THE ECONOMIC IMPACT OF SMART PHONE APPS IN HOME CARE OF DIABETES

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Abstract

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Millions of people around the world today use the mobile app technology to provide convenience for themselves in their daily routines, such as booking a flight, booking a taxi, or paying a traffic ticket. In 2016, the global mobile internet user penetration expanded to almost half of the World's population with an average time spent assessing online content from a mobile device app exceeding 185minutes a day[1]. The healthcare industry, has not shown any naivety in the adoption of this technology as there are hundreds of mobile apps designed to help patients manage their disease conditions at home, including chronic diseases like Diabetes. It is unclear if these apps provide any cost saving benefit or if the giant tech companies in Silicon Valley are just making a fortune out of this technology.

Purpose: The SPAT-D qualitative study was conducted to learn more about the potential economic role of a smart phone app in the management of Diabetes at home and to explore patient perceived benefit of this technology in terms of treatment compliance and provider communication using both a pre-test survey (before using the app) and a post-test survey (after using the app).

Study Design: Quasi-experimental, mixed qualitative study conducted among patients attending the UW Medical Center Diabetes Clinic and participants recruited online via the active studies section on ITHS website (Institute of Translational Health Sciences). The goal of this qualitative design is to collate participant perspective and experience using the diabetes app technology. Pilot data was also collected to better inform future studies.

Sample size: A total of 15 participants took the pre-test and post-test surveys and where stratified into four groups to elicit a wide range of responses, with each of the first 3 groups assigned to one of 3 different diabetes apps vs the last group not using any app.

Methods: The pre-test and post-test surveys were generated from question categories and themes surrounding the home care of Diabetes and the limitations commonly encountered by patients which lead to poor control of their disease. The survey was administered to patients attending the University of Washington Diabetes Clinic as well as participants recruited via a web ad by soliciting their participation and perceptions of their disease control under the following categories: Knowledge of disease; Home glucose monitoring; Attitude to poor glycemic control; Affordability of treatment; Physician communication and Adaptability to use of technology in disease control. The survey was given to the patients before and after receiving the intervention which included downloading and using one of three diabetes apps; **Diabetes:M app, Diabetes and diet tracker app** and the **Glucose buddy Diabetes tracker app** (found on the google play

store for Android users and I-tunes app store for Apple users) for 3 months duration. These apps were selected based on the differences in their features ranging from the educational content, glucose log sheet, calorie count, exercise log sheet and provider communication. Again, the decision to use three apps for this study was to evoke differential responses to the different features in each app. Qualitative research methods were used to detect common themes from the pre-test survey and used to generate the post-test survey in order to accurately identify the benefit of the intervention.

Results: Pre-app use themes included good knowledge of disease condition and self-organization challenges. Subsequently, the most notable theme at the 3-month follow up was better recall of Hb A1c. Barriers to sharing results with providers emerged, including usability issues.

Conclusions: The positive themes that emerged from this study suggest that Diabetes apps may play a useful role in home management of diabetes. Barriers which emerged might be overcome with technical changes to apps.

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First, I would like to express my sincere gratitude to the Faculty and staff of University of Washington, School of Public Health for giving me the opportunity to pursue this Executive MPH degree in such a prestigious institution, without which I would not be writing a project on Technology and Health. Specifically, I will like to mention the past program coordinator; Angela Cross, who was a major source of motivation to my decision in joining the program. Secondly, I will like to thank my thesis committee members: Dr. Ian Painter and Dr. Ellen Schur for their unparalleled support and guidance throughout the script writing, which led to the successful completion of this work.

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Ellen, thanks for the collaboration and agreeing to serve as my faculty committee member, your professional input did not go un-noticed. Even with your very busy schedule, you still found time to promptly respond to all my emails and directed me to a pool of Diabetic participants for the study.

Next, I will like to say a big thank you to Debra Revere, (UW faculty Qualitative methods) for your contribution to my work. When I approached you to review my proposal from a qualitative standpoint, you never hesitated in providing your professional recommendations as well as giving me good templates to work with.

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Lastly, I would like to thank all my classmates in the E-17 cohort for their inspirational and intellectual write ups on canvas, you have all contributed directly and indirectly to my education in public health and life in general. A Special shout out goes to John, Gib and Ryan, my group members for the BIOSTAT courses; you served as a pillar of support for me during a remarkably busy period of my life when I was combining acute care and trauma calls as a surgery resident with my MPH course work because I did not get my requested academic time off approved.

For me, this may be the beginning of my journey in public health; God willing, I aspire to work for the WHO in the future after clinical retirement. Despite my carrier choice to pursue surgery, I am very passionate to join a global campaign against non-communicable diseases both in my home country Nigeria and all over the world.

DEDICATION

This project is dedicated to anyone living with Diabetes or anyone who has lost a family or friend from complications resulting from Diabetes. The devastating health and economic impact of this disease on human lives is my biggest motivation to carry out this research. To my wife, Frances and my son Nathan, I love you both and want you to know that you are the source of my mental energy.

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Problem Definition

Diabetes is a chronic metabolic disease of glucose utilization characterized by the inability of the body to produce insulin or respond to insulin, resulting in a devastating multi-system consequence when not adequately controlled. Insulin is one of the regulatory hormones of metabolism produced by the pancreas in response to glucose load or foods containing carbohydrate. Therefore, this hormone is expected to be in low amounts during periods of starvation and high amounts after every meal to avoid dangerously elevated glucose levels, a condition called hyperglycemia. The absence or malfunction of insulin in any form leads to the disease condition called Diabetes Mellitus.

Diabetes can be classified into two major types depending on the absolute or relative need for insulin; Type 1 Diabetes (absolute insulin requirement) and Type II Diabetes (relative insulin requirement). While Type 1 variant, also known as Juvenile Diabetes or insulin dependent diabetes is usually caused by genetic factors resulting in autoimmune destruction of the pancreas (site of insulin production), Type II Diabetes or adult onset Diabetes on the other hand is largely a result of poor physical activity and obesity resulting in insulin resistance and relative insulin deficiency. Type II accounts for 90% of all reported Diabetes, while the other forms account for only 10% (WHO Diabetes Fact Sheet)[2]. Other sub-types of diabetes include pregnancy related diabetes also called gestational diabetes and pre-diabetes which is early stage of Type II Diabetes. Whatever the cause is, the common endpoint is the body's inability to process glucose properly.

Diabetes is a very serious disease condition that can be life threatening if left under poor control. Simple lifestyle modifications, such as eating healthy foods, regular exercise and compliance to

medication have shown to be very effective in the prevention and control of the disease. In the absence of adequate control, diabetes can lead to increased risk of vision loss, heart disease, stroke, kidney failure, nerve damage, amputation of toes, feet, or legs and even premature death; all of which have financial implications. Many families have been left devastated by some of these complications and are financially indebted because of hospital bills, cost of medications, and time off work.

Medical treatment of Diabetes is centered around exogenous insulin replacement or use of medications that stimulate the pancreas to produce endogenous insulin. For Type II Diabetics, a big part of their management is lifestyle modification which includes diet control and increased physical activity. This goal of this later method is to promote weight loss and reduce excess fat which in turn reduces insulin resistance and enhances disease control.

Health education has been shown to play a vital role in the home care of Diabetes because the disease requires a lot of participation and skill by the patients to care for themselves; an important factor that usually results in improved quality of life[3]. In multiple studies, Diabetes Self-Management Education (DSME) has also demonstrated an overall improvement in the biometrics of the diabetic patient across most clinical markers such as HbA1c, glucose levels, BMI (body mass index) and lipids. Lavelle et al concluded with other researchers on DSME that in-home educational programs can improve the self-management of diabetes and lead to improvement in health indicators[4].

The use of smart phone apps as an organizational tool for its educational content and compliance strategies in the management of Diabetes should be one of interest in this digital age where access to internet is rapidly increasing.

Understanding Diabetes as a public health burden

Over the past few decades, the prevalence of Diabetes in the United States has been increasing steadily at an alarming rate primarily due to unhealthy lifestyle choices among Americans[5]. It now constitutes not only a major public health problem, but also a substantial financial burden on the affected individuals, health plans and the government in terms of healthcare spending.

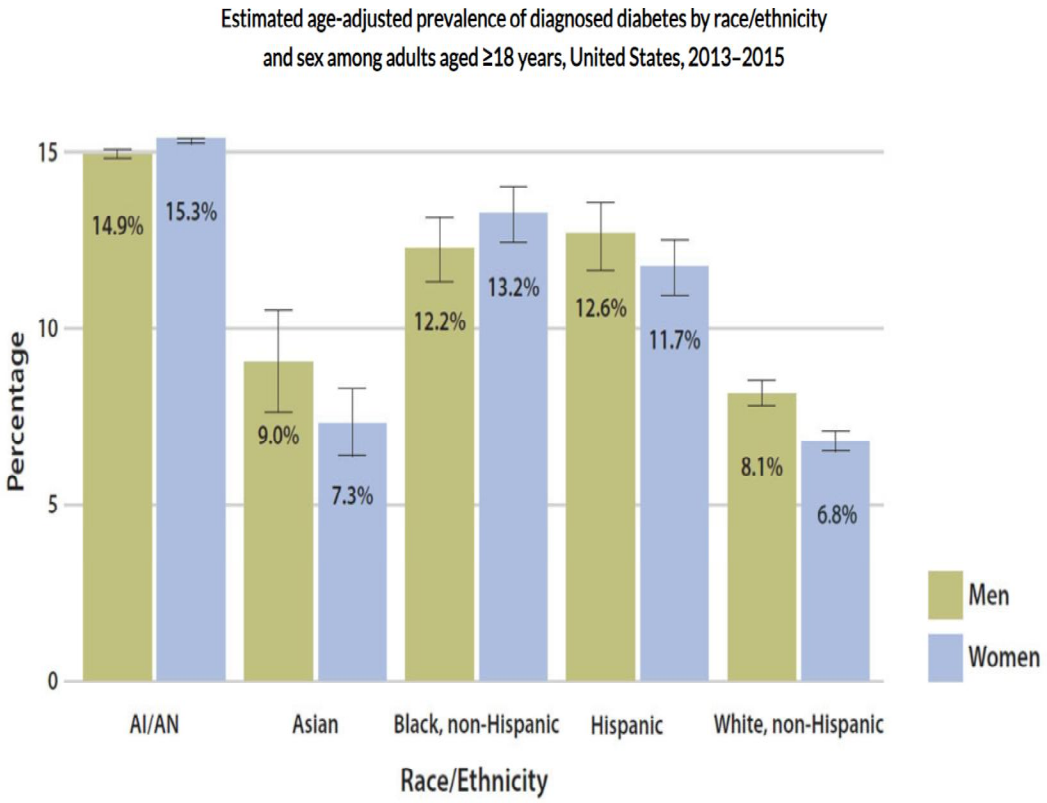
According to the CDC's (Centers for Disease Control) most recent *National Diabetes Statistics Report for 2017*[5], more than 100 million U.S. adults are now living with diabetes or prediabetes. As of 2015, 30.3 million Americans – 9.4 percent of the U.S. population were confirmed to have diabetes while another 84.1 million had prediabetes, a condition which if not treated often leads to type 2 diabetes within five years. The report confirms that the rate of new diabetes diagnoses remains steady and continues to be the seventh leading cause of death in the U.S[5]. The report also confirmed that county-level data shows that some areas of the country bear a heavier diabetes burden than others based on lifestyle choices, – counties in the Southern and Appalachian regions of the United States tended to have the highest prevalence of diagnosed diabetes.

Summary of key findings from the National Diabetes Statistics Report[5]

- There are 30.3 million people of all ages living with Diabetes (9.4% of the U.S population)
- An estimated 23.1 million people have been diagnosed (including 132,000 children and adolescents younger than age 18 years) while 7.2 million people are undiagnosed (23.8% of Diabetes population, i.e. 1 in 4 people are unaware they have it)

- In 2015, an estimated 1.5 million new cases of diabetes were diagnosed among people ages 18 and older, more than half of these new cases were among adults aged 45 to 64 years, and the numbers were about equal for men and women
- Rates of diagnosed diabetes increased with age. Among adults ages 18-44, 4% had diabetes, among those aged 45-64 years, 17% had diabetes while among those aged 65 years and older, 25% had diabetes.
- Rates of diagnosed diabetes were higher among American Indians/Alaska Natives (15.1%), non-Hispanic blacks (12.7%), and Hispanics (12.1%), compared to Asians (8.0%) and non-Hispanic whites (7.4%). See Fig 1.

- Lower level of education is a risk factor; among U.S. adults with less than a high school diploma, 12.6 percent had diabetes, those with at least a high school education accounted for 9.5% of diabetics; while among those with more than a high school education, 7.2% had diabetes.
- Diabetes remains the 7th leading cause of death in the United States in 2015, with 79,535 death certificates listing it as the underlying cause of death, and a total of 252,806 death certificates listing diabetes as an underlying or contributing cause of death



AI/AN = American Indian/ Alaska Native. Note: Error bars represent upper and lower bounds of the 95% confidence interval.

Fig 1: Data source: 2013–2015 National Health Interview Survey, except American Indian/Alaska Native data, which are from the 2015 Indian Health Service National Data Warehouse.

Understanding the economic burden of Diabetes

Diabetes constitutes a significant financial burden on the U.S health care system through a combination of direct and indirect costs and it features prominently as a major part of healthcare spending every year. This economic burden goes beyond the cost of tangible expenses such as medication and hospitalization to include non-tangible factors such as pain and suffering from

daily needle sticks, time off work, disability adjusted life years, and cost of non-paid family care givers. The American Diabetes Association (ADA) released new research on March 22, 2018 estimating that the total cost of diagnosed diabetes had risen to $327 billion in 2017 from $245 billion in 2012, when the cost was last examined[6] (See Fig 2). This represents almost a 26% increase over a 5-year period due to increasing obesity and poor lifestyle choices. There is no indication of this pace to slow down as the diagnosis of diabetes continues to exceed 700,000 new cases annually[7]. Approximately $237 billion of the current spending is used to cover direct medical cost, while about $90 billion accounts for reduced productivity. A breakdown of this robust spending shows that about one third the amount (approximately 30%) goes into inpatient care and hospitalization costs, another 30% goes into prescription medications and treating complications while the remaining spending is used to cover diabetic supplies and out-patient provider visits[8].

On an individual basis, the estimated healthcare spending per person living with Diabetes is about at $16,752 per year, of which about $9,601 is attributed to diabetes alone[5] (See Fig 3). In terms of the cost categories analyzed in the ADA 2017 report, care for people with diagnosed diabetes accounts for 1 in 4 health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes. A breakdown of the indirect costs of diabetes every year shows that about $3.3 billion dollars is lost due to absenteeism, $26.9 billion dollars is lost to reduced productivity while at work for the employed diabetics and about $37.5 billion is spent on diabetics with disease related disability. Pre-diabetes cost about $443 annually per person (medical costs only); undiagnosed diabetes, $2,864; type 2 diabetes, $9,677; and type 1 diabetes, $14,856. Gestational diabetes cost per case averaged $3,514 ($3,305 in higher pregnancy cost and $209 in higher cost during the newborn's first year of life)[8].

The reports from the ADA indicates that 67.3% is provided by government insurance (including Medicare, Medicaid, and the military) while the rest is paid for by private insurance (30.7%) or by the uninsured (2%)[6].

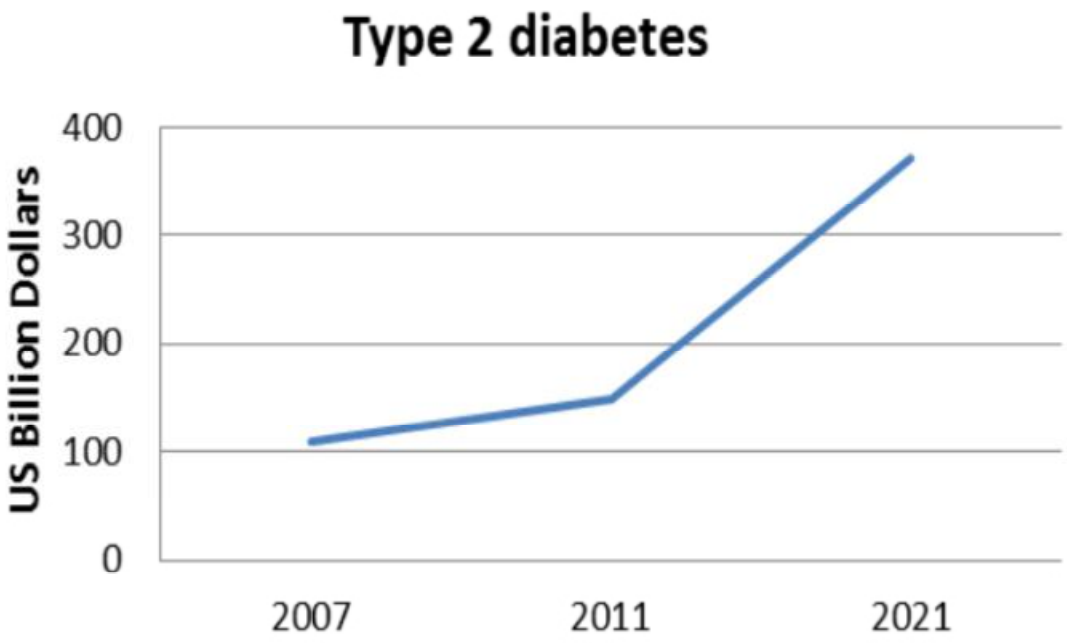


Fig 2: Annual spending on Diabetes in billions of dollars per year - Data source: Vojta D, De Sa J, Prospect T, Stevens S. Effective interventions for stemming the growing crisis of diabetes and prediabetes: a national payer's perspective. Health Affairs (Project Hope). 2012;31(1):20-26

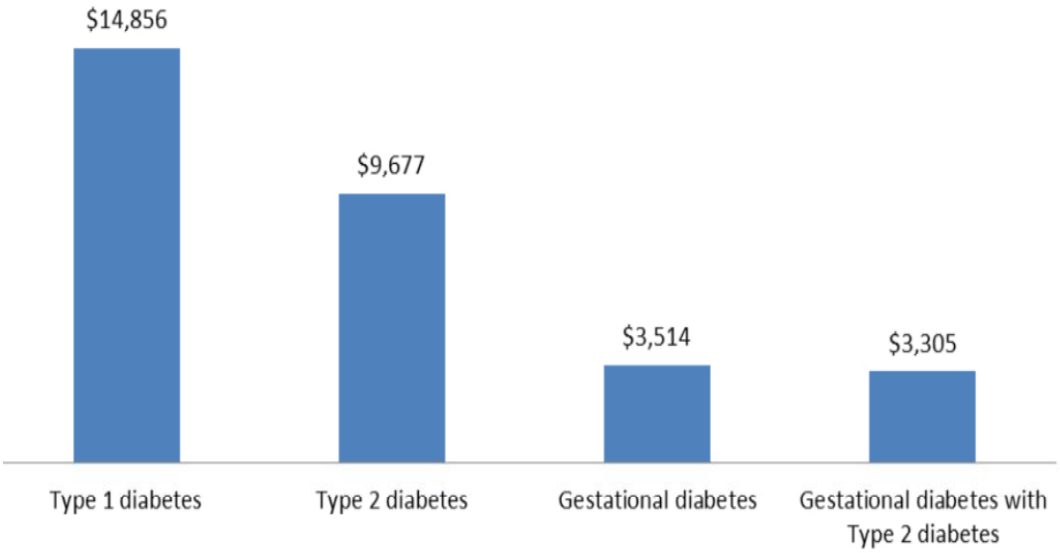


Fig 3: Average cost of Diabetes per patient per year - Data source: Dall TM, Zhang Y, Chen YJ, Quick WW, Yang WG, Fogli J. The economic burden of diabetes. Health Affairs (Project Hope). 2010;29(2):297-303

Insurance coverage also plays a big role in the direction of Diabetes economics. For example, people with diabetes who do not have health insurance have 60% fewer physician office visits and are prescribed 52% fewer medications than people with insurance coverage—but they also have 168% more emergency department visits than people who have insurance[6], contributing significantly to the inpatient cost. The total per-capita health expenditures of Diabetes are higher among men than women ($10,060 vs. $9,110), lower among Hispanics ($8,050), higher among non-Hispanic blacks ($10,470) and among non-Hispanic whites ($9,800)[6]. In terms of ethnicity, compared to non-Hispanic whites, per capita hospital inpatient costs are 23% higher among non-Hispanic blacks and 29% lower among Hispanics. Non-Hispanic blacks also have 65% more emergency department visits than the population with diabetes[6].

Regardless of being diagnosed with diabetes or your diabetes control status, experts believe that every American contributes an indirect approximate cost of $700 annually to the financial burden of Diabetes[9]. This unfortunate fact emphasizes the importance of patient education and home care of their diabetes which has the potential of better disease control, lower complication rates and lower cost.

Smart phone Technology as a tool for home care of Diabetes

A smart phone is a phone that performs many of the functions of a computer, typically having a touchscreen interface, internet access, and an operating system capable of running downloaded applications. A mobile application (*abbreviation: app*) is a software program designed and programmed to run on a mobile device, such as a smartphone or tablet computer, frequently serving the user with similar services to those accessed on PCs. Apps are generally small, individual software units with limited function and are represented as small squares on our mobile home screens. Use of the app software was originally popularized by Apple Inc. and its App Store, which offers thousands of applications for the iPhone, iPad and iPod Touch. Today, many other mobile phone companies like Samsung and LG (which use Android operating systems) have included this software into their smart phones and the use of apps is now universal[10].

The functions of this phone technology has been utilized in many industries including transportation, gaming, ticketing, bill pay and healthcare. There are numerous healthcare apps available in the app store that focus on chronic disease conditions like diabetes. Most app developers customize their apps with unique features that meets the need of their users and this was apparent when we reviewed numerous Diabetes apps from the google play store and Apple-I tunes store. While some of these Diabetes apps are focused on nutritional content and promoting

healthy diets, others are focused on improved physical activity, physician communication and graphical representation of glucose trends. Despite these varying functionalities of each app, they all contain a glucose logbook with the ability to record daily glucose levels and Hb A1c value.

Currently, there are few studies in the literature that have examined the benefits of the app technology in the home care of Diabetes. This has resulted in divergent views and lack of substantial evidence on what constitutes the minimum standards for inclusion in the development of such apps that will maximize disease control and overall cost reduction. While some researchers have reported success with evaluation of these apps, others have issued out warnings to users about the safety of medication dosing errors. Huckvale et al – 2015[16], conducted a systematic review to determine the accuracy of all English language insulin dose calculator apps available on iOs and Android phones, and concluded that the majority of insulin dose calculator apps provide no protection against, and may actively contribute to, incorrect or inappropriate dose recommendations that put current users at risk of both catastrophic overdose and more subtle harms resulting from suboptimal glucose control.

Mcmillian et al – 2017[17], conducted a systematic review of mobile based technology to promote active lifestyles in people with Type II Diabetes (T2D) and concluded that limited research has examined the feasibility, acceptability, and effectiveness of mobile-based technology to promote active lifestyles and subsequently good diabetes management in people with T2D. Similarly, Cui – 2016[18] carried out a systematic review and meta-analysis to identify relevant studies of the benefit of smart phone apps in self-management of Diabetes using random effects model to estimate pooled results. They concluded that Smartphone apps offered moderate benefits for T2DM self-management. However, more research with valid study designs and longer follow-up is needed to evaluate the impact of health apps for diabetes care and self-management.

There is some preliminary data from a recently concluded 3-arm RCT on mobile phone support for diabetes care among diverse adults, that was carried out at the center for health behavior and health education department of medicine, Vanderbilt University Medical Center by a team of researchers. According to Lindsay S Mayberry et al[11], the aim of the study was to evaluate the effects of mobile phone–based diabetes support interventions on hemoglobin A1c (HbA1c) among adults with Type II Diabetes (T2D). In their initial report, the authors did not mention analysis of cost savings of their intervention but attested to the fact that their study will be one of the first to evaluate a long-term theory-based text messaging intervention to promote self-care adherence among racially/ethnically and socioeconomically diverse adults with T2D.

RESEARCH DESIGN AND METHODS:

The SPAT-D qualitative study was conducted to explore patient perception and experience using a smart phone app technology in enhancing home care of their diabetes as well as to understand barriers and facilitators of any cost saving benefit of this intervention. The research assumes that lifestyle modification enhanced by a mobile app will lead to better disease control, which leads to fewer complications, fewer medication requirements, fewer ER visits or hospital admissions and fewer loss of work productivity which in turn leads to overall cost savings. The SPAT-D study was approved by the University of Washington Human Subjects Division (HSD) as IRB exempt, with ID number; STUDY 00006065.

We recruited a sample of fifteen participants from a pool of interested people in variable locations across the country using descriptive flyers and public web ads. These participants all came in either through the University of Washington Institute of Diabetes where flyers were left with contact

information, or through an online ad that was posted on the ITHS website (Institute of Translational Health Sciences)[15]. Participants were provided a detailed explanation of the study in writing and asked to sign an electronic consent form before enrollment. The eligibility criteria used for this study is as follow; having diabetes that is treated with medications but inadequately controlled, defined as Hemoglobin A1c (HbA1c) >8 (American College of Physician Guidelines)[12], owning a smart phone, never used a diabetes app, owning a glucometer at home, fluent in English, age >18yrs and minimum of high school diploma. Of the 32 people who expressed interest in the study, we randomly selected 15 of them who met criteria and there was no drop out throughout the study.

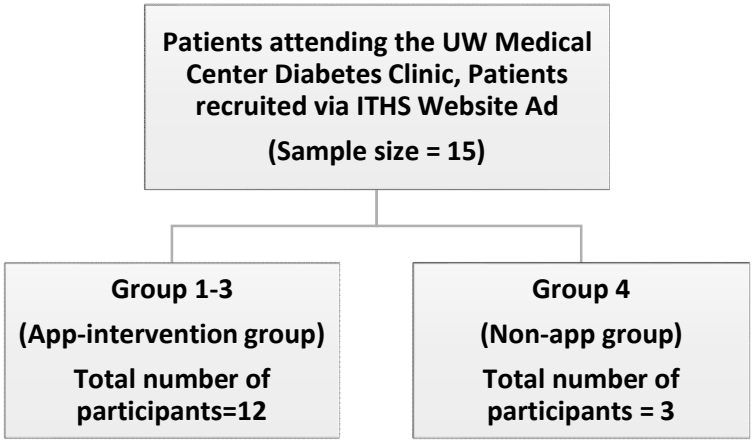
In order to capture a variety of experiences that different Diabetes apps may provide, participants were randomized into one of four groups; participants in the first three groups were asked to install one of three Diabetes apps on their smart phones, while participants in the fourth group did not use a diabetes app. Selection of groups was done by study investigators using a random number generator. 15 participants were thus placed into these 4 groups and asked to complete a 19-question pre-app use survey and a 16-question post-app survey 12 weeks after the pre-app use survey.

The four groups consisted of 1) Group 1: Consisting of 4 people using the **Diabetes: M app** which includes a medication log book, insulin calculator, a food tray and log book as well as graphs to monitor trends and a clinician access code to review progress 2) Group 2: Consisting of 4 people using the **Glucose buddy Diabetes tracker app** which includes glucose log entry, A1c and calorie monitoring but excludes the physical activity log book. It also allows the user to communicate with their clinician by simply emailing the log records. 3) Group 3: Consisting of 4 people using the **Diabetes and diet tracker app** which includes all the features in the Diabetes:M app, but in addition has other features like blood pressure monitoring and target BMI, smart food search with a bar code scanner (which allows the user choose healthy foods in the grocery store) and daily

highlights of progress. 4) Group 4: Consisting of 3 people who were not assigned to any app but took the pre-app use test and post-app use test surveys.

SURVEY:

We developed electronic surveys consisting of 19 questions for the pre-app use survey (Table 5) and 16 questions for the post-app use survey (Table 6), then administered them to the participants via survey monkey (an online survey website) before and after the app-intervention. Once a participant was deemed eligible to participate by meeting all the inclusion criteria posted online, we sent them an electronic consent form followed by the pre-test survey link. The 19 questions in the pre-test survey were based on 7 key categories that we attributed to be causes of poor disease control at home: *Knowledge about disease condition; Attitude towards disease control; Barriers to disease control; Current home care of disease; Provider communication; Cost perception and Perception of using a diabetes app*. We generated at least 1-4 questions from each category to evoke common themes about the topic area.



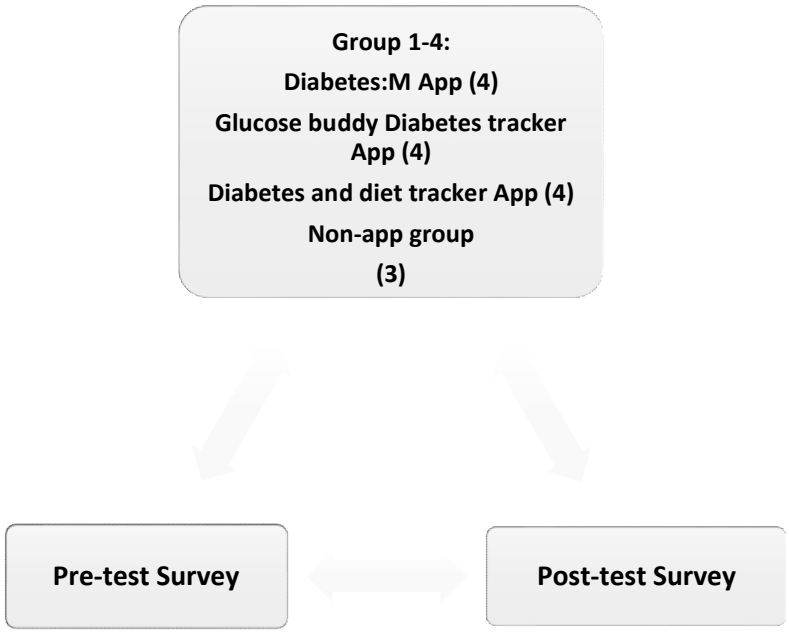


Fig 4: Conceptual diagram of participant selection with control and intervention arms

Questions were a mix of polar questions and open-ended prompts. The respondents who were placed in groups 1 to 3 were asked to complete the pre-app use survey within 72 hours of receipt. After completing the survey, they were instructed to download and start using the app they were assigned to. The non-app group (Group 4), were asked to complete the survey at their leisure but submit it before the end of the study, at which time they also completed a post-test survey.

After completing the pre-test survey, participants in the app-intervention group were emailed a detailed instruction on how to download and use the respective apps. The researcher was blinded to the demographic and disease control status of the respondents before group assignment, while the respondents were not told of the existence of features that were part of the apps other than the app they were assigned to. We provided vouchers to cover any paid downloads and in-app function required to meet intervention goals (the Diabetes and Diet tracker charges $9.99 for purchase from app store) and recommended they start using the app immediately according to their routine home care.

For example, if their primary care doctor told them to check their blood glucose levels three times a week, they were only expected to log in their numbers on the app three times weekly. Every two weeks, a generic message was sent out to ensure they were still using the app and not experiencing any technical difficulty. This message also included instructions on what to do and how to use each app. After 12 weeks (3 months) of intervention using the app, the participants completed a post-test survey which included a repetition of some of the pre-test questions in addition to 5 new categories; "*Disease control"; "Medication compliance"; "Reported complications"; "Exercise and Dietary improvement"; "App experience"*.

To assess disease control from a cost saving perspective, we used 4 questions in the post-test survey: 1.) Have you been prescribed a new medication in the last 3 months? 2.) Have you been admitted to the hospital or have you visited the ER in the last 3 months because of poor control of your Diabetes? 3.) Has your Doctor discussed any new complication from your Diabetes with you? 4.) Can you recall your most recent Hb A1c? (some of these questions were repeated from the pre-test survey).

The assumption behind these question categories is that lifestyle modification, using the app as an intervention improves disease control which in turn reduces disease complication and overall cost. Therefore, a diabetic patient with better attitude to their disease control is more likely to have improved medication compliance, knowledge on all their numbers, including weight, BMI, highs and lows on glucose readings and will know their Hb A1c trend. This results in better disease control, less complications and less use of health care resources including PCP visits and Emergency Room visits, all of which drive cost in a downward direction.

For the new prescription category, we framed one question in the post-test survey to evoke a polar response yes or no; "*Have you been prescribed any new medication for your Diabetes control including insulin or non-insulin injectables within the last 3 months*?".

We attempted to determine for any new disease complication within the 3-month period by providing a list of diabetes complications and asking them to check one or more boxes. The complications we provided in this question included: Retinopathy (eye damage), Neuropathy (Nerve damage), Nephropathy (kidney damage), Erectile dysfunction, Vasculopathy (blood vessel damage), Limb or Toe amputation, DKA (Diabetic Keto-acidosis), Hyperglycemic event, Hypoglycemic event (Mental status change from low blood sugar), and others (Specify). Our decision to use appropriate medical terminologies was because we had established in the pre-test survey that all participants being studied had superior knowledge of Diabetes.

Lastly, we reviewed the question category that contain the discourse on provider communication via the app and asked participants a set of questions on the pre-test survey including; Are you confident in interpreting your numbers without your doctor's help? This question also reflects knowledge of disease discussed above and all respondents answered "yes". We followed up on this response to generate post intervention questions including 1.) What do you do when your blood sugar numbers are persistently high; 2.) Have you been able to email your logbook to your provider?

ANALYSIS:

To determine participant perceptions within the 7 pre-defined categories, we used a manual inductive method to identify commonalities in the data and organized them into relevant themes using responses from the open-ended questions. These responses were then used to generate

themes that were reviewed independently by the two investigators to ensure interrater reliability. The polar questions requiring “yes” or “no” answers were reported in a standard bar chart format comparing the proportion of answers.

Pre-determined themes were used to examine “the economic impact of a smart phone app in the home care of diabetes”. These themes were: New prescription medication, Hospital admission, ER visits, Disease complication (e.g. Neuropathy, Retinopathy, Nephropathy, Vasculopathy, Disability status related to Diabetes, Surgical procedures or other reported disease complication) and Hb A1c recall ability. Coding of participant responses into these themes was done on the basis of the pre-app use survey.

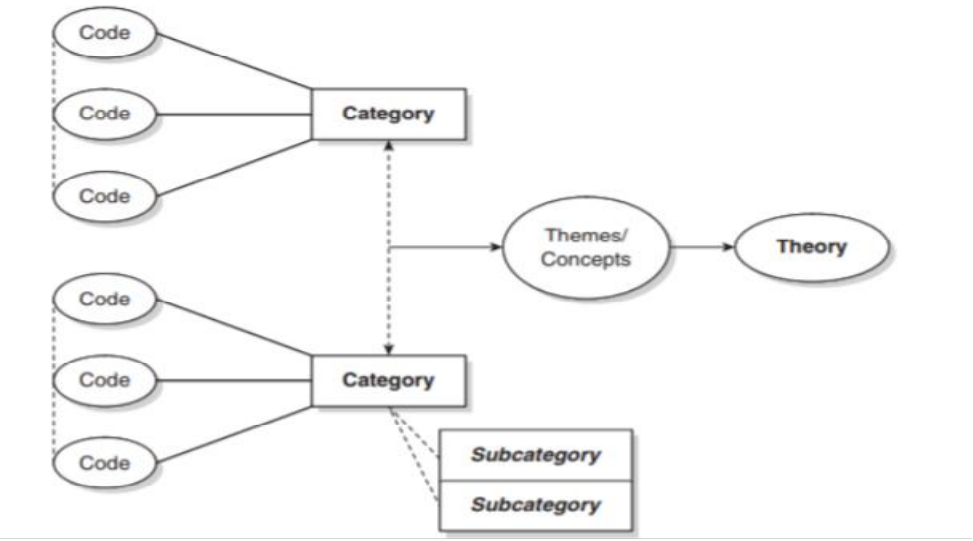


Fig 5: Conceptual diagram of inductive coding method used for analysis

Theme identification: Using the lean coding method described above, data was reduced to shorthand labels by hand and common themes per category was identified. After establishing the baseline themes from the pre-test survey, we used it as a guide to create the categories of interest

in the post-test survey to determine any differences between the app-intervention group and the non-app group.

RESULTS:

Numerous themes common to the pre-test and post-test survey data was observed. The 12 participants that were followed in the app-intervention group all completed the 3-month period of using one of the three different apps, while the other 3 participants in the non-app group submitted their surveys at varying times before the end of the study. Majority of the respondents were over the age of 35 with an approximately equal distribution ratio of male to female gender. The predominant race of the survey takers were white, and the most frequent educational level was 2 years of college. Results are present below by pre-determined category:

Knowledge about disease condition:

The discourse on the knowledge about disease condition had common themes that suggested a good understanding of Diabetes. In this category, we graded responses by scoring 1 – 3 based on depth of knowledge. For poor knowledge, score 0; for fair knowledge, score 1; for good knowledge, score 2; and for very good knowledge; score 3. All participants demonstrated a background knowledge of their disease condition with a mean score over 2. Examples of participant responses under this category are shown in Table 1.

Attitude to disease, Current home care of disease and *Barriers to disease control:*

A varying degree of positive attitude towards their disease control was observed. All respondents reported having a glucometer at home (a device that allows patients to test their blood sugar at home by themselves) and used it regularly. Poor organizational skills ranging from forgetfulness to compliance issues such as compliance to daily medication, healthy diets and exercise regimen was a commonly observed barrier to their disease control.

Question Category	Participant Responses:	Common Theme
Knowledge about Disease condition	*" My Diabetes is better than previously controlled but not optimal. I've been hospitalized twice with DKA and have had a seizure due to hypoglycemia as well as many other serious hypoglycemic events"* *Score: 3* *"My insulin doesn't seem to be working, this makes me believe I may have insulin resistance Diabetes"* *Score: 2* *"My Diabetes is complicated; I have neuropathy and retinopathy"* *Score: 3*	Very Good Knowledge
Attitude to home care of disease	*"I do whatever my doctor tells me to do, not really interested in doctoring myself at home"* *"I am frustrated with the way things are going, my sugar is not coming down, so I don't bother checking it daily again"* *"I don't take any action when my blood sugar is high"* *"I often forget to take my medications"* *"Irregular eating habits due to diagnosed anorexia nervosa and social/generalized anxiety disorder"* *"I don't exercise often"*	Poor Organizational Skills

Table 1: Examples of responses to knowledge and attitude to disease control at home across all dataset in the pre-test survey

When we reviewed the post-test surveys after the intervention, we noticed a few changes in these responses, especially in the attitude category. Most of the respondents acknowledged better compliance to their medications and endorsed better disease control. These two question categories (*attitude to home care and barriers to disease control*) created similar themes across all app groups without any obvious difference. For example, we asked the question; Have you forgotten to take your medication at least 3 or more times during these past 3 months? There was not one participant from the intervention group that answered yes, however some respondents stated they had missed their meds on one or two occasions for varying reasons including being out of town or running out of supply (See Table 2).

The attitude of the participants to home care of their disease varied from unchanged to better after receiving the intervention. This may be explained by the selective use of some of the app features over the others or the absence of a desired feature that has the potential to alter participants behavior.

Question Category	**Participant Responses:**	**Common Themes**
Attitude to home care of Disease	*"I felt the app made me more organized with my medications"* *"I had better memory of my highs and lows, and this influenced the timing of my dinner"* *"My weight dropped by 5lbs, not sure if I became more disciplined with my calorie intake, it be better if this thing had a step count"* *"I have witnessed no change in my physical activity using the app, but I am still self-motivated to join a gym"* *"The food scanner helped me choose lower calorie foods when shopping, but can expand scannable food items to get full benefit"*	▪ App Provides better Organizational skills ▪ App provided Improved Motivation

Table 2: Examples of responses to attitude to disease control at home across all dataset in the post-test survey

Provider communication; Cost perception and Perception of using a diabetes app:

Within the category of *"Provider communication"*, the Diabetes:M app had the easiest ability to export participant glucose logbook (as rated by the researcher) and allow physician recommendation; this was done by providing participants with a physician code to give their doctors (who must also download the app). However, none of the 4 study participants in this group reported success in using this feature. The participants in the other app groups generally expressed frustration in trying to operate the data export feature.

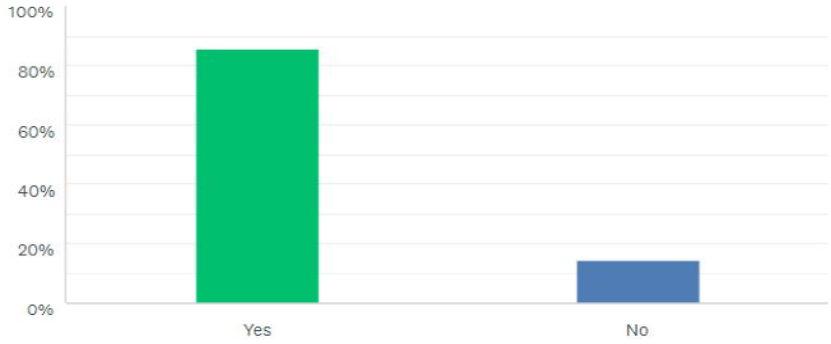
App	Physician communication feature	Participant perception and app experience	Common Theme
Diabetes: M	Yes	*"Loved this app, discussed it with my doctor and he is willing to use it with me to monitor my progress but yet to do so"* *"I have not been able to share my results with my doctor, but I plan on doing so, it seemed easy to operate"*	App is User friendly

Glucose Buddy Diabetes tracker	No	*"No food scanner, I heard this is a good feature, had troubles manually entering my calorie intake"* *"I was unable to login my glucose level on some occasion because the app crashed"* *"I was unable to communicate with my doctor with the app, will be good if I could"*	App has Limited features or difficult to operate
Diabetes and Diet Tracker	No	*"Good weight app, I wish my doctor could see my progress"* *"Helps tracks your carbs and calories really good"*	App provides good weight loss strategies

Table 3: Examples of participant responses to each app in the post-test survey

Within the category of *"Cost perception and Experience using a diabetes App"*, we were able to elicit common themes in the pre-test survey that suggest Diabetes is an expensive disease to live with, while in the post-test survey, participants expressed appreciation of the app technology. Overall, they had a positive experience, stating that a smart phone app is a useful tool to managing their diabetes at home.

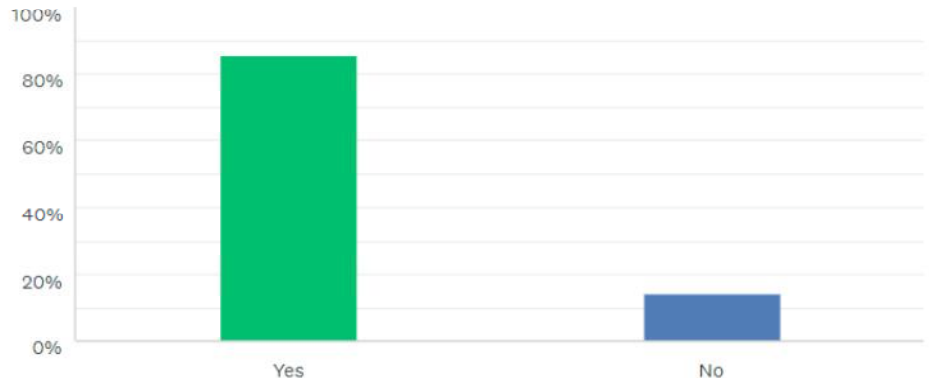
Response to the question "Do you believe Diabetes is an expensive disease to live with"?



ANSWER CHOICES	RESPONSES
Yes	85.71%
No	14.29%

Fig 6: Cost perception of Diabetes (Pre-test survey)

Response to the question "Do you believe a smart phone app that includes features for recording your blood sugar, your Hemoglobin A1c, your calorie count, exercise level as well as provide a reporting system to your Primary Care Doctor will improve your Diabetes control"?



ANSWER CHOICES	RESPONSES
Yes	85.71%
No	14.29%

Fig 7: Patient response to app intervention in Home care of Diabetes (Post-test survey)

Study Participants (15)	Gender (m=8) (f=7)	Education	HbA1c Recall (Pre-test)	HbA1c Recall (Post-test)	Prescribed new medication	Hospital Admission	ER visit	New Complication
1 *	F	HS	No	No	No	No	No	No
2 *	M	BD	No	No	Yes	No	No	No
3 *	M	AD	Yes	Yes	No	No	No	No
4 ∞ μ	M	AD	Yes	Yes	Yes	No	No	Not sure
5 ∞ μ	F	AD	No	Yes	No	No	Yes	No
6 ∞ μ	F	AD	No	Yes	No	No	No	No
7 ∞ μ	M	AD	Yes	Yes	No	No	No	No
8 ∞ β	F	HS	No	Yes	Yes	No	No	Not sure
9 ∞ β	M	BD	No	Yes	Yes	No	No	No
10 ∞ β	F	HS	No	Yes	No	No	No	No
11 ∞ β	F	GD	No	Yes	No	No	No	No
12 ∞ α	F	HS	Yes	Yes	No	No	No	No
13 ∞ α	M	AD	No	Yes	No	No	No	No
14 ∞ α	M	AD	No	Yes	No	No	No	No
15 ∞ α	M	BD	Yes	Yes	No	No	No	No

Table 4: Participant response to disease control

Key:

*: Group 4 (non-app group)

∞: Group 1-3 (app group)

μ: Diabetes: M app

β: Glucose buddy tracker app

HS: High School

AD: Associate Degree

BD: Bachelor's Degree

GD: Graduate degree

α: Diabetes and Diet tracker app

DISCUSSION:

The results demonstrated varied survey responses, but with common themes that suggest a modest benefit of the intervention. The depth of knowledge about self-care of Diabetes was a common theme across all participants, suggesting that, at least in potential users of Diabetes apps, lack of knowledge is not a limiting factor for home care of Diabetes. The depth of insight demonstrated by the respondents was not surprising, as the selected participants were people with long standing diabetes who must have received rigorous health education by their primary providers or respective clinics.

Some research studies have shown that Diabetes Self-Management Education (DSME) and home visits improve clinical outcomes[13]. In addition, it is difficult to ascertain if the excellent knowledge of disease demonstrated among our participants reflect the actual knowledge of all diabetics or newly diagnosed diabetics, since our sample population are people with long standing disease and/or poor disease control; which means they have had longer exposure to diabetes management and information.

Several factors beyond knowledge base were described by patients as hindering their home care of Diabetes. The main theme deduced from these questions was poor organizational skills (either forgetfulness or indifference to disease control was the predominant response). When asked the question “do you often forget to take your medications” 5 of the respondents across all groups answered yes, however this number reduced to 0 in the post-intervention survey; indicating a potential benefit of the diabetes app.

In the pre-app use survey, while some of the respondents where pro-active as to how they would approach a high or a low blood sugar, most stated they will do nothing; an effect that may pose an

immediate health risk. However, new themes were developed during the post app-use survey that suggested positive attitudes to managing high and low blood sugar. Some of the apps provide instructions to users on what to do when faced with very high or very low glucose levels, especially regarding correctional insulin dosing. The Diabetes:M app offers a means to calculate the Blood glucose index (BGI), which is a risk indicator for hypoglycemia and hyperglycemia probability. The BGI is an important tool that provides additional clarification to the Hb A1c number. A secondary focus of this study was to collect pilot data on potential for cost savings by using a Diabetes app, by assessing the awareness of disease control status (Hb A1c recall), new disease complication, hospital admissions or ER visits relating to Diabetes and finally prescription of a new medication; all of which result in increased health care cost.

In response to Hb A1c recall, the non-app group did not show any change in their response to recall of this biomarker, while the comparator group all reported recall of their last HbA1c dates and the numeric value; an unsurprising outcome simply because it was already recorded in their app. In both the pre-test and post-test surveys, we had asked the question “Do you remember the last time you had your Hb A1c checked?”. Two of the three participants in the non-app group answered” No” while the other participant answered “Yes”, and these answers were the same in their post-test surveys (See Table 3). However, all participants in the intervention arm answered Yes to this question in the post-test survey, including those who had previously answered No.

The Hb A1c is an important indicator of long-term glycemic control with the ability to reflect the cumulative glycemic history of the preceding two to three months as this is the time it takes for red blood cells to turn over. HbA1c not only provides a reliable measure of chronic hyperglycemia, but also correlates well with the risk of long-term diabetes complications. Elevated HbA1c has

also been regarded as an independent risk factor for coronary heart disease and stroke in subjects with or without diabetes[14].

While two of the intervention apps have built in provider communication ability, participants either reported having a hard time getting this to work or are yet to explore this feature. Lack of user friendliness and inability to make app function as desired where themes that emerged as barriers to using the apps for communication. Another barrier was getting their physician to sign up for the respective app and get a physician code to monitor their progress. Technical barriers to user friendliness might be overcome by better app design, provider system and behavior barriers may play a role in preventing ease of communication of results to physicians. The ability to directly send results to the electronic medical record system used by the physician would be one method that could circumvent these barriers.

STUDY LIMITATIONS:

One limitation of the study was the restriction of the intervention to only English-speaking participants. This eliminates a large population of Diabetic patients who may have a different perspective of managing their disease at home (perhaps driven by a different culture) as well as their home care needs.

Conclusions and future recommendations:

This study highlights some of the importance of a smart phone app in home care of Diabetes, particularly in the realm of data organization and attitude to disease control. As the world grows smaller with massive internet penetration, it becomes more important for medical practitioners and patients to exploit the digital app technology in managing chronic diseases like Diabetes. It is not

only a promising method to reduce health care cost, but an accurate way of recording medical information. A key recommendation for future app builders or programmers is to pay more attention to patient needs and convenience by creating simplicity of app interface and page navigation. An app that is built with a combination and integration of all the features of the 3 apps used for this study, may hold the most promise for maximizing patient experience and reducing health care cost.

Ethics and dissemination

The SPAT-D study was approved as IRB exempt with ID number 00006065. Informed consent was obtained from all participants and confidentiality of the issues raised during the study will be strictly maintained. All data will be kept anonymous and maintained in accordance with the guidelines of the University Human Subject Division (HSD).

PRE-TEST SURVEY FOR THE SPAT-D STUDY

	(SMART PHONE APPLICATION TRIAL FOR HOME CARE OF DIABETES) **Please circle all that apply to you:** **Age range:** <18yrs, 18-34yrs, 35-64yrs, >65yrs **Sex:** Male / Female **Ethnicity:** Black/African American, Hispanic, Asian, Asian American, White, other (specify) **Educational level:** PhD, Master's degree, Bachelors, Associate degree, MD/DO/DDS other professional degree, High school diploma, some high school **Language proficiency:** English, Spanish, other **Work status:** Employed, Unemployed, Retired, Disability benefit
Q1	Do you think your Diabetes is currently under control? Y/N, give reasons for your answer
Q2	Do you own a glucometer at home for monitoring your blood sugars? If yes, do you use it regularly; if no, how do you keep track of your glucose levels, and do you think that method is accurate
Q3	Do you know what your highest and lowest blood sugar is in the past week or month
Q4	When was your last HbA1c test and do you recall what it was? Y/N
Q5	How confident are you in interpreting your numbers as relates your disease control?
Q6	Do you think you have any complication from your Diabetes which your Doctor has discussed with you?
Q7	What are some of the barriers you encounter in controlling your disease at home? Do you think affordability of your medications is a problem
Q8	Do you often forget to take your medication or forget to go for your scheduled clinic visit
Q9	If you take multiple medications daily, do you know which ones are prescribed for your Diabetes
Q10	If you noticed your blood sugar within the last month was consistently higher than expected, what do you usually do?
Q11	How do you share your abnormal glucose test results with your Doctor?
Q12	Do you have any way to keep track of your physical activity or nutrition based on calorie count
Q13	Do you think living with Diabetes is expensive to keep up with? If yes, how much do you think it costs the U.S every year and how much do you spend averagely every month
Q14	Do you have any Out of Pocket Spending for your Disease, including medications, insulin pumps, syringes or physician visits
Q15	Have you ever filed for disability benefit or missed work due to poor control of your Diabetes
Q16	Has your doctor prescribed you a new medication in the last 6 months for better control of your disease? If yes, do you think this could have been avoided with better control.
Q17	Have you been hospitalized, been to the ER for your Diabetes or had any procedure related to your Diabetes in the past 6 months? If yes, how much on average did you pay out of pocket

Q18	Do you think a better way of tracking your blood sugar, your HbA1c, your calorie count and exercise level as well as provide a reporting system to your PCP will improve your Disease control
Q19	Do you think that better control of your Disease will lead to overall cost benefit to you, your health-plan and the Government?

Table 5: Pre-test survey questions

POST-TEST SURVEY FOR THE SPAT-D STUDY (SMART PHONE APPLICATION TRIAL FOR HOME CARE OF DIABETES)	
Q1	Do you think your Diabetes has been better controlled in the last 3 months? Y/N. Give reasons for your answer
Q2	Do you know what your highest and lowest blood sugar is in the past week or month? Y/N
Q3	Have you had a HbA1c test in the last 3 months? Y/N
Q4	If yes, please specify what it was?
Q5	How confident are you in interpreting your numbers as relates your disease control? Not confident/Confident/Very confident
Q6	Did you have any Diet modification in the last 3 months? Y/N. If yes, please explain?
Q7	Do you believe you have lost weight in the past 3 months? Y/N. If yes, how much?
Q8	Have you had any improvement in your physical activity in the last 3 months? Y/N
Q9	Have you been prescribed a new medication for better control of your Diabetes in the last 3 months? Y/N
Q10	Did you have days where you forgot to take your Diabetes medication in the past 3 months? Y/N. If yes, please specify how many days?
Q11	Have you had any new complication from your disease in the past 3 months? Y/N/Not sure
Q12	If yes, please check one of the following boxes that apply to you: Retinopathy (eye damage), Neuropathy (Nerve damage), Nephropathy (kidney damage), Erectile dysfunction, Vasculopathy (blood vessel damage), Limb or Toe amputation, DKA (Diabetic Keto-acidosis), Hyperglycemic event, Hypoglycemic event (Mental status change from low blood sugar), and others (Specify)

Q13	Have you been Admitted to the Hospital for a Diabetes related complication in the last 3 months? Y/N
Q14	Have you visited the ER or urgent care in the last 3 months because of a Diabetes related complication? Y/N
Q15	Have you been able to communicate your glucose log sheet with your Doctor? Y/N. If No, please give reason?
Q16	Do you believe a smart phone app that includes features for recording your blood sugar, your Hemoglobin A1c, your calorie count, exercise level as well as provide a reporting system to your Primary Care Doctor will improve your Diabetes control? Y/N

Table 6: Post-test survey questions

Category	Baseline Themes
Knowledge of Disease	• Understanding of disease process • Knows numbers (blood sugar, most recent HbA1c) • Number interpretation • Existing complications
Attitude to disease	• Reports abnormal numbers to PCP • Ignores abnormal numbers • Compliance to treatment
Barriers to Disease control	• Affordability of treatment • Forgetfulness • Polypharmacy (Taking more than 2 medications for diabetes control) • Psychological factors • Physician accessibility
Patient-Provider communication	• PCP knowledge about recent numbers • Clinic Attendance
Home glucose monitoring	• Uses glucometer regularly • Keeps paper log sheet • Adheres to Diabetic diet • Physical activity
Cost Perception	• National economic burden • Out of pocket spending • Hospital admissions • Prescribed medications • Managing Disease complications
Access to Diabetic Apps	• App literacy • Benefit to disease control • Knowledge enhancement • Compliance benefit • Cost benefit
Technology recommendation	• Technology reminder system

Table 7: Question categories and generated Themes

Fig 8: Study Flyer used for Online (ITHS Website) and Clinic Ad

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