Diabetes Mobile App Usability for Adult Patients with Diabetes

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Helen Nai Chi Fu

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Dedication

I dedicate this nursing research to my grandmother, Chen Hsiang, who encouraged me to be a nurse and to press on for higher education despite hard circumstances, as well as to all patients with diabetes, who have a special place in my heart.

Abstract

More than 1,100 diabetes apps are available, but are infrequently used. A systematic review identified unsatisfactory diabetes app usability and its clinical effect to lower hemoglobin A1c level (0.15% to 1.9%), with variations in interactive app features for real-time feedback through automatic data analysis, clinician text messages, reminder alerts, or an app-initiated phone call. This result identified the need for health behavior theory applications to guide diabetes app usability evaluation. This study applied the Self-Determination Theory on human motivation to select app testing functions and to understand adult patient perspectives to use apps. A total of 92 adults with diabetes type 1 or 2 participated in a randomized crossover trial to test the usability of two top-rated Android diabetes apps (*mySugr* and *OnTrack).* Multivariable linear regression models assessed the effects of patient characteristics (i.e., age, education, and diabetes) and psychological needs on user satisfaction and user performance. Psychological needs important for motivation and behavioral change were associated with diabetes app usability. Higher user satisfaction was observed for participants who reported competence, autonomy, or connectivity with a healthcare provider. To enhance motivation to use apps for self-management, clinicians should consider addressing the patient's competence, autonomy, and connectivity. User performance was associated with patient characteristics of age, sex, education, and diabetes duration because they affect the patient's ability to use apps efficiently, successfully, and accurately. App training and ongoing technical support should be tailored for older adults, men, patients with less education, and those with diabetes duration more than 10 years.

Table of Contents

List of Tables

List of Figures

Abbreviations

AADE – Association of American Diabetes Educator

ANOVA – Analysis of Variance

App – Application

BG – Blood Glucose

b/t – between

Carb(s) – Carbohydrate(s)

CI – Confidence Interval

F/U – Follow-Up

FBG – Fasting Blood Glucose

HbA1c – Hemoglobin A1c

HCCQ – Health Care Climate Questionnaire

iOS – iPhone Operating System

ISO – International Organization for Standardization

mHealth HbA1c – Mobile Health

NR – Not Reported

OS – Operating system

PCP – Primary Care Provider

PCS – Perceived Competence Scale

PERF – Performance

PHR – Personal Health Record

QUIS – Questionnaire for User Interaction Satisfaction

RAI – Relative Autonomy Index

RCT – Randomized Control Trial

SCT – Social Cognitive Theory

SD – Standard Deviation

SDT – Self-Determination Theory

SMS– short message service

SUS – System Usability Scale

TSRQ – Treatment Self-Regulation Questionnaire

Tech– technology

WEB – Website

Wt. – Weight

UPT – Usability Problem Taxonomy

US – United States

Chapter 1: Introduction

1.1 Background

Diabetes is a leading chronic disease in the United States that affects 9.4% of the American population, an estimated 30.3 million people of all ages, with 25.5% among those aged 65 years or older (Centers for Disease Control and Prevention, 2017). Poor diabetes management is associated with increased morbidity and mortality with 2.3 times higher healthcare expenditures than those without diabetes (Ozieh, Bishu, Dismuke, & Egede, 2015). The economic burden for diabetes in the United States exceeded $322 billion in 2012 (Dall et al., 2014). Patients with diabetes experience more work limitations (Tunceli et al., 2005) and sickness episodes (De Backer et al., 2006). They leave the work force earlier, a 30% increase compared to those without diabetes (Rumball-Smith, Barthold, Nandi, & Heymann, 2014). Using mobile health (mHealth) technology, which allows health services and information to be delivered via a patient's mobile device, can facilitate quicker access to information, fill gaps of care, and promote adherence to self-management behaviors (Kumar, Nilsen, Pavel, & Srivastava, 2013).

Smartphones can deliver a diabetes care plan in the form of a software application (app). Apps can assist patients in identifying and incorporating healthy behaviors into their daily lives (Heinrich, Schaper, & de Vries, 2010). However, the rate of diabetes app use is low despite more than 1,100 apps available in the market (Research2Guidance, 2014). Most health apps did not consistently apply a health behavior theory (Riley et al., 2011) in their design, which may be important for positive patient experience and long-term app use. Most diabetes apps have limited functionality because their primary functions are data input and output only (Arnhold, Quade, & Kirch, 2014). Examples of other standard app functions include data analysis, data upload for cloud storage, data sharing, alert reminders, and low-carb diet recipes. Additional app functions can make it confusing for some users (Arnhold et al., 2014). Screens may have too many icons, which may make it difficult for patients to navigate to different screens and read data reports (Caburnay et al., 2015; Georgsson & Staggers, 2016a). Poor usability experience leads to low app usage. Therefore, it is important to study diabetes app qualities and patients' perspectives of their usability.

1.2 Diabetes App Usability

Usability is the extent to which a product can be used by a specific person in a specific context to achieve realistic goals of effectiveness, efficiency, and satisfaction as defined by the International Organization for Standardization 9241-11 (ISO 9241-11, 1998). With diabetes apps, usability refers to the interface experience for a particular user (e.g., patient, clinician, or caregiver) to use the app with an expectation of good satisfaction, reasonable efficiency to save time, and adequate effectiveness that the app works successfully and accurately in a desired use context (e.g., tracking and analyzing BG and carb intake). Individual patient characteristics can influence usability experience. Adequate patient confidence and satisfaction are tied with health behaviors and long-term app use (Goldwater, 2014). As such, it is essential to apply health behavior theories to understand patient perspective and experience of usability of an app to support patients to make behavior changes important in diabetes self-management.

1.3 Health Behavior Theories for mHealth Tools

Four health behavior theories commonly used in mHealth interventions are: Social Cognitive Theory (SCT) (Bandura, 2001, 2008), Theory of Planned Behavior (Ajzen, 1991), Transtheoretical Model of Behavior Change (Prochaska & Velicer, 1997), and Self-Determination Theory (SDT) (Ryan & Deci, 2000). According to SCT, self-efficacy is the patient's belief in their ability to control their level of functioning and events. (Bandura, 2001). App functions for data input and output may increase self-efficacy. Patients can visualize data and formulate goals to improve their diabetes control. According to the Theory of Planned Behavior, patients expend more effort in performing a behavior when they believe they can control that behavior (Ajzen, 1991). A diabetes app can improve "perceived behavior control" by setting an alarm schedule for testing BG. According to the Transtheoretical Model, patients progress through six stages of change when adapting health behavior changes (Prochaska & Velicer, 1997). This theory may be applied to apps that tailor feedback educational messages based on the patient's reported stage of change and associated needs. SDT suggests motivation for behavior change is increased when patients experience satisfaction of their inherent psychosocial needs for competence, autonomy, and relatedness (Ryan & Deci, 2000). Some smoking cessation apps applied SDT by including app messages on patient education on smoking risk (e.g., lung cancer) to address the need for competence such as gaining knowledge. The apps can also provide a menu of smoking cessation aids (e.g., nicotine patch, gum, and lozenge) as choice that supports the patient's autonomy to choose how to quit smoking. The apps can target the need for relatedness by providing a link to support groups in social media. Few diabetes apps explicitly use health behavior theory in their designs. Some apps may have implicit theoretical underpinnings.

1.4 Significance

Additional research can help identify the relationships between diabetes app usability and individual patient characteristics and how this relationship may explain patient motivation to use this technology with a health behavior theory. Self-Determination Theory on motivation can serve as a guiding principle for diabetes app design and usability testing. This theory was selected because of it has been used to understand patient engagement in diabetes care (Kasser & Ryan, 1999; Koponen, Simonsen, Laamanen, & Suominen, 2015; Mohn et al., 2015; Nouwen et al., 2011) and to design diabetes research interventions (Hunt, Sanderson, & Ellison, 2014; Johnson, 2007). Research indicates that motivational support from healthcare providers is critical for successful patient self-management (Graffigna, Barello, Bonanomi, & Menichetti, 2016). Currently, many diabetes apps offer functions that may provide motivational support such as helping patients gain competence in diabetes management. These apps can analyze BG readings and help patients track how often their BG readings are in range. The degree to which patients are satisfied with diabetes apps and their effectiveness of motivational support provided is unknown.

Testing diabetes app usability and understanding how patient characteristics affect usability will fill a critical knowledge gap related to best practices in promoting diabetes self-management using mHealth tools. To date, mHealth studies have included diabetes apps as part of a communication platform, data sharing, patient portal, web-based program, and text messaging interventions (Lyles, Sarkar, & Osborn, 2014; Sutcliffe et al., 2011). These studies did not assess how well diabetes apps met patients' self-management needs, and whether individual patient differences influence usability. Applying SDT to guide the usability evaluation of app design can help close this research gap. Furthermore, application of health behavior theory can provide the linkages between product design, mobile technology adoption, and motivation factors pivotal for patient engagement in diabetes self-management. This contribution adds knowledge to mHealth science.

1.5 Application of the Self-Determination Theory to Diabetes Apps

SDT posits that motivation regulates health behavior. Inner motivation is self-initiated when one personally endorses the importance of healthy behaviors (Ryan, Deci, & Williams, 2008). When patients recognize the personal benefit of using an app, they are more motivated to initiate and sustain their use of the app. Diabetes apps need to have a user-centered design that can be adjusted to fit individual patient characteristics and needs. Likewise, diabetes apps need to address psychosocial needs. Patients have inherent needs for competence, autonomy, and relatedness (Ryan & Deci, 2000).

Competence refers to patient confidence to manage their diabetes such as keeping their BG in target range (Williams, Freedman, & Deci, 1998). An app can address competence needs by providing a function that allows patients to analyze their BG levels. The analysis reports of BG patterns for each day of the week serve to increase the knowledge of diabetes numeracy. An app can help patients understand the BG reading numbers and how they were affected by their diet, medication, and physical activity. An app can help patients plan which day of the week to target behavior change, for example, seeing a higher frequency of elevated BG reading in the weekends due to eating out with friends in restaurants may help a patient realize the need to change and to choose restaurants that offer a diabetic diet.

Autonomy means that patients desire empowerment in having a menu of options or choices to change their behavior (R. Ryan et al., 2008). Patients are more likely to use apps when the apps can personalize a care plan and help to identify areas to improve diabetes self-management behaviors. An app can address the need for autonomy by providing BG reports and carb intake patterns for each meal. Patients can visualize which meal requires better carb control and create an action plan with various choices to improve diabetes control in behavior modification for diet, physical activity, medication taking, and stress management, among others.

Relatedness is “the need to care and be cared for” (Deci & Ryan, 1985). Patients are more likely to adopt behaviors promoted by people with whom they are connected and trust (R. Ryan et al., 2008). In an mHealth setting, one translation of this is “connection with healthcare providers,” as well as with people from their social network or caregivers. Apps might address this need by providing communication and data sharing support through email functionality.

1.6 Purpose and Specific Aims

The overall purpose for this dissertation was to appraise diabetes app usability based on the Self-Determination Theory to understand patient perspectives and motivation to use diabetes apps. To accomplish this, this study was composed of two phases. Phase One was to conduct a systematic review of the research literature on diabetes app usability and its clinical effectiveness in improving diabetes outcomes.

Evidence of diabetes app components and patient response to diabetes apps in a clinical setting laid the foundation for usability testing design in the second phase. Phase Two included a crossover randomized trial of patient testing diabetes apps that used SDT as the theoretical underpinnings to select app functions and measurements of psychosocial needs related to motivation in diabetes self-management. The specific research aims for this phase were to:

(1) Determine the relationships between patient characteristics (e.g., age, sex, race/ethnicity, education, technology use, diabetes history, glycemic status, BG monitoring frequency, and motivation) and diabetes app usability. This study hypothesized that,

A. Patient characteristics will predict user satisfaction with two diabetes apps, and

B. Patient characteristics will predict user performance with two diabetes apps measured in time, success, and accuracy rates.

(2) Determine the relationships between psychosocial needs important for motivation (e.g., competence, autonomy, and healthcare provider connectivity) and diabetes app usability. This study hypothesized that,

C. Higher satisfaction of psychosocial needs will be associated with higher user satisfaction with diabetes apps.

1.7 Overview

In this dissertation, we are exploring the applicability of using a health behavior theory in the usability evaluation mHealth tools such as diabetes apps for adult patients with diabetes. This dissertation is organized into four chapters. Chapter 1 provides background information and overview of the research. Chapter 2 describes past and present research related to diabetes app usability and its clinical effectiveness in improving glycemic control for adult patients with type 2 diabetes. Type 2 diabetes was selected as the focus for the review because type 2 diabetes is more prevalent in the United States (US) accounting for 90–95% of all diabetes cases (Centers for Disease Control and Prevention, 2017). Chapter 3 presents a quantitative study of patients testing diabetes app usability guided by the Self-Determination Theory on motivation. A total of 92 adults with type 1 or type 2 diabetes were recruited to test two top-rated diabetes apps. Patient characteristics and behavior needs were examined for their influence in user satisfaction and user performance using two diabetes apps for the first time.

The final section of this dissertation, Chapter 4, integrates prior research evidences of diabetes app usability and new evidence from patient evaluation of diabetes apps together to create a summary and a set of recommendations for future research and clinical practice implication. This includes revealing key patient characteristics and behavior needs critical for user-centered app designs. Chapter 4 also discusses study limitations and more importantly the role of health behavior theory in mHealth intervention design and implementation.

Chapter 2: Usability and Clinical Efficacy of Diabetes Mobile Applications for Adults with Type 2 Diabetes: A Systematic Review

Helen Fu[a*], Siobhan K. McMahon[a], Cynthia R. Gross[a,b], Terrence J. Adam[b,c], Jean F. Wyman[a,d]

[a] School of Nursing, University of Minnesota, Minneapolis, MN, United States

[b] College of Pharmacy, University of Minnesota, Minneapolis, MN, United States

[c] Institute for Health Informatics, University of Minnesota, Minneapolis MN, United States

[d] Department of Family Medicine and Community Health, Medical School, University of Minnesota, Minneapolis MN, United States

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Synopsis

Objectives: To assess the usability and clinical effectiveness of diabetes mobile applications (diabetes apps) developed for adults with type 2 diabetes.

Method: A systematic review of the usability and effectiveness of diabetes apps was conducted. Searches were performed using MEDLINE, EMBASE, COMPENDEX, and IEEE XPLORE for articles published from January 1, 2011, to January 17, 2017. Search terms included: diabetes, mobile apps, and mobile health (mHealth).

Results: The search yielded 723 abstracts of which seven usability studies and ten clinical effectiveness studies met the inclusion criteria from 20 publications. Usability, as measured by satisfaction ratings from experts and patients, ranged from 38% to 80%. Usability problem ratings ranged from moderate to catastrophic. Top usability problems are multi-steps task, limited functionality and interaction, and difficult system navigation. Clinical effectiveness, measured by reductions in HbA1c, ranged from 0.15% to 1.9%.

Conclusion: Despite meager satisfaction ratings and major usability problems, there is some limited evidence supporting the effectiveness of diabetes apps to improve glycemic control for adults with type 2 diabetes. Findings strongly suggest that efforts to improve user satisfaction, incorporate established principles of health behavior change, and match apps to user characteristics will increase the therapeutic impact of diabetes apps

1. Introduction

Type 2 diabetes (T2D) affects 382 million patients worldwide. This number is expected to increase by 35% globally in the coming years [1]. Poor glycemic control leads to complications, such as coronary heart disease or stroke (36.6%) [2]; visual impairment (19.1%) [3]; death related to hyperglycemic crisis (12.3% rate per 100,000 diabetic population) [4]; and limb amputation (3.3% rate per 1,000 diabetic population) [5]. Mobile health applications (apps) delivered through smartphones or tablets have the potential to help patients manage their diabetes. In 2014, 90% of Americans owned mobile phones, with 64% using smartphones [6]. Research indicates that using a diabetes app through a smartphone to track blood glucose (BG) and diet can increase adherence to diabetes management and self-monitoring [7]. However, the evidence of diabetes app clinical effectiveness is inconclusive. Small clinical trials have reported reductions in hemoglobin A1c (HbA1c) ranging from minimal to 0.49% [8,9] with 0.5% reduction as the benchmark for clinically meaningful change [10]. Furthermore, the rate of diabetes app usage is low [11]. One reason for their low use could be problems in their usability or the ease of using the app.

Mobile apps are a relatively new technology, so few studies have tested them as a clinical intervention. Some diabetes app usability studies are not routinely published because app developers perform usability evaluations internally before releasing the product to the market [12]. Furthermore, with limited regulatory oversight, diabetes apps do not need to have documentation of effectiveness [13,14]. Current usability literature tends to focus on communications platforms, data sharing, patient portal, web-based intervention, and text messaging capabilities of diabetes apps [12,15]. When studies tested clinical effectiveness, diabetes app functions were limited to data upload, education access, and text messaging notification [8,14,16]. Clinical effectiveness was increased when the app design promoted greater interactivity between patients and providers [17].

This systematic review aims to: (1) to describe the usability evidence specific to diabetes apps, and (2) to identify the clinical effectiveness of diabetes app use in T2D. Usability is "the extent to which a product can be used by a specific user for a specific goal in a specific context or environment, and provides an effective, efficient, and satisfying experience [18]." Usability evaluation is a method for identifying specific product usability and involves collecting qualitative and quantitative data [19]. The clinical effectiveness of diabetes app use is defined as improvement in glycemic control.

2. Materials and methods

2.1 Search strategy

The MEDLINE database did not add the subject heading "mobile application" until 2014. To capture publications from before this date, a broad keyword strategy was employed to supplement the subject heading strategy. The subject heading "diabetes mellitus" and the keyword diabet* were used for the concept of diabetes. For the concept of mobile applications, subject headings (mobile applications, computers, handheld, and cell phones) as well as keywords (mobile, application*, app, apps, mHealth, smartphone*, iPhone*, iPad*, android*, handheld computer*, tablet*, and cell* phone*) were used. For the concept of diabetes management, subject heading (self-care) and keywords (self-manage*, self-care, and self-monitor*) were used. The search strings for the three concepts were combined to retrieve the final search set, and limits for English language and 2011-2017 were applied. These searches were executed in MEDLINE, EMBASE, COMPENDEX (Engineering Village) and IEEE XPLORE (Institute of Electrical and Electronic Engineering Database). A manual search for additional publications checked the references of prior reviews and included articles.

2.2 Selection of studies

To be included as a usability study, the app had to be designed for adults with T2D and offer two or more app functions, and the article had to report at least one quantitative usability outcome. To be included as a clinical effectiveness study, the article had to meet four criteria: (1) the mobile app had to be multi-functional, (2) the study design had to be either a randomized controlled trial (RCT), quasi-experimental design, or pre-test and post-test, (3) the study population had to consist of adults with T2D, and (4) the study had to record at least one glycemic outcome of HbA1c or BG level change. Studies pertaining to type 1 diabetes (T1D) were excluded because some patients with T1D use a different technology such as an insulin pump with a built-in BG sensor and an accompanying app. Also, excluded from this review were app interventions studies that had a singular app function for text messaging, data upload, phone or video calls, education, and access to electronic health records. App interventions of data upload and text messaging have been previously reviewed extensively.

2.3 Study quality assessment

To evaluate the methodology quality, the Cochrane tool was modified for the assessment of bias in usability studies [20]. A study was rated as high, low, or unknown potential bias. This evaluation examined how the diabetes app or mHealth system was selected and tested. It also considered whether testing order had randomized sequencing if more than one product was tested. Performance bias checks if the evaluators had systematic differences in their ratings. For example, a patient's rating may differ from a caregiver's rating. Detection bias checks whether the usability outcomes are measured in reliable and consistent ways over time and across the different products being tested. Attrition refers to whether all the apps were the same version at the different time points of the study period (e.g. they did not have a software update or become unavailable in the app store). Assessment for selection bias did not apply to four studies when one group of participants performed all usability testing [21-24]. The domain area for usability assessment was wide ranging. To standardize comparison of all usability findings, we used a percentage rating by dividing a raw usability score by the maximum possible usability score (e.g., usability percentage of 60% is obtained by dividing a score of three with its possible maximum score of five).

Downs and Black checklist was used to assess the quality of clinical effectiveness studies because it accounts for randomized and not randomized study designs [25]. Studies received scores based on 27 items for five biases: (1) reporting, (2) external validity, (3) internal validity, (4) confounding factors, and (5) statistical power. Internal validity included measurement bias, performance bias, and attrition. The maximum methodological quality score was modified from 32 to 28, because a dichotomous rating was used instead of a 5-point scale to be consistent with other systematic reviews [26].

This modification was necessary because this review contained pilot studies for which a power analysis was not suitable. Studies with a score below 14 were rated as having low methodological quality [25].

3. Results

The search identified 1189 articles: 269 were from MEDLINE, 204 from OVID in process, 388 from EMBASE, 161 from COMPENDEX, and 167 from IEEE XPLORE. A manual search of four additional articles came from reference lists. After removing duplicates, the first author screened 953 articles (see PRISMA flow chart in Figure 1), and excluded 865 articles. Twenty articles were included: seven unique usability studies from eight publications [21-24,27-30] and unique clinical effectiveness studies from 12 publications [31-42].

3.1 Usability overview

Table 1 summarizes the characteristics of the usability studies - evaluator type, app domain, and rating scale. These studies used diverse methods: heuristic (user friendly principle) evaluation [30], patient satisfaction surveys [21,28], "think aloud" video recording when performing the required tasks of operation [22,23], screen interactions tracked by eye movement [24], and usability inspection [27,29]. Usability evaluators included experts [27,29,30], patients [21-24], and caregivers [24]. Types of experts were also diverse. For example, some were medical students supervised by diabetologists [27]. Others were mobile device experts, informaticists, nurses, and community health workers [29,30]. Reviewed studies also applied assorted theoretical frameworks. These frameworks included Shneiderman's Object-Action Interface Model [43], the International Organization for Standardization [18], Framework Analysis [44], and Nielsen's Ten Heuristics [45]. The domain for usability assessment was wide-ranging due to the varied theoretical frameworks [21-23,28-30].

3.2 Usability outcomes

Diabetes app usability ratings ranged from poor (38%) to average (80%) across the seven studies, with specific usability weaknesses found (Table 1). Usability experts and T2D patients indicated manual data entry restricted usability [28,29]. Patients took more time and made more errors than expected when exporting and correcting BG values [23]. They also encountered difficulty in system navigation whenever tasks required multiple steps [22,23]. Identified usability problems were mainly product design flaws (e.g., screen layout, system capability of reliability, and general characteristics) [21,27-29]. Usability experts reported design flaws that violated heuristic design principles [29,30]. This reflected that a mismatch existed between technology design and the real-world experience of patients living with T2D.

3.3 Usability study limitations

Limitations of the usability studies varied. For most studies, app product selection was limited to one app [24] or one mHealth system [21-24,28,30]. This limitation may impact the ability to generalize the findings. In some studies, recruited patients participated in prior mHealth studies; so they may have used another app which could have influenced their rating [22,23]. One study recruited caregivers who have roles and perspectives that differed from those of patients [24]. Another potential performance bias involved the influence of the app testing order on the evaluators. None of the usability testing had randomized testing order [27,29]. An app tested second or subsequent order may receive better score because the evaluators became more familiar with testing. Study reports lacked details of the mobile devices used [27,29,30]. No study in this review included statistical analysis of confounders such as current history of technology uses and patient motivation to control diabetes.

3.4 Clinical effectiveness overview

Clinical effectiveness studies were diverse with respect to design, setting, intervention type, and study follow up (Table 2). The included studies were randomized clinical trials with two arms [34,35,41], three arms [36] or four arms [31], as well as one group pre- and post-test design studies [39,40,42,46]. Study settings included primary care, community, and university hospital clinics. The majority of studies took place outside the United States: Canada [40], Norway [33,36,37], Finland [35], the United Kingdom [34], South Korea [39,42], and Japan [41]. Only two studies occurred in the US [31,32,38]. Most studies used diabetes apps in combination with other intervention components such as website, decision support, health provider feedback, or personal health record. Only one study reported a theoretical basis (Information-Motivation-Behavioral Skills Model) for the app intervention [35]. Of the remaining six studies, two studies applied the theoretical framework for an education class [36,37] and disease management counseling [38]. Duration of app use ranged from 2 to 12 months. The majority of the studies reported duration of app use as six months or less (n=6) [33,34,39-42].

3.5 Clinical outcomes

Diabetes app use in all studies decreased HbA1c, ranging 0.15% to 1.9% from baseline. However, the reductions were only statistically significant in four studies where the app design provided the greatest interactive features – HbA1c reduction of 0.4% to 1.9% [31,35,41,42]. Three studies of these studies used between groups comparison [31,35,41]. Glycemic changes are difficult to pinpoint because some of the studies had concomitant effects with other intervention components such as a website. Most studies used a diabetes app in conjunction with a website, healthcare provider feedback, or Bluetooth-enabled devices such as glucometers and blood pressure monitors (Table 2). All studies concluded glycemic improvement with diabetes app use. Of the studies that showed statistically significant HbA1c reductions, instant app messages came from an algorithm database website [31,42], a primary care provider [31], or a dietician [41] (Table 3). The apps provided feedback messages [31,34,34,39,42] and alert reminders [35,39-41]. This functionality adapts for real time data which is helpful for tailoring healthy behaviors. In one study, the app analyzed a meal photo for its carb content to be reviewed by a dietician, who then text messages of diet improvement to patients [41].

3.6 Clinical effectiveness study limitations

The use of diabetes apps in combination with other interventions posed a risk of confounding. Only two of the ten studies reported a power analysis [31,37]. Eight out of the ten studies did not use any form of blinding [34-37,39-42]. Five studies did not report intervention adherence rates [31,33-35,39]. Most studies neglected to report the name of the diabetes app and the study device (e.g., smartphone and tablet). Only four studies reported specific diabetes app names [33,36-39]. One diabetes app called Few Touch appeared in two studies [33,36,37]. Five out of the ten studies reported the app's operating system [34,36-40]. Study phone devices included Nokia, HTC Windows, Tungsten E2, Samsung, and Blackberry.

4. Discussion

4.1 Interpretation of usability findings

This review identified diabetes app usability limitations like those noted in prior reviews. Many diabetes apps have few functions targeting diabetes self-management [46]. The four most common app functions were documentation of diet and medication, weight management, and data export [46]. Problem solving strategies for diabetes self-management were less common [47]. Diabetes apps can provide longitudinal analytics of time sensitive BG and carb intake data. This way patients can improve problem solving in self-management by identifying their trends of elevated BG readings and plan when to improve self-management behaviors (e.g. following a low carb diet) [48]. Unfortunately, many diabetes apps' analytic features do not meet standards of health literacy. Only one-third of apps displayed clear images to facilitate learning and understanding of diabetes numbers [49]. Without the right literacy level and user-friendly app features and functions, it is difficult for patients to use diabetes apps [50]. Other than intuitive design, diabetes app usability may depend on patient factors such as age or sex. Patients who were under age 55 took less time in adapting the use of diabetes management software app and its accompanied website [23].

4.2 Interpretation of clinical effectiveness findings

The use of diabetes apps was associated with improved glycemic control. However, the app use was usually part of multi-component interventions, so it was not always possible to distinguish the individual effect. Most studies used a combination of a diabetes app plus other product (e.g., Bluetooth-enabled glucometer and decision support). Greater HbA1c reductions were observed among patients with poor glycemic status of HbA1c above 9% [31]. This may influence higher patient motivation to adopt positive behavior changes since the primary care providers recruited these patients to enroll in the study. Real-time feedback appeared to be the most beneficial app feature. This may be because it enables patients to respond to a specific BG value or carb intake in a timely way. Interactive feedback between diabetes apps and patients involved automatic message from an app algorithm such as “You have met your target of blood glucose reading five times this week” [31], a text message from a dietician who reviewed data and customized a meal plan [41], or an alert message whenever a BG reading is out-of-range [35,40,41,46]. Diabetes apps with less interactive features had less effect on HbA1c reductions (Table 3) [36-38]. Furthermore, diabetes app usability could be limited by the number of available app functions to support diabetes self-management behaviors recommended by the Association of American Diabetes Educator (AADE7™) that advocate healthy eating, being active, monitoring BG, taking medication, problem solving, reducing health risk, and healthy coping. Many iOS diabetes apps targeted two out of seven self-management behaviors: BG monitoring and medication use [47]. Diabetes apps designs need to be more user-friendly for patients and have enough app functions that support self-management behaviors.

4.3 Theory and clinical application

Without health behavior theory guiding diabetes app design, diabetes apps may be perceived by patients as not being helpful in promoting positive behaviors. A recent review of health apps showed that most health apps are not consistently grounded in a theoretical basis since their designs were mostly information input or output functions [51]. Of all the clinical effectiveness studies covered in this review, only one out of nine studies (11%) reported the use of a health behavior theory [35], even though it has been shown that patient motivation is a strong factor in diabetes management [52,53]. According to the Self-determination theory (SDT) of motivation, inner motivation (personal endorsement of health behaviors) facilitates long-term behavior change, but it requires support for three behavior needs: (1) Competence - gaining confidence and skill in diabetes self-management such as testing and understanding BG values, (2) Autonomy to choose from safe management choices that are personalized or individualized for them, and (3) Relatedness or connectivity, which usually means ongoing and supportive communication and positive relationship with healthcare providers [54].

Diabetes apps, then, need to offer patients motivational support to be effective aids in self-management. One way to do this would be to create an easy-to-understand BG pattern report that supports patient motivation by teaching which BG values are in-range and out-of-range. Another way diabetes apps can help motivate patients to manage diabetes is to offer a visual report that shows them which days of the week and which meals require their focus for improvement. This would support autonomy and personalize specific behavior changes to control diabetes. Another app function important for patient motivation is to promote healthcare provider connectivity by sharing health data and reports via email. Such function would support ongoing communication between patients and their healthcare providers, which has been shown to improve diabetes management and clinical outcomes [55]. Future studies are needed to identify and assess what specific diabetes app features and functions can help promote usability and patient motivation for self-management.

4.4 Ethical considerations

Data privacy and security pose significant ethical and potentially legal challenge to making diabetes app use common. No federal legal protection exists around the disclosure of app data to third parties [56]. In addition, the Health Insurance Portability and Accountability Act (HIPAA) does not prohibit app companies from sharing sensitive health information [57]. According to a 2014 review, 81 percent of Android diabetes apps did not provide privacy policies [57], and whatever privacy protection exists can be negligible since the data is shared with a third party such as Google [57]. Clinicians must take precautions when recommending diabetes apps to patients, then, and specifically warn patients to review the privacy policy to determine what health information can be shared and with whom.

4.5 Research implications

Future studies need to (1) rigorously focus on how to improve diabetes app design so that it supports patient motivation for self-management, (2) provide a methodologically sound rationale for the selection of a diabetes app and its related mHealth tools, and (3) assess the evidence of the usability and adoption of diabetes app use among diverse population. For more specific evidence of diabetes app clinical effectiveness, future studies should include: randomized controlled trials using larger sample sizes, effective recruitment strategy, and appropriate sampling of intended users. Monitoring adherence (app use frequency) is critical to determining an optimal usage rate required to have clinically meaningful significance. Future studies of diabetes apps also need to incorporate individual patient factors of behavior and technology experiences. Most studies in this review did not report important health behavior factors that influence diabetes self-management such as patient motivation, health literacy, and health numeracy. Research has shown that motivational support from healthcare providers was associated with an increase in the use of mHealth tools [55]. Most studies in this review did not report patient background in technology experience such as comfort level in using mobile technology and the length of smartphone ownership. Patients reported that low technology literacy was a barrier for the use of well-known apps such as Glucose Buddy and MyFitnessPal [58]. Statistical analysis should take account of these important patient characteristics.

5. **Conclusion**

Diabetes apps have great potential to support diabetes self-management. However, this potential is limited since diabetes apps are often not intuitive to use and did not always have health behavior theory applied in their design and development. Health behavior theory can provide a guiding basis for mHealth intervention designs. Future research should focus on the following questions: What evidence exists to show mHealth interventions are most user-friendly and supportive of self-management? Are diabetes apps combined with Bluetooth enabled devices, decision support, and remote provider messaging system, the most effective combinations or are other combinations equally or more effective? Future studies also need to examine whether certain patient characteristics are more likely to result in initiating and sustaining the use of diabetes apps. Randomized controlled trials that incorporate large sample sizes to detect short-term effects and long term effects will add knowledge of diabetes mHealth interventions. Patient characteristics such as motivation, behavior needs related to motivation, technology experience, and app use adherence rate need to be assessed for their effect on patient outcomes. Ethical considerations for the risk of data privacy also need to be carefully addressed.

Conflict of interest statement

Author declares no conflict of interest.

Author contributions

HNF conceived the review topic, drafted the protocol, performed literature search, conducted data extraction, data analysis and authored the manuscript.

SKM contributed to manuscript authorship and editing.

CRG contributed to manuscript authorship and editing.

TJA contributed to manuscript authorship and editing.

JFW provided technical oversight and contributed to manuscript authorship and editing.

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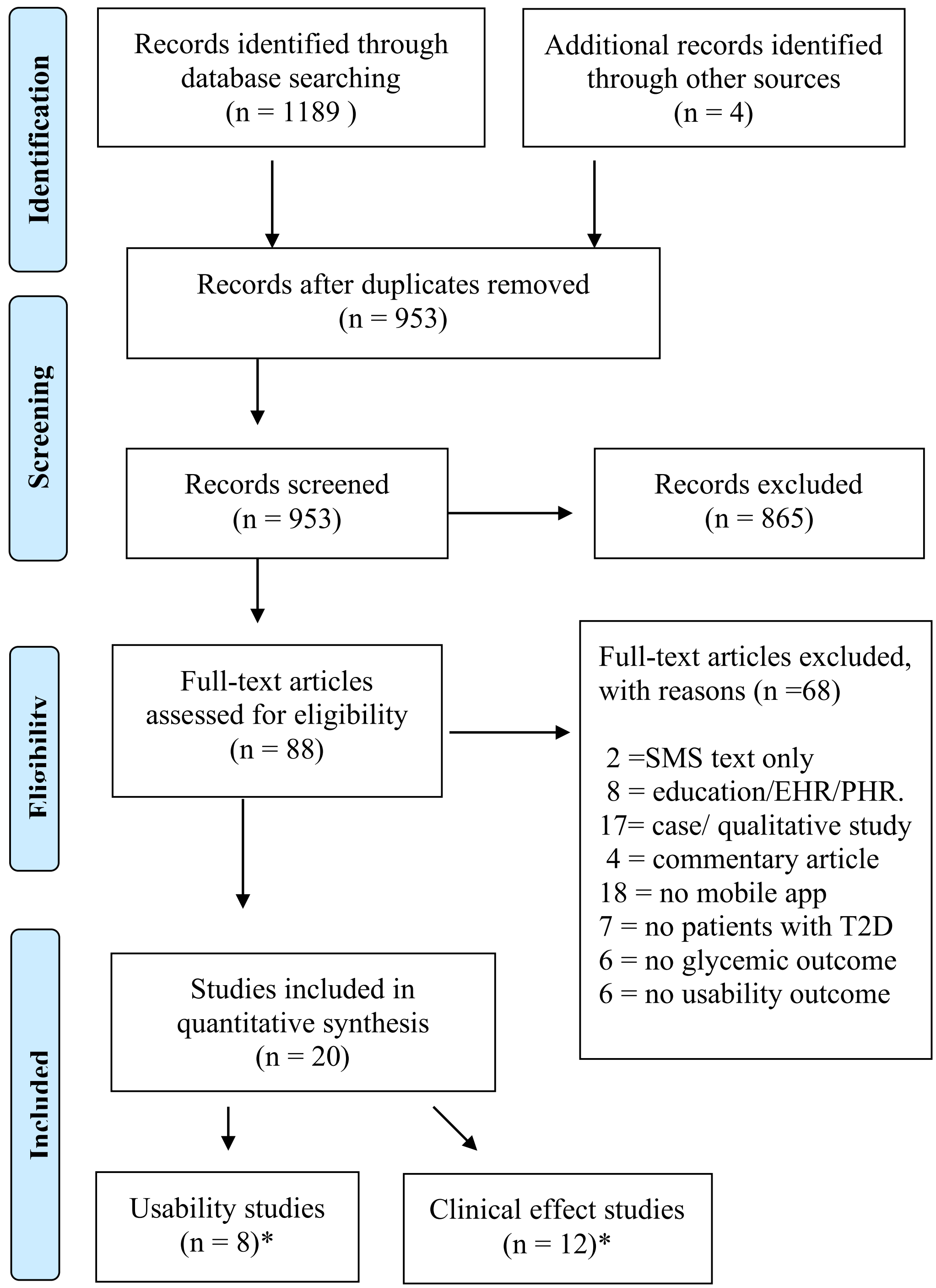
Figure 1 – PRISMA Flow chart of study literature search.



* A total of 7 unique usability studies (one publication was an extension of prior publication) and 10 unique clinical effectiveness studies (two publications were each an extension of prior publication).

Table 1 – Summary of included usability studies.

Author	Method Evaluator Theoretical framework	Tech. platform	App domain/ Rating scale	Usability outcome examples (rating, % of possible maximum)	Potential bias
Demidowich et al. (2012)	Usability inspection 2 medical students	4 Android apps	6 areas Rating 1-5	**Overall usability**: 11.3 out of 30 (38%) **Usability per app function**: 3 (60%)	(?) Selection (?) Detection (+) Other bias
Alanzi et al. (2014) & (2016)	Usability survey 32 patients Shneiderman	1 app/ mHealth	5 areas of QUIS Rating 1-9	**Overall reaction**: Ease of use (6.3, 70%), **Screen factor**: Layout helpful (6.03, 67%) **Terminology and System Information**: Clarity (6.09, 67%) **Learning factor**: Error (6.12, 68%), **System Capabilities**: Reliability (5.97, 66%)	(?) PERF (+) Other bias
Arnhold et al. (2014)	Usability inspection 3 usability experts ISO, Nielsen, Sarodnick, and Brau	66 apps Androids and iOS	4 areas Rating 1-5	**Overall usability** (3.3, 66%) **Comprehensibility overall** (4, 80%) **Presentation overall** (3.5, 70%) **General characteristics** (2.8, 56%) Analysis function reduced usability by 0.21	(?) Selection (?) Detection
Georgsson al. (2016a)	Think aloud, interview, and usability survey 10 patients Framework Analysis	1 SMS-based	UPT: 2 areas, 5 categories, 21 subcategories Severity 1-4	19 problems reported Severity of medium to serious (2.47, 62%) Most frequent problem: multi-steps task, interaction, navigation and functionality	(+) PERF (+) Other bias
Georgsson et al. (2016b)	Observation and survey 10 patients ISO	1 “Care4Life” SMS	7 areas SUS:10 items Error Time	SUS for satisfaction: 80.5, good Task failure and longest: correcting and exporting BG values	(+) PERF (+) Other bias
Georgsson et al. (2016c)	Heuristic evaluation, 3 experts from various area Nielsen’s Ten Heuristics	1 mHealth plus SMS	7 areas Severity 0-4	Usability problem: n= 129 Heuristic violation: n= 274 Severity catastrophic: (12/129, 9.3%) Average severity: moderate (2.8, 70%)	(?) Selection (?) Detection (+) Other bias

Tulu et al. (2016)	Screen reaction: eye movement tracking 5 patients	1 Android app	3 areas Time	Longest task time: physical activity	(+) PERF (+) Other bias

Note:
(+) for high risk, (-) for low risk, (n/a) not applicable, (?) for unknown potential bias in the study.
Abbreviations: App, application; BG, blood glucose; b/t, between; ISO, International Organization for Standardization; PERF, performance; QUIS, questionnaire for user interaction satisfaction; SMS, short message service; SUS, System Usability Scale; Tech., technology; UPT, Usability Problem Taxonomy.

Table 2 – Summary of included clinical effectiveness studies.

Author	Design	Number	Intervention Components	F/U mos.	Baseline HbA1c (%), FBG	Follow up HbA1c %/ Fasting BG at Follow up	Methodology Quality Score[b]
Quinn et al. (2011) & (2014)	4 arm cluster RCT Secondary analysis stratified for age	26 clinics, 163 patients	App Website Decision Support PCP review PHR	12	9.2 9.3 9.3 9.9	Usual care (*n*=56, 9 clinics): 8.5 App only (*n*=23, 4 clinics): 7.7, *p*=0.027[*] App + WEB (*n*=22, 6 clincs): 7.9, *p*=0.40 App + WEB + decision support (*n*=62, 7 clinics): 7.9, *p*=0.001[*]	21
Chomutare et al. (2013)	1 group pre-post	7	App Social forum	3	6.8	6.79, *p*=NR (not significant)	12[d]
Nagrebetsky et al. (2013)	2 arm RCT at	17	App Bluetooth sync Glucometer Paper manual for drug titration	6	8.2 8.0	Usual care: NR, Treatment group: 7.2, *p*=0.35[a]	13[d]
Orsama et al. (2013)	2 arm RCT	48	App Website Decision support PHR Research nurse	10	7.1 6.86	Usual care: 7.1 Treatment group: 6.46, *p*=0.022[a*]	20
Holmen et al. (2014), Torbjørnsen et al. (2014)	3 arm RCT	151	Diary app Bluetooth sync Glucometer Counseling staff	4 12	8.3 8.1 8.2 8.4 8.1 8.2	Usual care (n=50): 8.0 App only (n=51): 7.8 App + counseling (n=50): 7.8, *p* =0.65 Usual care (n=41): 8.2 App only (n=39): 7.8 App + counseling (n=40):8.0, *p* =0.57	18[c]
Forjuoh et al. (2014)	4 arm RCT	376	App Glucometer BP monitor 6 weeks education	12	9.2 9.3 9.4 9.2	Usual care (n=95): 8.5 App only (n=81): 8.6 Education only (n=101): 8.3 App + education (n=99): 8.1	21[c]
Kim et al. (2014)	1 group pre-post,	35	App Glucometer BP monitor	3	7.7	7.5, *p*=0.077	16

Read (2014)	1 group pre-post	25	App Glucometer Bluetooth sync BP monitor Pedometer	2	6.0	5.88, *p*=NR (not significant)	13[cd]
Waki et al. (2014)	2 arm RCT	54	App Website Bluetooth sync Glucometer BP monitor Scale Pedometer Dietitian review	3	7.0 7.1 127.4 (FBG) 140.2 (FBG)	Usual care: 7.1 Treatment group: 6.7, *p*=0.015* Usual care FBG: 144.3 Treatment group FBG:134.7, *p*=0.019*	15[c]
Kim et al. (2016)	1 group pre-post,	29	App Glucometer Website Provider review	3	7.7 140.9 (FBG)	7.1, *p*<0.0001* FBG:120.1, *p*=0.013*	15

Note:
Abbreviations: App, application; HbA1c, hemoglobin A1c; CI, confidence interval; F/U, follow-up; FBG, fasting blood glucose; NR, not reported; PCP, primary care provider; PHR, personal health record; WEB, website.
P values are reflective of between group comparison (RCTs), or pre-post comparison (quasi-experimental trials)
*Statistically significant difference in HbA1c or fasting blood glucose reduction compared to usual care.
[a]Adjusted for baseline HbA1c.
[b]This methodology quality score is based on Down's and Black's checklist (Downs & Black, 1998). The score can range from 0- 28.
[c]Studies reported adherence rate.
[d]Methodology quality scoring less than 14 reflects below less than average quality.

Table 3 – Clinical improvement and associated app functions and features.

Author	App Name/ Study device OS	HbA1c% Reduction	App Functions	Interactive App Features
Quinn et al. (2011)	NR	1.2 -1.9*	Documentation and monitoring: BG, carbohydrate intake, medication, and other diabetes data Receiver for message Education	Real time message based on data
Chomutare et al. (2013)	Few Touch/ NR NR	0.18	Documentation and monitoring: BG, diet, physical activity, and medication Social media chat User controlled data sharing	Exchange information in social forum electronically
Nagrebetsky et al. (2013)	NR/ Nokia Android	0.6	BG upload and monitoring Website decision support algorithm	Real time BG feedback
Orsama et al. (2013)	"Monica"/ NR NR	0.4*	Documentation and monitoring: BG, BP, and weight	Feedback message Alert reminder
Holmen et al. (2014) Torbjørnsen et al. (2014)	Few Touch/ HTC Windows Android	0.15-0.41	Documentation and monitoring: BG, diet, physical activity, and medication Personal goal setting Education	NR
Furjuoh et al. (2014)	Diabetes Pilot/ Tungsten E2, Palm OS	0.7 -1.1	Documentation and monitoring: BG, diet, physical activity, and medication	NR
Kim et al. (2014)	Smartcare/ Samsung Android	0.2	Documentation: BG and BP	Weekly BG and BP feedback from healthcare staff
Read (2014)	NR/ NR Blackberry	0.14	Documentation: BG, BP, physical activity, and Wt	Alert reminder
Waki et al. (2014)	NR	0.4*	Data transmission and monitoring: BG, diet, activity, BP, and Wt Interpretation of BG data Patient voice/text dietary intake Meal photo evaluated by dietician	BG alert to providers Dietician feedback
Kim et al. (2016)	NR/ NR Android	0.6*	Documentation and monitoring: BG upload, diet, medication, and physical activity Insulin dose Social network Exercise and education video	Real time BG feedback

Note:
Abbreviation: App, mobile application; BG, blood glucose; BP, blood pressure; NR, not reported; OS, Operating system; PHR, personal health record; Wt, weight.
*Statistically significant difference in clinical improvement compared to usual care.

Chapter 3: Patient Factors, Psychological Needs, and Diabetes App Usability

Helen N.C. Fu, MSN, School of Nursing, University of Minnesota

Terrence J. Adam, PhD, MD, Institute for Health Informatics, University of Minnesota

Joseph Konstan, PhD, Department of Computer Science and Engineering, University of Minnesota

Julian Wolfson, PhD, School of Public Health, University of Minnesota

Diane J. Treat-Jacobson, PhD, School of Nursing, University of Minnesota

Thomas R. Clancy, PhD, School of Nursing, University of Minnesota

Siobhan K. McMahon, PhD, School of Nursing, University of Minnesota

Jean F. Wyman, PhD, School of Nursing, University of Minnesota

Helen Fu, School of Nursing, University of Minnesota

5-140 Weaver-Densford Hall, 308 Harvard Street SE, Minneapolis MN 55455

Tel: 612-308-6214, Fax: 612-625-7180, Email: helen007@umn.edu

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SYNOPSIS

OBJECTIVE – More than 1,100 diabetes apps are available, but are infrequently used. Guided by Self-Determination Theory on motivation, this study assessed the usability of diabetes apps and whether usability was associated with patient characteristics and psychological needs for competence, autonomy, and connectivity.

RESEARCH DESIGN AND METHODS – Using a crossover randomized design, 92 adults with type 1 or 2 diabetes tested two Android apps (*mySugr and OnTrack*) for tasks including data entry, blood glucose reports, and data sharing. Multivariable linear regression models examined associations between patient characteristics, psychological needs, and user satisfaction and user performance (task time, success, and accuracy).

RESULTS – User satisfaction was independent of patient characteristics except for education but associated with psychological needs ($P < 0.05$). Higher user satisfaction was observed for patients with less education and those reported more competence, autonomy, or connectivity with a healthcare provider ($P < 0.05$). User performance was associated with age, sex, education, and diabetes duration. Older patients required more time and had less successful task completion. Men needed more time and technical support than women. Having high school education or less and a diabetes duration 10+ years were associated with lower task accuracy ($P < 0.01$).

CONCLUSIONS – Diabetes app usability was associated with psychological needs that are important for motivation. To enhance patient motivation to use diabetes apps for self-management, clinicians should consider addressing patient's competence, autonomy, and connectivity. Older male users and those with less education and greater diabetes duration may benefit from patient-centered app training and ongoing technical support.

Patients with diabetes may benefit from self-management interventions to prevent diabetes-related complications including stroke and vision loss. Poor diabetes management is associated with greater healthcare expenditures, 2.3 times higher than those without diabetes (Ozieh et al., 2015). Adhering to medical nutritional therapy, following a diabetes diet, and determining what to eat on a regular basis are the most challenging for many patients with diabetes (American Diabetes Association, 2016b). In 23% of cases, poor adherence was associated with uncontrolled hemoglobin A1c (HbA1c) (American Diabetes Association, 2016a). Using a diabetes app through a smartphone to track blood glucose (BG) and diet shows promise to improve diabetes self-management adherence (Padhye & Wang, 2015). Small trials have shown that using a diabetes app can improve glycemic control with a 0.4%–1.9 % reduction in HbA1c levels (Orsama et al., 2013; Quinn et al., 2011; Waki et al., 2014). However, diabetes app use is low possibly due to design problems and limited usability (Research2Guidance, 2014). According to the International Organization for Standardization 9241-11, usability refers to how well a specific person uses a product to achieve goals of effectiveness, efficiency, and satisfaction in the desired context (Barum, 2011). Hence, diabetes app usability is the degree to which an intended user is satisfied with using the app and uses it efficiently and effectively to accomplish tasks such as tracking of BG readings.

Patient characteristics may influence the usability experience, but few studies have examined usability differences based on individual patient characteristics (Alanzi, Istepanian, & Philip, 2014; Georgsson & Staggers, 2016b; Tulu, Strong, Agu, Wang, & Pedersen, 2016). Age and sex appear to influence the app experience. For example, patients aged 56 years and older have reported less satisfaction with using diabetes apps

(Conway, Campbell, Forbes, Cunningham, & Wake, 2015), and women make more errors compared to men in completing tasks such as submitting BG measurements (Georgsson & Staggers, 2016b). Other background characteristics, such as technology experience and confidence, influence patients' ability to use diabetes apps. One study showed that popular apps such as *Glucose Buddy* and *MyFitnessPal* did not match patient knowledge and ability, and patients reported that app designs were too complicated (Peng, Yuan, & Holtz, 2016). Many health apps mainly provide information input and output only, and most do not apply health behavior theory in their design (Riley et al., 2011), which may be important for a positive experience and long-term app use. Prior usability studies also did not assess the quality of diabetes apps based on health behavior theories. Assessing app usability and its relationship with patient characteristics and health behavior theoretical constructs will fill critical knowledge gaps related to user-centered design and best practices in promoting diabetes self-management.

The purpose of this study was to test two top-rated diabetes apps and examine the association of usability with patient characteristics and psychological needs important for motivation and behavioral change. Aim 1 was to determine the relationships between patient characteristics (e.g., age, sex, education, technology use, diabetes history, and motivation) and diabetes app usability. We hypothesized that patient characteristics will predict user satisfaction and user performance in task time, success, and accuracy. Aim 2 was to determine the relationships between psychological needs important for motivation and app usability. We hypothesized that user satisfaction will be associated with psychological needs for competence, autonomy, and healthcare provider connectivity, theoretical constructs from Self-Determination Theory.

RESEARCH DESIGN AND METHODS

Theoretical Framework

This study used Self-Determination Theory (SDT) by Deci and Ryan (2000), a theory of motivation, as the framework to understand patient perspectives on app usability. Motivation to change is enhanced when patients experience satisfaction for three inherent psychological needs: competence, autonomy, and relatedness (Ryan & Deci, 2000). Intrinsic motivation is self-initiated when one personally endorses the importance of healthy behaviors, while extrinsic motivation is external endorsement for which one acts to get an external award, avoid punishment, or to comply with social pressure (R. Ryan et al., 2008). When patients recognize the personal benefit of using an app, they are more motivated to use it. Figure 1 outlines the influence of patient characteristics on psychological needs and product needs that subsequently contribute to user-centered design and app use. Competence refers to patient confidence to manage their diabetes by keeping their BG in target range (G. Williams et al., 1998). Apps can address the need for competence by displaying a summary report of out-of-range BG readings that will in turn help patients learn diabetes numeracy (understanding of BG numbers). Autonomy refers to patient empowerment to have a menu of options to change behaviors (R. Ryan et al., 2008). Diabetes apps can address the need for autonomy by providing BG reports and carbohydrate (carb) intake patterns by meal. Patients can visualize which meals require better carb control and create a personalized behavior action plan. Relatedness is “the need to care and be cared for” (Deci & Ryan, 1985). Patients are more likely to adopt behaviors when they feel supported and connected with people they trust such as a healthcare provider (R. Ryan et al., 2008). Apps can assist healthcare provider connectivity by providing communication support with a healthcare provider and data sharing through email functionality.

Study Design and Participant Eligibility

This study used a randomized crossover design to test two Android apps (*OnTrack* and *mySugr*) listed as "the Best Diabetes Apps 2016" by *Healthline* (health forum). The Android platform was selected because it has the greatest number of users (52.7%) in the market (Lella, 2016). Because age is a potential confounder in usability testing (Bangor, Kortum, & Miller, 2008), we created two age-based strata: adults age ≥ 56 years and adults < 56 years. Using a computer software program, a statistician randomly assigned an app testing order of AB or BA within each age strata sealed in an opaque envelope for each patient. The primary usability outcome was user satisfaction measured by the System Usability Scale (SUS) (Brooke, Jordan, Thomas, Weerdmeester, & McClelland, 1996). Secondary outcomes assessed user performance including efficiency (task time) and effectiveness (task success and task accuracy). The University of Minnesota Institutional Review Board approved the study, and all participants signed an informed consent document prior to app testing. Participants received a $50 honorarium at the end of each study session.

From July 26, 2017, to November 30, 2017, we conducted in-person app testing with participants who responded to flyers posted at community or veteran clinics, support groups, universities, and community bulletins, as well as online postings on Craigslist and Facebook. A total of 110 participants (57% of 193 respondents) were enrolled and 92 participants completed the study. Participants met all inclusion criteria: (1) age 18 or older, (2) type 1 or 2 diabetes, (3) insulin therapy for at least 6 months, (4) Android smartphone use for at least 6 months, (5) English proficiency, (6) adequate vision to read email or text messages on their current smartphone, and (7) smartphone use proficiency. Individuals were excluded who used *OnTrack* or *mySugr* or any diabetes app in the past 6 months.

Procedures

Individual study sessions were held in a private room located in a public library or community center mutually agreed upon. The sessions lasted on average 2 hours, with a range of 1–3.5 hours. App training included watching YouTube videos posted by the app developers. Participants practiced using the app on a study phone, a Samsung 5S, based on a task checklist that included seven functions: (1) enter a carbohydrate (carb) intake, (2) enter an exercise activity, (3) enter an insulin dose, (4) enter a BG reading, (5) locate a BG report for days of the week, (6) locate a BG report for each meal, and (7) email a BG report. Participants tested the two apps following a checklist with a different task order and data units compared to the practice session. The SUS questionaire was completed at the end of each app test. A 30-minute break took place between the first and second app test. During the break, participants completed the background survey and were given an opportunity to eat a light snack and use the restroom. App training and testing was conducted by the principal investigator following the study protocol that included a standardized tip sheet used to provide technical support requested by the participants. Another research staff member checked fidelity from the audio recording of the study sessions. Field notes and app preference comments were recorded by the principal investigator.

Measurements

User satisfaction (primary outcome) was determined by the SUS, a10-item questionnaire administered immediately after each app test (Brooke et al., 1996). The SUS is widely used in technology usability evaluation with a reliability coefficient alpha of 0.91 (Bangor et al., 2008) and a loading factor > 0.3 for construct validity (Lewis & Sauro, 2009). Scores > 70 show acceptable usability with scores ≥ 85 considered excellent usability. Scores between 50 and 69 reflect marginally acceptable usability, and scores ≤ 50 are unacceptable usability (Bangor, Staff, Kortum, Miller, & Staff, 2009). Secondary outcomes were user performance evaluation: (1) app efficiency measured by task time, and (2) app effectiveness measured by task success and accuracy. Task time is the total task completion time per app. Task success is the degree to which a user independently completed required tasks (Nielsen, 2001). Each app task success was rated from 0% to 100%, accounting for the degree of independent use. The rating is zero when the app is missing one of the seven testing functions or the patient received more than 50% of the tips listed in the standardized tip sheet. The user success rate was computed by compiling the different ratings for each testing function and then averaging them. Accuracy rating is whether the patient performed tasks correctly (e.g., correct insulin dose). Its score was an average accuracy of all tested app tasks.

Patient characteristics were self-reported using a background survey of 32 items that included demographics (age, sex, race/ethnicity, and education), smartphone brand, technology use, diabetes factors (types, HbA1c, duration, insulin use, BG testing, and prescribed BG testing), plus an established motivation scale, the Treatment Self-Regulation Questionnaire (TSRQ), assessing patients' reasons for engaging in diabetes self-management behaviors with 8 items for intrinsic motivation and 11 items for extrinsic motivation rated on a seven-point Likert scale (G. Williams et al., 1998). Both types of motivation scores were calculated by averaging the response ratings, which ranged from 1 (not true at all) to 7 (very true). Overall motivation was assessed by the Relative Autonomy Index (RAI), calculated by subtracting the intrinsic motivation score from the extrinsic motivation score. Positive scores indicate higher relative autonomy from intrinsic motivation, whereas negative scores indicate lower relative autonomy from more extrinsic motivation. TSRQ has been validated across settings and for other health behaviors with an internal consistency alpha coefficient > 0.73 in a prior study (Levesque et al., 2007) and 0.82 in this study.

Competence was measured by the Perceived Competence Scale (PCS), which assesses competence in diabetes self-management rating, which ranged from 1 (*not true at all*) to 7 (*very true*) on a 7-point Likert scale with four items and scored by averaging the responses (G. C. Williams, Ryan, & Deci, 1999). Its internal consistency alpha coefficient was > 0.80 in a prior study (G. Williams et al., 1998) and 0.88 in this study. Taking an interest in learning is a subcomponent of autonomy (R Ryan & Deci, 2006). Autonomy in diabetes management was measured by four items designed by the investigator and validated with expert testing that estimated patient interest in personal trends for BG readings and carb intake. Responses are on a 5-point Likert scale rating from 1 (strongly disagree) to 5 (strongly agree) and scored by averaging the responses. Its alpha coefficient of 0.74 was acceptable. Healthcare provider connectivity was rated by the Health Care Climate Questionnaire (HCCQ), assessing the degree to which primary healthcare providers offer autonomous support in diabetes management (G. Williams, McGregor, Zeldman, Freedman, & Deci, 2004). The score is based on an average response to six items on a 7-point Likert scale rating from 1 (strongly disagree) to 7 (strongly agree). Its reliability alpha coefficient was 0.82 in a prior study (G. Williams et al., 2004) and 0.94 in this study.

Statistical Analysis

The sample size calculation for a linear mixed effect multiple regression model (n = 84) was based on 13 predictor variables, R^2 correlation matrix of 0.2, and 0.05 alpha. To account for 10% attrition, the target sample size for this study was 92. All analyses were performed using R statistical software version 3.4.1 released June 30, 2017 (Team, 2017). The only missing data was a HbA1c level from one participant. Residual plots showed no evidence of heteroskedasticity. Paired t tests of *mySugr* and *OnTrack* usability scores showed significant differences ($P < 0.05$), which called for all analyses to be adjusted for app group and testing order with an interaction term. Analyses of t tests and Chi-square assessed differences between two age strata and sex groups using a 0.05 significance level.

For Aim 1 to determine patient characteristics' association with app usability, a linear mixed effect multiple regression model of ANOVA analyzed both random effect (app group) and fixed effect (repeated app testing). The full model was run separately for each usability outcome and checked for $P < 0.05$ statistical significance. A full model included 15 predictors of patient characteristics with smartphone brand and education collapsed into dichotomous variables. For Aim 2 to assess the relationship between psychological needs and app usability, the model for Aim 1 was used by adding a psychological need predictor (e.g., competence) while adjusting patient characteristics covariates (key demographics, technology factors, diabetes history, and motivation), testing order, app group, and interaction term between testing order and app group. We assessed the individual mediation effect of task time, success, and accuracy on user satisfaction to explain all or part of the relationship between the psychological need and user satisfaction (Tingley, Yamamoto, Hirose, Keele, & Imai, 2014). For any significant finding ($P < 0.05$), multiple analysis correction with Bonferroni was used with a cutoff of 0.0008333 (derived from 0.05 divided by 60, because there were 15 hypotheses tested with four models assessing the effects of patient characteristics on SUS, time, success, and accuracy). Meanwhile a cutoff of 0.000781 (derived from 0.05 was divided by 64) was used for four models assessing psychological needs' effects.

RESULTS

Sample Recruitment and Characteristics

Diverse recruitment sites yielded 92 participants living in urban and suburban Minnesota locations: 46 were recruited from Facebook (50%), eight from patient referrals (9%), seven from a community clinic (8%), six from a university (6.5%), six from public housing (6.5%), five from Craigslist (5%), four from a veteran clinic (4%), three from diabetes support groups (3%), and seven from miscellaneous sites such as a state fair, church, and library (8%). Participant characteristics are presented in Table 1. More than half of participants were women, nearly half used Samsung brand phones, and 70% had type 2 diabetes. The mean age was 54 years (range 19–79), and the mean HbA1c was 8.2% (range 5–14) or 66 mmol/mol (range 31–130).

App Usability

Participants rated the two top-rated apps as having marginally acceptable usability (SUS scores between 50 and 69). *OnTrack* received an SUS score of 68 that is considered a "D" grade usability, e.g., scores between 60 and 69. Meanwhile, *mySugr* received a SUS score of 55 that is a "F" grade usability, e.g., scores less than 60. Task time (efficiency) was significantly better for *OnTrack* compared *mySugr* (mean 6.6 vs 7.5 minutes, respectively, $P < 0.001$). *OnTrack* had higher user performance effectiveness scores than *mySugr* with 84% vs. 80% task success ($P = 0.03$) and 74% vs. 63% task accuracy ($P < 0.001$).

Patient Characteristics and App Usability Outcomes

Demographics, technology use, diabetes factors, or motivation of the patients did not predict user satisfaction assessed by the SUS for tested apps (Table 2). However, patient characteristics of age, sex, and education predicted secondary outcomes of task time and success rate. Adults over age 56 years took an extra 2.2 minutes [95% CI 1.1–3.2] for task time, had lower task success [95% CI 3.5–14.3], and made more task errors [4.2–16.4] compared with adults age 18–55 years. On average, for every 10 years of age, adult patients spent 0.8 minute longer ($P < 0.05$) and the task success rate decreased by 4.6% ($P < 0.01$). Men were less proficient compared with women. They took an extra 1.7

minutes ($P < 0.05$) and were 6.9% less successful ($P < 0.05$). Participants who had education beyond high school had less user satisfaction by 6.4 ($P < 0.41$) and greater success by 10.5% compared to those who did not. There was a trend for a significant difference in higher accuracy for current Samsung smartphone users by 7.3% ($P = 0.054$).

Although neither type 1 or 2 diabetes predicted task time or success, other diabetes characteristics played a significant role in user performance. Diabetes duration had a negative effect on accuracy ($P = 0.023$). The longer duration of diabetes, the less accurate participants were in using diabetes apps. A 10-year increase in diabetes duration was associated with an 8.5% drop in task accuracy, whereas, the duration of insulin use tended to be associated with an increase of 7.1% in accuracy ($P = 0.058$). Glycemic control of HbA1c level demonstrated no association between user satisfaction and user performance. Other factors of self-reported BG testing frequency, prescribed BG testing frequency, and motivation for diabetes care were not associated with usability outcomes.

Psychological Needs and App Usability Outcomes

Psychological needs were significantly associated with user satisfaction ($P < 0.05$), but they were not associated with user performance. This supports our study hypothesis that patient ratings of psychological needs of competence, autonomy, and healthcare provider connectivity are related to user satisfaction in diabetes apps. Patients who rated competence in diabetes care, perceived satisfaction with diabetes apps. A one-unit increase in diabetes competence score was associated with an increase of the SUS score by 3.1 points ($P < 0.05$). Similarly, patients who reported greater autonomy and interest in learning their personal BG and carb patterns perceived greater user satisfaction with the diabetes apps ($P < 0.01$). A one-unit increase in the autonomy score regarding patient interest to learn personal BG and carb patterns was associated with an increase of the SUS score by 5.9 points ($P < 0.01$). Patients who rated a higher connectivity with healthcare providers expressed higher user satisfaction. A one-unit increase of connectivity score was associated with increased SUS score of 2.5 points ($P < 0.05$). The association between user satisfaction and psychological needs was mediated by task time, success, and accuracy in a small proportion (0.5%–19.7%), which was not statistically significant.

CONCLUSIONS

To our knowledge, this study is the first to report how patient characteristics and psychological needs are related to diabetes app usability. A strength of our approach was the relatively large and diverse study population ($n = 92$) for usability testing, because most mHealth usability evaluations have fewer than 30 participants and limited recruitment sites. Our study population had a mix of residents from urban and suburban counties including African Americans and Native Americans. Our findings indicate that psychological needs and education are important factors in app usability, whereas, patient characteristics are important for user performance or the ability to use an app efficiently, successfully, and accurately.

Diabetes app usability, as assessed by user satisfaction (SUS), was not associated with age, sex, diabetes profiles, technology factors, or motivation. Psychological needs were associated with user satisfaction. Competence in diabetes care was associated with greater user satisfaction. In our study, patients reported a desire to use the app to increase their competence and preferred the convenience of being able to track data on the go. A middle-aged patient noted that "this would work for me since I always have my phone." Apps offering an analysis report make it "easy to see the BG was out of range," according to another patient. These findings are consistent with prior research in which patients report liking educational information and goal setting in apps to help them plan self-management activities (Peng et al., 2016).

Autonomy in diabetes care as assessed by interest in personal patterns correlated with greater usability satisfaction. This finding is consistent with prior research, which found that diabetes app use helped patients set realistic goals and see choices to modify their behaviors (Peng et al., 2016). Patients are also interested in a customized diabetes care plan within an app to help them control diabetes and learn to change their eating habits (Sarkar et al., 2016). According to one 62-year-old patient, a diabetes app can show "the last three months … how food influenced my BG, eating habits, and time frame in the schedule fluctuation."

Addressing patient desire or need for connectivity with a healthcare provider is important for patient engagement in a mHealth intervention. Patients who were well-connected and received autonomous support from their healthcare provider rated higher user satisfaction with diabetes apps. Patients were more motivated to engage in diabetes care and use mHealth tools when they perceived their healthcare providers to be autonomous supportive (Graffigna et al., 2016). Diabetes apps can facilitate data sharing and patient–provider communication. As one 58-year-old patient indicated. "[I do] not rely on my memory to tell my doc how I have been doing, … I can just show her my phone." Clinicians can view data trends and patterns in analysis reports emailed to them or view them on patients' smartphones during clinic visits. Clinicians can pinpoint areas for behavior changes based on real-time data.

Patient characteristics correlated with patients' ability to use an app. There were user performance differences based on patient characteristics. Age, sex, education, and diabetes duration were related to task time, success, and accuracy when controlled for covariates (e.g., education, diabetes types, HbA1c, BG testing, and motivation). A10-year age difference was associated with slower task performance of 0.8 minutes and lower task success by 4.6%. However, when taking into account the covariates, age was not associated with accuracy. This is somewhat surprising as the typical expectation is that younger users are more accurate with technology use. This may be related to the design of this study, which provided as much technical support and time as desired. In contrast to prior studies, women outperformed men in time efficiency and task success. This result held when accounting for other participant factors and might be explained by the greater amount of time that women spend on smartphones and apps than men. For example, one study that tracked 75,000 people using the most popular websites and apps found that women spend more time than men on smartphones (49% vs. 39%) (Burmaster, 2016). Women also use social media apps (e.g., Facebook) more often than men (83% vs. 75%) (Greenwood, Perrin, & Duggan, 2016). We ran a separate full model adjusted for Facebook recruitment and the statistical significance did not change, thus we concluded that Facebook recruitment factor did not affect results. Another important user performance factor was education. Education beyond high school only correlated with user success performance but not user efficiency or accuracy. This potentially means that when participants with high school education or less are provided with technical support, they can learn to use an app as efficiently and accurately as those with more education.

Diabetes duration was significantly related to user accuracy performance. A 10-year diabetes history was associated with a decrease of 8.5% in user accuracy. This might be because of diabetes complications such as peripheral neuropathy and retinopathy. Diabetes peripheral neuropathy rate increases by twofold for those with diabetes for longer than 10 years (Jaiswal et al., 2017). Diabetes retinopathy prevalence at 10 years diabetes duration is 60% (Fong et al., 2004). Finger nerve pain may make it hard and painful to tap correct app icons. Icons and prints in a small smartphone screen would be hard to read for those with vision complications. In this study, the majority of participants had uncontrolled diabetes with elevated mean HbA1c level of 8.2% (66 mmol/mol). A HbA1c level of < 7.5% (58 mmol/mol) for adults older than age 65 years (Care, 2016) and ≤ 7% (53 mmol/mol) for adults under age 65 without a history of hypoglycemia is considered well-controlled diabetes (American Diabetes Association, 2016b). However, glycemic status was not related to app usability, nor was BG monitoring frequency or motivation in diabetes care.

Several limitations for this study give direction for future app research. Two diabetes apps were tested in a single study session. Although results are applicable for a short-term app experience, user satisfaction may be different when patients use diabetes apps long-term in their home environments. Future research should include long-term follow-up, record app adherence rate, and assess factors affecting whether or not long-term app use will be sustained. Different proportion of White versus non-White participants were recruited through sites such as public housing and a community clinic classified as a federal qualified health center. This heterogeneity in race breakdown by recruitment made it challenging to distinguish between race effect and recruitment effect. Therefore, we did not include race/ethnicity as a covariate in the final model.

There may be significant covariates that we did not measure such as socioeconomic status (e.g., income), types of medical insurance, diabetes complications, and obesity status that could have influenced the results. However, our study used multiple recruitment sites through both in-person and online advertisement. We obtained participants with different backgrounds in education level, insulin use types (insulin pump users on private insurance as wells those on public insurance program on injection therapy), and both private and public housing facilities. Covariates such as education and smartphone model included in the analysis may count as proxy for socioeconomic status. We also used a multiple variable model taking into account common patient characteristics in demographics and diabetes history. Our study excluded adolescents living with diabetes as well as family caregivers. Future studies should consider recruiting minority patients, adolescents, and caregivers. We did not include laboratory-based usability measures. The addition of usability tests that include video recording screen reaction, counting keystrokes, and tracking eye movements may further identify usability problems and barriers to diabetes app use.

Our study provides new insights into the theoretical basis of health behavior in diabetes app usability. Application of the Self-Determination Theory in diabetes app design proved to be important for bridging the gap between patient needs and technology experience. Psychological needs of competence, autonomy, and connectivity with a healthcare provider (motivational constructs), were associated with app user satisfaction.

These findings suggest that clinicians should address these psychological needs when recommending the use of a diabetes app. For example, clinicians could address competence by providing education on pattern recognition and teaching patients how to plan lifestyle modifications (e.g., lowering carb intake). Clinicians could customize a care plan and target range for BG to address autonomy need so that patients can set up a parameter in their apps and have the app analyze BG data accordingly. Clinicians could also offer autonomous support and receive home-monitored data via email to promote patient motivation to use app long-term.

App vendors could better support data sharing and data aggregation (e.g. BG analysis reports import into medical record) to make information more accessible to clinicians. The length of diabetes duration greater than 10 years should alert clinicians to screen for diabetes complications that may affect user accuracy. In addition, user-centered apps are desired by patients, regardless of their background. App designs and features should match appropriate user age and ability such as having high school education or less, technology learning, health literacy, and health numeracy. Patient-centered app training and ongoing technical support would improve usability experience for older male users and those with less education and greater diabetes duration. Other app considerations include enabling voice-over commands and wireless data uploads to improve accuracy by eliminating manual data entry.

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Figure 1–Usability model of diabetes app use

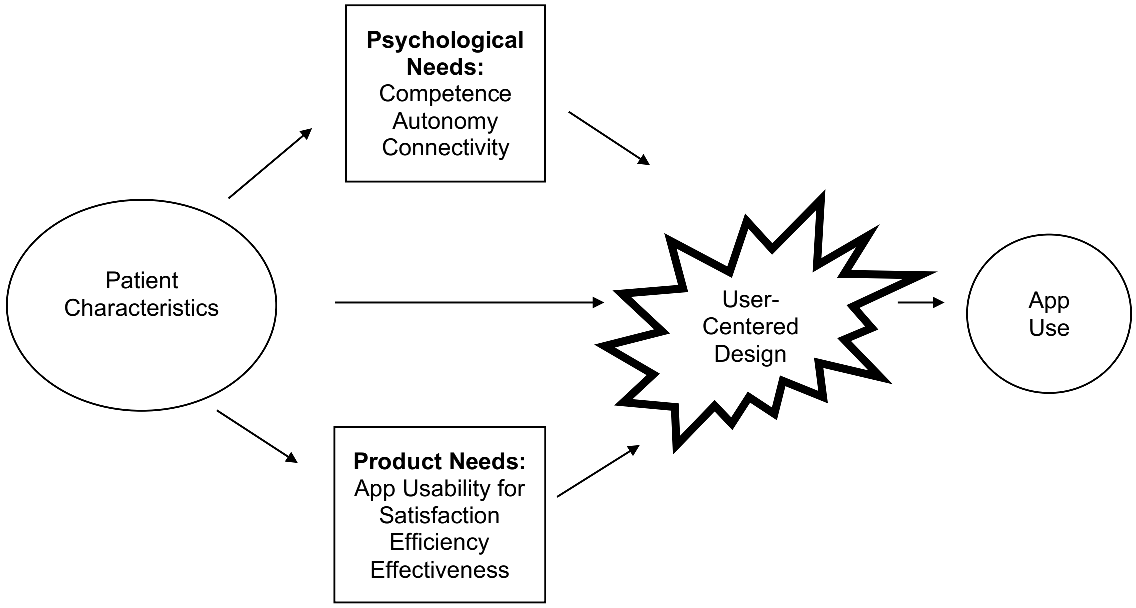

Table 1–Sample characteristics and psychological needs

Characteristics/ psychological needs	(*n* = 92)
Age, years (SD)	54 (13)
Men, *n* (%)	38 (41)
Race, *n* (%)	
White	57 (62)
Black/African American	23 (25)
Native American	10 (11)
Asians	2 (2)
Highest completed education, *n* (%)	
Elementary	4 (4)
High school or equivalent	27 (29)
Community/technical school	31 (34)
Bachelor's degree	19 (21)
Graduate degree	11 (12)
Device brand, *n* (%)	
Samsung	44 (48)
LG	19 (20)
iPhone	8 (9)
ZTE	7 (8)
Motorola	6 (6)
Other	8 (9)
Smartphone comfort level, *n* (%)	
Very uncomfortable	23 (25)
Neither	12 (13)
Comfortable	33 (36)
Very comfortable	24 (26)
Diabetes types, *n* (%)	
Type 1	28 (30)
Type 2	64 (70)
HbA1c % (ranges 5–14)	8.2^{*} (1.5)
Diabetes duration (years)	17 (11)
Insulin duration (years)	12 (12)
Insulin use types, *n* (%)	
Insulin pump	14 (15)
Long- and short-acting injection	46 (50)
Long-acting injection	28 (30)
Short-acting injection	2 (2)
None (stopped use)	2 (2)
BG testing prescribed per day	3.8 (1.8)
BG testing per day	6.2 (1.4)
Daily or less, *n* (%)	19 (21)
2 times a day, *n* (%)	34 (37)
4 times a day, *n* (%)	21 (23)
> 4 times a day, *n* (%)	18 (19)
Overall motivation**	2.16 (1.3)
Intrinsic motivation	5.43 (0.9)
Extrinsic motivation	3.26 (1.2)
Competence	5.38 (1.1)
Autonomy	3.92 (0.6)
Connectivity with healthcare provider	6.05 (1.2)

Data are mean (SD) unless otherwise indicated. Abbreviation: BG, blood glucose and HbA_{1c}, hemoglobin a1c. *66 mmol/mol, **Also known as the self-determination index obtained from intrinsic motivation score minus extrinsic motivation score.

Table 2–Adjusted associations between patient characteristics and app usability

Predictors	Satisfaction (SUS)	Efficiency (min)	Success (%)	Accuracy (%)
Characteristics, effect (*P*)	**Model 1**	**Model 2**	**Model 3**	**Model 4**
Age per 10 years	−0.5 (0.683)	0.8 (0.016) *	−4.6 (0.003) **	−2.5 (0.149)
Men vs. women	0.1 (0.965)	1.7 (0.012) *	−6.9 (0.038) *	−0.1 (0.988)
> HS vs. ≤ HS¶	−6.4 (0.041) *	−1.2 (0.096)	10.5 (0.003) **	0.3 (0.942)
Samsung vs. not Samsung	1.5 (0.603)	−0.8 (0.240)	5.3 (0.112)	7.3 (0.054)
Smartphone comfort	0.6 (0.508)	−0.1 (0.694)	0.6 (0.605)	−0.3 (0.793)
Diabetes type 2 vs. type 1	−5.5 (0.224)	1.6 (0.121)	−4.7 (0.355)	−7.4 (0.199)
Diabetes duration per 10-year	3.6 (0.224)	0.5 (0.483)	−0.1 (0.982)	−8.5 (0.023) *
Insulin duration per 10-year	−1.3 (0.660)	0.6 (0.372)	−3.1 (0.356)	7.1 (0.058)
HbA1c	0.4 (0.674)	−0.2 (0.322)	1.8 (0.071)	0.7 (0.505)
BG testing per day	−0.4 (0.779)	0.2 (0.398)	−1.7 (0.238)	−1.0 (0.671)
BG testing prescribed per day	−0.2 (0.840)	−0.2 (0.445)	0.9 (0.441)	−1.2 (0.456)
Motivation (TRSQ)	−0.4 (0.71)	−0.03 (0.881)	0.7 (0.562)	−0.1 (0.937)
Testing order	−3.9 (0.276)	−1.2 (0.079)	11.2 (0.001) **	3.6 (0.407)
App group	8.4 (0.019) *	−1.3 (0.048) **	9.8 (0.006) **	11.1 (0.010) *
Interaction order and app	8.3 (0.131)	0.9 (0.468)	−11.3 (0.071)	−0.5 (0.942)
Adjusted R^2¶¶	0.14	0.35	0.31	0.17

N = 184 observations from randomized 92 patients. No significant P met the cutoff of 0.0008333 with Bonferroni multiple comparison. ¶Completed highest education greater than high school compared with those who's highest completed education was high school or less, those who did not; $^{*}P < 0.05$; $^{**}P < 0.01$; ¶¶obtained from linear regression model analysis without repeated measures.

Table 3–Adjusted associations between psychological needs and app usability

	Satisfaction (SUS)	Efficiency (min)	Success (%)	Accuracy (%)
Competence	**Model 1A**	**Model 2A**	**Model 3A**	**Model 4A**
Adjusted effect (*P*)	3.1 (0.023) [*]	0.2 (0.616)	−0.1 (0.936)	−2.9 (0.101)
Adjusted $R^{2¶}$	0.16	0.35	0.31	0.18
Autonomy	**Model 1B**	**Model 2B**	**Model 3B**	**Model 4B**
Adjusted effect (*P*)	5.9 (0.006) [**]	−0.8 (0.105)	4.9 (0.049) [*]	1.2 (0.677)
Adjusted $R^{2¶}$	0.17	0.37	0.33	0.17
Connectivity	**Model 1C**	**Model 2C**	**Model 3C**	**Model 4C**
Adjusted effect (*P*)	2.5 (0.029) [*]	0.2 (0.479)	−0.02 (0.862)	−0.01 (0.953)
Adjusted $R^{2¶}$	0.16	0.35	0.31	0.17

N = 184 observations from randomized 92 patients, adjusted all models with 15 covariates listed in model 1 from Table 2, which included: age, sex, education, use of Samsung, smartphone comfort, diabetes types, diabetes duration, insulin duration, hemoglobin a1c, blood glucose testing per day, blood glucose testing prescribed per day, motivation, testing order, app group, and interaction term between order and app. No significant *P* met the cutoff of 0.000781 with Bonferroni multiple comparison. [*]$P < 0.05$; [**]$P < 0.01$; and [¶]obtained from linear regression model analysis without repeated measures.

Supplemental Table 4–Diabetes app usability outcomes

Usability	Overall (*N* = 184)	*mySugr* (*n* = 92)	*OnTrack* (*n* = 92)	*d* [95%CI] (*n* = 92)	*P**
Practice time, minutes					
Mean (SD)	19 (8)	22 (9)	16 (6)	5.6 [4.0, 7.2]	< 0.001
Median (IQR)	17 (9)	20 (8)	14 (8)	5 (7)	
Satisfaction					
Mean (SD)	62 (18)	55 (18)	68 (15)	12.7 [8.2, 17.2]	< 0.001
Median (IQR)	65 (23)	56 (25)	70 (15)	-15 (25)	
Efficiency, minutes					
Mean (SD)	7.0 (3.8)	7.5 (3.8)	6.6 (3.7)	0.8 [0.3, 1.3]	< 0.001
Median (IQR)	6.0 (4.5)	6.4 (4.5)	5.6 (4.0)	0.7 (2.3)	
Success, %					
Mean (SD)	82 (19)	80 (20)	84 (18)	-3.9 [0.3, 7.5]	< 0.05
Median (IQR)	92 (33)	83 (33)	92 (25)	0 (16.7)	
Accuracy, %					
Mean (SD)	68 ± 21	63 (22)	74 ± 20	-11.0 [6.0, 16]	< 0.001
Median (IQR)	67 (33)	67 (33)	67 (17)	-16.6 (33.3)	

N = 184 observations from randomized 92 patients who tested two apps in randomized order *Obtained from paired *t* test comparing two apps, *mySugr* and *OnTrack*.

Chapter 4: Synthesis

The rise in popularity of smartphones creates a wide reach for mobile health intervention. The majority of Americans now own a cellphone (95%) and 77% do use a smartphone (PewResearchCenter, 2018). The health app market boomed with sales projected to reach $31 billion by 2020 (Research2Guidance, 2014). Because of the high percentage of adults aged 65 years who have diabetes (25.2%) (Centers for Disease Control and Prevention, 2017) and a substantial number of older adults aged 65+ (46%) who use smartphones (Anderson & Perrin, 2017), diabetes apps are high priority for app developers (Comstock, 2016). According to the mHealth Economic 2017 study, 68% of mobile health app developers and publishers believe that diabetes continues to be the therapy field with the best market potential for digital health solutions (Nikolova, 2017). Nevertheless, despite the availability of more than 1,100 diabetes apps, their usage is so low that less than 2% of diabetes apps have a significant number of downloads (Research2Guidance, 2014). Diabetes apps also fall off the market so quickly that 60 Android apps became unavailable within 6 months (Blenner et al., 2016).

There is much to be learned about diabetes apps and why they are not being used. This dissertation aimed to understand diabetes app usability and its fit for patient users based on individual characteristics and behavior needs posited by the Self-Determination Theory on motivation. This was accomplished in two phases: (1) a systematic review of diabetes app usability testing and clinical effectiveness, and (2) patient testing of diabetes app usability. Low diabetes app usage may be explained by evidence of suboptimal user satisfaction and major usability problems. Clinical studies with interactive app components demonstrated app clinical efficacy to improve diabetes control. New findings from patient app testing revealed the importance of health behavior theory application in app usability. Patient user satisfaction with diabetes apps is driven by the satisfaction of inherent psychological needs that are important for motivation.

Prior Usability Evidence

Diabetes app research is an interdisciplinary science with a wide range of testing methods and perspective, which makes it an interesting science. It is a new field with limited numbers of published quantitative usability studies and clinical studies specific to diabetes apps. The systematic review on diabetes apps yielded only seven usability studies in a comprehensive search of the literature in computer science, engineering, informatics, medicine, and nursing. We examined findings from heuristic (user-friendly principle) evaluation, satisfaction surveys, and "think aloud" video recording when performing the required tasks of operation, screen interactions tracked by eye movement, tracking user performance, and usability inspection. The systematic review synthesized the evidence of app usability in testing mode as well as clinical setting mode. In testing mode, patients as well as clinical and informatics experts rated low satisfaction with diabetes app usability. In the clinical setting mode, the evidence of diabetes apps to assist self-management and improve glycemic control was limited. Diabetes app effectiveness to lower HgA1c level ranged from 0.15% (a minimal change) to 1.9% (a significant change that is clinically meaningful > 0.5%). Most studies found no statistically significant change in diabetes outcomes. Although four studies did report significant findings, they used an app intervention component that included interactive features for real-time feedback in the forms of: 1) automatic messages from an app algorithm that monitored whether a reading was abnormal; 2) text messages from clinicians; 3) reminder alerts; and 4) app-initiated phone calls in response to a critical need for a clinic visit.

Evidence of diabetes app usability in testing and clinical setting modes suggested the need for health behavior theory applications to guide app development and research toward a user-centered tool that is interactive and enables patients to engage in health behavior change. Testing app usability in randomized trials and having patients evaluate app tasks specific for self-management are important to understand why a patient will or will not use an mHealth tool, such as a diabetes app.

New Evidence: Adult Patients Testing Diabetes App Usability

Given the daily demands of managing their diabetes, adult patients desire an efficient and effective app to promote and reinforce positive health behavior change. Applying health behavior theory in app design to increase diabetes app usability is the first step to better understand the patient's perspective of good usability. This dissertation applied the Self-Determination Theory on human motivation to select app testing functions and to understand patient perspectives on using diabetes apps. This dissertation tested the usability of app functions to record health data as well as those functions meant to target patient competence, autonomy, and connection with a healthcare provider for diabetes care. A total of 92 adults living with diabetes type 1 or 2 participated in a randomized crossover trial to evaluate the usability of two top-rated Android diabetes apps (*mySugr* and *OnTrack)* listed as "The Best Diabetes Apps in 2016" by *Healthline* (health forum). Multivariable linear regression models examined the effects of individual patient characteristics and psychological needs on user satisfaction (primary outcome) and user performance (secondary outcomes: task time, success, and accuracy).

Application of a health behavior theory such as SDT proved to be a link between patients and a mHealth tool. The psychological needs of the patient that are important for motivation and behavioral change were associated with diabetes app usability. Patients have three inherent needs: competence, autonomy, and connectivity with a healthcare provider (relatedness with someone they trust). When patients recognize the personal benefit of using diabetes apps to address their psychological needs, they may be more motivated to use them. Psychological needs were associated with user satisfaction in diabetes apps. Higher user satisfaction was observed for patients who reported competence, autonomy, or connectivity with a healthcare provider. To enhance motivation to use diabetes apps for self-management, clinicians should consider addressing the patient's competence, autonomy, and connectivity.

Patient characteristics of age, sex, education, and diabetes duration were associated with user performance because they affect the patient's ability to use diabetes apps efficiently, successfully, and accurately. On average, for every 10 years of age, adult patients spent 0.8 minutes longer and the task success rate decreased by 4.6%. Our study found women were faster and more successful time than men to use apps, contradictory to prior study that tested one diabetes mHealth system and its app (Georgsson & Staggers, 2016b). A high school education or less and a diabetes duration greater than 10 years correlated with lower task accuracy. Therefore, app training and ongoing technical support should be tailored for older adults, men, and those with less education and diabetes duration more than 10 years.

Limitations of Prior Evidence of Diabetes App Usability

The literature review on diabetes app usability was limited by a number of factors, including app selection, participant recruitment, performance bias, the lack of randomized testing order, and the absence of key technology use and psychological confounders (e.g., adherence rate and motivation to control diabetes). Usability testing with end users such as patients or caregivers mainly used one app product or mHealth system that the research team developed. Their findings may be generalizable to features offered by that particular study app system. There was product selection bias and performance bias related to how participants were selected and the lack of randomized testing order. Two studies pooled patients who were registered or participated in a prior mHealth study (Georgsson, Staggers, & Weir, 2016; Georgsson & Staggers, 2016a, 2016b). Experts that tested multiple apps did not randomize their testing order; therefore, the second app reviewed may have a biased rating from a carryover learning effect and the subsequent app may be rated as a better app (Arnhold et al., 2014; Demidowich, Lu, Tamler, & Bloomgarden, 2012). Half the reviewed clinical studies did not report app use adherence rate. It is unknown whether the app effect was diminished owing to a drop in adherence.

Limitations of Current Study on Diabetes App Usability

This dissertation study tested two diabetes apps in a one-time session. The results are applicable for a short-term experience; user satisfaction may be different for long-term use. This study included different proportions of White versus non-White participants from recruitments sites such as a public housing and a community clinic classified as a federal qualified health center. This heterogeneity in race breakdown by recruitment made it challenging to distinguish between race effect and recruitment effect. There may be significant covariates that were not measured, such as socioeconomic status (e.g., income), types of medical insurance, diabetes complications, and obesity status that could have influenced the results. Another limitation of our study was exclusion of adolescent patients and family caregivers. We also did not include laboratory-based usability measures (e.g., eye tracking movement) to quantify user efforts to perform each required app task. An automatic data upload feature with the potential to improve user accuracy was not included in the study, because during the pilot, the features were not reliable and its supporting Bluetooth device had to be returned to the manufacturer.

Future Directions

Mobile app research is an exciting new field. Several important improvements in study design and app development would advance knowledge in mHealth science. Future studies should apply health behavior theory to guide study design, measure patients' psychological needs, and compare behavior changes in response to app use. Future research should also include long-term follow-up, measure health literacy and numeracy, record overall intervention and app use adherence rates, and assess factors affecting whether or not long-term app use will be sustained. Studies should also consider recruiting minority patients, adolescents, and caregivers. The additional usability evaluation that includes video recording screen reactions, counting keystrokes, and tracking eye movements may further identify usability problems and barriers to diabetes app use. App features of voice-over commands and wireless data uploads should be included to determine whether it improves user accuracy performance by eliminating manual data entry.

Implications

Application of the Self-Determination Theory in diabetes app design helped explain the gaps in patient adoption of diabetes app technology. Psychological needs of competence, autonomy, and connectivity with a healthcare provider were key factors for promoting user satisfaction with diabetes apps. Clinicians should consider patients' wishes for diabetes care competence, autonomy, and connectivity with a healthcare provider when making referrals to a diabetes app. Clinicians could address competence by providing education on pattern recognition and teaching patients how to plan lifestyle modifications. Clinicians could customize a care plan with a BG target range to promote autonomy so patients can program it in a diabetes app. Clinicians could offer autonomous support and review home-monitored data via email to optimize patient motivation to use diabetes apps regularly. The length of diabetes duration greater than 10 years should alert clinicians to assess whether these patients are good candidates to use an app well in the presence of diabetes complications such as neuropathy and retinopathy.

App vendors or companies could offer app interoperability with electronic health record and supporting data aggregation so clinicians can quickly access analysis reports from diabetes app during clinic visits or phone encounters with patients. Furthermore, user-centered apps are desired by patients, regardless of their background. App designers and developers should make apps that fit user age and ability, such as the confidence to learn new technology, health literacy, and health numeracy. Patient-centered app training and ongoing technical support would improve the usability experience for older adults, men, and those with less education and greater diabetes duration. A simple design that makes completing tasks less complicated may be preferred by some patients. Minority populations such as African Americans, Hispanics/Latinos, Native Americans, and Asians may benefit from an app design tailored with culturally appropriate language and educational content messages.

Summary

To our knowledge, this is the first large randomized study to evaluate app usability by patients guided by a health behavior theory. The application of a health behavior theory demonstrated to an important factor that Self-Determination Theory on motivation provided the basis for selecting app tasks as well as the guiding framework to understand patient motivation to use diabetes apps. Diabetes apps have the potential to promote personalized care as part of precision medicine, including addressing the inherent psychological needs for patient motivation in diabetes care. Diabetes care competence, autonomy, and connectivity with a healthcare provider are the foremost considerations for assessing if a patient is ready to use a diabetes app, because user satisfaction is associated with these psychological needs. Patient characteristics of age, sex, education, and diabetes durations are key patient profiles and should be considered in app design, training, and ongoing technical support because they may affect patients' ability to use apps efficiently, successfully, and accurately, initially as well as long term.

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Appendix A: IRB Approval Letter

University of Minnesota

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Phone: 612-626-5654
Fax: 612-626-6061
Email: irb@umn.edu
http://www.research.umn.edu/subjects/

April 12, 2017

Helen N Fu
6113 Baney Ct
Minnetonka, MN 55345-6301

RE: "Patient Factors Influencing Diabetes App Usability"

IRB Code Number: 1703P10161

Dear Ms. Fu:

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form received April 4, 2017.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 150 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

On March 23, 2017, the IRB approved the referenced study through March 22, 2018, inclusive.

The Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur. Notify the IRB when you intend to close this study by submitting the Study Inactivation Request Form.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

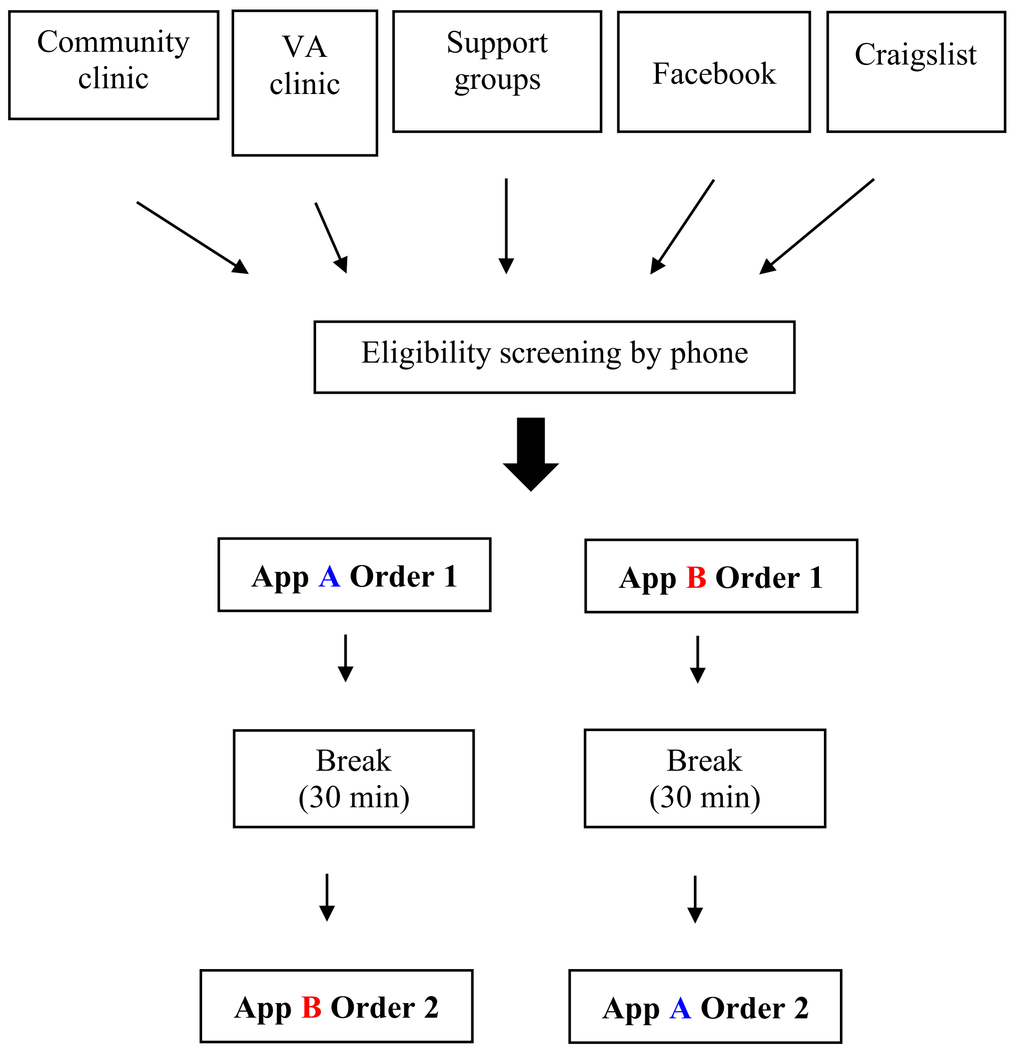
Sincerely,

Jeffery Perkey

Jeffery Perkey, CIP, MLS
IRB Analyst

CC: Jean Wyman

Appendix B: Study Flow Chart



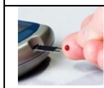
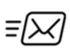
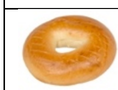
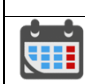
Appendix C: *mySugr* Practice Checklist

Instruction for mySugr
Task #1: Enter what you ate. ☐ apple ☐ 30 gm ☐ BREAKFAST, ☐ 6 AM, ☐ TODAY
Task #2: Enter exercise ☐ Jogging ☐ 30 min, ☐ After lunch ☐ 1 pm, ☐ 2 DAYS AGO
Task #3: Enter medication ☐ Lantus insulin ☐ 10 units ☐ 6 pm ☐ DINNER ☐ YESTERDAY
Task #4: Enter blood sugar reading ☐ 200 mg/dl ☐ BREAKFAST ☐ 7 am ☐ TODAY
Task #5: Read a report on WHICH day of the week (such as MONDAY) the blood sugar readings were not normal.
Task #6: NOT AVAILABLE
Task #7: Email a blood sugar report to sugrTIPS@gmail.com

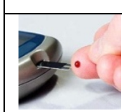
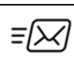
Appendix D: *OnTrack* Practice Checklist

Instruction for OnTrack
Task #1: Enter what you ate. ☐ Apple ☐ 2 carb choices, ☐ BREAKFAST, ☐ 6 AM, ☐ TODAY
Task #2: Enter exercise ☐ Jogging ☐ 30 min, ☐ After lunch, ☐ 1 pm ☐ 2 days ago
Task #3: Enter medication ☐ Lantus insulin ☐ 10 units, ☐ 6 pm, ☐ Dinner ☐ YESTERDAY
Task #4: Enter blood sugar reading ☐ 200 mg/dl ☐ BREAKFAST ☐ 7 am ☐ TODAY
Task #5: NOT AVAILABLE
Task #6: Read a blood sugar report on WHICH MEAL (breakfast, lunch, dinner, or snacks) the blood sugar readings were not normal.
Task #7: Email a blood sugar report to sugrTIPS@gmail.com

Appendix E: *mSugr* Test Checklist

MYSUGR	
	Task #4: Enter blood sugar reading. ☐ **380** mg/dl ☐ DINNER, ☐ 7:30 PM ☐ YESTERDAY ☐ STOP - staff needs to check app
	Task #3 - Enter what diabetes drug you took: ☐ Lantus insulin 12 units ☐ at BEDTIME, ☐ 10:30 PM ☐ YESTERDAY ☐ STOP - staff needs to check app
	Task #7: Email a blood sugar report to sugrTIPS@gmail.com ☐ STOP - staff needs to check app
	Task #1: Enter what you ate. ☐ BREAKFAST ☐ 6:00 AM ☐ TODAY ☐ Pizza ☐ 48 gram ☐ STOP - staff needs to check app
	Task #2: Enter what activity or exercise you did. ☐ 7 AM ☐ TODAY ☐ Before Breakfast ☐ swimming 30 min ☐ STOP - staff needs to check app
	Task #6: NOT AVAILABLE
	Task #5: Read a report on WHICH day of the week (such as MONDAY) the blood sugar readings were not normal. ☐ STOP - staff needs to check app

Appendix F: *OnTrack* Test Checklist

ONTRACK	
	Task #1: Enter what you ate. ☐ Bagel ☐ 3 carb choices ☐ BREAKFAST ☐ 8:00 am ☐ YESTERDAY ☐ STOP - staff needs to check app
	Task #2: Enter what activity or exercise you did. ☐ After LUNCH, ☐ 1 PM ☐ TODAY ☐ Jogging 30 min ☐ STOP - staff needs to check app
	Task #6: Read a blood sugar report on WHICH MEAL (breakfast, lunch, dinner, or snacks) the blood sugar readings were not normal. ☐ STOP - staff needs to check app
	Task #4: Enter blood sugar reading. ☐ **180** mg/dl ☐ DINNER, ☐ 5:30 PM ☐ YESTERDAY ☐ STOP - staff needs to check app
	Task #5: NOT AVAILABLE
	Task #7: Email a blood sugar report to sugrTIPS@gmail.com STOP - staff needs to check app
	Task #3 - Enter what diabetes drug you took: ☐ Lantus insulin 8 units, ☐ BREAKFAST, ☐ 8 AM ☐ TODAY ☐ STOP - staff needs to check app

Appendix G: Trademark and Copyright

In preparation for the implementation of the ideas described in this dissertation, at my request the University has filed an application with the US Patent and Trademark Office to register the trademark "SugrTIPS" (derived from "Self-Determined Glucose Roadmap TIPS") in International class 009, electrical and scientific apparatus (for the device – diabetes app), and International class 044, medical analysis services (for the service). The application serial number is # SN 87225550. The application was filed on an "intent to use" basis, and a Notice of Allowance was issued August 29, 2017. Once the mark is used in commerce, a Statement of Use may be filed and registration will issue. A Statement of Use may not be filed later than the date that is thirty-six (36) months from the date on which the Notice of Allowance was issued.

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