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Peer Support for Achieving Independence in Diabetes (Peer-AID): Design, methods and baseline characteristics of a randomized controlled trial of community health worker assisted diabetes self-management support

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Abstract

Background & Objectives—Community health workers (CHWs) may be an important mechanism to provide diabetes self-management to disadvantaged populations. We describe the design and baseline results of a trial evaluating a home-based CHW intervention.

Methods & Research Design—Peer Support for Achieving Independence in Diabetes (Peer-AID) is a randomized, controlled trial evaluating a home-based CHW-delivered diabetes self-management intervention versus usual care. The study recruited participants from 3 health systems. Change in A1c measured at 12 months is the primary outcome. Change in blood pressure, lipids, health care utilization, health-related quality of life, self-efficacy and diabetes self-management behaviors at 12 months are secondary outcomes.

Results—A total of 1,438 patients were identified by medical record review as potentially eligible, 445 patients were screened by telephone for eligibility and 287 were randomized. Groups were comparable at baseline on socio-demographic and clinical characteristics. All participants were low-income and were from diverse racial and ethnic backgrounds. The mean A1c was 8.9%, mean BMI was above the obese range, and non-adherence to diabetes medications was high. The cohort had high rates of co-morbid disease and low self-reported health status. Although one-third

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reported no health insurance, the mean number of visits to a physician in the past year was 5.7. Trial results are pending.

Conclusions—Peer-AID recruited and enrolled a diverse group of low income participants with poorly controlled type 2 diabetes and delivered a home-based diabetes self-management program. If effective, replication of the Peer-AID intervention in community based settings could contribute to improved control of diabetes in vulnerable populations.

Keywords

diabetes self-management; community health workers

1. Introduction

Successful management of diabetes is a complex process. People with diabetes require skills to assess their disease control, practice healthy behaviors and utilize their medications appropriately.[1] Provision of self-management education and ongoing support is effective in helping them acquire and practice these skills,[1] yet the majority of people with diabetes do not obtain such assistance [2, 3]. Low-income individuals and minority populations are less likely to receive self-management support, [4] contributing to the poor diabetes control and high rates of complications [5]. These disadvantaged groups face greater challenges in accessing self-management support classes or clinic-based education and practicing self-management skills on a daily basis. Conditions in their homes and neighborhoods, such as access to safe places for physical activity, inadequate access to healthy food, or psychosocial stressors are barriers to self-management, but traditional diabetes education may not account for these factors.[6] Thus, translating effective interventions into diverse community settings to address these unique needs remains a public health challenge.[7]

A promising approach to overcoming these challenges is utilizing community health workers (CHWs) to provide home-based self-management support.[8] CHWs are peer educators who promote health in their communities through information distribution, assistance, social support and organizing community networks.[9] CHWs are effective in promoting behavior change because they share community, culture, and life experiences with their clients.[9-12] Two reviews suggest CHW interventions improve participant knowledge and behavior among persons with diabetes.[8, 9] Improvements in physiologic measures were noted in some, but not all, studies.[9] However, widespread adoption of the CHW model has been hindered by lack of strong evidence.[9] Limitations of prior studies include limited data on cost effectiveness and lack of attention to intervention fidelity.[9] Additional methodologically rigorous research is needed to understand the effectiveness of CHWs among diverse population and in a variety of settings to determine how CHWs could most effectively impact diabetes care.[8, 9]

The purpose of the Peer-AID study is to provide a rigorous test of the effectiveness and to assess the cost-effectiveness of a home-based CHW intervention to improve health outcomes among a diverse group of low-income patients with poorly controlled type 2 diabetes receiving care in 3 different health systems. We recruited participants from a county hospital, a VA hospital and a local community health center. Our aim is to help

participants who had poor diabetes control despite their access to clinic and hospital-based services. We also seek to understand better the barriers to translation of the CHW model into home-based settings and strategies to overcome these barriers. The CHW activities translate self-management support approaches shown to be effective in research settings into community-based settings and practice.[1] CHWs worked with participants in their homes and link them to community resources to support diabetes self-management. The purpose of the current article is to provide an overview of the study design, intervention protocol, outcome measures and baseline participant characteristics.

2. Research design and Methods

Peer-AID is an ongoing 2-arm randomized controlled trial in which n=297 low-income participants with poorly controlled diabetes receive a home-based intervention over 12 months or usual care. The study was approved by the Institutional Review Boards at the University of Washington, Sea Mar Clinic, and VA Puget Sound. All participants completed an informed consent process and HIPAA authorization at the beginning of their baseline research visit. In addition, Veterans completed an additional HIPAA authorization to allow the initial release of their contact information to Public Health Seattle-King County (PHSKC), the local health department and home to the CHWs and participant recruiters..

2.1. Study setting

Participants were recruited from Harborview Medical Center (HMC), the VA Puget Sound Health Care System and Sea Mar Community Health Centers. HMC is the local public hospital and one of the largest safety-net providers in King County, where patients are seen regardless of their ability to pay. The VA Puget Sound Health Care System is a tertiary hospital that serves Veterans from a large area including King County. Sea Mar Community Health Centers is a community-based organization providing comprehensive health and human services to diverse communities, specializing in service to Latinos. The intervention took place in participants' homes. Community health workers and supporting staff were based at PHSKC.

2.2. Population and eligibility criteria

Eligible participants had a diagnosis of type 2 diabetes, an A1c of 8.0% or greater at their clinic site during the 3-month period prior to enrollment, a household income of less than 250% of the federal poverty level (which in 2011 was an annual income of \$27,225 or less for a single individual), be between 30 and 70 years old, speak English or Spanish, and live within King County, Washington. We chose 70 years of as the upper limit because the prevalence of significant co-morbidities increases with age, thus complicating disease self-management. Exclusion criteria included participation in another diabetes study, previous diabetes education in the past 3 years, being homeless or planning on moving out of the King County area, having a serious illness including cancer, end stage renal disease (ESRD) on hemodialysis, dementia or inability to give informed consent.

2.3. Recruitment

Lists of potentially eligible participants were generated from the three clinic sites based on a diagnosis of diabetes and A1c values ($\geq 8\%$). The electronic health records of each clinic sites were queried approximately every 3 months to identify potentially eligible participants. Potentially eligible participants were then sent an introductory letter describing the study and a number to call if they wanted to opt-out. If no response was received within 2 weeks, study staff called potential participants and administered a telephone screening to ascertain other eligibility criteria including address verification, income level and age. See Figure 1 for the flow chart describing the number of participants at each stage. Participants were compensated for their time to complete baseline (\$25) and 12 month assessments (\$25).

2.4. Randomization

We randomly assigned participants to the intervention or usual care control arms after completing baseline data collection in a 1:1 ratio. We assigned participants to study groups using a stratified, permuted block design with varying block size. Stratification was by clinic site to assure an approximately equal number of treatment and control subjects at each site and to meet the site-specific recruitment targets. The nature of the intervention makes it impossible to blind participants and staff to group assignment.

2.5. Community Health Worker Intervention

2.5.1. Intervention design—A key component of our intervention is promoting adoption of self-management behaviors that result in improved control of type 2 diabetes. CHWs work with clients in their homes to set behavioral goals, identify actions that were feasible and likely to help them achieve goals, assess the impact of the actions on progress toward goals, and revise actions to make them more effective. We placed an emphasis on increasing self-efficacy because increased self-efficacy is linked to improved quality of life, patient satisfaction, and glycemic control among individuals with diabetes.[13-15] CHWs use motivational interviewing techniques, a client-centered style of counseling that helps individuals explore and resolve their ambivalence about making behavioral changes, while the provider focuses on increasing readiness to change.[16, 17] The CHWs mobilize social support for participants, as social support for disease management is effective in increasing self-management practices.[18] They encourage family and other members of participants' support networks to help participants by encouraging lifestyle changes and medication adherence, attending clinic visits, and providing emotional support. CHWs tailor support to meet cultural preferences.[19] Bi-lingual CHWs communicated in the client's primary language. They provide educational materials in Spanish and English. Assessment instruments were translated, pilot tested and revised for use with Spanish speaking participants, and interviews were conducted in the participant's primary language.

2.5.2. Training of Community Health Workers—We designed the study to provide content that is consistent with the American Diabetes Association and American Association of Diabetes Educators self-management education recommendations.[1] Completion of 60 hours of comprehensive training was mandatory for the CHWs prior to any intervention delivery. This training included didactic sessions, in-class exercises, and field practice. The

CHWs received training in health coaching and motivational interviewing by a professional health coach. CHWs were trained to utilize an automated blood pressure monitor. Each CHW passed a competency test prior to beginning work.

2.5.3. Intervention home visits by CHW—The intervention is performed by 2 CHWs who are employed by PHSKC. The CHWs have a combined research experience of thirteen years, are long term health department employees, are bilingual in Spanish and English, live in the same geographic area and share a similar cultural background as the clients they served. A CHW makes an initial intake and 5 follow-up home visits to each intervention group participant. The protocols specify education content, client skill development goals, and client and CHW actions. Participants receive low-literacy educational materials collected into a diabetes resource guide available in English and Spanish.

Baseline assessment: During the baseline visit, the CHW assess diabetes self-management behaviors, health history, health care access, and health care utilization (Table 1). Data collection is done with an automated system that identified behaviors with suboptimal values and triggered alerts to patients' providers regarding elevations in blood pressure, blood sugars, depression and alcohol misuse. The CHW use the information from the assessment to collaboratively develop an individualized diabetes self-management plan with the participant. There are 6 mandatory education topics (What is diabetes, sign and symptoms of low and high blood sugar, blood glucose monitoring, treating diabetes, food and diabetes, diabetes and physical activity, diabetes medications) and an additional 17 topics dependent on the baseline assessment and client motivation. A complete set of education and training protocols is available online: <http://www.kingcounty.gov/healthservices/health/chronic/peeraid.aspx>.

Participant Timeline: The CHW support the participant in self-management plan implementation at follow-up visits that took place 0.5, 1.5, 3.5, 7 and 10 months after the initial visit. At these visits, the CHW assess diabetes and blood pressure control, learn more about participant challenges and concerns, review progress on implementing the self-management plan, provide targeted education to help with plan implementation, revise self-management goals and the plan as the participant progressed, and make referrals to group activities and community resources. Participants with inadequate medication adherence receive pillboxes and those with hypertension receive blood pressure monitoring devices.

Community supports for self-management and behavior change: CHWs offer participants opportunities to join group community-based activities that complemented home visits. Participants selected ones best suited to their needs and interests. The following programs are offered:

(1) Group education opportunities: We link participants to locally available classes including diabetes education classes and chronic disease self-management classes.[20]

(2) Community Kitchens: We developed a community kitchen at a local community center, adapted from the Vancouver, BC Community Kitchens model.[21]

(3) **Shopping:** CHWs conduct “Shop Arounds” in which the CHW led tours of a supermarket to show how to make healthy yet economical food choices.[22]

Coordination with primary care and case managers: CHWs communicate with primary care providers by faxing the initial assessment, the diabetes self-management plan and follow-up visit encounter forms. Emerging urgent issues are communicated by telephone and email by the project nurse or program staff. The CHW encouraged clients to see their providers for regular review of diabetes management. CHWs are available by pager and email so that clinic staff could contact them for assistance in reaching patients (e.g. helping re-establish care for a patient who had missed an appointment or connecting with a patient with an abnormal lab result) and for care coordination.

Control patients: Control participants received usual care, defined as the medical care received by participants in the absence of the intervention plus information about community resources that support diabetes self-management (such as classes and support groups) and educational pamphlets. Control patients received the baseline assessment and a 12 month follow up interview. At the end of the study period, CHWs visit usual care participants and provided one education visit.

2.6. Intervention fidelity

To document fidelity to the intervention protocols, the CHWs complete an encounter form at each visit.[23] The CHW document the skill or goal that was the primary focus for each visit and the self-management strategies that are discussed during that visit. Teaching content and self-management are documented at each visit by the CHWs and reviewed by either a nurse or CDE. Monthly review ensures that each participant receives the required components of the intervention.

2.7. Primary and secondary outcomes (Table 1)

The primary outcome of the study is A1c. Laboratory examination at both baseline and one year of follow up include an A1c and a non-fasting lipid panel (total, LDL and HDL cholesterol; triglycerides). Secondary outcomes include health-related quality of life (HRQOL) and diabetes-specific quality of life. Health-related quality of life is measured with the SF-12[24] and diabetes-specific quality of life by a previously validated instrument. [25] We use the Summary of Diabetes Self-Care Activities, a validated and reliable measure of self-management and disease knowledge to assess specific self-management activities. [26] In addition we include other measures of nutrition, physical activity and medication adherence. The nutritional assessment at baseline includes a kitchen pantry audit [27] and a self-reported assessment of dietary intake “Starting the conversation”, an eight-item validated, simplified food frequency instrument designed for use in primary care and health-promotion settings.[28] Level of physical activity at baseline and follow-up is assessed using the International Physical Activity Questionnaire (IPAQ), a validated and reliable measure of physical activity level that classifies participants as high (e.g. over 60 minutes of moderate-intensity activity per day), moderate (e.g. half an hour of at least moderate-intensity PA on most days), or low.[29] Medication adherence is assessed using a standardized participant interview.[30]

We collect data on potential covariates that have been shown in previous studies to be associated with diabetes control and self-care. Demographic covariates include age, gender, marital status, education, primary language and race/ethnicity. We ask participants to describe their race as American Indian or Alaskan Native, Asian, Pacific Islander, black, or white. We ask them separately to define their ethnicity as Hispanic or non-Hispanic. Because low health literacy has been shown to correlate with poor glycemic control,[31] we include questions to measure health literacy in adults.[32] We assess alcohol consumption using the Alcohol Use Disorders Identification Test (AUDIT-C), a 3-item screening test for heavy drinking and/or abuse.[33] Because of the strong link between depression and poor self-care among individuals with diabetes,[34] depressive symptoms are assessed using the PHQ-8.[35] We also collect data on costs and utilization. Costs associated with the intervention including CHW time, training and supervision are documented. Health care utilization documented during the study includes self-reported clinic utilization, hospitalization and medication use.

2.8. Sample size justification

We powered our study to detect a clinically significant difference in the change in A1c between baseline and one year with a power of 0.80 when $\alpha = 0.05$. The sample size chosen for this study was based on a difference in change in A1c of 0.7% between the intervention and control groups. The minimal clinically important difference (MCID) for A1c ranges from 0.7 – 1.0%.[36] Previous reviews of diabetes self-management trials report a change of 0.76% in the intervention groups relative to control groups [37] and a RCT using CHWs that showed a decrease in A1c of 0.8%.[38] Under these assumptions, 134 individuals per group were required. Assuming a 10% attrition rate, we recruited 287 participants to maintain an adequate sample size.

2.9. Data collection, management and analysis

2.9.1. Baseline assessment—The baseline assessment was conducted in the participants' home by the CHW and prior to randomization to avoid bias in data collection associated with knowledge of group assignment. During this visit, a questionnaire was administered using a web-based survey administration tool. This electronic system allowed for remote data collection in real-time. In addition, height, weight and blood pressure were obtained and a finger stick blood sample was taken. The "Micro Sample Collection Convenience Kit" is used to process the blood sample. It is a mail-in finger stick kit provided by the Home Access Health Corporation that includes a collection kit, mailing kit, laboratory test services, and support from a contact center. This product allows an individual to self-test with a finger stick sample of blood and includes total cholesterol, HDL and LDL cholesterol, triglycerides, and hemoglobin A1c. The participant performs the testing themselves, with assistance from the CHW as needed. All testing is performed in a CLIA-regulated, CAP-certified laboratory. Blood pressure and height and weight are measured by the CHW at baseline and exit. Standing height and body weight were measured in light street clothes without shoes on calibrated electronic scales. All participants over 300 pounds had a self-reported weight ($n=21$), since the program's scales did not provide weights above this amount. Diastolic and systolic blood pressure was measured using an automated calibrated blood pressure cuff in a seated position after 5 minutes of rest at 3 different times

during the baseline interview. The average of these 3 blood pressure readings are used as the baseline and exit values.

2.9.2. Outcome assessment—A 12 month exit visit will be performed in the participants' home by a CHW who did not provide the intervention. Weight, blood pressure, a finger stick blood sample and questionnaires will be obtained.

2.10. Planned statistical analysis

The primary outcome is change in A1c from baseline to one year. Randomly assigned group (intervention vs. control) will be the main independent variable. Analysis will follow the intention-to-treat approach which includes all randomized participants in the analyses according to their original assignment. Participants who withdraw or do not complete the one year follow up will be included in the analysis by multiply imputing missing values for exit data.[40] Linear models and logistic models will be used to conduct a difference in differences analysis comparing changes in outcome in the intervention group relative to the control group, controlling for baseline covariates that are unbalanced between groups, or could potentially affect the outcomes, such as demographics or other medical co-morbidity. Secondary analysis will evaluate the intervention on several secondary outcomes, including self-care behaviors including physical activity, nutrition, and medication adherence, and health care utilization. We will assess heterogeneity of treatment effects by looking at interaction terms that include group assignment and demographics and level of disease control at baseline.

If the Peer-AID intervention demonstrates improvements in A1c relative to control, a cost-effectiveness analysis will be performed. To estimate quality of life (QoL), we will translate the SF-12 to Health Utilities Index-III using published algorithms.[41, 42] We will assign a QoL score of zero at follow-up for subjects who die during the trial. We will calculate quality-adjusted life-years as the area of the trapezoid created by connecting baseline and 12-month QoL scores using straight lines. We will assess differences in QALYs between treatment groups as the coefficient on treatment assignment from a linear model with individual-level QALY as the dependent variable, and treatment assignment and QoL at baseline as independent variables.[43] We will estimate cost effectiveness ratio as the difference in costs divided by the difference in QALYs.

RESULTS

Baseline assessments were completed between September 2010 and May 2013, while one year follow-up visits are ongoing. Figure 1 displays the number of potential participants identified by medical record review with a HbA1c > 8% (n=1,438), number unable to reach (n=703), number screened (n=445), and number agreeing to participate with final randomization of 287 individuals.

Population characteristics are summarized in Table 2. None of the socio-demographic characteristics were significantly different between the randomization groups. All participants were low-income [annual income < 250% of the federal poverty level (FPL)], one quarter were employed, the majority of participants had a high school education or less

and were equally divided among males and females. The cohort was from diverse racial and ethnic backgrounds: 45% white, 26.7% black, and 43% Hispanic. The mean A1c at enrollment was 8.9% (Table 3). This was lower than the A1c (mean 10.1%) obtained for initial eligibility assessment from the 3 health systems. Other cardio-metabolic risk factors were under better control, with a mean LDL of 94.7 mg/dl, mean systolic blood pressure of 129 mm HG, and mean diastolic blood pressure of 81 mmHg. Only 13.3% of participants had a measured blood pressure of 140/90 mm Hg or more. The mean BMI was 33.6 kg/m², with 58% of the sample in the obese range (BMI > 30 kg/m²). There was a slightly higher mean body mass index (BMI) in the control group compared to the intervention group (34.7 kg/m² vs. 32.5 kg/m² respectively, $p = 0.04$), however there was no difference in the percentage of each group who were in the obese BMI range. Almost all participants were on oral hypoglycemic agents, and 61% reported taking insulin. Over half of participants reported low levels of physical activity. Forty five percent of participants had low self-reported medication adherence.

Almost two-thirds of participants rated their health as fair or poor. The population had significant self-reported medical comorbidity: depression (52%), high cholesterol (65%), and hypertension (70%). About a quarter of participants had PHQ-8 scores classified as moderately to severely depressed. Although 30% reported no health insurance, the mean number of visits to a physician in the prior 12 months was 5.7.

DISCUSSION

Despite widespread recognition of the benefits associated with diabetes control, rates of recommended levels of control remain suboptimal.[7] Self-management support is a recommended component of care for all patients with diabetes.[1] However, many people with diabetes do not regularly practice self-management behaviors. We describe the design and rationale of a randomized clinical trial that seeks to determine the effectiveness of a home-based CHW intervention among participants with poorly controlled diabetes from 3 health systems. Results from this study will help inform how CHWs can be utilized in low-income populations of patients with diabetes. At the conclusion of the study, we will assess the impact of the Peer-AID intervention on our cohort, with the primary outcome of glycemic control (A1c). Secondary outcomes include other disease markers (hypertension, hyperlipidemia) and health related quality of life, and intermediate measures consist of health behaviors (e.g., nutrition, physical activity, and self-reported medication adherence), and self-efficacy. If the Peer-AID intervention demonstrates improvements in A1c relative to control, we will also assess the costs and cost-effectiveness of implementing the intervention in community practices.

We successfully recruited a low-income population with poor diabetes control. The demographics and clinical characteristics of the Peer-AID cohort document the well-defined challenges that low-income patients with diabetes face when self-managing their condition, including high rates of un-insurance, significant medical co-morbidity (especially high rates of depression and depressive symptoms), poor medication adherence, inadequate nutrition and low levels of physical activity. Self-reported quality of life in this sample is lower than in a general population with diabetes.[44] Self-reported clinic utilization was high, with an

average of almost 6 visits in the prior year. The CHWs screen for important mental health conditions (e.g., depression,[35] alcohol use[33]) and social determinants of health including food insecurity[45] and health literacy in the baseline assessment.[32] They help participants address these conditions through provision of social support, linkage to community resources and referral to primary care providers.

The delivery of the diabetes self-management support intervention is in participants' homes, a strategy that is being tested[46] and has been successful in other CHW studies.[47-49] Basing the intervention in the home allows observation of home and social conditions affecting diabetes management, provides participants a more relaxed and comfortable setting, eliminates logistical barriers to attending diabetes education in classes or clinics, provides opportunities for CHWs to role-model and observe participants in practicing self-management behaviors and allows CHWs to meet household members and enlist their support in helping the participant self-manage. Previous CHW studies have been delivered in community health centers or community based organizations (although a few have included HMOs and academic health centers)[50] leaving questions about the generalizability of the CHW model to other settings. Several recent CHW studies have included group and telephone interventions.[51]

Results of this study are not without limitations. First, generalizability may be limited as this study takes place in one geographic area of the country with a well-developed public health system and includes primarily white, black and Hispanic participants. Internal validity may be affected by inability to blind participants to the intervention (inevitable due to nature of intervention). Lack of follow-up after the intervention ends (due to resource constraints) precludes assessment of durability of potential impacts. In addition, we encountered several challenges to study implementation. Due to VA regulatory issues that required Veterans to sign a waiver to release their contact information to the health department, our recruitment of Veterans was significantly lower than expected. However, we were able to enroll adequate numbers from the other 2 clinical sites, suggesting there was sufficient community interest and participants viewed the intervention as potentially beneficial.

Despite these limitations, the Peer-AID study has several strengths that address practical and scientific questions. The Peer-AID program has carefully documented participant recruitment and CHW training and intervention protocols that are publically available on our website. The evaluation includes both physiologic and self-reported outcomes, in addition to an assessment of intervention fidelity. The results of the planned economic analysis will provide information for health care payers and plans that may convince them to adopt the intervention, if effective. We utilized minimal exclusion criteria to expand generalizability. Generalizability and replicability are also enhanced by inclusion with of participants from diverse clinical settings (a county hospital system, a community clinic and a VA hospital) and use of intervention protocols that were designed to be practical and feasible to replicate in other communities.

Reviews of CHW interventions suggest that much additional research is needed to understand how and in what settings CHWs could most effectively impact diabetes care.[8] Peer-AID should add information to the growing body of well-designed RCTs about

positive impacts of CHWs on diabetes care outcomes.[47-49, 52] Despite decades of CHW programs in the US, widespread adoption of this model has not occurred, in part due to the lack of cost effectiveness data. One recent study provides the best evidence for the cost-effectiveness and return on investment of CHW interventions using QALYs as the effectiveness measure.[53] We hope the Peer-AID study will add to the growing evidence base regarding the clinical and cost effectiveness of CHW programs for low-income patients with poorly controlled diabetes.

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Figure 1.
Peer-AID recruitment patient flow

Table 1

Outcome Measures

Outcome Measures		Source of data	Time of measurement
Primary outcome	A1c	Finger stick blood sample	Baseline, 3 months (intervention only), 12 months
Secondary outcomes	Lipid panel (LDL, HDL, triglycerides) Blood Pressure, Height, Weight, BMI	Finger stick blood sample and physical measurements at home visits	Baseline & 12 months
Health-related quality of life	General health status Diabetes-specific QOL	SF-12 [54] Diabetes-39 [25]	Baseline, 12 and 18 months
Utilization	Outpatient and ER visits, hospitalizations, pharmacy utilization	Administrative data and participant self-report	Baseline, 12 and 18 months
Mediators/Intermediate outcomes			
Self-efficacy	Psychosocial self-efficacy	Diabetes self-efficacy [55]	Baseline, 12 and 18 months
Self-management Behaviors	Self-care behaviors: Physical activity, nutrition, medication adherence	Summary of diabetes self-care [26] IPAQ [29] “Starting the conversation” [28] Morisky Medication adherence questionnaire [56]	Baseline, 12 and 18 months
Perceived Stress	Diabetes-related emotional distress	Diabetes distress scale [57]	Baseline & 12 months
Social Support	Perceptions related to diabetes and related social support,	Multidimensional diabetes questionnaire [58]	Baseline & 12 months

Table 2

Population Characteristics

Measure	Control (n=142)	Intervention (n=145)	Total Population (n=287)	P Value*
Female, %	52.8	44.8	48.8	0.18
Age (years), mean (SD)	51.7 (9.5)	53.3 (9.1)	52.5 (9.3)	0.13
Education, %				
Grade 8 or less	20.6	26.2	23.4	0.57
Grade 9-11	12.1	9.7	10.8	
Grade 12 or GED	29.1	23.4	26.2	
College 1-3 years	29.1	28.3	28.7	
College 4 years	9.2	12.4	10.8	
Marital Status, %				
Married	32.4	33.1	32.8	0.9
Not Married	67.6	66.9	67.3	
Employment, %				
Employed	25.3	31.7	28.6	0.52
Unemployed	14.8	14.5	14.6	
Homemaker, student, or Retired	16.2	17.9	17.1	
Unable to work	43.7	35.9	39.7	
Hispanic, %	40.9	44.8	42.9	0.50
Race, %				
White	42.8	48.3	45.6	0.61
Black	29	24.1	26.5	
American Indian/Alaska Native	7.3	4.8	6.0	
Asian	5.8	5.5	5.7	
Multira	5.0	9.0	7.0	
Other	10.1	8.3	9.2	

* p value for chi-square test for categorical variables, and t-test for continuous variables

Table 3

Baseline Clinical Characteristics

Measure	Control (n=142)	Intervention (n=145)	Total Population (n=287)	P Value
HbA1C, mean (SD)				
Initial Clinic Value	10.1 (1.9)	10.2 (1.8)	10.1 (1.8)	0.81
Baseline Study Enrollment Value	8.9 (1.9)	9.0 (1.6)	8.9 (1.8)	0.77
LDL, mean (SD)	90.6 (34.8)	98.7 (33.2)	94.7 (34.2)	0.09
Systolic Blood Pressure, mean (SD)	127.5 (21.1)	130.5 (20.6)	129.0 (20.9)	0.22
Diastolic Blood Pressure, mean (SD)	80.5 (11.7)	82.2 (11.1)	81.4 (11.4)	0.21
BMI, mean (SD)	34.7 (9.4)	32.5 (8.3)	33.6 (8.9)	0.04
Oral agents for diabetes, %	100.0	98.3	99.1	0.16
Duration of diabetes, mean years (SD)	11.4 (8.2)	10.6 (6.9)	10.9 (7.6)	0.38
Medication Adherence, % ^a				
Low	44.4	45.1	44.7	0.56
Medium	38.7	33.8	36.3	
High	16.9	21.1	19.0	
Self-rated health, %				
Excellent	1.4	3.5	2.5	0.012
Very Good	3.5	6.9	5.2	
Good	27.5	38.9	33.2	
Fair	52.1	33.3	42.7	
Poor	15.5	17.4	16.4	
# days diabetes self-care activities, mean days per week (SD)				
Followed healthful eating plan	3.8 (2.7)	4.0 (2.7)	3.9 (2.7)	0.60
5 or more servings of fruits/vegetables	3.1 (2.8)	3.3 (2.9)	3.2 (2.8)	0.50
Physical activity level, %				
Low	56.3	46.9	51.6	0.24
Moderate	28.2	36.6	32.4	
High	15.5	16.6	16.0	
Depressive symptoms, %				
Minimal (PHQ 1-4)	46.1	46.2	46.1	0.99
Mild (PHQ 5 – 9)	26.9	25.9	26.4	
Moderate (PHQ 10 -14)	12.1	14.0	13.0	
Moderately severe (PHQ 15-9)	10.6	10.5	10.6	

Measure	Control (n=142)	Intervention (n=145)	Total Population (n=287)	P Value
Severe (PHQ 20 +)	4.3	3.5	3.9	
Self-Reported Medical Conditions, %				
Depression/Anxiety	55.6	49.0	52.3	0.26
High Cholesterol	62.7	67.0	64.8	0.45
High Blood Pressure	73.2	67.6	70.4	0.29
COPD	29.6	24.1	26.8	0.30
Arthritis	36.6	40.0	38.3	0.55
Physician visits, past 12 months, mean (SD)	6.0 (6.6)	5.3 (4.9)	5.7 (5.8)	0.24
Insurance status, %				
Private	6.4	5.7	6.0	0.88
Public	51.8	49.6	50.7	
Uninsured	41.8	44.7	43.3	

* p value for chi-square test for categorical variables, and t-test for continuous variables