EFFECTIVENESS OF A PEER LEADER SUPPORTED DIABETES SELF-MANAGEMENT SUPPORT PROGRAM ON PATIENT ASSESSMENT OF CARE FOR CHRONIC CONDITIONS (PACIC)

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ABSTRACT

Diabetes is a complex chronic disease which requires patients to integrate numerous actions into their daily lives for successful management. Peer leader supported diabetes self-management support (DSMS) is a promising efficient method for delivery of diabetes education in high risk communities.

The objective of this study was to evaluate the effectiveness of a peer leader supported DSMS program on the Patient Assessment of Care for Chronic Conditions (PACIC). This paper specifically focused on the impact of peer leaders on patient-rated experience of self-management support as measured by the PACIC. The study was a prospective, multisite, cluster randomized controlled trial. The intervention group received diabetes self-management education (DSME) plus peer leader supported DSMS, while in the control group, patients participated in DSME and DSMS conducted by diabetes educators. Two-hundred-twenty-one patients with diabetes were recruited from seven primary care practices at baseline, 119 in the intervention group and 102 in the control group.

The overall PACIC score was not significantly associated with the peer leaders support, however the model revealed a significant positive interaction between the groups and the change in the slope of the PACIC score throughout the study (p=0.004). This indicated that

there was a steeper increase in total PACIC scores over time in the intervention group than in

the control group. PACIC scores increased with baseline PACIC scores, but the increasing rate

declined as baseline scores increased. In this study, there were no associations between the

PACIC score and age or education level. However, there was a relationship between overall

Diabetes Empowerment Scale score and total PACIC score. Associations were also seen in the

subscales of patient activation, delivery system design, collaborative problem solving and follow

up.

This study provided a patient-centered approach to assess the quality of service in a

peer support DSMS program. Additionally, given limited health resources, this study has public

health significance in confirming that peer leader supported DSMS can make greater use of

community resources and gain similar effectiveness at lower cost.

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1.0   INTRODUCTION

1.1   DIABETES

Diabetes mellitus is one of the most common chronic diseases in the United States. According to national statistics, diabetes affects 25.8 million people of all ages, 8.3 percent of the U.S. population[1]. About 1.9 million people aged 20 years or older were newly diagnosed with diabetes in 2010[1]. A CDC study projected that one of three U.S. adults could have diabetes by 2050 if current trends continue[2]. Type 2 diabetes is the most common form of diabetes, accounting for about 95% of diagnosed diabetes in adults[1] .

Diabetes is a metabolic disease in which the body fails to produce any or enough insulin, resulting in elevated levels of glucose in the blood[1]. Diabetes is caused by a variety of factors, such as obesity, physical inactivity, insulin resistance, genetic susceptibility, and environmental factors[3]. Obesity and physical inactivity are strongly associated with the development of type 2 diabetes, and cause insulin resistance, a condition in which the body does not use insulin effectively[3]. Diabetes can lead to serious complications such as blindness, kidney damage, and neuropathy. Having diabetes can also increase the risk of heart disease, stroke and peripheral vascular disease[3].

1.2 DIABETES THERAPY

Diabetes is a complex disease requiring an integrated therapeutic approach. It is essential in this integrated care approach that individuals with diabetes assume an active role in their care[4]. The primary goal of diabetes care is to prevent acute complications and reduce the risk of long-term complications in people of diabetes. There is abundant evidence to show that risk of microvascular and macrovascular complications is related to glycemia, as measured by A1C, which is a major focus of therapy[5-7]. Hemoglobin A1C is a minor component of hemoglobin to which glucose is bound. The level of A1C depends on the blood glucose concentration. That is, the higher the glucose concentration in blood, the higher the level of A1C. Results of some prospective randomized trials have demonstrated that tight control of blood glucose can prevent or delay diabetic complications [8, 9]. According to 2014 Standards of Medical care in Diabetes, a reasonable glycemic goal for nonpregnant adults is less than 7%. But the A1C goal can be varied from 6.5% to 8% depending on individual situations[4].

1.2.1 Pharmacological Therapy

Advances in pharmacologic therapy have increased the treatment options available to people with diabetes. However, information on whether specific agents are able to control glycemia without adversely affecting quality of life is incomplete; answering to these questions requires long-term, large scale clinical trials which are not available for most drugs. The Standards of Medical Care in Diabetes 2014 from the American Diabetes Association reaffirm the four-step strategy of pharmacological therapy[4]. A patient-centered approach is recommended,

accounting for patient preferences, cost, potential side effects of each class, impacts on body weight, and risk for hypoglycemia[4].

It is generally agreed that metformin, barring contraindication or intolerance, is the preferred and most cost-effective first agent. Metformin, a biguanide, has a long-standing evidence base for efficacy and safety, which predominately involves reducing hepatic glucose production [10]. It is initiated at or soon after diagnosis, particularly when lifestyle efforts alone have not achieved or are unlikely to achieve glycemia goals.

When metformin fails to achieve or maintain glycemia goals over 3 months, another agent should be added, which could be sulfonylurea, thiazolidinedione, DPP-4 inhibitor, GLP-1receptor agonist or basal insulin [11]. If the glycemic targets are not achieved after 3 months, adding insulin to a two-drug combination could have a more robust response, compared to adding a third noninsulin agent. In using triple combinations, the essential consideration is to use agents with complementary mechanisms of action. [12]

Diabetes is a progressive disease. Many patients with diabetes eventually require and benefit from insulin therapy. Basal insulin alone is usually the optimal initial regimen, beginning at 0.1-0.2 units/kg body weight.[4] If combination therapy that included basal insulin has not worked after 3 to 6 months, it is necessary to proceed to a more complex insulin strategy, depending on patients' condition, either twice-daily premixed insulin or basal plus mealtime insulin. Individualization of therapy is key, incorporating the degree of hyperglycemia and the overall capacities of the patient[4].

1.2.2 Lifestyle Change

Healthy eating   A position statement from ADA illustrated the benefit of healthy eating for those with diabetes, including improvement in blood glucose control, improvement of lipid profiles, maintenance of blood pressure in the reference range, and weight loss or weight maintenance[13].

Individuals with diabetes are recommended to receive Medical Nutrition Therapy (MNT), preferably provided by a registered dietitian who is familiar with the components of diabetes MNT[4]. However, there is no consistent evidence suggesting a clear nutrition intervention[14]. There is no one set of nutrition recommendations or interventions that apply to all persons with diabetes. Instead of specific healthy eating or dietary interventions, an individualized approach with nutrition recommendations is developed to meet treatment goals and desired outcomes. Using this approach, nutrition intervention is dynamic and determined by nutrition assessments and expert opinion, combined with individual patient needs[15].

Exercise   Physical activity has long been one of the cornerstones in diabetes management. Persons with type 2 diabetes are recommended to undertake at least 150 min/week of moderate to vigorous aerobic exercise, combined with resistance training at least 2–3 days/week[4]. Studies provide considerable evidence for the benefits of aerobic training and resistance training in improving insulin action and management of blood glucose, lipids, and blood pressure[16-19].

Varying type of regular exercise has continued benefits, although their outcomes are often apparently in conflict. Results of studies are often contradictory and can be explained by

the variability in measurements and exercise interventions including their duration (of both individual exercise sessions and length of participation), intensity, and mode of physical activity[20]. The current knowledge base still strongly supports the assertion that becoming and remaining physically active is critical to living long and well with diabetes[4].

1.2.3   Psychosocial Support

It is critical to include assessment and screening for psychological and social support as an ongoing part of the management of diabetes. Multiple studies have found psychological and social problems are associated with hyperglycemia [21, 22] and impair patients' ability to carry out diabetes self-management which may compromise their health status [23]. Psychosocial support refers to a continuum of care and supports which influence both the individual and the social environment in which people live. It emphasizes the need to view these issues within the interpersonal contexts of wider family and community networks in which they are located.[24] A systematic review showed a modest A1C lowering in psychosocial interventions, but a limited association between effects on A1C and mental health [25].

Psychological problems include depression, diabetes-related distress, anxiety, eating disorders, and cognitive impairment[4]. One review clarified the difference between depression and diabetes-related distress. Diabetes distress refers to a broad range of emotional responses to specific acute or chronic stressors and is a progressive process[23], which can be measured by Problem Areas in Diabetes (PAID) or the Diabetes Distress Scale (DDS). One study reported insulin-treatment led to higher diabetes-related emotional distress compared with those

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treated with oral medication or diet [26]. Greater distress was largely explained by greater

disease severity and self-care burden [26].

Diabetes distress is related to specific stressors and Fisher et al. suggested that

identifying the content of the distress during the intervention were necessary and would make

the intervention more efficient [23]. Another study showed the benefit from ongoing DSME and

DSMS which consider distress as an expected part of diabetes [27].

Reducing depressive symptoms might also improve patient self-management with

consequent benefits for diabetes outcomes [28]; in return, improved diabetes control might

reduce distress associated with complications and poor physical health, and enable an

individual to better handle other stressful life events. However, clarifying different types of

psychological issues and achieving simultaneous improvements with low cost and effective

interventions presents a challenge.

1.3   CHRONIC CARE MODEL

Under a system designed for acute symptoms, patients with chronic illness often receive care

which features a passive patient interacting with an unprepared practice team, resulting in

ineffective encounters and frustrating outcomes[29]. The Chronic Care Model (CCM) can lead

to a higher-quality of chronic illness management [30]. Chronic care usually takes place within

three overlapping galaxies: the entire community, with its myriad of resources and numerous

public and private policies; the health care system; and the provider organization, like small

clinics, or a loose network of physician practices[30]. Within this trigalactic universe, the

workings of each component may help or hinder optimal chronic care. The CCM identified six

interrelated elements: self-management support, clinical information systems, delivery system

redesign, decision support, health care organization, and community resources. Assessment

tools were designed to assess the primary tenets of the CCM, such as the Assessment of

Chronic Illness Care (ACIC) and the Patient Assessment of Chronic Illness Care (PACIC). The ACIC

is intended for use by medical teams to identify areas for improvement and to evaluate the

level and nature of improvements made in response to quality improvement interventions[31].

The PACIC provides an approach to evaluate the quality of chronic illness care delivery from the

patient perspective and reflects patient satisfaction [32].

Care modeled after the CCM includes providing self-management support to patients

through goal-setting, follow-up, and links to community resources, as well as providing support

to care providers through delivery system redesign, decision support, and clinical information

systems [33]. Patient-centered care is defined as: "providing care that is respectful of and

responsive to individual patient preferences, needs, and values and ensuring that patient

values guide all clinical decisions".[34] Both patient-centered care and the CCM call for efforts

to assess and understand patient's information in multiple aspects to individualize treatment,

and emphasize the importance of patient participation in the process of treatment, and a more

active role to play in defining and reforming healthcare to achieve optimal care. Therefore,

CCM is viewed as fundamentally patient-centered because of concordance between the

dimensions of patient-centered care and the features of self-management support[35].

For patients with diabetes, self-management support is a critical element of care in

CCM. Patients have to live with diabetes for many years and deal with the day to day

management of their illness including diet, exercise, glucose monitoring, and medication use. Self-management support involves helping patients and their families acquire the skills and confidence to manage their chronic illness, and routinely assessing problems and accomplishments [30]. According to CCM, self-management support is supposed to build on the other elements of the CCM to produce higher-quality care in which informed, activated patients interact with prepared, proactive practice teams. Diabetes self-management education (DSME) and peer leader supported diabetes self-management support (DSMS) primarily fit into self-management support and the community resource elements in CCM. Therefore, the Patient Assessment of Chronic Illness Care (PACIC) was used as an instrument to measure patients' perceptions of the quality of the self-management support received and to assess the extent to which care received aligns with CCM[36].

1.4   DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT

Diabetes is a complex disease requiring patients to integrate numerous actions (e.g., taking medication, monitoring glucose, eating healthily, being active) into their daily lives for successful management. However, patients are not always adept at self-management skills, including basic knowledge acquisition, skill in applying practical information, setting realistic goals, problem solving, coping and self-efficacy. In addition, many people with diabetes have or are at risk for developing comorbidities, including both diabetes-related complications or other medical conditions that may make self-care even more difficult[33]. As recommended in the Standards of Medical Care in Diabetes 2014, diabetes self-management education (DSME) and

diabetes self-management support (DSMS) are essential elements of diabetes management[4]. The overall objectives of DSME and DSMS are to support informed decision making, self-care behaviors, problem solving and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life in a cost-effective manner[37].

1.4.1 Diabetes self-management education (DSME)

DSME is the ongoing and evidence-based process of facilitating the knowledge, skill and ability necessary for prediabetes and diabetes self-care, incorporating the needs, goals and life experiences of patients[38]. The American Association of Diabetes Educators (AADE) defined seven diabetes self-care behaviors as key behaviors to DSME. They are healthy eating, being active, monitoring, taking medication, problem solving, healthy coping, and reducing risks. Multiple studies have shown that DSME is associated with improved diabetes knowledge and improved self-care behavior [38, 39], positive effects in clinical outcomes[40] and quality of life[41].

DSME is mainly provided by registered nurses, registered dietitians, pharmacists or other professionals with certification in diabetes care and education. There is no overt discrepancy in the effectiveness and quality of services delivered by different professionals [39, 42]. However, a body of studies endorse a multidisciplinary team approach to diabetes education [43, 44]. People with diabetes should receive medical care from a collaborative team, which can include, but is not limited to physicians, nurses, dietitians, pharmacists and mental health professionals.

DSME can be offered via an evidence-based and flexible set of courses, the content of which can include practical problem-solving approaches, behavior change, psychosocial issues and strategies to sustain self-management efforts[38]. The most successful diabetes-specific self-management group classes that have been rigorously evaluated to date are based on empowerment theory[45]. Empowerment is the process of discovery and development of one's inherent capacity to be responsible for one's own life [46]. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of their decisions. Empowerment-based patient education is designed to improve quality of life by enabling them to take charge of their health through recognition and promotion of individual strengths, informed choices and personal goals, instead of enhancing their compliance with the treatment recommendations[47].

1.4.2 Diabetes self-management support (DSMS)

Diabetes self-management support (DSMS) refers to activities that assist the person with prediabetes or diabetes in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis beyond or outside of formal self-management training[38]. A variety of strategies are available for providing DSMS both within and outside the DSME organization, such as involving trained peers, ongoing education, support groups and information technology[48, 49]. Better clinical outcomes and self-care behaviors were reported for DSME intervention that included follow-up support (DSMS) [50, 51].

While DSME is necessary and effective in diabetes care management, current short-term DSME interventions have not been shown to persist over the long term [39, 52]. Ongoing DSMS is needed to help people with diabetes maintain effective self-management throughout a lifetime of diabetes as they face new challenges and treatment advances become available[38]. Additionally, because self-management takes place in a patient's daily life and not in clinical or educational settings, it is critical for patients to seek community-based resources that may support their ongoing diabetes self-management with assistance from DSMS providers. Finally, many DSME interventions follow organized lesson plans to deliver information in a prescribed order using a classroom approach. DSMS can reinforce and enhance self-management gains achieved from initial DSME programs under real-world environment and life circumstances.

1.4.3   Peer supported DSMS

With the increasing prevalence of diabetes and resource constraints worldwide, it is imperative to develop and evaluate efficient methods for delivery of DSMS in high risk communities. Most DSME programs, to some degree, have failed to provide enough self-management support due to lack of personnel with protected time or budget limitations. Although the importance of DSME is known and attempts to sustain follow-up are being made, the number of DSME programs and educators cannot meet the demands of the increasing rates of diabetes, especially in low-income communities [53, 54]. To bridge the gap between supply and demand, having peer support involved in DSME is a potential solution. A recent report from the World Health Organization (WHO) indicated that peer support offers a promising solution and

presented recommendations for developing and evaluating peer support programs (WHO, 2007). There is a growing body of literature considering peer supported DSME and DSMS as a promising approach [45, 55].

Peer support is "the provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behavior or stressor and similar characteristics as the target population, to address a health-related issue of a potentially or actually stressed focal person."[56] A peer is someone who has been successful in managing his or her conditions and is able to provide relevant and meaningful information to others with the same condition [57]. Through training, peers are able to voluntarily help individuals with diabetes overcome psychosocial barriers through empathy, support, enhanced knowledge, and obtain health care professional assistance.

There is no one standard set of peer support that applies to all persons with diabetes under various cultural and demographic circumstances. However, actual provision of peer support comprises four key functions, developed by the Peers for Progress initiative [58, 59]. This offers a standardized structure in which peer support programs may be built and evaluated.   In the scope of DSME, the four key functions of a peer leader consist of assisting in self-management, providing social and emotional support, linking patients to clinical care, and providing ongoing support [58, 60].

Indeed, the evidence is sparse for the effectiveness of peer leaders improving clinical outcomes; however, the literature is beginning to consistently demonstrate that peer leaders are effective at facilitating behavior change such as physical activity and helping individuals to

improve their self-efficacy[55]. However, more studies are required to support firm recommendations, particularly for consistent benefit of glycemic control [55, 61].

1.5   PURPOSE OF STUDY

Although a growing number of studies investigated the beneficial role of peers in DSME and DSMS[45, 55, 61], many questions remain unanswered, including influences on patient centeredness, impact on clinical and psychological outcomes, and the ability of practitioners and health care systems to implement, adopt, and maintain patient-centered interventions over time.

Therefore, the objective of this work is to evaluate the impact of a peer leader supported DSMS program on an array of patient outcomes. This paper specifically focused on the impact of peer supported DSMS on patient outcomes as measured by the PACIC.

Hypothesis 1: Participants in peer supported DSMS programs will have higher total PACIC scores, compared with those who do not receive peer supported DSMS.

Hypothesis 2: Compared with those who do not receive peer supported DSMS, participants in peer supported DSMS programs will have higher scores on the five subscales of the PACIC-patient activation, delivery system design, goal setting, problem solving and follow up, respectively.

2.0   METHODS

2.1   STUDY DESIGN

2.1.1 Study Setting

This analysis was conducted using data from Project SEED: Support, Education, and Evaluation in Diabetes. The project objective was to evaluate the effectiveness of peer leader supported vs. non-peer leader supported DSMS programs in rural primary care sites.

The study was a prospective, multisite, cluster randomized controlled trial with the primary care office as the unit of randomization.

Participants were recruited from patients with diabetes at six rural primary care practices in Southwestern, Pennsylvania from April 1, 2011 to March 21, 2012. The six recruited primary care practices were randomized to the intervention group which involved DSME plus peer leader supported DSMS or control group which contained DSME and DSMS conducted by diabetes educators.

Due to failure in achieving recruitment goal, the Uniontown office of Centerville Clinics, as the extension of Carmichaels clinic, was added in the second phase of recruitment from June 29, 2012 to September 30, 2012.

Inclusion criteria were individuals with type 1 or type 2 diabetes over age 18 (ICD9 code 250.xx) receiving care at one of seven primary care practices, comprising Carmichaels clinic, Uniontown Clinic, Joseph F. Yablonski Memorial Clinic, Washington Family Doctors, Partners in Health (Murrysville), Partners in Health (Level Green), Partners in Health (Delmont). Individuals who did not have diabetes, those with gestational diabetes or non-ambulatory patients were excluded in this study. Participants were recruited via mailings, referrals of physicians and diabetes educators in practices, and advertising in local media publications.

2.1.2 Peer Leaders and Training

Peer leaders in this project had to meet the following criteria: having diabetes, being a patient in one of the intervention practices, having attended diabetes self-management education and possessing inherent qualities, such as empathy, which would lend them to being a successful peer leader.

Eligible peer leader candidates were selected from the intervention practices (Carmichaels, Delmont, Uniontown and Murrysville) based on the recommendations from diabetes educators or physicians in the practices. Glycemic control was not one of the eligibility criteria for a peer leader as there are controversial results showing whether good glycemic control was associated with being a successful peer leader [62-66].

Peer leader candidates were identified one to two months prior to the start of the intervention to allow time for training. Candidates who expressed interest in serving as a peer leader were invited to the peer leader training held by the diabetes educator, which included 2-3, 2-hour training sessions in addition with follow-up sessions for each peer leader. The University of Michigan Peer leader Training Curriculum, developed by Dr. Tricia Tang and Ms. Martha Funnell, was used to train the study's peer leaders how to facilitate self-management support groups. All peer leaders signed an agreement before beginning their work as peer leader, outlining their responsibilities in this role.

2.1.3   Intervention

This study was carried out in three phases (Figure 1). The major part of phase 1 was DSME and the interventions in phase 2 and phase 3 were DSMS. Both of DSME and DSMS was based on the empowerment approach[47], which focused on reflecting on participants' self-management experiences, discussing their emotional experience of living with diabetes, engaging in systematic patient-centered goal setting and problem solving. The University of Pittsburgh approved the study and all patients provided informed consent prior to any procedures.

Phase 1 (Baseline Assessments+ DSME + Post-DSME Assessments):

Participants in both groups completed demographic data and baseline assessments before the intervention. In the intervention group, participants were offered four weekly DSME classes and peer leaders also attended. Activities in the control group and the contents of DSME classes

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were identical to those in the intervention practices with the exception that there was no peer leader attending. In DSME sessions, participants received their clinical data results along with information about self-care behaviors [53]. All of the same data that were collected at baseline were also collected following DSME, starting on May 1, 2011.

The DSME curriculum was based on the ADA Standards for DSME[37]. The core content of the curriculum stemmed from the American Association of Diabetes Educators 7 Self Care Behaviors[38] and the American Diabetes Association Medical Standards of Care[4].

Phase 2 (Support Group+ 6 months Assessments):

Following DSME, participants were invited to attend a series of six monthly support group meetings from June 1, 2011 to April 2013, which addressed discussions for overcoming challenges in management, goal setting, and problem solving. The same content was provided and discussed in support groups for both intervention and control groups; however, the peer leader facilitated the intervention practice support groups, whereas the diabetes educator facilitated the sessions for the control groups. Participants in both groups completed post support group assessments at 6 months after intervention.

Phase 3 (Monthly phone calls+12 months assessments):

Following the series of six monthly support groups, participants received monthly support via phone calls. The phone call log (Appendix A) was used for both intervention and control practices to capture data related to medication changes, previous short-term goals, future

short-term goals, and progress and confidence in achieving the goals. The calls were made by

peer leaders in the intervention practices, and by diabetes educators in control practices.

Participants in the intervention groups received a more thorough talk about goal setting and

long term self-management from peer leaders, compared with routine follow up calls from

diabetes educators in the control group. Participants in both groups completed assessments at

12 months post intervention.

2.2   MEASUREMENTS

2.2.1   Clinical Measurements

Clinical measurements in the project included A1C (%), blood pressure (mmHg), weight (lbs),

height (inches), BMI (kg/m^2), LDLc (mg/dL), triglyceride levels (mg/dL) and total cholesterol

(mg/dL) (Table 1). In order to capture fasting laboratory values for A1C and lipids, all

participants were provided with a lab requisition form to take to their local lab to have their

blood drawn. Results were then faxed to the study team and the participants and their

physicians were provided with the results. Appendix B is a copy of the lab requisition form and

an example of the participant results. Blood pressure was assessed according to the

Hypertension Detection and Follow-Up (HDFP) protocol. Three consecutive BP readings (right

arm, sitting) using a standard mercury manometer were taken.

2.2.2 Sociodemographic And Survey Measurements

Sociodemographic data Sociodemographic data were collected at baseline, which consisted of age, gender, ethnicity, type of diabetes, yearly income and education level.

Diabetes Distress Scale (DDS) The diabetes distress scale (DDS) measures diabetes-related emotional distress and consists of four unique subscales, which when summed together, produce a total diabetes distress score, ranging from 1 to 6 (higher score is worse). The four scales that make up the DDS include Emotional burden, Interpersonal Related Distress, Physician related distress, and Regimen related distress. The higher score indicated the severer diabetes-related distress. The DDS has a consistent, generalizable factor structure and good internal reliability (Cronbach's coefficient alpha > 0.87) [67]. (Appendix C)

SF-12 The 12-Item Short Form Health Survey (SF-12) was developed for the Medical Outcomes Study (MOS), a multi-year study of patients with chronic conditions. The SF-12 was used to measure general quality of life in the study population, ranging from 0 to 100, where a zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health. The SF-12 consists of 12 items and two dimensions, physical functioning (PCS-12) and mental functioning (MCS-12). The 12 items scale achieved a multiple R^2 of 0.911 in the prediction of PCS-36 and 0.918 in the prediction of MCS-36 in the general US population (n =2,474). The test-retest reliability estimates coefficients were 0.890 and 0.760 in PCS-12 and MCS-12, respectively [68]. MCS-12 was used as a measurement for mental function in analyzing. (Appendix D)

Diabetes-39 The Diabetes-Specific Health-Related Quality Of Life (Diabetes-39) was used to measure diabetes specific quality of life in the study population. The D-39 consists of five subscales, including diabetes control, anxiety and worry, social burden, sexual functioning, and energy and mobility. The scale of each question ranges from 1 to 7, in which 1 represents quality of life not affected at all, and 7 extremely affected. After standardization, the scores of each subscale ranges from 0 to 100, in which higher score implies worse quality of life. The Cronbach's alpha values from the six scales ranged from 0.81 to 0.92. [69]. The subscales of diabetes control, anxiety and worry, social burden were considered as covariates in model analyzing, since they were related to psychological traits. (Appendix E)

Diabetes Empowerment Scale (Short Form) (DES-SF) The diabetes empowerment scale (DES-SF) is a brief overall assessment of diabetes related psychosocial self-efficacy. The scale ranges from 1 to 5, with 1 being low self-efficacy and 5 being high self-efficacy. This scale contains three subscales: managing the psychosocial aspects of diabetes with 9 items, assessing dissatisfaction and readiness to change with 9 items and setting and achieving goals with 10 items. The scale is highly reliable (α = 0.96) [70]. (Appendix F)

Patient Assessment of Care for Chronic Conditions (PACIC) The Patient Assessment of Care for Chronic Conditions (PACIC) is a brief, validated patient self-report instrument measuring specific actions or qualities of care that is patient-centered, proactive, planned and includes collaborative goal setting, problem-solving, and follow-up support[32]. The PACIC contains 20 items, which make up five subscales. The five subscales are averaged to create a total PACIC

score. The five subscales consist of patient activation, delivery system design/decision support, goal setting, problem solving/contextual counseling, and follow up/coordination. The scale of each subscale and overall score is from 1 to 5, higher score indicating better response to health services. The PACIC demonstrated moderate test-retest reliability (r = 0.58) [32]. (Appendix G)

2.3   STATISTICAL ANALYSIS

The primary outcome of this study is change in the total PACIC score. Secondary outcomes included changes in the PACIC subscales (a) scores in patient activation; (b) scores in delivery system design; (c) scores in goal setting; (d) scores in problem solving and (e) scores in follow up.

Primary and secondary outcomes were collected at baseline, post-DSME classes, post-support groups (6 month time point) and post phone calls (12 month time point). The same anthropometric, laboratory, sociodemographic and survey variables were collected at each time point. Demographic and clinical data were reported using measures of central tendency (percentage, mean for continuous variables with normal distribution, median for countiuous variables with innormal distribution). All analyses were conducted as intention to treat. According to the principle of intention-to-teat, Last observation carried forward (LOCF) imputation technique was applied, in which missing values were replaced by the last observed value of that variable for each individual.

Given dropout rate throughout the study, power calculations were conducted based on preliminary studies, using PASS 12, NCSS. Paired t-tests for continuous data and McNemar's

test for categorical data were used to determine differences between those who completed four assessments and non-completers in demographic variables in two groups.

In cross-sectional analyses, paired t-tests for continuous data and McNemar's test for categorical data were used to determine between group differences at four time points and within group differences between baseline and follow-up visits. In order to examine differences between the study groups, a combined between and within group analysis was performed for each outcome of interest at each time point in mixed models adjusted for the corresponding baseline values.

In longitudinal analyses, mixed models were used to analyze the change in outcome values throughout the study between study groups. Univariable modeling was performed followed by multivariable modeling. Those covariates whose p-values were < 0.20 were considered for multivariable models. Potential covariate variables for consideration included: overall DDS score (continuous), overall DES score (continuous), MCS-12 (continuous), D39_anxiety and worry (continuous), D39_social burden (continuous) and D39_diabetes control (continuous) (Table 2). A1C was also used as an effect modifier to detect whether the effect of peer support on outcomes differed by change in A1C. All of covariates were time-varying so that values at four time points of each variables were fitted into model.

Then, the selected covariates as well as demographic variables were forced into multivariable model. Multicollinearity was tested among covariates. To distinguish the longitudinal impact of the intervention on the two study groups, a time*PACIC interaction term was added as a covariate in the model. The effect of study group was adjusted for the clustering

of patients within primary care practices and the baseline values of the corresponding

dependent variables in all models. All data were analyzed using SAS 9.3, Cary, NC.

3.0   RESULTS

3.1   DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

Demographic and clinical characteristics of participants by intervention status at baseline are

shown in Table 3 and Table 4. There were 119 participants in the intervention group and 102 in

the control group. Participants in the intervention group were younger (61 yr vs 64 yr, p=

0.4883), attended at least some college or higher education (66% vs 51%, p=0.0201) and had

lower systolic blood pressure (134.5mmHg vs. 142.7mmHg, p=0.0079), compared to

participants in the control group. There were no significant differences between the

intervention and the control group in the proportion of participants who were male, white, had

type 2 diabetes, earned over $20,000 annually, used insulin, and monitored blood glucose

status. The A1C level, low-density lipoprotein cholesterol (LDLc) and body mass index (BMI) did

not significantly differ between the intervention and the control group on average.

Of the initial 221 participants, 76 patients (35%) dropped out by the end of study, 46

(39%) and 30 (30%) in the intervention and the control group, respectively (Figure 2). Given

different dropout rates between the two groups (p=0.149), the distribution of demographic

characteristics among those who completed four assessments and those who didn't were tested and no significant differences were found between completers and non-completers, with the exception of age (Table 5). In the intervention group, completers tended to be older than those who dropped out during the study (p=0.02).

3.2   CROSS-SECTIONAL ANALYSIS

The average PACIC score in the intervention group was similar to the control group at baseline (2.8 vs. 2.6, p=0.39) (Table 6). In the intervention group, the average PACIC score decreased from 2.8 at baseline to 2.7 at post DSME assessment, but increased to 2.9 at 6 months and remained at this level at the end of the study. In the control group, the PACIC score increased by 0.2 on average at post DSME assessment and declined to 2.7 at the end of study (Figure 3). From baseline to post DSME assessment, PACIC score decreased by 0.1 in the intervention group, which was opposite with the increase of 0.2 in the control group (p=0.02). The changes between baseline and the other two time points were similar between the intervention and control groups (Table 7).

Changes in the PACIC score between baseline and follow-up time points were significantly negatively associated with the baseline PACIC score. A higher baseline PACIC score predicted less change in the PACIC score at each of the following time points (Table 8).

3.3   LONGITUDINAL ANALYSIS

Mixed models were used to evaluate the effects of the intervention on the PACIC score over

time adjusting for relevant covariates (Table 9). In model 1, the PACIC score was not associated

with the intervention (p=0.6), but the average within-person change in the PACIC score was

statistically significant (p= 0.01). The PACIC score increased over time during the 12 month

follow up. In model 2, participants with higher baseline PACIC scores were more likely to have

higher PACIC scores during follow up (p <.0001), adjusting for intervention group and slope of

within-person change.

In model 3, four relevant behavioral covariates were added into model, including MCS-

12, D39-anxiety and worry subscale, DDS and DES. In the unadjusted model, MCS-12, DDS and

DES were significantly associated with the PACIC score at each time point (Table 9). After

adjusting for covariates, the association between the DDS score and the PACIC score was

attenuated (p = 0.3). Results were similar to MCS-12 (p = 0.9). The average PACIC score in the

intervention group was similar to the control group (p = 0.9), after adjusting for covariates and

baseline PACIC score. In model 6, age and education level were added to the model, since

significant differences in these variables were found at baseline. The intervention group was

not significantly different in the PACIC score than the control group with the trained diabetes

educators.

In model 7, the interaction term of the change in slope of the PACIC score and group

was included in the model. The slope of the change in the PACIC score was steeper in the

intervention group, compared to the control group (β=0.023, p=0.004).

Potential associations of DES, D39-anxiety and worry, MCS12 and DDS were explored to understand their relative contribution in the multivariate model. The results indicated that DDS and D39-anxiety and worry, MCS12 and D39-anxiety and worry were modestly associated (Table 10). In the linear regression model based on baseline values of each variable, the variance inflation factor (VIF) of D39-anxiety and worry was 2.5, which showed the variance of the coefficient estimate of D39-anxiety and worry was inflated by 2.5 times by multicollinearity (Table 11). In model 3, 4 and 5 in Table 9, the reversal of the sign of the beta coefficient of the groups variable indicated modest multicollinearity in this multivariable model.

3.4   SECONDARY OUTCOME

In cross-sectional analysis, patients in the intervention group had higher scores on the patient activation subscales at the end of study compared to the control group (p=0.04) (Table 6). For the subscales patient activation, delivery system design, problem solving and follow up, the change in scores between baseline and other time points were consistent with total PACIC score, in both the intervention group and the control group. In the goal setting subscale, the score increased throughout the follow up period in the intervention group; while the control group had an increase in score at 1 month which remained at a high level until the end of the study (Table 7).

In multivariate models of patient activation, delivery system design, problem-solving and follow-up subscales, the slope of change varied depending on group. D39-anxieity and worry score (p< 0.05) and DES score (p<.0001) were significantly positively associated with

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PACIC-patient activation score and delivery system design rating, adjusting for the

corresponding subscale score at baseline, DDS score, MCS-12, age and education level (Table

10).

4.0   DISCUSSION

4.1   SUMMARY OF FINDINGS

This study tested the influence of peer leaders on patient-rated experience of self-management

support in a cluster randomized trial of DSME and peer leader supported DSMS. It was assumed

that participants in peer supported DSMS programs would have higher total PACIC scores,

compared with those who did not receive peer supported DSMS. Compared to the control

group, there was a steeper and continuous increase in PACIC scores throughout the study in the

intervention group, despite the lower PACIC scores on average. PACIC scores increased with

baseline PACIC score, but the increasing rate declined as baseline score increased. In this study,

there was no association between the PACIC score and age or education level. However, there

was a relationship between DES score and PACIC score. Associations were also seen in the areas

of patient activation, delivery system design, collaborative problem solving and follow up

subscales.

The PACIC is a reliable instrument for measuring patients' perceptions of the quality of

the self-management support received. The PACIC also reliably assesses the extent to which

health care received aligns with the CCM[36]. Researchers have found that PACIC scores were significantly related to the quality of diabetes care received (i.e., patient reported blood tests and behavioral counseling) [36] and reported self-care behaviors [71], although few demographic or clinical characteristics were associated with the PACIC [36]. One study reported gender and education-based variability in the PACIC scores, with females and those with higher education levels scoring higher on the PACIC [33]. However, results from another study demonstrated that non-white patients and those with lower level of education were more likely to report that the diabetes care system was in line with the goals of the CCM [72]. All studies presented above were cross-sectional surveys. No other study was found that considered the temporal association between PACIC score and clinical outcomes, psychological outcomes and self-care behaviors.

4.2   POSSIBLE EXPLANATIONS

The success of peer support seen in the present study may be due to the reciprocal relationship that was created through the sharing of similar life experiences [56, 73], emotional support and appraisal or information supports [45], as seen in other studies. In DSME, peer leaders exert their influence in four respects, which are 1) assisting in self-management, 2) providing social and emotional support, 3) serving as a linkage to healthcare, and 4) providing ongoing support [58, 60]. Therefore, it is rational to explain the impact of peer support in PACIC scores based on these four aspects.

Peer leaders can help patients to reinforce and apply the concepts of DSME into their daily life. For instance, peer leaders can continuously work on helping patients improve self-care behaviors after DSME through sharing reachable resources, setting applicable goals together, practicing and rehearsing of behaviors, trouble-shooting barriers and problem solving[58]. In this study, compared to the control group, patients in the intervention group may have received more flexible, non-threatening, timely support from their peer leaders, which may explain better feedback in quality of management care they received.

The potential mechanistic model for peer leaders from Heisler et. al. implies that peer support was beneficial in promoting motivation, increasing positive mood and understanding, dealing with diabetes-specific distress and building up an extensive social network [45, 56]. In addition, the finding that patients with chronic disease attained benefits from peer support programs when used as a means of improving psychosocial outcomes was documented widely in the literature [74, 75]. Other studies supported the relationship between psychological outcomes and patient satisfaction [76, 77]. In SEED, peer leaders spent more time in supportive interaction with patients, generally including attentive listening, encouragement and reassurance, compared to routine counsel from diabetes educators. Emotional support from peers may foster the experience of feeling accepted, cared for, admired, empathized, respected and valued, thus alleviating distress and depression and positively impacting PACIC scores[56].

Meanwhile, peer involvement may facilitate communication between patients and health care professions and construct more effective visits that focus on making informed self-management decisions and achieving personal self-care goals. In the intervention group, the peer leader may have had more opportunities for participants to discuss self-management

barriers and goals, and to talk about upcoming physician appointments during the follow up

period, compared with support provided by diabetes educators in the control group. The

connections between participants and members of the health care team which involved peer

leaders could have a positive influence on patients' responses to certain questions in PACIC,

such as "Asked how my visits with other doctors were going" or "Told how my visits with other

types of doctors, like an eye doctor or other specialist, helped my treatment".

4.3   LIMITATIONS

This study had limitations that are worth consideration. First, the relatively small sample size

(n=221) may lead to failure in detecting significant differences between the intervention and

the control group and may explain the decreasing then increasing trend in the PACIC score. The

results of power calculation were shown in Table 13. Setting the significance level at 0.05, the

variance of random effect matrix as 0.15, and a residual variance as 0.35 based on the above

data and results, to detect the size effect of 0.1 between intervention and control group, the

present sample size can only gained approximately 29% power.

Additionally, the dropout rates were 39% in the intervention group and 30% in the

control group, which may have overestimated the relationship between PACIC and

intervention, because the higher dropout rate in intervention group may have resulted from

lack of confidence in the information and support offered by peer leaders rather than the

professionals. The difference in age between the groups implied that those who dropped out in

the intervention group tended to be younger, which may have also biased results.

Third, variability in the patients' ability to interpret survey questions across literacy levels may have resulted in reporting bias, although this study reported little association between education level and survey score. In addition, social desirability bias cannot be ignored when explaining these survey data. Patients may tend to provide more positive feedback to peers given the frequency of communication.

Moreover, due to lack of information about established confounders for the PACIC, the impact of the intervention was less convincing without adjusting for the effects of potential confounders.

Finally, the fidelity of intervention may be a limitation in this trial. Although all peer leaders received training before study and received follow-up support from the diabetes educators, the effects of intervention may vary depending on the personality, literacy level and the enthusiasm of the peer and the collaboration with patients. Moreover, there was also lack of formally monitoring of intervention fidelity to determine if it was administered as intended.

4.4   SIGNIFICANCE OF STUDY

Optimizing outcomes among patients with diabetes requires an engaged, competent patient receiving the most effective care, treatment and support [35]. It is a priority to encourage active patient participation in care, including an active role in defining and reforming their chronic disease management. Few studies exist evaluating if peer support programs assessed the overall quality of diabetes care delivered in primary care settings from the patient

perspective. This study provided a patient-centered approach to assess the quality of service in a peer led DSMS program.

This study explored the possible temporal association between PACIC scores and intervention with peer leaders, which may be considered as complementary evidence to support the mechanisms by which peer support may lead to improved or equal outcomes. Moreover, given limited health resources, this study examined an approach that can make greater use of community resources to gain equal effectiveness with lower cost.

4.5   FUTURE STUDIES

Based on our findings, the PACIC score was related to certain psychological variables such as diabetes-related distress or empowerment. Yet, relatively little is known about how robust these relationships may be. It is possible that patients with diabetes distress are less likely to receive disease management or be satisfied with the health care they receive. Thus in future studies, it is necessary to examine the effect of distress on PACIC scores in studies considering factors associated with diabetes care.

In the analysis of PACIC subscales, there was a positive association between the degree of anxiety and patient activation and delivery system design scores. Further explanations for these correlations are needed.

This study found a potential association between baseline PACIC scores and the pattern of changes in the PACIC score over time. It was a rational assumption that a benign interaction between patients and health care team, such as sharing responsibility for management and

sharing control of clinical interactions and decisions could have continuous and accumulated influence in patient satisfaction but the degree of that increase would decrease with higher levels of satisfaction at baseline. Thus, more studies exploring patients characteristics at the start of DSME and DSMS may help to target populations who need more support where may yield more effective and efficient healthcare management in the future.

4.6   PUBLIC HEALTH SIGNIFICANCE

With the growing prevalence of diabetes and shortage of diabetes educators, it is increasingly important to integrate and utilize low-cost interventions in high-risk communities that build on available resources. Using peers is promising to optimize DSME and DSMS to meet increasing demands from patients. Interventions supported by trained peers are much less resource intensive than current care models, since peers are an important component of existing community sources. Additionally, peer support may have a positive impact in optimizing health care delivery and addressing psychosocial aspects of chronic conditions and hence self-management.

The involvement of peer leaders expands the boundary and depth of DSME and DSMS, and makes it possible to reach more and more patients with diabetes, especially in a health care system facing severe resource constraints.

5.0   FIGURES AND TABLES
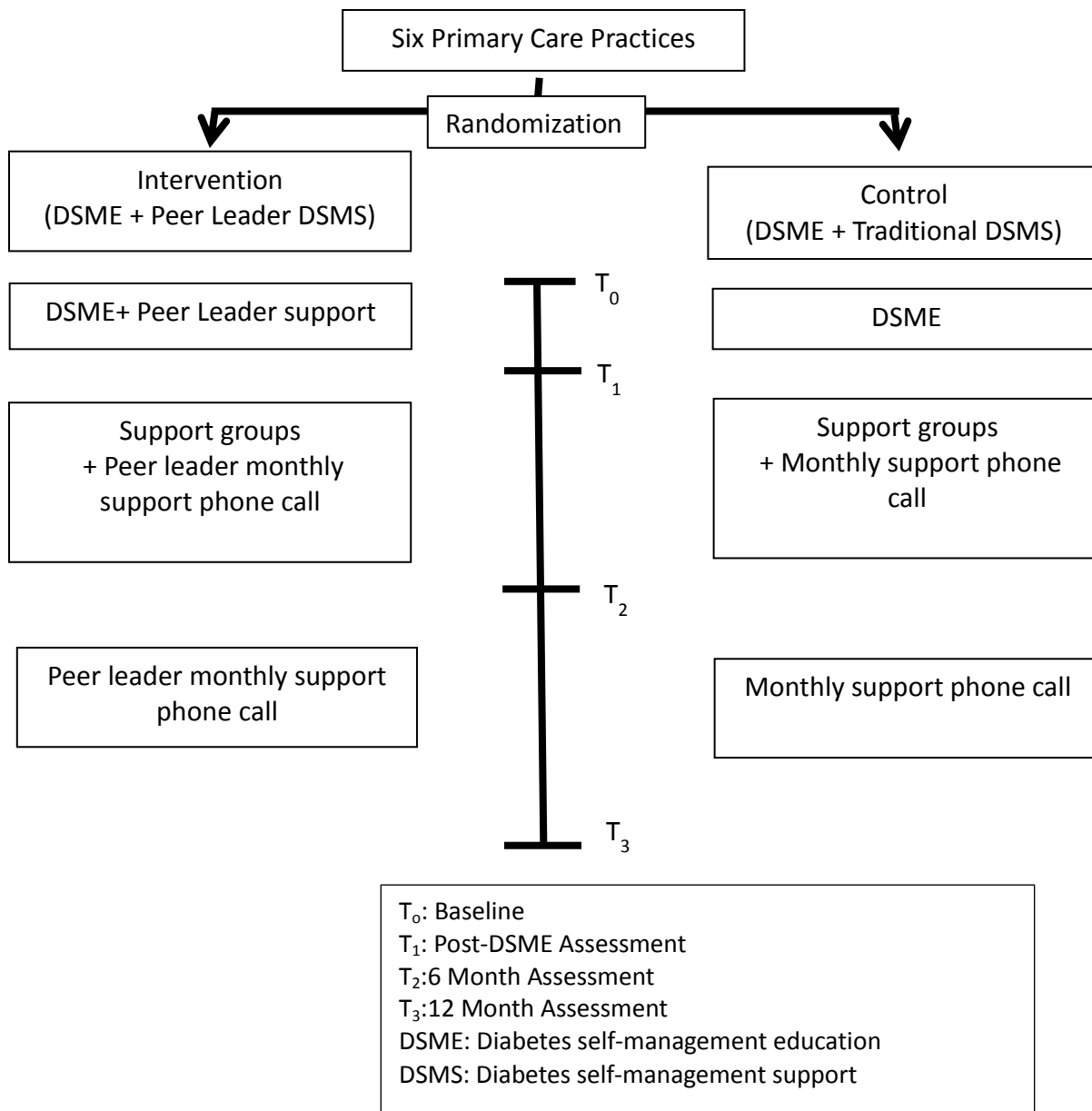
Figure 1 Flowchart of Study Process in the SEED Project

Table 1 Available measurements in the SEED Project*

Measures	Method	Expected change with intervention
Clinical characteristic		
A1C (%)	Quest Labs	% of subjects with A1c<7% ↑ Mean A1c values↓
LDLc(mg/dL)	Quest Labs	% of subjects with LDLc < 100 mg/dL ↑
Blood Pressure (mmHg)	HDFP protocol	% of subjects with BP< 130/80mmHg ↑
Weight (lbs)		Average values ↓
Height (inches)		-
BMI(kg/m^2)	Calculated based on weight and height	% of subjects with BMI in 25-30 kg/m^2↓ % of subjects with BMI in 30-40 kg/m2↓
Triglyceride (mg/dL)	Quest Labs	Average values ↓
Total Cholesterol (mg/dL)	Quest Labs	Average values ↓
Survey data		
DDS	Self-report	Average score ↓
SF-12	Self-report	Average score in MCS and PCS ↑
Diabetes-39	Self-report	Average score in five subscales↓
DES-SF	Self-report	Average score ↑
PACIC	Self-report	Average score ↑

A1C: Glycosylated Hemoglobin
HDFP: Hypertension Detection and Follow-Up program
BMI: Body mass index
LDL: Low-Density Lipoprotein
DDS: Diabetes Distress Scale
SF-12: 12-item Short Form Health Survey
Diabetes-39: The Diabetes-Specific Health-Related Quality Of Life
DES-SF: Diabetes Empowerment Scale (Short Form)
PACIC: Patient Assessment of Care for Chronic Conditions
SEED: Support, Education, and Evaluation in Diabetes
*All measurements were examined at four time points.

Table 2 Selection of covariates for the final mixed model for PACIC score in the SEED project

	Covariate*	Coefficient Estimate	P-Value
PACIC_total	DDS	-0.2215	<.0001
	DES	0.3748	<.0001
	MCS-12	0.01069	0.0023
	D39_AW	-0.00256	0.0897
	D39_SB	0.1362	0.8044
	D39_DC	-0.00191	0.2492
	A1C	-0.01771	0.5719

PACIC: Patient Assessment of Care for Chronic Conditions
DDS: Diabetes Distress Scale
DES: Diabetes Empowerment Scale (Short Form)
MCS-12: Mental health component scale
D39_AW: Anxiety and worry subscale in Diabetes-39
D39_SB: Social burden subscale in Diabetes-39
D39_DC: Diabetes control subscale in Diabetes-39
*Mixed models were used for test, where total PACIC score for were dependent variables, and each values of covariates at four time points were independent variables.

Table 3 Sociodemographic Characteristics of Participants in the SEED project at Baseline

Demographic Characteristics	Overall	Intervention	Control	p-value*
Total	221	119	102	-
Gender				
Female, N (%)	142(64.3)	74(61.9)	68(66.7)	0.4883
Ethnicity				
White, N (%)	210 (95.0)	113 (95.0)	97(95.1)	0.9619
Age(yr)				
Mean (SD)	62.9(10.8)	61.3 (11.5)	64.7 (10.7)	0.0237
Type of diabetes				
Type 2 diabetes, N (%)	189 (85.52)	104(87.4)	85 (83.3)	0.8357
Education level				
College or higher, N (%)	131 (59.3)	79 (66.4)	52(51.0)	0.0201
High school or lower, N (%)	90 (40.7)	40(33.6)	50(49.0)	
Income				
<$20,000, N (%)	65(31.0)	35 (30.2)	30(31.9)	0.7859
≥$20,000, N (%)	145 (69.1)	81 (69.8)	64(68.1)	
Missing value	11	3	8	
Blood glucose monitor				
Yes, N (%)	174 (79.1)	90 (76.3)	84(82.4)	0.2686
No, N (%)	46 (20.9)	28 (23.7)	18(17.7)	
Missing value	1	1	0	
Insulin use				
Yes, N (%)	66 (30.3)	38(32.8)	28(27.5)	0.3947
No, N (%)	152 (69.7)	78(67.8)	74(72.6)	
Missing value	3	3	0	

SD: standard deviation

SEED: Support, Education, and Evaluation in Diabetes project

* Chi-square test were used for categorical variables; t-test was used for continuous variables.

Table 4 Clinical Characteristics of Participants in the SEED project at Baseline

Clinical Outcome Profile	Overall	Intervention	Control	p-value*
Total	217	115	102	-
A1C (%)				
Mean(SD)	7.5 (1.6)	7.6(1.7)	7.4(1.4)	0.6262
Median	7.1	7.0	7.1	
<7%, N (%)	90(47.1)	49(46.7)	41(47.7)	0.8896
≥7%, N (%)	101(52.9)	56(53.3)	45(52.3)	
Missing value	26	10	16	
LDL (mg/dL)				
Mean(SD)	98.4(31.3)	95.8(27.9)	101.2(34.6)	0.2534
<100, N (%)	102(56.7)	56(59.6)	46(53.5)	0.4105
≥100, N (%)	78(43.3)	38(40.4)	40(46.5)	
Missing value	37	21	16	
SBP(mmHg)				
Mean(SD)	138.3(18.0)	134.5(15.6)	142.7(19.6)	0.0079
Median	136.0	135.0	136.8	
<140mmHg, N (%)	126(58.6)	72(62.6)	54(54.0)	0.2012
≥140 mmHg, N (%)	89(41.4)	43(37.4)	46(46.0)	
Missing value	2	0	2	
DBP(mmHg)				
Mean(SD)	76.6(9.6)	75.6(9.5)	77.8 (9.6)	0.0920
Median	78.0	77.0	79.8	
<80 mmHg, N (%)	121(56.3)	71(61.7)	50(50.0)	0.0835
≥80 mmHg, N (%)	94(43.7)	44(38.3)	50(50.0)	
Missing value	2	0	2	
BMI				
Mean(SD)	34.9(7.3)	35.5(7.7)	34.3(6.8)	0.2029
Median	33.7	33.8	32.8	
<25, N (%)	12(5.6)	6(5.2)	6(5.9)	0.8526
≥25 and <30, N (%)	44(20.4)	22(19.1)	22(21.8)	
≥30, N (%)	160(74.1)	87(75.7)	73(72.3)	
Missing value	1	0	1	

A1C: Glycosylated Hemoglobin
LDL: Low-Density Lipoprotein
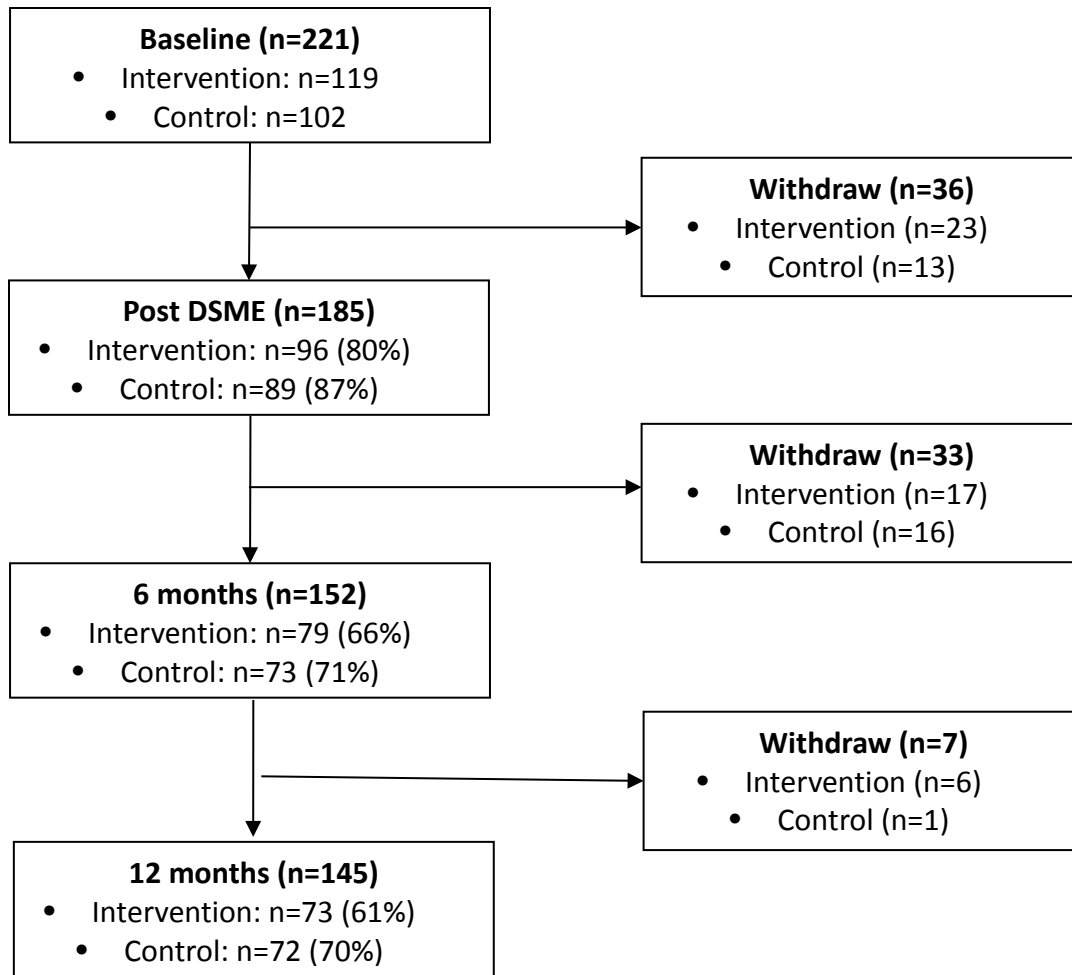SBP: Systolic Blood Pressure
DBP: Diastolic Blood Pressure
BMI: Body mass index
* Chi-square test were used for categorical variables; t-test was used for continuous variables.
SEED: Support, Education, and Evaluation in Diabetes project

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┌─────────────────────────────────┐
│        Baseline (n=221)         │
│   •  Intervention: n=119        │
│        •  Control: n=102        │
└─────────────────────────────────┘
                │
                │            ┌─────────────────────────────────┐
                │─────────►  │        Withdraw (n=36)          │
                │            │   •  Intervention (n=23)        │
                ▼            │       •  Control (n=13)         │
┌─────────────────────────────────┐└─────────────────────────────────┘
│        Post DSME (n=185)        │
│   •  Intervention: n=96 (80%)   │
│     •  Control: n=89 (87%)      │
└─────────────────────────────────┘
                │
                │            ┌─────────────────────────────────┐
                │─────────►  │        Withdraw (n=33)          │
                │            │   •  Intervention (n=17)        │
                ▼            │       •  Control (n=16)         │
┌─────────────────────────────────┐└─────────────────────────────────┘
│        6 months (n=152)         │
│   •  Intervention: n=79 (66%)   │
│     •  Control: n=73 (71%)      │
└─────────────────────────────────┘
                │
                │            ┌─────────────────────────────────┐
                │─────────►  │        Withdraw (n=7)           │
                │            │   •  Intervention (n=6)         │
                ▼            │       •  Control (n=1)          │
┌─────────────────────────────────┐└─────────────────────────────────┘
│        12 months (n=145)        │
│   •  Intervention: n=73 (61%)   │
│     •  Control: n=72 (70%)      │
└─────────────────────────────────┘
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Figure 2 Flowchart of Participants in the SEED project

SEED: Support, Education, and Evaluation in Diabetes project

Table 5 Comparison of Demographic Characteristics between completers and non-completers in the two study groups In the SEED project

Time points	Group	Completers	Non-completers	p-value**
Female, N(%)	Intervention	41 (56.1%)	33 (71.7%)	0.08
	Control	46 (63.9%)	22 (73.3%)	0.35
White, N(%) *	Intervention	67 (91.8%)	46 (100%)	0.08
	Control	28 (93.3%)	69 (95.8%)	0.62
College or higher education, N (%)	Intervention	67(69.8%)	27 (58.7%)	0.15
	Control	38 (52.8%)	14 (46.7%)	0.57
Income>=$20,000, N (%)	Intervention	51(72.9%)	30 (65.2%)	0.38
	Control	48 (72.7%)	16 (57.1%)	0.14
Age, Mean (SD)	Intervention	63.2 (10.4)	58.3 (12.4)	0.02
	Control	65.8 (9.9)	61.8 (11.9)	0.08

*Fish's exact test was used;

**Chi-square test were used for categorical variables, except for ethnicity; t-test was used for continuous variables.

SEED: Support, Education, and Evaluation in Diabetes project

Table 6 Comparisons of mean scores of PACIC and its subscales between two groups at four time points in the SEED project

Scales	Visit	Intervention Mean(SD)	Control Mean(SD)	p-value*	Coefficient estimate[ɫ]
PACIC_total	Baseline	2.76(1.11)	2.63(1.06)	0.3939	0.1280
	Visit 1	2.69(1.07)	2.85(1.07)	0.2868	-0.1558
	Visit 2	2.94(1.17)	2.86(1.11)	0.6175	0.07781
	Visit 3	2.95(1.15)	2.71(1.11)	0.1295	0.2350
Patient Activation	Baseline	2.88(1.31)	2.70(1.23)	0.3184	0.1736
	Visit 1	2.69(1.22)	2.75(1.22)	0.7454	-0.05389
	Visit 2	2.94(1.32)	2.86(1.32)	0.6709	0.07671
	Visit 3	3.04(1.28)	2.68(1.33)	0.0488	0.3521*
Delivery System Design	Baseline	2.94(1.18)	2.79(1.14)	0.3928	0.1369
	Visit 1	2.83(1.14)	2.96(1.19)	0.4319	-0.1247
	Visit 2	3.05(1.22)	2.94(1.13)	0.4874	0.1120
	Visit 3	3.11(1.19)	2.85(1.15)	0.1095	0.2572
Goal Setting	Baseline	2.64(1.30)	2.51(1.13)	0.4386	0.1294
	Visit 1	2.66(1.18)	2.82(1.13)	0.3268	-0.1548
	Visit 2	2.91(1.26)	2.83(1.15)	0.6127	0.08335
	Visit 3	2.86(1.24)	2.71(1.18)	0.3629	0.1501
Problem-solving	Baseline	2.70(1.32)	2.61(1.37)	0.5886	0.1001
	Visit 1	2.60(1.30)	2.85(1.31)	0.1616	-0.2507
	Visit 2	2.93(1.36)	2.88(1.39)	0.7579	0.05777
	Visit 3	2.91(1.35)	2.69(1.36)	0.2094	0.2329
Follow-up	Baseline	2.73(1.15)	2.58(1.10)	0.3318	0.1508
	Visit 1	2.69(1.12)	2.83(1.11)	0.3754	-0.1357
	Visit 2	2.90(1.21)	2.85(1.20)	0.7103	0.06138
	Visit 3	2.88(1.21)	2.66(1.15)	0.1575	0.2284

*p-value<0.05
ɫ: The control group as reference group
Visit 1: post DSME assessment at 1 month
Visit 2: post supports group assessment at 6 months
Visit 3: post phone calls assessment at 12 months
PACIC: Patient Assessment of Care for Chronic Conditions
*Mixed models at specific time points were used
SEED: Support, Education, and Evaluation in Diabetes project
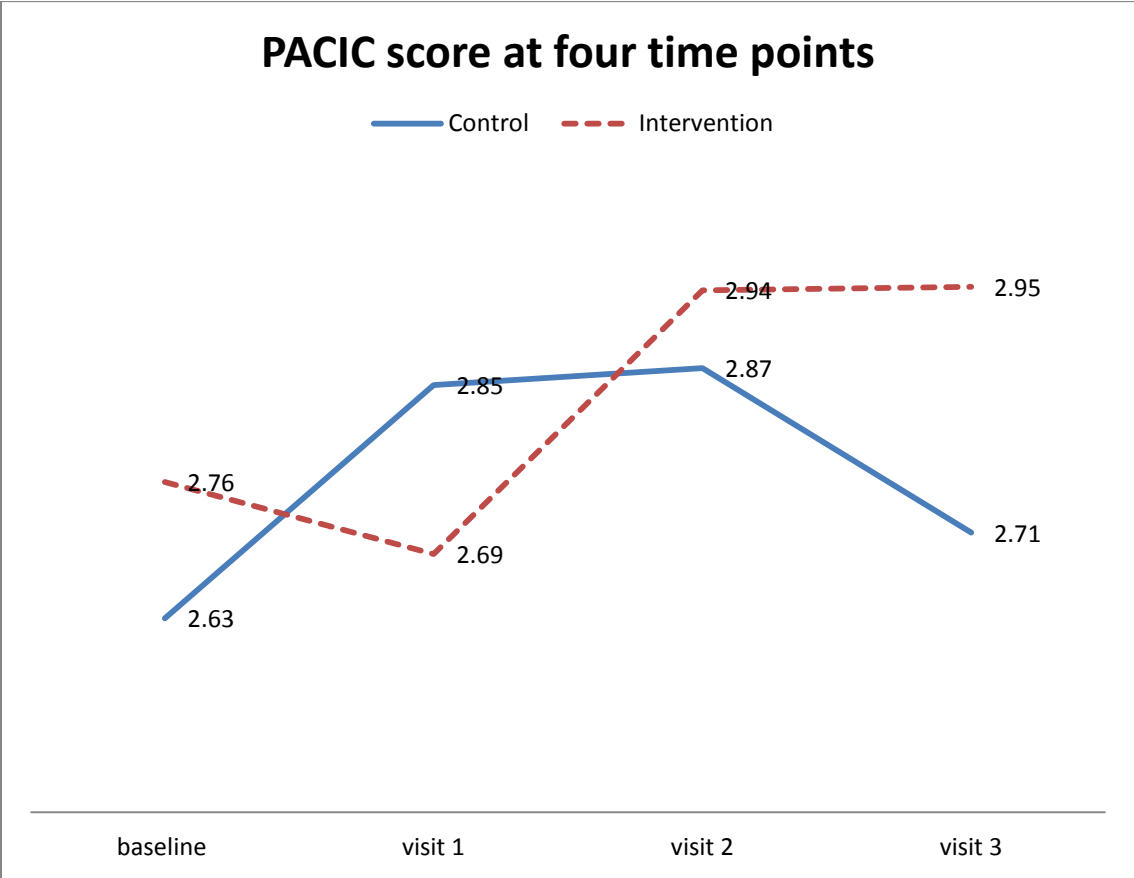
Figure 3 Trends of mean PACIC Scores over Time in the Intervention and the Control Group in the SEED project

PACIC: Patient Assessment of Care for Chronic Conditions
SEED: Support, Education, and Evaluation in Diabetes project

Table 7 Relationship of groups and average change between baselines and subsequent time points for PACIC and the subscales in the SEED project

Scales	Pair of time points	Intervention Mean(SD)	Control Mean(SD)	p-value**	Coefficient estimate‡
PACIC_total	V1 vs. Baseline	-0.07 (0.72)	0.22 (0.92)	0.0204	-0.2399*
	V2 vs. Baseline	0.18 (0.82)	0.24 (0.97)	0.8967	-0.0149
	V3 vs. baseline	0.19 (0.75)	0.08 (1.00)	0.1724	0.1551
Patient Activation	V1 vs. Baseline	-0.17(1.04)	0.04(1.03)	0.2078	-0.1609
	V2 vs. Baseline	0.07(1.07)	0.15(1.11)	0.8454	-0.02701
	V3 vs. baseline	0.17(1.06)	-0.02(1.21)	0.0594	0.2678
Delivery System Design	V1 vs. Baseline	-0.11(0.92)	0.17 (1.07)	0.0829	-0.2143
	V2 vs. Baseline	0.10(0.91)	0.14(1.08)	0.9226	0.01208
	V3 vs. baseline	0.17(0.91)	0.05(1.05)	0.1828	0.1628
Goal Setting	V1 vs. Baseline	0.01(0.93)	0.32(1.05)	0.0398	-0.2468*
	V2 vs. Baseline	0.28(1.03)	0.32(1.10)	0.9317	0.01123
	V3 vs. baseline	0.23(0.91)	0.20(1.10)	0.5681	0.07207
Problem -solving	V1 vs. Baseline	-0.11(1.03)	0.25(1.24)	0.0333	-0.2983*
	V2 vs. Baseline	0.24(1.10)	0.28(1.24)	0.9368	-0.01167
	V3 vs. baseline	0.22(1.07)	0.10(1.35)	0.2499	0.1732
Follow-up	V1 vs. Baseline	-0.03(0.78)	0.26(1.03)	0.0477	-0.2245*
	V2 vs. Baseline	0.17(0.90)	0.28(1.14)	0.7639	-0.03961
	V3 vs. baseline	0.15(0.87)	0.07(1.08)	0.2266	0.1512

*p<0.05

**Mixed models were used, where difference between baseline and other time points were used as dependent variable.

$\ddagger$: The control group as reference group; this model included baseline PACIC score as covariate.

Visit 1: post DSME assessment at 1 month

Visit 2: post supports group assessment at 6 months

Visit 3: post phone calls assessment at 12 months

PACIC: Patient Assessment of Care for Chronic Conditions

SEED: Support, Education, and Evaluation in Diabetes project

Table 8 Relationship of baseline scores and average change between baseline and each subsequent time point for PACIC and its subscales in the SEED project

Scales	Pair of time points	Intercept	Coefficient estimate[‡]	p-value
PACIC_total	V1 vs. Baseline	0.8177	-0.2864	<.0001
	V2 vs. Baseline	0.9936	-0.2860	<.0001
	V3 vs. baseline	0.9656	-0.2808	<.0001
Patient Activation	V1 vs. Baseline	1.0422	-0.3680	<.0001
	V2 vs. Baseline	1.0460	-0.3276	<.0001
	V3 vs. baseline	1.0038	-0.3789	<.0001
Delivery System Design	V1 vs. Baseline	1.1763	-0.3668	<.0001
	V2 vs. Baseline	1.1151	-0.3465	<.0001
	V3 vs. baseline	1.0058	-0.3393	<.0001
Goal Setting	V1 vs. Baseline	1.2594	-0.3754	<.0001
	V2 vs. Baseline	1.3029	-0.3890	<.0001
	V3 vs. baseline	1.0758	-0.3452	<.0001
Problem-solving	V1 vs. Baseline	1.2031	-0.3705	<.0001
	V2 vs. Baseline	1.2094	-0.3530	<.0001
	V3 vs. baseline	1.1231	-0.3940	<.0001
Follow-up	V1 vs. Baseline	1.0104	-0.2980	<.0001
	V2 vs. Baseline	1.1098	-0.3255	<.0001
	V3 vs. baseline	0.8499	-0.3059	<.0001

‡: The mixed model included the intervention term as a covariate; the dependent variable was the changes in the PACIC score between baseline and the subsequent time point.
Visit 1: post DSME assessment at 1 month
Visit 2: post support group assessment at 6 months
Visit 3: post phone calls assessment at 12 months
PACIC: Patient Assessment of Care for Chronic Conditions
SEED: Support, Education, and Evaluation in Diabetes project

Table 9 Estimated Coefficients of Covariates in The Mixed models of PACIC score and other covariates in the SEED project

Variables	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7	Model 8	Model 9
Intercept	2.713**	0.650**	-0.300	-0.417	-0.177	-0.100	-0.032	-0.159	0.169
Group$^\Delta$	0.069	-0.027	-0.001	0.005	0.015	-0.006	-0.119	-0.117	-0.113
Within-person change slope	0.011*	0.011*	0.011*	0.011*	0.011*	0.011*	-0.001	-0.001	-0.001
Baseline of PACIC	-	0.783**	0.712**	0.719**	0.722**	0.710**	0.709**	0.712**	0.713**
DDS	-	-	-0.042	-	-0.015	-0.043	-0.047	-	-0.020
DES	-	-	0.294**	0.300**	0.286**	0.295**	0.295**	0.305**	0.292**
MCS12	-	-	-0.000	0.000	-0.002	-0.000	-0.000	-0.000	-0.002
D39_Anxiety and worry	-	-	0.002	0.002	-	0.002	0.002	0.001	-
Age	-	-	-	-	-	-0.003	-0.003	-0.003	-0.004
Education‡	-	-	-	-	-	0.009	0.009	0.013	0.006
Slope*group	-	-	-	-	-	-	0.023*	0.023*	0.023*
AIC	2113.2	1811.0	1745.1	1747.0	1744.1	1744.5	1744.2	1741.0	1736.7

PACIC: Patient Assessment of Care for Chronic Conditions
DDS: Diabetes Distress Scale
DES: Diabetes Empowerment Scale (Short Form)
MCS-12: Mental health component scale
D39_AW: Anxiety and worry subscale in Diabetes-39
AIC: Akaike Information Criteria
* P-value<0.05
** P-value<0.0001
Δ: The control group as reference group;
ǂ: Attending high school or lower group as reference group
SEED: Support, Education, and Evaluation in Diabetes project

Table 10 The Pearson Correlation Coefficients Between Covariates In The Multivariable Model*

	PACIC	DES	DDS	D39_AW	MCS12
PACIC	1.00				
DES	0.34	1.00			
DDS	-0.18	-0.33	1.00		
D39_AW	-0.09	-0.28	0.68	1.00	
MCS12	0.15	0.24	-0.51	-0.66	1.00

PACIC: Patient Assessment of Care for Chronic Conditions
DDS: Diabetes Distress Scale
DES: Diabetes Empowerment Scale (Short Form)
MCS-12: Mental health component scale
D39_AW: Anxiety and worry subscale in Diabetes-39
*Only baseline values of covariates were used.

Table 11 Variance inflation factor of covariates in multivariable model in the SEED project*

Variable	Parameter estimates	Standard Errors	t Value	Pr > |t|	VIF
Intercept	0.362	0.65984	0.55	0.5839	0
DES	0.47579	0.10375	4.59	<.0001	1.16429
DDS	-0.1111	0.10454	-1.06	0.2892	1.99503
D39_aw	0.00634	0.00382	1.66	0.0985	2.52431
MCS12	0.01087	0.0081	1.34	0.1814	1.79566

PACIC: Patient Assessment of Care for Chronic Conditions
DDS: Diabetes Distress Scale
DES: Diabetes Empowerment Scale (Short Form)
MCS-12: Mental health component scale
D39_AW: Anxiety and worry subscale in Diabetes-39
VIF: variance inflation factor

Table 12 Estimated Coefficients of Covariates in The Mixed models of subscales of PACIC and other covariates in the SEED project

Variables	Patient Activation	Delivery System Design	Goal Setting	Problem-solving	Follow-up
Intercept	0.108	0.062	-0.146	0.251	0.101
Group$^\Delta$	-0.114	-0.123	-0.096	-0.153	-0.099
Within-person change slope	-0.005	-0.003	0.006	-0.000	-0.002
Baseline value of each subscales	0.679**	0.674**	0.656 **	0.654 **	0.691 **
DDS	-0.055	-0.083	-0.029	-0.069	-0.022
DES	0.222**	0.252**	0.322 **	0.343 **	0.314 **
MCS12	0.005	0.003	-0.000	-0.000	-0.005
D39_Anxiety and worry	0.004*	0.005*	0.002	0.002	0.0002
Age	-0.005	-0.003	-0.002	-0.006	-0.001
Education‡	0.018	0.018	0.068	-0.035	-0.004
Slope*group	0.028*	0.023*	0.018	0.027*	0.019*

PACIC: Patient Assessment of Care for Chronic Conditions
DDS: Diabetes Distress Scale
DES: Diabetes Empowerment Scale (Short Form)
MCS-12: Mental health component scale
D39_AW: Anxiety and worry subscale in Diabetes-39
AIC: Akaike Information Criteria
* P-value<0.05
** P-value<0.0001
Δ: The control group as reference group;
ǂ: Attending high school or lower group as reference group
SEED: Support, Education, and Evaluation in Diabetes project

Table 13 Power calculation in the SEED project

Size effect	Within subject		Between subjects	
	N=200	N=240	N=200	N=240
0.1	28%	38%	29%	41%
0.15	58%	65%	62%	66%
0.2	77%	86%	90%	88%
0.3	100%	99%	100%	100%

N: total number of subjects in two groups

Size effect: the minimum detectable difference of PACIC score

APPENDIX A: THE CONTACT LOG IN THE SEED PROJECT

SEED Contact Log

V. Other Areas Covered Today						
Topic initiated by:	**Peer**	**Participant**		**Topic initiated by:**	**Peer**	**Participant**
Exercise	☐	☐		Exercise	☐	☐
Diet	☐	☐		Diet	☐	☐
Stress Management	☐	☐		Stress Management	☐	☐

☐ No other issues discussed

VI. Next Phone Call		Next Doctor's visit:	
Date:	*Time:*	Date:	Time:
		Make appointment to call participant in about one week in advance as date appraoches.	

SEED Contact Log

I. Contact Information			
1. Initiation of Contact	2. Length of Contact	3. Mode of Contact	4. Was this a scheduled contact?
☐ Peer Leader	☐ 0-15 minutes	☐ Phone	
☐ Participant	☐ 16-30 minutes	☐ Person-to-Person	☐ Yes ☐ No
☐ Other,_____	☐ 31-45 minutes	☐ Email	
	☐ 46-60 minutes	☐ Other,	

II. Medication Check (for scheduled contact)	III. Review Short Term Goal Set Last Time
Prompt participant to take out their medicine list to review.	Prompt participant to take out their Action Plan.
5. Problems/concerns with medication since last phone call.	6. Last goal was: _____
☐ No problems or concerns	
☐ Problem or concerns: _____	7. Goal met?
_____	☐ Completely achieved and sustained behavior change
	☐Completely achieved but not sustained
	☐Not achieved but some behavior change
	☐No behavior change
	8. Goal attainment reinforced? ☐ Yes ☐ No

IV. New Short Term Goal (Review Initial Needs Assessment if needed)										
SMART Goal *Specific, Measurable, Achievable, Realistic*										
										☐ No New Goal Set
Time (when, how often, how long)										
Assess Confidence If confidence is less than 7, ask client to revise	No confidence 1 2 3 4 5 6 7							Completely confident 8 9 10		
New Goal (put N/A if confidence is 7 or greater)										
Assess Confidence If confidence is less than 7, ask client to revise	No confidence 1 2 3 4 5 6 7							Completely confident 8 9 10		
Participant will track their progress by:										

APPENDIX B: THE LAB REQUISITION FORM IN THE SEED PROJECT

Requisition for Outpatient Laboratory Services for Project SEED (Support, Education, and Evaluation in Diabetes)

Laboratory Services:
Please FAX blood work results to: (Name)
Please call (name), if any questions at (phone number).
Mail invoices to (Name)
(Address)

ATTENTION: Do not charge study participant or his/her insurance for this blood work. Mail invoices as directed above.

This form is used to identify procedures/services to be provided to a research participant. It must be used each time a participant presents for any services. Only those services listed below will be reimbursed by the research program.

Location of service: Name of site: _____
                   Address:
                   Phone number: Appointment needed? Yes No
                                  Appointment date:_____ Time: _____

Participant Information

Name	
Address	
Address	
Phone:	
DOB	
Gender	[ ] Male [ ] Female
Date referred	

Procedures to be performed	CPT Codes
Venipuncture Routine Spec Coll	36415
HbA1c	83036
Lipid Profile	80061
Microalbumin, random urine with creatinine	82043
ICD-9 Code	250.0
Collected by:	Date:
Test Number:	

Physician Signature:
<physician name>

_____

_____

Date:

You MUST bring this sheet with you in order to get your blood drawn.

Study title: Project SEED: Support, Education, and Evaluation in Diabetes
IRB #   PRO10020504
Anticipated Study Start Date:
Primary Investigator: Gretchen A. Platt, PhD
Email address: plattg@upmc.edu   Phone number: 412-692-4291

THE DIABETES DISTRESS SCREENING SCALE

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 2 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1".   If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
2. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

DDS

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Feeling angry, scared, and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
5. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
6. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
7. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
8. Feeling that diabetes controls my life.	1	2	3	4	5	6

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
10. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
11. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

DDS17 SCORING SHEET

<u>INSTRUCTIONS FOR SCORING</u>:

The DDS17 yields a total diabetes distress scale score plus 4 sub scale scores, each addressing a different kind of distress. To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale. The letter in the far right margin corresponds to that item's subscale as listed below. **We consider a mean item score of 3 or higher (moderate distress) as a level of distress worthy of clinical attention.** Place a check on the line to the far right if the mean item score is ≥ 3 to highlight an above-range value.

We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored 3 or higher.

Total DDS Score:
      a. Sum of 17 item scores.   _____
      b. Divide by: _____17_____
      c. Mean item score: _____ ≥ 3 _____

A. Emotional Burden:
      a. Sum of 5 items (1, 3, 8, 11, 14)   _____
      b. Divide by: _____5_____
      c. Mean item score: _____ ≥ 3 _____

B. Physician-related Distress:
      a. Sum of 4 items (2, 4, 9, 15)   _____
      b. Divide by: _____4_____
      c. Mean item score: _____ ≥ 3 _____

C. Regimen-related Distress:
      a. Sum of 5 items (5, 6, 10, 12, 16)   _____
      b. Divide by: _____5_____
      c. Mean item score: _____ ≥ 3 _____

D. Interpersonal Distress:
      a. Sum of 3 items (7, 13, 17)   _____
      b. Divide by: _____3_____
      c. Mean item score: _____ ≥ 3 _____

APPENDIX D: SF-12v1® HEALTH SURVEY

SF-12 Health Survey

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

	Excellent	Very good	Good	Fair	Poor
	☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health *now* limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
3. Climbing **several** flights of stairs	☐	☐	☐

During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the **kind** of work or other activities	☐	☐

During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐
7. Didn't do work or other activities as **carefully** as usual	☐	☐

---

8. During the *past 4 weeks*, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little	Moderately	Quite a	Extremely

	bit		bit	
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*...

	All of the time	Most of the time	A Good Bit of the Time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the *past 4 weeks*, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	☐	☐	☐	☐	☐

APPENDIX E: DIABETES-SPECIFIC HEALTH-RELATED QUALITY OF LIFE (DIABETES-39)

Source: Boyer Jg, Earp Ja. The Development of an Instrument for Assessing the Quality Of Life

of People with Diabetes: Diabetes-39. Med Care 1997;35:440-53.

Diabetes-Specific Health-Related Quality of Life (Diabetes-39)

This questionnaire is designed to help us to learn more about what affects the quality of life of people with diabetes.

How to complete this questionnaire?

- For each of the following questions, we want to know how much your quality of life has been affected. Please answer the questions by putting a cross (X) somewhere on the line following each question.

- The line starts at **number 1** and a cross here means that your quality of life has **not** been affected **at all**. The line ends at **number 7** and a cross here means that your quality of life has been **extremely** affected. Place your cross on the line at the point which you think best describes how you quality of life has been affected in the **past month**.

- It is very important that you answer **every question**. However, some of the questions which ask about your personal life may not be applicable to you. Please leave them and go on to the next question. All replies will be treated in confidence.

- Example:
  - ► If you thought "air pollution" affected your quality of life to some extent, but not extremely, you might mark the line as shown below.

*During the **past month**, how much was the quality of **your** life affected by:*

Q1.   Air pollution

Not affected at all	1	2	3	4	5	6	7	Extremely affected
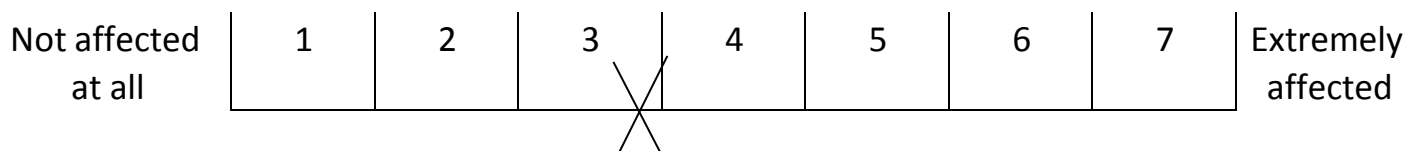
- ► If you were to answer the same question, where would you put your cross?
  If you think you have been **more affected** by air pollution in the past month than the person in the above example, you should place your cross somewhere to the **right** of the existing cross. However, if you think you have been **less affected**, then your cross should be placed somewhere to the **left** of the existing cross. To practice, please put your cross on the line.

*During the **past month**, how much was the quality of **your** life affected by:*

Q1.   your daily medication for your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q2.   worries about money matters

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q3.   limited energy levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q4.   following your doctor's prescribed treatment plan for diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q5.   food restrictions required to control your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q6.   concerns about your future

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q7.   other health problems besides diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

*During the **past month**, how much was the quality of **your** life affected by:*

Q8.　　stress or pressure in your life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q9.　feelings of weakness

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q10.　restrictions on how far you can walk

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q11.　any daily exercises for your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q12.　loss or blurring of version

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q13.　not being able to do what you want

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q14.　having diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

*During the **past month**, how much was the quality of **your** life affected by:*

Q15. losing control of your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q16. other illnesses besides diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q17. testing your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q18. the time required to control your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q19. the restrictions your diabetes places on your family and friends

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q20. being embarrassed because you have diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q21. diabetes interfering with your sex life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

*During the **past month**, how much was the quality of **your** life affected by:*

Q22. feeling depressed or low

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q23. problems with sexual functioning

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q24. getting your diabetes well controlled

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q25. complications from your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q26. doing things that your family and friends don't do

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q27. keeping a record of your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q28. the need to eat at regular intervals

Not affected at all	1	2	3	4	5	6	7	Extremely affected

*During the **past month**, how much was the quality of **your** life affected by:*

Q29. not being able to do housework or other jobs around the house

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q30. a decreased interest in sex

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q31. having to organize your daily life around diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q32. needing to rest often

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q33. problems in climbing stairs or walking up steps

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q34. having trouble caring for yourself (dressing, bathing, or using the toilet)

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q35. restless sleep

Not affected at all	1	2	3	4	5	6	7	Extremely affected

*During the **past month**, how much was the quality of **your** life affected by:*

Q36. walking more slowly than others

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q37. being identified as a diabetic

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q38. having diabetes interfere with your family life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Q39. diabetes in general

Not affected at all	1	2	3	4	5	6	7	Extremely affected

OVERALL RATINGS

Q1.   Please place a cross (X) on the line below to indicate your overall rating of quality
of life

Lowest quality	1	2	3	4	5	6	7	Highest quality

Q2.   Please place a cross (X) on the line below to show how severe you think your
diabetes is

Not severe at all	1	2	3	4	5	6	7	Extremely severe

APPENDIX F: DIABETES EMPOWERMENT SCALE-SHORT FORM (DES-SF)

Source: Diabetes Research and Training Center © University of Michigan, 2003

Diabetes Empowerment Scale-Short Form (DES-SF)

The 8 items below constitute the DES-SF. The scale is scored by averaging the scores of all completed items (Strongly Disagree =1, Strongly Agree = 5)   des

Check the box that gives the best answer for you.

In general, I believe that I:

1. ...know what part(s) of taking care of my diabetes that I am **dissatisfied** with.

   ☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

2. …am able to turn my diabetes goals into a workable plan.

   ☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

3. ...can try out different ways of overcoming barriers to my diabetes goals.

   ☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

4. ...can find ways to feel better about **having** diabetes.

   ☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

5. ...know the **positive** ways I cope with diabetes-related stress.

☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

6. ...can ask for support for having and caring for my diabetes when I need it.

☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

7. ...know what helps me stay motivated to care for my diabetes.

☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

8. ...know enough about myself as a person to make diabetes care choices that are right for me.

☐1 Strongly Disagree   ☐2 Somewhat Disagree   ☐3 Neutral   ☐4 Somewhat Agree   ☐5 Strongly Agree

APPENDIX G: ASSESSMENT OF CARE FOR CHRONIC CONDITION (PACIC)

Assessment of Care for Chronic Conditions

Staying healthy can be difficult when you have a chronic condition. We would like to learn about the type of help with your condition you get from your health care team. This might include your regular doctor, his or her nurse, or physician's assistant who treats your illness. Your answers will be kept confidential and will not be shared with your physician or clinic.

Over the past 6 months, when I received care for my chronic conditions, I was:

	None of the time	A Little of the Time	Some of the Time	Most of the Time	Always
1. Asked for my ideas when we made a treatment plan.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
2. Given choices about treatment to think about.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
3. Asked to talk about any problems with my medicines or their effects.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
4. Given a written list of things I should do to improve my health.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
5. Satisfied that my care was well organized.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
6. Shown how what I did to take care of myself influenced my condition.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
7. Asked to talk about my goals in caring for my condition.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
8. Helped to set specific goals to improve my eating or exercise.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
9. Given a copy of my treatment plan.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
10. Encouraged to go to a specific group or class to help me cope with my chronic condition.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$
11. Asked questions, either directly or on a survey, about my health habits.	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$

Over the past 6 months, when I received care for my chronic conditions, I was:					
	None of the time	A Little of the Time	Some of the Time	Most of the Time	Always
12. Sure that my doctor or nurse thought about my values, beliefs, and traditions when they recommended treatments to me.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
13. Helped to make a treatment plan that I could carry out in my daily life.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
14. Helped to plan ahead so I could take care of my condition even in hard times.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
15. Asked how my chronic condition affects my life.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
16. Contacted after a visit to see how things were going.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
17. Encouraged to attend programs in the community that could help me.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
18. Referred to a dietitian, health educator, or counselor.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
19. Told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$
20. Asked how my visits with other doctors were going.	$\Box_1$	$\Box_2$	$\Box_3$	$\Box_4$	$\Box_5$

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For more information go to www.improvingchroniccare.org

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