth.''* [P005, T2D]. Several features in My Care Hub supported different self-management activities and were perceived to improve easy accessibility to necessary support: *''I think just having everything there at your fingertips, the BGL levels, the exercise, your food, your diet, your carbs counting sort of thing. It was all there for you. You know the flexibility of it.''* [P009, T2D].

Continuity: Participants also expressed strong interest in future use and recommendation of the app to other users. Participants reiterated their intention to continue using the app if accessible: *''If you are serious about looking after yourself and stay within your target blood glucose range, I would definitely say yes to the app.''* [P007, T2D]. In addition, a participant narrated that his doctor was positive about the app's content and willing to recommend it to his other patients: *''I told my doctor I was doing a study and he had a look (at the app) and said yeah, that looks good. He asked what the green things were and I said, the green ones are what* *you should be eating and the other ones are high in carb. He thought that was OK and wanted to know what it is called because if he had other patients, he said he could direct them to downloading that app.''* [P13, T2D]

7.5 DISCUSSION

This pilot study investigated the preliminary efficacy and acceptability of the My Care Hub app, which was designed to improve participation in DSM in people with type 1 and type 2 diabetes.

Preliminary efficacy

In this study, patients reported improved levels of participation in all domains of measured DSM activities and this may be due to increased motivation to engage in self-management activities through the use of My Care Hub as reported in the interviews. Few short-term research studies have reported on the preliminary efficacy of mobile phone apps either in relation to overall DSM activities or for single self-management activity change (e.g. dietary or physical activity only). Agarwal et al., (2019b) and Faridi et al., (2008) tested the effect of a mobile technology on overall DSM, while others have monitored diet or physical activity (Rossi et al., 2010b) as part of program evaluation for diabetes support. Preliminary efficacy results of these apps vary from none (Agarwal et al., 2019b) to moderate (Faridi et al., (2008); Rossi et al., 2010b) among participants in the intervention settings. Therefore, the significant improvements in DSM observed in our study are unique and could be termed to have clinical significance when viewed in the context of impact on diabetes management.

In reality, continuing health-care provider support for DSM is not always available. Ongoing DSMES for improved self-management is needed to reduce or prevent the risk of developing complications and other poor health outcomes (Shrivastava, Shrivastava & Ramasamy, 2013; Beck et al., 2017), which are particularly prevalent among Australian rural populations

(Wakerman et al., 2008; Phillips, 2009; Australian Institute of Health and Welfare, 2019d). The provision of a potentially highly effective mobile health app such as My Care Hub for improving DSM could be an important supportive measure among this patient population. The My Care Hub intervention provides educational features, documentation features, Analytics and feedback i.e guidance based on information entered by users. The use of multi-component behavioural change strategies and mHealth features as described above have the greatest potential impact on behavioural change in self-management (Middelweerd et al., 2014; Direito et al., 2014;Danaher et al., 2015).

In recent years, several mHealth applications have been developed in order to support self-management in people with diabetes, with these interventions deemed feasible and acceptable, though evidence of improved self-management is either unclear or weak (Schoeppe et al., 2016; Whitehead & Seaton, 2016). This may be due to a lack of proper consideration of the mediating factors necessary to produce improved DSM. Adequate skills and self-efficacy are major pivoting mechanisms for behavioural change in diabetes management (Persell et al., 2004; Sarkar, Fisher & Schillinger, 2006; Wu et al., 2007; Aronson et al., 2018). The consequent impact of these factors to produce improved DSM is therefore expected and confirmed our hypothesis. Skills is the understanding and ideas that patient possesses about a subject (*diabetes and its management*), potentially with the ability to use it for a specific purpose (self-management) (Boger et al., 2015) and it fosters self-efficacy - the confidence a patient has in his/her self to achieve the purpose (Bandura et al., 1999). Self-efficacy is a prerequisite for informed health decision-making (Tomky et al., 2000; Mulcahy et al., 2003) and greatly influences the probability for behavior initiation, level of applied effort and how long behaviour will be sustained (Bandura et al., 1999). Therefore, the results of this study is a further proof-of-concept, supportive of previous literature on the value of improved self-efficacy to promote behavioural change (Holloway & Watson, 2002; Williams & French, 2011). Nevertheless, the non-significant predictive power of self-efficacy on DSM which we found in this study might be an indicator that self-efficacy is not strong enough to make a large effect in a short time frame. As such, it is likely that the strong causal relationship will require more prospective investigations.

Participants in this study emphasised that the intervention motivated them to engage in their DSM as well as reinforced their knowledge of diabetes. My Care Hub educational content serving as just-in-time resource to increase motivation and prompts to action in self-management have also been described in other studies (Webb et al., 2010; Klasnja & Prat, 2012). This result suggests that the app could be a feasible means of augmenting self-management education and support. Furthermore, the app was perceived to be a particularly useful tool for people who are newly diagnosed with diabetes to remind them of many issues discussed during face-to-face diabetes education session with their health providers on the importance of self-management and adherence to it for improved health outcomes.

Acceptability

The acceptability of a mHealth technology is an indication of its value and importance for wider implementation into the healthcare system (Kim, 2015). The result of this study indicates good level of acceptability of My Care Hub as most participants endorsed the app components as useful and supportive of their DSM. Other studies assessing acceptability of mobile apps for diabetes self-management were similarly positive (Kollmann et al., 2007; Torbjørnsen et al., 2018). This result might have also fostered higher levels of DSM reported in the post-intervention, because studies have demonstrated a positive association between higher levels of acceptability of a mHealth and self-management (Harrison et al., 2014; Westergaard et al., 2017). Likewise, perceived ease of use and satisfaction with health apps positively affect continued intention of use (Li et al., 2019). These were reflected in our study, as participants expressed overall satisfaction with the simplicity of My Care Hub with intentions of continued use and recommendation to others. Nevertheless, acceptability has been described as only 'one piece of a puzzle'; because even with high acceptance levels, uptake and upscale of the intervention may diverge. Hence, the recommendation that healthcare providers who perceive strong benefits of mHealth technology should endeavour to encourage patients' adherence to it (VanAnh, Auroy & Sarradon-Eck, 2019).

Strengths and limitations

The study utilised mixed-methods research design, which allowed for detailed exploration of participants' experiences and perspectives about the app. In addition, the study provided explanation of the preliminary-efficacy of My Care Hub app on diabetes self-management in relation to its mediating factors as targeted in the intervention. Such report is often lacking in many preliminary efficacy studies of mHealth technologies. The use of theory-driven and evidenced based intervention support strategies is also a notable strength of this study.

There are some limitations to the current research. A longer follow-up period would have provided clearer insights into sustenance of the reported behaviour changes. However, the short-term intervention period in this study is comparable to that of other studies with 2-3week intervention period (Herrejon et al., 2009; Heinrich et al., 2012). Furthermore, our study population were patients registered with NDSS and interested in research, potentially implying many participants were already on top of their self-management, as reflected in the high level of DSM at baseline. This reduces to an extent, the generalisability of the study findings to other populations. Also, the tools adapted for measuring acceptability of the intervention were not used in their entirety as items not relevant to the current study were removed. Using only few items from a validated tool might compromise its uniformity. Nevertheless, the selected set of items in each validated tool demonstrated good internal consistencies with Cronbach alpha from 0.70 to 0.91. We noted that our sample size like many similarly published pilot trials was modest. In addition, measured outcomes were self-reported and thus may be subjected to social desirability and recall bias. Lastly, the lack of control group may limit the conclusions that can be made regarding the beneficial impact of the app. Nevertheless, preliminary work such as this is a useful and necessary precursor to more rigorous examination of the intervention in a large-scale trial with longer-term follow up.

Future Directions

Automatic push notifications

The education component in My Care Hub specifically delivered through the push notification feature requires human coaching whereby a diabetes educator provides daily education through this platform during the intervention period. Intervention that relies on human input requires substantial human resources, which if lacking may limit the scalability of the intervention. Therefore, further improvement of My Care Hub requires automation of the push notification educational components free of human involvement as much as possible. This will lower the cost of operation and improve scalability of the intervention.

Long-term trial

The promising result of this pilot My Care Hub app project which shows preliminary efficacy, acceptability (as reported in this study) as well as good level of retention and engagement with the intervention (Adu et al., 2020b) will require further confirmation using long term controlled trials in the future. An adaptive randomised controlled trial design (Pham, Wiljer & Cefazzo, 2016) may be best suited due to the rapidly evolving nature of mHealth. The design will enhance dynamic adaptation of the app to the advancing field of information technology thus facilitating better understanding of the unique impact of each of the app features, thereby fostering improvement and long-term utility of the My Care Hub intervention in the support and management of diabetes.

7.6 CONCLUSION

The use of mobile phone application intervention among underserved population represents a novel approach to augmenting self-management education and support. We propose an innovative app–My Care Hub, as a self-management tool for Australians with type 1 or type 2 diabetes. The results of this pilot trial suggest that My Care Hub app can be an acceptable and potentially effective intervention that can be replicated in other contexts to improve diabetes self-management. Future work should employ larger and long-term trials to further establish the efficacy of the app and impact on glycaemic control and other health outcomes.

Overall, this chapter contributed to addressing the fifth aim of this thesis by reporting the pilot testing of the novel mobile app in order to ascertain its efficacy in diabetes self-management as well as level of acceptability among patients with type 1 and type 2 diabetes.

Chapter EIGHT: General Discussion

8.1 Chapter Overview

A discussion of the key findings of this research project in the light of current knowledge is presented herein. Novel contributions of the different components, practical implications within a broader context, strengths and limitations of the research are highlighted. The chapter also outlines prospects for future research to enhance self-management education and support for patients with type 1 or type 2 diabetes.

8.2 Research Findings and Novel Contributions

A systematic process was utilised to develop and examine preliminary efficacy of a mobile phone app to provide DSMES to Australians with type 1 or type 2 diabetes. An over-arching framework (Figure 1.2) was developed to guide the series of studies (each with its own hypothesis) presented as research chapters in this thesis. A summary of the key findings and novel contributions of each chapter is presented in Table 8 and discussed below.

8.2.1 Guidelines and Developments of the Essential Elements Required in Diabetes App Development

Chapter 2b tested the hypothesis that *a systematic review and evaluation of evidence from existing literature on the impact of diabetes app intervention on patient health outcomes will assist in the establishment of guidelines that outline important considerations required for the development of effective mobile phone apps to support diabetes self-management*. The review revealed a general lack of consideration of the key elements of app development by previous app developers and researchers. The key elements identified as lacking in large-scale trials with every diabetes app prior to use as an intervention tool were: inclusion of health behavioural theory, views of users and clinical experts, data security and privacy as well as pilot testing.

Poor considerations of health behavioural theoretical constructs in the development of mobile diabetes app interventions highlighted a missed opportunity of using digital interventions to inform the refinement of existing theories or developing new suitable diabetes apps. Theoretical components could facilitate health behavioural change; therefore, their inclusion is an important first steps in improving the efficacy of apps targeting the promotion of health behaviours (Noar & Zimmerman, 2005; Glanz & Bishop, 2010).

Insufficient consideration of users' expectations and preferred components in a diabetes app resulted in poor adoption of user-entered design principles. Non-inclusion of the opinions of end users (diabetes patients) in terms of usability requirements and preferences in app features caused low retention and engagement with apps when used as intervention tools (Arsand & Demiris, 2008; Yardley et al., 2016).

The lack of involvement of healthcare professionals (HCP) in developing apps was consistent with previous studies (Arnhold, Quade & Kirch, 2014). Involving HCP in the early phase of mobile app development ensures accuracy, precision and quality of the intervention components. Inaccuracy of intervention content is one of the major barriers to the implementation of technology in clinical care settings (Maguire et al., 2008; Murray et al., 2016), hence, involving HCP in developing apps for patients provides an opportunity to minimise imprecisions and inaccuracies.

Furthermore, most of the apps reviewed lacked information on data security and privacy in line with previous analyses of mobile health and fitness apps (Ackerman, 2013). Both patients and clinicians have indicated that privacy policy and data security inclusion in apps are important for gaining user trust (Fife & Orjuele, 2012; Schueller et al., 2018). As such, security measures to protect patients' information must be initiated at the time of app development and maintained long-term. Providing privacy policies, encrypting personal identifiable information on cyberspace and data encryption are some of the ways app data security and privacy could be guaranteed.

In most apps reviewed, pilot testing processes prior to use in either randomised controlled trials or quasi-experimental studies were not reported. A pilot study is a necessary step in exploring the feasibility of novel interventions prior to use on a larger scale (Leon, Davis & Kraemer, 2011). Well-conceived and implemented piloting of apps could reduce the risk of several long-term problems in large-scale studies; including the inability to recruit and retain an effective sample size and the subsequent reduction in statistical power. Piloting reveals the need to modify an intervention or protocol prior to use, in order to minimise the percentage of failed trials and maximise the opportunity to efficiently utilise research funds on developing feasible and impactful app interventions.

Most importantly, the review found a significant association between the inclusion of educational components in apps and improved glycaemic control which is the ultimate goal of self-management interventions. This highlighted the need for using self-management education to advance the efficacy of diabetes app as a supporting tool for patients.

Overall, the systematic review filled the gap of providing evidence-based information and clear guidelines on essential elements for app development (Kohatsu, Robinson & Torner, 2004; Ben-Zeev et al., 2015; Lhachimi, Bala & Vanagas, 2016) as a delivery mode for DSMES. The review revealed the need to carry out other preparatory studies that facilitated the identification of these essential elements (Chapter 3) and preferred features / educational content (Chapter 4) in apps that promote DSMES prior to developing the new mobile app (chapter 5), which was then pilot tested for efficacy (Chapter 6) and acceptability (Chapter 7).

8.2.2. Understanding the Perceptions of People Living With Type 1 or Type 2 Diabetes on the Mediating Factors of Skill and Self-Efficacy for Diabetes Self-Management

Chapter 3 tested the hypothesis that *skills and self-efficacy are important mediating factors that stimulate behavioural change and improved self-management in people with type 1 and type 2 diabetes.* A multinational audience across four continents (USA, Australia, Europe and United Kingdom) was utilised to provide a relatively generalisable data set to foster the understanding of the phenomenon of interest. The findings revealed a strong positive correlation between skills and self-efficacy, which could lead to improved DSM due to behavioural change. Patients across all continents reported high levels of skills and self-efficacy to monitor the impact of physical activity, medication and diet on their blood glucose levels. However, they reported lower levels of skills and self-efficacy in identifying and managing the impact of stress on diabetes, exercise planning to avoid hypoglycaemia and interpreting blood glucose patterns. These revealed common areas of low skills and self-efficacy for self-management among diabetes patient could guide health providers and researchers in prioritising areas of need when providing education and support intervention to patients with type 1 or type 2 diabetes.

The study confirms the importance of adequate skills and self-efficacy acquisition in relation to disease management (Johnston-Brooks, Lewis & Garg, 2002; Persell et al., 2004; Aronson et al., 2018). Previous research on diabetes has established that increasing patients' skills and understanding of their illness alone does not lead to actual improvement in health-related behaviour (Atak, Gurkan & Kose, 2008). This phenomenon is known as 'knowledge-behaviour gap' (Sligo & Jameson, 2000). Therefore, in addition to relevant skills acquisition, individuals need to believe (self-efficacy) that they are capable of executing and maintaining a behaviour in order to devote the necessary effort to succeed (Bandura, Freeman & Lightsey, 1999). In addition, this study showed that patients who were more educated had higher levels of skills and self-efficacy (Bandura, Freeman & Lightsey, 1999), thus suggesting that low educational status in patients is a risk factor for low levels of skills and self-efficacy for DSM. This corroborates several researchers in diabetes and other health conditions (Gazmararian et al., 2003; Wilson et al., 2010). Low health literacy (Kindig, Panzer & Nielsen-Bohlman, 2004) and reduced health prevention behaviours (Bennett et al., 2009) occur as a result of poor knowledge and difficulty with recalling information from consultation (Poon et al., 2004; Wilson et al., 2010). Therefore, there is the need to ensure that educational materials developed as part of this research are written in concise and plain languages in order to improve readability of the intervention.

Taken together, the findings of this study point to the need for inclusion of skills and self-efficacy as key mediators in any intervention targeting behavioural change towards improved self-management among people with type 1 and type 2 diabetes. Therefore, the intervention developed and evaluated in subsequent studies (Chapter 5, 6 and 7), considered features and content targeting skills and self-efficacy in users. This was in addition to educational materials being written in plain language in order to increase the efficacy and acceptability of the intervention and the users' self-management behaviours.

8.2.3 Understanding the Perceptions of People Living with Type 1 or Type 2 Diabetes about the Features and Educational Contents Necessary for Engagement with Apps and ongoing Diabetes Self-Management.

As earlier identified in the systematic review (**Chapter 2b**), it is essential to involve end-users in app development process. Therefore, **Chapter 4** hypothesised that *needs analysis among type 1 and type 2 diabetes patients will elucidate essential features and educational contents in apps to foster retention and engagement with diabetes self-management activities.* **Chapter 4** utilised a multinational target audience of type 1 and type 2 patients from Australia, USA, Asia and UK. The primary aim was to identify the highest priority mobile app features and educational needs that encouraged participation in diabetes self-management. Such empirical evidence with an international focus is rare in the published literature. Firstly, the findings revealed that patients with diabetes valued a multi-component app with three broad features. These include features that supported monitoring of self-management activities (documentation), facilitated visual representation of reported activities (visual analytics) and provided general education and feedback related to specific blood glucose levels per time (personalised education). These findings could guide diabetes researchers to design DSMES interventions that are of more value to patients, compared to intervention designed without direct involvement of target users.

Secondly, this chapter identified patients' preferences for an app that had its contents related to problem-solving and basic guidelines on how to manage diabetes. The patients' information needs reflected their experiences of barriers to information gathering and in-depth understanding of disease management between consultations with their health care providers. Nonetheless, the stated information needs are required for optimal attainment of self-management behaviours, which could consequently prevent acute diabetes complications (Tomky et al., 2008; Lambrinou, Hanson & Beulens, 2019).

Thirdly, this chapter highlighted the conditions under which apps might be embraced by patients. The strategies recommended to mostly engage users were: ease of use, improved functionalities for healthy recipes, actionable goals, data consolidation and reliable information sources for problem solving in DSM. Again, suggestions on reliable information sources for problem solving revealed the difficulties patients had in accessing reliable information outside of consultations. These findings emphasised the importance of adopting evidence-based protocols (such as providing information for problem solving and other recommended strategies) in the development of intervention apps. Although, data consolidation was recommended to promote engagement with apps, it was not implemented in the app intervention developed as part of this thesis. This was because the provision of other monitoring gadgets such as blood glucose monitors and insulin calculators were well beyond the scope of this study. Besides, data streaming from other health devices would have required a much more complex level of guaranteeing data security, privacy and accuracy of consolidated data.

Finally, this study confirmed previous findings that the use of mobile app for self-management appeared to be more common among individuals with type 1 diabetes, young, employed and of higher educational status (Boyle et al., 2017). This finding suggests that app developers and researchers need to consider the demographic characteristics of end-users and their different requirements in an intervention app. This finding further emphasises the importance of developing intervention apps with an information component that is easy to comprehend. This could improve the tendency of the intervention to serve those of lower literacy level, most likely unemployed and within the older age bracket.

Altogether, the findings of this chapter are of particular value to the wider diabetes intervention field as they describe patients' needs and the underlying contexts. Thus, the results were prioritised to inform decisions on the intervention components used in developing a brand new app as reported in Chapter 5.

8.2.4 Development of a Novel Mobile App for Diabetes Self-Management Education and Support and Assessment of its Usability among Type 1 and Type 2 Diabetes Patients.

While Chapters 2b – 4 (the first three aims of this thesis) justified and informed the design of an app intervention for patients with type 1 or type 2 diabetes, **Chapter 5** reported on the systematic process that was used to create the novel app called 'My Care Hub' app, following the guidelines produced in Chapter 2b. This consisted of an iterative development process that included the choice of underlying health behavioural constructs, selection and development of app features and educational contents based on users' preferences. Other aspects of the process included the involvement of clinical experts, data and privacy security considerations and app interphase design. These were followed by a two-stage usability testing with non-patient and patient population groups to inform the final version of the app. The app is purposely targeted to support people with type 1 or type 2 diabetes whose recommended blood glucose (BG) ranges are between 4 and 8mmol/L for type 1 and 6 and 10mmol/L for type 2 diabetes; according to the Australian guidelines (Diabetes Australia, 2015). Following the guideline is essential for accurate feedback to users in response to BG data logged into the app.

Several other smartphone apps for patients with diabetes such as mySugr, Health2Sync and Diabetes Connect currently exist, but the 'My Care Hub' app has several unique advantages: First, the 'My Care Hub' app is evidence-based with underlying theoretical mechanisms to drive behavioural change in patients. This ingrained mechanism maximises its potential to foster behavioural change (Davis et al., 2015). This is in contrast to most of the existing mHealth apps which lack theoretical models for behavior change, resulting in technologies that are not intuitive and neither useful nor evidence-based (Conroy, Yang & Maher, 2014; Chib & Lin, 2018). Second, My Care Hub provides patients with a unique and multiple combination of diabetes self-management supporting tools and education that are all accessible in a single platform. Third, the app offers monitoring documentation features for diet, blood glucose, physical activity and body weight, visual graphic tends of all monitored activities and immediate feedback in response to logged BG values. Fourth, the app also allows patients to troubleshoot key aspects of DSM that are out of the recommended BG range. Fifth, unlike most existing apps (Chomutare et al, 2011), My Care Hub highlights all the significant and fundamental differences between the self-management of type 1 and type 2 diabetes.

Findings from the first stage of the app usability testing highlighted the need to provide additional access to the documentation features of the app. This omission was immediately addressed, highlighting the importance of detecting and solving usability problems (Hoegh et al., 2006; Knuth et al., 2019). The second stage of the usability testing provided evidenced based on the participants' perceptions that the app accomplished its intended goals of being user-friendly, informative and motivational for DSM. The positive results obtained from the usability testing validated the My Care Hub novel system design and indicated that users can achieve specific DSM goals when using the app (Volentine et al., 2017).

8.2.5 Understanding the Potential of the New App for Improved Self-Management and its Acceptability

Chapters 6 and 7 tested the final hypothesis that *the developed mobile phone app will be an effective and acceptable diabetes self-management education and support tool.* The studies utilised participants with type 1 and type 2 diabetes residing in North Queensland, Australia. This region was chosen because of its rural and remote location, as well as its high prevalence of people living with diabetes (Queensland health report, 2018). As obtainable in other rural and remote areas of Australia, people in North Queensland also have poor accessibility to specialised diabetes support services (Australian Institute of Health and Welfare, 2019e). The studies provided several novel contributions to existing knowledge on retention, engagement, preliminary efficacy on behavioural change and acceptability of the new intervention app among end users. First, a satisfactory and high level of retention rate was demonstrated since most participants returned to use the app in weeks 2 and 3, and completed the study. During the feasibility testing, regular reminders and calls to participants to engage with the app were not used. This is because My Care Hub was designed to be an independent stand-alone app without the need for cajoling end users. This approach is important for planning future studies with My Care Hub because a satisfactory level of study completion minimises the methodological problem of accurately measuring the effectiveness of digital trials (Eysenbach, 2002). In addition, high retention minimises the problem of missing data, which undermines outcome validity and credibility of inferences from trial findings (Eysenbach, 2005); Murray et al., 2009). Therefore, the high usage and retention rate imply that the app was fully used and has the potential to retain users in future studies.

Second, the use of a theoretical framework to assess the potential of the app's components to stimulate behavioural change identified the strategies by which engagement with My Care Hub features leads to behavioural change. Several benefits of using the app were reported and patients found all the features to be useful. The 'Documentation' and 'Analytics' features provided patients with clarity to take better responsibility for their self-management. The 'Feedback' and 'Educational tips' features reinforced health providers' recommendations and general knowledge on DSM. These features also raised alerts to potential problems in BG levels and suggested appropriate solutions. Patients perceived the 'Carbohydrate components in foods' feature to be useful for planning meals, prompting self-awareness of calorie consumption and knowledge about carbohydrate and caloric values of foods. These findings suggested that the app's components supported diverse areas of DSM regimen as intended in the intervention goal.

Interventions like My Care Hub, which furnish users with information based on key elements of skills and self-efficacy in fostering DSM; coupled with provision of feedback on logged BG and graphical display of all logged lifestyle behaviours enabled patients to draw a well-defined association between lifestyle and glycemic control (Caban & Gorz, 2015). It also provided patients with reassurance and motivation for behavior modification to foster improved health outcomes (Quinn et al., 2008). Such interventions that ease monitoring of lifestyle activities improve adherence to self-management (Room et al., 2017). Therefore, the benefits of the app features coupled with the results obtained on engagement with all features during the intervention period, were evidenced-based proofs that support the inclusion of all the tested components in future versions of My Care Hub app.

Other Unique Aspects of My Care Hub

The most frequently used feature in this app was the blood glucose tracker. This observed engagement could have been due to the coupling of the feature with immediate feedback. My Care Hub's approach of providing actionable lifestyle related information and individualised education was essential for behaviour change based on logged data. This in turn, enhanced continued skills acquisition and self-efficacy; a concept closely linked to information literacy and lifelong learning. This was in stark contrast to other existing apps with engagement methods that do not provide tactics for improving skills and self-efficacy on an on-going basis.

In contrast to the findings in **Chapter 4**, indicating that older patients were less likely to use an app compared to younger patients, many of the participants retained in the pilot testing of My Care Hub were over 50 years of age. This implied that a patient's age was only a temporary barrier to the use of new technology, and older patients were willing to learn to use it if they think it will benefit them (Parker et al., 2013; Joe & Demiris, 2013). This was encouraging because it suggested that the novel app could be a useful platform for delivering diabetes interventions that include older patients who may lack experience with new technology. This current study anticipated that patients who had less experience with apps would be able to easily learn to use My Care Hub due to its simple design and user-friendly navigation.

This study highlighted the benefits of promoting the intervention to people newly diagnosed with diabetes in order to reinforce the knowledge gained during face to face consultations with healthcare providers. It is well established that diabetes patients' information needs are highest following diagnosis (Grobosch et al., 2018). Therefore, presenting an app to patients early in their consultations in order to maximise the benefits of the apps and subsequently reduce complications is essential. Nonetheless, the present study found that the app was generally useful in enhancing improved DSM in all durations of diagnosis including those that had been diagnosed for over 15 years.

The high level of acceptability of My Care Hub was evidenced by the high ratings for ease of use, perceived value for DSM, recommendation to others with diabetes and intention for future use by participants. This finding could be interpreted using the new technology adoption model whose items were used as part of the acceptability assessment of My Care Hub (Davis, 1989; Vankatesh & Davis, 2000). The theory stipulates that when end-users are exposed to a technology and perceive it to be useful and easy to use, they are likely to accept and use it. Thus, these findings were positive indicators of high uptake of the app in the future.

Furthermore, the pilot-testing highlighted only minor suggestions for modifications of the app, indicating an overall patient satisfaction with the app design and its components. It was thought that documenting activities in the app could be made easier by including a ‘Bluetooth’ interface and the creation of feedback feature specific to logged physical activities data. In addition, some patients suggested information update on a regular basis in the app, believing that this will further improve engagement. Lastly, more analytic histories were suggested in future versions of the app. However, none of the suggested additional features were mentioned in the needs analysis study in Chapter 4**,** therefore they were either unpopular or not essential for improving self-management and engagement with apps. However, the suggested additional features could be considered in the future version of My Care Hub as long as ease of use is not in any way compromised.

Generally, the app was able to retain and engage users. It also improved behavioural change and acceptability to patients in real life settings. However, the generalisability of these findings were restricted to a particular sub-group of patients - Android smartphone owners, most of whom probably had high motivation for their self-management going by their registration of research interest with the National Diabetes Service Scheme. It is possible that patients included in the pilot testing found the app easier to use and more acceptable than their other counterparts. Therefore, future field-testing with a more generalisable sample of patients is required to further confirm the present findings.

Table 8.1: Major findings of each chapter and contributions to the thesis.

Chapters	Major findings	Contribution to the thesis
2b	The systematic review found that: • Considerations of health behavioural theory, user and clinical expert involvement are crucial in app development. Ensuring data security and privacy in addition to pilot testing are other factors essential in the process of developing a diabetes app. • Inclusion of self-management education in an app was found to improve glycaemic control.	**Chapter 2b** addressed the first Research Question – *What are the necessary elements in an app development process to foster an effective diabetes self-management education and support intervention?* The findings of this review gave an understanding of the essential elements required in an app development process prior to use as an intervention for self-management education and support by patients with type 1 or type 2 diabetes. This stimulated the need for the studies presented in chapters 3 and 4, which were used to gather information in preparation for the development of a novel diabetes app. This chapter also contributed to the questions used in the online survey and study interviews in chapters 3 and 4. In addition, the results of the review were used in the development of the novel diabetes app (Chapter 5).
3	• There were highly positive correlations between skill and self-efficacy in both the preparatory and pilot testing phases of the novel app ($r = 0.906$ and 0.835 respectively). In addition, the scores of skills and self-efficacy during pilot testing were significantly increased among participants, pre- and post-intervention ($P = 0.04$ and 0.03 respectively).	Chapter 3 contributed to Research Question 2 – *To what extent do skills and self-efficacy stimulate behavioural change for self-management in patients with type 1 and type 2 diabetes?* This first original-research component of the study established the groundwork for behavioural change mediators that were utilised in Chapters 5. In addition, the chapter shed light on the areas to accentuate (in relation to skills and self-efficacy)

	• Patients' skills set was a strong predictor of self-efficacy required for diabetes self-management. • Common gaps were highlighted in the areas of identifying and managing the impact of stress on diabetes, exercise planning to avoid hypoglycaemia and interpreting blood glucose patterns	when providing educational support to patients. Thus, revealing areas to accentuate when providing educational support to patients. The Chapter was key in the development of intervention elements presented in Chapters 5. This chapter further established mHealth as an important facilitator of self-management in patients.
4	• The most preferred features in a diabetes app are food nutrient composition, visual analytics, general and personalised education, trackers for blood glucose and body weight • Recommendations on fostering better engagement with apps were improved functionalities on healthy recipes, actionable goals with reminders, ease of use, data consolidation, customised features, certified and reliable information sources. • Specific educational topics of interest to patients were approaches to problem solving and basic guidelines for the management of diabetes	**Chapter 4** addressed Research Question 3 - *What are the type 1 and type 2 diabetic patients' preferred features and educational contents in apps that will foster retention and engagement with diabetes self-management activities?* This preparatory phase of the research provided information on patients' preferences for features and education contents in apps. The findings of this study largely contributed to the development of the My Care Hub intervention reported in Chapter 5.
5	This study presents a full description of the development of a novel app (My Care Hub) and its usability testing using mixed-methods design. • The first stage of usability testing of the app among non-patient populations highlighted minor modifications to the design which were promptly addressed.	**Chapter 5** contributed to answering Research Question 4 - *To what extent would a newly developed diabetes app stimulate improved diabetes self-management and acceptability among type 1 and type 2 diabetic patients?* The findings from **Chapters 2b – 4** were utilised in developing the new app. Specifically, the app development was described following the framework derived in **Chapter 2b** and using the

	• The second stage of the usability testing revealed that patients were satisfied with the app's performance, navigation between screens and features, quality of graphics and general visual appeal. Additionally, the app was deemed by patients to be user-friendly, informative and motivational in inducing and sustaining DSM.	mediating components of skills and self-efficacy (**Chapter 3**). This was in addition to the type of app features and educational components preferred by patients as well as their recommendations to improve engagement (**Chapter 4**).
6 and 7	A mixed-methods pilot testing of the novel app revealed that demonstrated: • High acceptability and retention rates. • High levels of engagement with significantly increased DSM activities from pre-to post intervention time periods (p<.01). Effect size: 0.24, which corroborated patients' perception of the app's usability. Various perceived benefits of the app, including increased accountability, reinforcement of health providers' recommendation and., highly educational level. • Perceived enhanced self-management skills and self-efficacy for long-term improved behavioural change and DSMES	**Chapters 6 and 7** contributed to answering Research Question 2- *To what extent do skills and self-efficacy stimulate behavioural change for self-management in patients with type 1 and type 2 diabetes*? And Research Question 4 - *To what extent would a newly developed diabetes app stimulate improved diabetes self-management and acceptability among type 1 and type 2 diabetic patients?* Potential outcomes of the novel app were identified in terms of retention, engagement, behavioural change and acceptability.

8.2.6 Theoretical Underpinning Models

In chapters 1 and 2, several models and theories were cited as commonly utilised for developing and evaluating public health behavioural change interventions. It was apparent that similar elements permeate the model or theories in terms of providing insight into a disease, its impact and coping mechanisms. The theories also provide insight into the determinants of patients' engagement with care and self-management of their condition. However, major approaches relating more to fostering positive behavioural changes for improved health outcomes include utilisation of frameworks to develop interventional support for chronic diseases (Araújo-Soares et al., 2019). The self-efficacy constructs of the Social Cognitive Theory (SCT) posits that the capacity of being confident influences the thought pattern necessary to perform self-management tasks (Bandura, Freeman & Lightsey, 1999). Thus, individuals could acquire and maintain behaviours through this essential mechanism (Bandura, 1998; Bandura, Freeman & Lightsey, 1999). On the other hand, Information Motivation Behavioural Skill (IMBS) model believes that information and motivation influences behavioral skills in an individual (Fisher, Fisher & Harman, 2003). Adoption of these models in this research project provided insight into patients' preferences for app components (Chapter 4). For example, the recommendation of educational components such as basic steps of managing diabetes and strategies for problem-solving might suggest that patients were attempting to increase their diabetes related information and motivation towards building their skills and self-efficacy to enable effective self-management of their conditions (Atak, Gurkan & Kose, 2008; Hill-Briggs, 2003; Stetson et al., 2010; Mohebi et al., 2013). Similarly, preferences for features to self-monitor blood glucose and behavioural activities might suggest that patients would use this feature as a mechanism to further enhance their self-efficacy (Brackney, 2018).

The self-efficacy construct of the SCT (Bandura, 1999) and information and motivation constructs of IMBS were considered particularly useful during the development of My Care

Hub due to their frameworks of building mechanism to foster successful behavior change initiative towards on-going self-management for chronic diseases (Fisher, Fisher & Harman, 2003; Ashford, Edmunds & French, 2010). Features that could be used to foster these mechanisms were selected for inclusion in the novel app based on patients' recommendations. For example, the use of self-monitoring features could enhance self-efficacy because frequent self-monitoring is a multistage process of observing and recording one's behaviour (Mace, Belfiore & Shea, 1989). The two steps involved in self-monitoring where an individual must initially identify the occurrence of a target behaviour, then self- record some aspect of the target behaviour (Craig & Nemeroff, 2004), are approaches to prevent relapse and motivate lifestyle modification (Gallagher et al., 2013). Similarly, immediate feedback on BG data provides continuous avenue either for reassurance of recommended BG levels or reinforcement of knowledge for problem solving (when needed) (Quinn et al., 2008). This builds patients' skills, motivation and confidence on how best to attain self-management goals. The visual analytic feature provided an opportunity for patients to identify patterns in their BG control in relation to lifestyle activities (physical activities, diet and weight). This provided a clearer guide towards decision making on how to self-manage (Caban & Gotz, 2015). Information on the seven essential ways to manage diabetes (Tomky et al., 2008) may further guide decision-making and ultimately improve patient's ability to self-manage.

Findings from the field-testing of the novel app provided further insight into the relevance of the adopted theories to this type of intervention. Reported benefits experienced by patients, including clarity of self-management activities and impact, as well as improved awareness of BG levels suggest that the app increased their skills as reported. This is in addition to reports on the app providing guidance on meal planning, knowledge provision and reinforcement. Furthermore, some patients noted that they experienced accountability, and awareness of calorie consumption as a result of using the app. These findings indicate that the app was useful for improving self-efficacy with the condition, as anticipated by the SCT. However, the development of the app for this thesis was largely investigative, so the studies carried out cannot yet confidently determine the most or least useful theories. Nevertheless, as the app is a multi-featured comprehensive intervention, it is likely that the constructs of these models and approaches discussed throughout this thesis will be relevant for the development of its future versions and long-term evaluation.

8.2.7 Strengths and Limitations of the Research

To the best of my current knowledge, this is the first study to use a systematic process to develop and examine the preliminary efficacy of a mobile phone app to provide DSMES to Australians with type 1 or type 2 diabetes. The development and reporting of My Care Hub were transparent and detailed. This transparent reporting is in accordance with 'Open Science', which encourages making materials, data, results and publications freely available for efficient scientific progress (Munafo, 2016). The app development process right from all preparatory studies, details of the design and content as well as results of pilot testing are available in open access journals. This may provide a good illustration to other researchers developing health-related behavioural change apps.

This research filled the gap on existing needs to understand the important elements required in an app development process to increase its potential as an effective self-management tool. The developed guideline for app development could provide a standard approach to the design of effective diabetes care apps and inform policy, practice and research.

The incorporation of users' preferences into My Care Hub allowed improved user engagement with the app, as reflected in the app usage data and interview with participants. While assessing common gaps in skills and self-efficacy, establishing the relationship between these variables and targeting them as mediators in the intervention led to improved health behaviours.

Furthermore, the pilot testing provided preliminary findings in the context of a diabetes mobile app intervention, that there is support for the role of multi-component features in an app. These features for documenting lifestyle and blood glucose, feedback and analytics and educational content enhanced skills and self-efficacy in improving diabetes self-management. Therefore, the development of the app with initial studies at the preparatory phase prior to actual development provided an evidence-based approach on which intervention components could be effective.

Another strength of the research is that assessing behavioural engagement with My Care Hub using a theoretical model provided an understanding of the usefulness and impact of all available app features. The use of this method gave insights to other diabetes app developers and researchers on how to assess their intervention components. Moreover, practice-based evidence derived from programmes implemented in real-life settings was a more suitable source of evidence for inspiring and guiding public health intervention (Ng & de Colombani, 2015). Thus, the use of field trial to pilot test the potential of the novel app is a strength of this research. Publication of the present research studies (see List of Publications) introduced a comprehensive body of internationally relevant knowledge to researchers and app developers on how to foster the potential effectiveness of a diabetes app intervention.

However, there were some limitations within this research. Acknowledgement of such limitations would assist readers in clearly understanding the scope of this research. The main limitations were time and resource constraints inherent in conducting a PhD research. Therefore, pragmatic decisions on categories and number of participants, type and time available for data collection were paramount. More pertinently, some of the processes in a diabetes pilot intervention studies were waived. For example, it would have been more ideal to include a control or comparator group in the trial to get an idea of whether the overall improvement in DSM was a ‘natural improvement’ or a regression to the mean - observations that differ substantially from the true mean tend to align with observations closer to the true mean (Barnett, Van Der Pols & Dobson, 2005). Nevertheless, the choice of a comparator group when evaluating a digital behavior change intervention is an issue with multiple options such as intervention and wait list control groups or pre- and post- trials as used in the current research. No ideal option has been stipulated because each of the options has its own advantages and disadvantages (West & Michie, 2016). Furthermore, due to time and resource constraints, it was impossible to continue the pilot testing of the app for data collection of glycosylated hemoglobin (HbA1c) as an outcome measure after a minimum period of 3 months of the app use. Measuring HbA1c would have provided the opportunity to evaluate the efficacy of the intervention on glycaemic control. Although, the study did not evaluate clinical outcomes, it did a comprehensive evaluation of the app in terms of usage, behavioural engagement strategies and self-management outcomes. This facilitated a thorough understanding of how the app component engaged patients and improved self-management, which consequently foster improved glycaemic control.

The study in Chapter 3 had another section that identified some barriers to DSM. This included lack of enthusiasm towards self-management due to the chronic nature of diabetes, financial burden, work and environment related conditions and unrealistic demands from friends and family. Further studies that were carried out after that chapter were unable to make use of most of the identified barriers because of non-alignment with the overall goal of the research. However, My Care Hub components provide motivation for improved self-management and could ameliorate the issue of low interest in DSM due to its chronic nature.

A further limitation of the study is that samples of the pilot testing were drawn from the database of registrants with the National Diabetes Service Scheme Australia. Information on the key characteristics of those who declined to participate was not collected, although this may be due to not having an Android phone, which was a main recruitment criterion. The samples included in the pilot study may therefore not be truly representative of the general population. The sample included in the pilot testing, apart from having an android phone, may be those who have a favourable perception of an app than those who choose not to participate. It is therefore possible that this limitation artificially inflated the positive findings in the app's pilot testing. Also, participants in the pilot testing already owned or had access to smart phones. These individuals were likely to be more familiar with the use of a smartphone than those who did not own such technology. Those who declined to participate and who did not have access to smart technology might not have found the app as easy to use as those included in the trial.

A further limitation of the pilot testing of the app is that about 95% of participants identified as White Caucasian. It is possible that other Australian ethnic groups such as the Aboriginal and Torres Strait Islanders, may have different experiences of diabetes as well as needs and perceptions regarding an app. Further testing of the app may be required with other population samples in order to support the present findings. Some studies had suggested little evidence for a digital divide by race or ethnicity (Kontos et al., 2014).

It is possible that participants' use of the app was influenced by the awareness that their activities were being recorded. Thus, the app use data may have been subjected to the Hawthorne effect, where participants alter their behaviour due to being observed (Merrett, 2006). However, in order to minimise this potential bias, participants were instructed at the start of the trial to use the app as often as they wished and to the extent to which they found it useful.

Furthermore, the lower sample size in the pilot trialing of the intervention (phase 3) in comparison to studies in its pre-development stage (phase 1) is an additional limitation. The requirement that eligibility for participation in the pilot trialing includes access to an Android smartphone could be a reason for low numbers of participants showing interest in the study in relation to phase 1 of the project, which does not require the use of any intervention. However, the sample size in phase 3 was moderate, well characterized with both participants with type 1 and type 2 diabetes and similar to published pilot trials.

8.2.8 Suggestions for Future Improvement of My Care Hub and Future Research Directions

During the evaluation of the app, users expressed their concerns about the limitations in the variety of foods listed in the app. Due to the amount of time for this research, available foods with information on calories and carbohydrate contents were kept as simple as possible. It is suggested that in future, more research on other foods, calories and carbohydrate contents could be carried out in order to make the 'carbs in foods' section of the app more comprehensive. It will also be useful for the food choices to be updated on a regularly basis as users suggested.

Although My Care Hub was developed after the emergence of the using Bluetooth with app, this interface was not included in the My Care Hub due to limited funding available for the research. Future versions of My Care Hub may consider an incorporation of Bluetooth interface as recommended by participants. This will enable users to wirelessly upload their BG readings or other behavioural activities into the app, thereby reducing the burden on patients when reporting their self-monitoring activities. However, it should be noted that apart from this improvement requiring extra funding, most Bluetooth interfaces are only compatible with specific monitoring devices and corresponding mobile phones housing the app. The disadvantage of providing participants with study-provided mobile phones rather than installing an app directly on their own personal devices is that it may add an unanticipated burden on the subject with the need to use an extra mobile phone within the study period (Ben-Zeev et al, 2014; Lenhart et al., 2015). This may defeat the concept of embedding health interventions into the daily routines of patients, which is a key strength of mobile health. Therefore, the deployment of My Care Hub app directly onto personal mobile phones in future studies is still recommended because it is the best method to improve usage and facilitate seamless integration into daily life (Goyal et al., 2017).

The results of the pilot trial demonstrated rigorous evaluation of mHealth apps for understanding user engagement, impact on behavioural outcomes and acceptability among end users. While traditionally, the next stage of evaluation of My Care Hub will be a randomised controlled trial (RCT), which has been considered as a ‘gold standard’ for the evaluation of interventions, a review by Pham et al (2016) emphasised that RCT may not be best suited for evaluating rapidly evolving softwares such as mHealth. Traditionally, RCT are costly, time consuming (average 5.5 years from enrolment to publication) and follow a rigid protocol, which in the context of apps might restrict the intervention to a static design. This prevents the dynamic adaptation of the app to fast emerging technological developments. Future evaluation of My Care Hub and other mHealth apps may consider the use of adaptive RCT designs. For example, a study using a sequential multiple assignment RCT would facilitate a better understanding of the impact of each app feature on an individual by evaluating outcomes at pre-determined time intervals. Future participants can be allocated to specific combinations of My Care Hub features where a re-allocation may occur based on the outcomes of individuals at a specific time point or anticipated trajectories. This adaptive study design can enable the rigorous evaluation of apps in a timely manner, while facilitating improved development of the intervention to keep pace with a rapidly evolving mHealth environment (Collins, Murphy & Strecher, 2007).

Given the limitation of the sample size in the pilot trial of My Care Hub, future research should include a sample of patients that better reflect the general population, including those from other ethnic group and patients who do not own a smart-phone. Additionally, the future sample of patients should include more recently diagnosed patients (e.g less than 6 months) in order to further explore the full range of the potential benefits of this app.

Chapter NINE: Conclusions and Recommendations

9.1 Chapter Overview

This chapter provides summary of the research and recommendations that were made based on the findings. The research focuses on enhancing diabetes self-management education and support (DSMES) using mobile phone apps. The research question specifically focused on the necessary elements in the development of a mobile app for diabetes self-management (DSM), the levels and relationship between skills and self-efficacy in patients. It also assessed patients preferred features and contents in an app, and how a novel app could improve DSM as well as its acceptability among patients. To do so efficiently and accurately, the research was conducted in three main phases (preparatory, development and feasibility phases), where each phase built on the preceding phase providing a logical and evidenced-based process to the app development.

9.1.2 Summary of the Study Findings

This research identified that the use of health behavioural theories, user and clinical expert involvements, privacy and security considerations as well as pilot testing are very essential in the development of an app targeting diabetes self-management education and support. The applicability of the result may be extended to apps targeting behavioural modification for other chronic diseases, for example apps for cancer or hypertension. This research also confirmed a strong positive correlation between skills and self-efficacy as mediating factors for diabetes self-management. In addition, some common gaps in patients' skill set and self-efficacy were identified in the areas of: identifying and managing the impact of stress on diabetes, exercise planning to avoid hypoglycemia as well as interpreting and adjusting food intake to ensure targeted blood glucose levels are reached. Given that these findings were reported by an international audience, it may be inferred that these are common areas of difficulties experienced by many patients. Hence, it is recommended that health professionals involved in the management in diabetes lay more emphasis on these areas when providing consultations to patients.

Furthermore, this research provided evidence that multicomponent features, which could aid self-management and access to educational contents on basic steps for diabetes care and problem solving, are preferred in a diabetes app. The blended constructs of social cognitive theory and information motivation behavioural theories applied into developing a novel app intervention (My Care Hub) to provide the preferred components appeared to be effective. My Care Hub aimed to support self-management and education in people with type 1 or type 2 diabetes. The app was specifically designed for those who have type 1 diabetes with recommended blood glucose levels (BGL) of 4-8mmol/L-fasting and <10 mmol/L-2 hours postprandial, and fasting levels of 6-8 mmol/L and 2-hour post prandial levels of 6-10 mmol/L for those with type 2 diabetes. The app can promote level of skills, self-efficacy and diabetes self-management activities outcomes with a small or moderate effect size (Eta squared raged from 0.11 to 0.25). The app encouraged behavioural change through different strategies including accountability; clarity of self-management activities and impact; mindfulness of calorie consumption; motivation for self-management; and knowledge improvement and reinforcement. Overall, the results of My Care Hub app on usability, retention and engagement of users, efficacy on behavioural change and acceptability may be interpreted as a positive preliminary indicator of the potential efficacy and uptake of future versions of the app. This information could be used to design future versions, longer-term and larger scale evaluation of the app. This study also provides evidence and adds to the body of knowledge that delivering an app intervention entailing multiple components (features), can provide multiple exposure to different behavioural change strategy to consequently influence behaviour change. In addition, the study supports previous evidence that behaviour change initiatives should have components that improve skills and build the self-efficacy of patients.

The pilot testing of the My Care Hub was conducted in North Queensland, Australia. In general, as demonstrated by the results, the app has the capability to improve self-management in Australians with type 1 or type 2 diabetes with the previously stipulated recommended blood glucose levels. Replication of the app evaluation in various settings would be beneficial. The knowledge obtained from this study could enhance future development of mobile apps to support diabetes self-management and education. This requires taking steps to identify relevant health behavioural theories to target as mediating factors to underpin the behavioural change in the intervention coupled with app features and educational contents preferred by patients. This is followed by the use of the aforementioned acquired information to develop an app and its comprehensive evaluation for usability, retention, usage, behavioural change and acceptability among target users.

9.2 RECOMMENDATIONS.

9.2.1 Patients

Attaining adequate level of skills and self-efficacy for self-management could be challenging for people with diabetes (Aljasem et al., 2001, Persell et al., 2004; Smoorenburg et al., 2019), because of the multiple areas of the required regimen (Tomky et al., 2008; Lambrinou et al., 2019), interrelationship between these regimen and overall effect on health outcomes (Herschbach et al., 1997; Tomky et al., 2008; Lambrinou et al., 2019). As noted in this study, attaining adequate levels of skills and self-efficacy on how to identify and manage the impact of stress on diabetes, how to plan exercise to avoid hypoglycaemia are common areas of regimen many patients often find difficult. Other areas include interpreting blood glucose patterns and adjusting food intake to reach targeted blood glucose levels. Assessing the services of care team members such as diabetes educators, exercise physiologists and dieticians could assist in ameliorating such struggles. This is highly recommended in the early years of diagnosis, after which, knowledge and skills acquired could be complemented and reinforced on an ongoing basis through access to support and education in a reliable diabetes app.

9.2.2. Health Professionals

Internationally including Australia, healthcare systems are challenged with the rising rates of diabetes coupled with inability of many patients to adhere to recommended self-management strategies and the resulting complications. People with type 1 or type 2 diabetes living in rural and remote areas of Australia have a disproportionate number of complications attributed to compromised self-management (Wan et al., 2008; Australian Government Department of Health, 2015). Under-resourced diabetes education and limited access to speciality care services and community resources are common in those areas (Maguire et al., 2008; Wakerman et al., 2008; Australian Institute of Health and Welfare, 2018; 2019f) and could encourage compromised self-management. Lacking regular access to education and support may predispose patients to little or no understanding of the implications of diabetes complications and insufficient skills to handle complex self-management regimens (e.g when best to monitor blood glucose, planning exercise to avoid extreme low blood glucose, best type of foods for consumption) (Burke, Sheer & Lipman, 2014, Powers et al., 2017). Hence, health systems need to accommodate changes to bridge these gaps in order to enable patients meet their information and support needs in outpatient settings. Therefore, leveraging the potential of apps to provide these education and support is recommended. This is especially important in rural and remote areas where there is increasing rates of diabetes, its complications and yet low access to speciality healthcare services for ongoing DSMES (Wan et al., 2008; Australian Government Department of Health, 2015).

Apps have the potential to decrease barriers such as patient burden, cost and low motivation for adherence; to traditional prescriptions for behavioural change of self-management in patients. The use of apps could be a medium to reduce these barriers particularly when the apps are engaging, convenient and easy to use as found in the novel app (My Care Hub) developed in this research. My Care Hub encompasses more than a didactic, educational program and goes beyond simple dissemination of information on diabetes and its management. The pivotal objective of the novel app is to change behaviour to produce sustainable effects. These are intended to be achieved through improved patients' skills and self-efficacy to manage their diabetes through regular access to information, motivation and problem-solving support provided by the app. The research results revealed that the use of My Care Hub supports diabetes patients to self-manage their health and leads to improvements in behavioural outcomes.

9.2.3 Researchers and App Developers

Researchers and app developers should ensure that they develop diabetes app using the best available evidence. This research has identified important considerations when developing an app such as health behavioural theory, users and clinical expert involvement, ensuring data privacy and security and pilot testing. In addition, applying the elements of theoretical models such as skills and self-efficacy will foster the understanding of behavioural change that patients are going through when using the app (Norris, Engelgau & Narayan, 2001; Hilliard et al., 2016; Fitzgerald & McClelland (2016); Hekler et al., 2017; Klonoff, 2019). Co-developing apps with patients is necessary to improve their appeal, acceptability, uptake and continual engagement with the technology (McCurdi et al., 2012; Woods et al., 2018; Woods et al., 2019). Furthermore, seeking the opinions of clinical experts when developing apps will confirm the quality and relevance of the intervention components. It will also ascertain the health security of patients by ensuring that information provided by the app is not misleading. In addition, procedure must be in place for app data security and privacy, to ensure that personal health information of patients are not accessible to unauthorised persons. These aforementioned processes are then followed by testing of the developed app using a carefully phased approach, starting with a series of usability and pilot testing and moving to a definitive evaluation using long-term and larger scale studies.

In addition, it is essential for app developers and researchers to note that one of the reasons why app interventions are better and preferred interventions for DSMES than other delivery methods such as SMS is the ability to monitor desired behavioural or clinical outcomes and provide feedback (Cushing & Steele, 2010; Goyal & Cafazzo, 2013; Hartin et al., 2016). This gives the app an opportunity to go beyond providing general education regarding DSM by including more interactive levels of user interaction. The provision of health information alone is less likely to stimulate meaningful and long-term behaviour change (Molaison, 2002) but integration of self-monitoring and a two-way interaction such as providing feedback to users are significant elements of success in modifying behaviour (Payne et al., 2015; Hermsen et al., (2016). This is also supported by the results of this research.

Researchers involved in the management of diabetes may likely lack the technical ability to develop apps independently. Nevertheless, they specialise in understanding behavioural change theories and their attending constructs to carry out research related to patients' preferences, usability and pilot testings of developed apps. While on the other hand, app developers have the technical expertise relating to software development. Collaborating with each other and capitalising on each discipline's strengths will be essential to produce diabetes apps capable of providing behavioural change support and meeting the self-management needs of patients. Such apps may prove to be valuable tools for healthcare professionals in their efforts to address the current diabetes epidemic and its resulting complications.

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APPENDICES

Appendix 2.1: Some of the developmental considerations in the reviewed studies in Chapter 2b

Author, Year	Name of app / Origin (existing or developed for the study)	Users involvement	Clinical expert involvement	Functions and functionalities of the app
Kirwan et al., 2013	Glucose buddy / existing	Not reported	Not reported	Manual logs of BG, diet (food items in gms), physical activities, insulin dosages and other medications into app. Analytic function, which can present data in a customised graphical format. Allows users' to forward data via email. Also have a reminder function.
Quinn et al., 2011	Not specific, just called Smart Phone app / developed for the study	Not reported	Mobile app was designed by endocrinologists and Credentialed Diabetes Educators (Quinn et al., 2008)	Manual logs of BG, CHO intake, medications and other diabetes management information into app. In response to specific logged data, users can receive automated real-time educational, behavioural and motivational messages. Additionally, App could be used to forward data to physician.
Charpentier et al., 2011	Diabeo / developed for the study	Not reported	Not reported	Manual logs of BG, CHO counts, planned activity into app to calculate insulin dose or CHO adjustment. Data transfer to provider through GPRS and Secured website.
Quinn et al., 2016	See Quinn et al., 2011	Not reported	See Quinn et al., 2011	See Quinn et al., 2011

Waki et al., 2014	DialBetics / not reported	Not reported	Not reported	Automated logs of BG, BP, weight and pedometer count for physical activity level into app. Dietary evaluation of inputted meal through a feedback from a dietician (not automated; feedback takes 2 days). Analysis of BG and BP data with graphic outputs of measurements. Reminders for self-monitoring. Also, have a natural language processing method such that patient voice/text messages about meal and exercise that is not counted by the pedometer are sent to the server and the voice input is converted to text and matched with text in the app. Automated feedback advice on lifestyle modification in response to logged data. Alert for missed or late readings.
Orsama et al., 2013	Monica / developed for the study	Not reported	Not reported	Manual logs of BP, BG, weight and physical activity into app. Analytic function in form of graphs. Participants received automated real time education, behavioural skills and motivational messages in response to logged data.
Kim et al., 2014	Henceforth app / developed for the study	Not reported	Not reported	Manual logs of BG and BP into app with automated transfer to participants hospital.
Rossi et al., 2010a	Diabetes Interactive Diary / developed for the study	Not reported	Not reported	Manual logs of BG and insulin dose into app. Analysis to provide automated suggestion for insulin bolus dose and CHO count. General pre-stored data on; BG values, individualised correction factor: CHO ratio set by physician, food intake and physical activity. Logged data could be sent on an average of 1-3 weeks as short messages to physician for review purpose to provide feedback to the patient via text messages. (Rossi et al., 2009)

Holmen et al., 2014	The Few Touch App / developed for the study	12 - 15 end users were involved in the design process. Through incorporation of focus group meetings, semi-structured interviews, usability testing, questionnaires, and paper prototyping. Results generated the design requirements and answers to research questions (Arsand et al., 2010)	Not reported	Automated log of BG readings from meter into app. Manual log of physical activity and food intake. Analytic function in form of visual graph, trend reports and feedbacks through colour coding (below normal, normal and above normal). Provided general information on disease. It also have a personal goal setting system and automated data transfer of logged data into a secure server.
Rossi et al., 2013	See Rossi at al., 2010a	See Rossi et al., 2010a	See Rossi et al., 2010a	See Rossi et al., 2010a
Istepanian et al., 2009	Not specific just generally called m-health system / not reported	Not reported	Not reported	Automated log of BG from meter into App. Alert to remind users when measurement are due. Data transfer from mobile phone to a hospital server.

BG: Blood glucose; CHO: carbohydrate; GPRS: General Packet Radio Service; BP: Blood pressure

Appendix 2.2: Other developmental considerations and key clinical outcome-glycosylated hemoglobin in the reviewed studies in Chapter 2b

Author, Year	Data security and privacy consideration	Pilot testing	Health behavioural theory consideration	Key Clinical Outcome ($HbA1_c$)[1]
Kirwan et al., 2013	Not reported	Not reported	Not reported	The intervention group showed a significantly improved $HbA1_c$ from baseline to 9-month follow up compared to the control group.
Quinn et al., 2011	Data security in the mobile phone app was not reported. But for the web-based system; BG data were captured in real time into a HIPAA[3]-compliant secured web-based system, where it is processed to receive personalised feedback. (Quinn et al., 2008, Quinn & Gruber-Baldin, 2009)	Pilot tested for 3 months on 30 participants with type 2 diabetes with the aim to assess the impact of the software on $HbA1_c$, and assessed provider's and patients satisfaction with the technology (Quinn et al., 2008)	Not reported	One of the intervention group (maximal treatment) showed a significantly improved $HbA1_c$ from baseline to 12-month follow up compared to other intervention and control groups.
Charpentier et al., 2011	Data logged into app were automatically uploaded into a secured website, where they are available to the investigators at any time	Four-month observational study of 35 type 1 diabetes patients. The aim was to confirm the use of personalised flexible intensive insulin therapy results in good control of the postprandial state. (Frac et al., 2009)	Not reported	The full intervention group showed a significantly improved $HbA1_c$ from baseline to 6 month follow up compared to the control group.
Quinn et al., 2016	See Quinn et al., 2011	See Quinn et al., 2011	See Quinn et al., 2011	Both the intervention and control group had reduced improvement in $HbA1_c$ after 12 months follow up.

Waki et al., 2014	Not clear. Reported that participants measured data were transmitted to a server, following each new measurement that patient profile was updated which controlled access to patient's data and recorded access history.	One month pilot testing on 11 participants with type 2 diabetes. The aim was to assess the safety, usability and impact of mobile app on $HbA1_c$ and the effect on home BP[4] monitoring as a way of managing the complications related to diabetes. (Waki et al., 2012)	Not reported	The intervention group showed a significantly improved HbA1c from baseline to 3-month follow up compared to the control group.
Orsama et al., 2013	Not reported	Not reported	Information-Motivation behavioural skill model was used as the basis for the formulation of automated personalised feedback message contents	The intervention group showed a significantly improved $HbA1_c$ from baseline to 10-month follow up compared to the control group.
Kim et al., 2014	Not reported	Not reported	Not reported	Both the intervention and control groups had a non-significantly improved $HbA1_c$ from baseline to 3-month follow up.

Rossi et al., 2010a	Not reported	The first pilot study was done with a questionnaire to assess the feasibility and acceptability of the app. A second pilot study was done on 41 patients using DID under routine clinical practice condition were evaluated after a medium of 9 months of follow up. The aim is to investigate effectiveness of the app on metabolic control. The second pilot study was on 50 people with type 1 diabetes aged 18-65 years, with the aim of investigating the feasibility and acceptability of the app (Rossi et al., 2009)	Not reported	Both the intervention and control groups had a non-significantly improved $HbA1_c$ from baseline to 6-month follow up.
Holmen et al., 2014	Not reported	12 people with type 2 diabetes participated in the testing of the app during an average test period of 167 days (Arsand et al., 2009)	Not reported.	Both the intervention and control groups had a non-significantly improved $HbA1_c$ from baseline to 12-month follow up.
Rossi et al., 2013	See Rossi et al., 2010a	See Rossi et al., 2010a	See Rossi et al., 2010a	Both the intervention and control groups had a non-significantly improved $HbA1_c$ from baseline to 6-month follow up.
Istepanian et al., 2009	Not reported	Not reported	Not reported	$HbA1_c$ in the intervention and control groups remain unchanged after 9-month follow up.

HbA1c: glycosylated hemoglobin; BG: Blood glucose; HIPAA: Health Insurance Portability and Accountability Act

Appendix 3.1: Interview guide utilised in Chapter 3

Prompts:

General prompt on key areas of diabetes self-management. This includes regular participation in physical exercise, eating the ideal diet, regular monitoring of blood glucose, problem solving such as correcting hypoglycemia and hyperglycemia, healthy coping with the condition, reducing risk to help prevent or minimise diabetes complications (for example limiting alcohol intake, smoking cessation, regular eye examination, foot care, oral health).

For those who have type 1 diabetes, in addition to the above, other areas of diabetes management were buttressed including, adjusting insulin and diet to avoid hypoglycemia/hyperglycemia, adjusting insulin/exercise to avoid hypoglycemia.

Enablers

1. Can you identify some strategies you find particularly helpful to facilitate or support you to perform your diabetes management activities?
2. Are there things (people or services) that have made it easier for you to manage your diabetes?
3. What are the factors that have contributed to success in your self-management
4. Anything else to add?

   Barriers
5. What areas (if any) of your diabetes management do you find difficult?

   Probe: What makes this /these (mention the area(s) stated) difficult?
6. On a day to day basis, is there anything you struggle with or find difficult in your diabetes management?
7. Are there factors that have served as obstacles to managing your diabetes?
8. What do you believe are the barriers to your self-management?
9. Anything else to add?

Appendix 4.1: The quantitative instrument utilised in Chapter 4

Preface:

Welcome to this survey and thank you in advance for your interest to participate. The survey aims to examine the use and preference of features in mobile apps to manage diabetes. The result of this study will help in gaining better understanding of the important features and components to consider when developing future apps for diabetes self-management.

Your responses, including your demographics will remain anonymous. At the end of the survey, you will be asked if you are interest in participating in additional telephone interview, if you choose to provide your phone number, your responses to the phone interview may not be anonymous to the researcher. However, you will not be identified in any way in the research publications and the results from this study.

Eligibility:

- Only people who have type 1 or type 2 diabetes and
- 18 years and above

Instructions to complete the survey:

Please read the following questions carefully. Your candid responses are essential to ensure the reliability of this study

1. **What is your gender?**

   ☐ Male ☐ Female ☐ Others (Pls. specify) ……………..

2. **How old are you?** _____________(years)

3. **What is the highest level of education you have completed?**

   ☐ High school or equivalent ☐ Technical or vocational education

   ☐ College ☐ Bachelor degree ☐ Post graduate degree

   ☐ No formal education ☐ Others

4. **What is your employment status?**

   ☐ Employed ☐ Unemployed ☐ Retired

5. **What continent do you presently live in or reside?**

   ☐ America ☐ Asia ☐ Australia ☐ Europe

   ☐ Africa ☐ Antarctica

6. **What type of diabetes do you have?**

   ☐ Type 1 ☐ Type 2 ☐ Gestational

   ☐ I don't have diabetes ☐ Others (Please specify) ………………………….

7. **How long have you been diagnosed with diabetes (years)?**

   ☐ < 1 ☐ 1- 5 ☐ 6 - 10 ☐ 11 -15 ☐ ≥ 15 years ☐ Never

Section B

1. Do you currently have apps on your mobile phones that provides support related to your diabetes management?

   Yes ☐ **(please go to question 2)**

   No ☐ **(please go to question 5)**

2. If yes, what are the features in the apps available on your smart phone which you use to manage your diabetes (tick all that applies to you).

   ☐ Blood pressure tracker

   ☐ Blood glucose tracker

   ☐ Reminder (e. g to take medication or attend a health appointment)

   ☐ Fitness / exercise monitor

   ☐ Body weight tracker

   ☐ Food calorie counter

   ☐ Feature to transfer electronic health information to your doctor

   ☐ Others (Please Specify……………………………………………)

3. **Which of these features in apps do you use regularly? Only tick the ones you use at least 4 times in a week**

   ☐ Blood pressure tracker

   ☐ Blood glucose tracker

   ☐ Reminder (e. g to take medication or attend a health appointment)

   ☐ Fitness/ exercise monitor

   ☐ Body weight tracker

☐ Food calorie counter

☐ Feature to transfer electronic health information to your doctor

☐ Others (Please Specify…………………………………………)

4. **Are there specific reasons why you don't use other features regularly? Please state them: ………………………………………………………………….**
5. **If No to question 1 of this section, which of the following is a reason for not using apps to support your diabetes management (tick all that applies to you).**

☐ I am not interested

☐ I am not aware

☐ Lack of smart phone

☐ It is expensive

☐ Limited access to the internet

☐ Others (please specify………………………………………..)

6. Please rate each of these app features by indicating the extent to which you think they are useful to support your diabetes self-management. Pick only one number for each of the app feature. Score 10 being the most useful and 1 being the least useful.

Health Applications	**Perceived order of usefulness**									
	Most useful									**Least useful**
	10	**9**	**8**	**7**	**6**	**5**	**4**	**3**	**2**	**1**
Blood pressure tracker	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Blood glucose tracker	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Food nutrient composition	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fitness / exercise monitor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Body weight monitor	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Data transfer to health care team (e. g doctor)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Task reminder app (e.g to take medication, appointment with doctor)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

7. **If offered the option of using a new mobile diabetes application (app) to support your diabetes management? Please choose the features you would like the app to have. (Tick all that applies to you).**

   ☐ Provide access to nutritional information on nutrient contents of foods

   ☐ Log blood glucose levels

   ☐ Physical exercise tracker

   ☐ Task reminders (e.g reminder to take my medication)

   ☐ General information on diabetes; its management and complication prevention

   ☐ Graphical display of logged data

   ☐ Logs and display of body weight maintenance

   ☐ Feature that allows me to network with other people having diabetes

8. **Are there other suggestions or improvements that is not listed which you think are very important in apps that support the management of diabetes**

Would you be interested to be contacted for an individual interview session? The session is to hear your experience on managing diabetes and your opinion on how mobile phone apps could be improved to manage diabetes and some of the important components to include in future apps for diabetes management. If yes, please indicate and provide your phone number and best time to contact you.

☐ Yes

Phone number…………….Best time to contact…………………………

☐ No

Appendix 4.2: Interview guide utilised in Chapter 4

Introduction of study and interviewer:

Hello, my name is ……………..I'm calling in regards to an online questionnaire that you participated in a while ago relating to diabetes management and the use of mobile phone application (app). You left a phone number to indicate your interest in participating in a follow up interview to the survey and a text was sent to you few days ago. The interview will take about 10 minutes, is it ok to proceed with the interview now or you would like me to call back at a later time?

Thank you for your willingness to participate and be interviewed. Please note that I will be recording this interview, and it will be transcribed and analysed. You are free to choose what to disclose for any of your answers to the questions or refuse to answer a particular question. The aim of the interview is to gather information on how apps could be improved to self-manage diabetes. An app is any program downloadable to a smart phone, which is used to support any aspect of your diabetes management to foster improved health outcomes. It could be an app for lifestyle monitoring such as those for tracking diet and exercise or for monitoring your clinical outcomes such as blood glucose or blood pressure.

We have observed that often times, when a lot of people with diabetes use apps to manage any aspect of their health, their interest in using the app decreases over time. I would like to explore your opinions on what to include in apps to prevent such decrease in usage over time.

Questions:

1. Do you currently use an app to support your diabetes care?

    a. If yes, what are the ones you use/what aspect of your diabetes care do they support?
    b. If no, have you in time past used any?

c. If yes to question b above, what are your reasons for stopping? (if no, reasons for non-usage)?

2. What do you think could be the reason why people with diabetes use an app for a period of time with a subsequent decrease / stoppage in its use over time?

3. What do you think would be a motivator to encourage you to continually use an app for your diabetes management?

4. Is there any feature or function you would consider very important for inclusion in a good app which could stimulate your interest to use it regularly?

5. What are possible improvements in app features that might motivate you to use it regularly?

6. Are there other aspects/components/features you would like to see in future apps, which could encourage you to use it more frequently and regularly? What are your expectations of future apps to manage diabetes?

For all questions involving app features, there were specific probes on features for blood glucose monitoring, activity tracking, reminder, features on nutrition to foster healthy eating, etc.)

Educational topics desired in diabetes apps

1. When it comes to diabetes and its management, what sort of education or information would you desire to be included in future apps to support diabetes management? (Specifically probe on healthy eating, preventing diabetes complications, risk reduction, engaging in physical activities, adherence to medication intake, responding to challenges of diabetes clinical outcomes and self-management).

Appendix 5.1: Usability instrument utilised in Chapter 5

Introductions

Welcome to this survey and thank you in advance for your interest to participate. This survey aims to examine the usability (how easy and pleasant the features) of a newly developed mobile app (My Care Hub) to support diabetes self-management. The outcome of this survey will be of great value to determine the area of improvement, which may be required in the app. The survey should take approximately 10 minutes. Your responses including your demographic information will remain anonymous. Participation is voluntary.

Instructions on completing the survey

Please read and consider the following questions carefully. Your candid responses are essential to ensure the reliability of this study.

Section A: Demographic

Below are questions about your background. Please pick one response for the multiple-choice questions.

1. **What is your gender?**

   ☐ Male ☐ Female ☐ Other (Please specify) ……………..

2. **How old are you?** ______________(years)

3. **What is the highest level of education you have completed?**

   ☐ High school or equivalent ☐ Technical or vocational education

   ☐ College ☐ Bachelor degree ☐ Post graduate degree

   ☐ No formal education ☐ Other

4. **What type of diabetes do you have?**

   ☐ Type 1 ☐ Type 2 ☐ I don't have diabetes (please move to section B) ☐ Other (Please specify) ………………………….

5. **How long have you been diagnosed with diabetes (years)?**

   ☐ < 1 ☐ 1- 5 ☐ 6 - 10 ☐ 11 -15 ☐ ≥ 15 years ☐ Never

6. **What is the present fasting blood glucose range recommended by your health care provider? Please input your response in mmol/L. For example 4 to 6 mmol/L**

   ………………………………………………………..

7. **What is the present 2 hours post prandial blood glucose range recommended by your healthcare provider? Please input your response in mmol/L. For example 6 to 10mmol/L.**

   ………………………………………………………..

Section B

The next set of questions are related to your experiences with the use of My Care Hub App over the last 7 days. Please answer each question based on your experience with the app. Your candid responses are essential to ensure the reliability of this information.

Functionality

1. **Performance**: How accurate/ fast do My Care Hub features (functions) and components (buttons/ menu) work?

   1. App is broken; no/ insufficient/inaccurate response (e.g crashes/bugs/broken features e.t.c)

   2. Some functions work, but lagging or contains major technical problems

   3. App works overall. Some technical problems need fixing/Slow at time

   4. Mostly functional with minor/negligible problems

   5. Perfect/timely response; no technical bugs found

2. **Ease of use:** How easy is it to learn how to use My Care Hub; how clear are the menu labels/icons?

   1. Menu labels/icons are confusing; complicated

   2. Useable after a lot of time/effort

   3. Usable after some time/effort

   4. Easy to learn how to use the app

   5. Able to use app immediately; intuitive; simple

3. **Navigation:** Is moving between My Care Hub screens logical /accurate/appropriate/uninterrupted; are all necessary screen link present?

   1. Different sections within My Care Hub app seem logically disconnected and random/confusing/navigation is difficult

2. Usable after a lot of time/effort

3. Usable after some time/effort

4. Easy to use or missing a negligible link

5. Perfectly logical, easy, clear and intuitive screen flow throughout or offers shortcut

4. **Gestural design:** Are interaction (taps/scrolls) consistent and spontaneous across all components/ screens of My Care Hub?

1. Completely inconsistent/confusing

2. Often inconsistent/confusing

3. OK with some inconsistencies/confusing elements

4. Mostly inconsistent/spontaneous with negligible problems

5. Perfectly consistent and spontaneous

Aesthetics

5. **Layout:** Is arrangement and size of buttons/icons/menus/content on the apps' screen appropriate?

1. Very bad design, cluttered, some options impossible to select/locate/see/read device display not optimised

2. Bad design, random, unclear, some options difficult to select/locate/see/read

3. Satisfactory, few problems with selecting/locating/seeing/reading items or with minor screen size problems

4. Mostly clear, able to select/locate/see/ read items

5. Professional, simple, clear, orderly, logically organised, device display optimised. Every design component has a purpose

6. **General Graphics:** How high is the quality/resolution of graphics used for buttons/icons/menus/content of My Care Hub?

1. Graphic appear amateur, very poor visual design-disproportionate, completely stylistically inconsistent

2. Low quality resolution graphics; low quality visual design-disproportionate, stylistically inconsistent

3. Moderate quality graphics and visual design (generally consistent in style)

4. High quality/resolution graphics and visual design-mostly proportionate, stylistically consistent

5. Very high quality/resolution graphics and visual design-proportionate, stylistically consistent throughout

7. **Visual appeal:** How good does My Care Hub look?

1. No visual appeal, unpleasant to look at, poorly designed
2. Little visual appeal-poorly designed, bad use of colour.
3. Some visual appeal-average, neither pleasant nor unpleasant
4. High level of visual appeal-seamless graphics-consistent and professionally designed
5. As above + attractive, memorable, stands out; use of colour enhances app features/menu

8. **Graphic visual appeal of the analytics:** is the visual display of the log of graphs clear and understandable? Note, this refer to the analytic function called ‘‘view insight’’ present in My Care Hub?

1. Graphic appear amateur, very poor visual design-disproportionate, completely stylistically inconsistent
2. Low quality/resolution graphics; low quality visual design-disproportionate, stylistically inconsistent
3. Moderate quality graphics and visual design (generally consistent in style)
4. High quality/resolution graphics and visual design-mostly proportionate, stylistically consistent
5. Very high quality/resolution graphics and visual design-proportionate, stylistically consistent throughout

9. **What is your overall rating of My Care Hub?**

1. * One of the worst apps have used
2. **
3. *** Average
4. ****
5. ***** One of the best apps have used

Additional Questions for participants who have diabetes

Satisfaction with My Care Hub for Diabetes Self-Management

1. **Usefulness**: Features of My care Hub are useful for diabetes self-management.

   1. Strongly Disagree
   2. Disagree
   3. Neither agree nor disagree
   4. Agree
   5. Strongly Agree

2. **Target group:** Is My Care Hub features appropriate for people with type 1 or type 2 diabetes?

   1. Completely inappropriate/unclear/ confusing
   2. Mostly inappropriate/unclear/confusing
   3. Acceptable but not targeted. May be inappropriate/unclear/confusing
   4. Well targeted, with negligible issues
   5. Perfectly targeted, no issues found

3. **Quality of information:** Is My Care Hub educational content well written, understandable and appropriate for people with type 1 or type 2 diabetes? This refers to the feature called "Educational tips" in My Care Hub and the messages under it.

   1. Irrelevant/inappropriate/incoherent/incorrect
   2. Poor. Barely relevant/appropriate/may be incorrect
   3. Moderately relevant/appropriate/coherent/correct
   4. Relevant/appropriate/coherent/correct
   5. Highly relevant, appropriate, coherent and correct

4. **App feedback**: Is the feedback messages in My Care Hub understandable and appropriate for your type of diabetes? This refers to the feedback (pop-up) messages displayed when blood glucose data is inputted into the app.

   1. Irrelevant/inappropriate/incoherent/incorrect
   2. Poor. Barely relevant/appropriate/may be incorrect
   3. Moderately relevant/appropriate/coherent/correct
   4. Relevant/appropriate/coherent/correct
   5. Highly relevant, appropriate, coherent and correct

5. **Awareness:** My Care Hub educational information is useful for improving knowledge/awareness about the importance of diabetes self-management

   1. Strongly Disagree
   2. Disagree
   3. Neither agree nor disagree
   4. Agree
   5. Strongly Agree

6. **Motivation:** The use of My Care Hub is likely to increase motivation of people with diabetes to engage in their self-management activities.

   1. Strongly Disagree
   2. Disagree
   3. Neither agree nor disagree
   4. Agree
   5. Strongly Agree

7. **Intention to use:** If I have continual access to this app. I predict that I could use it.

   1. Strongly Disagree
   2. Disagree
   3. Neither agree nor disagree

4. Agree
5. Strongly Agree

8. **Recommendation:** Would you recommend this app to people with type 1 diabetes (T1D) or Type 2 Diabetes (T2D)

1. I would not recommend this app to anyone with T1D or T2D
2. I could recommend this app to few people with T1D or T2D
3. I could recommend My Care Hub to several people with T1D or T2D
4. I could recommend My Care Hub to many people with T1D or T2D
5. I could recommend My Care Hub to anyone with T1D or T2D

General impressions

1. Is there anything about My Care Hub that you like in particular?

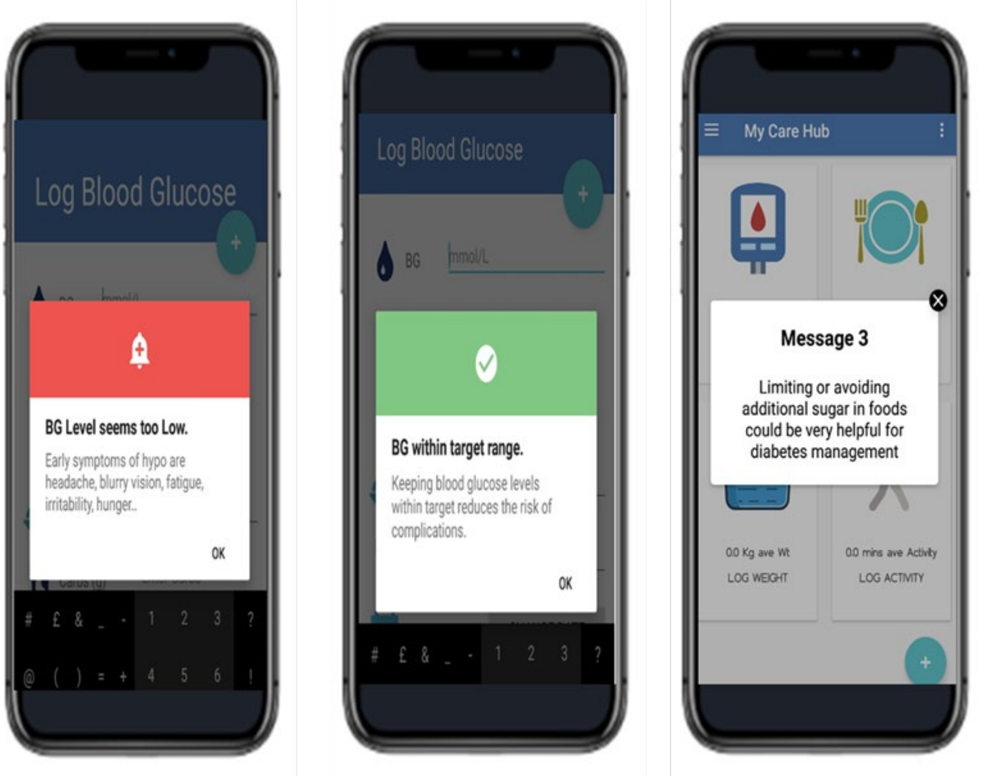
2. Anything that you did not like. Anything that annoyed you?

3. Are there other observations you noted during your use of My Care Hub or you have some suggestions, please state it.

Appendix 6.1: Other Screen Shots for My Care Hub that were published in Chapter 6

Documentation | Analytics | Overview of Diabetes Management | Carbs and Calorie content of foods

Sample Feedback Messages | Sample Push Notification



Appendix 6.2: Semi-structured interview guide utilised in Chapter 6

<u>Prologue</u>

1. Introduce myself and the reason for calling etc.

Set the focus of the interview and explain the app and the previous 3 weeks' study. Use the following script:

''Thank you for agreeing to take part in this interview and for using My Care Hub app in the past 3 weeks. I want to understand what you think about the app. The app is aimed to provide support and education to foster diabetes self-management by providing a platform to document and monitor self-management activities, give feedback on inputted blood glucose levels per time, provide information within the app on how to self-manage diabetes. In this interview, we aim to know your opinion and experience with the app during the course of usage. There are no right or wrong answers to my questions.''

2. Give opportunity for questions (if any),

3. Explain that the interview will be recorded:

''I would like to record what you say as that saves me having to scribble when you're talking and give opportunity for me to concentrate on what you're saying. The interview will be transcribed and your identity will be anonymised in the published work. Is that okay with you?

Questions.

Before you go into details about your experience with the app, I want to ask you some background information about your health and personal self-management

<u>Opening questions</u>

- Can you tell me, what type of diabetes you have and how long you have been diagnosed?

- Can you tell me how or the various steps you take to manage your diabetes? *e.g Therapeutic regimen, mediation intake, frequency of exercise, diet management?*

(*Please note, if participant has mentioned the type of diabetes from interview start, please refer to it in particular when asking these questions, instead of using the Phrase Your type of diabetes''*

Experience of using My Care Hub

- Did you use My Care Hub?
  - How often
  - If the app was not used, why?
- Describe your experience of learning how to use the app
  - Did you have any problem installing/using the app?
- Tell me about your experience with using My Care Hub app over the past 3 weeks?
  - How did you find navigating the pages and finding information?
  - How did you find inputting your data into the app?
  - Was there anything you find particularly hard to use?
  - If you have problems with the app, what were they?
  - How did you find using My Care Hub for your diabetes self-management?

Views about features provided

- What are your views about the feature where you input your blood glucose?
  -How did you find inputting blood glucose into that feature?
- What are you views about the automated feedback messages received immediately after inputting your blood glucose into the app?
  -Were they useful?
  -What was your response to it?
- Did you use the analytic feature to monitor trends?
  -If not, why?

-If yes, what are your views about it?

- Did it help you in your diabetes management? How?

- What are you views about the diabetes educational tips embedded in the app? i.e the feature containing information on what diabetes is, carbohydrates in foods, healthy eating, exercise, medication usage, monitoring of blood glucose e.t.c

  -What do you think of them?
  -Did you find them useful?
  - Is there any other useful information that you would have liked to be included in the app?

- What are your views about the daily educational messages that are intermittently displayed in the app (push notifications)?

  -Was there anything you dislike about this messages in particular?
  - Did you find them useful?

- What feature(s) in the app did you find most useful? Why?
- What feature(s) in the app did you find least useful? Why?
- What do you think about the overall content and functionality of the App?
- Was there anything you disliked in the app?

<u>Perceived ongoing benefit /Impact/intention for continue usage</u>

- What ongoing benefit do you think there might be for patients with your type of diabetes who continue to use My Care Hub app?
- Is there anything you would do differently regarding your self-management following your participation in the study?
- What factors/features in the app interest you most which could help you engage regularly with the app.
- Were there benefits you derived from using the app during the intervention period?

- What are your views about the educational component of the app?
- Would you continue to use My Care Hub, if it were available?
- Would you recommend the app to other people with your type of diabetes?

<u>Recommendations</u>

- Do you have suggestions on how the app could be improved?
- Do you think any features should be removed from the app?

  -If yes, please explain
- Was there anything you wanted or expected to see in the app but didn't?
- What would you ask the app developers to change? E.g colour, layout, icons, font size, any feature.

Is there anything we have not talked about that you think it is important to share before we end the interview?