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Effects of Patient Empowerment and Health Literacy on Blood Pressure Control in Patients with Type 2 Diabetes at Grady Hospital

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Bachelor of Science
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2008

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An abstract of
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ABSTRACT

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RESULTS: Participants were predominantly older (mean age: 58.5 ± 9.9), female (72.6%), African American (96.3%), non-working (83.0%), on government insurance (26.0%) or uninsured (21.62%), poor (56.4%), and un-married (77.8%). Among intervention and control group participants, SPB decreased over the in-trial period by a mean of 13.23 mmHg (±29.42) ($p=0.0003$) and 12. 22 mmHg (±31.86) ($p=0.0015$), respectively. Significant DBP reductions between pre- and post-intervention levels were also observed in both groups (-6.46±20.76 and -4.37±18.94) ($p<0.05$ for both). There were no significant between-group differences in blood pressure change. We observed no significant changes in knowledge, reported exercise barriers, and recognition of long-term benefit scores ($p>0.05$) in either treatment group. Baseline health literacy did not significantly mitigate the intervention effect in the analysis ($p=0.9889$).
CONCLUSIONS: Patient empowerment interventions may have short-term benefits. However, further studies will be needed to determine whether benefits are sustained, and the specific mechanisms that are responsible.

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CHAPTER 1

LITERATURE REVIEW

Epidemiology of Diabetes

Diabetes affects 8.3% percent of the U.S. adult population, and 26.9% of the elderly population (65 years and older) [1]. Type II Diabetes accounts for 90-95% of diagnosed cases of diabetes in adults and is associated with multiple complications including cardiovascular disease (CVD), other co-morbid cardio-metabolic risks (e.g., hypertension, dyslipidemia), vision-threatening eye diseases (e.g., diabetic retinopathy, cataracts, glaucoma), chronic kidney disease and end-stage renal disease, as well as nervous system damage. Comprehensive management of diabetes is important to reduce the risk of life-threatening and disabling complications associated with diabetes.

Achieving and maintaining tight glycemic control (HbA1C≤7.0) is a central component of diabetes care, *comprehensive* management of all risk factors is recommended for both men and women to reduce microvascular and neuropathic complications of diabetes [2]. The recommendations for blood pressure control (specifically, systolic blood pressure (SBP) <130mmHg and diastolic blood pressure(DBP) < 80 mmHg), and maintenance of a healthy cholesterol profile (LDL cholesterol <100 mg/dl, HDL cholesterol >50 mg/dl, triglycerides <150mg/dl) are significant benchmarks of diabetes control and evidence suggests that achieving these targets help to reduce risk of complications [1-3]. Studies have shown, for every percentage point reduction of HbA1c, the risk of complications of the eye, kidney, and nerve disease is reduced by 40% [1, 4-6]. Good blood pressure control reduces the risk of both microvascular and major cardiovascular events [4]. The risk of any complication of diabetes is reduced by 12% for a 10 mmHg reduction in systolic blood pressure [4]. Improving cholesterol markers, such as reducing LDL cholesterol, can reduce cardiovascular complications by 20-50% [7-9].

Managing diabetes according to evidence-based guidelines greatly reduces risk. However, glycemic control is only achieved by approximately one-third of patients[10]. In addition, African Americans have been shown to have worse glycemic control than their Caucasian counterparts [11]. Meta-analyses have shown that self-management interventions can improve glycemic control though increasing patient knowledge of diabetes and facilitating behavior change [12, 13]. Management of cholesterol, according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP-III), which set levels of total cholesterol less than 200 mg/dL (5.18 mmol/L) was only achieved by 51.8% of the 1999-2000 NHANES participants with diabetes [14]. Management of blood pressure targets (SBP ≤130mmHg, DBP≤ 80 mmHg), was only achieved by 35.8% of people with previously diagnosed diabetes in the NHANES 1999-2000 survey [14]. Clearly, there is much room for improvement in achieving HbA1C, cholesterol, and hypertension targets in patients with diabetes, especially for African American and low-SES groups.

Diabetes Self-Management Education

It is estimated that there are knowledge and skill deficits in 50-80% of individuals with diabetes [10]. In part, this is related to the burden of diabetes being higher in minority and lower socioeconomic strata populations [15]. These populations have been shown to have limited access to diabetes self-management resources and support [16, 17]. In addition, patients who do not receive any outpatient education after diagnosis are four times more likely to develop major diabetes complications than those who receive any kind of education [15]. Diabetes self-management education (DSME) is crucial towards increasing patient education and has been shown to improve glycemic control in patients with diabetes [17] Since diabetes is managed by patients themselves the majority of the time, effective self-care requires patients to understand medications, complex treatment strategies, and use problem-solving skills to make day-to-day decisions regarding the control of their disease [18]. Self-management training focuses on self-care behaviors such as adopting healthy dietary habits, being active, and monitoring blood sugar, which help people gain skills needed to regulate blood glucose levels. In addition, DSME should include awareness building and guidance on managing other risks, such that patients can avoid longer term complications [2]. It is currently recommended that all people with diabetes receive DSME after diagnosis with diabetes[19]. However, only 40% of all people with diabetes were documented to have ever received DSME in 1998; and when stratified by highest level of education obtained, only 26% of people with less than a high school education received the DSME [20]. As a result, the government's *Healthy People* 2010 initiative has set targets to ensure that 60% of people with diabetes receive formal DSME by 2010 [21].

The overall goal of DSME is patient empowerment. Empowerment has been shown to positively influence patient participation in decision-making, self-care, self-efficacy, and reducing risk of depression [22]. Empowerment for diabetes patient education is not clearly defined in the literature, but involves enabling patients to improve their communication skills with providers and raise their consciousness about health values, needs, and goals. In addition, it can be measured by assessing feelings of self-esteem, ability to manage disease, and level of autonomy in care sought [23].

Health Literacy

A 2004 Institute of Medicine (IOM) report entitled “ Health Literacy: A Prescription to End Confusion” states that nearly half of all American adults have difficulty understanding and acting upon health information [24]. The IOM divides health literacy into four categories: cultural and conceptual knowledge, oral literacy, print literacy, and numeracy [25]. Limited general literacy has been shown to affect multiple domains of health including: timely use of preventative services, understanding disease(s) and treatment(s), adherence to medical instruction(s), self management skills, and health outcomes[26]

Measuring health literacy is a difficult task as it is often associated with respondents experiencing feelings of shame and inadequacy [26]. Several tests are currently used to assess health literacy including word recognition tests, reading comprehension tests, and functional health literacy tests [27]. The Rapid Estimate of Adult Literacy (REALM) is an example of a word recognition test which examines the reader's ability to recognize, read, and pronounce individual words. It works under the assumption that if patients have difficulty with word recognition, then they are also likely to have difficulty comprehending health information presented. The Test of Functional Health Literacy in Adults (TOFHLA) is a functional health literacy test which examines both comprehension and how individuals are able to function in a health care environment [27]. The REALM test has been shown to be highly correlated with both standardized reading tests and the TOFHLA [7].

The Department of Pharmacy Practice at Auburn University found that approximately 40% of state-funded clinic patients tested had reading levels corresponding to levels expected of a 5th grader or lower [9]. In another study of 151 adult primary care patients, 60% were found to read (and be able to comprehend) at least three grade levels below their last grade completed [28]. In a review of patient education materials by Hill-Briggs, brochures provided by the American Diabetes Association (ADA) and American Heart Association (AHA) were evaluated for reading grade level needed for comprehension[29]. It was found that only 5 of the 21 ADA brochures were comprehensible to an audience of less than 5th grade reading capabilities. All of the 19 AHA brochures required greater than a 5th grade reading level for comprehension. Studies have shown that lower health literacy is associated with lower knowledge of diabetes [30].

In summary, many view patient knowledge of health and illness as an integral part of health literacy and possibly also long-term self-care for chronic diseases like diabetes and CVD. However, most health education materials are written at a high literacy level and are of little use to individuals in the lowest health literacy groups. We sought to evaluate whether patient education and empowerment strategies in a publicly-funded general medical clinic in metropolitan Atlanta could improve control of CVD risk factors, in particular hypertension, in a population of predominantly low-SES, African American patients with type 2 diabetes known to be at risk for poor health literacy.

CHAPTER 2

ABSTRACT

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Patients with Type 2 Diabetes at Grady Hospital
By Lara Roberson

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CONCLUSIONS: Patient empowerment interventions may have short-term benefits. However, further studies will be needed to determine whether benefits are sustained, and the specific mechanisms that are responsible.

INTRODUCTION

The National Library of Medicine defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [31, 32] . Low and inadequate health literacy is recognized as a barrier to obtaining satisfactory health care and is associated with poorer and sometimes even adverse health outcomes. Functional health literacy is essential to understanding prescription dosing, health instructions, appointment slips, etc. [25]. It has also been observed that people with the lowest health literacy (correlating to less than [≤] third grade level) utilize health services more frequently and have poorer health outcomes than those with adequate health literacy [24]. In addition, patients with inadequate health literacy have greater difficultly participating in their own health care process, a key component of managing chronic diseases [31]

Patient empowerment is seen as a key tool to increasing patient knowledge and participation in health care processes and achievement of health. With chronic diseases, patients manage up to 95% of their own care as only a tiny fraction of their time is spent within clinical facilities or with providers [33]. In diabetes care, patients manage their own diet planning, medication, blood-glucose monitoring, and physical activity.

Studies have previously examined the effects of patient literacy on health management, participation, disease knowledge, and clinical outcome. Individualized goal setting, a component of patient empowerment, has also been shown to be effective in vulnerable populations in increasing participant knowledge and participation in the disease management process [34]. However, there are few studies which examine whether an increase in patient knowledge over a short-term leads to better clinical outcomes and how baseline *health literacy*, specifically, modifies this relationship.

The purpose of this study is to test the efficacy of a patient empowerment intervention among those with differing levels of health literacy and to examine the extent to which baseline health literacy is able to mitigate the effect(s) of generally poor circumstances in chronic disease management. Using data from a study of low-income patients with diabetes attending a large, urban hospital in Atlanta, Georgia, I will explore the question of whether individualized counseling, conducted by trained research coaches (while patients are waiting to see their primary care physician) improves hypertension control, diabetes knowledge, and other clinical outcomes through the lens of health literacy.

METHODS

Null Hypothesis

There will be no statistically significant differences in change in hypertension, other cardiovascular risk factor control indicators, or patient knowledge of diabetes from study beginning to end between participants randomized to control and intervention groups. In addition, baseline level of health literacy does not modify the relationship between treatment intervention and change in systolic blood pressure (SBP).

Setting and Study Participants

From December 1, 2008 to November 9, 2009, adult patients with diabetes attending the Medical Outpatient Clinic at the Grady Health System (GHS) – a major metropolitan hospital that delivers care to 5,532 adults with diabetes in the Atlanta Metropolitan area – were recruited to participate in the Patient Empowerment to Improve Hypertensive Care (PEIHiC) study. PEIHiC is a randomized controlled trial intended to assess change in blood pressure levels, medication and appointment adherence, perceived patient empowerment, and patient knowledge in patients with diabetes, examining the effects of a 'pre-visit patient coaching session' intervention to set blood pressure management goals and apply key strategies to achieve these goals. Emory IRB approval was received for this study.

Inclusion Criteria

Pre-specified inclusion criteria were applied and informed selection of participants with the following characteristics:

- Type 2 diabetes,
- At least two GHS Medical Clinic visits in the year prior, and
- Systolic blood pressure (SPB) greater than or equal (≥) to 130 mmHg.

Eligible participants were selected from among those waiting in the GHS Medical Clinic to see a primary care physician. Patients were informed about the study and asked to participate in order of arrival at the clinic.

Exclusion Criteria

The exclusion criteria for participation in PEIHiC included the following:

- language barriers that would make communication difficult,
- mental impairment that precludes informed participation,
- visual or physical impairments that prohibited the patient from participating fully in the study, and
- lack of access to a phone number that could be used for follow up communication.

Study Procedures

After obtaining consent, patient details were entered into the study database and randomly assigned to either the intervention or control group according to their Medical Record Number (MRN). MRN is a computer-generated random assignment patient identifier; those with MRN’s ending in an even number were assigned to the control group, and those with an odd MRN were assigned to the intervention. All study participants then responded to survey questions, which was interviewer administered. The survey included questions assessing demographics, patient knowledge of diabetes and blood pressure, and perceived barriers to exercise as well as knowledge of long term benefits of diabetes care. Over the two-year period after enrollment, patients were given follow-up surveys at six-month intervals. In the first follow-up survey, in addition to reassessing patient knowledge, patient health literacy was examined using the Rapid Estimate of Adult Literacy in Medicine (REALM). The REALM is a word recognition test including 66 health-related words and is commonly used to assess patient literacy in medical settings [25, 26, 31, 35]. The REALM survey takes approximately 3 minutes to administer and consists of the patient reading aloud from a list of increasingly difficult medical terms. Patients who reported being unable to see the chart were excluded from the REALM portion of the survey.

Individuals randomized to the control group (n=172) received care as usual in the clinic setting. Individuals randomized to the intervention (n=162) received coaching sessions in which they were given a roadmap displaying BP values over time, a communication card listing questions patients should feel comfortable to ask their providers about hypertension, and personalized feedback on BP readings. Coaching was conducted by trained research interviewers and lasted approximately 15-20 minutes per session in the patient room while waiting for the physician. During every visit to the GHS Medical Clinic, intervention subjects received a coaching session until the study concluded on December 16, 2010.

Measures

Primary Outcomes

The primary outcomes measured in this study were change in systolic and diastolic blood pressure from baseline in control and intervention groups. Blood pressure was measured by the research interviewer using an automated sphygmomanometer approximately 5 minutes following triage by nurses. Blood pressure used for study analysis represented only one single measurement. Blood pressure was taken at each clinic visit with patients in a comfortable seated position. For this study, only baseline blood pressure and last measured blood pressure were used for analysis. Blood pressure was treated as a continuous variable. Change in systolic blood pressure was coded as ΔSBP and defined by SBP at last clinic visit minus SBP at start date.

In addition, to determine the difference in management of diabetes between control and intervention groups, we measured intermediate biochemical outcomes including baseline and ending values of total cholesterol (TC), low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides (TG), body mass index (BMI), and glycated hemoglobin (HbA1C). These values were gathered from patient records and labs at first visit and again at last recorded clinic visit prior to 12/16/2010. All biochemical indicators were measured using standard Grady Medical Clinic protocols and were treated as continuous variables. BMI was calculated using height and weight and reported in kg/m^2, and also treated as a continuous variable.

Secondary Outcomes

A secondary focus of this investigation included the psychosocial and behavioral outcomes. Improvements from baseline in patient knowledge of diabetes, perceived exercise barriers, and better awareness of long-term care benefits were assessed between groups. The patient knowledge questionnaire included questions requiring patients to correctly identify normal HbA1C levels, what their sugars should be prior to eating, and normal SBP and DBP values. It was scored out of 5 points, with 0 being the lowest. Exercise barriers were assessed using a Likert scale ranking how often individuals have trouble getting enough exercise in various situations with 1 being "Rarely" and 5 being "Often". The lowest possible score was 5 and maximum was 25, with lower scores correlating to less reported barriers. Long term care benefits were also assessed using a Likert scale. Participants were asked how strongly they agreed with the statements "Taking the best possible care of diabetes will delay or prevent…" followed by various complications of diabetes (eye problems, kidney problems, foot problems, etc.). A score of 1 correlated with "Strongly disagree" and a score of 5 correlated with "Strongly agree". The lowest possible score was 5 and maximum was 25, with higher scores indicating patient was better able to identify long-term care benefits.

Covariates

The covariates measured in this study included:

AGE: Treated as continuous for this study with a range of eligibility from 18-99.

SEX: Categorized as dichotomous with male=0, female=1.

RACE: Survey included categories for Black, White, Hispanic, Native American, Asian or Pacific Islander, Arabic, and Other. For data analysis, we categorized race/ethnicity into Black, White, and Other due to sparse data amonst minority groups.

MARITAL STATUS: The survey included categories for: “Never married”, “Married”, “Separated/Divorced”, and “Widowed”. We re-categorized marital status into a 3-level variable with “Separated/Divorced” and “Widowed” as one category, while “Never married” and “Married” remained independent categories.

EDUCATION: The survey included categories for: “≤8th grade”, “Some high school”, “High school graduate or GED”, “Some college or technical school”, “College graduate (bachelor’s degree)”, and “Graduate degree”. We re-categorized education level to “Did not graduate high school” (combining “≤8th grade” and “Some high school”), “High school graduate or GED”, and “College” (combining “Some college”, “College graduate” and “Graduate degree”) due to sparse data.

EMPLOYMENT: The survey included categories for: “Working full-time, 35 hours or more a week”, “Working part-time, less than 35 hours a week”, “Unemployed and looking for work”, Unemployed and NOT looking for work”, “Homemaker”, “In school”, “Retired, disabled, or not able to work”, and “Other”. We re-categorized it into a 3 level variable with “Work” combining “Working full-time, 35 hours or more a week” and “Working part-time, less than 35 hours a week”; “Unemployed/Other” including both “Unemployed and looking for work”, “Unemployed and NOT looking for work”, “Homemaker”, “In school”, and “Other” ; while “Retired/Disabled/Unable” remained its own category.

HOUSEHOLD INCOME: The survey included categories for: “Less than $5,000”, “$5,000-$9,999”, “$10,000-$14,999”, “$15,000-$19,999”, “$20,000-$29,999”,

“$30,000-$39,999”, “$40,000-$49,999”, “$50,000-$59,999”, “$60,000-$69,999”, “70,000 and over”. We re-categorized it into to 5 levels including “Less than $5,000”, “$5,000-$9,999”, “$10,000-$14,999”, “$15,000-$19,999”, “$20,000 and over” due to the majority of the sample being in the lowest groups.

INSURANCE STATUS: The survey included categories for the insurance plan an individual had in the last 12 months: “An individual plan-member pays premium”, “A group plan through an employer-the employer pays all or part of the premium”, “U.S. Governmental Health Plan”, “Medicaid”, “Medicare”, “I have not had an insurance plan in the past 12 months.” We re-categorized it into a 3-level variable, “Private/Group” included “An individual plan-member pays premium” and “A group plan through an employer-the employer pays all or part of the premium”; “Government” included “U.S. Governmental Health Plan”, “Medicaid”, and “Medicare”, and “No Insurance” for those reporting “I have not had an insurance plan in the past 12 months.”

SMOKING: Smoking status was not asked on the original survey. It was ascertained after the study concluded (2/15/2011) through patient medical record inquiry. The categories included “Current Smoker”, “Never Smoked”, and “Quit”. “Current Smoker” and “Quit” were combined into a single category to make a dichotomous “Ever smoked/Never smoked” variable.

CLINIC VISITS: Clinic visits were recorded each time the participant came to the Grady Medical Clinic. This number was summed for the entire length of follow up. It was treated as continuous for analysis.

PEIHIC VISITS: PEIHiC visits were recorded each time the participant came to the Grady Medical Clinic AND was contacted by a study coach. This number was summed for the entire length of follow up. It was treated as continuous for analysis.
HEALTH LITERACY: Health literacy was measured at the 6-month follow-up using the REALM survey. Raw scores were calculated by summing correctly pronounced words which add up to a total of 66. The raw scores can be converted into four reading grade levels: Level I, third grade or less (0-18); Level II, fourth to sixth grade (19-44); Level III, seventh to eighth grade (45-60); and Level IV, ninth grade and above (61-66).

Statistical Analysis

Continuous variables (e.g. age, biochemical variables, etc.) were assessed for normality by examining histograms, examining box plots, skewness, and deviation. Categorical variables were described using frequency distributions, and continuous variables were described using means and standard deviations for the entire study sample and by intervention assignment. Differences relating to study arm assignment in these variables between groups was evaluated using chi-square tests for categorical variables and independent t-tests for continuous variables. Fisher's exact chi-squares were reported where less than 5 were expected in a category. For the t-tests, pooled p-values were reported when the Folded-F test was satisfied and the variances were equal. When variances were unequal, Satterthwaite p-values were reported. A p-value of less than 0.05 was considered statistically significant.

Intervention effects were evaluated using paired t-tests for the main outcome variable (blood pressure) and each of the secondary outcomes (intermediate biochemical outcomes, patient knowledge of diabetes, perceived exercise barriers, awareness of long-term care benefits). Available data from every participant who was randomized were included in the analysis using linear regression models. A series of linear regression analyses were conducted to explore potential mediators (Health Literacy, Length of follow-up, Medical Clinic Visits, etc.) of the intervention's effects on blood pressure. These potential mediators are more proximal intermediate outcomes associated with the intervention and are hypothesized to serve as mechanisms through which the intervention's effects on the ultimate outcome are achieved. The analyses are conducted by entering the potentially mediating variables into the regression model containing the treatment variable and observing the patterns of attenuation in treatment effects. All analyses were conducted using the statistical software programs SPSS (PASW Statistics 18, Polar Engineering and Consulting) and SAS (version 9.2, Cary, NC). In these analyses, p-values <0.05 were considered indicative of statistical significance.

RESULTS

Participant Characteristics

Participant accrual and enrollment are shown in the PEIHiC Study flow chart (Figure 1). The study assessed 529 individuals for eligibility into the study; 195 people were excluded (24 individuals did not meet inclusion criteria, 18 had missing MRN for randomization, and 171 refused participation). Finally, 334 individuals were randomized to the intervention (N=162) and control groups (N=172). Out of these trial participants, data from 38 individuals (23 controls, 15 intervention subjects) were excluded for not having follow-up data. In total, 296 individuals (149 controls, 147 intervention subjects) were included in this study analysis.

The distribution of baseline demographic characteristics of the study population between treatment groups (intervention versus control) shows balanced group assignment, and is shown in Table 2A (there were no significant differences noted, $p \geq 0.05$ significance level). The sample was 72.6% female and 96.3% African American, with a mean age of 58.5 years. Fifty percent (50%) of individuals had some missing information for one or more of the following socio-demographic variables: educational status, employment, insurance, household income, and/or marital status. On average, respondents were non-working (83.0%), on government insurance or uninsured (47.6%), poor (56.4% had annual household incomes less than $10,000), and un-married (77.8%). Smoking information was missing for 76% of individuals. Of those that reported smoking status, approximately half reported current or past smoking and half reported never smoking (48.9% and 51.0%, respectively).

The distribution of baseline clinic measures of the study population by intervention assignment is shown in Table 2B and shows no significant differences between intervention and control study groups. Across all study participants, mean HbA1c was 7.51±8.23% and average duration of diabetes was 11.34±8.23 years. The sample had a mean SBP of 153.61±19.61 mmHg. The mean DBP was 81.85±13.37 mmHg.

At baseline, the distribution of knowledge measures among study population by intervention assignment is shown in Table 2C. The mean REALM generated health literacy score was 48.53±19.34, which corresponds with a 7th-8th grade reading level and is considered inadequate health literacy. The mean diabetes health knowledge score was 1.86±1.52 (out of 5 possible). The mean exercise barriers score reported was 19.38 ±4.04 (out of 25 possible). The mean knowledge of long term complications score was 15.05 ± 3.17 (out of 25 possible). None of these measures were significantly different between control and intervention participants.

The average number of clinic visits for the duration of the trial was 4.38±2.08 for all participants. In the control group, 43 of 76 individuals completing the enrollment survey (56.8%) completed the 6-month follow-up survey. In the intervention group 47 of 73 individuals (64.4%) completed the 6-month follow-up. This was not a statistically different between the groups. Compared with those with baseline information only, persons who completed the 6-month follow-up tended to be female (75.56%), had a shorter mean duration of diabetes (10.90±8.05), and had a higher mean number of medical clinic visits (4.78±1.79). We were not able to ascertain whether baseline literacy differed because it was measured at the 6-month follow up.

Treatment Effect on Clinical and Behavioral Outcomes

Table 3A displays the mean changes in SBP, DBP, BMI, Cholesterol profile, and HbA1C from study beginning to the last recorded visit date. In the intervention arm, the primary outcome variable (SPB) decreased by a mean of 13.23 mmHg (±29.42). In the control arm, SBP decreased by 12.22 mmHg (±31.86). Both pre-post reductions were statistically significant with reported p-values of 0.0003 and 0.0015 respectively. There were no significant between-group differences in SBP change (p=0.8434). Significant DBP reductions were also shown in both intervention and control participants (-6.46±20.76 and -4.37±18.94) ($p<0.05$ for both) with no significant difference between groups (P=0.5307). Participants also experienced fluctuations in glycemic control (HbA1C) – the intervention group subjects, for example, experienced an increase of 0.77±2.14 (p=0.0305) while HbA1c declined in control arm participants (-0.33±1.84 (p=0.3911)). While not significant, there was a trend toward increases in TC, LDL, TG, and BMI, and a decrease in HDL among control subjects. The intervention group experienced an opposite pattern (decreases in TC, LDL, TG, BMI and an increase in HDL from baseline). There were no significant between-group differences in change of any of these clinic variables.

Table 3B displays the mean changes from baseline in knowledge of diabetes, reported exercise barriers, and recognition of long-term care benefits. At the 6-month follow up there were no significant changes in knowledge, reported exercise barriers, and recognition of long-term benefit scores (p>0.05) in either treatment group.

Potential Mediators of Intervention Effect on Systolic Blood Pressure

Table 4 presents the overall p-values for each model and the least squares means for treatment groups. Linear regression models to investigate whether the following possible mediators influenced the trial outcomes:

- Treatment Assignment Only
- Treatment Assignment +Age + Sex + Smoke + Duration of Diabetes
- Treatment Assignment + Length of Follow-up
- Treatment Assignment + Length of Follow-up + Treatment Assignment*Length of Follow-up
- Treatment Assignment +Realm
- Treatment Assignment + Medical Clinic Visits
- Treatment Assignment + PEIHiC Visits
- Realm Score Only
- Medical Clinic Visits Only
- PEIHiC Visits Only

None of the models attained statistical significance in the overall model, and none of the mediating variables attained statistical significance in their parameter estimates. While not significant, adjusting for age, sex, smoking, and duration of diabetes increased the change in SBP from -13.23 to -15.30 in the treatment group and attenuated the reduction from -12.22 to -9.12 in controls (p=0.5280). In addition, adding health literacy into the model with treatment group attenuated the change across groups (-11.39 in intervention participants, -9.87 in control participants) (p=0.5706). Although the treatment-only model did not attain statistical significance, models were run to assess if other potential reasons mediated the overall SBP decrease. Health literacy, number of medical clinic visits, and number of PEIHIC visits were not predictive of SBP decrease independent of treatment group.

DISCUSSION

The purpose of this study was to test whether a patient empowerment intervention improves hypertension control in type 2 diabetes patients in an underserved publicly-funded hospital outpatient service. We examined changes in blood pressure, other cardiovascular risk factors, and patient knowledge of diabetes over 6 months in participants randomized to control and intervention groups and compared between-group findings. In addition, baseline health literacy was examined as a possible treatment effect modifier.

The Primary Intervention

There were no statistically significant differences between treatment groups in any of the clinical or knowledge measures at 6-month follow-up. However, there were overall reductions in SBP and DBP pre- and post-intervention, both of which were very significant. In addition, the intervention group experienced small decreases in BMI, total cholesterol, LDL cholesterol, and triglycerides, while control arm participants showed a non-significant opposite trend. A statistically significant increase in HbA1C was reported in the intervention group. It was not clear why HbA1C went up in this group, but we hypothesize that shifting the focus from glucose control to blood pressure control may have led to multiple physician and patient-level changes favoring blood pressure control over glucose control. Examples of this are reductions in glucose-lowering medication prescribed by physicians, lower glucose-lowering medication adherence by patients (potentially in favor of blood-pressure lowering medications), and overall changes in lifestyle, such as choosing low-salt foods over low-sugar foods.

There were no significant changes from baseline in knowledge measures in either controls or interventions. We propose that a combination of volunteer bias and study effects were associated with benefits demonstrated in both groups, limiting the size of between-group differences. Each of these is explored in greater detail individually.

Volunteer bias was present in our study, as nearly one-third (N=171) of those contacted refused to participate. The literature has shown that those who choose not to participate in studies often have lower self-reported health, are less educated, and have a less active social life [36]. This suggests that those who are likely to have benefited most from our intervention may have chosen not to participate. In our study, those that joined the study, both in control and intervention arms, were likely concerned about their diabetes and blood pressure and were motivated to improve their self-management and reduce hypertension. This explanation is supported by the fact there was no difference in the change scores for both BP variables and knowledge variables between groups, indicating the education part of the intervention was unlikely to have had substantial effect.

Study effects may have also played a role in diminishing between-group differences. Research has shown that doctors communicate more poorly with minority patients and that doctor-patient communication has received little attention as a cause of health disparity [37]. However, there is evidence to suggest that providing study data to physicians of study participants had an intervention effect on mean HBA1C, cholesterol, SBP, and DBP, especially in patients in high-risk groups [38]. In our study, it seems plausible that simply by being aware of the study, physicians made an effort to communicate and intensified treatment for all study participants.

Health Literacy

In our study, health literacy was measured at the 6-month follow-up interview. It was done this way because adding to the baseline survey would have made the survey too time-intensive to complete in a single 15-20 minute session (and was deemed burdensome to patient participants). This reduced the number of individuals with data for the REALM (N=61) and severely limited our ability to assess the impact of health literacy. In addition, the people who did complete the REALM portion of the survey, while not different in baseline demographic characteristics, may have had different health literacy than those who were lost to follow up or chose not to answer. In Wolf et al.'s study, 40% of patients with poor literacy skills admitted feelings of shame and discomfort with literacy screening procedures [26]. In addition 2/3rds of these patients in Wolf et al.'s study admitted they had never divulged their difficulty reading to their spouses. Patients choosing not to answer the REALM in our study likely had lower health literacy, thus our study lost important information for those most at risk.

Loss to Follow-up

Loss to follow-up was significant in this study. Due to poor retention after the 6-month survey, data were only analyzed up to 6 months. Our retention rate was

60.4% for those who completed the 6-month survey. This reduced our power to find significant changes between groups. In addition, important information was lost about the individuals who dropped out. Future efforts to replicate this study should examine techniques to increase retention of study participants.

Strengths and Limitations

Strengths

This study also had a number of important strengths. It utilized a unique sample representing a minority and socioeconomic group at increased risk, including mostly African American, poor, uninsured or government insured individuals, with limited support networks (nearly 80% unmarried). Measurements for biochemical data used validated tools and strict protocols. A combination of social, demographic, and biochemical data was collected allowing a comprehensive evaluation of care management and risk. The statistical methods employed were appropriate to account for biases including controlling for differential length of follow up, and evaluation of characteristics at baseline between study arms. Lastly, this study was innovative. We attempted to identify the mediators of change that were responsible for change in the biochemical profiles of our study participants. While unsuccessful, it is useful in stimulating thought for what other factors may be at work in changing the profiles. Lastly, the intervention was conducted in a very real-life scenario: a busy clinic where barriers to access are high, low awareness, low penetration, and poor adoption of change behavior are pervasive.

Limitations

This study also has its limitations. The small sample size (N=296) was possibly underpowered to show true effects of an intervention of this nature – with a modest effect size, either a large sample size or a long duration of follow-up would be required to demonstrate effectiveness. In addition, retention was low at 6-month follow-up; however, we noted that there were no significant differences between completers and non-completers.

In this analysis, we did not report medication use pre- and post-study. As this is a patient empowerment study, it was assumed interventions and controls would be on the same amount of medication at baseline. At follow-up, we would have expected changes in medications prescribed and used in the intervention group at least, as patients were empowered to question their physicians about medications. However, there may have been a universal intensification of medication of patients with diabetes at the clinic over the study period due to heightened physician awareness. This may have caused contamination bias of the control group, who experienced heighted care even though they were assigned to receive only standard of care. Appropriate intensification of medication therapy by clinicians is essential for patients to reach recommended targets for conditions such as hypertension, hyperglycemia, and hyperlipidemia [39]. Low rates of clinician responsiveness or “clinical inertia” is common in primary care settings [40]. In a previous study of overcoming clinical inertia, only 21% of clinic visits met recommended intensifications at baseline [40]. However, at both 6 month and 1 year follow-up, all heath care providers increased rates of appropriate intensification, regardless of intervention group [40]. The changes between groups were not seen until after 1 year, when intervention physicians continued to increase intensification, and control groups did not.

We did not measure proximal behavior changes such as diet, exercise, medication adherence (which may have changed significantly), or smoking cessation. However, previous studies suggest that up to 10–30% of patients with type 2 diabetes are reported to stop taking prescribed medicinal regimens within 1 year of diagnosis [41]. In addition, either poor adherence or lack of treatment intensification was found for 53–68% of all patients who were not meeting the ADA guidelines for managing microvascular and neuropathic complications of diabetes [41]. While we measured health literacy, other barriers to adherence, such as side effects, medication costs, and regimen complexity were not measured and are recognized as challenges to increasing medication adherence [42].

We were unable to completely blind participants to their intervention group because this was a patient empowerment study. In addition, research coaches were not blinded as they gave the intervention. Lack of blinding of clinicians can result in systematic differences in care provided, or performance bias [43]. In addition, lack of blinding research interviewers who measure the outcomes of interest, could have lead to ascertainment bias [43].

Summary

This study was meant to test whether a patient empowerment intervention in a busy urban hospital setting with primarily low income, African American patients would be effective in controlling hypertension. While hypertension was reduced in the population, both those who received treatment and those who did not, benefited. Patient knowledge did not change from baseline, which may indicate that patient knowledge is not a perfect proxy measurement of patient empowerment. We were unable to show mediation of effects by baseline health literacy. Loss-to-follow up was a major barrier and limited the scope of analyses. However, our implementation of the study in a busy urban clinic was able to teach a lesson in real world application of research trials.

REFERENCES

1. *National Diabetes Fact Sheet, 2011*. [cited 2011 3/20/2011]; Available from: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf.
2. *Executive summary: Standards of medical care in diabetes--2010.* Diabetes Care, 2010. **33 Suppl 1**: p. S4-10.
3. *Standards of medical care in diabetes--2011.* Diabetes Care, 2011. **34 Suppl 1**: p. S11-61.
4. *Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group.* BMJ, 1998. **317**(7160): p. 703-13.
5. *Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group.* Lancet, 1998. **352**(9131): p. 837-53.
6. *Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group.* Lancet, 1998. **352**(9131): p. 854-65.
7. Colhoun, H.M., et al., *Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial.* Lancet, 2004. **364**(9435): p. 685-96.
8. Ali, M.K., K.M. Narayan, and N. Tandon, *Diabetes & coronary heart disease: current perspectives.* Indian J Med Res, 2010. **132**(5): p. 584-97.
9. RB, G., et al., *Cardiovascular events and their reduction with pravastatin in diabetic and glucose-intolerant myocardial infarction survivors with average cholesterol levels: subgroup analyses in the cholesterol and recurrent events (CARE) trial. The Care Investigators.* Circulation, 1998. **98**: p. 2513-9.
10. Gucciardi, E., P.L. Smith, and M. DeMelo, *Use of diabetes resources in adults attending a self-management program.* Patient Education and Counseling, 2006. **64**: p. 322-330.
11. Anderson, R., et al., *Evaluating a problem-based empowerment program for African Americans with diabetes; results of a randomized controlled trial.* Ethnicity & Disease, 2005. **15**(Autumn): p. 671-678.
12. Brown, S.A., *Interventions to promote diabetes self-management: state of the science.* Diabetes Educ, 1999. **25**(6 Suppl): p. 52-61.
13. Norris, S.L., M.M. Engelgau, and K.M. Narayan, *Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials.* Diabetes Care, 2001. **24**(3): p. 561-87.

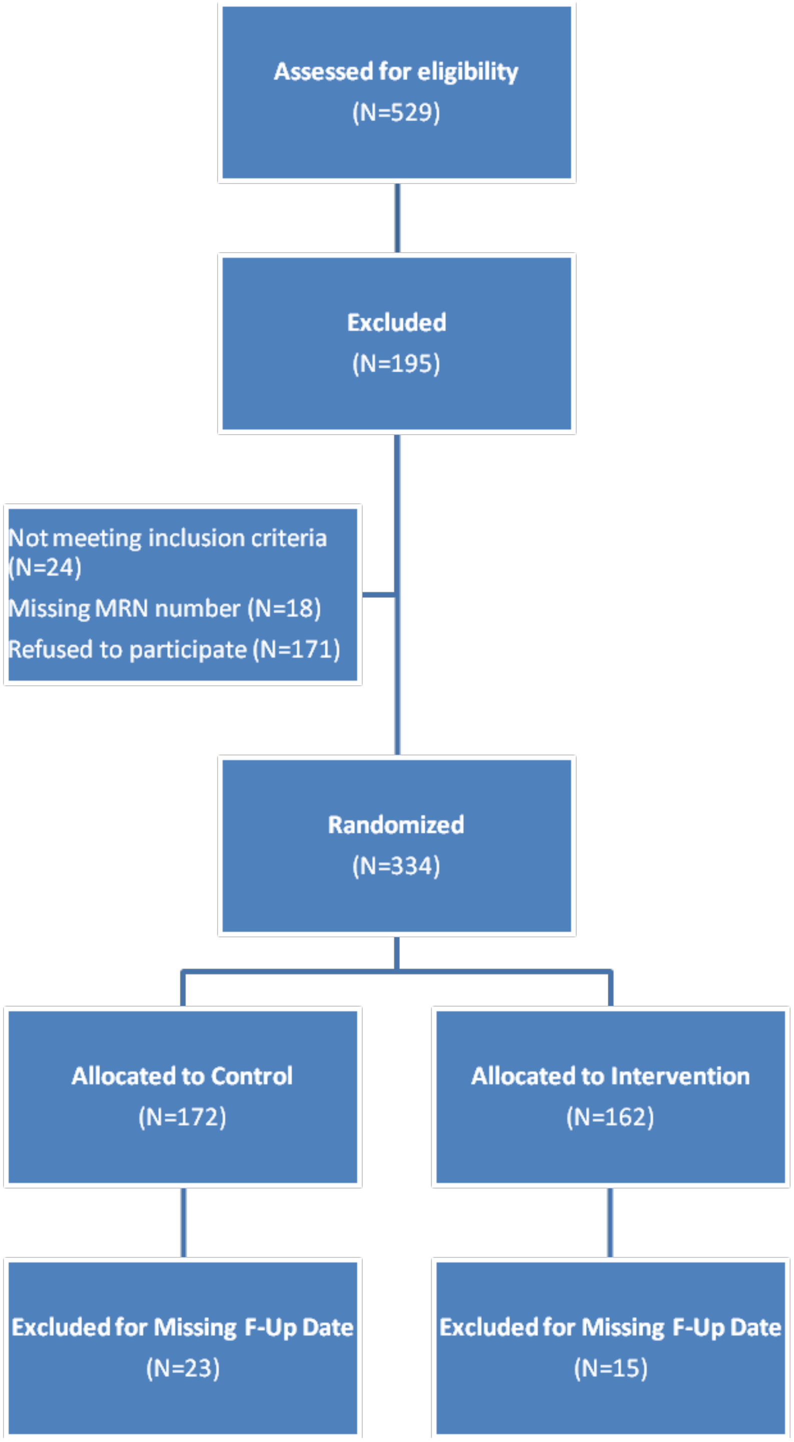
14. Saydah, S.H., J. Fradkin, and C.C. Cowie, *Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes.* JAMA, 2004. **291**(3): p. 335-42.
15. JS, C., P. JA, and M. A, *Non-insulin-dependent diabetes mellitus in minorities in the united states.* Ann Intern Med, 1996. **125**: p. 221-232.
16. Bruce, D.G., et al., *Diabetes education and knowledge in patients with type 2 diabetes from the community: the Fremantle Diabetes Study.* J Diabetes Complications, 2003. **17**(2): p. 82-9.
17. Eakin, E.G., et al., *Reaching those most in need: a review of diabetes self-management interventions in disadvantaged populations.* Diabetes Metab Res Rev, 2002. **18**(1): p. 26-35.
18. Warsi, A., et al., *Self-management education programs in chronic disease: a systematic review and methodological critique of the literature.* Archives of Internal Medicine, 2004. **164**(15): p. 1641-9.
19. *Executive summary: standards of medical care in diabetes--2011.* Diabetes Care, 2011. **34 Suppl 1**: p. S4-10.
20. Kemper, P., et al., *A study of the level of knowledge about diabetes management of low-income persons with diabetes.* J Community Health Nurs, 2005. **22**(4): p. 231-9.
21. Peyrot, M., et al., *Access to diabetes self-management education: results of national surveys of patients, educators, and physicians.* Diabetes Educ, 2009. **35**(2): p. 246-8, 252-6, 258-63.
22. Virtanen, H., H. Leino-Kilpi, and S. Salantera, *Empowering discourse in patient education.* Patient Educ Couns, 2007. **66**(2): p. 140-6.
23. Kettunen, T., et al., *Developing empowering health counseling measurement. Preliminary results.* Patient Educ Couns, 2006. **64**(1-3): p. 159-66.
24. Barrett, S.E. and J.S. Puryear, *Health literacy: improving quality of care in primary care settings.* J Health Care Poor Underserved, 2006. **17**(4): p. 690-7.
25. Baker, D.W., *The Meaning and the Measure of Health Literacy.* Journal of General Internal Medicine, 2006. **21**(8): p. 878-883.
26. Wolf, M., et al., *Patients' Shame and Attitudes Toward Discussing the Results of Literacy Screening.* Journal of Health Communication, 2007. **12**(8): p. 721-732.
27. Department of Pharmacy Practice, A.U.S.o.P., Auburn, Alabama and S.o.P. Division of Pharmacotherapy, Univeristy of North Carolina, Chapel Hill, North Carolina.
28. Davis, T.C., J. Gazmararian, and E.M. Kennen, *Approaches to improving health literacy: Lessons from the field.* Journal of Health Communication, 2006. **11**(6): p. 551-554.
29. Hill-Briggs, F. and A.S. Smith, *Evaluation of diabetes and cardiovascular disease print patient education materials for use with low-health literate populations.* Diabetes Care, 2008. **31**(4): p. 667-71.
30. Wolff, K., et al., *The Diabetes Literacy and Numeracy Education Toolkit (DLNET): materials to facilitate diabetes education and management in patients with low literacy and numeracy skills.* Diabetes Educ, 2009. **35**(2): p. 233-6, 238-41, 244-5.

31. Gazmararian, J.A., et al., *Health literacy and knowledge of chronic disease.* Patient Education and Counseling, 2003. **51**(3): p. 267-275.
32. Jeppesen, K.M., J.D. Coyle, and W.F. Miser, *Screening Questions to Predict Limited Health Literacy: A Cross-Sectional Study of Patients With Diabetes Mellitus.* The Annals of Family Medicine, 2009. **7**(1): p. 24-31.
33. Sprague, M.A., J.A. Shultz, and L.J. Branen, *Understanding patient experiences with goal setting for diabetes self-management after diabetes education.* Fam Community Health, 2006. **29**(4): p. 245-55.
34. Wallace, A.S., et al., *Literacy-appropriate educational materials and brief counseling improve diabetes self-management.* Patient Educ Couns, 2009. **75**(3): p. 328-33.
35. Gazmararian, J.A., et al., *Health literacy and knowledge of chronic disease.* Patient Educ Couns, 2003. **51**(3): p. 267-75.
36. van Heuvelen, M.J., et al., *Differences between participants and non-participants in an RCT on physical activity and psychological interventions for older persons.* Aging Clin Exp Res, 2005. **17**(3): p. 236-45.
37. Ashton, C.M., et al., *Racial and ethnic disparities in the use of health services: bias, preferences, or poor communication?* Journal of General Internal Medicine, 2003. **18**(2): p. 146-52.
38. Hiss, R.G., et al., *Comprehensive evaluation of community-based diabetic patients: effect of feedback to patients and their physicians: a randomized controlled trial.* Diabetes Care, 2001. **24**(4): p. 690-4.
39. Schmittdiel, J.A., et al., *Why don't diabetes patients achieve recommended risk factor targets? Poor adherence versus lack of treatment intensification.* Journal of General Internal Medicine, 2008. **23**(5): p. 588-94.
40. Ziemer, D.C., et al., *An intervention to overcome clinical inertia and improve diabetes mellitus control in a primary care setting: Improving Primary Care of African Americans with Diabetes (IPCAAD) 8.* Archives of Internal Medicine, 2006. **166**(5): p. 507-13.
41. Heisler, M., et al., *Study protocol: the Adherence and Intensification of Medications (AIM) study--a cluster randomized controlled effectiveness study.* Trials, 2010. **11**: p. 95.
42. Heisler, M., et al., *When more is not better: treatment intensification among hypertensive patients with poor medication adherence.* Circulation, 2008. **117**(22): p. 2884-92.
43. Boutron, I., et al., *Methods of blinding in reports of randomized controlled trials assessing pharmacologic treatments: a systematic review.* PLoS Med, 2006. **3**(10): p. e425.
44. Sigurdardottir, A.K. and H. Jonsdottir, *Empowerment in diabetes care: towards measuring empowerment.* Scand J Caring Sci, 2008. **22**(2): p. 284-91.

FIGURES

Figure 1

PEIHiC Study Flow Chart



TABLES

Table 1

Loss to Follow-up

	Control Group, No (%)	Intervention Group, No (%)	P
Baseline Measures Taken	N=149	N=147	0.8670
Baseline/Accrual Questionnaire Completed	76 (100.00)	73 (100.00)	
1st Follow-Up/2nd Questionnaire Completed	43 (56.78)	47 (64.38)	
2nd Follow-Up/3rd Questionnaire Completed	27 (35.52)	23 (31.51)	
3rd Follow-up/4th Questionnaire Completed	3 (3.95)	4 (5.48)	

Table 2A

Baseline Characteristics of Control and Intervention Subjects
Demographic Variables

Characteristic	**Control Group (N= 149)**	**Intervention Group (N=147)**	**Total (N=296)**	**P-Value**
DEMOGRAPHICS				
Race				0.5054
African American	142 (95.30)	143 (97.28)	285 (96.28)	
White	3 (2.01)	3 (2.04)	6 (2.03)	
Other	4 (2.68)	1 (0.68)	5 (1.69)	
Sex				0.8401
Male	40 (26.85)	41 (27.89)	81 (27.89)	
Female	109 (73.15)	106 (72.11)	215 (72.64)	
Age, mean [SD], y	58.75 (9.18)	58.22 (10.58)	58.49 (9.89)	0.6515
Educational Status				0.9385
<High School	31 (20.81)	27 (18.37)	58 (19.59)	
High School Graduate or GED	22 (14.77)	26 (17.69)	48 (16.22)	
Some College	20 (13.42)	17 (11.56)	37 (12.50)	
College Graduate Or Higher	3 (2.01)	3 (2.04)	6 (2.03)	
Missing	73 (48.99)	74 (50.34)	147 (49.66)	
Insurance status				0.8947
Government	40 (26.84)	37 (25.17)	77 (26.01)	
Private/Group	4 (2.68)	3 (2.04)	7 (2.36)	
Uninsured	33 (22.15)	31 (21.09)	64 (21.62)	
Missing	72 (48.32)	76 (51.70)	148 (50.00)	

Employment				0.2880
Full Time/Part Time	10 (6.71)	17 (11.56)	27 (9.12)	
Unemployed/Other	13 (8.72)	7 (4.76)	20 (6.76)	
Retired/Disabled	53 (35.57)	49 (33.33)	102 (34.46)	
Missing	73 (48.99)	74 (50.34)	147 (49.66)	
Household Income ($)				0.3788
< 5,000	21 (14.09)	20 (13.61)	41 (13.85)	
5000-9999	16 (10.74)	18 (12.24)	34 (11.49)	
10,000-14,999	16 (10.74)	7 (4.76)	23 (7.77)	
15,000-19,999	5 (3.36)	9 (6.12)	14 (4.73)	
≥20,000	12 (8.05)	9 (6.12)	21 (7.09)	
Missing	79 (53.02)	84 (57.14)	163 (55.07)	
Marital Status				0.9528
Single/Never married	21 (14.09)	20 (13.61)	41 (13.85)	
Married/Living with Partner	18 (12.08)	15 (10.0)	33 (11.15)	
Divorced/Widowed	36 (24.16)	38 (25.85)	74 (25.00)	
Missing	74 (49.66)	74 (50.34)	148 (50.00)	
Smoking*				0.3343
Current or Past Use	21 (14.09)	26 (17.69)	47 (15.88)	
Never	29 (19.46)	20 (13.61)	49 (16.55)	
Missing	99 (66.44)	101 (68.71)	200 (67.57)	

Table 2B

Baseline Characteristics of Control and Intervention Subjects
Clinic Variables

Characteristic	**Control Group (N= 149)**	**Intervention Group (N=147)**	**Total (N=296)**	**P**
Body Mass Index, mean [SD], (kg/m^2)	N=136	N=126	N=262	
	34.85 (7.61)	34.92 (8.98)	34.89 (8.28)	0.9456
Blood Pressure, mean [SD], mmhg				
Systolic	N=74	N=71	N=145	0.9491
	153.70 (19.81)	153.50 (19.56)	153.61 (19.61)	
Diastolic	N=74	N=70	N=144	
	81.58 (11.67)	82.14 (15.04)	81.85 (13.37)	0.8034
Total Cholesterol, mean [SD]	N=57	N=53	N=110	
	161.10 (42.88)	171.50 (51.85)	166.12 (47.48)	0.2494
LDL	N=57	N=53	N=110	
	92.01 (37.08)	99.28 (43.72)	95.51 (40.39)	0.3485
HDL	N=57	N=53	N=110	
	41.93 (13.87)	45.13 (15.24)	43.47 (14.57)	0.2512
Triglycerides	N=55	N=53	N=108	0.1087
	113.91 (59.80)	135.70 (79.08)	124.63 (70.45)	
HbA1C, mean [SD]	N=60	N=58	N=118	
	7.74 (1.88)	7.27 (1.64)	7.51 (1.78)	0.1534

	N=126	N=124	N=250	
Duration of Diabetes, mean [SD], y	11.62 (8.83)	11.05 (7.60)	11.34 (8.23)	0.5847
	N=149	N=147	N=296	
Number of Clinic Visits	4.58 (2.18)	4.17 (1.93)	4.38 (2.07)	0.0849

Table 2C

Baseline Characteristics of Control and Intervention Subjects
Literacy and Knowledge Variables

Characteristic	Control Group, Mean [SD]	Intervention Group, Mean [SD]	Total Sample	P
REALM Reading Raw Score (0-66)	N=42	N=43	N=85	
	47.24 (20.39)	49.79 (18.40)	48.53 (19.34)	0.5460
Total Correct for Knowledge (0-5)	N=76	N=72	N=148	
	1.83 (1.40)	1.90 (1.65)	1.86 (1.52)	0.7694
Exercise Barriers (0-25)	N=75	N=71	N=146	
	19.55 (4.00)	19.20 (4.10)	19.38 (4.04)	0.6029
Knowledge of Long Term Complications (0-20)	N=76	N=72	N=148	0.9633
	15.07 (3.39)	15.04 (2.95)	15.05 (3.17)	

Table 3A

Mean Change from Baseline to End of Study in Control and Intervention Subjects
Clinic Variables

	Control-Mean Change	**P (With-in Group)**	**Intervention-Mean Change**	**P (With-in Group)**	**P (Between Group)**
CLINIC MEASURES					
	N=135		N=126		
Body Mass Index, mean [44], (kg/m^2)	0.28(2.55)	0.2036	-0.28 (1.91)	0.1038	0.2181
Blood Pressure, mean [SD], mmhg					
	N=72		N=71		
Systolic	-12.22 (31.86)	0.0015	-13.23 (29.42)	0.0003	0.8434
	N=73		N=71		
Diastolic	-4.37 (18.94)	0.0526	-6.46 (20.76)	0.0113	0.5307
	N=51		N=47		
Total Cholesterol, mean [SD]	8.86(50.28)	0.2139	-2.17 (38.42)	0.7004	0.2281
	N=51		N=47		
LDL	5.09(32.31)	0.2660	-1.51 (35.52)	0.7720	0.3378
	N=51		N=47		
HDL	-0.4510 (7.20)	0.6567	0.17(5.94)	0.8451	0.6440
	N=49		N=47		
Triglycerides	8.02(31.17)	0.0780	-4.49 (34.85)	0.3817	0.0666
	N=23		N=39		

HbA1C, mean [SD]	-0.33 (1.84)	0.3911	0.77 (2.14)	0.0305	0.5787

Table 3B

Mean Change from Baseline to End of Study in Control and Intervention Subjects
Knowledge Variables

	Control-Mean Change	P (With-in Group)	Intervention-Mean Change	P (With-in Group)	P (Between Group)
KNOWLEDGE MEASURES	N=38		N=35		
Total Correct for Knowledge (0-5)	0.20 (1.07)	0.2326	-0.09 (1.07)	0.6378	0.2406
Exercise Barriers (0-25)	0.71 (4.62)`	0.3493	1.17 (0.21)	0.2073	0.6983
Knowledge of Long Term Complications (0-20)	0.05 (3.74)	0.9314	1.36 (4.68)	0.0897	0.1870

Table 4

Predictors of Change in SBP

	# of Observations Used	Control-SBP Mean Change	Intervention-SBP Mean Change	P-Value for Model
Change in SBP Model 1[a]	145	-12.22	-13.23	0.8434
Change in SBP Model 2[b]	51	-9.12	-15.39	0.5280
Change in SBP Model 3[c]	145	-12.12	-13.33	0.6407
Change in SBP Model 4[d]	145	-12.23	-13.45	0.5766
Change in SBP Model 5[e]	61	-11.39	-9.87	0.5706
Change in SBP Model 6[f]	145	-12.09	-13.36	0.6396
Change in SBP Model 7[g]	145	-12.24	-13.22	0.9760
Change in SBP Model 8[h]	61	--	--	0.2957
Change in SBP Model 9[i]	145	--	--	0.3609
Change in SBP Model 10[j]	145	--	--	0.9169

a: Treatment Assignment Only
b: Treatment Assignment +Age + Sex + Smoke + Duration of Diabetes

c: Treatment Assignment + Length of Follow-up
d: Treatment Assignment + Length of Follow-up + Treatment Assignment*Length of Follow-up
e: Treatment Assignment +Realm
f: Treatment Assignment + Medical Clinic Visits
g: Treatment Assignment + PEIHiC Visits
h: Realm Only
i: Medical Clinic Visits Only
j: PEIHiC Visits Only

CHAPTER 3

PUBLIC HEALTH IMPLICATIONS

This study makes an important contribution to the literature of management of diabetes in low-resource populations with high-risk of complications. By using a unique sample representing a minority and socioeconomic group who are typically medically underserved, and collecting a wealth of social, demographic, and biochemical data, we were able to show improvements in clinical outcomes, but no real gains in measured knowledge. However, there were clinical improvements from baseline, therefore something positive was at work from this study.

A future study aiming to control blood pressure in patients with type 2 diabetes in a low-resource setting should focus first on patient retention in order to maximize the effect of their intervention. Difficulty with patient retention was a major challenge in our study. High patient turnover is common in busy urban clinics and is a challenge that needs to be overcome at the clinic level to improve health outcomes for patients. Offering incentives for participation is an option, but the costs associated with incentives often are too expensive, especially in a low-resource setting, and not sustainably translatable for regular, long-term care of patients with chronic diseases. Reducing the size of the study, and including only patients who report that they plan on returning to the clinic would help with patient retention. Again, translating this to the wider community of less-motivated individuals holds challenges for future studies to consider.

Second, reducing the intervention contamination between intervention and control groups, and thus helping us expose between-group differences, could be achieved by randomizing the intervention at the physician or clinic level. This would help eliminate the universal intensification of treatment by physician's who treated both controls and interventions in our study. This would be a challenge to implement at a teaching hospital where physician turnover is high, such as at GHS. Logistically this would be difficult and costly due to the challenge to ensure correct patients were seen by the correct doctors at each visit, careful organization of medical records to maintain physician blinding, while still maintaining uninterrupted patient flow through the clinic.

Determining the mediating factors that help control CVD risk factors will also be important in future studies. Questions which better assess knowledge of diabetes in addition to assessing how well knowledge is being translated into behavior changes should be included. In addition, "empowerment" should be included as a measurement on the baseline and follow-up surveys. Currently there is no tool or scale assessing empowerment, so a focus group may be helpful in identifying key phrases and feelings that patients associate with empowerment. In addition, measuring medication intensification by physicians, and adherence to medications by patients through pharmacy records would be useful to examine which combination of behaviors the intervention is impacting. Lengthening the time of follow-up would also be helpful here in showing greater between-group differences. In addition, it would add to the literature of how to create long-term changes that are sustainable in a primary care setting.

Lessons that can be taken from the current study include the importance of increasing patient participation in their own care. It is especially important for a population such as the one in this study, where physicians change frequently. Patients being empowered to ask about medication and treatment options may influence physicians to intensify treatment. Special care needs to be taken, however, that the focus on treatment and prevention of singular complications (such as SBP control), are not at the cost of overall care (HbA1C increased in the intervention group). In sum, obtaining better treatment and hence, better control of their diabetes and its complications far outweighs the cost of hiring a diabetes educator to be available in the clinic, both ethically and from a healthcare reimbursement standpoint.

APPENDIX

Example of Survey

PEIHiC

Patient Knowledge: **Please help us by answering the following as best you can.**

1. How well is your diabetes under control? [Select one]
    a. Totally under control
    b. Under good control
    c. Somewhat under control
    d. Under bad control
    e. Totally out of control
    f. I don't know

2. Do you know what an A1C is? ☐ 1 No ☐ 2 Yes
    (If "no", skip the next question and go on to Q4)

3. What should your A1C be? [Select one]
    a. Less than 5.5
    b. Less than 6.0
    c. Less than 6.5
    d. Less than 7.0
    e. Less than 7.5
    f. Less than 8.0
    g. Other _______________
    h. I don't know what my A1C should be

4. What should your sugars be before meals? [Select one]
    a. Less than 70
    b. Less than 90
    c. Less than 130
    d. Less than 150
    e. Less than 200
    f. Other ______________
    g. I don't know what my sugars should be

h. Less than 120

5. What is a *normal* systolic (top number) blood pressure? [Select one]
   a. Less than 110
   b. Less than 120
   c. Less than 130
   d. Less than 140
   e. Less than 150
   f. Other ____________
   g. I don't know

6. What is a *normal* diastolic (bottom number) blood pressure? [Select one]
   a. Less than 60
   b. Less than 80
   c. Less than 90
   d. Less than 100
   e. Less than 110
   f. Other ____________
   g. I don't know

Demographics

Q1. What is your marital status? (Check one box)

☐1 Never married
☐2 Married
☐3 Separated/Divorced
☐4 Widowed

Q2. What is your ethnic origin/race? (Check one box)

☐1 White
☐2 Black
☐3 Hispanic
☐4 Native American
☐5 Asian or Pacific Islander
☐6 Arabic
☐7 Other ____________

Q3. How much schooling have you had? (Years of formal schooling completed) (Check one box)

☐1 8 grades or less

☐2 Some high school
☐3 High school graduate or GED
☐4 Some college or technical school
☐5 College graduate (bachelor's degree)
☐6 Graduate degree

Q4. Which of the following best describes your current employment status? (Check one box)

☐1 Working full-time, 35 hours or more a week
☐2 Working part-time, less than 35 hours a week
☐3 Unemployed or laid off <u>and</u> looking for work
☐4 Unemployed <u>and not</u> looking for work
☐5 Homemaker
☐6 In school
☐7 Retired, Disabled, or not able to work
☐8 Something else? (Please specify): ____________________

Q5. How would you describe the insurance plan(s) you have had <u>in the past 12 months</u>?

(Check all that apply) 1 = No 2 = Yes

☐1 An individual plan – the member pays for the plan premium
☐2 A group plan through an employer, union, etc. – the employer pays all or part of the plan premium
☐3 U.S. Governmental Health Plan (e.g., Military, CHAMPUS, VA)
☐4 Medicaid
☐5 Medicare
☐6 I have not had an insurance plan in the past 12 months

Q6. Which of the categories best describes your total annual <u>individual</u> income from <u>all</u> sources? (Check one box)

☐01 Less than $5,000
☐02 $5,000 to $9,999
☐03 $10,000 to $14,999
☐04 $15,000 to $19,999
☐05 $20,000 to $29,999
☐06 $30,000 to $39,999
☐07 $40,000 to $49,999
☐08 $50,000 to $59,999
☐09 $60,000 to $69,999

☐10 $70,000 and over

Q7. Which of the categories best describes your total annual <u>combined household</u> income from <u>all</u> sources? (Check one box)

☐01 Less than $5,000
☐02 $5,000 to $9,999
☐03 $10,000 to $14,999
☐04 $15,000 to $19,999
☐05 $20,000 to $29,999
☐06 $30,000 to $39,999
☐07 $40,000 to $49,999
☐08 $50,000 to $59,999
☐09 $60,000 to $69,999
☐10 $70,000 and over

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM)

Terry Davis, PhD, Michael Crouch, MD, Sandy Long, PhD

Chart #

Examine date:

Name:

Birth date:

REALM generated reading level:

Grade completed:

List 1		List 2		List 3	
Fat	____________	Fatigue	____________	Allergic	________
Flu	____________	Pelvic	____________	Menstrual	________
Pill	____________	Jaundice	____________	Testicle	________
Dose	____________	Infection	____________	Colitis	________
Eye	____________	Exercise	____________	Emergency	________
Stress	____________	Behavior	____________	Medication	________
Smear	____________	Prescription	____________	Occupation	________
Nerves	____________	Notify	____________	Sexually	________
Germs	____________	Gallbladder	____________	Alcoholism	________
Meals	____________	Calories	____________	Irritation	________
Disease	____________	Depression	____________	Constipation	________
Cancer	____________	Miscarriage	____________	Gonorrhea	________
Caffeine	____________	Pregnancy	____________	Inflammatory	________
Attack	____________	Arthritis	____________	Diabetes	________
Kidney	____________	Nutrition	____________	Hepatitis	________
Hormones	____________	Menopause	____________	Antibiotics	________
Herpes	____________	Appendix	____________	Diagnosis	________
Seizure	____________	Abnormal	____________	Potassium	________
Bowel	____________	Syphilis	____________	Anemia	________
Asthma	____________	Hemorrhoids	____________	Obesity	________
Rectal	____________	Nausea	____________	Osteoporosis	________
Incest	____________	Directed	____________	Impetigo	________
# of (+) Responses in List 1: ____________		**# of (+) Responses in List 2: ______________**		**# of (+) Responses in List 3: __________**	

EGEND: (+)=Correct (-)=Word not attempted (/)=Mispronounced word

Raw Score:

Red Lake Hospital, Red Lake MN 566

4/08/TM

Section XI - Exercise Barriers Scale

For the following questions, please circle the appropriate response (circle one answer for each line).

5 lowest possible and 25 is the highest: lower #'s are better

Q1.	How often do you have trouble getting enough exercise because:	Rarely		Sometimes		Often
	a) it takes too much effort?	1	2	3	4	5
	b) you don't believe it is useful?	1	2	3	4	5
	c) you don't like to do it?	1	2	3	4	5
	d) you have a health problem?	1	2	3	4	5
	e) it makes your diabetes more difficult to control?	1	2	3	4	5

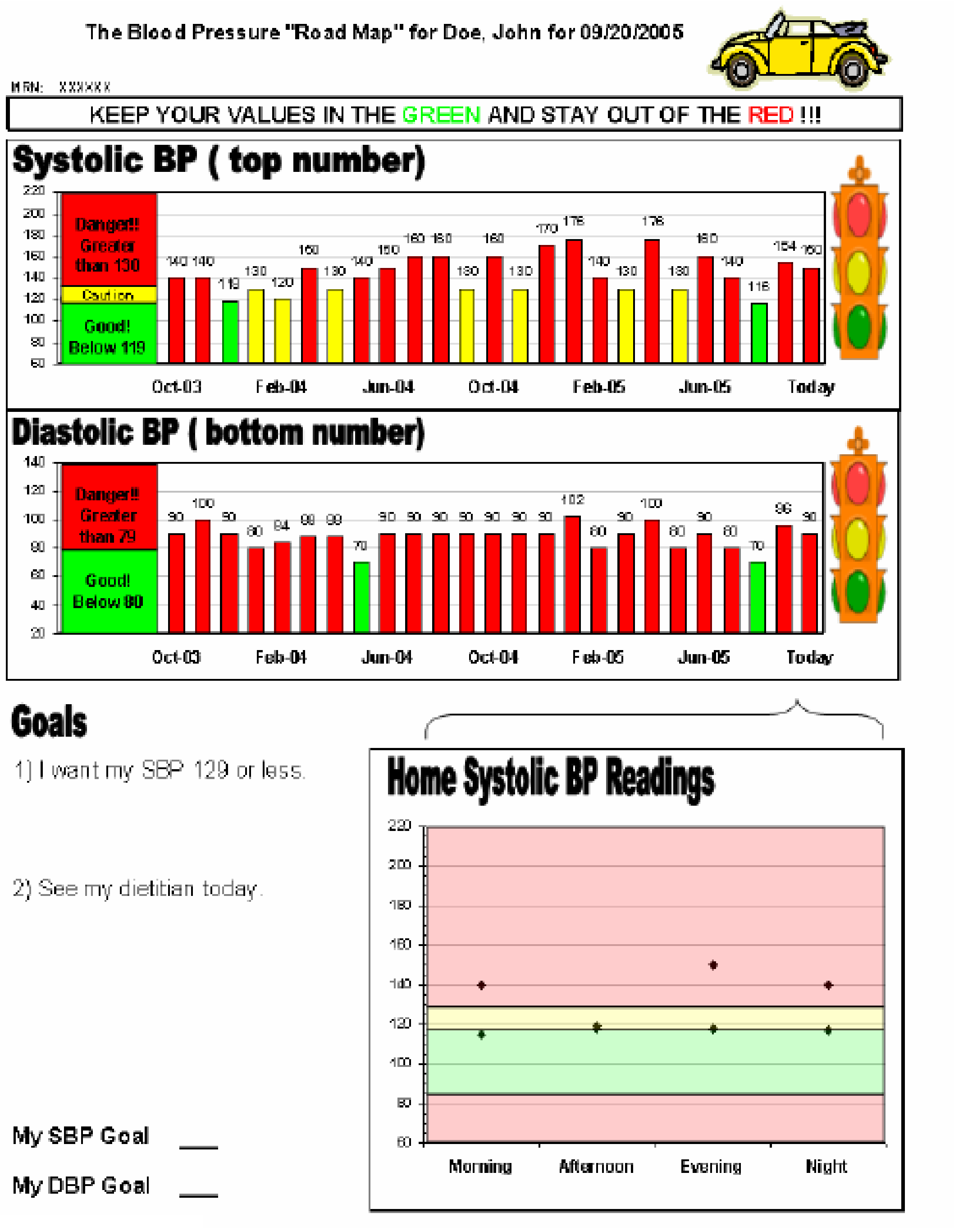
Section X - Long-Term Care Benefits Scale

For the following questions, please circle the appropriate response (circle one answer for each line).

5 lowest possible and 25 is the highest: higher #'s are better

Q1.	Taking the best possible care of diabetes will delay or prevent:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	a) eye problems	1	2	3	4	5
	b) kidney problems	1	2	3	4	5
	c) foot problems	1	2	3	4	5
	d) hardening of the arteries	1	2	3	4	5
	e) heart disease	1	2	3	4	5

Intervention Blood Pressure Road Map



The Blood Pressure "Road Map" for Doe, John for 09/20/2005

MRN: XXXXXX

KEEP YOUR VALUES IN THE GREEN AND STAY OUT OF THE RED !!!

Systolic BP (top number)

Diastolic BP (bottom number)

Goals

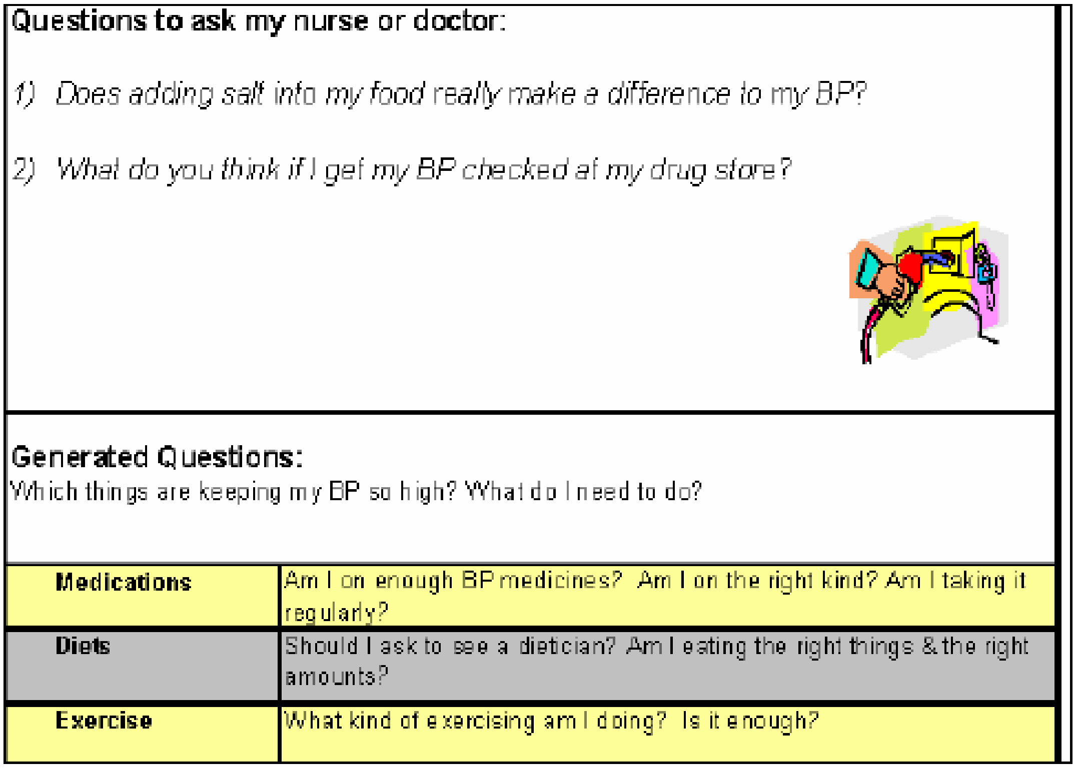
1) I want my SBP 129 or less.

2) See my dietitian today.

My SBP Goal ___

My DBP Goal ___

Home Systolic BP Readings



Questions to ask my nurse or doctor:

1) *Does adding salt into my food really make a difference to my BP?*

2) *What do you think if I get my BP checked at my drug store?*

Generated Questions:

Which things are keeping my BP so high? What do I need to do?

Medications	Am I on enough BP medicines? Am I on the right kind? Am I taking it regularly?
Diets	Should I ask to see a dietician? Am I eating the right things & the right amounts?
Exercise	What kind of exercising am I doing? Is it enough?