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A Comparative Analysis of the Outcomes of an E-health Intervention Program for Diabetes Self-management (DSM) Carried out in a Faith-based Setting and Clinic Settings.

Stella Kamanu

ABSTRACT

A COMPARATIVE ANALYSIS OF THE OUTCOMES OF AN E-HEALTH INTERVENTION PROGRAM FOR DIABETES SELF-MANAGEMENT (DSM) CARRIED OUT IN A FAITH-BASED SETTING AND CLINIC SETTINGS

By

STELLA KAMANU

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INTRODUCTION: Diabetes is one of the leading causes of morbidity and mortality in the United States and has a great economic impact as well. Despite pharmacological advancement in its treatment, diabetes care still remains suboptimal at best. Diabetes self-management education (DSME) has been recognized as a key element to improved diabetes self-care and better patient health outcome. However, attendance to traditional DSME classes has been reported to be low due to several factors like accessibility, The internet has great potential for bridging several of the challenges of the formal DSME classes. Many studies have looked at internet-based programs in the management of chronic diseases like diabetes but just a few have studied specifically the black American population.

AIM: The study sets out to assess the effectiveness of e-HealthyStrides tool in the management of diabetes in a minority African American population. We also aimed to compare the health outcomes of this tool across the two settings where it was administered, a community faith-based setting and clinic setting.

METHODS: The study analyzed 135 participants from a total of 3 physician practices in the Morehouse Community Physicians' network (CPN), and 110 participants from a black American church in the downtown Atlanta region, all of whom were diabetes patients. Participants from the three CPN practices were merged into one group coded as clinic while the other group was coded as church. Descriptive analysis at baseline was done and used to obtain frequencies and percentages of the study population with chi-square test used to determine the differences between the groups. The outcome variables of blood pressure, blood glucose and distance walked by the participants were analyzed within each group and between the groups. T-tests were used to compare differences in the outcomes from baseline to the 12th week of the e-HealthyStrides program. The level of significance was set at a P-value of <0.05.

RESULTS: The study population was 97.6% black, 73.7% female, with about 15% having high school education or less. Overall e-HealthyStrides proved more beneficial in blood glucose control with an increase in proportion of people with well-controlled sugar levels, from 48.4% at baseline to 72.9% at 12 weeks (P <0.0001). Clinic participants showed statistically significant improvement in glycemic control (baseline mean 142.0mg/dl Vs 12th week 122.7mg/dl, P=0.0152) and distance walked (1.0mile Vs 1.8miles, P<.0001). Though there was improvement in glucose levels noticed in the church participants (164.1mg/dl Vs 143.8mg/dl), this however was not statistically significant. There was little to no effect noticed on blood pressure management.

DISCUSSION: In general, e-HealthyStrides showed beneficial effects in glycemic control and behavioral pattern like physical activity judged by distance walked by the participants. Its effect on blood pressure control was however not clear. The findings from this study agree with most other studies that have found variable beneficial effects of online or internet-based interventions in chronic disease management. e-Health interventions should be encouraged, with future studies continuing to find out ways to make the people more engaged and reduce attrition which is one of the major problems with these interventions.

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APPROVAL PAGE

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Author's Statement Page

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Chapter I

INTRODUCTION

BACKGROUND

Diabetes is one of the well-known chronic diseases that is quite ubiquitous around the world today. According to the 2014 National Diabetes Statistics Report by the Centers for Disease Control and Prevention (CDC), 9.3% of the United States population currently have diabetes (CDC, 2014). Diabetes is a metabolic disease characterized by abnormal blood sugar levels caused by a buildup of glucose due to an absolute or relative lack of insulin, a hormone which helps glucose get into the body cells (CDC, 2015). Absolute lack of insulin occurs when the body is unable to produce this hormone, a condition known as Type 1 diabetes; whereas there is a relative lack of insulin if the body produces its own hormone but the cells are not responsive to it. This results in Type 2 diabetes (CDC, 2015, 2016a).

According to data from the American Diabetes Association (ADA) and the CDC, 1.4 million Americans are diagnosed with new cases of diabetes every year. The prevalence of diabetes has been on the increase with the total number of people living with diabetes in the U.S moving up from 25.8 million in 2010 to 29.1 million in 2012, and 27.8% of these people with diabetes are undiagnosed (American Diabetes Association, 2016c; CDC, 2014). Furthermore, 86 million Americans now have pre-diabetes, a condition where the blood sugar is high but however not high enough to be diagnosed as diabetes. About 90% of people with pre-diabetes are unaware of their status and without intervention 15% to 30% progress to develop overt Type 2 Diabetes within 5 years (American Diabetes Association, 2016c; CDC, 2015, 2016a).

Diabetes is associated with several other co-morbidities and complications including blindness, cardiac disease, kidney failure, stroke, nerve damage and amputation of lower extremities (American Diabetes Association, 2016c; SB, S, S, & B, 2011). In the United States, diabetes is the seventh leading cause of mortality and also have a significant economic impact, with a total estimated cost of diagnosed diabetes at 245 million dollars as at 2012 (American Diabetes Association, 2013; CDC, 2014). Like most other chronic diseases known for their incurability, diabetes has no cure and so effective management emphasizes preventive measures across all levels aimed at stopping its development or catching it early enough to apply appropriate measures aimed at preventing further complications (Melville, Richardson, Lister-Sharp, & McIntosh, 2000; W. Virgil Brown, 2008).

For a more effective management of chronic diseases, it is recommended to have a more patient-centered care approach rather than physician-centered care. This is one of the strategies of the chronic care model and have been shown to be beneficial for effective management of diabetes (Ameican Diabetes Association, 2016; Funnell et al., 2011). Diabetes self-management education (DSME) is one tool that has proven effectiveness in enhancing patients health outcomes and promotion of healthy behavioral practices that could prevent or potentially delay complications in the long run (CM et al., 2001; SL, MM, & KM, 2001; TW et al., 2005).

Despite evidence-based benefits of the DSME programs, not all people with diabetes use these programs. Only about 25% of newly diagnosed diabetics attend DSME classes and approximately 48% of all diabetics had never attended the DSME courses (P. M et al., 2005; Maine, 2006) . Several barriers have been identified as limitations to the use of traditional DSME face to face formats and these range from patients' perception factors, to lack of insurance, lack of transportation and time, as well as logistics regarding the course content and delivery (P. M et al., 2005; Maine, 2006). However, the online or digital delivery of these interventions has great potential in achieving desired health results and is more broad-reaching thus could possibly address some of the limitations of the traditional format of delivery (RE et al., 2006) and a community-based intervention could even be more beneficial in terms of reach and potential reduction in cost (RT, EA, E, H, & DG, 2008).

Purpose of Study

This study sets out to assess the effectiveness of an online diabetes self-management support program, e-HealthyStrides that was carried out in both clinic settings and a church setting. It is also aimed at comparing the outcomes from the different settings. With community-based interventions having great potential to be equally effective and at the same time less expensive and more broad-reaching (SL et al., 2002), assessing and comparing the effectiveness of this e-health program that was administered in two different settings, would shed more lights on our understanding of what we know regarding these platforms of intervention especially in the underserved African American population.

Research Questions

1) Is e-Healthystrides, an online diabetes self-management support tool, effective in improving diabetes outcomes?
2) Is e-Healthystrides more effective when administered through the Physician's practice than when administered in a community setting such as a faith-based institution?

Hypothesis

I hypothesize that:

1) E-healthyStrides would be effective in improving diabetes outcomes as measured by blood glucose, blood pressure and distance walked by participants.
2) There would be no difference between the two groups/intervention settings, in the changes in the mean health outcomes of blood pressure, blood glucose and the distance walked, at 12weeks post intervention and baseline measures.

Chapter 2

Literature Review

Diabetes, along with the complications sequel to it, poses a serious public health problem and is currently known as one of the leading causes of morbidity and mortality. Precisely in the United States, Diabetes is the seventh leading cause of death according to the data from the National Diabetes Statistics Report (American Diabetes Association, 2016c; CDC, 2014). This illness is complex and chronic, requiring continuous medical care with multifactorial risk reduction strategies that go beyond just controlling blood sugar levels (American Diabetes Association, 2016b).

Despite medical and pharmacological advancement in the treatment of diabetes in recent years, achieving optimal care in terms of glycemic control, lipid and blood pressure management in patients with diabetes still remains a big challenge. This inconsistency could be reflective of the vital role diabetes patients play in determining their own health status and the challenges associated with supporting them to self-manage their conditions (Clark, 2008). Diabetes Self-management education and support, has been recognized as a key element in all people with diabetes or at risk of diabetes, and is necessary in order to improve patients outcome (Ameican Diabetes Association, 2016; Funnell et al., 2011).

Diabetes Self-Management Education and Support

There has been a shift in care of patients with diabetes, to more patient-centered approaches which place the patient and his or her family at the core of the care model. This patient-centered empowerment paradigm recognizes that patients are already in control of the most important diabetes management decisions and requires providing them with information, expertise and support needed to make the best possible management decisions based on the patient's own goals and health preferences (American Diabetes Association, 2016a; Anderson & Funnell, 2005).

Diabetes self-management education (DSME) or training (DSMT) is defined as a collaborative process through which people with diabetes gain the knowledge and skills needed for behavior modification and successful self-management of the disease and its related conditions (NACDD, 2013). It is the ongoing process of facilitating the knowledge, skills and ability necessary for diabetes self-care (Funnell et al., 2011). This process fits in the needs, goals and life experiences of the patient with diabetes and it is guided by evidence-based standards, revised periodically every five years by some federal agencies and key organizations within the diabetes community (Funnell et al., 2011). The general aim of DSME is to improve clinical outcomes, health status and quality of life, of individuals with diabetes by providing support in areas of informed decision-making; self-care behaviors; as well as problem solving and active collaboration with health care teams (Funnell et al., 2011; NACDD, 2013).

The American Association of Diabetes Educators AADE, developed the seven specific self-care behaviors, known as AADE7 and these include: healthy eating, being active, taking medication, monitoring, problem solving, healthy coping and risk reduction. These help guide the DSME process and help the patients achieve the desired behavioral changes (NACDD, 2013). In accordance with the National Standards for DSME and Diabetes Self-Management Support (DSMS), it is recommended that all people with diabetes participate in DSME in order to facilitate the knowledge and skill for effective self-care and in DSMS to assist with the implementation and sustenance of skills and behaviors needed for ongoing self-management, both at diagnosis and subsequently as needed (American Diabetes Association, 2016a).

Diabetes Self-Management Education and support is not a one-time intervention but a continuous ongoing process, with the four important time points for delivery identified as follows: at diagnosis; annually for assessment of nutrition, education and emotional needs; when new complications arise that affect self-management; and when transitions in care happen (American Diabetes Association, 2016a; Funnell et al., 2011). There have been some reported evidences to support the effectiveness of DSME in diabetes care with regards to better health outcomes both in the short term and long term (SL et al., 2001; SL et al., 2002; T. TS, MM, & M, 2012; TW et al., 2005).

Effectiveness of Diabetes Self-Management Education and Support

The chronic care model which has been shown to be effective for improving diabetes care (S. M, K, & C, 2013), includes self-management support as one of its core elements (American

Diabetes Association, 2016d). Evidence-based research studies show that DSME is effective in improving health outcomes of patients with diabetes as well as delaying the onset of diabetes in people at risk (Ameican Diabetes Association, 2016).

Schillinger et al (2009) studied the effects of self-management support on structure, process and outcomes among vulnerable patients with diabetes. 339 participants with poorly controlled diabetes from county-run outpatient clinics, were assigned into one of three arms – the usual care, interactive weekly automated telephone self-management support with nurse follow up, or a monthly group medical visit with physician and health educator facilitation. The study found that providing tailored self-management support using patient-generated behavioral action plans led to improvements in patients' experiences with chronic illness care, self-efficacy and self-management behaviors (Dean Schillinger, Margaret Handley, Frances Wang, & Hali Hammer, 2009).

The completion of three to four sessions of a once weekly diabetes education program, in a cohort of adults patients with type 2 diabetes, resulted in significant improvement in metabolic parameters, lipid profiles, blood pressure clinical parameter as well as behavioral motivation (Liu, Lee, & Andrei Brateanu, 2014). In a retrospective study that assessed participants from the Cleveland clinic health care network in Ohio, Liu and the other researchers observed significant decrease by 1.2% points in the primary outcome of interest, variable A1C, 3-6 months post-intervention compared to baseline. The study also reported a decrease in Body mass index (BMI), systolic blood pressure and total cholesterol levels of the participants (Liu et al., 2014).

In a meta-analysis of 31 studies, Norris et al found that DSME improves glycemic control with the intervention decreasing glycosylated hemoglobin GHb by 0.76% more than the control group at immediate follow-up (Susan L. Norris, Joseph Lau, S. Jay Smith, Christopher H. Schmid, & Michael M. Engelgau, 2002). Another systemic review of 72 randomized trials carried out a year before the meta-analysis also concluded that DSME was effective in appropriate self-monitoring of blood glucose, self-reported dietary behaviors and glycemic control, especially in studies with <6months follow-up (SL et al., 2001).

Though these studies showed that DSME is effective in the short-term, there are other studies that have also examined the long-term effects of DSME (T. TS et al., 2012). Tang et al, examined the effect of a 2-year DSMS intervention and at 1-year follow-up reported a significant and sustained behavioral improvement as well as additional improvements in glycemic control and lipid profile levels (T. TS et al., 2012).

Despite the proven benefits of DSME programs, there are still existing gaps in the usage of these programs by people with diabetes and those with pre-diabetes. A study by Strine et al in 2005 showed that approximately 48% of all patients with diabetes had never attended a DSME course (TW et al., 2005). Other studies have examined the barriers to diabetes self-management and limitations to the use of DSME programs among those with diabetes (P. M et al., 2005; Maine, 2006).

Barriers of Diabetes self-management

Certain factors pose as barriers to diabetes self-management. These include some patients' characteristics, socio-environmental context, factors associated with the disease itself, and interaction between the patients and diabetes providers and educators (Clark, 2008).

A cross-national study, titled Diabetes Attitudes, Wishes and Needs (DAWN), found that psychological problems were quite common in people with diabetes and that these may be associated with worse outcomes in terms of diabetes self-care (P. M et al., 2005). The DAWN study was a large study that involved 13 countries representing from regions including North America, Europe, Asia and Australia. It included participants randomly selected from about 5100 adults with Type 1 and Type 2 diabetes and about 3800 providers. They also found that providers lack the resources for addressing these issues particularly regarding the skills, time and adequate referral sources. Addressing these factors could lead to improving care and quality of life of those living with diabetes (P. M et al., 2005).

Other perceived barriers of optimal self-management of diabetes include inadequate health literacy. A qualitative study among low-income minority with diabetes showed that many of the patients lack knowledge of the target blood glucose and blood pressure, and this limited their ability to self-manage their diabetes (NC et al., 2011). Also reported as potential limitations to patient self-management are barriers within the home and work places, inadequate neighborhood resources and suboptimal healthcare quality (P. TS et al., 2016).

Diabetes Self-management education (DSME) and training have been identified as a key element in achieving optimal diabetic self-management and better patient health outcomes, being a tool that provides useful information necessary for patients to make informed decisions concerning their health. However, the usage of these DSME programs still remains suboptimal among people living with diabetes.

A statewide study carried out by the Centers for disease control and prevention, Maine identified certain barriers that hinder the referral to and use of DSME programs by patients who have diabetes. Surveys of referring providers, diabetes educators and people living with diabetes were carried out and some of the barriers according to the report include: issues with perception, where the patients do not feel the need for the information, or do not know about the programs; barriers due to cost, transportation, location and timing of classes, as well as other structural issues (Maine, 2006).

In order to bridge the existing gap in the use of these traditional DSME programs, certain suggestions have been made for meeting the needs of the individuals related to diabetes education. Some of these suggestions include: addressing the structural issues like allowing more flexibility for appointment and conducting participant evaluation to know what works; community partnership/outreach; and improvement in the education delivery modes, such as the use of web-based programs or resources (Maine, 2006).

Effectiveness of Internet-based Interventions

With the advancement in technology in recent years, the American Diabetes Association (ADA), recognizes that technology may be an effective means of delivering core components of diabetes prevention programs. According to the 2016 Standards of Medical Care in Diabetes, there is a recommended addition to encourage the use of technology-assisted tools, internet-based social networking, and mobile applications as helpful elements of effective lifestyle modification in the prevention of diabetes (Ameican Diabetes Association, 2016). The CDC also recognizes online lifestyle change programs, as a great option for anyone who finds it difficult to attend on site meetings or who does not have an in-person program nearby (CDC, 2016b).

Sepah et al (2015), recruited 220 adult participants who were previously diagnosed with prediabetes into a study. The study was a single-armed quasi-experiment which involved the implementation of an internet-based diabetes prevention program with a pre- and post-intervention assessment of body weight, hemoglobin A1C and program engagement. After the 24month study period, there was a significant and maintained reduction in body weight and A1C among the users of the intervention program. The researchers observed average regression in A1C levels from within the prediabetes range of 5.7% - 6.4% initially to the normal range of <5.7% after 2 years (Sepah, Jiang, & Peters, 2015).

Similarly, an improved glycemic control was achieved in another randomized trial which assessed the effects of a web-based diabetes support program on glycemic control among adults with Type 2 diabetes (Ralston et al., 2009). The authors concluded that care management delivered through secure patient web communications led to an improvement in as the glycosylated hemoglobin levels declined by 0.7% on average among intervention patients compared to usual care patients (Ralston et al., 2009).

The effectiveness of web-based programs are not just limited to improved glycemic control. Reports have shown positive effects of computer-based programs on some targeted behaviors such as healthy dietary behaviors (RE et al., 2006), and weight loss (Allen, Stephens, & Patel, 2014).

Many studies have shown the effectiveness of different self-management programs in achieving optimal diabetes care, with a lot of them giving varying degrees of result. Both the online and traditional methods of delivery of self-management programs for diabetes have proven to be effective. Several of the studies that assessed web-based tools have either done so with individual participants from different clinics, managed care organizations or individual participants that volunteered after seeing advertisement over different platforms.

Studies on community-based interventions programs in the traditional format have proven both effective and potential reduction in cost (RT et al., 2008) but little is known about web-based or online interventions administered in community settings. It is therefore important to assess the effectiveness of an online self-management program in a community setting such as a faith-based institution, in comparison to clinic settings.

Chapter III

Methods and Procedures

Primary Data Collection

Participants Recruitment

- Clinic Participants: - A total of 145 participants were recruited and successfully enrolled from 3 different practices that are part of the Morehouse School of Medicine Community Physicians' Network (CPN). The Morehouse CPN is a practice-based research network of small independent practices that provide care to predominantly underserved patients (Pemu et al., 2011). The CPN physician practices, who were interested to participate in the study and who had electronic medical records, were invited to participate.

  At each site, a lead physician was identified who was responsible for championing the project. This lead physician in turn, identified a practice employee, usually a medical assistant who was trained as a health coach.

  All the diabetes patients in the practices were identified using the International Classification of Diseases Version 9 codes (ICD 9) for diabetes mellitus. All identified patients were sent letters and those interested were further contacted by the health coaches of each practice.

- Church Participants: - All participants were congregants from the Big Bethel AME church in Downtown Atlanta and other affiliate churches in the neighborhood recruited by the church health ministry. A total of 147 members volunteered to be enrolled but 110 were recruited by their attendance of the first training that preceded the study. 20 who participated as coaches were chosen based on their ability to be certified by AADE using the fundamentals of diabetes curriculum.

Inclusion and exclusion criteria –

Participants were included if they were aged over 21 year old and willing and/or able to use the internet during the course of the study. Exclusion criteria includes the presence of any insurmountable physical impairment (blindness).

Prior to attending a training orientation at Morehouse School of Medicine (MSM), the eligible participants received mailed packets of the informed consent forms and study protocol. Participants were enrolled on the orientation day after they had reviewed and signed the informed consent form, approved by the MSM Institutional Review Board (IRB).

The Intervention / E-HealthyStrides Program Description

The e-HealthyStrides is a diabetes self-management tool that was developed in Morehouse School of Medicine. It is an internet-based, interactive, patient-driven diabetes self-management support and social networking forum to engage diabetes patients, their physicians and health coaches in order to create a supportive environment to improve diabetes self-care skills and outcomes (Pemu et al., 2011). The e-HealthyStrides application consists of an integrated diabetes curriculum and pages for uploading and viewing self-monitored, graphic and color-coded parameters like blood pressure, blood glucose, body mass index and number of steps walked. Also included in the application, is a structured instrument used by the patient to identify and set self-management goals that are based on the American Association of Diabetes Educators (AADE) seven self-care behaviors (AADE7) goals. The health coaches supported each participants with required steps to track and attain the expected goals.

The main intervention was diabetes education using health information on diabetes pooled from the American Diabetes Association website. These educational materials from the ADA were converted into a 10-chapter electronic material for easy read on the MSM created webpage. The curriculum was made up of information the patients would have received in diabetes education classes. It also featured a structured support and feedback system. The e-HealthyStrides application can be accessed from https://www.ehealthystrides.org.

Study Procedure

The Participants:

The participants received IRB-approved consent forms prior to the training. The orientation process was a 4-5 hours of hands-on training that took place in a computer laboratory at the main campus of MSM. It was conducted by the researchers (PIP, FO) and the health coaches.

Once the participants were enrolled, they all had email accounts created, as well as usernames and passwords specific to the e-HealthyStrides. They were guided on how to use e-HealthyStrides including how to access their personal webpages from home, how to use their monitors, glucometer, sphygmomanometer, and pedometers to record and upload information into the Microsoft HealthVault database, as well as how to view the data. They were also oriented on the curriculum and related quizzes, use of the discussion forum and how to keep their usernames and passwords safe. The participants filled out several questionnaire forms at enrollment including the Diabetes empowerment scale (DES), Diabetes knowledge test (DKT), Patient assessment of chronic illness care (PACIC), Consumer Health Information Technology survey (CHITS), and the AADE7.

Each participant at the end of the orientation was provided with a sphygmomanometer, glucometer and pedometer, which were all universal serial bus (USB) enabled, so as to directly interface the e-HealthyStrides and upload all monitored data to the participants' Microsoft health vault account. Participants were encouraged to upload data at least once a week if they had access to home computers or every 3 weeks for those who had to go to the health coaches or practice offices for help. Incentive were given for the completion of quizzes at the end of each chapter of the curriculum. Health coaches contacted participants at least once a month to review their progress with self-management goal attainment.

The study was designed to last for a period of 12 months.

The Health Coaches:

The volunteer health coaches went through a one day training. The training curriculum included basic definitions such as, of Diabetes, body mass index (BMI), high blood pressure, cholesterol etc., the physiology of the disease, monitoring of blood glucose, healthy eating, risk reduction, problem solving and goal-setting, as well as other important information on diabetes. They were also taught on coaching skills and trained on how to use the devices used in the study including USB compliant Omron blood pressure kit, pedometer and glucose meter. There was hands-on demonstration of how to download the devices onto the Microsoft Vault center.

By signing a one page code of conduct, the coaches committed to respect participants' privacy and had the HIPAA explained. They also committed to a 12 week coaching assignment, weekly review of self-management goals with participants, assisting with the download from the devices and documentation of weekly interactions.

Measures

The study measures included data obtained from the questionnaire forms completed by the participants, clinical data from patients' medical records, self-reported demographics, as well as data uploaded into the Microsoft HealthVault database. The data used in this secondary analysis included measures of several parameters like blood pressure, pulse, blood glucose and distance walked by the study participants, recorded by their USB-enabled sphygmomanometers, glucometers and pedometers respectively and stored in the Microsoft HealthVault database. As mentioned earlier, participants uploaded these data into the HealthVault data at least once weekly if they had access to home computers or once every three weeks if they did not have computer access and had to go to the health coaches for the upload.

Secondary Data Analysis

The data from the e-HealthyStrides study was provided for this analysis by the e-HealthyStrides research team at the clinical research center of Morehouse School of Medicine, after the data was de-identified. This study was approved by the IRB at Georgia State University.

Study Variables

The data analysis utilized three main dependent variable: blood glucose, blood pressure (systolic and diastolic), and the distance moved by the participants. The independent variables were the e-HealthyStrides intervention program and demographics like age.

In this study, the systolic and diastolic blood pressures were measured in mmHg. Blood glucose was measured in mg/dl, and ideally was the fasting glucose measurement. Pulse was measured in beats per minute (BPM) and distance was in miles.

Data Management

For the data management and statistical analyses, the statistical analysis system (SAS) 9.4 software package was used. The participants were grouped into either church or clinic, if they are from any of the three clinics. Age, was the other independent variable and it was normally distributed. The dependent variables were all continuous variables. For some sub-analysis, blood pressures were categorized into either "high blood pressure", if systolic blood pressure (SBP) was >140mmHg and diastolic blood pressure (DBP) >90mmHg, or otherwise "normal". Another sub-classification of blood pressure was the recommended target for diabetes patients, a level of <130mmHg SBP and <80mmHg DBP. Blood glucose levels were group into a "well-controlled" category if glucose level was <130mg/dl and "poorly controlled" if blood glucose was >130mg/dl (American Diabetes Association, 2015).

Statistical Analysis

Descriptive analyses were conducted on the baseline demographic variables such as age, gender, and other participants' characteristics like SBP, DBP, pulse, blood glucose, and distance walked. The means and standard deviations (SD) were computed for all the continuous variables while frequencies and percentages were computed for the categorical variables. Chi-square test was used to compare the different categories of the outcomes. Dependent t-test was used to compare the differences in means of the outcome parameters within each group, from baseline to 12th week and independent t-test used to compare outcomes between the two groups. Statistical significance was established at *P*-value of <0.05.

Chapter IV

Results

The basic descriptive characteristics of the study population is shown in table 1. The overall sample was 73.7% female, 97.6% were black and about 15% reported attaining high school level or less. The study population mean age was 59.6 years (SD = 11.9) and the mean blood glucose was 143.8 (SD = 56.5). Mean SBP was 129.0, mean DBP 79.6 with SDs of 19.6 and 10.9 respectively. The study participants from the church were all black. The two groups did not differ on any other variable at baseline other than their mean ages (clinic 57.6 Vs church 62.2, P=0.0029). A total of 135 and 110 were analyzed from the clinics and church respectively.

Table 2a shows the proportion of the population across the different subgroups of the outcome parameters at baseline and week 12. It could be seen that while 67.6% of the overall population had their blood pressures within the recommended target, only 48.4% had well-controlled blood glucose levels at baseline. It shows an overall improvement in blood glucose level at the 12th week as compared to the baseline. The proportion of people with well controlled blood glucose went up from 47.3% at baseline to 74.0% at week 12, in clinic participants (P=0.0064) and from 54.6% to 63.6% in the church participants (P=0.0152). Of the overall study population, 48.4% had well controlled blood glucose at baseline but this increased to a 72.9% at week 12 (P=0.0004).

Dependent t-test was utilized to understand the changes in the outcome parameters within each group both at baseline and at the 12th week. As shown in table 2b and figures 1 and 2, participants from the clinic attained statistically significant improvement in their mean blood glucose (mean difference=19.3, $P = 0.015$) and distance walked (mean difference= 0.8, $P < 0.0001$). While there was an observed decrease in the mean blood glucose in church participants from baseline value of 164.1 (SD=88.6) to a 12th week mean of 143.8 (SD=58.7), this however was not statistically significant probably due missing values.

Since the mean ages were significantly different between the two groups, to determine whether age was associated with any changes in the outcome of glucose levels, a multi-variable linear regression model was run, using the pre-post difference in mean glucose as the dependent variable while group and age were the independent variables. However, this showed that age was not associated with the changes observed between the groups. A similar regression model was also run to determine the effect of age on the changes in blood pressure and there was no significant effect of age on the outcome.

Independent t-test was used to compare outcomes at week 12 between the two groups. As shown in table 3, the clinic participants achieved a significantly lower SBP mean compared to participants from the church (126.9 mmHg Vs 132.7mmHg, $P = 0.0075$). However, the overall effect on blood pressure is not clear as could be seen in figures 3a and 3b. Also the clinic participants walked more distance than the church participants (1.8 miles Vs 1.2 miles, $P = 0.0007$).

Table 1 Baseline Characteristics of Study Population

Participant Characteristics	*All (N=251)*	*Clinic (n=141)*	*Church (n=110)*	*P-value*
Age, years				0.0029
Mean (SD)	59.6 (11.9)	57.6 (9.8)	62.2 (13.8)	
Gender (n, %)				0.0688
Female	185 (73.7%)	108 (77%)	77 (70%)	
Male	66 (26.3%)	33 (23%)	33 (30%)	
Race/Ethnicity				-
Black	245 (97.6%)	135 (95.7%)	110 (100%)	
Hispanic	1 (0.40%)	1(0.71%)	-	
White	2 (0.80%)	2 (1.42%)	-	
Other	3 (1.20%)	3 (2.13%)	-	
Education				-
High School or less	38 (15.1%)	22 (15.5%)	16 (14.7%)	
Some college or Technical school	100 (39.8%)	57(40.4%)	43 (39.2%)	
College Grad	61 (24.3%)	35 (25.0%)	26 (23.5%)	
Post-graduate/professional degree	52 (20.7%)	27 (19.1%)	25 (22.6%)	
Clinical Parameters (Mean, SD)				
SBP (mmHg)	129.0 (19.6)	127.8 (19.4)	131.1 (20.0)	0.2874
DBP (mmHg)	79.6 (10.9)	79.6 (10.9)	79.7 (10.8)	0.9204
Blood glucose (mg/dl)	143.8 (56.5)	142.0 (52.5)	164.1 (88.6)	0.7940
Pulse (BPM)	78.1 (12.9)	78.6 (13.1)	76.9 (12.5)	0.4056
Behavioral				
Distance walked (miles)	1.0 (1.1)	1.0 (1.1)	-	-

SD = standard deviation; SBP = systolic blood pressure; DBP = diastolic blood pressure; BPM = beats per minute.

Table 2a Comparison of outcome parameters by proportion of study population

	Clinic (%)			Church (%)			Overall (%)		
Variables	Baseline	Week12	P-value	Baseline	Week12	P-value	Baseline	Week12	P-value
Blood Glucose									
Well Controlled	47.3	74.0	0.0064	54.6	63.6	0.0152	48.4	72.9	0.0004
Blood Pressure									
Recommended	68.8	62.0	<.0001	65.1	48.1	<.0001	67.6	55.2	<.0001
High	7.38	7.41	0.0564	11.1	12.5	<.0001	8.7	9.9	<.0001

Table 2b Baseline and 12th week comparison of variable means within each group

	Clinic			*Church*		
Variables	*Baseline*	*Week 12*	*P-value*	*Baseline*	*Week 12*	*P-value*
SBP (mmHg)	127.8 ± 19.4	126.9 ± 17.9	0.3088	131.1 ± 20.0	132.7 ± 16.1	0.1758
DBP (mmHg)	79.6 ± 10.9	79.7 ± 9.9	0.5609	79.7 ± 10.8	81.2 ± 9.9	0.1820
Glucose (mg/dl)	142.0 ± 52.5	122.7 ± 32.2	0.0150	164.1 ± 88.6	143.8 ± 58.7	0.1486
Pulse (BPM)	78.6 ± 13.1	79.9 ± 12.7	0.9257	76.9 ± 12.5	76.5 ± 11.4	0.9808
Distance (Miles)	1.0 ± 1.1	1.8 ± 1.3	<.0001	-	1.2 ± 0.9	-

SBP = systolic blood pressure; DBP = diastolic blood pressure; BPM = beats per minute.

Table 3 Comparison of outcome parameters at 12th Week

Variables	*Clinic (n=135)*	*Church (n=110)*	*P-value*
SBP (mmHg)	126.9 ± 17.9	132.7 ± 16.1	0.0075
DBP (mmHg)	79.7 ± 9.9	81.2 ± 9.9	0.2868
Blood Glucose (mg/dl)	122.7 ± 32.2	143.8 ± 58.7	0.3640
Pulse (BPM)	79.9 ± 12.7	76.5 ± 11.4	0.1310
Distance walked (miles)	1.8 ± 1.3	1.2 ± 0.9	0.0007

SBP = systolic blood pressure; DBP = diastolic blood pressure; BPM = beats per minute.

Figure 1

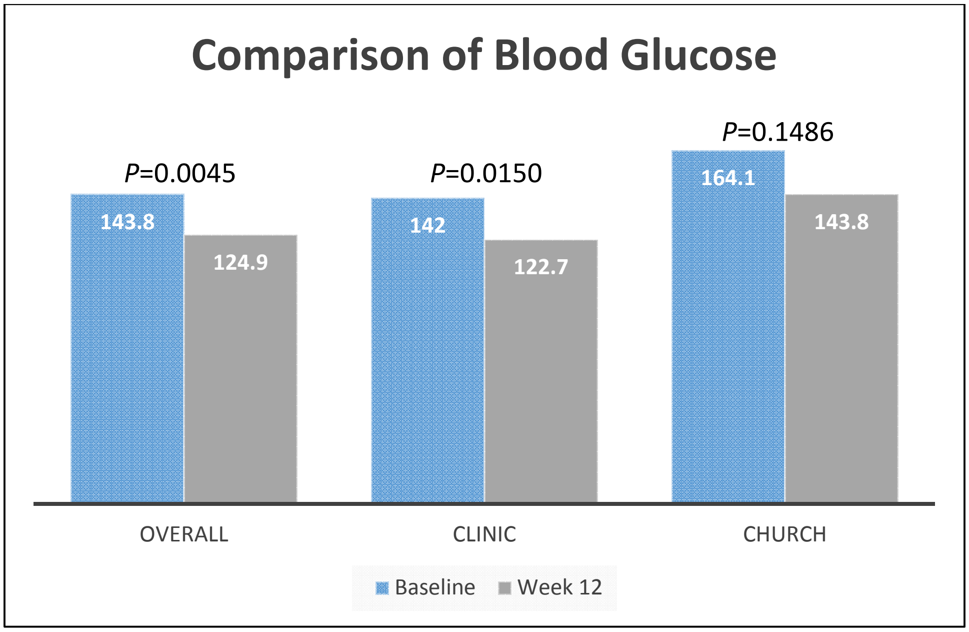


Figure 2

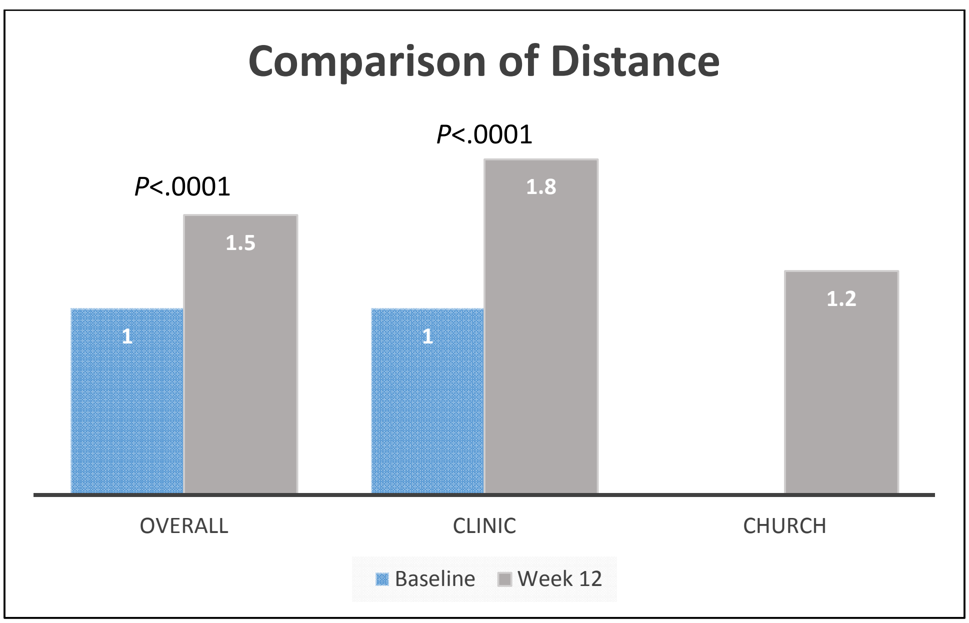


Figure 3a

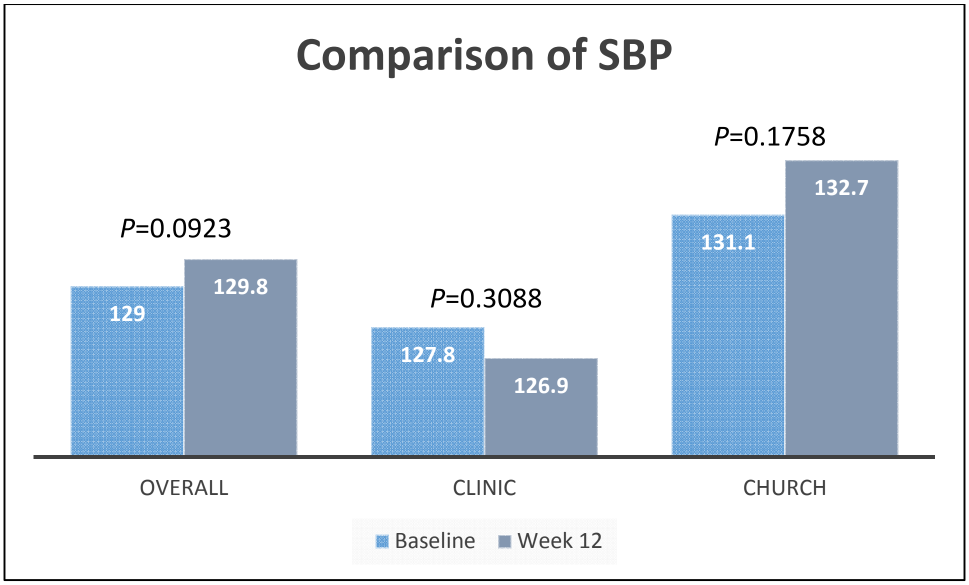
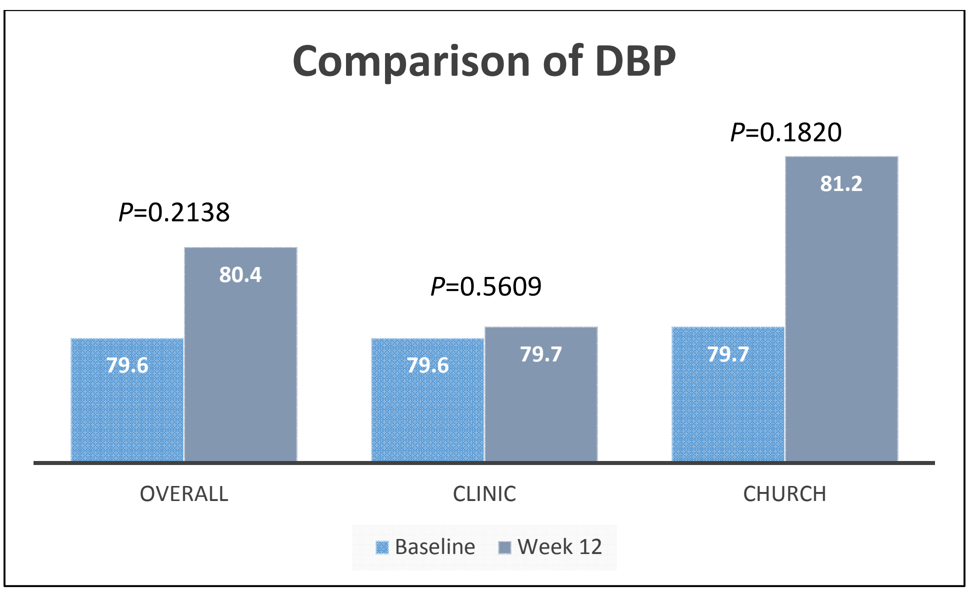


Figure 3b



Chapter V

Discussion and Conclusion

Discussion

Diabetes is a chronic disease and could be complex in its management. It is disproportionately more prevalent in blacks (Centers for Disease Control and Prevention, 2015). The demographics of our study was a predominantly black, female population with varying educational attainment. Less than 50% of our study population (48.4%) had well-controlled blood glucose at baseline (defined as fasting glucose <130mg/dl), this is similar to findings from other studies that utilized national data (Saydah, Fradkin, & Cowie, 2004). However, a higher proportion (67.6%) had baseline blood pressures at the target level of <130/80mmHg.

Overall, the e-HealthyStrides intervention showed some statistically significant improvement in glycemic control, as there was an increase in the proportion that attained well-controlled glucose to 72.9% at 12^{th} week, vs 48.4% at baseline (P=0.0004). Glycemic control in terms of proportion for the two individual groups also showed improvements which were statistically significant. The overall effect on blood pressure showed a decline in the proportion at recommended target from 67.6% baseline to 55.2% at 12^{th} week (P<0.0152). But the effect on blood pressure was variable for the different groups. These findings agree closely with other studies that have found web-based self-management interventions effective for glycemic control but with variable effects on other physiological outcomes like SBP, DBP and lipid levels (Ralston et al., 2009; RE et al., 2006).

For the comparison of actual mean differences in outcome within each group, our results show statistically significant decrease in mean blood glucose levels in the clinic participants, from a baseline of 142.0mg/dl to 122.7mg/dl at 12 weeks post intervention (Mean diff=9.13, P=0.0150). Also there was an improvement in the distance walked by the participants with a mean difference of 0.8miles from baseline to 12^{th} week (Mean Diff= -0.79, P<0.0001). A trend in direction favoring the intervention was noticed in SBP but this was however not significant. Participants from the church on the other hand showed trends in the opposite direction in both SBP and DBP but these were also not statistically significant. There was about 20 points difference in the means of blood glucose levels of the church participants though this did not reach any statistical significance probably due to missing values (Mean Diff=20.24, P=0.1486).

These findings agree with other studies that have found web-based DSME more effective when used in collaboration with patient's healthcare team (Dean Schillinger et al., 2009; Ralston et al., 2009). Though some studies have shown sufficient evidence of improvement of glycemic control with community-based DSME including those in gatherings like churches (RE et al., 2006), there is not much literature addressing effects of web-based DSME specifically in faith-based institutions. However one study that assessed the effectiveness of online self-management program in a non-clinic community setting - a worksite environment, concluded that the program was associated with improvement in dietary habits and physical activity (B et al., 2009).

Attrition is one major problem with long term duration of these web-based intervention studies and some of the factors that have been identified as obstacles to dissemination of these include some poorly designed interventions, glucose monitory technologies that are complex, lack of computer literacy among some patients especially older patients (A. M & R, 2009). This may have factored in the difference observed in the two groups in our own study as participants from the church were significantly older than those from the clinic.

Study Limitations

Our study participants were generally volunteers and this self-selection could lead to some differences from the general population, therefore affecting generalizability. There was also lots of missing data and the high attrition rate, necessitated the use of the 12th week outcomes instead of the end point outcomes (12th month).

Conclusion

E-healthyStrides, an internet-based, interactive, patient-driven diabetes self-management tool was effective in improving glycemic control in a population of black American patients in the short term. The intervention also showed more effectiveness when used in the clinics compared to the church setting. Based on an understanding of the importance of relational engagement in retention, the research team is exploring ways of successfully deploring a relationship component to enhance e-health interventions such as this.

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